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 24, 2023

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 2.02. Results of Operations and Financial Condition.

On March 28, 2023, Aadi Bioscience, Inc. (the "**Company**") issued a press release announcing its financial results for the fiscal year ended December 31, 2022. 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 5.02. Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

On March 24, 2023, Mohammad Hirmand, M.D. was appointed a Class II director by the Board of Directors (the "**Board**") of the Company, effective March 27, 2023. Dr. Hirmand fills the vacancy created in connection with the resignation of Brendan Delaney from the Board, as previously announced on March 3, 2023. Dr. Hirmand's term of office will expire at the Company's 2025 annual meeting of stockholders or until his successor is duly elected and qualified. The Board determined that Dr. Hirmand meets the requirements for independence under the applicable listing standards of the Nasdaq Stock Market LLC and the Securities and Exchange Act of 1934, as amended.

As a non-employee director, Dr. Hirmand will participate in the Company's compensation program applicable to all non-employee directors, which is summarized below. Under the Company's Outside Director Compensation Policy, each non-employee director receives a base annual retainer of $40,000, and the Board Chair receives an additional retainer of $26,000. Board committee members receive additional annual cash compensation for service on Board committees as follows: Audit Committee of the Board, $8,000 (member) or $20,000 (chair), Compensation Committee of the Board, $6,000 (member) or $12,000 (chair), and Nominating and Corporate Governance Committee of the Board, $4,500 (member) or $9,000 (chair). In addition, Dr. Hirmand will be granted an initial grant of a stock option to purchase shares of common stock of the Company with a grant date fair value (as determined in accordance with U.S. generally accepted accounting principles) equal to $325,000. The stock option will vest as to 1/36th of the total number of shares on each monthly anniversary of the grant date, subject to Dr. Hirmand's continued service through each applicable vesting date. In the event of a change in control (as defined in the Company's 2021 Equity Incentive Plan), the stock option will vest in full. Beginning with the Company's annual meeting of stockholders in 2023, Dr. Hirmand will be eligible for equity awards on the same terms as other continuing members of the Board.

There are no arrangements or understandings between Dr. Hirmand and any other person pursuant to which Dr. Hirmand was selected as a director, and there are no transactions between Dr. Hirmand and the Company that would require disclosure under Item 404(a) of Regulation S-K. In addition, the Company has entered into an indemnification agreement with Dr. Hirmand in connection with his appointment to the Board, which is substantially the same form as that entered into with other directors of the Company.

On March 27, 2023, the Company issued a press release announcing Dr. Hirmand's appointment as a director. The press release is attached hereto as Exhibit 99.2 and incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Press Release, dated March 28, 2023
99.2	Press Release, dated March 27, 2023
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 28, 2023

/s/ Scott Giacobello

Scott Giacobello

Interim Chief Executive Officer and President, and Chief Financial Officer

Exhibit 99.1

Aadi Bioscience Announces Financial Results for the Fourth Quarter and Full-Year 2022 and Provides Corporate Update

Total revenue on FYARRO® sales of $15.2 million for FY 2022

PRECISION 1 trial preliminary data expected in the second quarter of 2023

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

LOS ANGELES, CA, March 28, 2023 – Aadi Bioscience, Inc. (NASDAQ: AADI), a biopharmaceutical company focused on developing and commercializing precision therapies for genetically defined cancers with alterations in mTOR pathway genes, today provided a corporate update and announced financial results for the fourth quarter and full-year 2022.

"2022 was a year marked by successive milestones with the launch of FYARRO, the start of the PRECISION 1 trial, strengthening our balance sheet with a $72.5 million financing, taking our cash runway into 2025, and collaborating on a new combination of *nab*-sirolimus with Mirati's adagrasib," said Scott Giacobello, CFO and interim President and CEO of Aadi Biosciences. "We look forward to another year of advancements as we enter 2023 including the progression in our first collaboration, which is expected to initiate in the second quarter. As planned, we will provide preliminary data on patients in the PRECISION 1 trial in the second quarter of 2023."

Fourth Quarter 2022 Updates and Recent Operational Highlights

- **FYARRO net product sales were $5.2 million** in the fourth quarter, or 23% growth quarter-over-quarter, and were $15.2 million for full-year 2022, representing 10 months of sales.
- **Continued advancement of the PRECISION 1 registrational-directed trial** in patients with tumor agnostic *TSC1* and *TSC2* inactivating alterations is advancing with continued enrollment and the Company plans to provide preliminary data on a meaningful number of patients in the second quarter of 2023.
- **Announced the appointment of Mohammad Hirmand, M.D., Board of Directors.** Dr. Hirmand is the co-founder of Avenzo Therapeutics, Inc., and serves as executive vice president and chief medical officer of this privately held biotechnology company focused on oncology therapeutics. Previously, Dr. Hirmand served as executive vice president and chief medical officer of Turning Point Therapeutics, a publicly traded precision oncology company, where he was responsible for clinical development, clinical operations and regulatory affairs, from December 2019 until its acquisition by Bristol Myers Squibb in August 2022.
- **Closed on a $72.5M financing** during the fourth quarter, extending the Company's cash runway into 2025.
- **Signed a clinical collaboration agreement** during the fourth quarter with Mirati Therapeutics on combination of adagrasib with *nab*-sirolimus. The Phase 1/2 trial is expected to begin in the second quarter of 2023.

Fourth Quarter and Full-year 2022 Financial Results

- Cash, cash equivalents and short-term investments as of December 31, 2022 were $172.6 million as compared to $148.9 million as of December 31, 2021, which is expected to fund operations into 2025 based on current plans.

- Total revenue for the quarter ended December 31, 2022 was $5.2 million, and $15.2 million for the full-year ended December 31, 2022, resulting from sales of FYARRO.
- Net loss for the three months ended December 31, 2022 was $13.9 million as compared to $16.0 million for the three months ended December 31, 2021. Net loss for the full-year 2022 ended December 31, 2022 was $60.5 million, as compared to $110.1 million for the period in 2021 (The prior year included the non-cash impairment charge of $74.2 million related to the acquired contract intangible asset incurred in conjunction with the Aerpio merger).

Conference Call Information

The Aadi management team is hosting a conference call and webcast today at 8:30 am ET (5:30 am PT) to provide a corporate update and discuss results for the fourth quarter and full-year 2022.

Participants may access a live webcast of the call on the "Investors & News" page of the Aadi Biosciences 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 FYARRO®

FYARRO is an mTOR inhibitor indicated for the treatment of adult patients with locally advanced unresectable or metastatic malignant perivascular epithelioid cell tumor (PEComa).

About the PRECISION 1 Trial

The PRECISION 1 trial is a multi-center, open-label, tumor-agnostic pivotal study, of *nab*-sirolimus designed as a basket trial that will evaluate approximately 120 adult and adolescent patients with solid tumors harboring pathogenic inactivating alterations in *TSC1* or *TSC2* genes. The trial will have two independent arms of 60 patients each to separately evaluate patients with either *TSC1* or *TSC2* inactivating alterations. Aadi has received Fast Track designation to evaluate *nab*-sirolimus in this indication from the FDA. The first patient in the PRECISION 1 trial was dosed in March 2022.

About Aadi Bioscience

Aadi is a commercial-stage biopharmaceutical company focused on precision therapies for genetically defined cancers to bring transformational therapies to cancer patients with mTOR pathway driver alterations. Aadi received FDA approval in November of 2021 and in February of 2022 commercialized FYARRO® for the treatment of adult patients with locally advanced unresectable or metastatic malignant perivascular epithelioid cell tumor (PEComa).

About the PRECISION 1 Trial, Aadi has also initiated PRECISION 1, a Phase 2 tumor-agnostic registration-directed trial in mTOR inhibitor-naïve malignant solid tumors harboring *TSC1* or *TSC2* inactivating alterations. 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 Biosciences that are not a description of historical facts within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include statements regarding the Company's current beliefs and expectations; the Company's anticipated growth; plans and potential for success relating to commercializing FYARRO; expectations regarding the beneficial characteristics, safety, efficacy and therapeutic effects of FYARRO; expectations regarding management's performance; plans related to further development and manufacturing of FYARRO; pricing and reimbursement of FYARRO; the rate and degree of market acceptance of FYARRO; anticipated reception of FYARRO in the physician community; the clinical results and timing of additional clinical trials, including the registration-directed trial in patients harboring *TSC1* or *TSC2* inactivating alterations; the timing and likelihood of regulatory filings and approvals of FYARRO, including in potential additional indications and potential filings in additional jurisdictions; plans regarding clinical trials, in collaboration with Mirati Therapeutics, for the combination of adagrasib and nab-sirolimus in patients with

KRASG12C-mutant tumors and related timing and expectations regarding the efficacy of the combination; and the sufficiency of our existing capital resources and the expected timeframe to fund our 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, those associated with the ability to successfully commercialize FYARRO; risks related to reimbursement and pricing of FYARRO; 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; 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 related to Aadi's estimates regarding future expenses, capital requirements and need for additional financing; and risks related to the impact of the COVID-19 pandemic on Aadi's operations, the biotechnology industry and the economy generally.

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 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, 2022	December 31, 2021
Current assets:		
Cash and cash equivalents	$ 39,019	$ 148,989
Short-term investments	133,541	—
Accounts receivable, net	1,862	—
Inventory	1,861	—
Prepaid expenses and other current assets	3,746	2,283
Total current assets	180,029	151,272
Property and equipment, net	508	57
Operating lease right-of-use assets	1,522	557
Intangible asset, net	—	3,811
Other assets	2,178	2,213
Total assets	$ 184,237	$ 157,910
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 3,519	$ 6,439
Accrued liabilities	14,922	8,703
Operating lease liabilities, current portion	394	131
Total current liabilities	18,835	15,273
Operating lease liabilities, net of current portion	1,267	474
Due to licensor	5,757	5,757
Total liabilities	25,859	21,504
Stockholders' equity:		
Preferred stock	—	—
Common stock	2	2
Additional paid-in capital	361,689	279,089
Accumulated other comprehensive loss	(115)	—
Accumulated deficit	(203,198)	(142,685)
Total stockholders' equity	158,378	136,406
Total liabilities and stockholders' equity	$ 184,237	$ 157,910

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,	
	2022	2021	2022	2021
Revenue				
Product sales, net	$ 5,227	$ —	$ 15,216	$ —
License revenue	—	1,000	—	1,000
Grant revenue	—	—	—	120
Total revenue	5,227	1,000	15,216	1,120
Operating expenses				
Selling, general and administrative	11,106	9,718	40,176	18,511
Research and development	9,369	7,227	32,662	19,670
Cost of goods sold	222	—	1,335	—
Impairment of acquired contract intangible asset	—	—	3,724	74,156
Total operating expenses	20,697	16,945	77,897	112,337
Loss from operations	(15,470)	(15,945)	(62,681)	(111,217)
Change in fair value of convertible promissory notes	—	—	—	1,585
Gain upon extinguishment of debt	—	—	—	196
Interest income	1,606	12	2,398	13
Interest expense	(57)	(57)	(230)	(665)
Other income (expense), net	1,549	(45)	2,168	1,129
Loss before income tax expense	(13,921)	(15,990)	(60,513)	(110,088)
Income tax benefit (expense)	9	—	—	(2)
Net loss	$ (13,912)	$ (15,990)	$ (60,513)	$ (110,090)
Other comprehensive loss				
Change in unrealize loss on short-term investments	(16)	$ —	(115)	$ —
Comprehensive loss	$ (13,928)	$ (15,990)	$ (60,628)	$ (110,090)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.52)	$ (0.77)	$ (2.69)	$ (12.41) *
Weighted average number of common shares outstanding used in computing net loss per share attributable to common stockholders, basic and diluted	26,839,033	20,890,305	22,511,237	8,923,369

* Includes the effect of cumulative dividends on convertible preferred stock

PRESS RELEASE

Aadi Bioscience Appoints Mohammad Hirmand, M.D. to Board of Directors

LOS ANGELES, CA, March 27, 2023 – Aadi Bioscience, Inc. (NASDAQ: AADI), a commercial-stage biopharmaceutical company focused on developing and commercializing precision therapies for genetically-defined cancers with alterations in mTOR pathway genes, today announced the appointment of Mohammad Hirmand, M.D. to its Board of Directors. Dr. Hirmand has more than 20 years of biotechnology clinical development experience, and recently served as executive vice president and chief medical officer for Turning Point Therapeutics, which was acquired by Bristol Myers Squibb (BMS) for $4.1 billion in August 2022.

“We welcome Mohammad to our Board at an exciting time for Aadi, as we advance the development of FYARRO for unmet clinical needs beyond our approved indication of PEComa. Mohammad is a world-class clinical development leader in oncology and will be a great complement to our board and partner with our highly experienced team,” said Caley Castelein, M.D., Aadi Board Chairman. “Mohammad has been instrumental in the development of Medivation’s Xtandi and Welireg (belzutifan), when at Peloton Therapeutics. Most recently, he led the development of Turning Point Therapeutics’ clinical pipeline including the tyrosine kinase inhibitor repotrectinib prior to the company’s acquisition by BMS. We look forward to working together and to his contributions as we drive toward continued growth and clinical expansion here at Aadi.”

Dr. Hirmand is a co-founder of Avenzo Therapeutics, a privately held oncology company, and serves as its executive vice president and chief medical officer. Previously, Dr. Hirmand served as executive vice president and chief medical officer of Turning Point Therapeutics, a publicly traded precision oncology company, where he was responsible for all development functions from December 2019 until its acquisition by BMS in August 2022.

“I am excited to join Aadi's Board of Directors in their mission to unlock the potential of nab-sirolimus in addressing mTOR-driven diseases,” said Dr. Hirmand. “Aadi’s PRECISION-1 trial studying nab-sirolimus in solid tumors with TSC1 and TSC2 inactivating alterations represents an exciting potential advancement in targeted oncology. I look forward to working with the outstanding Aadi team to transform the lives of patients living with cancer.”

Dr. Hirmand also served as chief medical officer of Peloton Therapeutics from 2017 until its acquisition by Merck & Co., Inc. in 2019. Dr. Hirmand served in various roles at Medivation, Inc., a publicly traded biotechnology company, from 2007 to 2017, including most recently as its chief medical officer, through its acquisition by Pfizer Inc. He has also held clinical development roles of increasing responsibility at Nuvelo, Inc. (now ARCA Biopharma), SuperGen, Inc. (now Astex Pharmaceuticals, Inc.), Tularik, Inc. (now part of Amgen), and Theravance Biopharma, Inc. Dr. Hirmand received his M.D. from Harvard Medical School and his B.A. in Biological Sciences and Economics from Cornell University.

About Aadi Bioscience, Inc.

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Aadi has also initiated PRECISION 1, a Phase 2 tumor-agnostic registration-intended trial in mTOR inhibitor-naïve malignant solid tumors harboring TSC1 or TSC2 inactivating alterations. 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**.

Cautionary Note Regarding Forward-Looking Statements

This press release contains certain forward-looking statements regarding the business of Aadi Biosciences that are not a description of historical facts within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include statements regarding the Company's current beliefs and expectations; anticipated future growth; the potential commercialization of FYARRO in the tumor agnostic oncology market; expectations regarding management performance following the leadership transition; and the Company's potential as a commercial precision oncology company. 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, those associated with 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; the risk that unforeseen adverse reactions or side effects may occur in the course of commercializing, developing and testing FYARRO; and risks related to collaborations with third-parties.

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 Aadi's Quarterly Report on Form 10-Q filed November 9, 2022, 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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