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 10, 2022

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** **(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 10, 2022, Aadi Bioscience, Inc. issued a press release announcing its financial results for the fiscal quarter ended June 30, 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 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Press Release, dated August 10, 2022
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 10, 2022

/s/ Neil Desai, Ph.D.
Neil Desai, Ph.D.
President and Chief Executive Officer

PRESS RELEASE

Aadi Bioscience Announces Financial Results for the Second Quarter of 2022 and Provides Corporate Update

FYARRO® (nab-sirolimus) net product sales reached $3.4 million for the second quarter of 2022

PRECISION 1 Phase 2 tumor-agnostic registration-directed trial continues enrollment and rapid site activation at major cancer centers and large community networks; preliminary data expected 1H23

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

LOS ANGELES, CA, August 10, 2022 – 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 second quarter of 2022.

"We continue to progress in key areas after our first full quarter following FYARRO's launch. We are excited to see FYARRO reaching more patients through continued account adoption and steady growth in overall sales," said Neil Desai, Ph.D., Founder, President and Chief Executive Officer of Aadi. "We are also encouraged by the progress on our tumor agnostic PRECISION 1 trial targeting *TSC1* and *TSC2* inactivating alterations which continues to ramp up, with activation of additional clinical trial sites and patient enrollment. We anticipate providing preliminary data on a meaningful number of patients in this trial during the first half of 2023. In addition, we continue to evaluate strategies for new clinical indications of nab-sirolimus either as single agent or in combination with other targeted therapies with the potential for new programs as early as 2023."

Corporate Updates for the Second Quarter 2022

- FYARRO net product sales for the three months ended June 30, 2022 were $3.4 million, the first full quarter of sales following the product launch late in the first quarter.
- A product-specific permanent J-code (J9331) for FYARRO from Centers for Medicare and Medicaid Services (CMS) became effective on July 1, 2022. This code is expected to further facilitate reimbursement for FYARRO.
- The Company announced its addition to both the U.S. small cap Russell 2000® Index and broad-market Russell 3000® Index at the conclusion of the 2022 Russell indexes annual reconstitution, which captures the 4,000 largest U.S. stocks, ranking them by total market capitalization.
- Partnerships with prominent next generation sequencing (NGS) providers and leaders in genomic testing and profiling was announced during the quarter, which included Foundation Medicine, Tempus and others. The Company is leveraging these partnerships to expedite patient identification and recruitment for the ongoing PRECISION 1 trial of nab-sirolimus in patients harboring tumors with inactivating alterations in *TSC1* or *TSC2* genes, and is making significant progress toward opening the trial in at least 20 major cancer centers and upward of 120 treatment sites in the U.S. by the end of 2022.

PRESS RELEASE

- A poster presentation entitled, "*nab*-Sirolimus for patients with advanced malignant PEComa with or without prior mTOR inhibitors: Biomarker results from AMPECT and an expanded access program" was presented at the 2022 American Society of Clinical Oncology (ASCO) Annual Meeting. The data included exploratory biomarker results reported from the final analysis of mTOR inhibitor-naïve advanced malignant PEComa patients treated with *nab*-sirolimus in the Advanced Malignant PEComa Trial (AMPECT) trial as well as an analysis of prior mTOR inhibitor exposed advanced malignant PEComa patients treated with *nab*-sirolimus in the Expanded Access Program (EAP) through June 2021. Findings from both the AMPECT study and the EAP showed greater clinical benefit in patients with *TSC1* or *TSC2* inactivating alterations who received *nab*-sirolimus compared to all evaluable patients, regardless of prior mTOR inhibitor exposure.
- The Company sponsored a poster at the Annual Meeting of the American Association for Cancer Research (AACR) which indicated the incidence of advanced cancer patients carrying *TSC1* or *TSC2* inactivating gene alterations numbered approximately 12,000 annually in the US, thus potentially rendering these patients eligible for nab-sirolimus therapy.

Second Quarter 2022 Financial Results

- Cash and cash equivalents on June 30, 2022 were $118.7 million, compared to $149.0 million as of December 31, 2021. Based on current plans, the Company expects cash and cash equivalents to fund operations into 2024.
- Total revenue for the quarter ended June 30, 2022 was $3.4 million resulting from sales of FYARRO.
- In the second quarter of 2022, the Company recorded a non-cash impairment charge of $3.7 million to write-off the value of an intangible asset related to the Gossamer license agreement with the Company's predecessor, Aerpio.
- Net loss for the three months ended June 30, 2022 was $18.3 million compared to $1.5 million for the three months ended June 30, 2021.

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 second quarter of 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.

PRESS RELEASE

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 biopharmaceutical company focused on precision therapies for genetically defined cancers. Aadi's primary goal is to bring transformational therapies to cancer patients with mTOR pathway driver alterations where other mTOR inhibitors have not or cannot be effectively exploited due to problems of pharmacology, effective drug delivery, safety, or effective targeting to the disease site. In November 2021, Aadi received FDA approval for FYARRO® for the treatment of adult patients with locally advanced unresectable or metastatic malignant perivascular epithelioid cell tumor (PEComa), and in February 2022 Aadi announced the commercial launch of FYARRO in this indication.

Based on exploratory data from AMPECT, Aadi's registrational study supporting approval in malignant PEComa, and following a pre-IND meeting with the FDA, Aadi has 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 Aadi'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; plans and potential for success relating to commercializing FYARRO; expectations regarding the beneficial characteristics, safety, efficacy and therapeutic effects of FYARRO; 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; 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, 2021, including under the caption "Item 1. Risk Factors" and in Aadi's subsequent Quarterly Reports on Form 10-Q filed on May 12, 2022 and August 10, 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.

Contact:
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PRESS RELEASE

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

	June 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 118,737	$ 148,989
Accounts receivable, net	2,063	—
Inventory	727	—
Prepaid expenses and other current assets	2,808	2,283
Total current assets	124,335	151,272
Property and equipment, net	357	57
Operating lease right-of-use assets	1,653	557
Intangible asset, net	—	3,811
Other assets	2,291	2,213
Total assets	$ 128,636	$ 157,910
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 3,619	$ 6,439
Accrued liabilities	8,653	8,703
Operating lease liabilities, current portion	324	131
Total current liabilities	12,596	15,273
Other liabilities	109	—
Operating lease liabilities, net of current portion	1,444	474
Due to licensor	5,757	5,757
Total liabilities	19,906	21,504
Stockholders' equity:		
Preferred stock	—	—
Common stock	2	2
Additional paid-in capital	283,539	279,089
Accumulated deficit	(174,811)	(142,685)
Total stockholders' equity	108,730	136,406
Total liabilities and stockholders' equity	$ 128,636	$ 157,910

PRESS RELEASE

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

	Three months ended June 30,		Six months ended June 30,	
	2022	2021	2022	2021
Revenue				
Product sales, net	$ 3,437	$ —	$ 5,744	$ —
Grant revenue		—		120
Total Revenue	3,437	—	5,744	120
Operating expenses				
Selling, general and administrative	10,006	830	19,154	1,393
Research and development	7,726	3,045	14,519	6,689
Cost of goods sold	341	—	520	—
Impairment of intangible asset	3,724	—	3,724	—
Total operating expenses	21,797	3,875	37,917	8,082
Loss from operations	(18,360)	(3,875)	(32,173)	(7,962)
Other income (expense)				
Change in fair value of convertible promissory notes	—	2,371	—	1,206
Gain upon extinguishment of debt	—	196	—	196
Interest income	158	1	171	1
Interest expense	(58)	(227)	(115)	(451)
Total other income, net	100	2,341	56	952
Loss before income tax expense	(18,260)	(1,534)	(32,117)	(7,010)
Income tax expense	(9)	(2)	(9)	(2)
Net loss	$ (18,269)	$ (1,536)	$ (32,126)	$ (7,012)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.87)	$ (0.60)	$ (1.53)	$ (2.76)
Weighted average number of common shares outstanding used in computing net loss per share attributable to common stockholders, basic and diluted	20,970,459	2,542,358	20,942,804	2,542,358

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