



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

March 28, 2023

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, March 28, 2023 /PRNewswire/ -- 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 Bioscience. "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% sequential 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., to 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).

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 Bioscience 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 and continued advancements, including the progression and timing of the Company's first collaboration; 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, and the release of data with respect thereto; 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," anticipated to be filed on or about the date hereof, 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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AADI BIOSCIENCE, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands)
(Unaudited)

	December 31,		December 31,
	2022		2021

Assets

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 STATEMENTS OF OPERATIONS
(In thousands, except shares and earnings per share amounts)
(Unaudited)

	Three months ended		Year ended	
	December 31,		December 31,	
	2022	2021	2022	2021
Revenue				
Product sales, net	\$ 5,227	\$ -	\$ 15,216	\$ -
Grant revenue		1,000		1,000
License 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 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)
Other income (expense)				
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)
Total other income, net	1,549	(45)	2,168	1,129
Loss before income tax expense	(13,921)	(15,990)	(60,513)	(110,088)
Income tax expense	9	-	-	(2)
Net loss	\$ (13,912)	\$ (15,990)	\$ (60,513)	\$ (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	<u>26,839,033</u>	<u>20,890,305</u>	<u>22,511,237</u>	<u>8,923,369</u>
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* Includes the effect of cumulative dividends on convertible preferred stock.



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