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

November 9, 2022

Completed $72.5 million PIPE financing extending cash runway into 2025

PRECISION 1 trial on-track with preliminary data expected in the first half of 2023

24% revenue growth of FYARRO® (nab-sirolimus) over the second quarter 2022

Appointment of Neil Desai to Executive Chairman and transition of Brendan Delaney to CEO effective January 1, 2023

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

LOS ANGELES, Nov. 9, 2022 /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 third quarter of 2022.

"The last several months have been transformational for Aadi, most recently having strengthened our balance sheet with a $72.5 million PIPE financing. In addition, we saw continued progress in patient enrollment for the PRECISION 1 trial targeting *TSC1* and *TSC2* inactivating alterations, and we anticipate providing preliminary data on a meaningful number of patients from PRECISION 1 in the first half of 2023," said Neil Desai, Ph.D., Founder and Chief Executive Officer of Aadi. "We also expanded our pipeline through the recent clinical collaboration with Mirati to explore the combination of *nab*-sirolimus with the KRAS inhibitor adagrasib, which we believe could potentially overcome tumor resistance."

"We have made great progress in the last year, positioning us well for the next phase of growth. In preparation for the advancements to come, we are also realigning our management structure. We announced last evening that I am moving into the role of Executive Chairman while our current COO, Brendan Delaney, will transition to President and CEO," continued Desai. "Brendan's proven expertise, committed leadership and broad strategic vision have been key drivers of our success. Going forward, Brendan will assume leadership of the Company while my personal focus will turn toward advancement of our scientific initiatives."

Brendan Delaney, current Chief Operating Officer of Aadi commented, "It's such an exciting time at Aadi, and I couldn't be more pleased with the execution our team has demonstrated. I am honored to have been selected to lead this organization as we move forward and execute on the strategies that will support further growth. Our oncology franchise is growing, and I believe we are well-positioned to achieve our goal of becoming a leading precision oncology company that delivers on providing therapeutic benefit to patients in need."

Corporate Updates for the Third Quarter 2022 and Recent Highlights

- **Closed on a $72.5M financing and extended cash runway into 2025.** The proceeds from the financing will be used to support the continued advancement of the PRECISION 1 trial and growing FYARRO commercial efforts, and to fund research and development of additional clinical opportunities with FYARRO and for working capital and general corporate purposes.

- **Continued advancement of the PRECISION 1 registrational-directed trial**. The PRECISION 1 Phase 2 trial in patients with tumor agnostic TSC 1 and 2 inactivating mutations is advancing and on track to deliver preliminary data in the first half of 2023.

- **Grew FYARRO net product sales**. For the three months ended September 30, 2022, net product sales of FYARRO showed continued growth, ending with $4.2 million in sales in the third quarter, a 24% increase over the second quarter.

- **Leadership transition.** Current CEO, Dr. Neil Desai, has been appointed Executive Chairman, effective January 1, 2023. Current COO, Brendan Delaney, will transition to President and CEO, and will be joining the board of directors, effective January 1, 2023.

- **Signed a clinical collaboration agreement with Mirati Therapeutics on combination of adagrasib with *nab*-sirolimus**. The companies will conduct an open-label Phase 1/2 trial to determine the optimal dose and recommended Phase 2 dose for the combination of adagrasib and *nab*-sirolimus in patients with $KRAS^{G12C}$ - mutant solid tumors. The trial builds on preclinical data showing enhanced anti-tumor efficacy with the combination of adagrasib and *nab*-sirolimus relative to either agent alone. Initiation of the Phase 1/2 trial is expected in the first half of 2023.

- **Presented combination data of KRAS inhibitors and *nab*-sirolimus at the 34th EORTC-NCI-AACR Symposium.** The results of these studies showed that combining *nab*-sirolimus with either of the $KRAS^{G12C}$ inhibitors sotorasib or adagrasib significantly improved response against $KRAS^{G12C}$ mutant lung cancer and bladder cancer tumors *in vivo* and *nab*-sirolimus also showed significantly greater potency in the combination compared to everolimus.

Third Quarter 2022 Financial Results

- Cash, cash equivalents and short-term investments as of September 30, 2022 were $183.0 million as compared to $149.0 million as of December 31, 2021, which is expected to fund operations into 2025 based on current plans.
- Total revenue for the quarter ended September 30, 2022 was $4.2 million resulting from sales of FYARRO.
- Net loss for the three months ended September 30, 2022 was $14.5 million as compared to $87.1 million for the three months ended September 30, 2021. The prior year quarter 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 third 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.

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-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**.

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, 2021, including under the caption "Item 1A. Risk Factors," and in Aadi's subsequent Quarterly Reports on Form 10-Q filed on May 12, 2022, August 10, 2022 and 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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AADI BIOSCIENCE, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands)
(Unaudited)

	September 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 134,815	$ 148,989
Short-term investments	48,192	-
Accounts receivable, net	2,261	-
Inventory	734	-
Prepaid expenses and other current assets	3,861	2,283
Total current assets	189,863	151,272
Property and equipment, net	457	57
Operating lease right-of-use assets	1,573	557
Intangible asset, net	-	3,811
Other assets	2,210	2,213
Total assets	$ 194,103	$ 157,910
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 3,920	$ 6,439
Accrued liabilities	13,597	8,703
Operating lease liabilities, current portion	374	131
Total current liabilities	17,891	15,273
Operating lease liabilities, net of current portion	1,347	474
Due to licensor	5,757	5,757
Total liabilities	24,995	21,504
Stockholders' equity:		
Preferred stock	-	-
Common stock	2	2
Additional paid-in capital	358,490	279,089
Accumulated other comprehensive loss	(99)	
Accumulated deficit	(189,285)	(142,685)
Total stockholders' equity	169,108	136,406
Total liabilities and stockholders' equity	$ 194,103	$ 157,910

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

	Three months ended September 30,		Nine months ended September 30,	
	2022	2021	2022	2021
Revenue				
Product sales, net	$ 4,245	$ -	$ 9,989	$ -
Grant revenue		-	-	120
Total Revenue	4,245	-	9,989	120
Operating expenses				
Selling, general and administrative	9,915	7,401	29,069	8,793
Research and development	8,773	5,754	23,292	12,443
Cost of goods sold	593	-	1,113	-
Impairment of intangible asset	-	74,156	3,724	74,156
Total operating expenses	19,281	87,311	57,198	95,392
Loss from operations	(15,036)	(87,311)	(47,209)	(95,272)

Other income (expense)				
Change in fair value of convertible promissory notes	-	380	-	1,585
Gain upon extinguishment of debt	-	-	-	196
Interest income	620	-	791	1
Interest expense	(58)	(157)	(173)	(608)
Total other income, net	562	223	618	1,174
Loss before income tax expense	(14,474)	(87,088)	(46,591)	(94,098)
Income tax expense	-	-	(9)	(2)
Net loss	(14,474)	(87,088)	(46,600)	(94,100)
Other comprehensive loss				
Change in unrealized loss on short-term investments	(99)	-	(99)	-
Comprehensive loss	$ (14,573)	$ (87,088)	$ (46,699)	$ (94,100)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.68)	$ (9.17)	$ (2.21)	$ (19.37)
Weighted average number of common shares outstanding used in computing net loss per share attributable to common stockholders, basic and diluted	21,269,163	9,510,379	21,052,786	4,890,556

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