Aadi Reports Third Quarter 2021 Financial Results and Provides Business Update

November 10, 2021

- *FYARRO™ under review with FDA with a November 26, 2021 PDUFA target date*
- *Three key executive appointments made to the roles of Chief Operating Officer, Chief Medical Officer and Chief Financial Officer*
- *Appointment of new board member*
- *Registrational trial in patients harboring TSC1 and TSC2 inactivating alterations expected to be initiated by the end of 2021 or early 2022*
- *Ended third quarter 2021 with $161.4 million in cash and cash equivalents with expected cash runway into 2024 following merger with Aerpio Pharmaceuticals, Inc. and concurrent PIPE financing*

LOS ANGELES, Nov. 10, 2021 (GLOBE NEWSWIRE) -- Aadi Bioscience, Inc. (“Aadi”) (Nasdaq: AADI), a clinical-stage biopharmaceutical company focusing on precision therapies for genetically-defined cancers with alterations in mTOR pathway genes, today reported financial results for the three and nine months ended September 30, 2021 and provided a general business update.

Neil Desai, Ph.D., Founder, Chief Executive Officer and President of Aadi, commented, “Following the successful merger completed in the third quarter, we are now fortified on all fronts with a strengthened balance sheet and expanded management team ahead of our November 26 Prescription Drug User Fee Action (“PDUFA”) target date for FYARRO. With a sizeable PIPE financing that closed in connection with our merger with Aerpio, we can effectively deploy capital toward the commercialization of FYARRO in advanced malignant PEComa and for our planned tumor-agnostic registrational trial in patients with solid tumors harboring inactivating alterations of *TSC1* and *TSC2* genes in the mTOR pathway. In addition, we are also planning for new studies to investigate ABI-009 in combination with other targeted agents in different cancers.”

Key Business Updates for the Third Quarter:

Merger and PIPE Financing

- On August 26, 2021, Aadi merged with Aerpio Pharmaceuticals, Inc., a publicly traded biotechnology company (previously traded on the Nasdaq Capital Market under “ARPO”), with Aadi being the surviving entity. As part of the merger, each share of Aadi common stock was converted into the right to receive 0.3172 shares of Aerpio common stock following a 15:1 reverse split of Aerpio’s common stock. Aadi’s common stock is traded on the Nasdaq Capital Market (Nasdaq) under the ticker symbol “AADI”.
    - Concurrent to the closing of the merger, the combined company closed the previously announced $155 million private investment in public equity (PIPE) financing of its common stock.
    - Immediately following the merger, PIPE financing, and reverse split, Aadi had approximately 20.8 million shares of common stock outstanding, with prior Aadi stockholders collectively owning approximately 29.2% of the combined company, prior Aerpio stockholders owning approximately 15.2% of the combined company, and the PIPE investors collectively owning approximately 55.6% of the combined company, each on a fully-diluted basis.

NDA Acceptance

- In July, the U.S. Food and Drug Administration (FDA) accepted Aadi’s New Drug Application (NDA) for its nanoparticle albumin-bound mTOR inhibitor, FYARRO™ (sirolimus albumin-bound nanoparticles for injectable suspension *nab*-sirolimus ABI-009) for the treatment of advanced PEComa, and has granted the company Priority Review status with a PDUFA target action date of November 26, 2021.

Key Leadership Appointments

- In September, Aadi announced key appointments of an additional independent board member as well as a Chief Operating Officer:
    - Emma Reeve was appointed to Aadi’s Board of Directors and as chair of the Audit Committee. Ms. Reeve brings over 25 years of value creation in pharmaceutical, medical device and bio-pharma service companies and a successful track record of transitioning companies from private to public.
    - Brendan Delaney was appointed to the role of Chief Operating Officer. Brendan has had an established career in

oncology-focused commercial leadership roles, launching multiple groundbreaking new products and building effective and cohesive commercial teams.

Recent Updates Following the Close of the Quarter:

- In the fourth quarter, the Company made two more key executive appointments:
    - Loretta M. Itri, M.D., FACP® was appointed to the role of Chief Medical Officer. Dr. Itri's extensive career spans clinical and regulatory global-leadership roles at both major pharmaceutical and biopharmaceutical companies. Most recently, Dr. Itri was Chief Medical Officer at Immunomedics, Inc., where she oversaw the development program and approval of TRODELVY®, the first TROP-2 directed antibody-drug conjugate for the treatment of unresectable locally advanced or metastatic triple-negative breast and urothelial cancers. Immunomedics was subsequently acquired by Gilead Sciences, Inc.
    - Scott M. Giacobello, CPA, was appointed to the role of Chief Financial Officer and Treasurer, effective November 28, 2021. Most recently, Mr. Giacobello was the Chief Financial Officer of GW Pharmaceuticals plc until its $7.2 billion acquisition by Jazz Pharmaceuticals. Mr. Giacobello joined GW Pharmaceuticals in 2017 and played a key role in the buildout of the U.S. operations and commercial readiness for the company. While Chief Financial Officer, Mr. Giacobello was instrumental in devising the financing strategy to support the development, approval and highly successful launch of GW's lead product, EPIDIOLEX ®, which had sales of over $296 million in its first full year of commercialization. Mr. Giacobello also raised over $620 million via follow-on offerings prior to the company's acquisition by Jazz Pharmaceuticals.
- Also in October, the Company presented at a medical conference and announced the publication of its registrational study of FYARRO (ABI-009) in a major medical journal:
    - Lead researchers at Aadi presented a poster at the *Virtual International Conference on Molecular Targets and Cancer Therapeutics* held from October 7th -10th. The poster consisted of preclinical data evaluating *nab*-sirolimus (ABI-009) in *PTEN*-deleted and *TSC2*-deleted cancer models and demonstrated that ABI-009 showed significantly higher tumor accumulation, increased inhibition of downstream mTOR targets *S6* and *4EBP1* and greater tumor growth suppression in comparison with other mTOR inhibitors sirolimus and everolimus at equal dose.
    - The Company also announced the publication of "*nab*-Sirolimus for Patients With Malignant Perivascular Epithelioid Cell Tumors" in the American Society of Clinical Oncology's *Journal of Clinical Oncology* based on the results of the AMPECT registrational trial. The authors concluded that investigational *nab*-sirolimus (ABI-009), if approved, may represent an important new treatment option in malignant PEComa, a rare cancer and aggressive form of sarcoma, with no currently approved treatment.

Third Quarter 2021 Financial Highlights

As of September 30, 2021, cash and cash equivalents totaled $161.4 million, an increase from $4.5 million as of December 31, 2020, resulting primarily from the consolidated capital and proceeds received from the PIPE financing. Based on our current plans, we expect cash and cash equivalents to fund operations into 2024.

For the three months ended September 30, 2021, operating expenses totaled $87.3 million, an increase of $84.4 million compared to $2.9 million for the same period in 2020. For the nine months ended September 30, 2021, operating expenses totaled $95.4 million, an increase of $84.0 million compared to $11.4 million for the same period in 2020. The increase in operating expenses for the three- and nine-month periods ended September 30, 2021, is due primarily to a non-cash impairment charge related to an acquired contract intangible asset of $74.2 million incurred in conjunction with the merger compared to the same period in 2020.

Research and development expenses for the three months ended September 30, 2021, increased approximately $3.4 million, to $5.8 million compared to $2.4 million for the same period in 2020. Research and development expenses for the nine months ended September 30, 2021, increased approximately $2.7 million, to $12.4 million compared to $9.7 million for the same period in 2020. This increase was primarily the result of increased expenses associated with our clinical drug manufacturing process in the three and nine-month periods ended September 30, 2021, compared to the same periods in 2020.

General and administrative expenses for the three months ended September 30, 2021, increased approximately $6.9 million to $7.4 million compared to $0.5 million for the same period in 2020. General and administrative expenses for the nine months ended September 30, 2021, increased approximately $7.1 million, to $8.8 million from $1.7 million, in the nine months ended September 30, 2020. This increase was primarily the result of increased personnel expenses, including approximately $2.0 million of compensation expense related to former Aerpio executives as a result of the merger.

Net loss attributable to common stockholders for the three and nine months ended September 30, 2021, was $87.2 million and $94.7 million, respectively, primarily driven by the non-cash impairment charge of $74.2 million discussed above.

About Aadi Bioscience and FYARRO™

Aadi is a clinical-stage biopharmaceutical company developing precision therapies for genetically-defined cancers. Aadi's primary goal is to bring transformational therapies to cancer patients with mTOR pathway driver alterations such as alterations in *TSC1* or *TSC2* genes, 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. Aadi's lead product candidate is FYARRO ™ (sirolimus albumin-bound nanoparticles for injectable suspension; *nab*-sirolimus; ABI-009), an mTOR inhibitor bound to human albumin that has demonstrated significantly higher tumor accumulation, greater mTOR target suppression, and increased tumor growth inhibition over other mTOR inhibitors in preclinical models.

Aadi's registration trial of FYARRO in advanced malignant PEComa (the "AMPECT trial") demonstrated meaningful clinical efficacy in malignant PEComa, a type of cancer with the highest known alteration rate of *TSC1* or *TSC2* genes. FYARRO has received Breakthrough Therapy, Fast-Track and Orphan Designations from the U.S. Food and Drug Administration (FDA). A rolling New Drug Application (NDA) submission was completed in May 2021 for this indication and the FDA accepted the NDA in July 2021 and granted Aadi Priority Review status with a Prescription Drug User Fee Act ("PDUFA") target action date of November 26, 2021.

Based on the AMPECT trial and emerging data for FYARRO in other solid tumors with *TSC1* or *TSC2* inactivating alterations, and following discussions with the FDA, Aadi plans to initiate a tumor-agnostic registrational trial in mTOR inhibitor-naïve solid tumors harboring *TSC1* or *TSC2* inactivating alterations by the end of 2021 or early 2022. Aadi also has ongoing studies to evaluate dosing of FYARRO in combination regimens. FYARRO is an investigational drug that has not been approved by the FDA for commercial distribution in the United States. More information is available on the Aadi website at www.aadibio.com.

Forward-Looking Statements

Aadi Bioscience, Inc. ("Aadi", "The Company") cautions you that certain statements included in this press release that are not a description of historical facts are forward-looking statements. These statements are based on Aadi's current beliefs and expectations. Forward-looking statements include statements regarding: FYARRO, including expectations regarding the clinical responses and safety profile, regulatory approval and commercialization, and the timing of additional clinical trials, including the registrational trial in patients harboring *TSC1* and *TSC2* inactivating alterations whose initiation is expected by the end of 2021 or early 2022; and the expectation that Aadi's cash and cash equivalents will last into 2024. 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: risks related to Aadi's ability to obtain, or the timeline to obtain, regulatory approval from the FDA and other regulatory authorities for FYARRO in advanced malignant PEComa; risks related to Aadi's ability to successfully commercialize, including the timing of a commercial launch of FYARRO in advanced malignant PEComa; uncertainties associated with the clinical development and regulatory approval of FYARRO, including potential delays in the commencement, enrollment and completion of clinical trials; the risk that interim results of clinical trials may not be reproduced and do not necessarily predict final results; the risk that one or more of the clinical outcomes may materially change as patient enrollment continues, following more comprehensive reviews of the data, and as more patient data become available; the risk that unforeseen adverse reactions or side effects may occur in the course of 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 outbreak 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 under the caption "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 caution is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995.

FYARRO™ is a trademark of Aadi Bioscience, Inc.

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

	September 30, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 161,375	$ 4,455
Accounts receivable	-	14,149
Prepaid expenses and other current assets	643	81
Total current assets	162,018	18,685

Property and equipment, net	14	21
Operating lease right-of-use assets	597	119
Intangible asset, net	3,880	-
Other assets	2,263	-
Total assets	$ 168,772	$ 18,825
Liabilities and shareholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 5,205	$ 2,392
Accrued liabilities	6,250	4,099
Payable to related party	22	14,314
Convertible related party promissory notes payable at fair value	-	9,029
Operating lease liabilities, current portion	90	125
Other current liabilities	-	99
Total current liabilities	11,567	30,058
Convertible promissory notes payable at fair value	-	1,102
Payable to related party	5,757	-
Operating lease liabilities, net of current portion	523	-
Other liabilities	-	97
Total liabilities	17,847	31,257
Stockholders' equity (deficit):		
Series A preferred stock	-	1
Common stock	2	1
Additional paid-in capital	277,618	20,161
Accumulated deficit	(126,695)	(32,595)
Total stockholders' equity (deficit)	150,925	(12,432)
Total liabilities and stockholders' equity (deficit)	$ 168,772	$ 18,825

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

	Three months ended September 30,		Nine Months Ended September 30,	
	2021	**2020**	**2021**	**2020**
Grant revenue	$ -	$ 231	$ 120	$ 431
Operating expenses:				
Research and development	5,754	2,395	12,443	9,684
General and administrative	7,401	499	8,793	1,700
Impairment of intangible asset	74,156	-	74,156	-
Total operating expenses	87,311	2,894	95,392	11,384
Loss from operations	(87,311)	(2,663)	(95,272)	(10,953)
Other income (expense)				
Change in fair value of convertible promissory note	380	-	1,585	-
Gain upon extinguishment of debt	-	-	196	-
Interest income	-	1	1	41
Interest expense	(157)	(229)	(608)	(585)
Total other income (expense), net	223	(228)	1,174	(544)
Loss before income taxes	(87,088)	(2,891)	(94,098)	(11,497)
Income tax expense	-	(1)	(2)	(1)
Net and comprehensive loss	(87,088)	(2,892)	(94,100)	(11,498)
Cumulative dividends on convertible preferred stock	(154)	(247)	(647)	(740)
Net and comprehensive loss attributable to common stockholders	$ (87,242)	$ (3,139)	$ (94,747)	$ (12,238)
Net and comprehensive loss per share attributable to common stockholders, basic and diluted	$ (9.17)	$ (1.23)	$ (19.37)	$ (4.81)

Weighted average number of common shares outstanding used in computing net and comprehensive loss per share attributable to common stockholders, basic and diluted	9,510,379	2,542,358	4,890,556	2,542,358

Source: Aadi Bioscience