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): July 22, 2021

AERPIO PHARMACEUTICALS, 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.)**

9987 Carver Road **Cincinnati, OH**	**45242**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code (513) 985-1920

Not Applicable
(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, $0.0001 par value per share	**ARPO**	**Nasdaq Capital Market**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 or Rule 12b-2 of the Securities Exchange Act of 1934.

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 5.07. Submission of Matters to a Vote of Security Holders.

On July 22, 2021, Aerpio Pharmaceuticals, Inc. (the "Company") held its 2021 Annual Meeting of Stockholders (the "Annual Meeting") in a virtual-only format via live webcast. Proxies were solicited pursuant to the Company's Definitive Proxy Statement filed on June 9, 2021 with the Securities and Exchange Commission under Section 14(a) of the Securities Exchange Act of 1934, as amended (the "Proxy Statement"). As of June 7, 2021, the record date for the Annual Meeting, the number of shares of the Company's common stock, $0.0001 par value per share ("Common Stock"), outstanding and entitled to vote at the Annual Meeting was 47,371,482. The number of shares of Common Stock present or represented by valid proxy at the Annual Meeting was 33,963,382 thus establishing a quorum for the Annual Meeting. Each share of Common Stock was entitled to one vote with respect to matters submitted to the Company's stockholders at the Annual Meeting.

At the Annual Meeting, the Company's stockholders voted on the following matters, which are described in detail in the Company's Proxy Statement: (i) to elect two Class I director nominees, Caley Castelein, M.D. and Cheryl Cohen, to serve on the Company's board of directors (the "Board"), to hold office until the Company's 2024 annual meeting of stockholders and until their successors been duly elected and qualified, subject to their earlier resignation or removal ("Proposal 1") and (ii) to ratify the appointment of Ernst & Young LLP as the Company's independent registered public accounting firm for the fiscal year ending December 31, 2021 ("Proposal 2"). The voting results reported below are final.

Proposal 1

Caley Castelein, M.D. and Cheryl Cohen were duly elected to the Company Board as Class I directors. The results of the election were as follows:

Class I Director Nominee	For	Withhold	Broker Non-Votes
Caley Castelein, M.D.	20,859,073	3,908,603	9,195,706
Cheryl Cohen	20,886,608	3,881,068	9,195,706

Proposal 2

The appointment of Ernst & Young LLP as the Company's independent registered public accounting firm for the fiscal year ending December 31, 2021 was ratified. The results of the ratification were as follows:

For	Against	Abstain	Broker Non-Votes
33,161,694	770,446	31,242	0

No other matters were submitted to or voted on by the Company's stockholders at the Annual Meeting.

Item 7.01. Regulation FD Disclosure.

On July 26, 2021, the Company's merger partner, Aadi Bioscience, Inc., a Delaware corporation ("Aadi"), issued a press release titled "Aadi Bioscience Announces FDA Acceptance and Priority Review for the New Drug Application of FYARRO™ for the Treatment of Advanced Malignant PEComa." A copy of the press release is being furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in Item 7.01 of this Current Report on Form 8-K, including the information in the press release attached as Exhibit 99.1 to this Current Report on Form 8-K, is furnished pursuant to Item 7.01 of Form 8-K and shall not be deemed "filed" for the 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. Furthermore, the information in Item 7.01 of this Current Report on Form 8-K, including the information in the press release attached as Exhibit 99.1 to this Current Report on Form 8-K, shall not be deemed to be incorporated by reference in the filings of the Company under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	Description
99.1	Press release issued by Aadi Bioscience, Inc., on July 26, 2021 furnished herewith.

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.

Date: July 26, 2021

AERPIO PHARMACEUTICALS, INC.

By: /s/ Joseph Gardner, Ph.D.
Joseph Gardner
President and Founder

Exhibit 99.1

Aadi Bioscience Announces FDA Acceptance and Priority Review for the New Drug Application of FYARRO™ for the Treatment of Advanced Malignant PEComa

- *FDA grants Priority Review and sets PDUFA target action date of November 26, 2021*

LOS ANGELES, Ca.—July 26, 2021 - Aadi Bioscience, Inc. (“Aadi”), a privately-held, clinical-stage biopharmaceutical company focusing on precision therapies for genetically-defined cancers with alterations in mTOR pathway genes, today announced that the U.S. Food and Drug Administration (FDA) has accepted the company’s New Drug Application (NDA) for its nanoparticle albumin-bound mTOR inhibitor, FYARRO™ (sirolimus albumin-bound nanoparticles for injectable suspension, *nab*-sirolimus ABI-009) and has granted the company Priority Review status with a Prescription Drug User Fee Act (PDUFA) target action date of November 26, 2021.

Priority Review is granted to investigational therapies that, if approved, may offer significant improvements in the treatment, prevention, or diagnosis of a serious condition when compared to standard applications. FYARRO has previously been granted Orphan Drug, Fast Track and Breakthrough Therapy designations.

Neil Desai, Ph.D., Founder, CEO and President of Aadi, stated, “We are very pleased with FDA’s acceptance of our NDA with Priority Review for FYARRO in patients with advanced malignant PEComa, an ultra-rare sarcoma. If approved, FYARRO will be the first FDA-approved therapy for the treatment of patients with this disease. We look forward to working with the FDA during its review and would like to thank the many patients, caregivers and physicians whose contributions have been invaluable and allowed us to develop this important therapy. In parallel, we continue to work on our commercial preparations to ensure a timely launch for the PEComa patient population.”

Aadi’s NDA submission is based on data from the AMPECT registration trial evaluating FYARRO as a monotherapy in patients with advanced malignant PEComa. FYARRO achieved a 39% (95% CI: 22%-58%) independently reviewed confirmed overall response rate (ORR) in this patient population. These data were presented at the 2020 ASCO meeting.[1]

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 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.

Based on the AMPECT trial and emerging data for FYARRO in other solid tumors with *TSC1* or *TSC2* inactivating alterations[2], 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. 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 the initiation of additional clinical trials and Investigational New Drug (IND) application submissions. 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; risks related to Aadi's ability to obtain sufficient additional capital to continue to advance FYARRO; 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; and risks related to the impact of the COVID-19 outbreak on Aadi's operations, the biotechnology industry and the economy generally. 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.

References:

1 ASCO 2020 Abstract: https://ascopubs.org/doi/abs/10.1200/JCO.2020.38.15_suppl.11516?af=R

2 ASCO 2021 Abstract: https://meetings.asco.org/abstracts-presentations/197602

Contacts

Investors and Media:

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