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): November 10, 2020

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 2.02 Results of Operations and Financial Condition

On November 10, 2020, Aerpio Pharmaceuticals, Inc. announced its financial results for the quarter ended September 30, 2020. A copy of the press release is being furnished as Exhibit 99.1 to this Report on Form 8-K.

The information in this Report on Form 8-K and Exhibit 99.1 attached hereto is intended to be furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 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 Aerpio Pharmaceuticals, Inc. on November 10, 2020 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: November 10, 2020

AERPIO PHARMACEUTICALS, INC.

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

Exhibit 99.1

Aerpio Reports Third Quarter 2020 Financial Results and Provides Business Update

- *Enrollment completed in the 28-day Phase 2 razuprotafib glaucoma trial; topline data expected to be reported in December 2020 or possibly in early January 2021*
- *Initiated second clinical trial to evaluate razuprotafib for the prevention and treatment of acute respiratory distress syndrome ("ARDS") in COVID-19 patients and announced first patient dosing in October*
- *First patients dosed with razuprotafib in the I-SPY COVID trial to treat ARDS in critically-ill COVID-19 patients*
- *Ended third quarter 2020 with $47.3 million in cash and cash equivalents*

Conference Call Today, November 10, 2020 at 8:30 a.m. EST

CINCINNATI, Ohio, November 10, 2020 – Aerpio Pharmaceuticals, Inc. ("Aerpio") (Nasdaq: ARPO), a biopharmaceutical company focused on developing compounds that activate Tie2 to treat ocular diseases and diabetic complications, as well as other indications in which the Company believes that activation of Tie2 may have therapeutic potential, including ARDS associated with COVID-19 infections, today reported financial results for the third quarter ended September 30, 2020 and provided a business update.

Recent Company Highlights

- On August 4th, we announced a second randomized, double-blind Phase 2 clinical trial in patients with moderate-to-severe COVID-19 ("RESCUE" trial). The RESCUE trial is being supported by the U.S. Government operating through the Medical Technology Enterprise Consortium (MTEC). MTEC is a 501(c)3 non-profit organization constructed by the U.S. Army Medical Research and Development Command (USAMRDC). The RESCUE trial is a stand-alone trial managed by Aerpio designed to evaluate patients with moderate-to-severe COVID-19 prior to initiating high flow oxygen or ventilator support. Endpoints will include proportion of subjects alive and respiratory failure-free at Day 28; length of hospitalization from baseline to Day 7; and baseline to Day 28, or death. On October 26th, Aerpio announced that it had dosed its first patient in this clinical trial. For more details about this clinical trial, please click here.
- On September 1st, Aerpio and Quantum Leap Healthcare Initiative announced dosing of the first razuprotafib patient in the I-SPY COVID Trial (Investigation of Serial Studies to Predict Your COVID Therapeutic Response with biomarker Integration and Adaptive Learning) to evaluate razuprotafib for the treatment of COVID-19-related ARDS in adult patients with critical COVID-19 (requiring high flow oxygen or ventilator support). The I-SPY COVID Trial is a "platform study" currently planned to evaluate four drug candidates. The goal of the study is to identify agents with the potential to result in substantial improvements to the clinical condition of participants with critical COVID-19. The study is designed to include critical COVID-19 patients who are already intubated or receiving high flow oxygen. For more details about the I-SPY COVID Trial, please click here.
- On September 15th, we announced that we have completed enrollment in the 28-day double-blind, placebo-controlled Phase 2 trial of razuprotafib in elevated intraocular pressure associated with open angle glaucoma (OAG) or ocular hypertension (OHT). The Phase 2 trial is evaluating adjunctive therapy of 40 mg /ml of razuprotafib, administered once, or twice-daily on top of a baseline of latanoprost ophthalmic solution 0.005%. The study enrolled a total of 194 patients.
- Our partner Gossamer Bio (Nasdaq: GOSS) indicated that it has initiated its Phase 2 trial of GB004 in ulcerative colitis (NCT04556383). GB004 is an oral, gut-targeted HIF-1 alpha stabilizer that has been shown to improve disease indices in multiple models of inflammatory bowel disease. We out-licensed GB004 to Gossamer through an agreement under which we are eligible for up to a total of $90.0 million in milestone payments related to regulatory approvals and commercial sales. In addition, we are also eligible to receive tiered royalties on sales of licensed products at percentages ranging from the low to mid-single digits as well as 20% of proceeds from any transaction that Gossamer completes that includes the GB004 program.

- On November 12th at 11 AM ET, we are hosting a Key Opinion Leader call with Samir Parikh, MD (Beth Israel Deaconess/Harvard Medical School) and Wesley Self, MD (Vanderbilt University) on new therapeutic agents in COVID-19 entitled "*COVID-19: Evidence of Vascular Pathology and Potential of Vascular Stabilization via Tie2 Pathway Activation".* A link to the webcast can be found here.

"Enrollment in our Phase 2 glaucoma trial closed on time. We are now in the process of final database close activities and remain on track to report topline results from this study in December or possibly in early January 2021 to coincide with seasonal healthcare industry conferences. In addition, we continue to make progress in both ARDS clinical trials of COVID-19 patients. The potential for razuprotafib to prevent ARDS in COVID-19 patients or rescue current ARDS patients from COVID's devasting effects is very exciting. Assuming success in COVID-19 patients, we have the potential to expand the usage of razuprotafib into other life threatening diseases that produce a severe ARDS syndrome. We hope to provide an update from our COVID programs in the first half of 2021," said Joseph Gardner, President and Founder.

Third Quarter 2020 Financial Highlights

As of September 30, 2020, cash and cash equivalents totaled $47.3 million, compared to $38.5 million as of December 31, 2019. Shares outstanding as of September 30, 2020 totaled approximately 47.1 million which includes the 6.5 million shares sold during the quarter ended September 30, 2020. Weighted average shares (basic) outstanding for the three and nine months ended September 30, 2020 were 42.1 million and 41.1 million, respectively.

For the three months ended September 30, 2020, operating expenses totaled $5.9 million, an increase of 18.0% compared to $5.0 million for the same period in 2019.

Research and development expenses for the three months ended September 30, 2020, increased approximately $1.1 million, or 40.1%, to $4.0 million from $2.9 million in the three months ended September 30, 2019. This increase was primarily the result of increased expenses associated with our clinical programs.

General and administrative expenses for the three months ended September 30, 2020, decreased approximately $0.3 million, or 13.2%, to $1.9 million from $2.2 million, in the three months ended September 30, 2019. This decrease was primarily attributable to lower personnel related expenses and stock-based compensation expenses.

Net loss attributable to common stockholders for the three months ended September 30, 2020, was $5.0 million, or $0.12 per share, compared to $4.6 million, or $0.11 per share, for the same period in 2019.

Conference Call and Webcast

Aerpio management will host a live conference call at 8:30 a.m. EST today to discuss Aerpio's financial results and provide a general business update. Please call (877) 407-9716 (U.S.) or (201) 493-6779 (international) to listen to the live conference call. The conference ID number for the live call is 13711910. Please dial in approximately 10 minutes prior to the call.

A live audio webcast will be accessible here.

To ensure a timely connection to the webcast, it is recommended that users register at least 15 minutes prior to the start time. An archived version of the audio webcast will be available for replay on the Company's Archived Events page here.

About Aerpio Pharmaceuticals

Aerpio Pharmaceuticals, Inc. is a biopharmaceutical company focused on developing compounds that activate Tie2 to treat ocular diseases and diabetic complications, as well as other indications in which the Company believes that activation of Tie2 may have therapeutic potential, including acute respiratory distress syndrome ("ARDS") associated with COVID-19 infections. Recently published mouse and human genetic data implicate the Angpt/Tie2 pathway in maintenance of Schlemm's canal, a critical component of the conventional outflow tract. The Company's lead compound, razuprotafib (formerly AKB-9778), a first-in-class small molecule inhibitor of vascular endothelial protein tyrosine phosphatase ("VE-PTP"), is being developed as a potential treatment for open angle glaucoma, and the Company intends to investigate the therapeutic potential of razuprotafib in other indications.. The Company is also evaluating development options for ARP-1536, a humanized monoclonal antibody, for its therapeutic potential in the treatment of diabetic vascular complications including nephropathy and diabetic macular edema ("DME"). The Company's third asset is a bispecific antibody that binds both VEGF and VE-PTP which is designed to inhibit VEGF activation and activate Tie2. This bispecific antibody has the potential to be an improved treatment for wet age-related macular degeneration and DME via intravitreal injection. Finally, the Company has exclusively out-licensed AKB-4924 (now called GB004), a first-in-class small molecule inhibitor of hypoxia-inducible factor-1 (HIF). GB004 is being developed by AKB-4924's exclusive licensor, Gossamer Bio, Inc. (Nasdaq: GOSS). For more information, please visit www.aerpio.com.

About Razuprotafib (formerly known as AKB-9778)

Razuprotafib binds to and inhibits vascular endothelial protein tyrosine phosphatase (VE-PTP), an important negative regulator of Tie2. Decreased Tie2 activity contributes to vascular instability in many diseases including diabetes and more recently has been shown to contribute to the development of increased IOP and glaucoma. Razuprotafib activates the Tie2 receptor irrespective of extracellular levels of its binding ligands, angiopoietin-1 (agonist) or angiopoietin-2 (antagonist) and may be the most efficient pharmacologic approach to maintain normal Tie2 activation. Aerpio is studying a topical ocular formulation of razuprotafib in open angle glaucoma and exploring the utility of subcutaneous razuprotafib for diabetic complications, including diabetic nephropathy. In addition, a subcutaneous formulation of razuprotafib is being explored for its therapeutic potential in treating or preventing ARDS associated with COVID-19.

Forward Looking Statements

This press release contains forward-looking statements. Statements in this press release that are not purely historical are forward-looking statements. Such forward-looking statements include, among other things, the Company's product candidates, including razuprotafib, ARP-1536 and the bispecific antibody asset, the clinical development plan therefor and the therapeutic potential thereof, the Company's plans and expectations with respect to razuprotafib and the development therefor and therapeutic potential thereof in addressing COVID-19 and the intended benefits from the Company's collaboration with Gossamer Bio for GB004, including the continued development of GB004 and the milestone and royalty payments related to the collaboration. Actual results could differ from those projected in any forward-looking statements due to several risk factors. Such factors include, among others, the continued development of GB004 and maintaining and deriving the intended benefits of the Company's collaboration with Gossamer Bio; ability to continue to develop razuprotafib or other product candidates, including in indications related to COVID-19; the inherent uncertainties associated with the drug development process, including uncertainties in regulatory interactions, the design of planned or future clinical trials, commencing clinical trials and enrollment of patients in clinical trials; obtaining any necessary regulatory clearances in order to commence and conduct planned or future clinical trials; the impact of the ongoing COVID-19 pandemic on the Company's business operations, including research and development efforts and the ability of the Company to commence, conduct and complete its planned clinical activities; and competition in the industry in which the Company operates and overall market conditions; and the additional factors set forth in our Annual Report on Form 10-K for the year ended December 31, 2019, as updated by our subsequent Quarterly Reports on Form 10-Q and our other subsequent filings with the SEC.

These forward-looking statements are made as of the date of this press release, and the Company assumes no obligation to update the forward-looking statements, or to update the reasons why actual results could differ from those projected in the forward-looking statements, except as required by law. Investors should consult all the information set forth herein and should also refer to the risk factor disclosure set forth in the reports and other documents the Company files with the SEC available at www.sec.gov.

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Source: Aerpio Pharmaceuticals, Inc.

AERPIO PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands)

	September 30, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 47,282	$ 38,525
Prepaid research and development contracts	456	311
Other current assets	1,845	735
Total current assets	49,583	39,571
Furniture and equipment, net	137	164
Operating lease right-of-use asset	90	162
Deposits	20	40
Total assets	$ 49,830	$ 39,937
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 2,417	$ 3,232
Current portion of operating lease liability	95	103
Total current liabilities	2,512	3,335
Operating lease liability, net of current portion	—	67
Total liabilities	2,512	3,402
Stockholders' equity:		
Capital	189,151	178,771
Accumulated deficit	(141,833)	(142,236)
Total stockholders' equity	47,318	36,535
Total liabilities and stockholders' equity	$ 49,830	$ 39,937

AERPIO PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE (LOSS) INCOME
(In thousands, except per share amounts)

	Three months ended September 30,		Nine months ended September 30,	
	2020	2019	2020	2019
License revenue	$ —	$ —	$15,000	$ —
Operating expenses:				
Research and development	3,986	2,845	9,364	10,695
General and administrative	1,875	2,161	6,357	8,215
Restructuring expense	—	(39)	—	876
Total operating expenses	5,861	4,967	15,721	19,786
Loss from operations	(5,861)	(4,967)	(721)	(19,786)
Interest and other income	906	319	1,123	962
Net and comprehensive (loss) income	$ (4,955)	$ (4,648)	$ 402	$(18,824)
Net (loss) income per common share basic and diluted	$ (0.12)	$ (0.11)	$ 0.01	$ (0.46)
Weighted average common shares outstanding				
Basic	42,139	40,588	41,109	40,588
Diluted	42,139	40,588	41,477	40,588