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 5, 2020

AEGLEA BIOTHERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-37722**	**46-4312787**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

805 Las Cimas Parkway **Suite 100** **Austin, TX** **(Address of principal executive offices)**	**78746** **(Zip Code)**

(512) 942-2935
(Registrant's telephone number, including area code)

N/A

(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	AGLE	The Nasdaq Stock Market LLC (Nasdaq Global Market)

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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 5, 2020, Aeglea BioTherapeutics, Inc. issued a press release announcing its financial results for the quarter ended September 30, 2020. A copy of the press release is attached as Exhibit 99.1 to this report.

The information in this Item 2.02, including Exhibit 99.1 to this report, shall not be deemed to be "filed" for 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 or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended (the "Securities Act"). The information contained in this Item 2.02 and in the accompanying Exhibit 99.1 shall not be incorporated by reference into any other filing under the Exchange Act or under the Securities Act, except as shall be expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Press release issued by Aeglea BioTherapeutics, Inc. regarding its financial results for the quarter ended September 30, 2020, dated November 5, 2020.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURE

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.

AEGLEA BIOTHERAPEUTICS, INC.

Date: November 5, 2020

By: /s/ Charles N. York II
Charles N. York II
Chief Financial Officer

Aeglea BioTherapeutics Reports Third Quarter 2020 Financial Results and Corporate Highlights

Received U.S. Orphan Drug and Positive Opinion for EU Orphan Drug Designations for ACN00177

Continued Progress in Arginase 1 Deficiency Patient Identification and Engagement Efforts

Austin, Texas, November 5, 2020 - Aeglea BioTherapeutics, Inc. (NASDAQ:AGLE), a clinical-stage biotechnology company developing a new generation of human enzyme therapeutics as innovative solutions for rare and other high-burden diseases, today reported its third quarter 2020 financial results, and provided recent corporate and program highlights.

"Although it's been a challenging environment for biotech with the global pandemic, we have continued to be productive in our Arginase 1 Deficiency patient identification and engagement efforts. I am pleased with the progress we are making overall as well as specifically at our PEACE trial sites," said Anthony Quinn, M.B Ch.B, Ph.D., president and chief executive officer of Aeglea. "I am also excited by the momentum we are building in our Homocystinuria program with the recent granting of U.S. Orphan Drug Designation and a positive opinion for EU Orphan Drug Designation for ACN00177."

Recent Highlights and Updates
Pegzilarginase in Arginase 1 Deficiency

- In September, Aeglea announced the PEACE Phase 3 pivotal trial was more than 50% enrolled with nearly twice the number of patients needed to complete enrollment identified at active trial sites. Enrollment for the trial is anticipated to be completed in January 2021.
- As of September, Aeglea has identified over 250 Arginase 1 Deficiency patients in addressable markets, a 25% increase relative to the prior year. The number of currently identified patients represents more than 50% and 30% of the estimated genetic prevalence populations in the U.S. and EU5, respectively.

ACN00177 in Homocystinuria

- In October, Aeglea announced the U.S. Food and Drug Administration granted Orphan Drug Designation to ACN00177 for the treatment of Homocystinuria.
- Additionally, the European Medicines Agency Committee for Orphan Medicinal Products issued a positive opinion recommending Orphan Drug Designation for ACN00177 for the treatment of Homocystinuria in the European Union.

Corporate

- In October, the Company strengthened its financial position with proceeds from shares of common stock sold under its ATM program, resulting in gross proceeds of $25 million, extending its cash runway into 2023.

Upcoming Events

Aeglea will be attending the following virtual investor conferences in the fourth quarter:
- Piper Sandler 32nd Annual Virtual Healthcare Conference, December 1-3
- 3rd Annual Evercore ISI HealthCONx Conference, December 1-3

Third Quarter 2020 Financial Results

As of September 30, 2020, Aeglea had available cash, cash equivalents, marketable securities and restricted cash of $141.5 million. In addition, in October 2020 the Company raised approximately $24.6 million in net proceeds from shares of common stock sold under its ATM program. Based on Aeglea's current operating plan, and taking into account the net offering proceeds, management believes it has sufficient capital resources to fund anticipated operations into 2023.

Research and development expenses totaled $12.5 million for the third quarter of 2020 and $17.8 million for the third quarter of 2019. The decrease was primarily associated with completing certain manufacturing and pre-commercial activities for Aeglea's lead product candidate, pegzilarginase, completing a Phase 1/2 clinical trial in patients with Arginase 1 Deficiency and closing cancer trials; offset

by a ramp-up in manufacturing for ACN00177 in Homocystinuria and higher personnel-related expenses.

General and administrative expenses totaled $5.7 million for the third quarter of 2020 and $4.3 million for the third quarter of 2019. This increase was primarily due to ramping-up commercial capabilities and additional facilities to support company growth.

Net loss totaled $18.0 million and $21.6 million for the third quarter of 2020 and 2019, respectively, with non-cash stock compensation expense of $1.7 million and $1.4 million for the third quarter of 2020 and 2019, respectively.

About Pegzilarginase in Arginase 1 Deficiency

Pegzilarginase is an enhanced human arginase that enzymatically lowers levels of the amino acid arginine. Aeglea is developing pegzilarginase for the treatment of patients with Arginase 1 Deficiency (ARG1-D), a rare debilitating, progressive disease presenting in childhood with persistent hyperargininemia, spasticity, developmental delay, intellectual disability, seizures and early mortality. Pegzilarginase is intended for use as an enzyme therapy to reduce elevated blood arginine levels in patients with ARG1-D. Aeglea's Phase 1/2 and Phase 2 open-label extension data for pegzilarginase in patients with ARG1-D demonstrated clinical improvements and sustained lowering of plasma arginine. The Company's single, global pivotal Phase 3 PEACE trial is designed to assess the effects of treatment with pegzilarginase versus placebo over 24 weeks with a primary endpoint of plasma arginine reduction.

About ACN00177 in Homocystinuria

Aeglea is developing ACN00177 for the treatment of patients with cystathionine beta synthase (CBS) deficiency, also known as Classical Homocystinuria. Homocysteine accumulation plays a key role in multiple progressive and serious disease-related complications, including thromboembolic vascular events, skeletal abnormalities including severe osteoporosis, developmental delay, intellectual disability, lens dislocation and severe near-sightedness. ACN00177 has been designed as a novel recombinant human enzyme, which degrades the amino acid homocysteine and its related homocystine dimer. With this mechanism, ACN00177 is intended to lower the abnormally high blood levels of homocysteine in patients with Homocystinuria. Preclinical data demonstrated that ACN00177 improved important disease-related abnormalities and survival in a mouse model of Homocystinuria. The Company initiated a Phase 1/2 trial in the second quarter of 2020 and continues patient identification and administrative activities. The timing of first patient dosing in this Phase 1/2 trial will depend on determinations by individual sites as they adjust to impacts from COVID-19. ACN00177 has been granted Orphan Drug Designation by the U.S. FDA and received a positive opinion on Orphan Drug Designation from the European Medicines Agency.

About Aeglea BioTherapeutics
Aeglea BioTherapeutics is a clinical-stage biotechnology company redefining the potential of human enzyme therapeutics to benefit people with rare and other high burden diseases. Aeglea's lead product candidate, pegzilarginase, is in a pivotal Phase 3 trial for the treatment of Arginase 1 Deficiency and has received both Rare Pediatric Disease and Breakthrough Therapy Designations. The Company initiated a Phase 1/2 clinical trial of ACN00177 for the treatment of Homocystinuria in the second quarter of 2020. Aeglea has an active discovery platform, with the most advanced program for Cystinuria. For more information, please visit http://aegleabio.com.
Safe Harbor / Forward Looking Statements
This press release contains "forward-looking" statements within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. Forward-looking statements can be identified by words such as: "anticipate," "intend," "plan," "goal," "seek," "believe," "project," "estimate," "expect," "strategy," "future," "likely," "may," "should," "will" and similar references to future periods. These statements are subject to numerous risks and uncertainties that could cause actual results to differ materially from what we expect. Examples of forward-looking statements include, among others, statements we make regarding our cash forecasts, the timing and success of our clinical trials and related data, the timing and expectations for regulatory submissions and approvals, timing and results of meetings with regulators, the timing of announcements and updates relating to our clinical trials and related data, our ability to enroll patients into our clinical trials, the expected impact of the COVID-19 pandemic on our operations and clinical trials, success in our collaborations, the potential addressable markets of the our product candidates and the potential therapeutic benefits and economic value of our lead product candidate or other product candidates. Further information on potential risk factors that could affect our business and its financial results are detailed in our most recent Quarterly Report on Form 10-Q for the quarter ended September 30, 2020 filed with the Securities and Exchange Commission (SEC), and other reports as filed with the SEC. We undertake no obligation to publicly update any forward-looking statement, whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise.

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Financials

Aeglea BioTherapeutics, Inc.
Condensed Consolidated Balance Sheets
(Unaudited)

(In thousands, except share and per share amounts)

	September 30, 2020	December 31, 2019
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 54,223	$ 19,253
Marketable securities	85,753	52,696
Prepaid expenses and other current assets	4,423	2,556
Total current assets	144,399	74,505
Restricted cash	1,500	1,500
Property and equipment, net	5,216	2,385
Operating lease right-of-use assets	4,394	4,726
Other non-current assets	122	67
TOTAL ASSETS	$ 155,631	$ 83,183
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable	$ 2,295	$ 3,154
Operating lease liabilities	341	351
Accrued and other current liabilities	11,713	14,854
Total current liabilities	14,349	18,359
Non-current operating lease liabilities	4,947	4,712
Other non-current liabilities	61	31
TOTAL LIABILITIES	19,357	23,102
STOCKHOLDERS' EQUITY		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized as of September 30, 2020 and December 31, 2019; no shares issued and outstanding as of September 30, 2020 and December 31, 2019	—	—
Common stock, $0.0001 par value; 500,000,000 shares authorized as of September 30, 2020 and December 31, 2019; 44,692,030 shares and 29,084,437 shares issued and outstanding as of September 30, 2020 and December 31, 2019, respectively	5	3
Additional paid-in capital	389,543	255,142
Accumulated other comprehensive income	20	51
Accumulated deficit	(253,294)	(195,115)
TOTAL STOCKHOLDERS' EQUITY	136,274	60,081
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 155,631	$ 83,183

Aeglea BioTherapeutics, Inc.
Condensed Consolidated Statements of Operations
(Unaudited)

(In thousands, except share and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Operating expenses:				
Research and development	$ 12,451	$ 17,839	$ 43,882	$ 47,034
General and administrative	5,672	4,307	14,823	11,391
Total operating expenses	18,123	22,146	58,705	58,425
Loss from operations	(18,123)	(22,146)	(58,705)	(58,425)
Other income (expense):				
Interest income	88	585	549	1,711
Other income (expense), net	2	(12)	(23)	(45)
Total other income	90	573	526	1,666
Net loss	$ (18,033)	$ (21,573)	$ (58,179)	$ (56,759)
Net loss per share, basic and diluted	$ (0.29)	$ (0.66)	$ (1.18)	$ (1.80)
Weighted-average common shares outstanding, basic and diluted	62,240,412	32,894,205	49,473,350	31,596,321