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): May 7, 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 **78746**
(Address of principal executive offices) **(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 May 7, 2020, Aeglea BioTherapeutics, Inc. issued a press release announcing its financial results for the quarter ended March 31, 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 March 31, 2020, dated May 7, 2020.

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: May 7, 2020

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

Aeglea BioTherapeutics Reports First Quarter 2020 Financial Results and Corporate Highlights

Gross Proceeds of $138 Million from April 2020 Public Offering Extends Cash Runway Through 2022

Clinical Trial Application for ACN00177 Approved by MHRA; Progress Toward Phase 1/2 Clinical Trial in Homocystinuria Initiation

Austin, Texas, May 7, 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 first quarter 2020 financial results, and provided recent corporate and program highlights.

“These past few months have brought unique challenges as we navigate the impact of COVID-19, and reminds us all of the critical need for healthcare innovation and new medicines. These needs are all too familiar for people with rare diseases, like Arginase 1 Deficiency, where adequate treatment options are often not available,” said Anthony Quinn, M.B Ch.B, Ph.D., president and chief executive officer of Aeglea. “With our recently completed financing, we have the resources to advance our pegzilarginase program for Arginase 1 Deficiency through regulatory submission and potential FDA approval. With the recent approval of our Clinical Trial Application for ACN00177 for the treatment of Homocystinuria, the company is positioned to bring forward its second clinical-stage human enzyme – both with the potential to be transformative solutions for rare genetic disorders.”

Recent Highlights & COVID-19 Update

Pegzilarginase in Arginase 1 Deficiency

- Aeglea is working with treating physicians to implement individual treatment plans and potentially developing a home healthcare option for patients enrolled in the Phase 3 PEACE trial.
- To date, most enrolled patients have continued to receive treatment. The Company is developing a plan to analyze results for patients that are missing data points. The Phase 3 PEACE trial protocol is designed in such a way that a patient may miss a few doses without being disqualified from the trial.
- The supply chain has not experienced any significant impact at this time and the Company currently has sufficient supply available for completion of its ongoing clinical trials.
- The Company expects to complete enrollment of its Phase 3 PEACE trial in the third quarter of 2020 and to provide topline data in the first quarter of 2021.

ACN00177 in Homocystinuria

- In April, Aeglea announced the approval of its Clinical Trial Application (CTA) by the United Kingdom’s Medicines and Healthcare Products Regulatory Agency (MHRA) for ACN00177, a novel engineered human enzyme therapy designed to treat Homocystinuria, a serious metabolic disorder characterized by elevated plasma homocysteine which leads to a wide range of life-altering complications and reduced life expectancy.
- The Company continues its patient identification and administrative activities to quickly move forward with dosing patients once trial sites are able to initiate clinical trials.
- While Aeglea continues to prepare to initiate a Phase 1/2 trial for ACN00177 in the second quarter of 2020, the timing will depend on determination by individual sites that each is ready to open for recruitment in light of COVID-19; the Company’s priorities at this time are to avoid further overburdening hospital staff and to minimize the risk of trial participants exposure to COVID-19.

Corporate Highlights

- In April, the Company strengthened its financial position with a public offering resulting in gross proceeds of $138 million, which extended its cash runway through 2022.
- The Company implemented policies and practices to protect the health and wellbeing of the Company’s employees and communities, including asking employees to work from home and implementing a work rotation for essential lab employees.
- Aeglea suspended all business travel and transitioned all meetings, including conference attendance and industry events, to virtual meetings.

First Quarter 2020 Financial Results

As of March 31, 2020, Aeglea had available cash, cash equivalents, marketable securities and restricted cash of $50.5 million. In addition, in April 2020 the Company raised approximately $129.6 million in net proceeds from a public offering. 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 through 2022.

Research and development expenses totaled $14.6 million for the first quarter of 2020 and $14.4 million for the first quarter of 2019. The increase was primarily associated with investing in manufacturing and pre-commercial activities for Aeglea's lead product candidate, pegzilarginase; ramp-up in toxicology, nonclinical studies, and manufacturing activities for ACN00177 in Homocystinuria; and personnel-related expenses. The increase was offset by a decrease in clinical development expenses as a result of completing a Phase 1/2 clinical trial in patients with Arginase 1 Deficiency, a Phase 1 clinical trial in patients with advanced solid tumors, and concluding enrollment of a Phase 1/2 combination trial in patients with small cell lung cancer.

General and administrative expenses totaled $4.5 million for the first quarter of 2020 and $3.3 million for the first quarter of 2019. This increase was primarily due to additional employee headcount, ramping up commercial capabilities, and additional facilities to support company growth.

Net loss totaled $18.7 million and $17.2 million for the first quarter of 2020 and 2019, respectively, with non-cash stock compensation expense of $1.3 million and $1.1 million for the first 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 disease presenting in childhood with persistent hyperargininemia, severe progressive neurological abnormalities 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 received approval from the United Kingdom's Medicines and Healthcare Products Regulatory Agency (MHRA) for its Clinical Trial Application (CTA) and continues to prepare to initiate a Phase 1/2 trial in the second quarter of 2020.

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 Designation. Aeglea has an active discovery platform with programs for Homocystinuria and Cystinuria. The Company received approval of its Clinical Trial Application (CTA) for ACN00177 for the treatment of Homocystinuria by the United Kingdom's Medicines and Healthcare Products Regulatory Agency (MHRA) and continues to prepare to initiate a Phase 1/2 trial in the second quarter of 2020. 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 March 31, 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.

Media Contact:
Kelly Boothe, Ph.D.
Director, Corporate Communications
Aeglea BioTherapeutics
512.399.5458
media@aegleabio.com

Investor Contact:
Joey Perrone
Senior Director, Finance & Investor Relations
Aeglea BioTherapeutics
investors@aegleabio.com

Financials

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

(In thousands, except share and per share amounts)

	March 31, 2020	December 31, 2019
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 12,594	$ 19,253
Marketable securities	36,398	52,696
Prepaid expenses and other current assets	5,273	2,556
Total current assets	54,265	74,505
Restricted cash	1,500	1,500
Property and equipment, net	4,244	2,385
Operating lease right-of-use assets	4,712	4,726
Other non-current assets	60	67
TOTAL ASSETS	$ 64,781	$ 83,183
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable	$ 3,618	$ 3,154
Operating lease liabilities	293	351
Accrued and other current liabilities	13,227	14,854
Total current liabilities	17,138	18,359
Non-current operating lease liabilities	4,815	4,712
Other non-current liabilities	23	31
TOTAL LIABILITIES	21,976	23,102
STOCKHOLDERS' EQUITY		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized as of March 31, 2020 and December 31, 2019; no shares issued and outstanding as of March 31, 2020 and December 31, 2019	—	—
Common stock, $0.0001 par value; 500,000,000 shares authorized as of March 31, 2020 and December 31, 2019; 29,147,461 shares and 29,084,437 shares issued and outstanding as of March 31, 2020 and December 31, 2019, respectively	3	3
Additional paid-in capital	256,779	255,142
Accumulated other comprehensive (loss) income	(134)	51
Accumulated deficit	(213,843)	(195,115)
TOTAL STOCKHOLDERS' EQUITY	42,805	60,081
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 64,781	$ 83,183

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

(In thousands, except share and per share amounts)

	Three Months Ended March 31,	
	2020	**2019**
Operating expenses:		
Research and development	14,562	14,389
General and administrative	4,460	3,268
Total operating expenses	19,022	17,657
Loss from operations	(19,022)	(17,657)
Other income (expense):		
Interest income	300	507
Other expense, net	(6)	(17)
Total other income	294	490
Net loss	$ (18,728)	$ (17,167)
Net loss per share, basic and diluted	$ (0.57)	$ 0.59
Weighted-average common shares outstanding, basic and diluted	33,097,736	29,011,737