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): August 6, 2019

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.)**

901 S. MoPac Expressway
Barton Oaks Plaza One
Suite 250
Austin, TX **78746**
(Address of principal executive offices) **(Zip Code)**

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

(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 August 6, 2019, Aeglea BioTherapeutics, Inc. issued a press release announcing its financial results for the quarter ended June 30, 2019. 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 June 30, 2019, dated August 6, 2019.

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: August 6, 2019

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

Exhibit 99.1

Aeglea BioTherapeutics Reports Second Quarter 2019 Financial Results and Corporate Highlights

FDA Breakthrough Therapy Designation Received for Pegzilarginase in Treatment of Arginase 1 Deficiency

Dosed First Patient in Global Pivotal Phase 3 PEACE Trial

New Data from Arginase 1 Deficiency Phase 2 Extension Trial Expected in September 2019

Austin, Texas, August 6, 2019 - Aeglea BioTherapeutics, Inc. (NASDAQ:AGLE), a clinical-stage biotechnology company that engineers next-generation human enzymes to provide solutions for diseases with unmet medical need, today reported financial results for the second quarter ended June 30, 2019 and corporate highlights.

"We made tremendous progress this quarter with pegzilarginase, our lead product candidate for the treatment of Arginase 1 Deficiency (ARG1-D)," said Anthony G. Quinn, M.B. Ch.B., Ph.D., president and chief executive officer of Aeglea. "We dosed our first patient in our global pivotal Phase 3 PEACE trial, which is a major milestone toward providing our therapy to patients. The U.S. Food and Drug Administration's (FDA) breakthrough therapy designation highlights the clinical relevance of the emerging data from the Phase 1/2 and Phase 2 open-label extension clinical trials as well as the potential of pegzilarginase to provide meaningful clinical improvements over available therapy."

Recent Highlights

- Aeglea dosed the first patient in the Company's global pivotal Phase 3 PEACE trial. The pivotal trial is intended to further evaluate the efficacy and safety of pegzilarginase, the Company's lead product candidate for the treatment of ARG1-D, a progressive disease presenting in early childhood that results in severe complications and early mortality. The Company expects to report topline data from the PEACE trial in the first quarter of 2021.

- The FDA granted Breakthrough Therapy Designation (BTD) to the Company's lead product candidate, pegzilarginase, for the treatment of ARG1-D. The FDA's BTD is intended to expedite the development and review of new therapies that are aimed at treating a serious or life-threatening condition when preliminary clinical evidence demonstrates the therapy may have substantial improvement on at least one clinically significant endpoint over available therapy. The designation was based on data from the completed Phase 1/2 clinical trial and the ongoing Phase 2 open-label extension study. Aeglea expects to continue discussions with the FDA regarding the pegzilarginase program and the Company's next steps in the fourth quarter of 2019.

- Interim data from 35 patients in the Company's Phase 1/2 combination trial of pegzilarginase and KEYTRUDA® in extensive disease small cell lung cancer revealed to date one complete response, four partial responses and 11 patients with stable disease. The combination trial was well tolerated, and safety observations were consistent with prior studies of pegzilarginase in patients with cancer. The Company has concluded enrollment and intends on submitting the results for presentation or publication after the final dataset becomes available.

Upcoming Events

Aeglea will present at the following conferences, with details regarding the date and time of the presentations and webcasts to be announced prior to the events.

- Society for the Study of Inborn Errors of Metabolism (SSIEM) Annual Symposium, September 3-6, Rotterdam, Netherlands
- H.C. Wainwright & Co. 21st Annual Global Investment Conference, September 8-10, New York, NY

Second Quarter 2019 Financial Results

As of June 30, 2019, Aeglea had available cash, cash equivalents, marketable securities and restricted cash of $107.0 million. Based on Aeglea's current operating plan, management believes it has sufficient capital resources to fund anticipated operations through the first quarter of 2021.

Research and development expenses totaled $14.8 million for the second quarter of 2019, compared with $9.1 million for the second quarter of 2018. The increase was primarily due to expanded personnel-related expenses, clinical development activity, investment in manufacturing and pre-commercial activities for Aeglea's lead product candidate, pegzilarginase, and a ramp-up in manufacturing

activities for the Company's AEB4104 program for homocystinuria.

General and administrative expenses totaled $3.8 million for the second quarter of 2019, compared with $2.9 million for the second quarter of 2018. This increase was primarily due to additional employee headcount and compensation to support company growth.

Net loss totaled $18.0 million and $9.4 million for the second quarter of 2019 and 2018, respectively, with non-cash stock compensation expense of $1.2 million and $1.0 million for the second quarter of 2019 and 2018, respectively.

About Pegzilarginase in Arginase 1 Deficiency

Pegzilarginase is an enhanced human arginase that enzymatically depletes the amino acid arginine. Aeglea is developing pegzilarginase for the treatment of patients with Arginase 1 Deficiency, 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 replacement therapy in patients to reduce elevated blood arginine levels. Aeglea's Phase 1/2 and Phase 2 open-label extension data evaluating pegzilarginase in patients with Arginase 1 Deficiency demonstrated clinical improvements and sustained lowering of plasma arginine. Aeglea is currently recruiting patients for its single, global pivotal Phase 3 PEACE trial designed to assess the effects of treatment with pegzilarginase versus placebo over 24 weeks with a primary endpoint of plasma arginine reduction.

About Aeglea BioTherapeutics
Aeglea is a clinical-stage biotechnology company that engineers next-generation human enzymes with enhanced properties and novel activity to provide solutions for diseases with unmet medical need. Aeglea is developing pegzilarginase, its lead product candidate, for the treatment of Arginase 1 Deficiency which has received both rare pediatric disease and breakthrough therapy designation. Aeglea has two programs in IND-enabling studies for Homocystinuria and Cystinuria and an active discovery pipeline. 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 potential for expeditated development and review of pegzilarginase as of a result of the Breakthrough Therapy designation, the timing of announcements and updates relating to our clinical trials and related data, our ability to enroll patients into our clinical trials, success in our collaborations 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 June 30, 2019 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)

	June 30, 2019	December 31, 2018
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 25,430	$ 22,461
Marketable securities	80,111	52,052
Prepaid expenses and other current assets	4,394	2,158
Total current assets	109,935	76,671
Restricted cash	1,500	—
Property and equipment, net	921	1,018
Operating lease right-of-use assets	5,018	—
Other non-current assets	120	50
TOTAL ASSETS	$ 117,494	$ 77,739
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable	$ 2,724	$ 663
Operating lease liabilities	328	—
Accrued and other current liabilities	9,967	9,576
Total current liabilities	13,019	10,239
Non-current operating lease liabilities	4,815	—
Other non-current liabilities	45	72
TOTAL LIABILITIES	17,879	10,311
STOCKHOLDERS' EQUITY		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized as of June 30, 2019 and December 31, 2018; no shares issued and outstanding as of June 30, 2019 and December 31, 2018	—	—
Common stock, $0.0001 par value; 500,000,000 shares authorized as of June 30, 2019 and December 31, 2018; 28,848,303 shares and 24,140,097 shares issued and outstanding as of June 30, 2019 and December 31, 2018, respectively	3	2
Additional paid-in capital	251,592	184,314
Accumulated other comprehensive income (loss)	67	(27)
Accumulated deficit	(152,047)	(116,861)
TOTAL STOCKHOLDERS' EQUITY	99,615	67,428
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 117,494	$ 77,739

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

(In thousands, except share and per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Revenues:				
Grant	$ —	$ 2,378	$ —	$ 3,888
Operating expenses:				
Research and development	14,806	9,122	29,195	15,992
General and administrative	3,816	2,926	7,084	5,811
Total operating expenses	18,622	12,048	36,279	21,803
Loss from operations	(18,622)	(9,670)	(36,279)	(17,915)
Other income (expense):				
Interest income	619	263	1,126	406
Other expense, net	(16)	(7)	(33)	(24)
Total other income	603	256	1,093	382
Net loss	$ (18,019)	$ (9,414)	$ (35,186)	$ (17,533)
Net loss per share, basic and diluted	$ (0.55)	$ (0.46)	$ (1.14)	$ (0.94)
Weighted-average common shares outstanding, basic and diluted	32,840,357	20,598,711	30,936,623	18,646,265