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, 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))

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. ☒

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)

Item 2.02 Results of Operations and Financial Condition.

On May 7, 2019, Aeglea BioTherapeutics, Inc. issued a press release announcing its financial results for the quarter ended March 31, 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 March 31, 2019, dated May 7, 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: May 7, 2019

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

Exhibit 99.1

Aeglea BioTherapeutics Reports First Quarter 2019 Financial Results and Corporate Highlights

Statistically Significant Reductions in Plasma Arginine with Accompanying Clinical Improvements with Pegzilarginase in Phase 1/2 Reaffirm Pivotal Trial Design

Gross Proceeds of $69 Million from February 2019 Public Offering Extends Cash Runway Through Q1 of 2021

Pivotal Phase 3 Trial of Pegzilarginase for ARG1-D on Track for First Patient Dosing During 2Q19

Austin, Texas, May 7, 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 first quarter ended March 31, 2019 and corporate highlights.

"Aeglea built on its momentum from 2018 with a terrific start to the year, including the presentation of new compelling clinical data from the Phase 1/2 trial of pegzilarginase for Arginase 1 Deficiency," said Anthony G. Quinn, M.B Ch.B, Ph.D., president and chief executive officer. "We see marked and sustained reductions in plasma arginine in all patients with clinically meaningful improvements in mobility and adaptive behavior. We believe the emergent data from this trial reaffirms the design of our upcoming pivotal Phase 3 PEACE trial, with first patient dosing on track for this quarter."

Corporate Highlights

Pegzilarginase in Arginase 1 Deficiency: Continued progress towards commercialization of the Company's lead program

Aeglea presented new positive Phase 1/2 data for pegzilarginase in patients with Arginase 1 Deficiency (ARG1-D) at the 2019 Annual Meeting of the Society for Inherited Metabolic Disorders (SIMD). The oral presentation was delivered by Dr. George Diaz, M.D., Ph.D., Division Chief of Medical Genetics in the Department of Genetics and Genomic Sciences at the Icahn School of Medicine at Mt. Sinai, New York, NY, and a Principal Investigator on the pegzilarginase Phase 1/2 trial. Highlights of the presentation included the following:

- Plasma arginine reduction was statistically significant ($p<0.001$) at eight weeks with sustained control through longer-term dosing.
- Five of five (100%) and eight of 14 (57%) patients showed overall clinical response (mobility or adaptive behavior) at 20 weeks and eight weeks, respectively. Clinical responses were effectively captured using mobility and adaptive behavior assessments.
- Pegzilarginase was generally well tolerated. Serious adverse events included hypersensitivity and hyperammonemia. Hypersensitivity reactions were infrequent, managed with standard treatment and did not lead to any patient discontinuations.

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.

- Jefferies 2019 Healthcare Conference to be held June 4-7 in New York, NY.
- BMO 2019 Prescriptions for Success Healthcare Conference to be held June 25 in New York, NY.

First Quarter 2019 Financial Results

As of March 31, 2019, Aeglea had available cash, cash equivalents and marketable securities of $123.7 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 $14.4 million for the first quarter of 2019, compared with $6.9 million for the first quarter of 2018. The increase was primarily due to expanded 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 our Homocystinuria program.

General and administrative expenses totaled $3.3 million for the first quarter of 2019, compared with $2.9 million for the first quarter

of 2018. This increase was primarily due to additional employee headcount and compensation to support company growth.

Net loss totaled $17.2 million and $8.1 million for the first quarter of 2019 and 2018, respectively, with non-cash stock compensation expense of $1.1 million and $0.8 million for the first 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 data for pegzilarginase in patients with Arginase 1 Deficiency demonstrated clinical improvements and sustained lowering of plasma arginine. The Company intends to initiate 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 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 investigational therapy, for the treatment of Arginase 1 Deficiency and in combination with an immune checkpoint inhibitor for small cell lung cancer. In addition, Aeglea has an active pipeline of other human enzyme-based approaches including programs for both Homocystinuria and 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, 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 March 31, 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

(In thousands, except share and per share amounts)

	March 31, 2019	December 31, 2018
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 85,645	$ 22,461
Marketable securities	38,070	52,052
Prepaid expenses and other current assets	3,103	2,158
Total current assets	126,818	76,671
Property and equipment, net	952	1,018
Other non-current assets	749	50
TOTAL ASSETS	$ 128,519	$ 77,739
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable	$ 3,223	$ 663
Operating lease liabilities	317	—
Accrued and other current liabilities	8,266	9,576
Total current liabilities	11,806	10,239
Non-current operating lease liabilities	372	—
Other non-current liabilities	52	72
TOTAL LIABILITIES	12,230	10,311
STOCKHOLDERS' EQUITY		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized as of March 31, 2019 and December 31, 2018; no shares issued and outstanding as of March 31, 2019 and December 31, 2018	—	—
Common stock, $0.0001 par value; 500,000,000 shares authorized as of March 31, 2019 and December 31, 2018; 28,837,352 shares and 24,140,097 shares issued and outstanding as of March 31, 2019 and December 31, 2018, respectively	3	2
Additional paid-in capital	250,301	184,314
Accumulated other comprehensive income (loss)	13	(27)
Accumulated deficit	(134,028)	(116,861)
TOTAL STOCKHOLDERS' EQUITY	116,289	67,428
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 128,519	$ 77,739

Aeglea BioTherapeutics, Inc.
Condensed Consolidated Statements of Operations

(In thousands, except share and per share amounts)

	Three Months Ended March 31,	
	2019	**2018**
Revenues:		
Grant	$ —	$ 1,510
Operating expenses:		
Research and development	14,389	6,870
General and administrative	3,268	2,885
Total operating expenses	17,657	9,755
Loss from operations	(17,657)	(8,245)
Other income (expense):		
Interest income	507	143
Other expense, net	(17)	(17)
Total other income	490	126
Net loss	$ (17,167)	$ (8,119)
Net loss per share, basic and diluted	$ (0.59)	$ (0.49)
Weighted-average common shares outstanding, basic and diluted	29,011,737	16,672,125