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 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 November 6, 2019, Aeglea BioTherapeutics, Inc. issued a press release announcing its financial results for the quarter ended September 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 September 30, 2019, dated November 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: November 6, 2019

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

Exhibit 99.1

Aeglea BioTherapeutics Reports Third Quarter 2019 Financial Results and Corporate Highlights

Austin, Texas, November 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 third quarter ended September 30, 2019 and corporate highlights.

"We are excited about our pivotal Phase 3 PEACE trial in Arginase 1 Deficiency (ARG1-D), given the positive 20-dose data from our completed Phase 1/2 trial and ongoing Phase 2 open-label extension trial for pegzilarginase in patients with ARG1-D," said Anthony G. Quinn, M.B Ch.B, Ph.D., president and chief executive officer of Aeglea. "Additionally, we are delighted to welcome Dr. Ravi Rao as chief medical officer and Mike Hanley as chief commercial officer, key executive leadership team additions who will help shape our future and continue the momentum of our ARG1-D, homocystinuria and cystinuria programs."

Recent Highlights

- Aeglea presented positive 20-dose data on 14 patients from the Company's completed Phase 1/2 trial and ongoing Phase 2 open-label extension (OLE) trial for pegzilarginase in patients with ARG1-D at the 2019 Symposium of the Society for the Study of Inborn Errors of Metabolism (SSIEM). All patients achieved a substantial reduction in plasma arginine with the median reduction of 274 μm from baseline to 20 doses. Aeglea reported 79% (11 of 14) of patients were clinical responders, using mobility assessment components that correspond with the PEACE trial's secondary endpoint. Pegzilarginase was well tolerated and the rates of treatment-related adverse events decreased over time.
- Data from 10 patients dosed subcutaneously (sc) with pegzilarginase in the ongoing OLE trial for ARG1-D demonstrated that sc administration of pegzilarginase controls plasma arginine levels. All 10 patients remain on pegzilarginase sc with no patient discontinuations.
- Mike Hanley joined Aeglea as Chief Commercial Officer in October 2019. Mr. Hanley was previously Vice President and U.S. Chief Commercial Officer for Esteve Pharmaceuticals. He also served as Group Vice President and General Manager, Orphan Business Unit for Horizon Therapeutics. Mr. Hanley has 20 years of commercial leadership experience in the life sciences industry.
- Dr. Ravi Rao joined the Company as Chief Medical Officer in November 2019. Dr. Rao comes to Aeglea from GlaxoSmithKline, where he served as Vice President, Global Medical Affairs Head, Immunology and Specialty Franchise, leading programs across a number of emerging disease areas. Dr. Rao completed his residency training in London and is a Member of the Royal College of Physicians, London. He received his MB. BChir from Cambridge University and his Ph.D. in vascular biology from Imperial College, London in the United Kingdom and completed a postdoctoral fellowship at Harvard Medical School.

Upcoming Events

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

- Jefferies 2019 London Healthcare Conference, November 20-21, London, UK
- Evercore ISI HealthCONx, December 3, Boston, MA
- Piper Jaffray Healthcare Conference, December 4-5, New York, NY

Aeglea will present a poster presentation titled "Impact of Enzymatic Degradation of Plasma Cystine in a Mouse Model of Cystinuria Under Dehydration Challenge" on Thursday, November 7th from 10:00 a.m. - 12:00 p.m. ET at the American Society of Nephrology Kidney Week annual meeting being held November 5 – 10 at the Walter E. Washington Convention Center in Washington, DC.

The Company expects to discuss the trial design for the AEB4104 program for homocystinuria during the investor conferences in the fourth quarter of 2019, prior to its filing of an IND or CTA in the first quarter of 2020.

Third Quarter 2019 Financial Results

As of September 30, 2019, Aeglea had available cash, cash equivalents, marketable securities and restricted cash of $90.2 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 $17.8 million for the third quarter of 2019, compared with $8.9 million for the third quarter of 2018. The increase was primarily due to investing in manufacturing and pre-commercial activities for Aeglea's lead product candidate, pegzilarginase, a ramp-up in toxicology, IND-enabling studies, and manufacturing activities for the Company's AEB4104 program for homocystinuria, and expanded clinical development activity and personnel-related expenses.

General and administrative expenses totaled $4.3 million for the third quarter of 2019, compared with $3.3 million for the third quarter of 2018. This increase was primarily due to additional employee headcount, compensation, and facilities to support company growth.

Net loss totaled $21.6 million and $11.9 million for the third quarter of 2019 and 2018, respectively, with non-cash stock compensation expense of $1.4 million and $1.1 million for the third 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 OLE data for pegzilarginase in patients with Arginase 1 Deficiency 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 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 September 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)

	September 30, 2019	December 31, 2018
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 24,545	$ 22,461
Marketable securities	64,155	52,052
Prepaid expenses and other current assets	3,930	2,158
Total current assets	92,630	76,671
Restricted cash	1,500	—
Property and equipment, net	980	1,018
Operating lease right-of-use assets	4,872	—
Other non-current assets	114	50
TOTAL ASSETS	$ 100,096	$ 77,739
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable	$ 2,431	$ 663
Operating lease liabilities	289	—
Accrued and other current liabilities	12,676	9,576
Total current liabilities	15,396	10,239
Non-current operating lease liabilities	4,867	—
Other non-current liabilities	38	72
TOTAL LIABILITIES	20,301	10,311
STOCKHOLDERS' EQUITY		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized as of September 30, 2019 and December 31, 2018; no shares issued and outstanding as of September 30, 2019 and December 31, 2018	—	—
Common stock, $0.0001 par value; 500,000,000 shares authorized as of September 30, 2019 and December 31, 2018; 28,923,241 shares and 24,140,097 shares issued and outstanding as of September 30, 2019 and December 31, 2018, respectively	3	2
Additional paid-in capital	253,334	184,314
Accumulated other comprehensive income (loss)	78	(27)
Accumulated deficit	(173,620)	(116,861)
TOTAL STOCKHOLDERS' EQUITY	79,795	67,428
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 100,096	$ 77,739

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,	
	2019	2018	2019	2018
Revenues:				
Grant	$ —	$ —	$ —	$ 3,888
Operating expenses:				
Research and development	17,839	8,929	47,034	24,921
General and administrative	4,307	3,314	11,391	9,125
Total operating expenses	22,146	12,243	58,425	34,046
Loss from operations	(22,146)	(12,243)	(58,425)	(30,158)
Other income (expense):				
Interest income	585	339	1,711	745
Other expense, net	(12)	(13)	(45)	(37)
Total other income	573	326	1,666	708
Net loss	$ (21,573)	$ (11,917)	$ (56,759)	$ (29,450)
Net loss per share, basic and diluted	$ (0.66)	$ (0.54)	$ (1.80)	$ (1.49)
Weighted-average common shares outstanding, basic and diluted	32,894,205	21,986,989	31,596,321	19,772,077