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 8, 2018

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. ☒

Item 2.02 Results of Operations and Financial Condition.

On November 8, 2018, Aeglea BioTherapeutics, Inc. issued a press release announcing its financial results for the quarter ended September 30, 2018. 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, 2018, dated November 8, 2018.

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 8, 2018

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

Exhibit 99.1

Aeglea BioTherapeutics Reports Third Quarter 2018 Financial Results and Recent Corporate Highlights

Austin, Texas, November 8, 2018 - Aeglea BioTherapeutics, Inc. (NASDAQ:AGLE), a clinical-stage biotechnology company that designs and develops innovative human enzyme therapeutics for patients with rare genetic diseases and cancer, today reported financial results for the third quarter ended September 30, 2018.

“2018 continues to be a highly productive year for Aeglea as we advance our clinical experience in pegzilarginase and demonstrate our drug hunting capabilities in rare genetic diseases," said Anthony G. Quinn, M.B Ch.B, Ph.D., president and chief executive officer of Aeglea. “Our data in Arginase 1 Deficiency (ARG1-D) continues to demonstrate rapid, well-tolerated and sustainable control of arginine that corresponds with significant improvements in patients. This progress with pegzilarginase puts us in a strong position as we look to initiate our pivotal trial in ARG1-D in the first half of 2019.”

Recent Highlights

Pegzilarginase in Arginase 1 Deficiency: Significant Progress Towards Commercialization of the Company’s Lead Program

- In October, the Company presented new positive interim clinical data at the 2018 American Society of Human Genetics (ASHG) Conference from its ongoing Phase 1/2 trial of pegzilarginase in patients with ARG1-D. The Company completed and exceeded its enrollment target with 16 patients and observed significant clinical improvements. 100% of patients (6 out of 6) who completed Part 2 (repeat dosing) of the study achieved consistent levels of reduced arginine. 67% of patients (4 out of 6) had meaningful clinical improvements in mobility and/or adaptive behavior after only eight weeks of repeat dosing with pegzilarginase. Pegzilarginase continues to be generally well tolerated with over 180 infusions administered to date.
- In October, the Company announced that the U.S. Food and Drug Administration (FDA) has granted rare pediatric disease designation for pegzilarginase in ARG1-D.

Rare Genetic Disease Pipeline: Expansion and Acceleration

- In October, the Company presented positive preclinical efficacy data on two rare genetic disease programs in the Company’s pipeline at two major medical conferences. At the 2018 ASHG Conference, the Company presented data for AEB4104 demonstrating decreases in plasma homocysteine levels that improved important disease-related abnormalities and survival in a preclinical model of homocystinuria. At the 2018 American Society of Nephrology (ASN) Conference, the Company presented data for AEB5100 demonstrating reductions in plasma and urine cystine levels, accompanied by reduced kidney stone formation in a preclinical model of cystinuria. Both programs are advancing into IND-enabling studies.

Cancer: Promising Data at ESMO

- At the European Society for Medical Oncology (ESMO) 2018 Congress in October, the Company presented interim clinical data demonstrating monotherapy anti-tumor activity with pegzilarginase in heavily pre-treated patients with advanced melanoma. The investigator-assessed responses in 26 patients with cutaneous or uveal melanoma showed that one patient achieved a confirmed partial response (PR) at week 20 and eight patients had stable disease (SD) at week 8 or later. Six patients remained on treatment at the time of the data cutoff. Anti-tumor activity appeared greater in tumors lacking argininosuccinate synthetase 1 (ASS1) expression, which is consistent with preclinical studies that suggest tumors lacking ASS1 expression are dependent on extracellular arginine for survival.

Corporate Update

- Raised $17.0 million in a single transaction in October from new and existing shareholders. The capital will be used to fund the planned pivotal trial in ARG1-D, initiate IND-enabling studies for the Company’s pipeline programs, and accelerate commercialization activities for pegzilarginase in ARG1-D.

Upcoming Events

- Dr. Quinn will present a corporate update at the Evercore ISI Healthcare Conference being held November 27-29 in Boston, MA. Details regarding the date and time of the presentation and webcast will be announced prior to the conference.
- Dr. Quinn will present a corporate update at the BMO Capital Markets 2018 Prescription for Success Healthcare Conference being held December 12 in New York, NY. Details regarding the time of the presentation and webcast will be announced prior to the conference.

Third Quarter 2018 Financial Results

As of September 30, 2018, Aeglea had available cash, cash equivalents and marketable securities of $64.7 million, which excludes approximately $17.0 million in gross proceeds from shares of common stock sold in a single transaction to new and existing shareholders in October 2018. Based on Aeglea's current operating plan, and taking into account the $17.0 million raised in October 2018, management believes it has sufficient capital resources to fund anticipated operations to the middle of 2020.

Grant revenues were the result of a $19.8 million research grant received from the Cancer Prevention and Research Institute of Texas (CPRIT). The grant contract concluded in May 2018 with the full $19.8 million grant recognized as revenue over the life of the award. Aeglea did not recognize any grant revenues in the third quarter of 2018, compared with $1.3 million in the third quarter of 2017. As of September 30, 2018, Aeglea had a remaining grant receivable totaling $2.4 million.

Research and development expenses totaled $8.9 million for the third quarter of 2018, compared with $6.2 million for the third quarter of 2017. The increase was primarily due to expanded clinical development activity for Aeglea's lead product candidate, pegzilarginase. Aeglea completed enrollment in the ARG1-D Phase 1/2 clinical trial, continued single-agent cohort expansions in a Phase 1 clinical trial for advanced solid tumor patients and progressed the Phase 1/2 combination trial in patients with small cell lung cancer.

General and administrative expenses totaled $3.3 million for the third quarter of 2018, compared with $3.0 million in the third quarter of 2017. This increase was primarily due to additional employee compensation costs related to the building out of Aeglea's management team to support company growth. Net loss totaled $11.9 million and $7.9 million for the third quarter of 2018 and 2017, respectively, with non-cash stock compensation expense of $1.1 million and $0.7 million for the third quarter of 2018 and 2017, 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 interim Phase 1/2 data demonstrated clinical improvements and rapid and sustained lowering of plasma arginine in Arginase 1 Deficiency patients.

About AEB4104 (Homocysteinase) in Homocystinuria

AEB4104 is a novel recombinant human enzyme that degrades the amino acid homocysteine and its oxidized form homocystine. Aeglea is developing AEB4104 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 skeletal abnormalities, cognitive impairment, psychiatric disease, and thromboembolism. AEB4104 is intended to lower the abnormally high blood levels of homocysteine to the normal range in patients with homocystinuria. Preclinical data demonstrated that AEB4104 improved important disease-related abnormalities and survival in a mouse model of homocystinuria.

About AEB5100 (Cystinase) in Cystinuria

AEB5100 is a novel recombinant human enzyme that degrades cystine and the parent amino acid cysteine. Aeglea is developing AEB5100 for the treatment of patients with cystinuria, a rare genetic disease characterized by frequent and recurrent kidney stone formation requiring multiple procedural interventions, and by an increased risk of chronic kidney disease. Cystinuria occurs due to genetic mutations in amino acid transporters that lead to increased amounts of cystine in the urine. This results in high cystine concentrations in the urine and formation of kidney stones. Preclinical data demonstrated that AEB5100 lowered blood levels of cystine and cysteine, decreased the amount of cystine in the urine and reduced kidney stone formation in a mouse model of cystinuria.

About Pegzilarginase in Cancer

Pegzilarginase is an enhanced human arginase that enzymatically degrades the amino acid arginine. In some cancers, tumor cells are unable to produce specific amino acids and must acquire them from the blood, making the tumor cells susceptible to starvation through depletion of those amino acids. Aeglea is developing pegzilarginase to exploit vulnerabilities in some cancers that lead to an increased dependency on extracellular arginine. Pegzilarginase targets these arginine dependent cancers by depleting blood arginine levels to below the normal range. Preclinical data demonstrated that the resulting arginine starvation inhibits proliferation, induces cell death, increases turnover of cell components and promotes anti-tumor immune responses. The Company's Phase 1 data in advanced solid tumors demonstrated that pegzilarginase was well tolerated at doses that produced marked and sustained reductions in blood arginine levels below the normal range.

About Aeglea BioTherapeutics

Aeglea is a clinical-stage biotechnology company that designs and develops innovative human enzyme therapeutics for patients with rare genetic diseases and cancer. Aeglea is developing pegzilarginase, its lead investigational therapy, for the treatment of Arginase 1 Deficiency, as monotherapy in arginine-dependent cancers and in combination with an immune checkpoint inhibitor for small cell lung cancer. In addition, Aeglea has an active research pipeline of other human enzyme-based approaches in both therapeutic areas. 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 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, 2018 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:
David Calusdian
Sharon Merrill Associates
617.542.5300
AGLE@investorrelations.com

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

Financials

Aeglea BioTherapeutics, Inc.
Condensed Consolidated Balance Sheets

(In thousands, except share and per share amounts)

	September 30, 2018	December 31, 2017
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 14,532	$ 12,817
Marketable securities	50,203	37,482
Accounts receivable - grant	2,422	3,078
Prepaid expenses and other current assets	3,225	1,614
Total current assets	70,382	54,991
Property and equipment, net	846	854
Other non-current assets	49	232
TOTAL ASSETS	$ 71,277	$ 56,077
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable	$ 1,077	$ 389
Deferred revenue	—	20
Accrued and other current liabilities	6,438	5,220
Total current liabilities	7,515	5,629
Other non-current liabilities	81	111
TOTAL LIABILITIES	7,596	5,740
STOCKHOLDERS' EQUITY		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized as of September 30, 2018 and December 31, 2017; no shares issued and outstanding as of September 30, 2018 and December 31, 2017	—	—
Common stock, $0.0001 par value; 500,000,000 shares authorized as of September 30, 2018 and December 31, 2017; 22,098,218 shares and 16,670,188 shares issued and outstanding as of September 30, 2018 and December 31, 2017, respectively	2	2
Additional paid-in capital	165,675	122,950
Accumulated other comprehensive loss	(33)	(102)
Accumulated deficit	(101,963)	(72,513)
TOTAL STOCKHOLDERS' EQUITY	63,681	50,337
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 71,277	$ 56,077

Aeglea BioTherapeutics, Inc.
Condensed Consolidated Statements of Operations

(In thousands, except share and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Revenues:				
Grant	$ —	$ 1,261	$ 3,888	$ 3,723
Operating expenses:				
Research and development	8,929	6,239	24,921	17,024
General and administrative	3,314	3,020	9,125	7,749
Total operating expenses	12,243	9,259	34,046	24,773
Loss from operations	(12,243)	(7,998)	(30,158)	(21,050)
Other income (expense):				
Interest income	339	136	745	332
Other expense, net	(13)	(12)	(37)	(35)
Total other income	326	124	708	297
Net loss	$ (11,917)	$ (7,874)	$ (29,450)	$ (20,753)
Net loss per share, basic and diluted	$ (0.54)	$ (0.48)	$ (1.49)	$ (1.42)
Weighted-average common shares outstanding, basic and diluted	21,986,989	16,409,871	19,772,077	14,641,082