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 9, 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 August 9, 2018, Aeglea BioTherapeutics, Inc. issued a press release announcing its financial results for the quarter ended June 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 June 30, 2018, dated August 9, 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: August 9, 2018

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

Exhibit 99.1

Aeglea BioTherapeutics Provides Corporate Update and Reports Second Quarter 2018 Financial Results

Austin, Texas, August 9, 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 provided a corporate update and reported financial results for the second quarter ended June 30, 2018.

"We made good progress in the second quarter with our clinical programs, and we completed a follow-on financing that sets the stage for an exciting second half of the year," said Anthony G. Quinn, M.B Ch.B, Ph.D., president and chief executive officer of Aeglea. "We are looking forward to providing clinical updates at a number of medical conferences in the fall, including reporting the latest interim data from both our Arginase 1 Deficiency and cancer development programs. We also will provide updates on our clinical trial enrollment and our progress with one of our research enzyme programs, which we believe shows promise for treating the metabolic disorder homocystinuria."

"With the management team we now have in place, Aeglea is ready to take the next step in advancing therapies with the potential to improve the lives of patients with devastating diseases. I believe the Company is well positioned for future growth with our current pipeline programs and our expanded in-house drug-hunting capabilities," added Dr. Quinn.

Recent Highlights

- In July, the Company's Board of Directors named Anthony G. Quinn, M.B. Ch.B, Ph.D. as president and chief executive officer. Dr. Quinn has been a member of the Board of Directors since 2016 and had served as interim CEO since July 2017. Prior to joining Aeglea, Dr. Quinn served as executive vice president, head of research and development, and chief medical officer at Synageva Biopharma Corp., prior to its acquisition by Alexion Pharmaceuticals.
- In July, the Company announced the appointment of Bryan Lawlis, Ph.D., as an independent director. Dr. Lawlis served as CEO of Itero Biopharmaceuticals, LLC from 2011 to 2017 and from 2007 to 2011 was co-founder and CEO of Itero Biopharmaceuticals, Inc. He is currently on the boards of Biomarin Pharmaceutical, Inc., Geron, Inc., and Coherus Biosciences, Inc.

Upcoming Events

- Dr. Quinn will present a corporate update at the Wells Fargo Healthcare Conference being held September 5 – 6 in Boston, MA. Details regarding the date and time of the presentation and webcast will be announced before the conference.
- Aeglea will present new interim Phase 1/2 clinical trial data demonstrating clinically relevant treatment effects in patients with Arginase 1 Deficiency at the 2018 Society for the Study of Inborn Errors of Metabolism (SSIEM) Annual Symposium being held September 4 – 7 in Athens, Greece.
    - Title: Improvements in Arginase 1 Deficiency-related disease manifestations following plasma arginine reduction with pegzilarginase
    - Poster #P-164
    - Presentation Date/Time: Wednesday, September 5 at 5:45 p.m. – 8:30 p.m. EET and Thursday, September 6 at 12:15 p.m. – 1:15 p.m. EET
- Aeglea will deliver three poster presentations detailing clinical and preclinical data at the American Society of Human Genetics (ASHG) 2018 Annual Meeting being held October 16 – 20 in San Diego, California (schedule details to be announced):
    - Interim Phase 1/2 clinical trial data for the treatment of Arginase 1 Deficiency that will include additional clinical insights from recently enrolled adult and pediatric patients, as well as from longer-term dosing in previously enrolled patients
        - Title: Improvements in Arginase 1 Deficiency-related disease manifestations following plasma arginine reduction with pegzilarginase: early Phase 2 results
    - The effects of a novel homocysteine degrading enzyme in a preclinical model of homocystinuria.
        - Title: Improved survival and amelioration of disease-related liver pathology in a mouse model of homocystinuria with a novel homocysteine degrading enzyme
    - Summary of disease manifestation in Arginase 1 Deficiency case reports from scientific literature
        - Title: Clinical features of Arginase 1 Deficiency: Review of Literature Case Series

- Aeglea will present interim Phase 1 advanced solid tumor clinical trial data on melanoma expansion cohorts at the 2018 European Society for Medical Oncology (ESMO) Annual Congress being held October 19 – 23 in Munich, Germany.
    - Title: Initial cohort expansion results of sustained arginine depletion with pegzilarginase in melanoma patients in a Phase 1 advanced solid tumor trial
    - Abstract #1269P
    - Presentation Date/Time: Sunday, October 21 at 1:35 p.m. – 2:35 p.m. CEST

Second Quarter 2018 Financial Results

As of June 30, 2018, Aeglea had available cash, cash equivalents and marketable securities of $72.2 million, which includes $37.7 million in net proceeds from a follow-on public offering that closed in April 2018. Based on Aeglea's current operating plan, management believes it has sufficient capital resources to fund anticipated operations to the middle of 2020.

Aeglea recognized grant revenues of $2.4 million in the second quarter of 2018, compared with $1.5 million in the second quarter of 2017. The grant revenues were the result of a $19.8 million research grant received from the Cancer Prevention and Research Institute of Texas (CPRIT). The revenue increase was primarily due to higher qualifying expenditures associated with the clinical trials for pegzilarginase in cancer patients in the second quarter of 2018 compared with the second quarter of 2017. Additionally, the grant contract ended in May 2018 with the full $19.8 million grant recognized as revenue over the life of the award. As of June 30, 2018, Aeglea had a remaining grant receivable totaling $4.3 million.

Research and development expenses totaled $9.1 million for the second quarter of 2018, compared with $5.8 million for the second quarter of 2017. The increase was primarily due to expanded clinical activity for Aeglea's lead product candidate, pegzilarginase, as Aeglea advanced a Phase 1/2 clinical trial in patients with Arginase 1 Deficiency and initiated single-agent cohort expansions in a Phase 1 clinical trial for advanced solid tumor patients and a Phase 1/2 combination trial in patients with small cell lung cancer.

General and administrative expenses totaled $2.9 million for the second quarter of 2018, compared with $2.4 million in the second quarter of 2017. This increase was primarily due to additional employee compensation costs related to the building out of Aeglea's management team as well as to support expanding research and development activities. Non-cash stock compensation expense accounted for $0.2 million of the increase.

Net loss totaled $9.4 million and $6.6 million for the second quarter of 2018 and 2017, respectively, with non-cash stock compensation expense of $1.0 million and $0.7 million for the second quarter of 2018 and 2017, respectively.

Inducement Grants Under Nasdaq Listing Rule 5635(c)(4)

Aeglea also announced today that the Compensation Committee of its Board of Directors has granted non-qualified stock options to purchase an aggregate of 2,400 shares of Aeglea's common stock to two new employees under Aeglea's 2018 Equity Inducement Plan.

The 2018 Equity Inducement Plan is used exclusively for the grant of equity awards to individuals who were not previously an employee or non-employee director of Aeglea (or following a bona fide period of non-employment), as an inducement material to such individual's entering into employment with Aeglea, pursuant to Rule 5635(c)(4) of the NASDAQ Listing Rules.

The options have an exercise price of $8.98 per share, which is equal to the closing price of Aeglea's common stock on August 7, 2018. Each of the option awards vests as to 25% of the shares on the one-year anniversary of its grant, with the remainder of the shares vesting ratably over 36 months thereafter.

About Pegzilarginase in Arginase 1 Deficiency

Pegzilarginase is an enhanced human arginase that enzymatically degrades the amino acid arginine. Aeglea is developing pegzilarginase for the treatment of patients with Arginase 1 Deficiency, a debilitating urea cycle disorder caused by deficiency of a key arginine metabolizing enzyme that leads to severe and progressive hyperargininemia-related neurological abnormalities, hyperammonemia and early mortality. Pegzilarginase is intended for use as an enzyme replacement therapy in patients to reduce elevated blood arginine levels. The Company's interim Phase 1/2 data demonstrated clinically relevant treatment effects and rapid and sustained lowering of plasma arginine in Arginase 1 Deficiency patients.

About Pegzilarginase in Cancer

Pegzilarginase is an enhanced human arginase that enzymatically degrades the amino acid arginine. In some cancers, tumor cells stop producing 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 June 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.

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Financials

Aeglea BioTherapeutics, Inc.
Condensed Consolidated Balance Sheets

(In thousands, except share and per share amounts)

	June 30, 2018	December 31, 2017
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 20,579	$ 12,817
Marketable securities	51,614	37,482
Accounts receivable - grant	4,281	3,078
Prepaid expenses and other current assets	2,414	1,614
Total current assets	78,888	54,991
Property and equipment, net	776	854
Other non-current assets	49	232
TOTAL ASSETS	$ 79,713	$ 56,077
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable	$ 952	$ 389
Deferred revenue	—	20
Accrued and other current liabilities	5,223	5,220
Total current liabilities	6,175	5,629
Other non-current liabilities	91	111
TOTAL LIABILITIES	6,266	5,740
STOCKHOLDERS' EQUITY		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized as of June 30, 2018 and December 31, 2017; no shares issued and outstanding as of June 30, 2018 and December 31, 2017	—	—
Common stock, $0.0001 par value; 500,000,000 shares authorized as of June 30, 2018 and December 31, 2017; 21,908,192 shares and 16,670,188 shares issued and outstanding as of June 30, 2018 and December 31, 2017, respectively	2	2
Additional paid-in capital	163,547	122,950
Accumulated other comprehensive loss	(56)	(102)
Accumulated deficit	(90,046)	(72,513)
TOTAL STOCKHOLDERS' EQUITY	73,447	50,337
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 79,713	$ 56,077

Aeglea BioTherapeutics, Inc.
Condensed Consolidated Statements of Operations

(In thousands, except share and per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Revenues:				
Grant	$ 2,378	$ 1,479	$ 3,888	$ 2,462
Operating expenses:				
Research and development	9,122	5,835	15,992	10,784
General and administrative	2,926	2,364	5,811	4,729
Total operating expenses	12,048	8,199	21,803	15,513
Loss from operations	(9,670)	(6,720)	(17,915)	(13,051)
Other income (expense):				
Interest income	263	100	406	195
Other expense, net	(7)	(12)	(24)	(23)
Total other income	256	88	382	172
Net loss	$ (9,414)	$ (6,632)	$ (17,533)	$ (12,879)
Net loss per share, basic and diluted	$ (0.46)	$ (0.47)	$ (0.94)	$ (0.94)
Weighted-average common shares outstanding, basic and diluted	20,598,711	14,114,101	18,646,265	13,742,029