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 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 May 8, 2018, Aeglea BioTherapeutics, Inc. issued a press release announcing its financial results for the quarter ended March 31, 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 March 31, 2018, dated May 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: May 8, 2018

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

Exhibit 99.1

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

Austin, Texas, May 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 provided a corporate update and reported financial results for the quarter ended March 31, 2018.

"The first quarter was a terrific start to our year, with a number of positive and encouraging developments in our lead clinical investigational program, pegzilarginase," said Anthony G. Quinn, M.B Ch.B, Ph.D., interim chief executive officer of Aeglea. "I'm excited that we are seeing the first evidence that marked and sustained reductions in plasma arginine with pegzilarginase translated into clinically relevant treatment effects for two patients with Arginase 1 Deficiency. We plan to continue to build on this momentum by reporting additional repeat dose data in patients with Arginase 1 Deficiency in the third quarter of 2018 and finalizing our pivotal study design by the end of the year. In addition, we expect to report topline safety and clinical data from our cancer trials in the fourth quarter of 2018.

"Our April follow-on offering provides us with capital to continue to advance our planned operations and further develop our capabilities as we transition into a pivotal study and start planning for a commercial launch. Our strong cash position and our worldwide commercial rights for pegzilarginase position us favorably to build on recent clinical achievements with investments focusing on accelerating our clinical and pipeline programs."

Corporate Update

Arginase 1 Deficiency:

- Aeglea presented initial data that it believes demonstrated clinically relevant treatment effects with pegzilarginase in two Arginase 1 Deficiency patients after only eight weeks of dosing and confirmed the utility of standardized assessment tools in quantifying disease manifestations at the 2018 Annual Clinical Genetics Meeting of the American College of Medical Genetics and Genomics (ACMG) in April. This built upon data presented at the 2018 Annual Meeting of The Society for Inherited Metabolic Disorders (SIMD) that demonstrated pegzilarginase produces marked and sustained reductions in plasma arginine in patients with Arginase 1 Deficiency.
- Aeglea expects to report additional pediatric and adult repeat dose data in patients with Arginase 1 Deficiency in the third quarter of 2018.

Cancer:

- Aeglea dosed the first patients with pegzilarginase in two small cell lung cancer (SCLC) trials: the single-agent Phase 1 cohort expansion and the Phase 1/2 combination trial with KEYTRUDA®, an anti-PD-1 therapy marketed by Merck (known as MSD outside the United States and Canada).
- Aeglea presented Phase 1 dose escalation data regarding pegzilarginase in patients with advanced solid tumors at the 2018 Annual Meeting of the American Association for Cancer Research (AACR) in April.
- The Company expects to report topline data, including safety and clinical activity, for the advanced solid tumor cohort expansions and the SCLC combination trial in the fourth quarter of 2018.
- Aeglea expects to initiate Phase 2 of its combination trial for patients with SCLC in the third quarter of 2018.

Upcoming Events

Aeglea will participate and provide a corporate update at the UBS Global Healthcare Conference in New York, May 21-23, 2018.

First Quarter 2018 Financial Results

As of March 31, 2018, Aeglea had available cash, cash equivalents and marketable securities of $43.5 million, which excludes approximately $37.7 million in net proceeds from a follow-on public offering which closed on April 23, 2018. Based on Aeglea's current operating plan, management believes it has sufficient capital resources to fund anticipated operations through the middle of 2020.

Aeglea recognized grant revenues of $1.5 million in the first quarter of 2018, compared with $1.0 million in the first 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 first quarter of 2018 compared with the first quarter of 2017.

Research and development expenses totaled $6.8 million for the first quarter of 2018, compared with $4.9 million for the first 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 three single-agent cohort expansions in advanced solid tumor patients and a Phase 1/2 combination trial with KEYTRUDA in patients with small cell lung cancer.

General and administrative expenses totaled $2.8 million for the first quarter of 2018, compared with $2.3 million in the first quarter of 2017. This increase was primarily due to additional employee headcount and compensation costs to further strengthen Aeglea's management team and support expanding research and development activities.

Net loss totaled $8.1 million and $6.2 million for the first quarter of 2018 and 2017, respectively.

Inducement Grants

Aeglea also announced today that the Compensation Committee of its Board of Directors has granted non-qualified stock options to purchase an aggregate of 21,000 shares of Aeglea's common stock to three 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 $9.76 per share, which is equal to the closing price of Aeglea's common stock on May 3, 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 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 March 31, 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)

	March 31, 2018	December 31, 2017
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 10,760	$ 12,817
Marketable securities	32,715	37,482
Accounts receivable - grant	3,373	3,078
Prepaid expenses and other current assets	1,995	1,614
Total current assets	48,843	54,991
Property and equipment, net	810	854
Other non-current assets	133	232
TOTAL ASSETS	$ 49,786	$ 56,077
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable	$ 763	$ 389
Deferred revenue	—	20
Accrued and other current liabilities	5,002	5,220
Total current liabilities	5,765	5,629
Other non-current liabilities	101	111
TOTAL LIABILITIES	5,866	5,740
STOCKHOLDERS' EQUITY		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized as of March 31, 2018 and December 31, 2017; no shares issued and outstanding as of March 31, 2018 and December 31, 2017	—	—
Common stock, $0.0001 par value; 500,000,000 shares authorized as of March 31, 2018 and December 31, 2017; 16,809,669 shares and 16,670,188 shares issued and outstanding as of March 31, 2018 and December 31, 2017, respectively	2	2
Additional paid-in capital	124,648	122,950
Accumulated other comprehensive loss	(98)	(102)
Accumulated deficit	(80,632)	(72,513)
TOTAL STOCKHOLDERS' EQUITY	43,920	50,337
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 49,786	$ 56,077

Aeglea BioTherapeutics, Inc.
Condensed Consolidated Statements of Operations

(In thousands, except share and per share amounts)

	Three Months Ended March 31,	
	2018	2017
Revenues:		
Grant	$ 1,510	$ 982
Operating expenses:		
Research and development	6,870	4,949
General and administrative	2,885	2,364
Total operating expenses	9,755	7,313
Loss from operations	(8,245)	(6,331)
Other income (expense):		
Interest income	143	95
Other expense	(17)	(11)
Total other income	126	84
Net loss	$ (8,119)	$ (6,247)
Net loss per share, basic and diluted	$ (0.49)	$ (0.47)
Weighted-average common shares outstanding, basic and diluted	16,672,125	13,365,823