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): February 24, 2020

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.)**

805 Las Cimas
Suite 100
Austin, TX **78746**
(Address of principal executive offices) **(Zip Code)**

(512) 942-2935
(Registrant's telephone number, including area code)

901 S. MoPac Expressway
Barton Oaks Plaza One
Suite 250
Austin, TX, 78746

(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 February 24, 2020, Aeglea BioTherapeutics, Inc. issued a press release announcing its financial results for the quarter and year ended December 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 and year ended December 31, 2019, dated February 24, 2020.

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: February 24, 2020

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

Exhibit 99.1

Aeglea BioTherapeutics Reports Fourth-Quarter and Full-Year 2019 Financial Results, Highlights Recent Milestones

Company Expects to Complete Enrollment in Phase 3 Trial for Patients with Arginase 1 Deficiency in Third Quarter of 2020, with Topline Data Expected in First Quarter of 2021

Phase 1/2 Trial for Patients with Homocystinuria to Initiate in Second Quarter of 2020

Austin, Texas, February 24, 2020 - Aeglea BioTherapeutics, Inc. (NASDAQ:AGLE), a clinical-stage biotechnology company developing next-generation human enzyme therapeutics as solutions for diseases with high unmet medical need, today reported its fourth-quarter and full-year 2019 financial results, and provided recent corporate and program highlights.

“Our accomplishments this past year illustrate how we are working to reimagine the potential of human enzymes as transformative solutions for challenging rare genetic disorders,” said Anthony Quinn, M.B Ch.B, Ph.D., president and chief executive officer of Aeglea. “In addition to delivering compelling Phase 1/2 data from our lead program for Arginase 1 Deficiency, we’ve made solid progress with our pivotal trial enrollment and started laying the groundwork for the commercial launch. We have also continued to make significant progress in our pipeline, further demonstrating the effectiveness of our platform in advancing programs in multiple therapeutic areas.”

“We begin 2020 with a clear vision and heightened conviction of the impact for patients we can create with human enzyme therapeutics. We believe that we are well positioned to achieve a number of important milestones this year, armed with a strong leadership team with deep discovery, development and commercial expertise and driven by our collective goal to address the needs of the communities we serve,” concluded Dr Quinn.

Recent Highlights

Pegzilarginase in Arginase 1 Deficiency

- The Company expects to complete enrollment of its global, pivotal Phase 3 Pegzilarginase Effect on Arginase 1 Deficiency Clinical Endpoints (PEACE) trial in the third quarter of 2020 and to provide topline data in the first quarter of 2021.
- Based on a recent genetic prevalence analysis of Arginase 1 Deficiency (ARG1-D), and with more than 200 patients already identified worldwide, the Company now estimates an addressable patient population of greater than 2,500, up from an estimate of 1,000 patients based solely on initial insights using newborn screening data.
- The Company’s patient-identification strategy, informed by critical insights from disease analysis and trial experience, has already identified more than 100 patients in the United States, representing a 40% penetration into the genetic prevalent population.

ACN00177 in Homocystinuria

- In January, Aeglea announced the filing of its Clinical Trial Application (CTA) with the United Kingdom’s Medicines and Healthcare Products Regulatory Agency (MHRA) for ACN00177, a novel engineered human enzyme therapy designed to treat homocystinuria, a serious metabolic disorder that results in elevated levels of plasma homocysteine.
- The Company expects to initiate a Phase 1/2 trial for ACN00177 in the second quarter of 2020, with initial human proof of concept in the first quarter of 2021.
- The Company estimates an addressable homocystinuria patient population of greater than 5,000.

Upcoming Events

Aeglea will be attending the following investor conferences in the coming quarter. Details of the presentations and webcasts will be announced prior to the events.

- 19th Annual Needham Healthcare Conference, April 14-15, New York City
- H.C. Wainwright 2020 Global Life Sciences Conference, April 20-21, London, United Kingdom

Further, Aeglea leadership looks forward to participating in dialogue about our enzyme therapeutics platform during the following industry events, with additional details forthcoming.

- Annual Meeting of the Society for Inherited Metabolic Disorders (SIMD), April 26-29, Austin, Texas
- World Orphan Drug Congress USA 2020, April 29 to May 1, Oxon Hill, Maryland

Fourth Quarter and Full Year 2019 Financial Results

As of December 31, 2019, Aeglea had available cash, cash equivalents, marketable securities and restricted cash of $73.4 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 $17.6 million for the fourth quarter of 2019 and $11.8 million for the fourth quarter of 2018. The increase was primarily associated with investing in manufacturing and pre-commercial activities for Aeglea's lead product candidate, pegzilarginase; ramp-up in toxicology, investigational new drug (IND)-enabling studies, and manufacturing activities for ACN00177 in Homocystinuria; and personnel-related expenses.

Research and development expenses totaled $64.6 million for the year ended December 31, 2019, compared with $36.7 million for the year ended December 31, 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 ACN00177 in Homocystinuria; and expanded clinical development activity and personnel-related expenses.

General and administrative expenses totaled $4.3 million for the fourth quarter of 2019 and $3.5 million for the fourth quarter of 2018. This increase was primarily due to additional employee headcount, commercial readiness support, and facilities to support company growth.

General and administrative expenses totaled $15.7 million for the year ended December 31, 2019, compared with $12.6 million for the year ended December 31, 2018. This increase was primarily due to additional employee headcount, compensation, and facilities to support company growth.

Net loss totaled $21.5 million and $14.9 million for the fourth quarter of 2019 and 2018, respectively, with non-cash stock compensation expense of $1.2 million and $1.4 million for the fourth quarter of 2019 and 2018, respectively. Net loss totaled $78.3 million and $44.3 million for the years ended December 31, 2019 and 2018, respectively, with non-cash stock compensation expense of $4.9 million and $4.3 million for the years ended December 31, 2019 and 2018, respectively.

About Pegzilarginase in Arginase 1 Deficiency

Pegzilarginase is an enhanced human arginase that enzymatically lowers levels of the amino acid arginine. Aeglea is developing pegzilarginase for the treatment of patients with Arginase 1 Deficiency (ARG1-D), 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 therapy to reduce elevated blood arginine levels in patients with ARG1-D. Aeglea's Phase 1/2 and Phase 2 open-label extension (OLE) data for pegzilarginase in patients with ARG1-D 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 ACN00177 in Homocystinuria

Aeglea is developing ACN00177 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 thromboembolic vascular events, skeletal abnormalities including severe osteoporosis, developmental delay, intellectual disability, lens dislocation and severe myopia. ACN00177 has been designed as a novel recombinant human enzyme, which degrades the amino acid homocysteine and its related homocystine dimer. With this mechanism, ACN00177 is intended to lower the abnormally high blood levels of homocysteine in patients with homocystinuria. Preclinical data demonstrated that ACN00177 improved important disease-related abnormalities and survival in a mouse model of homocystinuria. The Company has submitted a Clinical Trial Application (CTA) with the United Kingdom's Medicines and Healthcare Products Regulatory Agency (MHRA) and expects to initiate a Phase 1/2 trial in the second quarter of 2020.

About Aeglea BioTherapeutics

Aeglea BioTherapeutics is a clinical-stage biotechnology company redefining the potential of human enzyme therapeutics to address rare and other high burden diseases with unmet medical need. Aeglea's lead product candidate, pegzilarginase, is in a Phase 3 pivotal trial for the treatment of Arginase 1 Deficiency and has received both Rare Pediatric Disease and Breakthrough Therapy Designation. Aeglea has an active discovery platform with programs for homocystinuria and cystinuria. The Company has submitted a Clinical Trial Application (CTA) for ACN00177 for homocystinuria with the United Kingdom's Medicines and Healthcare Products Regulatory Agency (MHRA) and expects to initiate a Phase 1/2 trial in the second quarter of 2020. 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 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, the potential addressable markets of the Company's product candidates 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 Annual Report on Form 10-K for the year ended December 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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Aeglea BioTherapeutics, Inc.
Consolidated Balance Sheets

(In thousands, except share and per share amounts)

	December 31, 2019	December 31, 2018
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 19,253	$ 22,461
Marketable securities	52,696	52,052
Prepaid expenses and other current assets	2,556	2,158
Total current assets	74,505	76,671
Restricted cash	1,500	—
Property and equipment, net	2,385	1,018
Operating lease right-of-use assets	4,726	—
Other non-current assets	67	50
TOTAL ASSETS	$ 83,183	$ 77,739
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable	$ 3,154	$ 663
Operating lease liabilities	351	—
Accrued and other current liabilities	14,854	9,576
Total current liabilities	18,359	10,239
Non-current operating lease liabilities	4,712	—
Other non-current liabilities	31	72
TOTAL LIABILITIES	23,102	10,311
STOCKHOLDERS' EQUITY		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized as of December 31, 2019 and 2018; no shares issued and outstanding as of December 31, 2019 and 2018	—	—
Common stock, $0.0001 par value; 500,000,000 shares authorized as of December 31, 2019 and 2018; 29,084,437 shares and 24,140,097 shares issued and outstanding as of December 31, 2019 and 2018, respectively	3	2
Additional paid-in capital	255,142	184,314
Accumulated other comprehensive income (loss)	51	(27)
Accumulated deficit	(195,115)	(116,861)
TOTAL STOCKHOLDERS' EQUITY	60,081	67,428
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 83,183	$ 77,739

Aeglea BioTherapeutics, Inc.
Consolidated Statements of Operations

(In thousands, except share and per share amounts)

	Year Ended December 31,		
	2019	**2018**	**2017**
Revenues:			
Grant	$ —	$ 3,888	$ 5,205
Operating expenses:			
Research and development	64,600	36,719	22,815
General and administrative	15,734	12,632	10,066
Total operating expenses	80,334	49,351	32,881
Loss from operations	(80,334)	(45,463)	(27,676)
Other income (expense):			
Interest income	2,143	1,172	482
Other expense, net	(63)	(57)	(42)
Total other income	2,080	1,115	440
Net loss	$ (78,254)	$ (44,348)	$ (27,236)
Net loss per share, basic and diluted	$ (2.45)	$ (2.13)	$ (1.80)
Weighted-average common shares outstanding, basic and diluted	31,949,633	20,822,560	15,128,192