

Aeglea BioTherapeutics, Inc.
Form 10-Q
May 08, 2018

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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended March 31, 2018

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from to

Commission File Number: 001-37722

AEGLEA BIOTHERAPEUTICS, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware 46-4312787
(State or other jurisdiction of (I.R.S. Employer

incorporation or organization) Identification No.)
901 S. MoPac Expressway

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Barton Oaks Plaza One

Suite 250

Austin, TX 78746

(Address of principal executive offices including
zip code)

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	Accelerated filer
Non-accelerated filer	(Do not check if a smaller reporting company)
Smaller reporting company	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.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

As of May 4, 2018, the registrant had 21,858,874 shares of common stock, \$0.0001 par value per share, outstanding.

AEGLEA BIOTHERAPEUTICS, INC.

QUARTERLY REPORT ON FORM 10-Q

FOR THE QUARTER ENDED MARCH 31, 2018

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NOTE ABOUT FORWARD-LOOKING STATEMENTS

This quarterly report contains forward-looking statements. All statements other than statements of historical fact are “forward-looking statements” for purposes of this Quarterly Report on Form 10-Q. These forward-looking statements may include, but are not limited to, statements regarding our future results of operations and financial position, business strategy, market size, potential growth opportunities, clinical development activities, efficacy and safety profile of our product candidates, our ability to maintain and recognize the benefits of certain designations received by product candidates, the timing and results of clinical trials and potential regulatory approval and commercialization of product candidates. The words “believe,” “may,” “will,” “potentially,” “estimate,” “continue,” “anticipate,” “predict,” “target,” “could,” “would,” “should,” “project,” “plan,” “expect,” and similar expressions that convey uncertainty of future events or outcomes are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described in “Risk Factors” and elsewhere in this quarterly report. Moreover, we operate in a very competitive and rapidly changing environment, and new risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this quarterly report may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur. We undertake no obligation to update publicly any forward-looking statements for any reason after the date of this report to conform these statements to actual results or to changes in our expectations, except as required by law.

As used in this Quarterly Report on Form 10-Q, the terms “Aeglea,” “the Company,” “we,” “us,” and “our” refer to Aeglea BioTherapeutics, Inc. and, where appropriate, its consolidated subsidiaries, unless the context indicates otherwise.

PART I. – FINANCIAL INFORMATION

Item 1. Financial Statements
Aeglea BioTherapeutics, Inc.

Condensed Consolidated Balance Sheets

(Unaudited)

(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
Commitments and Contingencies (Note 9)		
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		

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December 31, 2017, respectively

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

The accompanying notes are an integral part of these condensed consolidated financial statements.

Aeglea BioTherapeutics, Inc.

Condensed Consolidated Statements of Operations

(Unaudited)

(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

The accompanying notes are an integral part of these condensed consolidated financial statements.

Aeglea BioTherapeutics, Inc.

Condensed Consolidated Statements of Comprehensive Loss

(Unaudited)

(In thousands)

	Three Months Ended March 31,	
	2018	2017
Net loss	\$(8,119)	\$(6,247)
Other comprehensive income (loss):		
Unrealized gain (loss) on marketable securities	4	(33)
Total comprehensive loss	\$(8,115)	\$(6,280)

The accompanying notes are an integral part of these condensed consolidated financial statements.

Aeglea BioTherapeutics, Inc.

Condensed Consolidated Statements of Cash Flows

(Unaudited)

(In thousands)

	Three Months Ended March 31, 2018 2017	
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	\$(8,119)	\$(6,247)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	70	52
Purchase net premium on marketable securities	—	(55)
Net (accretion of discount) amortization of premium on marketable securities	(14)	49
Stock-based compensation	835	401
Research and development services settled with stock	30	—
Other, net	(11)	(5)
Changes in operating assets and liabilities:		
Accounts receivable-grant	(295)	234
Prepaid expenses and other assets	(102)	151
Accounts payable	396	95
Deferred revenue	(20)	(20)
Accrued and other liabilities	(217)	(87)
Net cash used in operating activities	(7,447)	(5,432)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchases of property and equipment	(83)	(271)
Purchases of marketable securities	—	(32,780)
Proceeds from maturities of marketable securities	4,785	7,440
Net cash provided by (used in) investing activities	4,702	(25,611)
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from employee stock plan purchases and stock option exercises	688	96
Net cash provided by financing activities	688	96
NET DECREASE IN CASH AND CASH EQUIVALENTS	(2,057)	(30,947)
CASH AND CASH EQUIVALENTS		
Beginning of period	12,817	47,748
End of period	\$10,760	\$16,801
Supplemental Disclosure of Non-Cash Investing and Financing Information:		
Unpaid amounts related to purchase of property and equipment	\$—	\$4

The accompanying notes are an integral part of these condensed consolidated financial statements.

Aeglea BioTherapeutics, Inc.

Notes to Condensed Consolidated Financial Statements

1. The Company and Basis of Presentation

Aeglea BioTherapeutics, Inc. (“Aeglea” or the “Company”) is a clinical-stage biotechnology company committed to developing enzyme-based therapeutics in the field of amino acid metabolism to treat rare genetic diseases and cancer. The Company was formed as a Limited Liability Company (LLC) in Delaware on December 16, 2013 under the name Aeglea BioTherapeutics Holdings, LLC and was converted from a Delaware LLC to a Delaware corporation (the “LLC Conversion”) on March 10, 2015. The Company operates in one segment and has its principal offices in Austin, Texas.

Stock Offering

In April 2018, the Company issued and sold 5,046,510 shares of common stock in an underwritten public offering (“2018 Stock Offering”) pursuant to a shelf registration statement on Form S-3 at a public offering price of \$8.00 per share, including 546,510 shares of common stock issued upon the partial exercise by the underwriters of their option to purchase additional shares. The net proceeds to the Company from this public offering were approximately \$37.7 million, after deducting underwriting discounts and commissions of \$2.4 million and estimated offering costs of \$280,000.

Liquidity

As of March 31, 2018, the Company had working capital of \$43.1 million, an accumulated deficit of \$80.6 million, and cash, cash equivalents, and marketable securities of \$43.5 million. The Company has not generated any product revenues and has not achieved profitable operations. There is no assurance that profitable operations will ever be achieved, and, if achieved, could be sustained on a continuing basis. In addition, development activities, clinical and nonclinical testing, and commercialization of the Company’s products will require significant additional financing.

The Company is subject to a number of risks similar to other life science companies, including, but not limited to, risks related to the successful discovery and development of product candidates, raising additional capital, development of competing drugs and therapies, protection of proprietary technology and market acceptance of the Company’s products. As a result of these and other factors and the related uncertainties, there can be no assurance of the Company’s future success.

Based upon the Company’s cash, cash equivalents, and marketable securities, in conjunction with the proceeds received in connection with its 2018 Stock Offering, the Company believes that it has sufficient resources to fund operations through the middle of 2020 with its existing cash, cash equivalents, and marketable securities. The Company will need to secure additional funding in the future, in order to carry out all of its planned research and development activities. If the Company is unable to obtain additional financing or generate license or product revenue, the lack of liquidity could have a material adverse effect on the Company’s future prospects.

Unaudited Interim Financial Information

The interim condensed consolidated financial statements included in this document are unaudited. The unaudited interim financial statements have been prepared on the same basis as the annual financial statements and reflect, in the opinion of management, all adjustments of a normal and recurring nature that are necessary for a fair statement of the Company's financial position as of March 31, 2018, and its results of operations for the three months ended March 31, 2018 and 2017, and cash flows for the three months ended March 31, 2018 and 2017. The results of operations for three months ended March 31, 2018 are not necessarily indicative of the results to be expected for the year ending December 31, 2018 or for any other future annual or interim period. The December 31, 2017 balance sheet was derived from audited financial statements, but does not include all disclosures required by accounting principles generally accepted in the United States ("U.S. GAAP"). These financial statements should be read in conjunction with the audited financial statements included in the Company's Form 10-K for the year ended December 31, 2017 as filed with the SEC.

2. Summary of Significant Accounting Policies

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. Such management estimates include those related to accruals of research and development related costs, stock-based compensation, and certain company income tax related items. Management bases its estimates on historical experience and on various other market-specific and relevant assumptions that management believes to be reasonable under the circumstances. Actual results could differ significantly from those estimates.

Cash and Cash Equivalents

The Company considers all highly liquid investments with original maturities of three months or less from the date of purchase to be cash equivalents. Cash equivalents consist of money market funds and debt securities and are stated at fair value.

Marketable Securities

All investments have been classified as available-for-sale and are carried at estimated fair value as determined based upon quoted market prices or pricing models for similar securities. Management determines the appropriate classification of its investments in debt securities at the time of purchase. The Company may or may not hold securities with stated maturities greater than one year until maturity. All available-for-sale securities are considered available to support current operations and are classified as current assets.

Unrealized gains and losses are excluded from earnings and are reported as a component of accumulated comprehensive loss. Realized gains and losses and declines in fair value judged to be other than temporary, if any, on available-for-sale securities are included in other income (expense). The cost of securities sold is based on the specific-identification method. There were no realized gains or losses on marketable securities for the three months ended March 31, 2018 and 2017. Interest on marketable securities is included in interest income.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to a concentration of credit risk consist of cash, cash equivalents, and marketable securities. The Company's investment policy limits investments to high credit quality securities issued by the U.S. government, U.S. government-sponsored agencies and highly rated banks, subject to certain