Aeglea BioTherapeutics Reports Second Quarter 2023 Financial Results

August 11, 2023

*Acquisition of Spyre's assets and concurrent oversubscribed $210.0 million private investment positions the company to advance a potentially best-in-class inflammatory bowel disease (IBD) portfolio, including α*4b7 and TL1A programs

Sale of legacy pipeline candidate, pegzilarginase, further streamlines operations and increases focus on IBD strategy

$236.7 million of cash and cash equivalents and restricted cash as of June 30, 2023

WALTHAM, Mass., Aug. 11, 2023 /PRNewswire/ -- Aeglea BioTherapeutics, Inc. ("Aeglea" or the "Company") (NASDAQ:AGLE), a biotechnology company advancing a pipeline of antibody therapeutics with the potential to transform the treatment of inflammatory bowel disease ("IBD"), today announced second quarter 2023 financial results and provided program and corporate updates.

"With the acquisition of Spyre Therapeutics and concurrent financing, we are in a privileged position to create meaningful new medicines for patients with IBD and build an industry-leading development organization," said Cameron Turtle, DPhil, Chief Operating Officer of Aeglea. "Our pipeline of differentiated and potentially best-in-class IBD programs, including a4b7 and TL1A, combined with a strategy to investigate therapeutic combinations and precision medicine approaches, offers the possibility to transform the treatment of this chronic and debilitating disease."

"In parallel, we have made significant progress streamlining the organization with the sale of pegzilarginase and pivoting our operations and strategy around the new IBD assets," said Jonathan Alspaugh, President and Chief Financial Officer of Aeglea. "We are working to rapidly advance our co-lead product candidates with an expectation of initiating clinical studies for both SPY001 and SPY002 in 2024."

Recent Program and Corporate Updates

Corporate

- Completed the asset acquisition (the "Acquisition") of Spyre Therapeutics, Inc. ("Spyre"), a privately held biotechnology company with a pipeline of antibody therapeutics possessing the potential to transform the treatment of IBD alongside its research partner, Paragon Therapeutics, Inc. ("Paragon")
- Raised $210.0 million in gross proceeds (before deducting approximately $12.7 million in placement fees and other offering expenses) through a sale of Series A non-voting convertible preferred stock (the "Series A Preferred Stock") in a private placement to a group of investors.

IBD Portfolio

With the Acquisition, Aeglea shifted its focus to the development of a potentially best-in-class IBD portfolio including:

- SPY001 – a highly potent and selective anti-α4β7 monoclonal antibody engineered with half-life extension technology and formulated for high concentration, convenient dosing.
    - SPY001 is currently progressing through IND-enabling studies and is expected to enter first-in-human ("FIH") studies in the first half of 2024. Data from a healthy volunteer study are expected by the end of 2024.
- SPY002 – a highly potent and selective anti-TL1A monoclonal antibody engineered with half-life extension technology. TL1A has emerged as one of the most promising targets in IBD and broader immunology indications.
    - We expect to begin FIH studies of the SPY002 program in the second half of 2024 with healthy volunteer data expected in the first half of 2025.

Pegzilarginase

- Sold global rights to pegzilarginase in development for Arginase 1 Deficiency to Immedica Pharma AB ("Immedica") for $15.0 million upfront cash proceeds and up to $100.0 million of contingent milestone payments. The sale of pegzilarginase to Immedica supersedes the previous license agreement between the companies.
    - Marketing Authorisation Application for pegzilarginase is under review by the European Medicines Agency.
    - The milestone payments are contingent on formal reimbursement decisions by national authorities in key European markets and pegzilarginase approval by the FDA, among other events.
    - Net proceeds of the sale are to be distributed to holders of contingent value rights ("CVR") pursuant to the terms of the CVR Agreement dated July 7, 2023 by and between the Company and a rights agent.

Second Quarter 2023 Financial Results

As of June 30, 2023, Aeglea had available cash and cash equivalents and restricted cash of $236.7 million, including the $210.0

million in gross proceeds from the private placement offering in June 2023.

Aeglea recognized development fee and royalty revenues of $0.7 million in the second quarter of 2023, as a result of its license and supply agreement with Immedica for the commercial rights to pegzilarginase in Europe and several countries in the Middle East. The revenues recorded in the second quarter of 2023 are related to drug supply and royalties from an early access program in France. Aeglea recognized $0.6 million for the second quarter of 2022 in development fee revenues.

Research and development expenses totaled $17.4 million for the second quarter of 2023 and $15.4 million for the second quarter of 2022. The increase was primarily related to restructuring costs net of savings and an increase in reimbursable costs under the Paragon Agreement (as described below).

General and administrative expenses totaled $12.1 million for the second quarter of 2023 and $7.7 million for the second quarter of 2022. This increase was primarily due to restructuring costs, net of savings.

Acquired in-process research and development expenses totaled $130.5 million for the second quarter of 2023 and no expenses for the second quarter of 2022. As the Spyre assets have no alternative use, the net assets acquired are expensed in the period acquired.

Change in the fair value of forward contract liability expense was $58.2 million for the second quarter of 2023 and no expenses for the second quarter of 2022. The stock consideration provided in the Acquisition was not issued until July 7, 2023. Accordingly, the Company recognized a forward contract liability to represent the contractual obligation to issue stock as of June 30, 2023. The increase in expense represents the change in fair value between June 22, 2023 (the Acquisition date) and June 30, 2023 for the redeemable Series A Preferred Stock.

Net loss totaled $217.1 million and $22.3 million for the second quarter of 2023 and 2022, respectively, which includes non-cash stock compensation expense of $1.9 million and $2.0 million for the second quarter of 2023 and 2022, respectively.

About Aeglea BioTherapeutics

In June 2023, Aeglea completed the asset acquisition of Spyre and shifted its disease focus to IBD. Aeglea is advancing a pipeline of antibody therapeutics with the potential to transform the treatment of IBD. The approaches combine novel antibody engineering, rational therapeutic combinations, and precision immunology approaches to maximize efficacy, safety, and convenience of treatments for IBD.

For more information, please visit http://aeglea.com.

Follow Aeglea BioTherapeutics on social media: @aegleabio and LinkedIn.

About the Paragon Agreement

In May 2023, Spyre entered into an antibody discovery option and license agreement with Paragon (the "Paragon Agreement"). As part of the Paragon Agreement, Paragon identifies, evaluates and develops antibodies directed against certain mutually agreed therapeutic targets of interest to the Company. The arrangement currently includes four selected targets: α4β7, TL1A, IL-23, and an undisclosed fourth target. Subsequent to the Acquisition, the Company has exercised its option for the α4β7 program and will be granted an exclusive license to develop, manufacture and commercialize the antibody and products directed to the target, and plans to exercise its option for the other programs upon development candidate selection. From time to time, the Company can choose to add additional targets to the arrangement by mutual agreement with Paragon.

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: "believe," "continue," "goal," "expect," "may," "intend," "potential," "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 the Company expects. Examples of forward-looking statements include, among others, statements the Company makes regarding any future payouts under the CVR, its ability to achieve the expected benefits or opportunities and related timing with respect to the Acquisition or to monetize any of its legacy assets, its future results of operations and financial position, its business strategy, its potential growth opportunities, its preclinical and future clinical development activities, the efficacy and safety profile of its product candidates, the potential therapeutic benefits and economic value of its product candidates, and the timing and results of preclinical studies and clinical trials, and other statements that are not historical fact. Actual results may differ materially from those indicated by such forward-looking statements. Factors that could cause actual results to differ include, but are not limited to, risks that the Company may not obtain stockholder approval of the conversion rights of the Series A Preferred Stock, the Company may fail to achieve the expected benefits or opportunities and related timing with respect to the Acquisition or to monetize any of its legacy assets, the Company's existing cash resources may not be sufficient to fund its future planned operations, the impact of macroeconomic conditions, including inflation, increasing interest rates and volatile market conditions, current or potential bank failures, as well as global events, including the ongoing military conflict in Ukraine and geopolitical tensions in China on the Company's operations, and the receipt and timing of potential regulatory designations, approvals and commercialization of product candidates. Additional risks and uncertainties regarding the Company's business can be found in the section titled "Risk Factors" in the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2023 filed with the United States Securities and Exchange

Commission ("SEC"), and future filings and reports that the Company makes from time to time with the SEC. The information contained in this press release is as of the date of this release, and the Company undertakes no duty to update forward-looking statements contained in this press release except as required by applicable laws.

Aeglea BioTherapeutics, Inc.

Condensed Consolidated Balance Sheets

(Unaudited, in thousands, except share and per share amounts)

	June 30, 2023	December 31, 2022
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 235,358	$ 34,863
Marketable securities	—	20,848
Development receivables	1,646	375
Prepaid expenses and other current assets	2,882	6,172
Total current assets	239,886	62,258
Restricted cash	1,317	1,553
Property and equipment, net	—	3,220
Operating lease right-of-use assets	2,316	3,430
Other non-current assets	10	683
TOTAL ASSETS	$ 243,529	$ 71,144
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable	$ 2,854	$ 677
Forward contract liability	164,382	—

CVR liability	10,500	—
Operating lease liabilities	4,331	625
Deferred revenue	930	517
Accrued and other current liabilities	28,427	12,837
Related party accounts payable	20,810	—
Total current liabilities	232,234	14,656
Non-current CVR liability	19,000	—
Non-current operating lease liabilities	—	4,004
Deferred revenue, net of current portion	2,341	2,179
TOTAL LIABILITIES	253,575	20,839
Commitments and Contingencies (Note 11)		
Series A non-voting convertible preferred stock, $0.0001 par value; 1,086,341 and no shares authorized as of June 30, 2023 and December 31, 2022, respectively; 721,452 and no shares issued and outstanding as of June 30, 2023 and December 31, 2022, respectively	197,323	—
STOCKHOLDERS' (DEFICIT) EQUITY		
Preferred stock, $0.0001 par value; 8,913,659 shares and 10,000,000 authorized as of June 30, 2023 and December 31, 2022; no shares issued and outstanding as of June 30, 2023 and December 31, 2022	—	—
Common stock, $0.0001 par value; 500,000,000 shares authorized as of June 30, 2023 and December 31, 2022; 81,001,676 shares and 65,350,343 shares issued and outstanding as of June 30, 2023 and December 31, 2022, respectively	6	6
Additional paid-in capital	453,741	475,971
Accumulated other comprehensive income (loss)	11	(48)
Accumulated deficit	(661,127)	(425,624)
TOTAL STOCKHOLDERS' (DEFICIT) EQUITY	(207,369)	50,305
TOTAL LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' (DEFICIT) EQUITY	$ 243,529	$ 71,144

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Aeglea BioTherapeutics, Inc.

Condensed Consolidated Statements of Operations

(Unaudited, in thousands, except share and per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	**2022**	**2023**	**20**
Revenue:				
Development fee and royalty	$ 688	$ 625	$ 886	$
Total revenue	688	625	886	1,
Operating expenses:				
Research and development	17,386	15,373	31,162	32
General and administrative	12,062	7,675	17,290	16
Acquired in-process research and development	130,486	—	130,486	–
Total operating expenses	159,934	23,048	178,938	48
Loss from operations	(159,246)	(22,423)	(178,052)	(4
Other income (expense):				
Interest income	350	104	770	13
Change in fair value of forward contract liability	(58,170)	—	(58,170)	–
Other income (expense), net	(8)	5	(80)	1
Total other (expense) income	(57,828)	109	(57,480)	14
Loss before income tax expense	(217,074)	(22,314)	(235,532)	(4

Income tax (expense) benefit	(7)	(9)	29	(3
Net loss	$ (217,081)	$ (22,323)	$ (235,503)	$
Net loss per share, basic and diluted	$ (2.27)	$ (0.27)	$ (2.48)	$
Weighted-average common shares outstanding, basic and diluted	95,565,118	82,209,032	94,917,487	73

SOURCE Aeglea BioTherapeutics, Inc.