Aeglea BioTherapeutics Reports Third Quarter 2023 Financial Results and Provides Corporate Update

November 9, 2023

Continued progress across the Company's potentially best-in-class inflammatory bowel disease (IBD) portfolio

SPY001, a half-life extended anti-α4β7 antibody, is on track for an expected IND filing in the first half of 2024, with interim healthy volunteer, proof of concept pharmacokinetic data expected year-end 2024

SPY002, a half-life extended anti-TL1A antibody with potential best-in-class picomolar binding affinity for both the monomer and trimer forms of the target, is on track for expected IND filing in the second half of 2024

Stockholder vote scheduled for November 21 to allow conversion of preferred stock to common stock

Strengthened leadership team with the appointments of Scott Burrows as Chief Financial Officer and Heidy King-Jones as Chief Legal Officer and Corporate Secretary

$205 million of cash, cash equivalents, marketable securities, and restricted cash as of September 30, 2023, with expected runway into 2026

WALTHAM, Mass., Nov. 9, 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 its third quarter 2023 financial results and provided program and corporate updates.

"We have made significant progress in our first quarter following the Spyre acquisition towards our goal of creating new, best-in-class medicines for patients with IBD. We believe that our combination strategy and pipeline, including SPY001, an extended half-life anti-α4β7 antibody, and SPY002 a dual monomer / trimer anti-TL1A antibody with picomolar affinity and extended half-life, offer the potential to meaningfully improve both efficacy and convenience relative to today's standard of care," said Cameron Turtle, D.Phil., Chief Operating Officer of Aeglea. "In addition to progressing our portfolio towards first-in-human studies next year, we have built out our team with passionate and experienced biotechnology leaders."

Development Pipeline Overview and Update

With its acquisition of Spyre Therapeutics, Inc. ("Spyre") in June 2023, Aeglea shifted its disease focus to IBD. The Company's approach combines best-in-class antibody engineering, rational therapeutic combinations, and precision immunology with the goal of maximizing efficacy, safety, and convenience of its IBD treatments under development. IBD is a chronic condition characterized by inflammation within the gastrointestinal tract, including two main disorders: ulcerative colitis ("UC") and Crohn's disease ("CD"). In the United States, it is estimated that approximately 2.4 million individuals are diagnosed with IBD.

The Company has four product candidates in preclinical development, three of which are validated targets in IBD. The fourth product candidate is a novel, undisclosed target.

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.
- Interim data from a healthy volunteer study are expected by the end of 2024. The Company expects pharmacokinetic data to demonstrate proof of concept for its ability to potentially reach an every-eight-week or every-twelve-week dosing interval.

SPY002 – a highly potent and selective anti-TL1A monoclonal antibody engineered with half-life extension technology. The Company believes TL1A has emerged as one of the most promising targets in IBD and broader immunology indications.

- The Company's extensive discovery campaign has identified lead clones which bind both TL1A monomers and trimers with picomolar affinity and have *in vitro* potency and pharmacokinetic half-lives that exceed all clinical-stage TL1A antibodies.
- The Company expects to begin FIH studies of the SPY002 program in the second half of 2024 with healthy volunteer interim data expected in the first half of 2025.

SPY003 – a highly potent and selective monoclonal antibody targeting the p19 subunit of IL-23 engineered with half-life extension technology.

- The Company continues preclinical development efforts on a potential best-in-class IL-23 monoclonal antibody. Recent data from the Phase 3 SEQUENCE study of risankizumab versus ustekinumab in Crohn's disease validates the Company's

targeting of the p19 subunit as it demonstrated superiority to targeting the p40 subunit of IL-23.
- An IND/CTN is expected in 2025.

Corporate Updates

- In October 2023, the Company filed a definitive proxy statement regarding the Special Meeting of Stockholders to be held on November 21, 2023 (the "Special Meeting"). At the Special Meeting, stockholders are expected to vote on four proposals, including the conversion of the Company's Series A Preferred Stock to common stock and an increase to the Company's authorized shares.
- In September 2023, the Company strengthened its leadership team with the appointments of industry veterans Scott Burrows, as Chief Financial Officer, and Heidy Abreu King-Jones, as Chief Legal Officer and Corporate Secretary.
- In September 2023, the Company completed a reverse stock split of all outstanding shares of common stock at a ratio of 1-for-25, with trading on a split-adjusted basis on the Nasdaq Capital Market beginning on September 8, 2023.
- In July 2023, the Company sold the global rights to pegzilarginase to Immedica Pharma AB ("Immedica") for $15 million in upfront cash proceeds and up to $100 million in contingent milestone payments. In November 2023, holders of the Company's contingent value rights (CVRs) are expected to receive a payment representing the Immedica sale proceeds net of expenses and adjustments pursuant to the CVR agreement entered into in connection with Aeglea's acquisition of Spyre.

Third Quarter 2023 Financial Results

Cash Position: As of September 30, 2023, Aeglea had available cash and cash equivalents, marketable securities, and restricted cash of $204.9 million.

Research and Development (R&D) expenses: R&D expenses totaled $24.7 million for the third quarter of 2023 and $12.0 million for the third quarter of 2022. This increase was primarily related to increases in preclinical development and manufacturing expenses for the Company's IBD pipeline, partially offset by a decrease in expenses associated with the legacy Aeglea rare disease pipeline.

General and Administrative (G&A) expenses: G&A expenses totaled $8.6 million for the third quarter of 2023 and $7.0 million for the third quarter of 2022. This increase was primarily due to an increase in legal and employee separation costs.

Gain on Sale of In-Process Research & Development Asset: During the third quarter of 2023, the Company recognized a $14.6 million gain on the sale of the global rights of pegzilarginase to Immedica.

Other Income and Expenses: Other Income and Expenses were a net $21.8 million expense in the third quarter of 2023, primarily driven by a $25.4 million non-cash forward contract liability expense related to an increase in fair value of the underlying Series A Preferred Stock between June 30, 2023 and the forward contract's settlement on July 7, 2023.

Net Loss: Net loss totaled $40.1 million and $18.2 million for the third quarter of 2023 and 2022, respectively, which includes non-cash stock compensation expense of $4.8 million and $1.6 million for the third 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. Aeglea's approach combines novel antibody engineering, rational therapeutic combinations, and precision immunology with the goal of maximizing efficacy, safety, and convenience of treatments for IBD. The company is developing antibodies targeting α4β7, TL1A, and IL-23.

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

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

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. All statements contained in this press release, other than statements of historical fact are forward-looking statements. These forward-looking statements include statements regarding stockholder approval of the conversion rights of the Series A Preferred Stock, any future payouts under the non-transferable contingent value right agreement (the "CVR Agreement"), the Company's ability to achieve the expected benefits or opportunities and related timing with respect to its asset acquisition of Spyre or to monetize its legacy assets, its future results of operations and financial position, business strategy, including the success of its refocus towards developing therapeutics for IBD, the length of time that the Company believes its existing cash resources will fund its operations, its market size, its potential growth opportunities, its preclinical and future clinical development activities, including the expected timing of submission of investigational new drug applications, the efficacy and safety profile of its product candidates, the potential therapeutic benefits and economic value of its product candidates, the timing and results of preclinical studies and clinical trials, including the timing of interim data and whether the data demonstrates proof of concept, the expected impact of macroeconomic conditions, including inflationary pressures, rising interest rates, general economic slowdown or a recession, changes in monetary policy, the prospect of a shutdown of the U.S. federal government, volatile market conditions, financial institution instability, as well as geopolitical instability, including the ongoing military conflict in Ukraine, conflict in Israel and surrounding areas, and geopolitical tensions in China on its operations, and the

receipt and timing of potential regulatory designations, approvals and commercialization of product candidates. The words "believe," "may," "will," "potentially," "estimate," "continue," "anticipate," "predict," "target," "intend," "could," "would," "should," "project," "plan," "expect," the negatives of these terms, 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 the Company's Quarterly Reports on Form 10-Q, Annual Reports on Form 10-K, as well as in other filings and reports that the Company makes from time to time with the Securities and Exchange Commission. Moreover, the Company operates in a very competitive and rapidly changing environment, and new risks emerge from time to time. It is not possible for the Company's management to predict all risks, nor can the Company assess the impact of all factors on the 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 it may make. In light of these risks, uncertainties, and assumptions, the forward-looking events and circumstances discussed in this press release 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 the Company believes that the expectations reflected in the forward-looking statements are reasonable, the Company 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. The Company undertakes no obligation to update publicly any forward-looking statement for any reason after the date of this press release to conform these statements to actual results, to reflect changes in the Company's expectations, or otherwise, except as required by law. You should read press release with the understanding that the Company's actual results, levels of activity, performance, events, outcomes, and the timing of results and outcomes, and other circumstances may be materially different from what the Company expects.

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Aeglea BioTherapeutics, Inc.
Condensed Consolidated Balance Sheets
(Unaudited, in thousands, except share and per share amounts)

	September 30, 2023	D
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 90,592	$
Marketable securities	113,007	
Development receivables	163	
Prepaid expenses and other current assets	2,187	
Total current assets	205,949	
Restricted cash	1,307	
Property and equipment, net	—	
Operating lease right-of-use assets	—	
Other non-current assets	9	
TOTAL ASSETS	$ 207,265	$
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable	$ 1,678	$
CVR liability	7,510	
Operating lease liabilities	—	
Deferred revenue	—	
Accrued and other current liabilities	15,861	
Related party accounts payable	19,823	
Total current liabilities	44,872	
Non-current CVR liability	20,690	
Non-current operating lease liabilities	—	
Deferred revenue, net of current portion	—	
TOTAL LIABILITIES	65,562	

Commitments and Contingencies		
Series A non-voting convertible preferred stock, $0.0001 par value; 1,086,341 and no shares authorized as of September 30, 2023 and December 31, 2022, respectively; 1,086,339 and no shares issued and outstanding as of September 30, 2023 and December 31, 2022, respectively.	387,105	
STOCKHOLDERS' (DEFICIT) EQUITY		
Preferred stock, $0.0001 par value; 8,913,659 shares and 10,000,000 authorized as of September 30, 2023 and December 31, 2022; no shares issued and outstanding as of September 30, 2023 and December 31, 2022.	—	
Common stock, $0.0001 par value; 20,000,000 shares authorized as of September 30, 2023 and December 31, 2022; 4,048,687 shares and 2,614,014 shares issued and outstanding as of September 30, 2023 and December 31, 2022, respectively.	7	
Additional paid-in capital	455,957	
Accumulated other comprehensive income (loss)	(132)	
Accumulated deficit	(701,234)	
TOTAL STOCKHOLDERS' (DEFICIT) EQUITY	(245,402)	
TOTAL LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' (DEFICIT) EQUITY	$ 207,265	$

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Aeglea BioTherapeutics, Inc.
Condensed Consolidated Statements of Operations
(Unaudited, in thousands, except share and per share amounts)

	Three Months Ended September 30,		Nine Months Ende September 30,	
	2023	**2022**	**2023**	**20**
Revenue:				
Development fee and royalty	$ —	$ 174	$ 886	$
Total revenue	—	174	886	
Operating expenses (income):				
Research and development [(1)]	24,660	11,977	55,822	
General and administrative	8,584	6,952	25,874	
Acquired in-process research and development	(298)	—	130,188	
Gain on sale of in-process research and development asset	(14,609)	—	(14,609)	
Total operating expenses	18,337	18,929	197,275	
Loss from operations	(18,337)	(18,755)	(196,389)	(
Other (expense) income:				
Interest income	1,251	288	2,021	
Change in fair value of forward contract liability	(25,360)	—	(83,530)	
Other income, net	2,342	24	2,262	
Total other (expense) income	(21,767)	312	(79,247)	
Loss before income tax expense	(40,104)	(18,443)	(275,636)	(
Income tax (expense) benefit	(3)	209	26	
Net loss	$ (40,107)	$ (18,234)	$ (275,610)	$ (
Net loss per share, basic and diluted	$ (9.34)	$ (4.84)	$ (69.57)	$
Weighted-average common shares outstanding, basic and diluted	4,293,812	3,767,918	3,961,546	3,2

(1) Includes $19.4 million and $20.8 million in related party expenses for the three and nine months ended September 30, 2023, respectively and no related party expenses for the three and nine months ended September 30, 2022

SOURCE Aeglea BioTherapeutics, Inc.