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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549**

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**FORM 8-K**

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**CURRENT REPORT**

**Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

**Date of Report (Date of earliest event reported): November 9, 2023**

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**AEGLEA BIOTHERAPEUTICS, INC.**

(Exact name of Registrant as Specified in Its Charter)

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**Delaware**  
(State or Other Jurisdiction  
of Incorporation)

**001-37722**  
(Commission File Number)

**46-4312787**  
(IRS Employer  
Identification No.)

**221 Crescent Street  
Building 23  
Suite 105  
Waltham, Massachusetts**  
(Address of Principal Executive Offices)

**02453**  
(Zip Code)

**Registrant's Telephone Number, Including Area Code: 617 651-5940**

**Not Applicable**

(Former Name or Former Address, if Changed Since Last Report)

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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 Capital 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.

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**Item 2.02 Results of Operations and Financial Condition.**

On November 9, 2023, Aeglea BioTherapeutics, Inc. (the “Company”) issued a press release announcing its financial results for the quarter ended September 30, 2023. A copy of the press release is furnished 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, nor shall it be deemed incorporated by reference into any filing under the Exchange Act or under the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such filing.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

<u>Exhibit Number</u>	<u>Description</u>
99.1	<a href="#">Press release issued by Aeglea BioTherapeutics, Inc. regarding its financial results for the quarter ended September 30, 2023 dated November 9, 2023.</a>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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**SIGNATURES**

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: November 9, 2023

By: /s/ Scott Burrows

Scott Burrows  
Chief Financial Officer



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

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

*SPY001, a half-life extended anti- $\alpha 4\beta 7$  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 Heidi 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, November 9, 2023** - 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- $\alpha 4\beta 7$  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- $\alpha 4\beta 7$  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  $\alpha\beta7$ , 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 this 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.

#### **Contact Information:**

##### **Media Contact**

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##### **Investor Contact**

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

	September 30, 2023	December 31, 2022
<b>ASSETS</b>		
<b>CURRENT ASSETS</b>		
Cash and cash equivalents	\$ 90,592	\$ 34,863
Marketable securities	113,007	20,848
Development receivables	163	375
Prepaid expenses and other current assets	2,187	6,172
<b>Total current assets</b>	<b>205,949</b>	<b>62,258</b>
Restricted cash	1,307	1,553
Property and equipment, net	—	3,220
Operating lease right-of-use assets	—	3,430
Other non-current assets	9	683
<b>TOTAL ASSETS</b>	<b>\$ 207,265</b>	<b>\$ 71,144</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>CURRENT LIABILITIES</b>		
Accounts payable	\$ 1,678	\$ 677
CVR liability	7,510	—
Operating lease liabilities	—	625
Deferred revenue	—	517
Accrued and other current liabilities	15,861	12,837
Related party accounts payable	19,823	—
<b>Total current liabilities</b>	<b>44,872</b>	<b>14,656</b>
Non-current CVR liability	20,690	—
Non-current operating lease liabilities	—	4,004
Deferred revenue, net of current portion	—	2,179
<b>TOTAL LIABILITIES</b>	<b>65,562</b>	<b>20,839</b>
<b>Commitments and Contingencies</b>		
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	—
<b>STOCKHOLDERS' (DEFICIT) EQUITY</b>		
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	6
Additional paid-in capital	455,957	475,971
Accumulated other comprehensive income (loss)	(132)	(48)
Accumulated deficit	(701,234)	(425,624)
<b>TOTAL STOCKHOLDERS' (DEFICIT) EQUITY</b>	<b>(245,402)</b>	<b>50,305</b>
<b>TOTAL LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' (DEFICIT) EQUITY</b>	<b>\$ 207,265</b>	<b>\$ 71,144</b>

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
<b>Revenue:</b>				
Development fee and royalty	\$ —	\$ 174	\$ 886	\$ 2,161
Total revenue	—	174	886	2,161
<b>Operating expenses (income):</b>				
Research and development <sup>(1)</sup>	24,660	11,977	55,822	44,328
General and administrative	8,584	6,952	25,874	23,452
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	67,780
Loss from operations	(18,337)	(18,755)	(196,389)	(65,619)
<b>Other (expense) income:</b>				
Interest income	1,251	288	2,021	427
Change in fair value of forward contract liability	(25,360)	—	(83,530)	—
Other income, net	2,342	24	2,262	25
Total other (expense) income	(21,767)	312	(79,247)	452
Loss before income tax expense	(40,104)	(18,443)	(275,636)	(65,167)
Income tax (expense) benefit	(3)	209	26	174
Net loss	\$ (40,107)	\$ (18,234)	\$ (275,610)	\$ (64,993)
Net loss per share, basic and diluted	\$ (9.34)	\$ (4.84)	\$ (69.57)	\$ (20.17)
Weighted-average common shares outstanding, basic and diluted	4,293,812	3,767,918	3,961,546	3,222,987

<sup>(1)</sup> 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