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): July 27, 2023

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)**	**(I.R.S. Employer Identification No.)**

221 Crescent Street, Building 17, Suite 102B
Waltham, MA 02453
(Address of Principal Executive Offices, including Zip Code)

(617) 651-5940
(Registrant's Telephone Number, including Area Code)

Not Applicable
(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, par value $0.0001 per share	AGLE	The 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. ☐

Item 1.01 Entry into a Material Definitive Agreement.

On July 27, 2023, Aeglea BioTherapeutics, Inc. (the "Company") entered into and closed the transactions contemplated by that certain Asset Purchase Agreement (the "Purchase Agreement") with Immedica Pharma AB, a limited company (*Aktiebolag*) organized and existing under the laws of Sweden ("Immedica").

Subject to the terms and conditions of the Purchase Agreement, at the closing of the transactions (the "Closing") contemplated by the Purchase Agreement (the "Asset Purchase"), Immedica purchased from the Company its assets related to its research, development and manufacturing program for pegzilarginase for the treatment of Arginase-1 Deficiency as well as other therapeutic, prophylactic, palliative and diagnostic uses (the "Program," and any pharmaceutical product containing, incorporating or comprising pegzilarginase, the "Product") for an initial payment in cash of $15,000,000 due at Closing and up to $100,000,000 after the Closing (the "Milestone Payments"), payable upon the achievement of certain milestones based on sale and regulatory approvals related to the Product (the "Milestone Events").

The Purchase Agreement contains customary representations, warranties and covenants of the parties. The Company, on the one hand, and Immedica, on the other hand, have agreed to indemnify each other from and against losses the respective parties may incur arising out of breaches of the other party's representations, warranties and covenants contained in the Purchase Agreement and for certain other liabilities, subject to specified survival limitations and other customary exceptions and limitations. Pursuant to the Purchase Agreement, Immedica has the right to set off indemnifiable amounts, subject to certain limitations, against any Milestone Payment that may become payable.

Item 1.02 Termination of a Material Definitive Agreement.

As previously disclosed on March 21, 2021, the Company entered into a License and Supply Agreement (the "License Agreement") with Immedica. In connection with the Asset Purchase and pursuant to the Purchase Agreement, the Company and Immedica terminated the License Agreement as of Closing.

Item 2.01 Completion of Acquisition or Disposition of Assets.

To the extent required by Item 2.01 of this Current Report, the information contained in Item 1.01 of this Current Report is incorporated herein by reference.

Item 7.01 Regulation FD Disclosure.

On July 27, 2023, the Company issued a press release announcing the Company's entry into the Purchase Agreement (the "Press Release"). The Press Release is attached hereto as Exhibit 99.1 and is being furnished herewith.

The information in this Item 7.01 of this Current Report and the Press Release being furnished herewith shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, 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 information contained in this Item 7.01 and in the Press Release attached as Exhibit 99.1 to this Current Report shall not be incorporated by reference into any filing with the Securities and Exchange Commission (the "SEC") made by the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Item 8.01 Other Events.

As previously disclosed on June 23, 2023, the Company entered into and closed the transactions contemplated by that certain Agreement and Plan of Merger (the "Merger Agreement") with Spyre Therapeutics, Inc., a Delaware corporation and the other parties thereto. As contemplated by the Merger Agreement, the Company entered into that certain Contingent Value Rights Agreement (the "CVR Agreement") with American Stock Transfer & Trust Company LLC, a Delaware limited liability company ("AST"), as rights agent on July 7, 2023.

The CVR Agreement entitles each holder of a contingent value right ("CVR") to receive a pro rata share of the net proceeds, subject to certain permitted deductions as described in the CVR Agreement, from the Asset Purchase. Pursuant to the terms of the CVR Agreement, the first payments are expected to be made to CVR holders on or around November 14, 2023.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1*	Press Release of the Company, dated July 27, 2023
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Furnished herewith

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.

Dated: July 27, 2023

By: /s/ Jonathan Alspaugh
Name: Jonathan Alspaugh
Title: Chief Financial Officer

Aeglea BioTherapeutics Announces Sale of Pegzilarginase to Immedica Pharma

Global rights to pegzilarginase in development for Arginase 1 Deficiency sold to Immedica Pharma for $15 million upfront cash proceeds and up to $100 million of contingent milestone payments

Marketing Authorisation Application for pegzilarginase is under review by the European Medicines Agency

WALTHAM, Mass., July 27, 2023 – Aeglea BioTherapeutics, Inc. ("Aeglea") (NASDAQ:AGLE), a biotechnology company advancing a pipeline of antibody therapeutics with best-in-class potential to transform the treatment of inflammatory bowel disease ("IBD"), today announced that it has entered into an agreement to sell the global rights to pegzilarginase, an investigational treatment for the rare metabolic disease Arginase 1 Deficiency ("ARG1-D"), to Immedica Pharma AB ("Immedica") for $15 million in upfront cash proceeds and up to $100 million in contingent milestone payments. The sale of pegzilarginase to Immedica supersedes the previous license agreement between Aeglea and Immedica.

"We are thrilled that Immedica will be continuing our efforts with pegzilarginase and consolidating development of the potential therapy for the treatment of ARG1-D," said Jonathan Alspaugh, President and Chief Financial Officer of Aeglea. "Immedica has made substantial progress in working towards a European market approval. We believe it is ultimately in the best interest of the ARG1-D community that Immedica will seek to continue the dialogue with the FDA to discuss a path forward for pegzilarginase in the United States while advancing the program globally."

The milestone payments are contingent on formal reimbursement decisions by national authorities in key European markets and pegzilarginase approval by the U.S. Food and Drug Administration ("FDA"), among other events. The upfront payment and contingent milestone payments if paid, net of expenses and adjustments, will be distributed to holders of Aeglea's Contingent Value Rights ("CVR") pursuant to the CVR agreement resulting from Aeglea's acquisition of Spyre Therapeutics, Inc. ("Spyre").

About Pegzilarginase in ARG1-D

Pegzilarginase is a novel recombinant human enzyme engineered to degrade the amino acid arginine and has been shown to rapidly and sustainably lower levels of the amino acid arginine in plasma. Pegzilarginase has been in development for the treatment of people with ARG1-D, a rare debilitating and progressive disease characterized by the accumulation of arginine. ARG1-D presents in early childhood and patients experience spasticity, seizures, developmental delay, intellectual disability and early mortality. The PEACE Phase 3 clinical trial met its primary endpoint with a 76.7% reduction in mean plasma arginine compared to placebo. Additionally, 90.5% of pegzilarginase treated patients achieved normal plasma arginine levels. Based on the results from PEACE and a previous Phase 1/2 clinical trial, a Marketing Authorisation Application was submitted to the European Medicines Agency by Immedica. In April 2022, Aeglea announced the submission of a Biologics License Application (BLA) to the FDA. In June 2022, Aeglea announced the receipt of a Refusal to File letter from the FDA for the BLA of pegzilarginase for the treatment of ARG1-D.

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.

Forward-Looking Statements

Certain statements in this press release, other than purely historical information, may constitute "forward-looking statements" within the meaning of the federal securities laws, including for purposes of the safe harbor provisions under the United States Private Securities Litigation Reform Act of 1995, concerning Aeglea, the sale of pegzilarginase by Aeglea and other matters. These forward-looking statements include, but are not limited to, express or implied statements relating to Aeglea's management team's expectations, hopes, beliefs, intentions or strategies regarding the future including, without limitation, statements regarding potential receipt of contingent milestone payments and the distribution of such payments to holders of CVRs, and the continued development of pegzilarginase. In addition, any statements that refer to projections, forecasts or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements. The words "opportunity," "potential," "milestones," "pipeline," "can," "goal," "aim," "strategy," "target," "seek," "anticipate," "achieve," "believe," "contemplate," "continue," "could," "estimate," "expect," "intends," "may," "might," "plan," "possible," "predict," "project," "should," "will," "would" and similar expressions (including the negatives of these terms or variations of them) may identify forward-looking statements, but the absence of these words does not mean that a statement is not forward-looking. These forward-looking statements are based on current expectations and beliefs concerning future developments and their potential effects. There can be no assurance that future developments affecting Aeglea will be those that have been anticipated. These forward-looking statements involve a number of risks, uncertainties (some of which are beyond Aeglea's control) or other assumptions that may cause actual results or performance to be materially different from those expressed or implied by these forward-looking statements. These risks and uncertainties include, but are not limited those uncertainties and factors described under the heading "Risk Factors," "Risk Factor Summary" and "Forward-Looking Statements" in Aeglea's most recent Annual Report on Form 10-K filed with the Securities and Exchange Commission (the "SEC") on March 2, 2023, the Quarterly Report on Form 10-Q filed with the SEC on May 11, 2023, as well as discussions of potential risks, uncertainties, and other important factors included in other filings by Aeglea from time to time. Should one or more of these risks or uncertainties materialize, or should any of Aeglea's assumptions prove incorrect, actual results may vary in material respects from those projected in these forward-looking statements. Nothing in this press release should be regarded as a representation by any person that the forward-looking statements set forth herein will be achieved or that any of the contemplated results of such

forward-looking statements will be achieved. You should not place undue reliance on forward-looking statements in this press release, which speak only as of the date they are made and are qualified in their entirety by reference to the cautionary statements herein. Aeglea does not undertake or accept any duty to release publicly any updates or revisions to any forward-looking statements. This press release does not purport to summarize all of the conditions, risks and other attributes of an investment in Aeglea.

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