

**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): November 01, 2023

Clearside Biomedical, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-37783
(Commission File Number)

45-2437375
(IRS Employer
Identification No.)

900 North Point Parkway
Suite 200
Alpharetta, Georgia
(Address of Principal Executive Offices)

30005
(Zip Code)

Registrant's Telephone Number, Including Area Code: 678 270-3631

(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 \$0.001 per share	CLSD	The Nasdaq Stock Market LLC

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 November 1, 2023, Clearside Biomedical, Inc. (the “**Company**”) entered into a license agreement (the “**License Agreement**”) with BioCryst Pharmaceuticals, Inc. (“**BioCryst**”) pursuant to which the Company granted BioCryst an exclusive, worldwide and sublicensable license to the Company’s SCS Microinjector for the delivery of BioCryst’s proprietary plasma kallikrein inhibitor known as avoralstat for the treatment and prevention of diabetic macular edema (“**DME**”).

The Company will receive an upfront license fee of \$5.0 million in connection with signing of the License Agreement. In addition, the Company is eligible to receive up to an additional \$30.0 million in clinical and regulatory milestone payments, and up to a total of \$47.5 million in a series of post-approval sales-based milestone payments based on the achievement of annual global net product sales milestones up to \$2.0 billion. Further, during the royalty term, BioCryst has also agreed to pay the Company tiered mid-single digit royalties on annual global net product sales, with the highest royalty rate applied to sales over \$1.5 billion, subject to reductions in specified circumstances.

BioCryst will be responsible for all development, regulatory and commercialization activities for avoralstat. The Company is responsible for supplying SCS Microinjectors to meet BioCryst’s reasonable needs.

During the term of the License Agreement, the Company has agreed not to (i) develop or commercialize, whether on its own or through partnership with a third party, any kallikrein inhibitor delivered via the Company’s SCS Microinjector for use in ocular disease and (ii) grant any license of the patent rights licensed to the Company by Emory University and Georgia Tech Research Corporation (together with Emory University, the “**Licensors**”) pursuant to the License Agreement, by and among the Company and the Licensors, dated July 4, 2012, as amended, to any third party to develop or commercialize any kallikrein inhibitor delivered via the Company’s SCS Microinjector for use in ocular disease. In addition, during the term of the License Agreement, BioCryst has agreed not to, whether on its own or through partnership with a third party, develop or commercialize a product incorporating (i) avoralstat for use in ocular disease or (ii) another kallikrein inhibitor for the treatment of DME, in each case that is administered or delivered through the use of a device for delivery of therapeutic agents to the eye other than the SCS Microinjector.

The License Agreement, unless earlier terminated, will expire (a) on a country-by-country basis upon the expiration of the royalty term in such country or (b) in its entirety upon the expiration of all payment obligations of BioCryst under the License Agreement in all countries pursuant to clause (a). Each party has the right terminate the License Agreement (i) upon a material breach of the License Agreement by the other party, subject to a specified cure period and specified exceptions, or (ii) if the other party encounters bankruptcy or insolvency. The Company may terminate the License Agreement if BioCryst or any of its sublicensees (a “**Sublicensee**”) commences a legal action challenging the validity, enforceability or scope of any of the licensed patents, provided that with respect to any such action initiated by a Sublicensee (a “**Sublicensee Action**”), the Company may terminate the License Agreement if the Sublicensee Action is not terminated within a specified period of time following BioCryst’s receipt of written notice from the Company or if BioCryst does not terminate the applicable sublicense, in each case within a specified period of time. BioCryst may terminate the License Agreement (i) immediately upon written notice to the Company if, after exercising commercially reasonable efforts, BioCryst determines in good faith that it is not advisable to continue development or commercialization of avoralstat as a result of a material safety issue and (ii) in its entirety or in part on a country-by-country basis, for any or no reason, upon prior written notice to the Company, provided that in the event of such a termination, BioCryst shall not, for a period of two years from the date of such a termination, initiate in the territory subject to the termination a Phase 3 clinical trial in which avoralstat is administered to the suprachoroidal space using a device other than the SCS Microinjector.

The foregoing is a summary description of certain terms of the License Agreement, is not complete and is qualified in its entirety by reference to the text of the License Agreement, which the Company expects to file as an exhibit to the Company’s Annual Report on Form 10-K for the year ending December 31, 2023.

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.

Date: November 3, 2023

CLEARSIDE BIOMEDICAL, INC.

By: /s/ Charles A. Deignan

Name: Charles A. Deignan

Title: Chief Financial Officer
