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): August 08, 2022

Clearside Biomedical, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-37783**	**45-2437375**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

900 North Point Parkway Suite 200 Alpharetta, Georgia	**30005**
(Address of Principal Executive Offices)	**(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 August 8, 2022 (the "***Closing Date***"), Clearside Biomedical, Inc. (the "***Company***"), through its wholly-owned subsidiary Clearside Royalty LLC, a Delaware limited liability company ("***Royalty Sub"***), entered into a Purchase and Sale Agreement (the "***Purchase and Sale Agreement***") with entities managed by Healthcare Royalty Management, LLC (collectively, "***HCR***").Clearside intends to use the proceeds from the agreement to support ongoing clinical development of its pipeline, including CLS-AX (axitinib injectable suspension) administered by suprachoroidal injection via Clearside's SCS Microinjector®.

Pursuant to the Purchase and Sale Agreement, Royalty Sub sold to HCR certain of its rights to receive royalty and milestone payments arising in respect of amounts due and payable to Royalty Sub, from and after July 1, 2022, until such time certain return thresholds are met as described below, under (a) that certain License Agreement, dated March 10, 2020, by and between the Company, Arctic Vision (Hong Kong) Limited and the other parties thereto, as amended from time to time and as assigned by the Company to Royalty Sub on the Closing Date; (b) that certain License Agreement, made as of October 22, 2019, by and between the Company and Bausch Health Ireland Limited, as amended from time to time and as assigned by the Company to Royalty Sub on the Closing Date; (c) that certain License Agreement, effective as of July 3, 2019, by and between the Company and Aura Biosciences, Inc., as amended from time to time and as assigned by the Company to Royalty Sub on the Closing Date; (d) that certain Option and License Agreement, dated as of August 29, 2019, by and between REGENXBIO Inc. and the Company, as amended from time to time and as assigned by the Company to Royalty Sub on the Closing Date; and (e) any and all out-license agreements following the Closing Date for, or related to XIPERE® (triamcinolone acetonide injectable suspension) for suprachoroidal use or the SCS Microinjector technology (to be used in connection with compounds or products of any Third parties) delivered, in whole or in part, by means of the SCS Microinjector technology), excluding, for the avoidance of doubt, any in-licensed or internally developed therapies following the Closing Date (collectively, the "***Royalties***") in exchange for up to $65 million in cash.

Under the terms of the Purchase and Sale Agreement, Royalty Sub will receive an initial payment of $32.5 million, less certain expenses, within 15 business days of the Closing Date. An additional $12.5 million will be deposited in an escrow account to be released to Royalty Sub upon attainment of a pre-specified XIPERE sales milestone achieved no later than March 31, 2024. The terms of the Purchase and Sale Agreement also provide for an additional milestone payment of $20 million to Royalty Sub upon attainment of a second pre-specified 2024 sales milestone for XIPERE.

The terms of the Purchase and Sale Agreement also include a conditional escrow provision that, if triggered by certain post-close conditions, requires the Company to deposit an additional $5 million in an escrow account (the "***Additional Escrow Amount***"). Release of the Additional Escrow Amount to the Company is subject to satisfaction of certain post-close conditions set forth in the Purchase and Sale Agreement and other Transaction Documents (as defined in the Purchase and Sale Agreement). The Additional Escrow Amount may be released to HCR under certain circumstances.

The Purchase and Sale Agreement will automatically expire, and the payment of Royalties from the Royalty Sub to HCR will cease, when HCR has received payments of the Royalties equal to 2.5 times the aggregate amount of payments made by HCR under the agreement (the "***2024 Threshold***") if the 2024 Threshold is achieved on or prior to December 31, 2024. If the 2024 Threshold is not achieved on or prior to December 31, 2024, the Purchase and Sale Agreement will automatically expire, and the payment of Royalties from the Royalty Sub to HCR will cease, when HCR has received payments of the Royalties equal to 3.4 times the aggregate amount of payments made by HCR under the agreement. After the Purchase and Sale Agreement expires, all rights to receive the Royalties return to Royalty Sub. The Purchase and Sale Agreement grants HCR the right to receive certain reports and other information relating to the Royalties and contains various representations and warranties, covenants, indemnification obligations and other provisions that are customary for a transaction of this nature.

On the Closing Date, the Company entered into (i) a Contribution and Servicing Agreement and (ii) a Pledge and Security Agreement. The Contribution and Servicing Agreement contains various representations and warranties, covenants, indemnification obligations and other provisions related to the contribution of the Royalties and certain related assets to Royalty Sub and the Company's maintenance and servicing obligations with respect to the Royalties and such assets. The Pledge and Security agreement contains various representations, warranties and covenants, and includes a limited recourse guaranty of Royalty Sub's obligations under the Purchase and Sale Agreement which is secured by the pledge in favor of HCR all of the capital stock of Royalty Sub. HCR is entitled to foreclose on the capital stock of Royalty Sub following the occurrence of certain remedies events, including, without limitation, a change of control or bankruptcy of the Company or the failure of the Company to perform its obligations under the Contribution and Servicing Agreement.

The foregoing summary does not purport to be complete and is qualified in its entirety by reference to the Purchase and Sale Agreement, which will be filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarter ending September 30, 2022.

Item 7.01 Regulation FD Disclosure.

On August 8, 2022, the Company issued a press release announcing the transaction with Healthcare Royalty. A copy of this press release is furnished herewith as Exhibit 99.1 to this Current Report. The information contained in the press release furnished as Exhibit 99.1 shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "***Exchange Act***"), and is not incorporated by reference into any of the Company's filings under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, except as shall be expressly set forth by specific reference in any such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Press Release, dated August 8, 2022
104	Cover Page Interactive Data File (embedded with the Inline XBRL document)

Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements within the meaning of Private Securities Litigation Reform Act of 1995, as amended. These statements may be identified by the words "may," "will," "could," "would," "should," "expect," "plan," "anticipate," "intend," "believe," "estimate," "predict," "project," "potential," "continue," "target" or other similar terms or expressions that concern the Company's expectations, strategy, plans or intentions. Forward-looking statements include, without limitation, statements related to the Company's intended use of the proceeds from the Agreement with HealthCare Royalty. Any forward-looking statements in this Current Report on Form 8-K are based on management's current expectations and beliefs. Actual events or results may differ materially from those expressed or implied by any forward-looking statements contained herein, including, without limitation, the risks and uncertainties described in the section entitled "Risk Factors" in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission (the "***SEC***") on March 11, 2022, and in subsequent filings the Company makes with the SEC from time to time. The Company undertakes no obligation to update the information contained in this Current Report on Form 8-K to reflect new events or circumstances, except as required by law.

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 thereunto duly authorized.

Date: August 8, 2022

CLEARSIDE BIOMEDICAL, INC.

By: /s/ Charles A. Deignan
Name: Charles A. Deignan
Title: Chief Financial Officer

Clearside Biomedical Enters into Non-Dilutive Financing Agreement with HealthCare Royalty Partners for up to $65 Million

- Transaction Supports Progression of CLS-AX Clinical Program -

ALPHARETTA, Ga., August August 8, 2022 -- Clearside Biomedical, Inc. (Nasdaq: CLSD), a biopharmaceutical company revolutionizing the delivery of therapies to the back of the eye through the suprachoroidal space (SCS®), announced today it has entered into a Royalty Interest Purchase and Sale Agreement (the agreement) with HealthCare Royalty Partners (HealthCare Royalty).

Clearside intends to use the proceeds from the agreement to support ongoing clinical development of its pipeline, including CLS-AX (axitinib injectable suspension) administered by suprachoroidal injection via Clearside's SCS Microinjector®.

"The approval and launch of our first commercial product, XIPERE, provides the opportunity to access this meaningful non-dilutive capital which adds financial flexibility as we advance our development pipeline," said George Lasezkay, Pharm.D., J.D., Clearside's President and Chief Executive Officer. "We are pleased to partner with HealthCare Royalty to support the funding of further clinical trials of CLS-AX, our proprietary small molecule suspension of the tyrosine kinase inhibitor, axitinib, delivered suprachoroidally by our SCS Microinjector."

Under the terms of the agreement, Clearside will receive an initial payment of $32.5 million, less certain expenses. At the same time, an additional $12.5 million will be deposited in an escrow account to be released to Clearside upon attainment of a pre-specified sales milestone for XIPERE® (triamcinolone acetonide injectable suspension) for suprachoroidal use. The terms of the agreement also provide for an additional milestone payment of $20 million to Clearside upon attainment of a second pre-specified 2024 sales milestone for XIPERE.

In exchange for the payments described above, HealthCare Royalty will receive all royalties and milestone payments due to Clearside from XIPERE and certain SCS Microinjector license agreements, subject to a cap of 2.5 times the total purchase price paid by HealthCare Royalty under the agreement; the cap may be increased under certain

circumstances. The arrangement with HealthCare Royalty specifically excludes all Clearside's internal development programs, including CLS-AX, as well as any future in-licensed assets.

"We are pleased to partner with Clearside Biomedical to support their platform delivering therapies to the back of the eye through the suprachoroidal space," said Clarke Futch, Chairman and Chief Executive Officer of HealthCare Royalty. "Our investment reflects our belief in the strong value of Clearside's SCS injection platform and XIPERE, the first approved therapeutic delivered into the suprachoroidal space. This underscores our mission to facilitate innovation by high growth biopharmaceutical companies globally."

The agreement includes customary provisions for a transaction of this nature, a repayment provision at Clearside's option, and change of control provisions. Clearside has concurrently filed a Form 8-K which includes further details. Clearside expects to close the transaction in August 2022.

JMP Securities LLC served as a financial advisor to Clearside on this transaction.

About XIPERE® (triamcinolone acetonide injectable suspension) for suprachoroidal use

XIPERE® (triamcinolone acetonide injectable suspension) for suprachoroidal use is a proprietary suspension of the corticosteroid triamcinolone acetonide for administration to the suprachoroidal space for the treatment of macular edema associated with uveitis. Bausch + Lomb, a leading global eye health company dedicated to helping people see better to live better, has the exclusive license for the commercialization and development of XIPERE in the United States and Canada. Arctic Vision, a specialty ophthalmology company based in China, has the exclusive license for the commercialization and development of XIPERE, which they refer to as Arcatus™, in Greater China, South Korea, Australia, New Zealand, India and the ASEAN Countries. XIPERE was approved by the U.S. Food and Drug Administration in October 2021 and is commercially available in the U.S.

About CLS-AX (axitinib injectable suspension)

CLS-AX (axitinib injectable suspension) is a proprietary suspension of axitinib for suprachoroidal injection. Axitinib is a tyrosine kinase inhibitor (TKI) currently approved to treat renal cell cancer that achieves pan-VEGF blockade, directly inhibiting VEGF receptors-1, -2, and -3 with high potency and specificity. Clearside believes this broad VEGF blockade may have efficacy advantages over existing retinal therapies by acting at a different level of the angiogenesis cascade, and may benefit patients who sub-optimally respond to current, more narrowly focused anti-VEGF therapies.

Suprachoroidal injection of this proprietary suspension of axitinib has demonstrated meaningful potential in preclinical studies in multiple species. Preclinical results from Clearside and independent investigators have shown pharmacodynamic effects with reduced growth of experimental neovascularization and decreased fluorescein leakage. With suprachoroidal administration of axitinib, there is the potential to achieve prolonged duration and targeted delivery to affected tissue layers to potentially treat VEGF-driven disorders such as wet AMD, diabetic macular edema and diabetic retinopathy.

About Clearside's SCS Microinjector®

Clearside's patented, proprietary suprachoroidal space (SCS®) injection treatment approach offers unprecedented access to the back of the eye where sight-threatening disease often occurs. Clearside's proprietary SCS Microinjector® can be used to inject a wide variety of drug candidates that are specifically formulated to be delivered via suprachoroidal injection. The SCS Microinjector provides targeted delivery to potentially improve efficacy and compartmentalization of medication to reduce or eliminate toxic effects on non-diseased cells. The SCS Microinjector is composed of a syringe and two 30-gauge hollow microneedles of varying lengths, each less than 1.2 millimeters, within a custom-designed hub that optimizes insertion and suprachoroidal administration of drugs.

About Clearside Biomedical

Clearside Biomedical, Inc. is a biopharmaceutical company revolutionizing the delivery of therapies to the back of the eye through the suprachoroidal space (SCS®). Clearside's SCS injection platform, utilizing the Company's proprietary SCS Microinjector®, enables an in-office, repeatable, non-surgical procedure for the targeted and compartmentalized delivery of a wide variety of therapies to the macula, retina or choroid to potentially preserve and improve vision in patients with sight-threatening eye diseases. Clearside is developing its own pipeline of small molecule product candidates for administration via its SCS Microinjector and strategically partners its SCS injection platform with companies utilizing other ophthalmic therapeutic innovations. Clearside's first product, XIPERE® (triamcinolone acetonide injectable suspension) for suprachoroidal use, is commercially available in the U.S. For more information, please visit www.clearsidebio.com.

About HealthCare Royalty Partners

HealthCare Royalty purchases royalties and uses debt-like structures to invest in commercial or near-commercial stage life science assets. HealthCare Royalty has $6.2 billion in cumulative capital commitments with offices in Stamford (CT), San Francisco, Boston and London. For more information, visit www.healthcareroyalty.com.

HEALTHCARE ROYALTY PARTNERS® is a registered trademark of HealthCare Royalty Management, LLC in the U.S. and a trademark in other countries.

Cautionary Note Regarding Forward-Looking Statements

Any statements contained in this press release that do not describe historical facts may constitute forward-looking statements as that term is defined in the Private Securities Litigation Reform Act of 1995. These statements may be identified by words such as “believe”, “expect”, “may”, “plan”, “potential”, “will”, and similar expressions, and are based on Clearside’s current beliefs and expectations. These forward-looking statements include statements regarding the Company’s expected use of the proceeds from the agreement with HealthCare Royalty, the potential benefits of therapies using Clearside’s SCS Microinjector® and statements regarding the clinical development of CLS-AX,. These statements involve risks and uncertainties that could cause actual results to differ materially from those reflected in such statements. Risks and uncertainties that may cause actual results to differ materially include uncertainties inherent in the conduct of clinical trials, Clearside’s reliance on third parties over which it may not always have full control, uncertainties regarding the COVID-19 pandemic and other risks and uncertainties that are described in Clearside’s Annual Report on Form 10-K for the year ended December 31, 2021, filed with the U.S. Securities and Exchange Commission (SEC) on March 11, 2022, and Clearside’s other Periodic Reports filed with the SEC. Any forward-looking statements speak only as of the date of this press release and are based on information available to Clearside as of the date of this release, and Clearside assumes no obligation to, and does not intend to, update any forward-looking statements, whether as a result of new information, future events or otherwise.

Investor and Media Contacts:

Jenny Kobin
Remy Bernarda
ir@clearsidebio.com
(678) 430-8206

Source: Clearside Biomedical, Inc.