UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended September 30, 2023

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

Commission File Number: 001-37783

Clearside Biomedical, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**45-2437375**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
900 North Point Parkway, Suite 200 Alpharetta, GA	**30005**
(Address of principal executive offices)	**(Zip Code)**

(678) 270-3631

Registrant's telephone number, including area code

N/A

(Former name, former address and former fiscal year, if changed since last report)

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 (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		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. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of November 8, 2023, the registrant had 62,408,866 shares of common stock, $0.001 par value per share, outstanding.

		Page
	PART I - FINANCIAL INFORMATION	
Item 1.	Financial Statements (unaudited)	
	Consolidated Balance Sheets as of September 30, 2023 and December 31, 2022	3
	Consolidated Statements of Operations for the three and nine months ended September 30, 2023 and 2022	4
	Consolidated Statements of Stockholders' (Deficit) Equity for the three and nine months ended September 30, 2023 and 2022	5
	Consolidated Statements of Cash Flows for the nine months ended September 30, 2023 and 2022	6
	Notes to the Consolidated Financial Statements	7
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	16
Item 3.	Quantitative and Qualitative Disclosures About Market Risk	25
Item 4.	Controls and Procedures	25
	PART II - OTHER INFORMATION	
Item 1.	Legal Proceedings	26
Item 1A.	Risk Factors	26
Item 2.	Unregistered Sales of Equity Securities and Use of Proceeds	27
Item 6.	Exhibits	28
Signatures		29

PART I – FINANCIAL INFORMATION
Item 1. Financial Statements

CLEARSIDE BIOMEDICAL, INC.
Consolidated Balance Sheets
(in thousands, except share and per share data)
(unaudited)

	September 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 28,802	$ 48,258
Accounts receivable	882	91
Prepaid expenses	1,117	704
Other current assets	14	348
Total current assets	30,815	49,401
Property and equipment, net	2,642	755
Operating lease right-of-use asset	933	1,117
Other assets	30	30
Total assets	$ 34,420	$ 51,303
Liabilities and stockholders' (deficit) equity		
Current liabilities:		
Accounts payable	$ 1,867	$ 1,050
Accrued liabilities	3,606	4,179
Current portion of operating lease liabilities	362	349
Deferred revenue	—	205
Total current liabilities	5,835	5,783
Liability related to the sales of future royalties, net	40,710	33,977
Operating lease liabilities	724	936
Total liabilities	47,269	40,696
Commitments and contingencies		
Stockholders' (deficit) equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized and no shares issued at September 30, 2023 and December 31, 2022	—	—
Common stock, $0.001 par value; 200,000,000 shares authorized at September 30, 2023 and December 31, 2022; 62,107,311 and 60,639,827 shares issued and outstanding at September 30, 2023 and December 31, 2022, respectively	62	61
Additional paid-in capital	303,180	298,984
Accumulated deficit	(316,091)	(288,438)
Total stockholders' (deficit) equity	(12,849)	10,607
Total liabilities and stockholders' (deficit) equity	$ 34,420	$ 51,303

See accompanying notes to the consolidated financial statements.

CLEARSIDE BIOMEDICAL, INC.
Consolidated Statements of Operations
(in thousands, except share and per share data)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
License and other revenue	$ 859	$ 266	$ 1,881	$ 997
Operating expenses:				
Cost of goods sold	142	—	355	—
Research and development	5,134	4,637	14,533	14,603
General and administrative	2,637	2,353	8,922	8,601
Total operating expenses	7,913	6,990	23,810	23,204
Loss from operations	(7,054)	(6,724)	(21,929)	(22,207)
Other income	409	194	1,359	220
Non-cash interest expense on liability related to the sales of future royalties	(2,622)	(1,297)	(7,083)	(1,297)
Net loss	$ (9,267)	$ (7,827)	$ (27,653)	$ (23,284)
Net loss per share of common stock — basic and diluted	$ (0.15)	$ (0.13)	$ (0.45)	$ (0.39)
Weighted average shares outstanding — basic and diluted	61,983,987	60,188,541	61,605,648	60,134,821

See accompanying notes to the consolidated financial statements.

CLEARSIDE BIOMEDICAL, INC.
Consolidated Statements of Stockholders' (Deficit) Equity
(in thousands, except share data)
(unaudited)

	Nine Months Ended September 30, 2023				
	Common Stock		Additional Paid-In-Capital	Accumulated Deficit	Total Stockholders' (Deficit) Equity
	Shares	Amount			
Balance at December 31, 2022	60,639,827	$ 61	$ 298,984	$ (288,438)	$ 10,607
Issuance of common shares under at-the-market sales agreement	214,128	—	295	—	295
Vesting and settlement of restricted stock units	471,390	—	—	—	—
Issuance of common shares under employee stock purchase plan	38,954	—	37	—	37
Share-based compensation expense	—	—	1,041	—	1,041
Net loss	—	—	—	(9,280)	(9,280)
Balance at March 31, 2023	61,364,299	61	300,357	(297,718)	2,700
Issuance of common shares under at-the-market sales agreement	328,147	1	361	—	362
Exercise of stock options	24,999	—	10	—	10
Share-based compensation expense	—	—	1,061	—	1,061
Net loss	—	—	—	(9,106)	(9,106)
Balance at June 30, 2023	61,717,445	62	301,789	(306,824)	(4,973)
Issuance of common shares under at-the-market sales agreement	303,894	—	266	—	266
Exercise of stock options	56,817	—	23	—	23
Issuance of common shares under employee stock purchase plan	29,155	—	28	—	28
Share-based compensation expense	—	—	1,074	—	1,074
Net loss	—	—	—	(9,267)	(9,267)
Balance at September 30, 2023	62,107,311	$ 62	$ 303,180	$ (316,091)	$ (12,849)

	Nine Months Ended September 30, 2022				
	Common Stock		Additional Paid-In-Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance at December 31,2021	59,722,930	$ 60	$ 293,406	$ (255,491)	$ 37,975
Exercise of stock options	22,727	—	3	—	3
Vesting and settlement of restricted stock units	375,331	—	—	—	—
Issuance of common shares under employee stock purchase plan	26,630	—	62	—	62
Share-based compensation expense	—	—	1,307	—	1,307
Net loss	—	—	—	(7,644)	(7,644)
Balance at March 31, 2022	60,147,618	60	294,778	(263,135)	31,703
Exercise of stock options	2,824	—	4	—	4
Share-based compensation expense	—	—	1,354	—	1,354
Net loss	—	—	—	(7,813)	(7,813)
Balance at June 30, 2022	60,150,442	60	296,136	(270,948)	25,248
Issuance of common shares under employee stock purchase plan	40,289	—	51	—	51
Share-based compensation expense	—	—	1,074	—	1,074
Net loss	—	—	—	(7,827)	(7,827)
Balance at September 30, 2022	60,190,731	$ 60	$ 297,261	$ (278,775)	$ 18,546

See accompanying notes to the consolidated financial statements.

CLEARSIDE BIOMEDICAL, INC.
Consolidated Statements of Cash Flows
(in thousands)
(unaudited)

	Nine Months Ended September 30,	
	2023	**2022**
Operating activities		
Net loss	$ (27,653)	$ (23,284)
Adjustments to reconcile net loss to net cash used in operating activities:		
Non-cash interest expense on liability related to the sales of future royalties, net of issuance costs accretion	7,083	1,297
Depreciation	47	123
Share-based compensation expense	3,176	3,735
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(1,030)	9,952
Other assets and liabilities	(15)	(125)
Accounts payable and accrued liabilities	(33)	431
Deferred revenue	(205)	113
Net cash used in operating activities	(18,630)	(7,758)
Investing activities		
Acquisition of property and equipment	(1,657)	(155)
Net cash used in investing activities	(1,657)	(155)
Financing activities		
Proceeds from at-the-market sales agreement, net of issuance costs	923	—
Proceeds from royalty purchase and sale agreement, net of $1.9 million of issuance costs	—	30,638
Payments to royalty purchase and sale agreement	(350)	—
Proceeds from exercise of stock options	33	7
Proceeds from shares issued under employee stock purchase plan	65	113
Net cash provided by financing activities	671	30,758
Net (decrease) increase in cash, cash equivalents and restricted cash	(19,616)	22,845
Cash, cash equivalents and restricted cash, beginning of period	48,418	30,696
Cash, cash equivalents and restricted cash, end of period	$ 28,802	$ 53,541
Supplemental disclosure		
Purchase of property and equipment included in accrued liabilities	$ 277	$ —

Reconciliation of cash, cash equivalents and restricted cash:

	September 30,	
	2023	**2022**
Cash and cash equivalents	$ 28,802	$ 53,381
Restricted cash	—	160
Cash, cash equivalents and restricted cash at end of period	$ 28,802	$ 53,541

See accompanying notes to the consolidated financial statements.

1. The Company

Clearside Biomedical, Inc. (the “Company”) is a biopharmaceutical company focused on revolutionizing the delivery of therapies to the back of the eye through the suprachoroidal space (SCS®). Incorporated in the State of Delaware on May 26, 2011, the Company has its corporate headquarters in Alpharetta, Georgia.

The Company’s activities since inception have primarily consisted of developing product and technology rights, raising capital and performing research and development activities. The Company is subject to a number of risks and uncertainties similar to those of other life science companies at a similar stage of development, including, among others, the need to obtain adequate additional financing, successful development efforts including regulatory approval of products, compliance with government regulations, successful commercialization of potential products, protection of proprietary technology and dependence on key individuals.

Liquidity

The Company had cash and cash equivalents of $28.8 million as of September 30, 2023.

In May 2023, the Company terminated its at-the-market sales agreement with Cowen and Company, LLC (the "ATM Agreement"). The Company sold 515,959 shares of its common stock for net proceeds of $0.7 million under its ATM Agreement with Cowen and Company, LLC during the six months ended June 30, 2023, prior to the termination of the ATM Agreement.

In May 2023, the Company entered into a Controlled Equity Offering℠ Sales Agreement (the "Sales Agreement") with Cantor Fitzgerald & Co. ("Cantor") under which the Company may offer and sell, from time to time at its sole discretion, shares of its common stock, having an aggregate offering price of up to $50.0 million through Cantor as its sales agent. During the nine months ended September 30, 2023, the Company sold 330,210 shares of its common stock for net proceeds of $0.4 million under the Sales Agreement. Subsequent to September 30, 2023, the Company sold an additional 301,555 shares of its common stock pursuant to the Sales Agreement for net proceeds of $0.3 million.

In August 2022, 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 (“HCR”) pursuant to which it sold its rights to receive royalty and milestone payments due to the Company from XIPERE and certain SCS Microinjector license agreements subject to a cap which may be increased under certain circumstances. The Company received a payment of $32.1 million in September 2022, representing the $32.5 million to which the Company was entitled, net of certain of HCR's transaction-related expenses which the Company agreed to reimburse. There were additional issuance costs of $1.5 million related to the Purchase and Sale Agreement resulting in net proceeds of $30.6 million.

The Company has suffered recurring losses and negative cash flows from operations since inception and anticipates incurring additional losses until such time, if ever, that it can generate significant revenue. The Company has no current source of revenue to sustain present activities. The Company does not expect to generate other meaningful revenue until and unless the Company's licensees successfully commercialize XIPERE and the Company has fulfilled its obligations under the Purchase and Sale Agreement, its other licensees receive regulatory approval and successfully commercialize its product candidates, or the Company commercializes its product candidates either on its own or with a third party. In the absence of product or other revenues, the amount, timing, nature or source of which cannot be predicted, the Company’s losses will continue as it conducts its research and development activities.

The Company will continue to need to obtain additional financing to fund future operations, including completing the development, partnering and potential commercialization of its primary product candidates. The Company will need to obtain financing to complete the development and conduct clinical trials for the regulatory approval of its product candidates if requested by regulatory bodies. If such product candidates were to receive regulatory approval, the Company would need to obtain financing to prepare for the potential commercialization of its product candidates, if the Company decides to commercialize the products on its own.

These conditions raise substantial doubt about the Company’s ability to continue as a going concern within one year after the date the financial statements are issued. Based on its current plans and forecasted expenses, the Company expects that its cash and cash equivalents as of the filing date, November 13, 2023, and assuming the receipt of the $5.0 million upfront payment that the Company is entitled to receive from BioCryst Pharmaceuticals, Inc. (as described in Note 13), will enable the Company to fund its planned operating expenses and capital expenditure requirements into the fourth quarter of 2024. The Company has based this estimate on assumptions that may prove to be wrong, and it could exhaust its capital resources sooner than expected. Until the Company can generate sufficient revenue, the Company will need to finance future cash needs through public or private equity offerings, license agreements, debt financings or restructurings, collaborations, strategic alliances and marketing or distribution arrangements.

The Company's financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result should the Company be unable to continue as a going concern.

2. Significant Accounting Policies

Basis of Presentation and Principles of Consolidation

The Company's consolidated financial statements include the results of the financial operations of Clearside Biomedical, Inc. and its wholly-owned subsidiary, Clearside Royalty, LLC. a Delaware limited liability company, which was formed for the purposes of the transactions contemplated by the Purchase and Sale Agreement describe in Note 5. All intercompany balances and transactions have been eliminated.

The Company's consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("U.S. GAAP"). In the opinion of management, the Company has made all necessary adjustments, which include normal recurring adjustments necessary for a fair statement of the Company's consolidated financial position and results of operations for the interim periods presented. Certain amounts reported in prior periods have been reclassified to conform to the current period financial statement presentation. These reclassifications are not material and have no effect on the previously reported consolidated financial statements and related disclosures. The results for the three and nine months ended September 30, 2023 are not indicative of results to be expected for the year ending December 31, 2023, any other interim periods or any future year or period. These unaudited financial statements should be read in conjunction with the audited financial statements and related footnotes, which are included in the Company's Annual Report on Form 10-K for the year ended December 31, 2022.

Use of Estimates

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and reported amounts of income and expenses during the reporting periods. Significant items subject to such estimates and assumptions include revenue recognition, the accounting for useful lives to calculate depreciation and amortization, clinical trial expense accruals, share-based compensation expense and income tax valuation allowance. Actual results could differ from these estimates.

Revenue Recognition

The Company recognizes revenue from its contracts with customers under Financial Accounting Standards Board Accounting Standards Codification ("ASC") Topic 606, *Revenue from Contracts with Customers.* The Company's primary revenue arrangements are license agreements, which typically include upfront payments, regulatory and commercial milestone payments and royalties based on future product sales. The arrangements may also include payments for the Company's SCS Microinjector devices as well as payments for assistance and oversight of the customer's use of the Company's technology. In determining the amount of revenue to be recognized under these agreements, the Company performs the following steps: (i) identifies the promised goods and services to be transferred in the contract, (ii) identifies the performance obligations, (iii) determines the transaction price, (iv) allocates the transaction price to the performance obligations and (v) recognizes revenue as the performance obligations are satisfied.

The Company receives payments from its customers based on billing schedules established in each contract. Upfront and other payments may require deferral of revenue recognition to a future period until the Company performs its obligations under the arrangement. Amounts are recorded as accounts receivable when the Company's right to consideration is unconditional. The Company does not assess whether a contract has a significant financing component if the expectation at contract inception is such that the period between payment by the customer and the transfer of the promised goods or services to the customer will be one year or less.

Research and Development Costs

Research and development costs are charged to expense as incurred and include:

- employee-related expenses, including salaries, benefits, travel and share-based compensation expense for research and development personnel;
- expenses incurred under agreements with contract research organizations, contract manufacturing organizations and consultants that conduct preclinical studies and clinical trials;
- costs associated with preclinical and clinical development activities;
- costs associated with submitting regulatory approval applications for the Company's product candidates;

- costs associated with training physicians on the suprachoroidal injection procedure and educating and providing them with appropriate product candidate information;
- costs associated with technology and intellectual property licenses;
- costs for the Company's research and development facility; and
- depreciation expense for assets used in research and development activities.

Costs for certain development activities, such as clinical trial activities, are recognized based on an evaluation of the estimated total costs for the clinical trial, progress to completion of specific tasks using data such as patient enrollment, pass-through expenses, clinical site activations, data from the clinical sites or information provided to the Company by its vendors on their actual costs incurred. Payments for these activities are based on the terms of the individual contracts and any subsequent amendments, which may differ from the patterns of costs incurred, and are reflected in the financial statements as prepaid or accrued expense.

Share-Based Compensation

Compensation cost related to share-based awards granted to employees, directors and consultants is measured based on the estimated fair value of the award at the grant date. The Company estimates the fair value of stock options using a Black-Scholes option pricing model. The fair value of restricted stock units granted is measured based on the market value of the Company's common stock on the date of grant. Share-based compensation costs are expensed on a straight-line basis over the relevant vesting period.

Compensation cost related to shares purchased through the Company's employee stock purchase plan, which is considered compensatory, is based on the estimated fair value of the shares on the offering date, including consideration of the discount and the look-back period. The Company estimates the fair value of the shares using a Black-Scholes option pricing model. Compensation expense is recognized over the six-month withholding period prior to the purchase date.

All share-based compensation costs are recorded in general and administrative or research and development costs in the statements of operations based upon the recipient's underlying role within the Company.

Cash Equivalents

Cash equivalents consist of short-term, highly liquid investments with an original term of three months or less at the date of purchase.

Concentration of Credit Risk Arising From Cash Deposits in Excess of Insured Limits

The Company maintains its cash in bank deposits that at times may exceed federally insured limits. The Company has not experienced any loss in such accounts. The Company believes it is not exposed to any significant risks with respect to its cash balances.

Liability Related to the Sales of Future Royalties and Non-Cash Interest Expense

The Company recognizes a liability related to the sales of future royalties under ASC 470-10 Debt and ASC 835-30 Interest - Imputation of Interest. The initial funds received by the Company pursuant to the terms of the Purchase and Sale Agreement were recorded as a liability and will be accreted under the effective interest method up to the estimated amount of future royalties and milestone payments to be made under the Purchase and Sale Agreement. The issuance costs were recorded as a direct deduction to the carrying amount of the liability and will be amortized under the effective interest method over the estimated period the liability will be repaid. The Company estimated the total amount of future royalty revenue and milestone payments to be generated over the life of the Purchase and Sale Agreement, and a significant increase or decrease in these estimates could materially impact the liability balance and the related interest expense. If the timing of the receipt of royalty payments or milestones is materially different from the original estimates, the Company will prospectively adjust the effective interest and the related amortization of the liability and related issuance costs.

3. Property and Equipment, Net

Property and equipment, net consisted of the following (dollar amounts in thousands):

	Estimated Useful Lives (Years)	September 30, 2023	December 31, 2022
Furniture and fixtures	5	$ 249	$ 249
Machinery and equipment	5	343	343
Computer equipment	3	20	13
Leasehold improvements	Lesser of useful life or remaining lease term	476	476
Work in process		2,454	527
Total property and equipment		3,542	1,608
Less: Accumulated depreciation		(900)	(853)
Property and equipment, net		$ 2,642	$ 755

4. Accrued Liabilities

Accrued liabilities consisted of the following (in thousands):

	September 30, 2023	December 31, 2022
Accrued research and development	$ 1,553	$ 1,817
Accrued employee costs	1,309	1,837
Accrued professional fees	41	49
Accrued expense	703	476
	$ 3,606	$ 4,179

5. Royalty Purchase and Sale Agreement

On August 8, 2022 (the “Closing Date”), the Company, through Royalty Sub, entered into the Purchase and Sale Agreement with HCR, pursuant to which Royalty Sub sold to HCR certain of its rights to receive royalty and milestone payments payable to Royalty Sub under the Arctic Vision License Agreement, the Bausch License Agreement, that certain License Agreement, effective as of July 3, 2019, by and between the Company and Aura Biosciences, Inc. (the “Aura License Agreement”), that certain Option and License Agreement, dated as of August 29, 2019, by and between REGENXBIO Inc. and the Company (the “REGENXBIO License Agreement”) and any and all out-license agreements following the Closing Date for, or related to XIPERE 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 connection with this transaction, the Company assigned the Arctic Vision License Agreement, Bausch License Agreement, Aura License Agreement, REGENXBIO License Agreement, the Company's license agreement with Emory University and The Georgia Tech Research Corporation and related intellectual property rights to Royalty Sub.

Under the terms of the Purchase and Sale Agreement, Royalty Sub received an initial payment of $32.1 million, representing the $32.5 million to which the Company was entitled, net of certain of HCR's transaction-related expenses which the Company agreed to reimburse. There were additional issuance costs of $1.5 million related to the Purchase and Sale Agreement resulting in net proceeds of $30.6 million. An additional $12.5 million was deposited by HCR 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 $20 million milestone payment to Royalty Sub upon attainment of a second pre-specified sales milestone related to 2024 XIPERE sales (the "Second Milestone Event").

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 if the Second Milestone Event is achieved on or prior to December 31, 2024 (the “Initial Cap”). If the Second Milestone Event is not achieved on or prior to December 31, 2024, payment of Royalties from Royalty Sub to HCR will cease when HCR has received Royalties payments equal to 3.4 times the aggregate amount of payments under the Purchase and Sale Agreement (the “Alternative Cap”, and together with the Initial Cap, the “Cap Amount”). In the event of a change in control, acquiror will have the option to make a payment to HCR of the Cap Amount then in effect, less the aggregate amount of Royalty payments made by

Royalty Sub to HCR under the Purchase and Sale Agreement as a one-time payment at which time, payment of Royalties to HCR will cease. Alternatively, in the event of a change in control, the acquiror will have the option to make an initial payment of 1.0 times the aggregate amount of payments made by HCR under the Purchase and Sale Agreement as of the date of such change in control, then in that event, payment of Royalties from Royalty Sub to HCR will cease when HCR has received total Royalties payments (including the initial payment) equal to the Alternative Cap. After the Purchase and Sale Agreement expires, all rights to receive the Royalties return to Royalty Sub.

Issuance costs pursuant to the Purchase and Sale Agreement consisting primarily of advisory and legal fees, totaled $1.9 million including the amount of HCR's transaction-related expenses that the Company reimbursed. The effective interest rate includes cash flow projections for future royalty and milestone payments, which are sensitive to certain assumptions, including market size, market penetration and sales price, that are forward looking and could be affected by future market conditions.

The following table summarizes the activity of the Purchase and Sale Agreement (in thousands):

Royalty purchase and sale agreement balance at December 31, 2022	$	33,977
Payments		(350)
Non-cash interest expense		7,083
Balance at September 30, 2023	$	40,710
Effective interest rate		23.3%

6. Common Stock

The Company's amended and restated certificate of incorporation authorizes the Company to issue 200,000,000 shares of $0.001 par value common stock. As of September 30, 2023 and December 31, 2022, there were 62,107,311 and 60,639,827 shares of common stock outstanding, respectively.

7. Stock Purchase Warrants

In September 2016, in connection with a loan agreement, the Company issued warrants to purchase up to 29,796 shares of common stock at a price per share of $10.74. The warrants expire in September 2026, or earlier upon the occurrence of specified mergers or acquisitions of the Company, and are immediately exercisable. The warrants were recorded in equity and had a weighted average remaining life of 3.0 years as of September 30, 2023.

8. Share-Based Compensation

Share-based compensation is accounted for in accordance with the provisions of ASC 718, *Compensation-Stock Compensation*.

Stock Options

The Company has granted stock option awards to employees, directors and consultants from its 2011 Stock Incentive Plan (the "2011 Plan") and its 2016 Equity Incentive Plan (the "2016 Plan"). The estimated fair value of options granted is determined as of the date of grant using the Black-Scholes option pricing model. The resulting fair value is recognized ratably over the requisite service period, which is generally the vesting period of the awards.

Share-based compensation expense for options granted under the 2016 Plan is reflected in the statements of operations as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Research and development	$ 308	$ 431	$ 914	$ 1,245
General and administrative	460	327	1,293	1,381
Total	$ 768	$ 758	$ 2,207	$ 2,626

The following table summarizes the activity related to stock options granted under the 2011 Plan and the 2016 Plan during the nine months ended September 30, 2023:

	Number of Shares	Weighted Average Exercise Price
Options outstanding at December 31, 2022	6,915,330	$ 3.58
Granted	3,684,750	1.28
Exercised	(81,816)	0.40
Forfeited	(402,190)	2.19
Options outstanding at September 30, 2023	10,116,074	2.82
Options exercisable at December 31, 2022	4,223,931	4.22
Options exercisable at September 30, 2023	5,366,708	3.87

As of September 30, 2023, the Company had $5.1 million of unrecognized compensation expense related to unvested stock options, which is expected to be recognized over a weighted average period of 2.5 years.

Restricted Stock Units

The Company has granted restricted stock units ("RSUs") to employees from the 2016 Plan. The shares underlying the RSU awards have vesting terms of four years from the date of grant subject to the employees' continuous service and subject to accelerated vesting in specified circumstances. The fair value of the RSUs granted is measured based on the market value of the Company's common stock on the date of grant and is recognized ratably over the requisite service period, which is generally the vesting period of the awards.

The total share-based compensation expense related to RSUs is reflected in the statements of operations as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Research and development	$ 143	$ 186	$ 475	$ 592
General and administrative	160	123	484	494
Total	$ 303	$ 309	$ 959	$ 1,086

The following table summarizes the activity related to RSUs during the nine months ended September 30, 2023:

	Number of Shares	Weighted Average Grant Date Fair Value
Non-vested RSUs outstanding at December 31, 2022	1,462,932	$ 3.04
Vested	(471,390)	3.09
Forfeited	(122,364)	3.12
Non-vested RSUs outstanding at September 30, 2023	869,178	3.75

As of September 30, 2023, the Company had $1.7 million of unrecognized compensation expense related to the RSUs which is expected to be recognized over a weighted average period of 1.7 years.

Employee Stock Purchase Plan

The 2016 Employee Stock Purchase Plan (the “2016 ESPP”) became effective on June 1, 2016. The 2016 ESPP is considered a compensatory plan and the fair value of the discount and the look-back period are estimated using the Black-Scholes option pricing model and expense is recognized over the six-month withholding period prior to the purchase date.

The share-based compensation expense recognized for the 2016 ESPP is reflected in the statements of operations as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Research and development	$ 3	$ 5	$ 8	$ 15
General and administrative	—	2	2	8
Total	$ 3	$ 7	$ 10	$ 23

During the nine months ended September 30, 2023, the Company issued 68,109 shares of common stock purchased under the 2016 ESPP.

9. Commitments and Contingencies

Lease Commitment Summary

In November 2022, the Company signed an amended office lease agreement to lease approximately 14,000 square feet of office space in Alpharetta, Georgia for its corporate headquarters. The amended office lease agreement is for a four year term with a renewal option for an additional 38 months. Rental payments are $30,747 per month subject to an increase of 3% per year. Rent expense under this lease is recognized on a straight-line basis over the term of the lease. In addition, the office lease agreement requires payment of the pro-rata share of the annual operating expenses associated with the premises.

The Company recognizes a right-of-use asset for the right to use the underlying asset for the lease term, and a lease liability, which represents the present value of the Company’s obligation to make payments over the lease term. The renewal option is not included in the calculation of the right-of-use asset and the lease liabilities as the Company has not yet determined if the Alpharetta, Georgia lease will be renewed.

Equipment leases with an initial term of 12 months or less are not recorded with operating lease liabilities. The Company recognizes expense for these leases on a straight-line basis over the lease term. The equipment leases were deemed to be immaterial.

Contract Service Providers

In the course of the Company’s normal business operations, it has agreements with contract service providers to assist in the performance of its research and development, clinical research and manufacturing. Substantially all of these contracts are on an as needed basis.

10. License and Other Agreements

Bausch + Lomb

On October 22, 2019, the Company entered into a License Agreement (as amended, the "Bausch License Agreement") with Bausch + Lomb (“Bausch”). Pursuant to the Bausch License Agreement, the Company has granted an exclusive license to Bausch to develop, manufacture, distribute, promote, market and commercialize XIPERE using the Company’s proprietary SCS Microinjector (the “Device”), as well as specified other steroids, corticosteroids and NSAIDs in combination with the Device (together with XIPERE, the “Products”), subject to specified exceptions, in the United States and Canada (the “Territory”) for the treatment of ophthalmology indications, including non-infectious uveitis.

Pursuant to the Bausch License Agreement, Bausch paid the Company an aggregate of $20.0 million in upfront and milestone payments. In addition, Bausch has agreed to pay up to an aggregate of $55.0 million in additional milestone payments upon the achievement of (i) specified regulatory approvals for specified additional indications of XIPERE and (ii) specified levels of annual net sales (as defined in the Bausch License Agreement). Further, during the applicable royalty term, the Company will also be entitled to receive tiered royalties at increasing percentages, from the high-teens to twenty percent, based on XIPERE achieving certain annual net sales thresholds in the Territory, in each case subject to reductions in specified circumstances; provided that the Company will not receive any royalties on the first $45.0 million of cumulative net sales of all products in the Territory. Bausch launched XIPERE in the United States in the first quarter of 2022. The Company's rights to these royalties and milestone payments have been sold pursuant to the terms and conditions of the Purchase and Sale Agreement described in Note 5 to the consolidated financial statements.

Arctic Vision (Hong Kong) Limited

On March 10, 2020, the Company entered into a License Agreement (the "Arctic License Agreement") with Arctic Vision (Hong Kong) Limited ("Arctic Vision"). Pursuant to the Arctic License Agreement, the Company has granted an exclusive license to Arctic Vision to develop, distribute, promote, market and commercialize XIPERE, subject to specified exceptions, in China, Hong Kong, Macau, Taiwan and South Korea (the "Arctic Territory"). Under the terms of the Arctic License Agreement, neither party may commercialize XIPERE in the other party's territory. Arctic Vision has agreed to use commercially reasonable efforts to pursue the development and commercialization of XIPERE for indications associated with uveitis in the Arctic Territory. In addition, upon receipt of the Company's consent, Arctic Vision will have the right, but not the obligation, to develop and commercialize XIPERE for additional indications in the Arctic Territory.

Pursuant to the Arctic License Agreement, Arctic Vision paid the Company an aggregate of $8.0 million in upfront and milestone payments. In addition, Arctic Vision has agreed to pay the Company up to $24.0 million in development and sales milestones. Further, during the applicable royalty term, the Company will also be entitled to receive tiered royalties of ten to twelve percent of net sales based on achieving certain annual net sales thresholds in the Territory, subject to customary reductions, payable on a product-by-product and country-by-country basis, commencing at launch in such country and lasting until the latest of (i) the date that all valid claims within the licensed patent rights covering XIPERE have expired, (ii) the date of the loss of marketing or regulatory exclusivity of XIPERE in a given country, or (iii) ten years from the first commercial sale of XIPERE in a given country. The Company's rights to these royalties and milestone payments have been sold pursuant to the terms and conditions of the Purchase and Sale Agreement described in Note 5 to the consolidated financial statements.

In August 2021, the Company entered into an amendment to the Arctic License Agreement to expand the territories covered by the license to include India and the ASEAN Countries (Brunei, Cambodia, Indonesia, Laos, Malaysia, Myanmar, the Philippines, Singapore, Thailand, and Vietnam). In September 2021, the Company entered into a second amendment to the Arctic Vision License Agreement to expand the Arctic Territory to include Australia and New Zealand. The Company received an aggregate of $3.0 million in consideration for the expansion of the Arctic Territory.

Other

The Company periodically enters into short-term agreements with other customers to evaluate the potential use of its proprietary SCS Microinjector with third-party product candidates for the treatment of various diseases. Funds received from these agreements are recognized as revenue over the term of the agreement.

11. Fair Value Measurements

The Company's material financial instruments at September 30, 2023 and December 31, 2022 consisted primarily of cash and cash equivalents. The fair values of cash and cash equivalents, other current assets and accounts payable approximate their respective carrying values due to the short term nature of these instruments and are classified as Level 1 in the fair value hierarchy. The fair value of liability related to the sales of future royalties approximates the carrying value due to the short period of time that has elapsed from the origination date and the absence of any identifiable factors that would be reasonably expected to materially impact the fair value of the liability.

There were no transfers between Levels 1, 2 and 3 during the nine months ended September 30, 2023 and the year ended December 31, 2022.

12. Net Loss Per Share

Basic net loss per share is calculated by dividing the net loss by the weighted average number of shares of common stock outstanding for the period, without consideration of the dilutive effect of potential common stock equivalents. Diluted net loss per share gives effect to all dilutive potential shares of common stock outstanding during this period. For all periods presented, the Company's potential common stock equivalents, which included stock options, restricted stock units and stock purchase warrants, have been excluded from the computation of diluted net loss per share as their inclusion would have the effect of reducing the net loss per share. Therefore, the denominator used to calculate both basic and diluted net loss per share is the same in all periods presented. The Company's potential common stock equivalents that have been excluded from the computation of diluted net loss per share for all periods presented because of their antidilutive effect consisted of the following:

	Nine Months Ended September 30,	
	2023	2022
Outstanding stock options	10,116,074	7,218,605
Non-vested restricted stock units	869,178	1,462,932
Stock purchase warrants	29,796	29,796
	11,015,048	8,711,333

13. Subsequent Event

On November 1, 2023, 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.

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 Chair of the Board of Directors of BioCryst also serves on the Company's Board of Directors. No amounts related to the License Agreement were recorded in these interim consolidated financial statements.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

Certain statements contained in this Quarterly Report on Form 10-Q may constitute forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. The words or phrases "would be," "will allow," "intends to," "will likely result," "are expected to," "will continue," "is anticipated," "estimate," "project," or similar expressions, or the negative of such words or phrases, are intended to identify "forward-looking statements." We have based these forward-looking statements on our current expectations and projections about future events. Because such statements include risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Factors that could cause or contribute to these differences include those below and elsewhere in this Quarterly Report on Form 10-Q and our other filings with the Securities and Exchange Commission, or SEC, under the heading "Risk Factors". Statements made herein are as of the date of the filing of this Form 10-Q with the SEC and should not be relied upon as of any subsequent date. Unless otherwise required by applicable law, we do not undertake, and we specifically disclaim, any obligation to update any forward-looking statements to reflect occurrences, developments, unanticipated events or circumstances after the date of such statement.

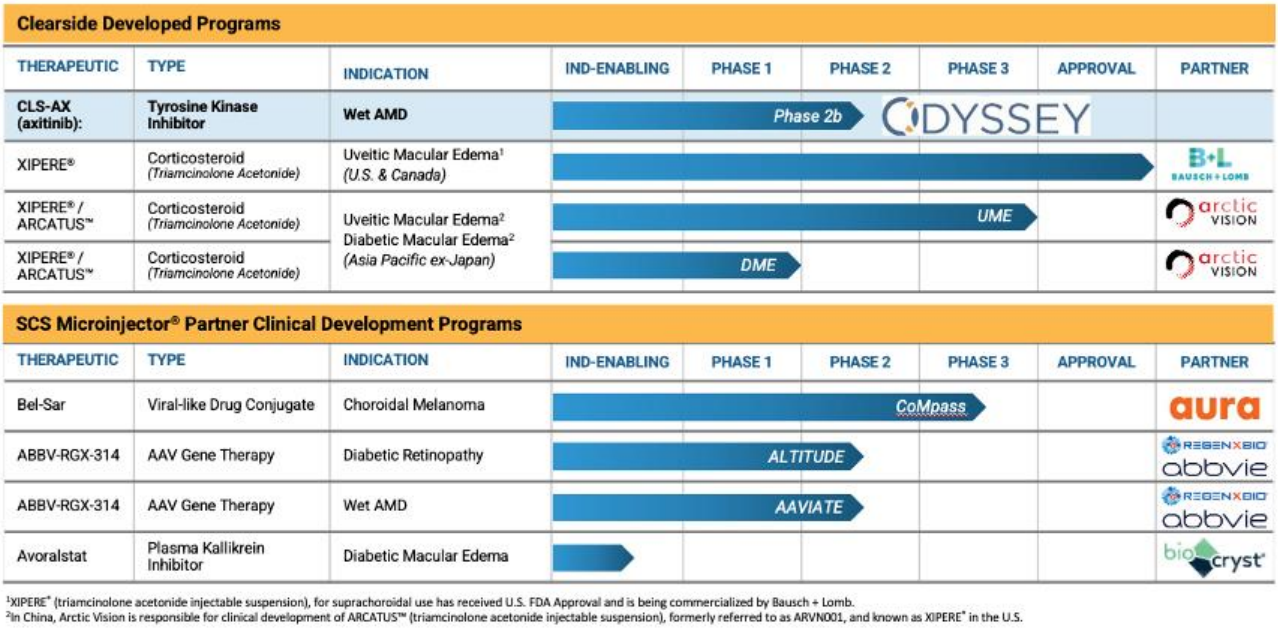
The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited financial statements and related notes that appear in Item 1 of this Quarterly Report on Form 10-Q and with our audited financial statements and related notes for the year ended December 31, 2022 appearing in our Annual Report on Form 10-K filed with the SEC on March 14, 2023.

Overview

We are a biopharmaceutical company focused on revolutionizing the delivery of therapies to the back of the eye through the suprachoroidal space, or SCS®. Our novel SCS injection platform, utilizing our 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. Our SCS injection platform can be used in conjunction with existing drugs designed for delivery to the SCS, novel therapies and future therapeutic innovations. We believe our proprietary suprachoroidal administration platform has the potential to become a standard for delivery of therapies intended to treat chorioretinal diseases.

We are leveraging our SCS injection platform by building an internal research and development pipeline targeting retinal diseases and by creating external collaborations with other companies. We are developing our own pipeline of small molecule product candidates for administration via our SCS Microinjector, and we also strategically partner with companies developing other ophthalmic therapeutic innovations to be administered using our SCS injection platform. Our first product, XIPERE® (triamcinolone acetonide injectable suspension) for suprachoroidal use, was approved by the U.S. Food and Drug Administration, or the FDA, in October 2021. Approval of XIPERE was a significant milestone for us as it is the first approved therapeutic delivered into the SCS, the first commercial product developed by us and the first therapy for macular edema associated with uveitis. We believe that we are creating a broad therapeutic platform for developing product candidates to treat serious eye diseases.

The current development status of our pipeline of internal product candidates and external collaborations is summarized in the chart below:



[1]XIPERE® (triamcinolone acetonide injectable suspension), for suprachoroidal use has received U.S. FDA Approval and is being commercialized by Bausch + Lomb.
[2]In China, Arctic Vision is responsible for clinical development of ARCATUS™ (triamcinolone acetonide injectable suspension), formerly referred to as ARVN001, and known as XIPERE® in the U.S.

Commercial Product

XIPERE® (triamcinolone acetonide injectable suspension) for suprachoroidal use, was approved by the FDA in October 2021. XIPERE is the first approved therapeutic delivered into the SCS, the first commercial product developed by us and the first therapy for macular edema associated with uveitis. XIPERE commercialization rights are licensed to Bausch + Lomb in the United States and Canada and Arctic Vision in Asia.

Clinical Development Pipeline

CLS-AX (axitinib injectable suspension)

CLS-AX, our most advanced product candidate, is our proprietary suspension of the TKI axitinib for suprachoroidal injection delivered via our SCS Microinjector. We are developing CLS-AX for administration to the SCS as a long-acting therapy for neovascular age-related macular degeneration (wet AMD), a retinal degenerative disease that causes a progressive loss of central vision.

In February 2023, we announced the final, positive results from the OASIS Phase 1/2a clinical trial in wet AMD. CLS-AX was well-tolerated and demonstrated a favorable safety profile across all cohorts. The full extension data for Cohorts 3 and 4 showed promising durability and signs of biologic effect.

Based on the results from the OASIS trial, we are conducting a randomized, controlled, double-masked, Phase 2b clinical trial of CLS-AX for the treatment of wet AMD, which we refer to as ODYSSEY. ODYSSEY will compare CLS-AX suprachoroidal injection and aflibercept intravitreal injection over 36 weeks and is expected to have 60 total participants with a 2:1 randomization. The primary outcome measure is a mean change in best corrected visual acuity from baseline to week 36. The secondary outcome measures are changes in visual function and ocular anatomy, need for supplemental treatment and treatment burden as measured by total injections over the trial duration. We began enrolling participants in May 2023 and randomized our first participants in July 2023. On October 31, 2023, we completed the recruitment of participants. We expect that the final participant will be randomized to the CLS-AX treatment of the aflibercept comparator arm by the middle of December 2023 and that we will report topline data in the third quarter of 2024.

Preclinical

We have an experienced team of scientists and researchers evaluating small molecules that may be utilized as potential treatment options for back of the eye diseases utilizing our SCS Microinjector for delivery in the suprachoroidal space.

External Collaborations Pipeline

In order to expand the global reach of our suprachoroidal injection platform, we have strategically partnered some of our assets for development and/or commercialization and intend to continue partnering our assets. By entering into these partnerships, we have been able to expand the use of our suprachoroidal injection platform to other indications and geographies globally. We currently have collaborations with Bausch Health, Arctic Vision, REGENXBIO, Inc., Aura Biosciences and BioCryst Pharmaceuticals, Inc.

In July 2023, Arctic Vision announced the acceptance in Australia of its new drug application for suprachoroidal use of Arcatus® (known as XIPERE in the United States) for the treatment of uveitic macular edema.

ISO and EC Certifications

We have received the International Organization for Standardization (ISO) Certification EN ISO 13485:2016 for "The design, development, and manufacture of sterile piston syringes, needles, and associated accessories for the area of ophthalmology." The certificate is available on our website. The information contained on our website is not incorporated by reference into this Quarterly Report on Form 10-Q.

We have received European Community (EC) Certification for the SCS Microinjector from our Notified Body, Intertek Medical Notified Body, AB. The Certificate of Conformance with the Medical Device Regulation 2017/745, Annex IV was issued July 21, 2023, with the Intended Purpose of the SCS Microinjector as "delivery of triamcinolone acetonide injectable suspension, 40 mg/mL to the suprachoroidal space of the eye".

Royalty Purchase and Sale Agreement

On August 8, 2022, or the Closing Date, we, through our wholly-owned subsidiary Clearside Royalty LLC, a Delaware limited liability company, or Royalty Sub, entered into a Purchase and Sale Agreement, or the Purchase and Sale Agreement, with entities managed by HealthCare Royalty Management, LLC, or HCR, pursuant to which Royalty Sub sold to HCR certain of its rights to receive royalty and milestone payments payable to Royalty Sub under the Arctic Vision License Agreement, the Bausch License Agreement, that certain License Agreement, effective as of July 3, 2019, by and between the Company and Aura, or the Aura License Agreement, the REGENXBIO Option and License Agreement and any and all out-license agreements following the Closing Date for, or related to XIPERE 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, or the Royalties, in exchange for up to $65 million. In connection with this transaction, we assigned the Arctic Vision License Agreement, Bausch License Agreement, Aura License Agreement, REGENXBIO Option and License Agreement, our license agreement with Emory University and The Georgia Tech Research Corporation and related intellectual property rights to Royalty Sub.

Under the terms of the Purchase and Sale Agreement, Royalty Sub received an initial payment of $32.1 million, representing the $32.5 million to which we were entitled, net of certain of HCR's transaction-related expenses which we agreed to reimburse. An additional $12.5 million was deposited by HCR 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 $20.0 million milestone payment to Royalty Sub upon attainment of a second pre-specified sales milestone related to 2024 XIPERE sales, or the Second Milestone Event.

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 if the Second Milestone Event is achieved on or prior to December 31, 2024, or the Initial Cap. If the Second Milestone Event is not achieved on or prior to December 31, 2024, payment of Royalties from Royalty Sub to HCR will cease when HCR has received Royalties payments equal to 3.4 times the aggregate amount of payments under the Purchase and Sale Agreement, or the Alternative Cap. In the event of a change in control, acquiror will have the option to make a payment to HCR of the Initial Cap or the Alternative Cap, depending on which is then in effect, less the aggregate amount of Royalty payments made by Royalty Sub to HCR under the Purchase and Sale Agreement as a one-time payment at which time, payment of Royalties to HCR will cease. Alternatively, in the event of a change in control, the acquiror will have the option to make an initial payment of 1.0 times the aggregate amount of payments made by HCR under the Purchase and Sale Agreement as of the date of such change in control, then in that event, payment of Royalties from Royalty Sub to HCR will cease when HCR has received total Royalties payments (including the initial payment) equal to the Alternative Cap. After the Purchase and Sale Agreement expires, all rights to receive the Royalties return to Royalty Sub.

Operating Outlook

We have incurred net losses since our inception. In recent years, our operations have consisted primarily of conducting preclinical studies and clinical trials, raising capital and undertaking other research and development initiatives. To date, we have not generated any revenue, other than license and other revenue, and we have primarily financed our operations through public offerings and private placements of our equity securities, issuances of convertible promissory notes and loan agreements. As of September 30, 2023, we had an accumulated deficit of $316.1 million. We recorded net losses of $9.3 million and $7.8 million for the three months ended September 30, 2023 and 2022, respectively, and net losses of $27.7 million and $23.3 million for the nine months ended September 30, 2023 and 2022, respectively. We anticipate that a substantial portion of our capital resources and efforts in the foreseeable future will be focused on completing the necessary development for and obtaining regulatory approval of our product candidates, as well as discovering compounds and developing proprietary formulations to utilize with our SCS Microinjector.

We expect to continue to incur significant and increasing operating losses at least for the next several years. We do not expect to generate significant product or license and other revenue unless and until XIPERE is successfully commercialized by our licensees or until we successfully complete the development of, obtain regulatory approval for and commercialize additional product candidates, either on our own or together with a third party. Our financial results may fluctuate significantly from quarter to quarter and year to year, depending on the timing of our clinical trials and our expenditures on other research and development activities. We expect clinical trial expenses to increase in the remainder of 2023 as a result of our Phase 2b clinical trial of CLS-AX, as well as continuing our pipeline development. We also will continue our efforts to discover, research and develop additional product candidates and regulatory approvals in additional regions for XIPERE for the treatment of macular edema associated with uveitis.

Components of Operating Results

License and Other Revenue

We have not generated any revenue from the sale of XIPERE and we do not expect to generate any other product revenue unless or until we obtain regulatory approval for and commercialize our other product candidates, either on our own or with a third party. The revenue received under the Bausch license agreement, as well as other certain payments from our licensees, will be recorded as non-cash revenue until we have fulfilled our obligations under the Purchase and Sale Agreement. Our revenue in recent years has been generated primarily from our license agreements. We are seeking to enter into additional licenses and other agreements with third parties to evaluate the potential use of our proprietary SCS Microinjector with the third party's product candidates for the treatment of various eye diseases. These agreements may include payments to us for technology access, upfront license payments, regulatory and commercial milestone payments and royalties.

Research and Development

Research and development expenses consist primarily of costs incurred for the research and development of our preclinical and clinical product candidates, which include:

- employee-related expenses, including salaries, benefits, travel and share-based compensation expense for research and development personnel;
- expenses incurred under agreements with contract research organizations, or CROs, as well as contract manufacturing organizations and consultants that conduct clinical trials and preclinical studies;
- costs associated with nonclinical activities and development activities;
- costs associated with submitting regulatory approval applications for our product candidates;
- costs associated with training physicians on the suprachoroidal injection procedure and educating and providing them with appropriate product candidate information;
- costs associated with technology and intellectual property licenses;
- costs for our research and development facility; and
- depreciation expense for assets used in research and development activities.

We expense research and development costs to operations as incurred. These costs include preclinical activities, such as manufacturing and stability and toxicology studies, that are supportive of the product candidate itself. In addition, there are expenses related to clinical trials and similar activities for each program, including costs associated with CROs. Clinical costs are recognized based on the terms of underlying agreements, as well as an evaluation of the progress to completion of specific tasks using data such as patient enrollment, clinical site activations and additional information provided to us by our vendors about their actual costs occurred. Expenses related to activities that support more than one development program or activity, such as salaries, share-based compensation and depreciation, are not classified as direct preclinical costs or clinical costs and are separately classified as unallocated.

The following table shows our research and development expenses by program for the three and nine months ended September 30, 2023 and 2022 (in thousands).

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
XIPERE (uveitis program)	$ 10	$ 118	$ 86	$ 315
CLS-AX (wet AMD program)	2,810	1,529	6,146	4,308
Total	2,820	1,647	6,232	4,623
Unallocated	2,314	2,990	8,301	9,980
Total research and development expense	$ 5,134	$ 4,637	$ 14,533	$ 14,603

Our expenses related to clinical trials are based on estimates of patient enrollment and related expenses at clinical investigator sites as well as estimates for the services received and efforts expended under contracts with research institutions, consultants and CROs that conduct and manage clinical trials on our behalf. We generally accrue expenses related to clinical trials based on contracted amounts applied to the level of patient enrollment and activity according to the protocol. If future timelines or contracts are modified based upon changes in the clinical trial protocol or scope of work to be performed, we would modify our estimates of accrued expenses accordingly on a prospective basis.

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. However, it is difficult to determine with certainty the duration and completion costs of our current or future preclinical programs and clinical trials of our product candidates, or if, when or to what extent we will generate revenues from the commercialization and sale of any of our product candidates that obtain regulatory approval. We may never succeed in achieving regulatory approval for any of our current or future product candidates.

The duration, costs and timing of clinical trials and development of our product candidates will depend on a variety of factors that may include, among others:

- the costs associated with process development, scale-up and manufacturing of our product candidates including the SCS Microinjector for clinical trials and for requirements associated with regulatory filings;
- the number of trials required for approval and any requirement for extension trials;
- per patient trial costs;
- the number of patients that participate in the trials;
- the number of sites included in the trials;
- the countries in which the trials are conducted;
- the length of time required to enroll eligible patients;
- the number of doses that patients receive;
- the drop-out or discontinuation rates of patients;
- potential additional safety monitoring or other studies requested by regulatory agencies;
- the duration of patient follow-up; and
- the efficacy and safety profiles of the product candidates.

In addition, the probability of success for each product candidate will depend on numerous factors, including competition, manufacturing capability and commercial viability. We will determine which programs to pursue and how much to fund each program in response to the scientific and clinical success of each product candidate, as well as an assessment of each product candidate’s commercial potential.

General and Administrative

General and administrative expenses consist primarily of salaries and other related costs, including share-based compensation, for personnel in executive, finance and administrative functions. General and administrative costs historically included commercial pre-launch preparations for XIPERE, and also include facility related costs not otherwise included in research and development expenses, as well as professional fees for legal, patent, consulting, and accounting and audit services.

Other Income

Other income consists of the accrued interest and interest income earned on our cash and cash equivalents. Interest income is not considered significant to our financial statements.

Non-cash Interest Expense on Liability Related to the Sales of Future Royalties

Non-cash interest expense on liability related to the sales of future royalties consists of imputed interest on the carrying value of the liability and the amortization of the related issuance costs.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America, or U.S. GAAP. The preparation of these consolidated financial statements requires us to make estimates, judgments and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities as of the dates of the balance sheets and the reported amounts of expenses during the reporting periods. In accordance with U.S. GAAP, we evaluate our estimates and judgments on an ongoing basis. Significant estimates include assumptions used in the determination of share-based compensation and some of our research and development expenses. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

We define our critical accounting policies as those accounting principles generally accepted in the United States of America that require us to make subjective estimates and judgments about matters that are uncertain and are likely to have a material impact on our financial condition and results of operations, as well as the specific manner in which we apply those principles. During the nine months ended September 30, 2023, there were no significant changes to our critical accounting policies disclosed in our audited financial statements for the year ended December 31, 2022, which are included in our Annual Report on Form 10-K, as filed with the SEC on March 14, 2023.

Results of Operations for the Three Months Ended September 30, 2023 and 2022

The following table sets forth our results of operations for the three months ended September 30, 2023 and 2022.

	Three Months Ended September 30,		Period-to-Period Change
	2023	2022	
		(in thousands)	
License and other revenue	$ 859	$ 266	$ 593
Operating expenses:			
Cost of goods sold	142	—	142
Research and development	5,134	4,637	497
General and administrative	2,637	2,353	284
Total operating expenses	7,913	6,990	923
Loss from operations	(7,054)	(6,724)	(330)
Other income	409	194	215
Non-cash interest expense on liability related to the sales of future royalties	(2,622)	(1,297)	(1,325)
Net loss	$ (9,267)	$ (7,827)	$ (1,440)

License and other revenue. In the three months ended September 30, 2023 and 2022, we recognized $0.9 million and $0.3 million, respectively, of revenue associated with our license agreements, which includes revenue for services and the sales of our SCS Microinjector kits to our licensees.

Cost of goods sold. For the three months ended September 30, 2023, we recognized $0.1 million in cost of goods sold related to the sales of our SCS Microinjector kits to our licensees.

Research and development. Research and development expense increased by $0.5 million from $4.6 million for the three months ended September 30, 2022 to $5.1 million for the three months ended September 30, 2023. This increase was primarily due to a $1.3 million increase in costs related to the CLS-AX program, which includes costs for ODYSSEY, our Phase 2b clinical trial. This was partially offset by a $0.4 million decrease for a research and development tax credit received in the current period and a $0.2 million decrease in costs related to our other preclinical programs.

General and administrative. General and administrative expenses increased by $0.3 million, from $2.4 million for the three months ended September 30, 2022 to $2.6 million for the three months ended September 30, 2023. This was primarily attributable to a $0.2 million increase in employee-related costs and $0.1 million increase in professional fees.

Other income. Other income for the three months ended September 30, 2023 and 2022 was comprised of interest income from cash and cash equivalents. The increase is due to the higher interest rates earned on our cash and cash equivalents.

Non-cash interest expense on liability related to the sales of future royalties. Non-cash interest expense on liability related to the sales of future royalties for the three months ended September 30, 2023 and 2022 was comprised of imputed interest on the liability related to the sales of future royalties and the amortization of the associated issuance costs.

Results of Operations for the Nine Months Ended September 30, 2023 and 2022

The following table sets forth our results of operations for the nine months ended September 30, 2023 and 2022.

	Nine Months Ended September 30,		Period-to-Period Change
	2023	2022	
		(in thousands)	
License and other revenue	$ 1,881	$ 997	$ 884
Operating expenses:			
Cost of goods sold	355	—	355
Research and development	14,533	14,603	(70)
General and administrative	8,922	8,601	321
Total operating expenses	23,810	23,204	606
Loss from operations	(21,929)	(22,207)	278
Other income	1,359	220	1,139
Non-cash interest expense on liability related to the sales of future royalties	(7,083)	(1,297)	(5,786)
Net loss	$ (27,653)	$ (23,284)	$ (4,369)

License and other revenue. In the nine months ended September 30, 2023 and 2022, we recognized $1.9 million and $1.0 million, respectively, of revenue associated with our license agreements, which includes revenue for services and the sales of our SCS Microinjector kits to our licensees.

Cost of goods sold. For the nine months ended September 30, 2023, we recognized $0.4 million in cost of goods sold related to the sales of our SCS Microinjector kits to our licensees.

Research and development. Research and development expense was $14.5 million and $14.6 million for the nine months ended September 30, 2023 and 2022, respectively. There was a $1.8 million increase in costs related to the CLS-AX program, which includes the final costs for our OASIS Phase 1/2a clinical trial and OASIS extension study, and the startup costs for ODYSSEY, our Phase 2b clinical trial. This was offset by a $0.8 million decrease due to a research and development tax credit received in the current period and a $0.8 million decrease in costs related to our other preclinical programs.

General and administrative. General and administrative expenses increased by $0.3 million, from $8.6 million for the nine months ended September 30, 2022 to $8.9 million for the nine months ended September 30, 2023. This was due to a $0.8 million increase in professional fees, partially offset by a $0.2 million decrease in employee-related costs and a $0.2 million decrease for insurance costs.

Other income. Other income for the nine months ended September 30, 2023 and 2022 was comprised of interest income from cash and cash equivalents. The increase is due to the higher interest rates earned on our cash and cash equivalents.

Non-cash interest expense on liability related to the sales of future royalties. Non-cash interest expense on liability related to the sales of future royalties for the nine months ended September 30, 2023 and 2022 was comprised of imputed interest on the liability related to the sales of future royalties and the amortization of the associated issuance costs.

Liquidity and Capital Resources

Sources of Liquidity

We have funded our operations primarily through the proceeds of public offerings of our common stock, sales of convertible preferred stock and the issuance of long-term debt. As of September 30, 2023, we had cash and cash equivalents of $28.8 million. We invest any cash in excess of our immediate requirements primarily with a view to liquidity and capital preservation. As of September 30, 2023, our funds were held in cash and money market funds.

In May 2023, we terminated our at-the-market sales agreement with Cowen and Company, LLC (the "ATM Agreement"). During the six months ended June 30, 2023, prior to the termination of the ATM Agreement, we sold 515,959 shares of its common stock for net proceeds of $0.7 million under the ATM Agreement.

In May 2023,we entered into a Controlled Equity Offering[SM] Sales Agreement (the "Sales Agreement") with Cantor Fitzgerald & Co. ("Cantor") under which we may offer and sell, from time to time at our sole discretion, shares of our common stock, having an aggregate offering price of up to $50.0 million through Cantor as our sales agent. During the nine months ended September 30, 2023, we sold 330,210 shares of our common stock for net proceeds of $0.4 million under the Sales Agreement. Subsequent to September 30, 2023, we sold an additional 301,555 shares of our common stock pursuant to the Sales Agreement for net proceeds of $0.3 million.

On August 8, 2022, or the Closing Date, we, through our wholly-owned subsidiary Clearside Royalty LLC, a Delaware limited liability company, or Royalty Sub, entered into a Purchase and Sale Agreement with entities managed by HealthCare Royalty Management, LLC, or HCR, pursuant to which Royalty Sub sold to HCR certain of its rights to receive royalty and milestone payments payable to Royalty Sub under the Arctic Vision License Agreement, Bausch License Agreement, that certain License Agreement, effective as of July 3, 2019, by and between us and Aura Biosciences, Inc., that certain Option and License Agreement, dated as of August 29, 2019, by and between REGENXBIO Inc. and us, and any and all out-license agreements following the Closing Date for, or related to XIPERE 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, in exchange for up to $65 million. Under the terms of the Purchase and Sale Agreement, Royalty Sub received a payment of $32.1 million, representing the $32.5 million to which we were entitled less certain expenses. There were additional issuance costs of $1.5 million related to the Purchase and Sale Agreement resulting in net proceeds of $30.6 million. An additional $12.5 million was deposited in an escrow account by HCR 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 $20 million milestone payment to Royalty Sub upon attainment of a second pre-specified sales milestone related to 2024 XIPERE sales.

Funding Requirements

Our primary uses of capital are, and we expect will continue to be, compensation and related expenses, research and development costs to build our product candidate pipeline, legal and other regulatory expenses and general overhead costs. In addition, we have certain contractual obligations for future payments. Refer to Note 9 to our consolidated financial statements included in this Quarterly Report on Form 10-Q.

The successful development of our product candidates is highly uncertain. As such, at this time, we cannot reasonably estimate or know the nature, timing and estimated costs of the efforts that will be necessary to complete the development of CLS-AX or any future product candidates. We are also unable to predict when, if ever, material net cash inflows will commence from product sales. This is due to the numerous risks and uncertainties associated with developing drugs, including the uncertainty of:

- successful enrollment in, and completion of, clinical trials;
- receipt of marketing approvals from applicable regulatory authorities;
- establishing commercial manufacturing capabilities or making arrangements with third-party manufacturers;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our product candidates; and
- launching commercial sales of the products, if and when approved, whether alone or in collaboration with others.

A change in the outcome of any of these variables with respect to the development of any of our product candidates would significantly change the costs and timing associated with the development of that candidate.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity offerings, debt financings and potential collaboration, license and development agreements. Other than potential payments we may receive under our license and other agreements, we do not currently have any committed external source of funds, though, as described above, we may also be able to sell our common stock under the ATM Agreement subject to the terms of that agreement and depending on market conditions. We expect that we will require additional capital to fund our ongoing operations. Additional funds may not be available to us on a timely basis, on commercially reasonable terms, or at all. Our ability to raise additional capital may be adversely impacted by potential worsening global economic conditions and the recent disruptions to, and volatility in, the credit and financial markets in the United States and worldwide resulting from macroeconomic conditions, such as inflation. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

If we raise funds through additional collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, including any future collaboration or licensing arrangement for XIPERE outside of the territories in which we have previously licensed or granted options to license XIPERE, we may be required to relinquish additional rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our drug development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

We also incur costs as a public company, including costs and expenses for fees to members of our board of directors, accounting and finance personnel costs, directors and officers insurance premiums, audit and legal fees, investor relations fees and expenses for compliance with reporting requirements under the Exchange Act and rules implemented by the SEC and Nasdaq.

Outlook

We have suffered recurring losses and negative cash flows from operations since inception and anticipate incurring additional losses until such time, if ever, that we can generate significant milestone payments and royalties from XIPERE and other licensing arrangements or revenues from other product candidates. We will need additional financing to fund our operations. These conditions raise substantial doubt about our ability to continue as a going concern within one year after the date of this report. Our plans primarily consist of raising additional capital, potentially in a combination of equity or debt financings, monetizing royalties, or restructurings, or potentially entering into additional collaborations, partnerships and other strategic arrangements.

Based on our current plans and forecasted expenses, we expect that our cash and cash equivalents as of the filing date, November 13, 2023, and assuming receipt of the $5.0 million upfront payment that we are entitled to receive from BioCryst, will enable us to fund our planned operating expenses and capital expenditure requirements into the fourth quarter of 2024. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our capital resources sooner than we expect. We will require additional capital in order to complete the clinical development of CLS-AX.

Our financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result should we be unable to continue as a going concern.

Cash Flows

The following is a summary of the net cash flows provided by (used in) our operating, investing and financing activities (in thousands):

	Nine Months Ended September 30,	
	2023	**2022**
Net cash provided by (used in):		
Operating activities	$ (18,630)	$ (7,758)
Investing activities	(1,657)	(155)
Financing activities	671	30,758
Net change in cash and cash equivalents	$ (19,616)	$ 22,845

During the nine months ended September 30, 2023 and 2022, our operating activities used net cash of $18.6 million and $7.8 million, respectively. The net cash used in operating activities for the nine months ended September 30, 2023 was due to ongoing research and development expenses to develop our pipeline and startup costs for ODYSSEY, the Phase 2b clinical trial for CLS-AX, as well as the supporting general and administrative costs. The net cash used in operating activities for the nine months ended September 30, 2022 was primarily due to research and development expenses related to the preclinical and clinical programs and general and administrative expenses offset by the receipt of the $10.0 million milestone payment received from Bausch in connection with pre-launch activities for XIPERE.

During the nine months ended September 30, 2023 and 2022, our investing activities used net cash of $1.7 million and $0.2 million, respectively, and consisted of the acquisition of property and equipment.

During the nine months ended September 30, 2023 and 2022 our net cash provided by financing activities was $0.7 million and $30.8 million, respectively. The cash provided by financing activities for the nine months ended September 30, 2023 consisted primarily of $0.9 million of net proceeds from the sale of shares of our common stock under the ATM Agreement and the Sales Agreement partially offset by a payment of $0.4 million related to the Purchase and Sale agreement. The cash provided by financing activities for the nine months ended September 30, 2022 primarily consisted of $30.6 million of proceeds received from the Purchase and Sale Agreement, net of issuance costs.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are not required to provide the information required under this item.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), refers to controls and procedures that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that such information is accumulated and communicated to a company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure.

In designing and evaluating our disclosure controls and procedures, management recognizes that disclosure controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the disclosure controls and procedures are met. Additionally, in designing disclosure controls and procedures, our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible disclosure controls and procedures. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a control system, misstatements due to error or fraud may occur and not be detected.

Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures as of the end of the period covered by this report. Based on that evaluation, our Chief Executive Officer and our Chief Financial Officer concluded that our disclosure controls and procedures were effective as of the end of the period covered by this report at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There has been no change in our internal control over financial reporting during the quarter ended September 30, 2023 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. We have not experienced any material impact to our internal control over financial reporting.

PART II – OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, we may be subject to litigation and claims arising in the ordinary course of business. We are not currently a party to any material legal proceedings and we are not aware of any pending or threatened legal proceeding against us that we believe could have a material adverse effect on our business, operating results, cash flows or financial condition.

Item 1A. Risk Factors

Our business is subject to risks and events that, if they occur, could adversely affect our financial condition and results of operations and the trading price of our securities. In addition to the other information set forth in this quarterly report on Form 10-Q, you should carefully consider the factors described below and in "Part I, Item 1A. Risk Factors" of our Annual Report on Form 10-K for the fiscal year ended December 31, 2022, filed with the Securities and Exchange Commission on March 14, 2023. Except as set forth below, there have been no material changes to the risk factors described in that report.

Our consolidated financial statements have been prepared assuming that we will continue as a going concern.

We have incurred recurring losses from operations since inception which, raises substantial doubt about our ability to continue as a going concern. If we are unable to obtain sufficient funding, our business, prospects, financial condition and results of operations will be materially and adversely affected, and we may be unable to continue as a going concern. If we are unable to continue as a going concern, we may have to liquidate our assets and may receive less than the value at which those assets are carried on our audited financial statements, and it is likely that investors will lose all or a part of their investment. In addition, if there remains substantial doubt about our ability to continue as a going concern, investors or other financing sources may be unwilling to provide additional funding to us on commercially reasonable terms, or at all.

If we fail to maintain compliance with the listing requirements of the Nasdaq Global Market, we may be delisted and the price of our common stock and our ability to access the capital markets could be negatively impacted.

Our common stock is currently listed on the Nasdaq Global Market. To maintain the listing of our common stock on the Nasdaq Global Market, we are required to meet certain listing requirements, including, among others, either: (i) a minimum closing bid price of $1.00 per share, a market value of publicly held shares (excluding shares held by our executive officers, directors and 10% or more stockholders) of at least $5 million and stockholders' equity of at least $10 million; or (ii) a minimum closing bid price of $1.00 per share, a market value of publicly held shares (excluding shares held by our executive officers, directors, affiliates and 10% or more stockholders) of at least $15 million and a total market value of listed securities of at least $50 million.

On September 27, 2023, we received a letter from the Listing Qualifications Department of The Nasdaq Stock Market, LLC notifying us that the listing of our common stock was not in compliance with Nasdaq Listing Rule 5450(a)(1) for continued listing on the Nasdaq Global Market, as the minimum bid price of our listed securities was less than $1.00 per share for the previous 30 consecutive business days. Under Nasdaq Listing Rule 5810(c)(3)(A), we have a period of 180 calendar days, or until March 25, 2024, to regain compliance with the rule referred to in this paragraph. To regain compliance, during this 180-day compliance period, our minimum bid price of listed securities must close at $1.00 per share or more for a minimum of 10 consecutive business days.

In the event that we do not regain compliance with the Nasdaq Listing Rules prior to the expiration of the 180-day compliance period, we may be eligible for additional time to regain compliance pursuant to Nasdaq Listing Rule 5810(c)(3)(A)(ii) by transferring to the Nasdaq Capital Market. To qualify, we would need to submit a Transfer Application and a $5,000 application fee. In addition, we would be required to meet the continued listing requirement for the market value of publicly held shares and all other initial listing standards for The Nasdaq Capital Market, with the exception of the minimum bid price requirement. In addition, we would need to provide written notice to Nasdaq of our intention to cure the minimum bid price deficiency during the second compliance period by effecting a reverse stock split, if necessary. As part of its review process, the Nasdaq staff will make a determination of whether it believes we will be able to cure the deficiency. Should the Nasdaq staff conclude that we will not be able to cure the deficiency, or should we determine not to submit a Transfer Application or make the required representation, Nasdaq will provide notice that our shares of common stock will be subject to delisting.

If we do not regain compliance within the allotted compliance period(s), including any extensions that may be granted by Nasdaq, Nasdaq will provide notice that our shares of common stock will be subject to delisting. At such time, we may appeal the delisting determination to a Hearings Panel.

There can be no assurance that we will be successful in maintaining the listing of our common stock on the Nasdaq Global Market, or, if transferred, on the Nasdaq Capital Market. This could impair the liquidity and market price of our common stock. In addition, the delisting of our common stock from a national exchange could have a material adverse effect on our access to capital markets. Any limitation on market liquidity or reduction in the price of our common stock as a result of that delisting could adversely affect our ability to raise capital on terms acceptable to us, or at all.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

Sales of Unregistered Securities

None.

Issuer Purchases of Equity Securities

None.

Item 6. Exhibits

Exhibit No.	Description
3.1	Amended and Restated Certificate of Incorporation (incorporated herein by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 001-37783) filed with the SEC on June 7, 2016).
3.2	Certificate of Amendment to Amended and Restated Certificate of Incorporation (incorporated herein by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 001-37783) filed with the SEC on June 23, 2022).
3.3	Amended and Restated Bylaws (incorporated herein by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K (File No. 001-37783) filed with the SEC on June 7, 2016).
31.1*	Certification of Principal Executive Officer under Section 302 of the Sarbanes-Oxley Act.
31.2*	Certification of Principal Financial Officer under Section 302 of the Sarbanes-Oxley Act.
32.1**	Certifications of Principal Executive Officer and Principal Financial Officer under Section 906 of the Sarbanes-Oxley Act.
101.INS	Inline XBRL Instance Document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101)

* Filed herewith.

** These certifications are being furnished solely to accompany this quarterly report pursuant to 18 U.S.C. Section 1350, and are not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and are not to be incorporated by reference into any filing of the registrant, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

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.

Clearside Biomedical, Inc.

Date: November 13, 2023

By: */s/ Charles A. Deignan*

Charles A. Deignan
Chief Financial Officer
(On behalf of the Registrant and as Principal Financial Officer)

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, George Lasezkay, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the period ended September 30, 2023 of Clearside Biomedical, Inc. (the "registrant");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 13, 2023

/s/ George Lasezkay, Pharm.D., J.D.
George Lasezkay, Pharm. D., J.D.
President and Chief Executive Officer
(principal executive officer)

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Charles A. Deignan, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the period ended September 30, 2023 of Clearside Biomedical, Inc. (the "registrant");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 13, 2023

/s/ Charles A. Deignan
Charles A. Deignan
Chief Financial Officer
(principal financial officer)

Exhibit 32.1

CERTIFICATIONS OF
PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), George Lasezkay, President and Chief Executive Officer of Clearside Biomedical, Inc. (the "Company"), and Charles A. Deignan, Chief Financial Officer of the Company, each hereby certifies that, to the best of his knowledge:

1. The Company's Quarterly Report on Form 10-Q for the period ended September 30, 2023, to which this Certification is attached as Exhibit 32.1 (the "Periodic Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

2. The information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

IN WITNESS WHEREOF, the undersigned have set their hands hereto as of the 13th day of November, 2023.

/s/ George Lasezkay, Pharm. D., J.D.	/s/ Charles. A. Deignan
George Lasezkay, Pharm. D., J.D. President and Chief Executive Officer (principal executive officer)	Charles A. Deignan Chief Financial Officer (principal financial officer)

* This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.