

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, 2024

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
(State or other jurisdiction of
incorporation or organization)
900 North Point Parkway, Suite 200
Alpharetta, GA
(Address of principal executive offices)

45-2437375
(I.R.S. Employer
Identification No.)
30005
(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 | <input type="checkbox"/> | Accelerated filer | <input type="checkbox"/> |
| Non-accelerated filer | <input checked="" type="checkbox"/> | Smaller reporting company | <input checked="" type="checkbox"/> |
| | | Emerging growth company | <input type="checkbox"/> |

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, 2024, the registrant had 75,843,504 shares of common stock, \$0.001 par value per share, outstanding.

PART I - FINANCIAL INFORMATION

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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, 2024 | December 31, 2023 |
|---|-----------------------|----------------------|
| Assets | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 13,888 | \$ 28,920 |
| Short-term investments | 9,703 | — |
| Accounts receivable | 788 | 170 |
| Prepaid expenses | 721 | 722 |
| Other current assets | 13 | 311 |
| Total current assets | 25,113 | 30,123 |
| Property and equipment, net | 3,351 | 2,996 |
| Operating lease right-of-use asset | 667 | 869 |
| Other assets | 30 | 30 |
| Total assets | <u>\$ 29,161</u> | <u>\$ 34,018</u> |
| Liabilities and stockholders' (deficit) equity | | |
| Current liabilities: | | |
| Accounts payable (includes \$232 and \$331 to a related party as of September 30, 2024 and December 31, 2023, respectively) | \$ 2,361 | \$ 2,205 |
| Accrued liabilities (includes \$304 and \$215 to a related party as of September 30, 2024 and December 31, 2023, respectively) | 2,859 | 4,169 |
| Current portion of operating lease liabilities | 373 | 364 |
| Deferred revenue | — | 75 |
| Total current liabilities | 5,593 | 6,813 |
| Liability related to the sales of future royalties, net | 49,188 | 41,988 |
| Warrant liabilities | 8,757 | — |
| Operating lease liabilities | 412 | 649 |
| Other non-current liabilities | — | 480 |
| Total liabilities | 63,950 | 49,930 |
| Commitments and contingencies | | |
| Stockholders' (deficit) equity: | | |
| Preferred stock, \$0.001 par value; 10,000,000 shares authorized and no shares issued at September 30, 2024 and December 31, 2023 | — | — |
| Common stock, \$0.001 par value; 200,000,000 shares authorized at September 30, 2024 and December 31, 2023; 74,745,572 and 62,850,841 shares issued and outstanding at September 30, 2024 and December 31, 2023, respectively | 75 | 63 |
| Additional paid-in capital | 313,100 | 304,948 |
| Accumulated deficit | (347,969) | (320,923) |
| Accumulated other comprehensive gain | 5 | — |
| Total stockholders' deficit | (34,789) | (15,912) |
| Total liabilities and stockholders' (deficit) equity | <u>\$ 29,161</u> | <u>\$ 34,018</u> |

See accompanying notes to the consolidated financial statements.

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

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|-------------------------------------|-------------------|------------------------------------|--------------------|
| | 2024 | 2023 | 2024 | 2023 |
| License and other revenue (includes \$81 and \$237 from a related party for the three and nine months ended September 30, 2024, respectively) | \$ 1,038 | \$ 859 | \$ 1,358 | \$ 1,881 |
| Operating expenses: | | | | |
| Cost of goods sold | — | 142 | — | 355 |
| Research and development (includes \$255 and \$473 to a related party for the three and nine months ended September 30, 2024, respectively, and \$559 and \$640 for the three and nine months ended September 30, 2023, respectively) | 4,128 | 5,134 | 14,346 | 14,533 |
| General and administrative | 2,844 | 2,637 | 8,745 | 8,922 |
| Total operating expenses | 6,972 | 7,913 | 23,091 | 23,810 |
| Loss from operations | (5,934) | (7,054) | (21,733) | (21,929) |
| Interest income | 338 | 409 | 1,104 | 1,359 |
| Other income, net | 365 | — | 783 | — |
| Non-cash interest expense on liability related to the sales of future royalties | (2,457) | (2,622) | (7,200) | (7,083) |
| Net loss | <u>\$ (7,688)</u> | <u>\$ (9,267)</u> | <u>\$ (27,046)</u> | <u>\$ (27,653)</u> |
| Net loss per share of common stock — basic and diluted | <u>\$ (0.10)</u> | <u>\$ (0.15)</u> | <u>\$ (0.37)</u> | <u>\$ (0.45)</u> |
| Weighted average shares outstanding — basic and diluted | <u>74,745,415</u> | <u>61,983,987</u> | <u>73,115,896</u> | <u>61,605,648</u> |
| Net loss | \$ (7,688) | \$ (9,267) | \$ (27,046) | \$ (27,653) |
| Unrealized gain on available-for-sale investments | 6 | — | 5 | — |
| Comprehensive loss | <u>\$ (7,682)</u> | <u>\$ (9,267)</u> | <u>\$ (27,041)</u> | <u>\$ (27,653)</u> |

See accompanying notes to the consolidated financial statements.

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

Three and Nine Months Ended September 30, 2024

| | Common Stock | | Additional Paid-In-Capital | Accumulated Deficit | Accumulated Other Comprehensive Gain (Loss) | Total Stockholders' (Deficit) Equity |
|--|-------------------|--------------|-------------------------------|------------------------|--|--|
| | Shares | Amount | | | | |
| Balance at December 31, 2023 | 62,850,841 | \$ 63 | \$ 304,948 | \$ (320,923) | \$ — | \$ (15,912) |
| Issuance of common stock under registered direct offering | 11,111,111 | 11 | 4,309 | — | — | 4,320 |
| Issuance of common stock under at-the-market sales agreement | 339,912 | — | 450 | — | — | 450 |
| Exercise of stock options | 10,000 | — | 12 | — | — | 12 |
| Vesting and settlement of restricted stock units | 397,594 | — | — | — | — | — |
| Issuance of common stock under employee stock purchase plan | 21,681 | — | 21 | — | — | 21 |
| Share-based compensation expense | — | — | 1,062 | — | — | 1,062 |
| Net loss | — | — | — | (11,763) | — | (11,763) |
| Balance at March 31, 2024 | 74,731,139 | 74 | 310,802 | (332,686) | — | (21,810) |
| Share-based compensation expense | — | — | 1,120 | — | — | 1,120 |
| Net loss | — | — | — | (7,595) | — | (7,595) |
| Other comprehensive loss | — | — | — | — | (1) | (1) |
| Balance at June 30, 2024 | 74,731,139 | 74 | 311,922 | (340,281) | (1) | (28,286) |
| Issuance of common stock under employee stock purchase plan | 14,433 | 1 | 13 | — | — | 14 |
| Share-based compensation expense | — | — | 1,165 | — | — | 1,165 |
| Net loss | — | — | — | (7,688) | — | (7,688) |
| Other comprehensive gain | — | — | — | — | 6 | 6 |
| Balance at September 30, 2024 | <u>74,745,572</u> | <u>\$ 75</u> | <u>\$ 313,100</u> | <u>\$ (347,969)</u> | <u>\$ 5</u> | <u>\$ (34,789)</u> |

Three and 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 stock under at-the-market sales agreement | 214,128 | — | 295 | — | 295 |
| Vesting and settlement of restricted stock units | 471,390 | — | — | — | — |
| Issuance of common stock 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 stock 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 | <u>61,717,445</u> | <u>62</u> | <u>301,789</u> | <u>(306,824)</u> | <u>(4,973)</u> |
| Issuance of common stock under at-the-market sales agreement | 303,894 | — | 266 | — | 266 |
| Exercise of stock options | 56,817 | — | 23 | — | 23 |
| Issuance of common stock 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 | <u>62,107,311</u> | <u>\$ 62</u> | <u>\$ 303,180</u> | <u>\$ (316,091)</u> | <u>\$ (12,849)</u> |

See accompanying notes to the consolidated financial statements.

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

| | Nine Months Ended September 30, | |
|--|------------------------------------|------------------|
| | 2024 | 2023 |
| Operating activities | | |
| Net loss | \$ (27,046) | \$ (27,653) |
| 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 | 7,200 | 7,083 |
| Depreciation | 147 | 47 |
| Share-based compensation expense | 3,347 | 3,176 |
| Change in fair value of warrant liabilities | (1,570) | — |
| Issuance costs allocated to warrant liabilities | 787 | — |
| Amortization and accretion of available-for-sale investments, net | (286) | — |
| Changes in operating assets and liabilities: | | |
| Prepaid expenses and other current assets | (319) | (1,030) |
| Other assets and liabilities | (506) | (15) |
| Accounts payable and accrued liabilities (includes \$223 to a related party for the nine months ended September 30, 2024) | (1,123) | (33) |
| Deferred revenue | (75) | (205) |
| Net cash used in operating activities | (19,444) | (18,630) |
| Investing activities | | |
| Acquisition of property and equipment | (533) | (1,657) |
| Purchase of short-term investments | (16,912) | — |
| Maturity of short-term investments | 7,500 | — |
| Net cash used in investing activities | (9,945) | (1,657) |
| Financing activities | | |
| Proceeds from issuance of common stock and warrants under registered direct offering, net of issuance costs | 13,860 | — |
| Proceeds from at-the-market sales agreement, net of issuance costs | 450 | 923 |
| Payments to royalty purchase and sale agreement | — | (350) |
| Proceeds from exercise of stock options | 12 | 33 |
| Proceeds from shares issued under employee stock purchase plan | 35 | 65 |
| Net cash provided by financing activities | 14,357 | 671 |
| Net decrease in cash and cash equivalents | (15,032) | (19,616) |
| Cash and cash equivalents, beginning of period | 28,920 | 48,418 |
| Cash and cash equivalent, end of period | <u>\$ 13,888</u> | <u>\$ 28,802</u> |
| Supplemental disclosure | | |
| Purchase of property and equipment included in accrued liabilities | \$ 31 | \$ 277 |

See accompanying notes to the consolidated financial statements.

CLEARSIDE BIOMEDICAL, INC.

Notes to the Consolidated Financial Statements (unaudited)

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, cash equivalents and short-term investments of \$23.6 million as of September 30, 2024.

Historically, the Company has funded its operations primarily through the sale of common stock and convertible preferred stock, the issuance of warrants, the issuance of long-term debt, and license agreements.

On February 6, 2024, the Company entered into a securities purchase agreement with institutional investors and an existing stockholder, pursuant to which the Company issued and sold, in a registered direct offering (the "Registered Direct Offering"): (i) an aggregate of 11,111,111 shares of its common stock; and (ii) warrants to purchase up to 11,111,111 shares of common stock (the "Warrants"). The combined purchase price of each share and accompanying Warrant was \$1.35. The exercise price for the Warrants is \$1.62 per share. The Warrants will be exercisable from August 9, 2024 and will expire on August 9, 2029. The net proceeds to the Company from the Registered Direct Offering were \$13.9 million.

On January 31, 2024 (the "Amendment Effective Date"), the Company entered into a fourth amendment to the license agreement (as amended, the "Emory License Agreement") with Emory University and Georgia Tech Research Corporation (collectively, the "Licensor") pursuant to which the parties agreed to reduce the Sublicense Percentage (as defined in the Emory License Agreement) from a low double digit percentage to a high single digit percentage that the Company will pay the Licensor applicable to any fees or payments paid to the Company by any Sublicensee (as defined in the Emory License Agreement) of the Licensed Patents and/or Licensed Technology (each as defined in the Emory License Agreement), excluding (i) amounts paid to the Company by a Sublicensee to reimburse the Company for certain research and development costs pursuant to a written agreement between the Company and such Sublicensee, (ii) the value of intellectual property transferred or granted to the Company if necessary or helpful to the development or commercialization of Licensed Products (as defined in the Emory License Agreement) and (iii) amounts paid for shares of the Company's stock. The payment to Licensor of any such Sublicense Percentage is due within 30 days of receipt by the Company of a qualifying payment from a Sublicensee, provided however, with respect to any qualifying payments received by the Company from a Sublicensee prior to January 1, 2025, the payment to Licensor of any such Sublicense Percentage is due to Licensor by March 31, 2025. The parties also agreed to a revised annual license maintenance fee due each year (the "Maintenance Fee") starting in 2023 through 2028, as follows: \$250,000 for 2023 through 2025, \$350,000 for 2026, \$400,000 for 2027 and \$500,000 for 2028. The Company paid the Maintenance Fee for 2023 in February 2024 and the Maintenance Fee for 2024 in October 2024. The remaining annual Maintenance Fee payments are due on October 1st of each year.

On December 22, 2023, Clearside Biomedical, Inc., through its wholly owned subsidiary Clearside Royalty LLC ("Royalty Sub"), entered into a letter agreement (the "Letter Agreement") with HCR (as defined below) and HCR Clearside SPV, LLC (as assignee of HCR Collateral Management, LLC) ("Agent") amending that certain Purchase and Sale Agreement, dated as of August 8, 2022, by and among Royalty Sub, HCR and Agent ("Purchase and Sale Agreement"). Pursuant to the terms of the Letter Agreement, Royalty Sub and Agent mutually agreed that Royalty Sub waived any and all rights to the \$12.5 million milestone payment which was deposited in an escrow account ("First Milestone Payment") in connection with the closing of the transactions contemplated by the Purchase and Sale Agreement and agreed to the release of the First Milestone Payment to Agent.

On November 1, 2023, the Company, entered into a license agreement (the "BioCryst 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 received an upfront license fee payment of \$5.0 million in connection with signing of the BioCryst 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. 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 as described in Note 5.

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 nine months ended September 30, 2023, prior to the termination of the ATM Agreement.

In May 2023, the Company entered into a Controlled Equity OfferingSM 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, 2024, the Company sold 339,912 shares of its common stock for net proceeds of \$0.5 million under the Sales Agreement. 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 pursuant to the Sales Agreement. Subsequent to September 30, 2024, the Company sold 1,097,932 shares of its common stock for net proceeds of \$1.3 million pursuant to the Sales Agreement.

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, cash equivalents and short-term investments as of the filing date, November 12, 2024, will enable the Company to fund its planned operating expenses and capital expenditure requirements into the third quarter of 2025. 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 Royalty Sub, which was formed for the purposes of the transactions contemplated by the Purchase and Sale Agreement described in Note 5. All intercompany balances and transactions have been eliminated.

The Company's consolidated financial statements have been prepared in conformity with U.S. generally accepted accounting principles ("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. The results for the three and nine months ended September 30, 2024 are not indicative of results to be expected for the full year ending December 31, 2024, any other interim periods or any future year or period. These unaudited financial statements should be read in conjunction with the audited consolidated financial statements and related footnotes, which are included in the Company's Annual Report on Form 10-K for the year ended December 31, 2023, filed with the Securities and Exchange Commission on March 12, 2024.

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 consolidated financial statements and reported amounts of income and expenses during the reporting periods. Significant items subject to such estimates and assumptions include the estimate of the total amount of future royalty revenue and milestone payments to be generated over the life of the Purchase and Sale Agreement, the fair value of common stock warrants, 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 participant 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 consolidated financial statements as prepaid expenses or accrued liabilities.

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 consolidated statements of operations and comprehensive loss 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.

Short-term Investments

Short-term investments are investments with original maturities of between 90 and 365 days when purchased and are comprised of treasury bills. The Company classifies its short-term investments as available-for-sale securities. Short-term investments are recorded at fair value and unrealized gains and losses are recorded within accumulated other comprehensive income (loss). Accretion on the discount associated with these investments is recorded in interest income. In addition, the Company evaluates the short-term investments with unrealized losses to determine whether such losses are other than temporary.

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

In connection with the Purchase and Sale Agreement, 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 are 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 are amortized under the effective interest method over the estimated period the liability will be repaid. The Company estimates 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.

Warrant Liabilities

The Company accounts for warrants as either equity-classified or liability-classified instruments based on an assessment of the warrant's specific terms and applicable authoritative guidance in FASB ASC Topic 480, *Distinguishing Liabilities from Equity* (ASC 480) and ASC Topic 815, *Derivatives and Hedging* (ASC 815). The assessment considers whether the warrants (i) are freestanding financial instruments pursuant to ASC 480, (ii) meet the definition of a liability pursuant to ASC 480, and (iii) meet all of the requirements for equity classification under ASC 815, including whether the warrants are indexed to the Company's own stock and whether the warrant holders could potentially require "net cash settlement" in a circumstance outside of the Company's control, among other conditions for equity classification. This assessment, which requires the use of professional judgment, is conducted at the time of warrant issuance and as of each subsequent quarterly period end date while the warrants are outstanding.

For warrants that meet all criteria for equity classification, the warrants are required to be recorded as a component of additional paid-in capital, on the consolidated statement of stockholders' deficit at the time of issuance. For warrants that do not meet all the criteria for equity classification, the warrants are required to be recorded at their initial fair value on the date of issuance and on each consolidated balance sheet date thereafter.

The Company's warrant liabilities are measured at fair value using a simulation model which takes into account, as of the valuation date, factors including the current exercise price, the expected life of the warrant, the current price of the Company's common stock, the expected volatility, holding cost, the risk-free interest rate for the term of the warrant and the likelihood of achieving certain future milestone events and the related impact to the price of the Company's common stock. The warrant liabilities are revalued at each reporting period and changes in fair value are recognized in other income (expense) in the consolidated statements of operations and comprehensive loss. The selection of the appropriate valuation model and the inputs and assumptions that are required to determine the valuation requires significant judgment and requires management to make estimates and assumptions that affect the reported amount of the related liability and reported amounts of the change in fair value. Actual results could differ from those estimates, and changes in these estimates are recorded when known.

Recently Issued Accounting Pronouncements Not Yet Adopted

In December 2023, the FASB issued ASU No. 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*. This ASU is intended to enhance the transparency and decision usefulness of income tax disclosures primarily related to the rate reconciliation and income taxes paid information. The main provisions to the rate reconciliation disclosure require public entities to disclose, on an annual basis, specific categories in the rate reconciliation and provide additional information for reconciling items that meet a quantitative threshold. The main provisions to the income taxes paid disclosure require that all entities disclose on an annual basis: the amount of income taxes paid disaggregated by federal, state and foreign taxes and the amount of income taxes paid disaggregated by individual jurisdictions in which income taxes paid meets a quantitative threshold. This ASU also requires all entities to disclose income (loss) from continuing operations before income tax expense (benefit) disaggregated between domestic and foreign and income tax expense (benefit) from continuing operations disaggregated by federal, state and foreign.

This ASU is to be applied on a prospective basis with an effective date for all public entities for annual periods beginning after December 15, 2024. Early adoption is permitted. The Company is currently evaluating the impact of this ASU.

3. Property and Equipment, Net

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

| | Estimated Useful Lives (Years) | September 30, 2024 | December 31, 2023 |
|--------------------------------|--|-----------------------|----------------------|
| Furniture and fixtures | 5 | \$ 249 | \$ 249 |
| Machinery and equipment | 5 | 1,544 | 581 |
| Computer equipment | 3 | 20 | 20 |
| Leasehold improvements | Lesser of useful life or remaining lease term | 476 | 476 |
| Work in process | | 2,129 | 2,590 |
| Total property and equipment | | 4,418 | 3,916 |
| Less: Accumulated depreciation | | (1,067) | (920) |
| Property and equipment, net | | <u>\$ 3,351</u> | <u>\$ 2,996</u> |

4. Accrued Liabilities

Accrued liabilities consisted of the following (in thousands):

| | September 30, 2024 | December 31, 2023 |
|----------------------------------|-----------------------|----------------------|
| Accrued research and development | \$ 1,050 | \$ 2,078 |
| Accrued employee costs | 1,474 | 1,862 |
| Accrued professional fees | 34 | 38 |
| Accrued expense | 301 | 191 |
| | <u>\$ 2,859</u> | <u>\$ 4,169</u> |

5. Royalty Purchase and Sale Agreement

On August 8, 2022 (the "Closing Date"), the Company, through its wholly owned subsidiary Clearside Royalty LLC, a Delaware limited liability company ("Royalty Sub"), entered into the Purchase and Sale Agreement with entities managed by HealthCare Royalty Management, LLC ("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) (collectively, "Post-Closing License Agreements"), 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.

On November 1, 2023, the Company entered into the BioCryst License Agreement. The Company's rights to milestone payments and royalties under the BioCryst License Agreement were sold to HCR pursuant to the terms of the Purchase and Sale Agreement providing for the sale of Royalties from Post-Closing License Agreements to HCR.

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 which was released to HCR pursuant to the Letter Agreement described below. 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 XIPEPE 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 Purchase and Sale 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.

On December 22, 2023, the Company, through its wholly owned subsidiary Royalty Sub, entered into the Letter Agreement with the Agent amending the Purchase and Sale Agreement. Pursuant to the terms of the Letter Agreement, Royalty Sub and Agent mutually agreed that Royalty Sub waived any and all rights to the First Milestone Payment in connection with the closing of the transactions contemplated by the Purchase and Sale Agreement and agreed to the release of the First Milestone Payment to Agent.

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 for the nine months ended September 30, 2024 (in thousands):

| | | |
|--|----|---------------|
| Royalty Purchase and Sale Agreement balance at December 31, 2023 | \$ | 41,988 |
| Non-cash interest expense | | 7,200 |
| Balance at September 30, 2024 | \$ | <u>49,188</u> |
| Effective interest rate | | 22.0% |

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, 2024 and December 31, 2023, there were 74,745,572 and 62,850,841 shares of common stock outstanding, respectively.

7. Common Stock 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 at the time of issuance and as of September 30, 2024, had a weighted average remaining life of 2.0 years.

On February 6, 2024, the Company entered into a securities purchase agreement with institutional investors and an existing stockholder, pursuant to which the Company issued and sold, in a registered direct offering (i) an aggregate of 11,111,111 shares of its common stock; and (ii) Warrants to purchase up to 11,111,111 shares of common stock. The combined purchase price of each share and accompanying Warrant was \$1.35. The exercise price for the Warrants is \$1.62 per share. The Warrants will be exercisable

beginning August 9, 2024 and will expire on August 9, 2029. The Company recorded the initial fair value of the Warrants of \$10.3 million as warrant liabilities and \$4.7 million attributable to common stock as additional paid in capital in the consolidated balance sheets. The issuance costs were allocated among the warrants and common stock consistent with the allocation between amounts recorded as warrant liabilities and common stock. The issuance costs allocated to the Warrants as well as the change in the fair value of the Warrants during the period are recorded in other income, net in the consolidated statements of operations and comprehensive loss. The issuance costs allocated to common stock were recorded as a reduction to additional paid in capital.

The following table summarizes the change in fair value of the warrant liabilities during the nine months ended September 30, 2024 (in thousands):

| | | |
|---|----|--------------|
| Fair value of warrants at issuance February 9, 2024 | \$ | 10,327 |
| Change in fair value during the period | | (1,570) |
| Fair value of warrants at September 30, 2024 | \$ | <u>8,757</u> |

The following table summarizes certain key inputs for the valuation of the Warrants at September 30, 2024:

| | | |
|-----------------------------|----|---------|
| Common stock price | \$ | 1.27 |
| Exercise price per share | \$ | 1.62 |
| Expected volatility | | 65.80 % |
| Risk-free interest rate | | 3.52 % |
| Contractual term (in years) | | 4.86 |
| Expected dividend yield | | — % |

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 consolidated statements of operations and comprehensive loss as follows (in thousands):

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|----------------------------|-------------------------------------|---------------|------------------------------------|-----------------|
| | 2024 | 2023 | 2024 | 2023 |
| Research and development | \$ 386 | \$ 308 | \$ 1,190 | \$ 914 |
| General and administrative | 521 | 460 | 1,383 | 1,293 |
| Total | <u>\$ 907</u> | <u>\$ 768</u> | <u>\$ 2,573</u> | <u>\$ 2,207</u> |

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, 2024:

| | Number of Shares | Weighted Average Exercise Price |
|---|---------------------|---------------------------------------|
| Options outstanding at December 31, 2023 | 9,865,770 | \$ 2.83 |
| Granted | 3,034,375 | 1.32 |
| Exercised | (10,000) | 1.24 |
| Forfeited | (138,724) | 2.86 |
| Options outstanding at September 30, 2024 | <u>12,751,421</u> | 2.47 |
| Options exercisable at December 31, 2023 | <u>5,494,746</u> | 3.83 |
| Options exercisable at September 30, 2024 | <u>7,353,005</u> | 3.27 |

As of September 30, 2024, the Company had \$4.8 million of unrecognized compensation expense related to unvested stock options, which is expected to be recognized over a weighted average period of 2.4 years.

Restricted Stock Units

The Company has granted restricted stock units ("RSUs") to employees under 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 consolidated statements of operations and comprehensive loss as follows (in thousands):

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|----------------------------|-------------------------------------|---------------|------------------------------------|---------------|
| | 2024 | 2023 | 2024 | 2023 |
| Research and development | \$ 118 | \$ 143 | \$ 355 | \$ 475 |
| General and administrative | 137 | 160 | 410 | 484 |
| Total | \$ 255 | \$ 303 | \$ 765 | \$ 959 |

The following table summarizes the activity related to RSUs during the nine months ended September 30, 2024:

| | Number of Shares | Weighted Average Grant Date Fair Value |
|---|---------------------|--|
| Non-vested RSUs outstanding at December 31, 2023 | 834,899 | \$ 3.01 |
| Vested | (397,594) | 3.07 |
| Non-vested RSUs outstanding at September 30, 2024 | <u>437,305</u> | <u>2.96</u> |

As of September 30, 2024, the Company had \$0.6 million of unrecognized compensation expense related to the RSUs which is expected to be recognized over a weighted average period of 0.9 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 consolidated statements of operations and comprehensive loss as follows (in thousands):

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|----------------------------|-------------------------------------|-------------|------------------------------------|--------------|
| | 2024 | 2023 | 2024 | 2023 |
| Research and development | \$ 2 | \$ 3 | \$ 7 | \$ 8 |
| General and administrative | 1 | — | 2 | 2 |
| Total | \$ 3 | \$ 3 | \$ 9 | \$ 10 |

During the nine months ended September 30, 2024, the Company issued 36,114 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.

Georgia Tech License Agreement

As described in Note 1, the Company entered into a fourth amendment to the Georgia Tech License Agreement pursuant to which the parties agreed to revised Maintenance Fee payments in exchange for a reduction to the contractual Sublicense Percentage owed by the Company on certain fees and other payments it may receive from future sublicensing activities. The Company paid the \$0.3 million Maintenance Fee for 2023 in February 2024 and the \$0.3 million Maintenance Fee for 2024 in October 2024. The remaining annual Maintenance Fee payments are due on October 1st of each year from 2025 through 2028, as show in the table below (in thousands).

| Year Ending December 31, | Amount | |
|--------------------------|--------|--------------|
| 2025 | \$ | 250 |
| 2026 | | 350 |
| 2027 | | 400 |
| 2028 | | 500 |
| Total | \$ | <u>1,500</u> |

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.

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 has paid the Company an aggregate of \$9.0 million in upfront and milestone payments. In addition, Arctic Vision has agreed to pay the Company up to \$22.5 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 Arctic 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.

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.

BioCryst Pharmaceuticals, Inc.

On November 1, 2023, the Company entered into the BioCryst License Agreement 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 DME.

The Company received an upfront license fee payment of \$5.0 million in connection with signing of the BioCryst 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. 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.

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.

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. Available-for-Sale Investments

The following table summarizes the fair value of the Company's short-term investments by type (in thousands):

| | September 30, 2024 | | | Fair Value |
|--------------------------------------|--------------------|------------------|-------------------|-----------------|
| | Amortized Cost | Unrealized Gains | Unrealized Losses | |
| Treasury bills | \$ 9,698 | \$ 6 | \$ (1) | \$ 9,703 |
| Total available-for-sale investments | <u>\$ 9,698</u> | <u>\$ 6</u> | <u>\$ (1)</u> | <u>\$ 9,703</u> |

12. Fair Value Measurements

The Company's material financial instruments at September 30, 2024 and December 31, 2023 consisted primarily of cash and cash equivalents and short-term investments. The fair values of cash and cash equivalents, short-term investments, 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 the warrant liabilities (see Note 7) require significant unobservable inputs and is classified as Level 3 in the fair value hierarchy.

There were no transfers between Levels 1, 2 and 3 during the nine months ended September 30, 2024 and the year ended December 31, 2023.

The following table summarizes the assets and liabilities that are measured at fair value and the classification by level of input within the fair value hierarchy (in thousands):

| | September 30, 2024 | | | Recorded Value |
|---------------------------|--------------------|-------------|-----------------|------------------|
| | Level 1 | Level 2 | Level 3 | |
| Assets: | | | | |
| Cash and cash equivalents | \$ 13,888 | \$ — | \$ — | \$ 13,888 |
| Short-term investments | 9,703 | — | — | 9,703 |
| Total assets | <u>\$ 23,591</u> | <u>\$ —</u> | <u>\$ —</u> | <u>\$ 23,591</u> |
| Liabilities: | | | | |
| Warrant liabilities | \$ — | \$ — | \$ 8,757 | \$ 8,757 |
| Total liabilities | <u>\$ —</u> | <u>\$ —</u> | <u>\$ 8,757</u> | <u>\$ 8,757</u> |

| | December 31, 2023 | | | Recorded Value |
|---------------------------|-------------------|-------------|-------------|------------------|
| | Level 1 | Level 2 | Level 3 | |
| Assets: | | | | |
| Cash and cash equivalents | \$ 28,920 | \$ — | \$ — | \$ 28,920 |
| Total assets | <u>\$ 28,920</u> | <u>\$ —</u> | <u>\$ —</u> | <u>\$ 28,920</u> |

13. Related Party Transactions

A member of the Company's Board of Directors is the chief executive officer of a company that is a vendor of the Company. As of September 30, 2024, the Company has recorded \$0.2 million in accounts payable and \$0.3 million in accrued expense with this vendor in the consolidated balance sheets. The Company has recorded \$0.3 million and \$0.6 million for the three months ended September 30, 2024 and 2023, respectively, and \$0.5 million and \$0.6 million for the nine months ended September 30, 2024 and 2023, respectively, of expense related to this vendor in the consolidated statements of operations and comprehensive loss.

The chair of the board of directors of BioCryst also serves on the Company's Board of Directors. For the three and nine months ended September 30, 2024, the Company has recorded \$81,000 and \$0.2 million, respectively, in license and other revenue in the consolidated statements of operations and comprehensive loss related to the BioCryst License Agreement.

14. 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 common stock 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, | |
|-----------------------------------|------------------------------------|-------------------|
| | 2024 | 2023 |
| Outstanding stock options | 12,751,421 | 10,116,074 |
| Non-vested restricted stock units | 437,305 | 869,178 |
| Common stock warrants | 11,140,907 | 29,796 |
| | <u>24,329,633</u> | <u>11,015,048</u> |

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 consolidated financial statements and related notes that appear in Item 1 of this Quarterly Report on Form 10-Q and with our audited consolidated financial statements and related notes for the year ended December 31, 2023 appearing in our Annual Report on Form 10-K filed with the SEC on March 12, 2024.

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 participants 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 charts below:

| Clearside Research and Clinical Development Programs | | | | | | | | |
|--|---------------------------------|-------------------------|---|---------|---------|---------|----------|---------|
| THERAPEUTIC | MECHANISM | INDICATION | PRE-CLINICAL | PHASE 1 | PHASE 2 | PHASE 3 | APPROVAL | PARTNER |
| CLS-AX (axitinib) | Tyrosine Kinase Inhibitor | Wet AMD | [Progress bar: Pre-clinical to Phase 2] | | | | | |
| Undisclosed | Improve choroidal perfusion | Geographic Atrophy (GA) | [Progress bar: Pre-clinical] | | | | | |
| Undisclosed | Modulate pro-inflammatory cells | Geographic Atrophy (GA) | [Progress bar: Pre-clinical] | | | | | |

| Commercial Asset: XIPERE® (triamcinolone acetonide injectable suspension), for suprachoroidal use | | | | | | | | |
|---|----------------------------|-------------------------------------|---|---------|---------|----------------|----------|----------------------|
| THERAPEUTIC | LOCATION | INDICATION | PRE-CLINICAL | PHASE 1 | PHASE 2 | PHASE 3 | APPROVAL | PARTNER |
| XIPERE® | United States | Uveitic Macular Edema ¹ | [Progress bar: Pre-clinical to Phase 2] | | | | | B&L BAUSCH + LOMB |
| XIPERE® / ARCATUS™ | Australia and Singapore | Uveitic Macular Edema ² | [Progress bar: Pre-clinical to Phase 2] | | | NDA's Accepted | | arctic VISION |
| XIPERE® / ARCATUS™ | China | Uveitic Macular Edema ² | [Progress bar: Pre-clinical to Phase 2] | | | | | arctic VISION |
| XIPERE® / ARCATUS™ | Asia Pacific ex-Japan | Diabetic Macular Edema ² | [Progress bar: Pre-clinical to Phase 1] | | | | | arctic VISION |

| SCS Microinjector® Partner Clinical Development Programs | | | | | | | | |
|--|-----------------------------|---|------------------------------|----------|---------|---------|----------|---------------------|
| THERAPEUTIC | TYPE | INDICATION | IND-ENABLING | PHASE 1 | PHASE 2 | PHASE 3 | APPROVAL | PARTNER |
| Bel-Sar | Viral-like Drug Conjugate | Choroidal Melanoma | [Progress bar: Ind-enabling] | | | CoMpass | | aura |
| ABBV-RGX-314 | AAV Gene Therapy | Diabetic Retinopathy (DR) Diabetic Macular Edema | [Progress bar: Ind-enabling] | ALTITUDE | | | | REGENXBIO abbvie |
| ABBV-RGX-314 | AAV Gene Therapy | Wet AMD | [Progress bar: Ind-enabling] | AAVIATE | | | | REGENXBIO abbvie |
| Avoralstat | Plasma Kallikrein Inhibitor | Diabetic Macular Edema | [Progress bar: Ind-enabling] | | | | | bio cryst |

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 biological effect.

Based on the results from the OASIS trial, we conducted a randomized, active-controlled, double-masked, parallel-group, multicenter, 36-week, Phase 2b clinical trial of CLS-AX in participants with wet AMD previously treated with intravitreal anti-vascular endothelial growth factor, or VEGF, which is the standard of care therapy for the treatment of wet AMD. The trial is referred to as ODYSSEY. A total of 60 participants were treated for 36 weeks and randomized to either CLS-AX (1 mg) or aflibercept (2 mg) with a 2:1 randomization schedule (40 participants in CLS-AX arm and 20 participants in aflibercept arm). CLS-AX was administered by suprachoroidal injection via our SCS Microinjector, and aflibercept was administered via intravitreal injection. Participants in the trial were determined to have active disease with a median duration of wet AMD diagnosis of 9.9 months. Eligible participants underwent diagnostic imaging at their screening visit, followed by masked reading center confirmation of persistent active disease.

On October 9, 2024, we announced positive topline results from the ODYSSEY trial of CLS-AX for the treatment of wet AMD. The ODYSSEY trial achieved its primary and secondary outcomes including the mean change from baseline in best corrected visual acuity, or BCVA, changes from baseline in visual function and ocular anatomy, the need for supplemental treatment, treatment burden as measured by total injections over the trial duration, and safety measures.

Participants in the trial maintained stable BCVA throughout the trial as measured by the mean change in BCVA from baseline to week 36. In addition, participants maintained stable central subfield retinal thickness, or CSRT, throughout the trial as measured by the mean change in CSRT from baseline to week 36, as confirmed by the independent reading center.

In terms of durability, after receiving the baseline CLS-AX dose, 100% (40/40) of participants went 3 months without receiving any additional treatment, 90% (35/39) of participants went 4 months without receiving any additional treatment, 81% (30/37) of participants went 5 months without receiving any additional treatment and 67% (26/39) of participants went 6 months without receiving any additional treatment before mandatory re-dosing at week 24. If intervention were strictly based on the disease activity assessment criteria, 100% (40/40) of participants would have gone 3 months without receiving any additional treatment, 95% (37/39) of CLS-AX participants would have gone 4 months without receiving any additional treatment, 87% (32/37) of participants would have gone 5 months without receiving any additional treatment and 79% (30/38) of participants would have gone 6 months without receiving any additional treatment before mandatory re-dosing at week 24.

Additionally, we observed reduced injection frequency by 84% in the 24 weeks after baseline compared to the average monthly injections in the 24 weeks prior to screening.

CLS-AX was well-tolerated with a safety profile through 36 weeks that included mandatory re-dosing of CLS-AX at week 24. There were no reported ocular serious adverse events, or SAEs, and no treatment or injection procedure-related SAEs. All ocular adverse events were considered clinically mild in both groups. We observed similar discontinuation rates in the CLS-AX and aflibercept arms.

Although our Phase 3 plans are in development and subject to change, we are currently planning to run two Phase 3 trials with aflibercept 2 mg as a comparator. We are likely to conduct the studies in treatment-naïve patients with a flexible dosing component, consistent with the Phase 3 trial designs for recently approved aflibercept high dose and faricimab. We expect to conduct an End-of-Phase 2 meeting with the FDA in early 2025 to align on the essential components of our Phase 3 program.

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. Our research team is currently evaluating various small molecules through in vivo models for the potential treatment of geographic atrophy, or GA. We believe that GA is primarily a choroidal disease. Delivery of small molecules via suprachoroidal injection enables comprehensive drug coverage of both the retina and choroid, while also potentially minimizing systemic and anterior segment side effects.

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 + Lomb, Arctic Vision, REGENXBIO, Inc., Aura Biosciences and BioCryst Pharmaceuticals, Inc.

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 the Asia Pacific region, not including Japan.

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".

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 primarily generated revenue through upfront payments and milestone payments related to license agreements and from collaboration agreements, and we have primarily financed our operations through public offerings and private placements of our equity securities, issuance of warrants, issuances of convertible promissory notes and loan agreements. As of September 30, 2024, we had an accumulated deficit of \$348.0 million. We recorded net losses of \$7.7 million and \$9.3 million for the three months ended September 30, 2024 and 2023, respectively, and \$27.0 million and \$27.7 million for the nine months ended September 30, 2024 and 2023, 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 2024 as a result of our Phase 2b clinical trial of CLS-AX and activities related to preparation for a Phase 3 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 obtain regulatory approvals in additional regions for XIPERE for the treatment of macular edema associated with uveitis.

Macroeconomic Conditions

Unfavorable conditions in the economy in the United States and abroad may negatively affect the growth of our business and our results of operations. For example, macroeconomic events, rising inflation, the U.S. Federal Reserve raising interest rates, and conflicts in Ukraine, Russia and the Middle East have led to economic uncertainty globally. The effect of macroeconomic conditions may not be fully reflected in our results of operations until future periods. If, however, economic uncertainty increases or the global economy worsens, our business, financial condition and results of operations may be harmed. For further discussion of the potential impacts of macroeconomic events on our business, financial condition, and operating results, see "Risk Factors" included in Part I, Item 1A of the Annual Report on Form 10-K filed with the SEC on March 12, 2024.

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.

Costs of Goods Sold

Cost of goods sold are related to the sales of our SCS Microinjector kits to our licensees for approved products.

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 preclinical activities and clinical trials;
- 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 participant enrollment, clinical site activations and additional information provided to us by our vendors about their actual costs incurred. 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, 2024 and 2023 (in thousands).

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|--|-------------------------------------|-----------------|------------------------------------|------------------|
| | 2024 | 2023 | 2024 | 2023 |
| XIPERE (uveitis program) | \$ 6 | \$ 10 | \$ 81 | \$ 86 |
| CLS-AX (wet AMD program) | 942 | 2,810 | 4,963 | 6,146 |
| Total | 948 | 2,820 | 5,044 | 6,232 |
| Unallocated | 3,180 | 2,314 | 9,302 | 8,301 |
| Total research and development expense | <u>\$ 4,128</u> | <u>\$ 5,134</u> | <u>\$ 14,346</u> | <u>\$ 14,533</u> |

Our expenses related to clinical trials are based on estimates of participant 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 participant 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 participant trial costs;
- the number of participants 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 participants;
- the number of doses that participants receive;
- the drop-out or discontinuation rates of participants;
- potential additional safety monitoring or other studies requested by regulatory agencies;

- the duration of participant 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.

Interest Income

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

Other Income, Net

Other income, net consists of expenses allocated to the warrants issued in connection with our registered direct offering in February 2024 and the change in fair value during the period.

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 U.S. generally accepted accounting principles 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 consolidated 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 consolidated 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, 2024, there were no significant changes to our critical accounting policies disclosed in our audited consolidated financial statements for the year ended December 31, 2023, which are included in our Annual Report on Form 10-K, as filed with the SEC on March 12, 2024, other than the warrant liabilities discussed in Note 2 to the consolidated financial statements.

Results of Operations for the Three Months Ended September 30, 2024 and 2023

The following table sets forth our results of operations for the three months ended September 30, 2024 and 2023.

| | Three Months Ended September 30, | | Period-to-Period Change |
|--|-------------------------------------|------------------------|----------------------------|
| | 2024 | 2023 (in thousands) | |
| License and other revenue | \$ 1,038 | \$ 859 | \$ 179 |
| Operating expenses: | | | |
| Cost of goods sold | — | 142 | (142) |
| Research and development | 4,128 | 5,134 | (1,006) |
| General and administrative | 2,844 | 2,637 | 207 |
| Total operating expenses | 6,972 | 7,913 | (941) |
| Loss from operations | (5,934) | (7,054) | 1,120 |
| Interest income | 338 | 409 | (71) |
| Other income, net | 365 | — | 365 |
| Non-cash interest expense on liability related to the sales of future royalties | (2,457) | (2,622) | 165 |
| Net loss | <u>\$ (7,688)</u> | <u>\$ (9,267)</u> | <u>\$ 1,579</u> |

License and other revenue. In the three months ended September 30, 2024 and 2023, we recognized \$1.0 million and \$0.9 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. In 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 of approved products.

Research and development. Research and development expenses decreased by \$1.0 million from \$5.1 million for the three months ended September 30, 2023 to \$4.1 million for the three months ended September 30, 2024. This decrease was primarily due to a \$1.9 million decrease in costs related to the CLS-AX program, which includes costs for ODYSSEY, our Phase 2b clinical trial. This is partially offset by a \$0.2 million increase in employee related costs, a \$0.2 million increase in device development and a \$0.3 million research and development tax credit received in the prior year.

General and administrative. General and administrative expenses increased by \$0.2 million from \$2.6 million for the three months ended September 30, 2023 to \$2.8 million for the three months ended September 30, 2024. This is primarily due to an increase in patent-related expenses and consulting fees.

Interest income. Interest income decreased by \$0.1 million from \$0.4 million for the three months ended September 30, 2023 to \$0.3 million for the three months ended September 30, 2024. The decrease is due to the lower balance of our cash, cash equivalents and short-term investments.

Other income, net. Other income, net was \$0.4 million for the three months ended September 30, 2024 and was due to the decrease in fair value of the warrant liabilities from the June 30, 2024 valuation date.

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 was \$2.5 million and \$2.6 million for the three months ended September 30, 2024 and 2023, respectively, and 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, 2024 and 2023

The following table sets forth our results of operations for the nine months ended September 30, 2024 and 2023.

| | Nine Months Ended September 30, | | Period-to-Period Change |
|---|------------------------------------|------------------------|----------------------------|
| | 2024 | 2023 (in thousands) | |
| License and other revenue | \$ 1,358 | \$ 1,881 | \$ (523) |
| Operating expenses: | | | |
| Cost of goods sold | — | 355 | (355) |
| Research and development | 14,346 | 14,533 | (187) |
| General and administrative | 8,745 | 8,922 | (177) |
| Total operating expenses | 23,091 | 23,810 | (719) |
| Loss from operations | (21,733) | (21,929) | 196 |
| Interest income | 1,104 | 1,359 | (255) |
| Other income, net | 783 | — | 783 |
| Non-cash interest expense on liability related to the sales of future royalties | (7,200) | (7,083) | (117) |
| Net loss | <u>\$ (27,046)</u> | <u>\$ (27,653)</u> | <u>\$ 607</u> |

License and other revenue. In the nine months ended September 30, 2024 and 2023, we recognized \$1.4 million and \$1.9 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. In 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 expenses decreased by \$0.2 million from \$14.5 million for the nine months ended September 30, 2023 to \$14.3 million for the nine months ended September 30, 2024. This decrease was primarily due to a \$1.2 million decrease in costs related to the CLS-AX program, which includes costs for ODYSSEY, our Phase 2b clinical trial, and a \$0.7 million decrease in costs related to our preclinical programs. This is partially offset by a \$0.3 million increase in consulting fees, a \$0.2 million increase in recruiting fees, a \$0.1 million increase in depreciation and a \$0.1 million increase in the amortization of a license maintenance fee. In addition, there was a \$0.8 million research and development tax credit received in the prior year.

General and administrative. General and administrative expenses decreased by \$0.2 million, from \$8.9 million for the nine months ended September 30, 2023 to \$8.7 million for the nine months ended September 30, 2024. This was primarily attributable to a \$0.6 million decrease in professional fees partially offset by a \$0.4 million increase in consulting fees.

Interest income. Interest income decreased by \$0.3 million from \$1.4 million for the nine months ended September 30, 2023 to \$1.1 million for the nine months ended September 30, 2024. The decrease is due to the lower balance of our cash, cash equivalents and short-term investments.

Other income, net. Other income, net was \$0.8 million for the nine months ended September 30, 2024 and was due to the decrease in fair value of the warrant liabilities of \$1.6 million from February 9, 2024, the issuance date of the warrants, to September 30, 2024 partially offset by \$0.8 million of direct registered offering costs that were allocated to the warrants.

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 was \$7.2 million and \$7.1 million for the nine months ended September 30, 2024 and 2023, respectively, and 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, issuance of warrants and the issuance of long-term debt. As of September 30, 2024, we had cash, cash equivalents and short-term investments of \$23.6 million. We invest any cash in excess of our immediate requirements primarily with a view to liquidity and capital preservation. As of September 30, 2024, our funds were held in cash, money market funds and treasury bills.

On February 6, 2024, we entered into the Purchase Agreement, pursuant to which we issued and sold, in a registered direct offering: (i) an aggregate of 11,111,111 shares of our common stock; and (ii) 11,111,111 Warrants. The combined purchase price of each share and accompanying Warrant was \$1.35. The exercise price for the Warrants is \$1.62 per share. The Warrants will be

exercisable from August 9, 2024 and will expire on August 9, 2029. The net proceeds to us from the Registered Direct Offering were \$13.9 million.

On January 31, 2024, or the Amendment Effective Date, we entered into a fourth amendment to the license agreement, or the Emory License Agreement, with Emory University and Georgia Tech Research Corporation, or, collectively, the Licensor, pursuant to which the parties agreed to reduce the Sublicense Percentage (as defined in the Emory License Agreement) from a low double digit percentage to a high single digit percentage that we will pay the Licensor applicable to any fees or payments paid to us by any Sublicensee (as defined in the Emory License Agreement) of the Licensed Patents and/or Licensed Technology (each as defined in the Emory License Agreement), excluding (i) amounts paid to us by a Sublicensee to reimburse us for certain research and development costs pursuant to a written agreement between us and such Sublicensee, (ii) the value of intellectual property transferred or granted to us if necessary or helpful to the development or commercialization of Licensed Products (as defined in the Emory License Agreement) and (iii) amounts paid for shares of our stock. The payment to Licensor of any such Sublicense Percentage is due within 30 days of receipt by us of a qualifying payment from a Sublicensee, provided however, with respect to any qualifying payments received by us from a Sublicensee prior to January 1, 2025, the payment to Licensor of any such Sublicense Percentage is due to Licensor by March 31, 2025. The parties also agreed to a revised annual license maintenance fee due each year, or the Maintenance Fee, starting in 2023 through 2028, as follows: \$0.3 million for 2023 through 2025, \$0.4 million for each of 2026 and 2027 and \$0.5 million for 2028. We paid the Maintenance Fee for 2023 in February 2024 and the Maintenance Fee for 2024 in October 2024. The remaining annual Maintenance Fee payments are due on October 1st of each year.

On December 22, 2023, we, through our wholly owned subsidiary Royalty Sub, entered into a letter agreement, or the Letter Agreement, with HCR and HCR Clearside SPV, LLC (as assignee of HCR Collateral Management, LLC), or the Agent, amending that certain Purchase and Sale Agreement, dated as of August 8, 2022, by and among Royalty Sub, HCR and Agent. Pursuant to the terms of the Letter Agreement, Royalty Sub and Agent mutually agreed that Royalty Sub waived any and all rights to the \$12.5 million milestone payment which was deposited in an escrow account, or the First Milestone Payment, in connection with the closing of the transactions contemplated by the Purchase and Sale Agreement and agreed to the release of the First Milestone Payment to Agent.

In November 2023, we entered into a license agreement, or the BioCryst License Agreement, with BioCryst Pharmaceuticals, Inc., or BioCryst, pursuant to which we granted BioCryst an exclusive, worldwide and sublicensable license to our SCS Microinjector for the delivery of BioCryst's proprietary plasma kallikrein inhibitor known as avoralstat for the treatment and prevention of diabetic macular edema, or DME. We received an upfront license fee payment of \$5.0 million in connection with signing of the BioCryst License Agreement. In addition, we are 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 us 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. Our 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 our consolidated financial statements included in this Quarterly Report on Form 10-Q.

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

In May 2023, we entered into a Controlled Equity OfferingSM Sales Agreement (the "Sales Agreement") with Cantor Fitzgerald & Co., or 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, 2024, we sold 339,912 shares of our common stock for net proceeds of \$0.5 million under the Sales Agreement. 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, 2024, we sold 1,097,932 shares of our common stock for net proceeds of \$1.3 million under the Sales Agreement.

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 5 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 remainder of 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 Sales Agreement with Cantor 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 disruptions to, and volatility in, the credit and financial markets in the United States and worldwide and related macroeconomic changes, such as rising 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. 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, cash equivalents and short-term investments as of the filing date, November 12, 2024, will enable us to fund our planned operating expenses and capital expenditure requirements into the third quarter of 2025. 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.

These factors raise substantial doubt regarding our ability to continue as a going concern. Our consolidated 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 consolidated 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 (used in) provided by our operating, investing and financing activities (in thousands):

| | Nine Months Ended September 30, | |
|---|------------------------------------|--------------------|
| | 2024 | 2023 |
| Net cash (used in) provided by: | | |
| Operating activities | \$ (19,444) | \$ (18,630) |
| Investing activities | (9,945) | (1,657) |
| Financing activities | 14,357 | 671 |
| Net change in cash and cash equivalents | <u>\$ (15,032)</u> | <u>\$ (19,616)</u> |

During the nine months ended September 30, 2024 and 2023, our operating activities used net cash of \$19.4 million and \$18.6 million, respectively. The net cash used in operating activities for the nine months ended September 30, 2024 was due to ongoing research and development expenses to develop our pipeline and ongoing costs for ODYSSEY, as well as the supporting general and administrative costs. 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, as well as the supporting general and administrative costs.

During the nine months ended September 30, 2024 and 2023, our investing activities used net cash of \$9.9 million and \$1.7 million, respectively. The net cash used in investing activities for the nine months ended September 30, 2024 consisted of \$16.9 million for the purchase of short-term investments and \$0.5 million for the acquisition of property and equipment, partially offset by \$7.5 million of maturity of short-term investments. The net cash used in investing activities for the nine months ended September 30, 2023 consisted of \$1.7 million for the acquisition of property and equipment.

During the nine months ended September 30, 2024 and 2023, our financing activities provided net cash of \$14.4 million and \$0.7 million, respectively. The cash provided by financing activities for the nine months ended September 30, 2024 consisted primarily of \$13.9 million of net proceeds from the sale of shares of our common stock in a registered direct offering and \$0.5 million of net proceeds from the sale of shares of our common stock under the Sales Agreement. The cash provided by financing activities for the nine months ended September 30, 2023 consisted primarily of \$0.9 million of proceeds received from the sale of our common stock under the ATM Agreement partially offset by a payment of \$0.4 million related to the Purchase and Sale Agreement.

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, 2024 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, 2023, filed with the Securities and Exchange Commission on March 12, 2024.

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

Our historical financial statements have been prepared under the assumption that we will continue as a going concern. As of September 30, 2024, we had an accumulated deficit of \$348.0 million and we had cash, cash equivalents and short-term investments of \$23.6 million. 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, cash equivalents and short-term investments as of the filing date, November 12, 2024, will enable the Company to fund its planned operating expenses and capital expenditure requirements into the third quarter of 2025. 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 perception of our ability to continue as a going concern may make it more difficult for us to obtain financing for the continuation of our operations and could result in the loss of confidence by investors and employees. Additionally, if we are unable to continue as a going concern, our stockholders may lose some or all of their investment in the Company.

Additional financing may not be available to us when needed or, if available, it may not be obtained on commercially reasonable terms. If we are not able to obtain the necessary additional financing on a timely or commercially reasonable basis, we will be forced to delay or scale down some or all of our development activities (or perhaps even cease the operation of our business). Our access to additional capital may be negatively affected by future recessions, downturns in the economy or the markets as a whole, or inflation.

We have no commitments for any additional financing and such commitments may not be obtained on favorable terms, if at all. Any additional equity financing will be dilutive to our stockholders, and debt financing, if available, may involve restrictive covenants with respect to dividends, raising future capital, and other financial and operational matters. If we are unable to obtain additional financing as needed, we may be required to reduce the scope of our operations or our anticipated expansion, which could have a material adverse effect on us.

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

Sales of Unregistered Securities

None.

Issuer Purchases of Equity Securities

None.

Item 5. Other Information

During the quarter ended September 30, 2024, none of our directors or officers (as defined in Rule 16a-1(f) under the Exchange Act) adopted, modified or terminated a “Rule 10b5-1 trading arrangement” or a “non-Rule 10b5-1 trading arrangement” (as each term is defined in Item 408 of Regulation S-K).

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 with Embedded Linkbase Documents |
| 104 | Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibits 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 12, 2024

By: */s/ Charles A. Deignan*
Charles A. Deignan
Chief Financial Officer
(On behalf of the Registrant and as
Principal Financial Officer)

**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, 2024 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 12, 2024

/s/ George Lasezkay, Pharm.D., J.D.

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

**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, 2024 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 12, 2024

/s/ Charles A. Deignan

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

**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, 2024, 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 12th day of November, 2024.

/s/ George Lasezkay, Pharm. D., J.D.

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

/s/ Charles A. Deignan

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.
