

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 March 31, 2022

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 May 9, 2022, the registrant had 60,150,442 shares of common stock, \$0.001 par value per share, outstanding.

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PART I – FINANCIAL INFORMATION
Item 1. Financial Statements

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

	March 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	\$ 34,372	\$ 30,436
Accounts receivable	—	10,000
Prepaid expenses	563	921
Other current assets	339	779
Total current assets	35,274	42,136
Property and equipment, net	301	238
Operating lease right-of-use asset	324	369
Restricted cash	160	160
Total assets	\$ 36,059	\$ 42,903
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 1,396	\$ 941
Accrued liabilities	2,171	3,312
Current portion of operating lease liabilities	391	387
Deferred revenue	198	—
Total current liabilities	4,156	4,640
Operating lease liabilities	200	288
Total liabilities	4,356	4,928
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.001 par value; 10,000,000 shares authorized and no shares issued at March 31, 2022 and December 31, 2021	—	—
Common stock, \$0.001 par value; 100,000,000 shares authorized at March 31, 2022 and December 31, 2021; 60,147,618 and 59,722,930 shares issued and outstanding at March 31, 2022 and December 31, 2021, respectively	60	60
Additional paid-in capital	294,778	293,406
Accumulated deficit	(263,135)	(255,491)
Total stockholders' equity	31,703	37,975
Total liabilities and stockholders' equity	\$ 36,059	\$ 42,903

See accompanying notes to the financial statements

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

	Three Months Ended March 31,	
	2022	2021
License and other revenue	\$ 347	\$ 34
Operating expenses:		
Research and development	4,536	5,490
General and administrative	3,457	2,893
Total operating expenses	7,993	8,383
Loss from operations	(7,646)	(8,349)
Other income	2	998
Net loss	\$ (7,644)	\$ (7,351)
Net loss per share of common stock — basic and diluted	\$ (0.13)	\$ (0.13)
Weighted average shares outstanding — basic and diluted	60,064,209	57,038,664

See accompanying notes to the financial statements.

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

	Three Months Ended March 31, 2022				
	Common Stock		Additional Paid-In-Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance at December 31, 2021	59,722,930	\$ 60	\$ 293,406	\$ (255,491)	\$ 37,975
Exercise of stock options	22,727	—	3	—	3
Vesting and settlement of restricted stock units	375,331	—	—	—	—
Issuance of common shares under employee stock purchase plan	26,630	—	62	—	62
Share-based compensation expense	—	—	1,307	—	1,307
Net loss	—	—	—	(7,644)	(7,644)
Balance at March 31, 2022	60,147,618	\$ 60	\$ 294,778	\$ (263,135)	\$ 31,703

	Three Months Ended March 31, 2021				
	Common Stock		Additional Paid-In-Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance at December 31, 2020	51,860,941	\$ 52	\$ 264,578	\$ (255,867)	\$ 8,763
Issuance of common shares under a direct registered offering	4,209,050	4	11,074	—	11,078
Issuance of common shares under at-the-market sales agreement	1,186,579	2	3,247	—	3,249
Exercise of stock options	62,493	—	38	—	38
Vesting and settlement of restricted stock units	227,754	—	—	—	—
Issuance of common shares under employee stock purchase plan	31,908	—	54	—	54
Share-based compensation expense	—	—	1,154	—	1,154
Net loss	—	—	—	(7,351)	(7,351)
Balance at March 31, 2021	57,578,725	\$ 58	\$ 280,145	\$ (263,218)	\$ 16,985

See accompanying notes to the financial statements.

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

	Three Months Ended March 31,	
	2022	2021
Operating activities		
Net loss	\$ (7,644)	\$ (7,351)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	46	45
Share-based compensation expense	1,307	1,154
Gain on extinguishment of debt	—	(998)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	10,689	279
Other assets and liabilities	(39)	(36)
Accounts payable and accrued liabilities	(686)	1,348
Deferred revenue	198	—
Net cash provided by (used in) operating activities	3,871	(5,559)
Investing activities		
Net cash used in investing activities	—	—
Financing activities		
Proceeds from registered direct offering, net of issuance costs	—	11,078
Proceeds from at-the-market sales agreement, net of issuance costs	—	3,249
Proceeds from exercise of stock options	3	38
Proceeds from shares issued under employee stock purchase plan	62	54
Net cash provided by financing activities	65	14,419
Net increase in cash, cash equivalents and restricted cash	3,936	8,860
Cash, cash equivalents and restricted cash, beginning of period	30,696	17,647
Cash, cash equivalents and restricted cash, end of period	\$ 34,632	\$ 26,507
Supplemental disclosure of noncash financing activities		
Forgiveness of PPP Loan and accrued interest	\$ —	\$ 998

Reconciliation of cash, cash equivalents and restricted cash:

	March 31,	
	2022	2021
Cash and cash equivalents	\$ 34,372	\$ 26,147
Restricted cash (including \$100 for each period recorded in other current assets)	260	360
Cash, cash equivalents and restricted cash at end of period	\$ 34,632	\$ 26,507

See accompanying notes to the financial statements.

CLEARSIDE BIOMEDICAL, INC.

Notes to the 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 has no current source of revenue to sustain present activities, and does not expect to generate meaningful revenue until and unless the Company's licensees successfully commercialize XIPERE[®], its other licensees receive regulatory approval and successfully commercializes its product candidates or the Company commercializes its product candidates either on its own or with a third party. The Company is subject to a number of risks and uncertainties similar to those of other life science companies at a similar stage of development, including, among others, the need to obtain adequate additional financing, successful development efforts including regulatory approval of products, compliance with government regulations, successful commercialization of potential products, protection of proprietary technology and dependence on key individuals.

Liquidity

The Company had cash and cash equivalents of \$34.4 million as of March 31, 2022.

On October 25, 2021, the Company announced that the U.S. Food and Drug Administration (the "FDA") approved XIPERE (triamcinolone acetate injectable suspension) for the treatment of macular edema associated with uveitis, a form of eye inflammation. In January 2022, the Company received \$10.0 million from Bausch + Lomb, a division of Bausch Health Companies, Inc. ("Bausch"), upon completion of pre-launch activities for XIPERE pursuant to the license agreement granting Bausch an exclusive license to develop and commercialize XIPERE in the United States and Canada. Bausch launched XIPERE in the United States in the first quarter of 2022.

The Company has funded its operations primarily through the sale of common stock and convertible preferred stock and the issuance of long-term debt. 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 products 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.

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 from its licensees' commercialization of XIPERE. 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.

Based on its current plans and forecasted expenses, the Company expects that its cash and cash equivalents as of the filing date, May 12, 2022, will enable it to fund its planned operating expenses and capital expenditure requirements for at least the next twelve months from that date. 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.

2. Significant Accounting Policies

Basis of Presentation

The Company's financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("U.S. GAAP").

Unaudited Interim Financial Information

The accompanying balance sheet as of March 31, 2022, statements of operations for the three months ended March 31, 2022 and 2021, statements of stockholders' equity for the three months ended March 31, 2022 and 2021 and statements of cash flows for the three months ended March 31, 2022 and 2021 are unaudited. The unaudited interim financial statements have been prepared on the same basis as the annual financial statements and, in the opinion of management, reflect all adjustments, which include normal recurring adjustments, necessary for the fair presentation of the Company's financial position as of March 31, 2022, its results of its operations for the three months ended March 31, 2022 and 2021, its changes in stockholders' equity for the three months ended March 31, 2022 and 2021 and its cash flows for the three months ended March 31, 2022 and 2021. The financial data and other information disclosed in these notes related to the three months ended March 31, 2022 and 2021 are unaudited. The results for the three months ended March 31, 2022 are not indicative of results to be expected for the year ending December 31, 2022, any other interim periods or any future year or period. These unaudited financial statements should be read in conjunction with the audited financial statements and related footnotes, which are included in the Company's Annual Report on Form 10-K for the year ended December 31, 2021.

Use of Estimates

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

Effects of COVID-19

The COVID-19 pandemic is expected to continue to result in global economic uncertainty. Estimates and assumptions about future events and their effects cannot be determined with certainty and therefore require the exercise of judgment. As of the date of issuance of these financial statements, the Company is not aware of any specific event or circumstance that would require us to update its estimates, assumptions and judgments or revise the carrying value of its assets or liabilities. These estimates may change as new events occur and additional information is obtained and are recognized in the consolidated financial statements as soon as they become known. Actual results could differ from those estimates and any such differences may be material to our financial statements.

Revenue Recognition

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

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

Research and Development Costs

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

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

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

Share-Based Compensation

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

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

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

Cash Equivalents

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

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

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

3. Property and Equipment, Net

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

	Estimated Useful Lives (Years)	March 31, 2022	December 31, 2021
Furniture and fixtures	5	\$ 337	\$ 337
Machinery and equipment	5	285	176
Computer equipment	3	13	13
Leasehold improvements	Lesser of useful life or remaining lease term	667	667
		1,302	1,193
Less: Accumulated depreciation		(1,001)	(955)
		<u>\$ 301</u>	<u>\$ 238</u>

4. Accrued Liabilities

Accrued liabilities consisted of the following (in thousands):

	March 31, 2022	December 31, 2021
Accrued research and development	\$ 1,114	\$ 1,083
Accrued employee costs	519	1,854
Accrued professional fees	106	30
Accrued expense	432	345
	<u>\$ 2,171</u>	<u>\$ 3,312</u>

5. CARES Act Paycheck Protection Program Loan

On April 20, 2020, the Company entered into a loan agreement with Silicon Valley Bank (the “PPP Lender”) under the terms of which the PPP Lender made a loan to the Company in an aggregate principal amount of \$1.0 million (the “PPP Loan”) pursuant to the Paycheck Protection Program (the “PPP”) under the Coronavirus Aid, Relief, and Economic Security Act (the “CARES Act”). The PPP Loan is evidenced by a promissory note (the “Note”) containing the terms and conditions for repayment of the PPP Loan.

Under the terms of the Note and the PPP Loan, interest accrued on the outstanding principal amount at the rate of 1.0% per annum. The term of the Note was until April 2022, with the Company obligated to make equal monthly payments of principal and interest, beginning in November 2020 and continuing until the maturity date.

The CARES Act and the PPP provide a mechanism for forgiveness of up to the full amount borrowed. On January 11, 2021, the Company was notified by the PPP Lender that the PPP Loan had been forgiven in full, including approximately \$7,000 of accrued interest. In accordance with ASC 405-20, *Extinguishment of Liabilities*, the income from the forgiveness of the amount borrowed and the accrued interest was recognized in the statement of operations in other income as a gain on extinguishment of debt.

6. Common Stock

The Company’s amended and restated certificate of incorporation authorizes the Company to issue 100,000,000 shares of \$0.001 par value common stock. As of March 31, 2022 and December 31, 2021, there were 60,147,618 and 59,722,930 shares of common stock outstanding, respectively.

7. Stock Purchase Warrants

In September 2016, in connection with a loan agreement, the Company issued warrants to purchase up to 29,796 shares of common stock at a price per share of \$10.74. The warrants expire in September 2026, or earlier upon the occurrence of specified mergers or acquisitions of the Company, and are immediately exercisable. The warrants were recorded in equity and had a weighted average remaining life of 4.5 years as of March 31, 2022.

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 2011 Plan and the 2016 Plan is reflected in the statements of operations as follows (in thousands):

	Three Months Ended March 31,	
	2022	2021
Research and development	\$ 402	\$ 377
General and administrative	514	422
Total	<u>\$ 916</u>	<u>\$ 799</u>

The following table summarizes the activity related to stock options during the three months ended March 31, 2022:

	Number of Shares	Weighted Average Exercise Price
Options outstanding at December 31, 2021	5,762,328	\$ 4.07
Granted	1,310,940	2.17
Exercised	(22,727)	0.15
Forfeited	—	—
Options outstanding at March 31, 2022	<u>7,050,541</u>	3.73
Options exercisable at December 31, 2021	<u>3,148,502</u>	4.59
Options exercisable at March 31, 2022	<u>3,743,739</u>	4.47

As of March 31, 2022, the Company had \$6.9 million of unrecognized compensation expense related to unvested stock options, which is expected to be recognized over a weighted average period of 2.8 years.

Restricted Stock Units

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

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

	Three Months Ended March 31,	
	2022	2021
Research and development	\$ 197	\$ 171
General and administrative	186	170
Total	<u>\$ 383</u>	<u>\$ 341</u>

The following table summarizes the activity related to RSUs during the three months ended March 31, 2022:

	Number of Shares	Weighted Average Grant Date Fair Value
Non-vested RSUs outstanding at December 31, 2021	1,317,347	\$ 3.58
Granted	648,460	2.19
Vested	(375,331)	3.44
Non-vested RSUs outstanding at March 31, 2022	<u>1,590,476</u>	<u>3.04</u>

As of March 31, 2022, the Company had \$4.5 million of unrecognized compensation expense related to the RSUs which is expected to be recognized over a weighted average period of 3.0 years.

Employee Stock Purchase Plan

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

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

	Three Months Ended March 31,	
	2022	2021
Research and development	\$ 5	\$ 8
General and administrative	3	6
Total	<u>\$ 8</u>	<u>\$ 14</u>

During the three months ended March 31, 2022, the Company issued 26,630 shares of common stock purchased under the 2016 ESPP.

9. Commitments and Contingencies

Lease Commitment Summary

In November 2016, the Company signed an office lease agreement to lease approximately 20,000 square feet of office space in Alpharetta, Georgia for its corporate headquarters. The lease agreement is for a 6.5 year term with a renewal option for one additional five-year term. Rental payments are \$35,145 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 lease agreement requires payment of the pro-rata share of the annual operating expenses associated with the premises.

The Company’s operating leases included on the balance sheet are as follows (in thousands):

	March 31, 2022
Operating lease right-of-use asset	<u>\$ 324</u>
Liabilities	
Current portion of operating lease liabilities	\$ 391
Operating lease liabilities	<u>200</u>
Total operating lease liabilities	<u>\$ 591</u>

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. The present value of the lease payments is calculated using an incremental borrowing rate as the Company’s leases do not provide an implicit interest rate. At March 31, 2022, the Company’s weighted average discount rate was 11.0% and the weighted average lease term was 1.5 years.

Minimum lease payments were as follows at March 31, 2022 (in thousands):

Year Ending December 31,	
2022	308
2023	316
Total minimum lease payments	624
Less imputed interest	(33)
Total operating lease liabilities	<u>\$ 591</u>

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.

Operating lease cost was \$62,000 for each of the three months ended March 31, 2022 and 2021. Variable lease cost was \$24,000 for each of the three months ended March 31, 2022 and 2021. Short-term lease cost was \$21,000 and \$2,000 for the three months ended March 31, 2022 and 2021. Cash payments included in operating activities on the statement of cash flows for operating lease liabilities were \$99,000 and \$95,000 for the three months ended March 31, 2022 and 2021, respectively.

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. 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 ("Other Products," and 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 upfront payment of \$5.0 million in October 2019. In October 2021, the FDA approved XIPERE. The Company received \$5.0 million from Bausch as a result of the approval. In December 2021, \$10.0 million was recorded upon completion of pre-launch activities for XIPERE and payment was received in January 2022. 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.

Arctic Vision (Hong Kong) Limited

On March 10, 2020, the Company entered into a License Agreement (the "License Agreement") with Arctic Vision (Hong Kong) Limited ("Arctic Vision"). Pursuant to the 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 License Agreement, neither party may commercialize XIPERE in the other party's territory. Arctic Vision has agreed to use commercially reasonable efforts to pursue 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 License Agreement, Arctic Vision paid the Company an upfront payment of \$4.0 million in March 2020. In December 2021, the Company received a milestone payment of \$4.0 million following the receipt of FDA approval of XIPERE in the United States. 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 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.

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

Other

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

11. Fair Value Measurements

The Company's material financial instruments at March 31, 2022 and December 31, 2021 consisted primarily of cash and cash equivalents. The fair values of cash and cash equivalents, other current assets and accounts payable approximate their respective carrying values due to the short term nature of these instruments and are classified as Level 1 in the fair value hierarchy.

There were no significant transfers between Levels 1, 2 and 3 during the three months ended March 31, 2022 and the year ended December 31, 2021.

12. Net Loss Per Share

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

	Three Months Ended March 31,	
	2022	2021
Outstanding stock options	7,050,541	5,816,856
Non-vested restricted stock units	1,590,476	1,504,861
Stock purchase warrants	29,796	29,796
	<u>8,670,813</u>	<u>7,351,513</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”. Such risks and uncertainties may be amplified by the COVID-19 pandemic and its potential impact on our business and the global economy. Statements made herein are as of the date of the filing of this Form 10-Q with the SEC and should not be relied upon as of any subsequent date. Unless otherwise required by applicable law, we do not undertake, and we specifically disclaim, any obligation to update any forward-looking statements to reflect occurrences, developments, unanticipated events or circumstances after the date of such statement.

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited financial statements and related notes that appear in Item 1 of this Quarterly Report on Form 10-Q and with our audited financial statements and related notes for the year ended December 31, 2021 appearing in our Annual Report on Form 10-K filed with the SEC on March 11, 2022.

Overview

We are a biopharmaceutical company focused on revolutionizing the delivery of therapies to the back of the eye through the suprachoroidal space, or SCS[®]. Our novel SCS injection platform, utilizing our proprietary SCS Microinjector[®], enables an in-office, repeatable, non-surgical procedure for the targeted and compartmentalized delivery of a wide variety of therapies to the macula, retina or choroid to potentially preserve and improve vision in patients with sight-threatening eye diseases. Our SCS injection platform can be used in conjunction with existing drugs designed for delivery to the SCS, novel therapies and future therapeutic innovations. We believe our proprietary suprachoroidal administration platform has the potential to become a standard for delivery of therapies intended to treat chorioretinal diseases.

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

We believe that we are creating a broad therapeutic platform for developing product candidates to treat serious eye diseases.

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

Internal Development Pipeline							
PROGRAM	THERAPEUTIC ENTITY	INDICATION	RESEARCH	PRECLINICAL	PHASE 1/2	PHASE 3	
CLS-AX (axitinib)	Small Molecule	Wet AMD	[Progress bar through Research, Preclinical, Phase 1/2]			OASIS	
CLS-301 (integrin inhibitor)	Small Molecule	Diabetic Macular Edema (DME)	[Progress bar through Research, Preclinical]				
GENE THERAPY	Non-Viral & Viral Vectors	Open to Partnering	[Progress bar through Research]				
SCS Microinjector® Partner Programs							
PARTNER	THERAPEUTIC ENTITY	LICENSED INDICATION	IND-Enabling	PHASE 2	PHASE 3	APPROVAL	
REGENXBIO	AAV-based Gene Therapy	Wet AMD (AAVIATE)	[Progress bar through IND-Enabling, Phase 2]				
REGENXBIO	AAV-based Gene Therapy	Diabetic Retinopathy (ALTITUDE)	[Progress bar through IND-Enabling, Phase 2]				
AURA BIOSCIENCES	Viral-like Drug Conjugate	Ocular Oncology/Choroidal Melanoma	[Progress bar through IND-Enabling, Phase 2]				
XIPERE® Commercial Partners							
PARTNER	INDICATION	LICENSED TERRITORY	PRE-CLINICAL	PHASE 1	PHASE 2	PHASE 3	APPROVAL
BAUSCH HEALTH	Uveitic Macular Edema	U.S. & Canada	[Progress bar through Pre-clinical, Phase 1, Phase 2, Phase 3]				U.S.A.
ARCTIC VISION	Uveitic Macular Edema	Greater China, South Korea, ASEAN Countries, India, Australia, New Zealand	[Progress bar through Pre-clinical, Phase 1, Phase 2]				Arcatus™
	Diabetic Macular Edema		[Progress bar through Pre-clinical]				Arcatus™

Internal Pipeline

XIPERE

Our first product, XIPERE, is a proprietary, preservative-free suspension of the corticosteroid triamcinolone acetonide, or TA, for suprachoroidal use. Corticosteroids are the standard of care in uveitis. They are effective at treating the inflammatory aspect of ocular disease, but when delivered locally, either topically as drops, intravitreally or by periocular injection, they have been associated with significant side effects, such as cataract formation or exacerbation and elevated intraocular pressure, or IOP, which can lead to glaucoma. XIPERE is delivered into the suprachoroidal space via a novel route of administration utilizing our SCS Microinjector. XIPERE was approved by the FDA for the treatment of macular edema associated with uveitis.

We are evaluating options for potential submissions to regulatory agencies to seek regulatory approval of XIPERE for the treatment of patients with macular edema associated with uveitis in additional territories outside of territories licensed by Arctic Vision and Bausch.

CLS-AX

CLS-AX, our most advanced product candidate, is our proprietary suspension of the tyrosine kinase inhibitor axitinib for suprachoroidal injection delivered via our SCS Microinjector. CLS-AX is an inhibitor of vascular endothelial growth factor receptor-1, -2 and -3 that we believe may benefit patients who respond sub optimally to current anti-VEGF therapies. We are developing CLS-AX for administration to the SCS as a long-acting therapy for wet age-related macular degeneration, or wet AMD, a retinal degenerative disease that causes a progressive loss of central vision.

In August 2020, we announced that the FDA had accepted our Investigational New Drug application, or IND, for CLS-AX. In January 2021, we announced that the first patients had been enrolled in our Phase 1/2a clinical trial of CLS-AX, known as OASIS. In OASIS, the primary endpoints were met in Cohorts 1 and 2. CLS-AX was well tolerated with no serious adverse events; there were no treatment emergent adverse events related to aflibercept, CLS-AX or the suprachoroidal injection procedure, no dispersion of drug into the vitreous, and no adverse events related to IOP, inflammation or vasculitis. OASIS is currently enrolling patients in Cohort 3, in which each patient will receive a dose of 0.5 mg. The preliminary one-month safety data from Cohort 3 has been reviewed by our Safety Monitoring Committee and there were no dose limiting toxicities. As a result, we are now enrolling patients in Cohort 4 in which each patient will receive a dose of 1.0 mg. Our extension study follows patients in Cohort 2, Cohort 3 and Cohort 4 for up to an additional three-month period.

In addition to enrolling Cohort 4, we plan to expand enrollment in Cohort 3 and run both cohorts simultaneously. With the Cohort 3 expansion and the addition of Cohort 4, we are targeting enrollment of up to 25 patients in total from all four OASIS cohorts. The expanded enrollment will allow us to collect more CLS-AX patient data in order to help guide our selection of the most

appropriate dosing protocol for our planned Phase 2b clinical trial. We expect to report individual patient safety and tolerability data from both Cohort 3 and Cohort 4 as well as the complete analysis from all four dosing cohorts of the OASIS trial in the fourth quarter of 2022. We have begun planning for our Phase 2b clinical trial. We anticipate that the the final data readout from OASIS will position us to initiate activities by the end of the year for our Phase 2b trial, which will enable us to begin enrolling patients soon thereafter.

CLS-301

We have initiated another small molecule program utilizing suprachoroidal administration of an integrin inhibitor suspension, which we refer to as CLS-301. Integrins are multi-functional cell-adhesion molecules that regulate critical cellular processes. Integrins play a role in pathologic processes, such as inflammation, angiogenesis and fibrosis. Integrin inhibition has had some recent preliminary validation in preclinical models and clinical studies of diabetic macular edema and macular degeneration conducted by others. We believe that integrin inhibition could potentially serve as primary therapy, adjunctive therapy to anti-VEGF agents or secondary therapy in refractory cases of diabetic macular edema and macular degeneration. Suprachoroidal delivery of an integrin inhibitor suspension could provide targeting, compartmentalization and durability advantages over topical or intravitreal delivery, similar to what we have observed in other preclinical studies of small molecule suspensions, such as triamcinolone acetonide and axitinib. Therefore, we are assessing ocular tolerability, distribution and pharmacokinetics of our integrin inhibitor suprachoroidal suspension in a series of preclinical studies. Our initial preclinical data has shown that the agent is well-tolerated with favorable ocular distribution targeting the chorio-retina, and we have seen encouraging initial signs of durability. We are optimizing the formulation and have initiated a second preclinical study. We expect to have results from this study in the second half of 2022.

External Collaborations Pipeline

In addition to growing our internal pipeline, we are also focused on collaborating with other companies to provide access to the suprachoroidal space.

During the second half of 2019, we entered into three license and other agreements that we believe validate and expand the reach of our suprachoroidal injection platform. In October 2019, we announced that Bausch + Lomb, a division of Bausch Health Companies, Inc., or Bausch, acquired an exclusive license for the commercialization and development of XIPERE (triamcinolone acetonide injectable suspension) in the United States and Canada. Bausch launched XIPERE in the United States in the first quarter of 2022.

In October 2019, REGENXBIO Inc., or REGENXBIO, exercised its option to license our SCS Microinjector technology for in-office delivery of adeno-associated virus, or AAV,-based therapeutics to the SCS to potentially treat AMD, diabetic retinopathy and certain other conditions for which chronic anti-VEGF treatment is currently the standard of care. REGENXBIO is currently conducting two multi-center, open-label, randomized, controlled, dose-escalation Phase 2 clinical trials evaluating the efficacy, safety and tolerability of suprachoroidal delivery of RGX-314 using our SCS Microinjector technology: a Phase 2 trial entitled AAVIATE for the treatment of wet AMD and a second Phase 2 trial entitled ALTITUDE for the treatment of diabetic retinopathy. REGENXBIO has reported positive initial data from both clinical trials. Both ALTITUDE and AAVIATE continue to enroll in the next cohorts.

In July 2019, Aura Biosciences, or Aura, licensed our SCS Microinjector to deliver Aura's proprietary drug candidates into the SCS for the potential treatment of certain ocular cancers, including choroidal melanoma. Aura is currently conducting a Phase 2 trial in choroidal melanoma comprised of an open-label, dose escalation phase and a randomized, masked dose expansion phase. Aura reported positive initial data on its Phase 2 clinical trial for the treatment of choroidal melanoma in October 2021. We expect Aura to disclose additional safety and efficacy data from this trial in 2022.

In March 2020, we entered into a license agreement, or the Arctic Vision License Agreement, with Arctic Vision (Hong Kong) Limited, or Arctic Vision. Pursuant to the Arctic Vision License Agreement, we 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, or the Arctic Territory. During 2021, we entered into amendments to the Arctic Vision 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) and Australia and New Zealand. In December 2020, Arctic Vision announced approval of its IND for a Phase 3 clinical trial of ARVN001 (known as XIPERE in the U.S.) in China. Arctic Vision has branded ARVN001 as Arcatus. In November 2021, Arctic Vision announced dosing of the first patient in a Phase 3 clinical trial of ARVN001 for the treatment of macular edema associated with uveitis. In March 2022, Arctic Vision announced dosing of the first patient in a Phase 1 clinical trial of ARVN011 in China for the treatment of diabetic macular edema.

These partnerships enable us to expand the use of our suprachoroidal injection platform to other indications and geographies globally. Under these license agreements, we are eligible to receive up to an aggregate of more than \$230 million in potential future development and sales milestones, as well as and royalties from net sales of covered products.

We have incurred net losses since our inception. In recent years, our operations have consisted primarily of conducting preclinical studies and clinical trials, raising capital and undertaking other research and development initiatives. To date, we have not generated any revenue, other than license and other revenue, and we have primarily financed our operations through public offerings

and private placements of our equity securities, issuances of convertible promissory notes and loan agreements. As of March 31, 2022, we had an accumulated deficit of \$263.1 million. We recorded net losses of \$7.6 million and \$7.4 million for the three months ended March 31, 2022 and 2021, 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 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 2022 as a result of our ongoing Phase 1/2a clinical trial of CLS-AX, the preparation of a Phase 2b clinical trial of CLS-AX, as well as continuing our pipeline development. We also will continue our efforts to seek to discover, research and develop additional product candidates and regulatory approvals in additional regions for XIPERE for the treatment of macular edema associated with uveitis. Based on our current research and development plans, we expect to have sufficient resources to fund our planned operations for at least the next twelve months.

Impact of COVID-19 on Our Business

Our financial results for the three months ended March 31, 2022 were not significantly impacted by COVID-19, and we currently do not expect any material impact on our financial results for the remainder of 2022.

Components of Operating Results

Revenue

We have not generated any revenue from the sale of XIPERE, and we do not expect to generate any until Bausch has reached the first \$45 million of net sales (refer to Footnote 11 to our financial statements included in this Quarterly Report on Form 10-Q) or any other product revenue unless or until we obtain regulatory approval of and commercialize our other product candidates, either on our own or with a third party. Our revenue in recent years has been generated primarily from our license agreements. We are seeking to enter into additional license and other agreements with third parties to evaluate the potential use of our proprietary SCS Microinjector with the third party's product candidates for the treatment of various eye diseases. These agreements may include payments to us for technology access, upfront license payments, regulatory and commercial milestone payments and royalties.

Research and Development

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

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

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

The following table shows our research and development expenses by program for the three months ended March 31, 2022 and 2021 (in thousands).

	Three Months Ended March 31,	
	2022	2021
XIPERE (uveitis program)	\$ 120	\$ 1,473
CLS-AX (wet AMD program)	1,108	1,278
CLS-301 (DME program)	373	189
Total	1,601	2,940
Unallocated	2,935	2,550
Total research and development expense	\$ 4,536	\$ 5,490

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

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

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

- the costs associated with process development, scale-up and manufacturing of our product candidates including the SCS Microinjector for clinical trials and for requirements associated with regulatory filings;
- the number of trials required for approval and any requirement for extension trials;
- per patient trial costs;
- the number of patients that participate in the trials;
- the number of sites included in the trials;
- the countries in which the trials are conducted;
- the length of time required to enroll eligible patients;
- the number of doses that patients receive;
- the potential impact of the COVID-19 pandemic on the enrollment in, and timing of, our clinical trials;
- the drop-out or discontinuation rates of patients;
- potential additional safety monitoring or other studies requested by regulatory agencies;
- the duration of patient follow-up; and
- the efficacy and safety profiles of the product candidates.

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

General and Administrative

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

Other Income

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

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

We define our critical accounting policies as those accounting principles generally accepted in the United States of America that require us to make subjective estimates and judgments about matters that are uncertain and are likely to have a material impact on our financial condition and results of operations, as well as the specific manner in which we apply those principles. During the three months ended March 31, 2022, there were no significant changes to our critical accounting policies disclosed in our audited financial statements for the year ended December 31, 2021, which are included in our Annual Report on Form 10-K, as filed with the SEC on March 11, 2022.

Results of Operations for the Three Months Ended March 31, 2022 and 2021

The following table sets forth our results of operations for the three months ended March 31, 2022 and 2021.

	Three Months Ended March 31,		Period-to-Period Change
	2022	2021 (in thousands)	
License and other revenue	\$ 347	\$ 34	\$ 313
Operating expenses:			
Research and development	4,536	5,490	(954)
General and administrative	3,457	2,893	564
Total operating expenses	7,993	8,383	(390)
Loss from operations	(7,646)	(8,349)	703
Other income	2	998	(996)
Net loss	<u>\$ (7,644)</u>	<u>\$ (7,351)</u>	<u>\$ (293)</u>

Revenue. In the three months ended March 31, 2022 and 2021, we recognized \$0.3 million and \$34,000, respectively, of revenue associated with our license agreements.

Research and development. Research and development expense decreased by \$1.0 million, from \$5.5 million for the three months ended March 31, 2021 to \$4.5 million for the three months ended March 31, 2022. This decrease was primarily due to a \$1.4 million decrease in costs related to the uveitis program as it was approved for commercial sales by the FDA in October 2021. The CLS-AX program, including costs for OASIS, a Phase 1/2a clinical trial of CLS-AX, had a decrease of \$0.2 million for the three months ended March 31, 2022 due to timing of expenses for the clinical trials. These decreases are partially offset by a \$0.2 million increase in costs for our CLS-301 program and a \$0.2 million increase in employee related costs.

General and administrative. General and administrative expenses increased by \$0.6 million, from \$2.9 million for the three months ended March 31, 2021 to \$3.5 million for the three months ended March 31, 2022. This was primarily attributable to a \$0.2 million increase in employee related costs and a \$0.2 million increase in consulting fees.

Other income. Other income for the three months ended March 31, 2022 was comprised of interest income from cash and cash equivalents. Other income for the three months ended March 31, 2021 was primarily comprised of the gain on the extinguishment of debt from the forgiveness of the PPP Loan and accrued interest.

Liquidity and Capital Resources

Sources of Liquidity

We have funded our operations primarily through the proceeds of public offerings of our common stock, sales of convertible preferred stock and the issuance of long-term debt. As of March 31, 2022, we had cash and cash equivalents of \$34.4 million. We invest any cash in excess of our immediate requirements primarily with a view to liquidity and capital preservation. As of March 31, 2022, our funds were held in cash and money market funds.

In April 2020, we entered into a loan agreement with Silicon Valley Bank under the terms of which Silicon Valley bank loaned us \$1.0 million, or the PPP Loan, pursuant to the Paycheck Protection Program, or PPP, under the Coronavirus Aid, Relief, and Economic Security Act, or CARES Act. In accordance with the requirements of the CARES Act, we used the proceeds primarily for payroll costs and other eligible expenses. The CARES Act and the PPP provide a mechanism for forgiveness of up to the full amount borrowed. On January 11, 2021, we received notification from Silicon Valley Bank that the PPP loan was forgiven in full, including approximately \$7,000 of accrued interest.

In March 2020, Arctic Vision paid us an upfront payment of \$4.0 million. In December 2021, we received a milestone payment of \$4.0 million following receipt of FDA approval of XIPERE in the United States. In addition, Arctic Vision has agreed to pay us up to a total of \$22.5 million in development and sales milestone payments. Further, during the applicable royalty term, we will also be entitled to receive tiered royalties of 10-12% of net sales in the Arctic Territory, subject to customary reductions. In August 2021, we entered into an amendment to the Arctic Vision 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, we entered into a second amendment to the Arctic Vision License Agreement to expand the Arctic Territory to include Australia and New Zealand. We received an aggregate of \$3.0 million in consideration for the expansion of the Arctic Territory.

In October 2019, we announced that Bausch acquired an exclusive license for the commercialization and development of XIPERE in the United States and Canada. On October 25, 2021, we announced that the FDA approved XIPERE for the treatment of macular edema associated with uveitis. We received \$5.0 million from Bausch in November 2021 relating to the FDA approval of XIPERE, and in January 2022, we received an additional \$10.0 million upon completion of pre-launch activities for XIPERE. Bausch launched XIPERE in the United States in the first quarter of 2022.

We have entered into an at-the-market sales agreement, or the ATM agreement, with Cowen and Company LLC, or Cowen, 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 Cowen acting as our sales agent. As of March 31, 2022, there was \$14.4 million available for sales of our common stock under the ATM 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 Footnote 9 to our financial statements included in this Quarterly Report on Form 10-Q.

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

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

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

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity offerings, debt financings and potential collaboration, license and development agreements. Other than potential payments we may receive under our license and other agreements, we do not currently have any committed external source of funds, though, as described above, we may also be able to sell our common stock under the ATM agreement with Cowen subject to the terms of that agreement and depending on market conditions. We expect that we will require additional capital to fund our ongoing

operations. Additional funds may not be available to us on a timely basis, on commercially reasonable terms, or at all. Our ability to raise additional capital may be adversely impacted by potential worsening global economic conditions and the recent disruptions to, and volatility in, the credit and financial markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic, the Russian Federation invasion of Ukraine and macroeconomic conditions such as inflation. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

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

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

Outlook

We have suffered recurring losses and negative cash flows from operations since inception and anticipate incurring additional losses until such time, if ever, that we can generate significant milestone payments and royalties from XIPERE and other licensing arrangements or revenues from other product candidates. We will need additional financing to fund our operations. Our plans primarily consist of raising additional capital, potentially in a combination of equity or debt financings, monetizing royalties, or restructurings, or potentially entering into additional collaborations, partnerships and other strategic arrangements.

Based on our current plans and forecasted expenses, we expect that our cash and cash equivalents as of the filing date, May 12, 2022, will enable us to fund our planned operating expenses and capital expenditure requirements for at least the next 12 months from that date. 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 clinical development of CLS-AX.

Cash Flows

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

	Three Months Ended March 31,	
	2022	2021
Net cash provided by (used in):		
Operating activities	\$ 3,871	\$ (5,559)
Investing activities	—	—
Financing activities	65	14,419
Net change in cash and cash equivalents	\$ 3,936	\$ 8,860

During the three months ended March 31, 2022, our operating activities provided net cash of \$3.9 million and during the three months ended March 31, 2021 our operating activities used \$5.6 million. The net cash provided for the three months ended March 31, 2022 was primarily due to the receipt of the \$10.0 million milestone payment received from Bausch in connection with pre-launch activities for XIPERE offset by research and development expenses related to the preclinical and clinical programs and general and administrative expenses. The net cash used in the three months ended March 31, 2021 was primarily attributable to higher research and development expenses related to the preclinical and clinical CLS-AX program.

During the three months ended March 31, 2022 and 2021 our net cash provided by financing activities was \$65,000 and \$14.4 million, respectively. The cash provided by financing activities for the three months ended March 31, 2022 consisted of stock option exercises and the sale of common shares under an employee stock purchase plan. The cash provided by financing during the three months ended March 31, 2021 primarily consisted of \$11.1 million of net proceeds from the sale of shares of our common stock in a registered direct offering and \$3.2 million of net proceeds from the sale of shares of our common stock under the ATM 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 March 31, 2022 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.

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. These risks could be amplified by the COVID-19 pandemic and its potential impact on the global economy generally and our business and industry in particular. 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, 2021, filed with the Securities and Exchange Commission on March 11, 2022. There have been no material changes to the risk factors described in that report.

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

Sales of Unregistered Securities

None.

Issuer Purchases of Equity Securities

None.

Item 6. Exhibits

<u>Exhibit No.</u>	<u>Description</u>
3.1	<u>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).</u>
3.2	<u>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).</u>
31.1*	<u>Certification of Principal Executive Officer under Section 302 of the Sarbanes-Oxley Act.</u>
31.2*	<u>Certification of Principal Financial Officer under Section 302 of the Sarbanes-Oxley Act.</u>
32.1**	<u>Certifications of Principal Executive Officer and Principal Financial Officer under Section 906 of the Sarbanes-Oxley Act.</u>
101.INS	Inline XBRL Instance Document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101)

* Filed herewith.

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

**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 March 31, 2022 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: May 12, 2022

/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 March 31, 2022 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: May 12, 2022

/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 March 31, 2022, 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 May, 2022.

/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.
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