

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, 2021

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 checked="" 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 5, 2021, the registrant had 59,666,519 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)

	September 30, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	\$ 25,217	\$ 17,287
Prepaid expenses	1,187	722
Other current assets	119	109
Total current assets	26,523	18,118
Property and equipment, net	283	416
Operating lease right-of-use asset	412	528
Restricted cash	160	260
Total assets	\$ 27,378	\$ 19,322
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 776	\$ 1,997
Accrued liabilities	2,996	1,582
Current portion of long-term debt	—	991
Current portion of operating lease liabilities	384	373
Deferred revenue	5,000	5,000
Total current liabilities	9,156	9,943
Operating lease liabilities	374	616
Total liabilities	9,530	10,559
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.001 par value; 10,000,000 shares authorized and no shares issued at September 30, 2021 and December 31, 2020	—	—
Common stock, \$0.001 par value; 100,000,000 shares authorized at September 30, 2021 and December 31, 2020; 59,626,519 and 51,860,941 shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively	60	52
Additional paid-in capital	291,988	264,578
Accumulated deficit	(274,200)	(255,867)
Total stockholders' equity	17,848	8,763
Total liabilities and stockholders' equity	\$ 27,378	\$ 19,322

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 September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
License and other revenue	\$ 3,074	\$ 3,432	\$ 3,888	\$ 7,883
Operating expenses:				
Research and development	5,147	3,490	14,697	10,601
General and administrative	2,816	2,374	8,525	8,107
Total operating expenses	7,963	5,864	23,222	18,708
Loss from operations	(4,889)	(2,432)	(19,334)	(10,825)
Other income	2	—	1,001	—
Other expense	—	(1)	—	(273)
Net loss	\$ (4,887)	\$ (2,433)	\$ (18,333)	\$ (11,098)
Net loss per share of common stock — basic and diluted	\$ (0.08)	\$ (0.05)	\$ (0.32)	\$ (0.24)
Weighted average shares outstanding — basic and diluted	59,474,346	46,976,649	58,095,080	45,653,068

See accompanying notes to the financial statements.

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

	Nine Months Ended September 30, 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
Issuance of common shares under at-the-market sales agreement	1,397,436	1	7,083	—	7,084
Exercise of stock options	21,673	—	33	—	33
Vesting and settlement of restricted stock units	93,757	—	—	—	—
Share-based compensation expense	—	—	1,331	—	1,331
Net loss	—	—	—	(6,095)	(6,095)
Balance at June 30, 2021	59,091,591	59	288,592	(269,313)	19,338
Issuance of common shares under at-the-market sales agreement	307,404	1	1,874	—	1,875
Exercise of stock options	100,194	—	149	—	149
Vesting and settlement of restricted stock units	93,757	—	—	—	—
Issuance of common shares under employee stock purchase plan	33,573	—	57	—	57
Share-based compensation expense	—	—	1,316	—	1,316
Net loss	—	—	—	(4,887)	(4,887)
Balance at September 30, 2021	59,626,519	\$ 60	\$ 291,988	\$ (274,200)	\$ 17,848

	Nine Months Ended September 30, 2020				
	Common Stock		Additional Paid-In-Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance at December 31, 2019	44,413,372	\$ 44	\$ 248,770	\$ (237,657)	\$ 11,157
Issuance of common shares under at-the-market sales agreement	455,186	1	1,192	—	1,193
Share-based compensation expense	—	—	1,001	—	1,001
Net loss	—	—	—	(2,911)	(2,911)
Balance at March 31, 2020	44,868,558	45	250,963	(240,568)	10,440
Issuance of common shares under at-the-market sales agreement	800,170	1	1,606	—	1,607
Exercise of stock options	58,333	—	72	—	72
Vesting and settlement of restricted stock units	512,550	—	—	—	—
Issuance of common shares under employee stock purchase plan	35,359	—	31	—	31
Share-based compensation expense	—	—	891	—	891
Net loss	—	—	—	(5,754)	(5,754)
Balance at June 30, 2020	46,274,970	46	253,563	(246,322)	7,287
Issuance of common shares under at-the-market sales agreement	1,382,564	2	2,283	—	2,285
Exercise of stock options	194,883	—	144	—	144
Vesting and settlement of restricted stock units	375,025	—	—	—	—
Share-based compensation expense	—	—	841	—	841
Net loss	—	—	—	(2,433)	(2,433)
Balance at September 30, 2020	48,227,442	\$ 48	\$ 256,831	\$ (248,755)	\$ 8,124

See accompanying notes to the financial statements.

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

	Nine Months Ended September 30,	
	2021	2020
Operating activities		
Net loss	\$ (18,333)	\$ (11,098)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	133	136
Share-based compensation expense	3,801	2,733
Gain on extinguishment of debt	(998)	—
Non-cash interest expense	—	59
Accretion of debt discount	—	129
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(475)	1,441
Other assets and liabilities	(115)	(105)
Accounts payable and accrued liabilities	200	(1,979)
Net cash used in operating activities	(15,787)	(8,684)
Investing activities		
Acquisition of property and equipment	—	(55)
Net cash provided by (used in) investing activities	—	(55)
Financing activities		
Proceeds from registered direct offering, net of issuance costs	11,078	—
Proceeds from at-the-market sales agreement, net of issuance costs	12,208	5,084
Proceeds from exercise of stock options	220	217
Proceeds from shares issued under employee stock purchase plan	111	31
Proceeds from long-term debt	—	991
Payments made on long-term debt	—	(5,340)
Net cash provided by financing activities	23,617	983
Net increase (decrease) in cash, cash equivalents and restricted cash	7,830	(7,756)
Cash, cash equivalents and restricted cash, beginning of period	17,647	22,955
Cash, cash equivalents and restricted cash, end of period	\$ 25,477	\$ 15,199
Supplemental disclosure of noncash financing activities		
Forgiveness of PPP Loan and accrued interest	\$ 998	\$ —

Reconciliation of cash, cash equivalents and restricted cash:

	September 30,	
	2021	2020
Cash and cash equivalents	\$ 25,217	\$ 14,839
Restricted cash (including \$100 for each period recorded in other current assets)	260	360
Cash, cash equivalents and restricted cash at end of period	\$ 25,477	\$ 15,199

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 \$25.2 million as of September 30, 2021. On January 6, 2021, the Company entered into a securities purchase agreement with certain institutional purchasers that purchased 4.2 million shares of its common stock in a registered direct offering at a price of \$2.851 per share. The Company raised net proceeds of \$11.1 million after deducting offering expenses. During the nine months ended September 30, 2021, the Company sold 2.9 million shares of its common stock for net proceeds of \$12.2 million under its at-the-market agreement with Cowen and Company, LLC.

In August 2021, the Company entered into an amendment to the Arctic Vision License Agreement (as defined in Note 10 - License and Other Agreements) 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 territories covered by the license to include Australia and New Zealand. The Company received an aggregate of \$3.0 million in consideration for the expansion of the licensed territory.

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. The Company is entitled to an aggregate of \$9.0 million in milestone payments related to the approval of XIPERE from Arctic Vision (Hong Kong) Limited and Bausch + Lomb. In addition, the Company is entitled to receive \$10.0 million from Bausch upon completion of pre-launch activities for XIPERE. Bausch expects to launch 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 conduct additional trials for the regulatory approval of its product candidates if requested by regulatory bodies, and completing the development of any product candidates. 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, November 10, 2021, will enable it to fund its planned operating expenses and capital expenditure requirements into 2023. This estimate assumes receipt of the \$9.0 million of milestone payments that the Company is entitled receive from its licensees as a result of the FDA approval of XIPERE. In addition, the estimate assumes receipt of the \$10.0 million milestone payment that the Company is entitled to receive from Bausch upon completion of pre-launch activities for XIPERE. 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 September 30, 2021, statements of operations for the three and nine months ended September 30, 2021 and 2020, statements of stockholders' equity for the three and nine months ended September 30, 2021 and 2020 and statements of cash flows for the nine months ended September 30, 2021 and 2020 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 September 30, 2021, its results of its operations for the three and nine months ended September 30, 2021 and 2020, its changes in stockholders' equity for the three and nine months ended September 30, 2021 and 2020 and its cash flows for the nine months ended September 30, 2021 and 2020. The financial data and other information disclosed in these notes related to the three and nine months ended September 30, 2021 and 2020 are unaudited. The results for the nine months ended September 30, 2021 are not indicative of results to be expected for the year ending December 31, 2021, 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, 2020.

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 has created global volatility, economic uncertainty and general market disruption. 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 trials, are recognized based on an evaluation of the progress to completion of specific tasks using data such as patient enrollment, clinical site activations, 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 arrangements, 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 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. Compensation expense for options granted to non-employees is determined as the fair value of consideration received or the fair value of the equity instruments issued, whichever is more reliably measured. 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 underlying employees' roles 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.

Recent Accounting Pronouncements

In December 2019, the FASB issued Accounting Standards Update ("ASU") 2019-12, Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes ("ASU 2019-12"), which simplifies the accounting for income taxes by removing certain exceptions related to the approach for intraperiod tax allocation, the methodology for calculating income taxes in an interim period and the recognition of deferred tax liabilities for outside basis differences. The new ASU also simplifies aspects of the accounting for franchise taxes and enacted changes in tax laws or rates. These changes aim to improve the overall usefulness of disclosures to financial statement users and reduce unnecessary costs to companies when preparing the disclosures. The Company adopted ASU 2019-12 on January 1, 2021, and the adoption did not have a material impact on its financial statements and related disclosures.

3. Property and Equipment, Net

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

	Estimated Useful Lives (Years)	September 30, 2021	December 31, 2020
Furniture and fixtures	5	\$ 337	\$ 337
Machinery and equipment	5	176	176
Computer equipment	3	13	13
Leasehold improvements	Lesser of useful life or remaining lease term	667	667
		1,193	1,193
Less: Accumulated depreciation		(910)	(777)
		<u>\$ 283</u>	<u>\$ 416</u>

4. Accrued Liabilities

Accrued liabilities consisted of the following (in thousands):

	September 30, 2021	December 31, 2020
Accrued research and development	\$ 1,594	\$ 234
Accrued employee costs	1,145	1,132
Accrued professional fees	82	56
Accrued expense	175	160
	<u>\$ 2,996</u>	<u>\$ 1,582</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 September 30, 2021 and December 31, 2020, there were 59,626,519 and 51,860,941 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 5.0 years as of September 30, 2021.

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 September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Research and development	\$ 391	\$ 290	\$ 1,182	\$ 882
General and administrative	525	384	1,461	1,176
Total	<u>\$ 916</u>	<u>\$ 674</u>	<u>\$ 2,643</u>	<u>\$ 2,058</u>

The following table summarizes the activity related to stock options during the nine months ended September 30, 2021:

	Number of Shares	Weighted Average Exercise Price
Options outstanding at December 31, 2020	4,248,193	\$ 3.95
Granted	1,794,906	3.93
Exercised	(184,360)	1.19
Forfeited	—	—
Options outstanding at September 30, 2021	<u>5,858,739</u>	4.03
Options exercisable at December 31, 2020	<u>2,355,900</u>	4.96
Options exercisable at September 30, 2021	<u>3,081,524</u>	4.58

As of September 30, 2021, the Company had \$6.5 million of unrecognized compensation expense related to unvested stock options, which is expected to be recognized over a weighted average period of 2.7 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 two to four years from the date of grant subject to the employees’ continuous service and subject to accelerated vesting in specified circumstances. The fair value of the RSUs granted is measured based on the market value of the Company’s common stock on the date of grant and is recognized ratably over the requisite service period, which is generally the vesting period of the awards.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Research and development	\$ 194	\$ 70	\$ 561	\$ 304
General and administrative	190	80	552	348
Total	<u>\$ 384</u>	<u>\$ 150</u>	<u>\$ 1,113</u>	<u>\$ 652</u>

The following table summarizes the activity related to RSUs during the nine months ended September 30, 2021:

	Number of Shares	Weighted Average Grant Date Fair Value
Non-vested RSUs outstanding at December 31, 2020	767,271	\$ 1.78
Granted	965,344	4.01
Vested	(415,268)	1.27
Non-vested RSUs outstanding at September 30, 2021	1,317,347	3.58

As of September 30, 2021, the Company had \$3.8 million of unrecognized compensation expense related to the RSUs which is expected to be recognized over a weighted average period of 3.1 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 September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Research and development	\$ 12	\$ 10	\$ 29	\$ 12
General and administrative	4	7	16	11
Total	\$ 16	\$ 17	\$ 45	\$ 23

During the nine months ended September 30, 2021, the Company issued 65,481 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):

	September 30, 2021
Operating lease right-of-use asset	\$ 412
Liabilities	
Current portion of operating lease liabilities	\$ 384
Operating lease liabilities	374
Total operating lease liabilities	\$ 758

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 September 30, 2021, the Company's weighted average discount rate was 11.0% and the weighted average lease term was 2.0 years.

Minimum lease payments were as follows at September 30, 2021 (in thousands):

Year Ending December 31,	
2021	\$ 99
2022	407
2023	316
Total minimum lease payments	822
Less imputed interest	(64)
Total operating lease liabilities	<u>\$ 758</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 September 30, 2021 and 2020, and \$185,000 for each of the nine months ended September 30, 2021 and 2020. Variable lease cost was \$24,000 for each of the three months ended September 30, 2021 and 2020, and \$71,000 for each of the nine months ended September 30, 2021 and 2020. Short-term lease cost was \$2,000 for each of the three months ended September 30, 2021 and 2020, respectively, and \$6,000 and \$10,000 for the nine months ended September 30, 2021 and 2020, respectively. Cash payments included in operating activities on the statement of cash flows for operating lease liabilities were \$293,000 and \$283,000 for the nine months ended September 30, 2021 and 2020, 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 with Bausch + Lomb, a division of Bausch Health Companies, Inc. ("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 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.

On April 27, 2020, the Company and Bausch entered into an amendment to the Company's License Agreement with Bausch dated October 22, 2019 (as amended, the "Bausch License Agreement").

Pursuant to the Bausch License Agreement, Bausch made an upfront payment of \$5.0 million (the "Upfront Payment") in October 2019. In October 2021, the FDA approved XIPERE. The Company is entitled to receive \$5.0 million from Bausch as a result of the approval. An additional payment of \$10.0 million is due upon completion of pre-launch activities for XIPERE. 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 expects to launch XIPERE in the United States in the first quarter of 2022.

The Bausch License Agreement will expire upon expiration of the royalty terms for all Products and countries in the Territory, with each royalty term for a given Product and country ending on the latest of (i) the date of expiration of the last-to-expire valid claim of any licensed patent rights covering such Product in such country in the Territory, (ii) the date of the loss of regulatory exclusivity for such Product in such country in the Territory, or (iii) ten years from the later of the first sale of such Product in such country in the Territory. Following the payment of the Pre-Launch Milestone Payments, Bausch may also terminate the Bausch License Agreement for convenience upon 180 days' written notice. In addition, the Company can terminate the Bausch License Agreement if Bausch commences a legal action challenging the validity, enforceability or scope of any of the licensed patents. Both parties may terminate the Bausch License Agreement (i) upon a material breach of the Bausch License Agreement, subject to a specified cure period and specified exceptions, or (ii) if the other party encounters bankruptcy or insolvency.

The Company was responsible for all development expenses for XIPERE in the Territory until the Company's New Drug Application ("NDA") was approved by the FDA, subject to specified exceptions, as well as manufacturing costs in connection with the NDA. The Company was also responsible for all clinical and development expenses conducted to satisfy the FDA's requests in the

complete response letter issued on October 18, 2019 related to the NDA and any subsequent complete response letter related to the NDA (the “CRL-related expenses”). Following FDA approval of XIPERE, Bausch is responsible for all such expenses.

Due to the refund provisions in the License Agreement, the upfront payment of \$5.0 million received from Bausch was included on the balance sheet as deferred revenue as of September 30, 2021 and December 31, 2020. The refund provisions lapsed upon FDA approval of XIPERE. The \$5.0 million will be recognized as revenue in the fourth quarter of 2021.

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 addition, Arctic Vision has agreed to pay up to \$31.5 million in development milestone payments for specified events, including \$4.0 million upon receipt of FDA approval of XIPERE in the United States and sales milestone payments for achievement of specified levels of net sales. 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 records certain financial assets and liabilities at fair value in accordance with the provisions of ASC Topic 820, *Fair Value Measurements and Disclosures*, on fair value measurements. As defined in the guidance, fair value, defined as an exit price, represents the amount that would be received to sell an asset or pay to transfer a liability in an orderly transaction between market participants. As a result, fair value is a market-based approach that should be determined based on assumptions that market participants would use in pricing an asset or a liability. As a basis for considering these assumptions, the guidance defines a three-tier value hierarchy that prioritizes the inputs used in the valuation methodologies in measuring fair value.

- Level 1—Unadjusted quoted prices in active, accessible markets for identical assets or liabilities.
- Level 2—Other inputs that are directly or indirectly observable in the marketplace.
- Level 3—Unobservable inputs that are supported by little or no market activity.

The fair value hierarchy also requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value.

The Company’s material financial instruments at September 30, 2021 and December 31, 2020 consisted primarily of cash and cash equivalents, and at December 31, 2020, also included long-term debt. The fair values of cash and cash equivalents, other current assets and accounts payable approximate their respective carrying values due to the short term nature of these instruments and are classified as Level 1 in the fair value hierarchy. The fair value of long-term debt approximates the carrying value due to variable interest rates that correspond to market rates and is classified as Level 1 in the fair value hierarchy.

There were no significant transfers between Levels 1, 2 and 3 during the nine months ended September 30, 2021 and the year ended December 31, 2020.

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 September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Outstanding stock options	5,858,739	4,249,443	5,858,739	4,249,443
Non-vested restricted stock units	1,317,347	861,025	1,317,347	861,025
Stock purchase warrants	29,796	29,796	29,796	29,796
	<u>7,205,882</u>	<u>5,140,264</u>	<u>7,205,882</u>	<u>5,140,264</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, 2020 appearing in our Annual Report on Form 10-K filed with the SEC on March 15, 2021.

Overview

We are a biopharmaceutical company focused on revolutionizing the delivery of therapies to the back of the eye through the suprachoroidal space (SCS[®]). Our 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. We are developing our own pipeline of small molecule product candidates for administration via our SCS Microinjector and strategically partner our SCS injection platform with companies utilizing other ophthalmic therapeutic innovations. 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.

We are leveraging our SCS injection platform by building an internal research and development pipeline targeting chorioretinal diseases and by creating external collaborations with other companies. Using our suprachoroidal injection technology in conjunction with proprietary formulations of existing drugs as well as novel therapies, we believe we have created a broad therapeutic platform for developing product candidates to treat serious back of the 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 injectable suspension)	Small Molecule	Wet AMD				
Integrin Inhibitor (Injectable suspension)	Small Molecule	Diabetic Macular Edema (DME)				
Gene Therapy	Non-Viral Vectors	"Therapeutic Biofactory" / Inherited Retinal Disease				

SCS Microinjector® Partner Programs						
PARTNER	THERAPEUTIC ENTITY	LICENSED INDICATION	IND-Enabling	PHASE 2	PHASE 3	NDA
REGENXBIO	AAV-based Gene Therapy	Wet AMD (AAVIATE)				
REGENXBIO	AAV-based Gene Therapy	Diabetic Retinopathy (ALTITUDE)				
AURA BIOSCIENCES	Viral-like Drug Conjugate	Ocular Oncology/Choroidal Melanoma				

XIPERE™ Commercial Partners							
PARTNER	THERAPEUTIC ENTITY	LICENSED TERRITORY	PRE-CLINICAL	PHASE 1	PHASE 2	PHASE 3	APPROVAL
BAUSCH HEALTH	Small Molecule	U.S. & Canada					
ARCTIC VISION	Small Molecule	Greater China, South Korea, ASEAN Countries, India, Australia, New Zealand					

XIPERE™ (triamcinolone acetonide injectable suspension), for suprachoroidal use has received U.S. FDA Approval

Internal Pipeline

Our first product, XIPERE, formerly known as CLS-TA, is a proprietary, preservative-free suspension of the corticosteroid triamcinolone acetonide, or TA, for administration via suprachoroidal injection. 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.

On October 25, 2021, we announced that the FDA approved XIPERE for the treatment of macular edema associated with uveitis. Uveitis is a set of ocular inflammatory conditions affecting approximately 350,000 patients in the United States and more than one million worldwide. Approximately one-third of uveitis patients develop uveitic macular edema, a build-up of fluid in the macula, the area of the retina responsible for sharp, straight-ahead vision. Macular edema is the leading cause of vision loss and blindness in uveitis patients and can occur from uveitis affecting any anatomic location—anterior, intermediate, posterior or panuveitis. The uveitis market is expected to grow to nearly \$550 million by 2024 in the United States, and over \$1 billion globally.

We are developing a proprietary suspension of axitinib, a tyrosine kinase inhibitor, or TKI, for suprachoroidal injection, which we refer to as CLS-AX. In our preclinical studies, administration of CLS-AX through suprachoroidal injection was well tolerated and showed durability over several months, providing us with the opportunity to potentially reduce treatment burden and address a primary need for neovascular age-related macular degeneration, or wet AMD, patients.

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 March 2021, we completed patient dosing in Cohort 1 of OASIS and in June 2021, reported that we achieved our safety and tolerability endpoints. In September 2021, we completed patient enrollment in Cohort 2 and expect to report data by the end of 2021. If the data from Cohort 2 are positive, we intend to continue the clinical trial with a dose escalation in Cohort 3. We have added a three-month extension study to follow Cohort 2 patients over a longer period of time.

We have initiated another small molecule program utilizing suprachoroidal administration of an integrin inhibitor suspension. 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. These studies are ongoing.

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 suprachoroidal suspension) in the United States and Canada.

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 Phase 2 clinical trials using our SCS Microinjector technology: the 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 reported positive initial data from both clinical trials in October 2021.

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. Aura has announced the randomized phase of the trial is planned to begin in the second half of 2022 and will serve as the first pivotal trial for the treatment of indeterminate lesions and choroidal melanoma.

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. In December 2020, Arctic Vision announced approval of its IND for a Phase 3 clinical trial of XIPERE in China and they expect to begin Phase 3 clinical trials later this year.

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.

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 \$200 million in potential future development and sales milestones, as well as 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 September 30, 2021, we had an accumulated deficit of \$274.2 million. We recorded net losses of \$4.9 million and \$2.4 million for the three months ended September 30, 2021 and 2020, respectively, and net losses of \$18.3 million and \$11.1 million for the nine months ended September 30, 2021 and 2020, 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 its 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 net losses 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. Our clinical trial expenses have decreased significantly following our decision to discontinue late-stage clinical trials of XIPERE for indications other than uveitis. However, we expect clinical trial expenses to increase in 2021 as a result of our Phase 1/2a clinical trial of CLS-AX. We also will continue our efforts to seek to discover, research and develop additional product candidates and seek regulatory approvals in additional regions for XIPERE for the treatment of macular edema associated with uveitis. Based on our current research and development plans and expected near-term partnership milestone payments, we expect to have sufficient resources to fund our planned operations into 2023.

Impact of COVID-19 on Our Business

We have been actively monitoring the novel coronavirus, or COVID-19, situation and its impact globally. Our financial results for the three and nine months ended September 30, 2021 were not significantly impacted by COVID-19, and we currently do not expect any material impact on our financial results for the remainder of 2021. We continue to operate normally with the exception of enabling our employees to work from home and abiding by travel restrictions issued by federal and local governments.

As the COVID-19 pandemic continues, we may experience other disruptions that could severely impact our business, results of operations and prospects. The extent to which COVID-19 may impact our business, preclinical development and clinical trials will depend on future developments, which are highly uncertain and cannot be predicted, such as the duration of the outbreak, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions, the effectiveness of actions taken in the United States and other countries to contain and treat the disease and the impact of new variants or mutations of the coronavirus, such as the Delta variant.

Components of Operating Results

Revenue

We have not generated any revenue from the sale of any drugs, and we do not expect to generate any product revenue unless or until XIPERE is commercialized by our licensees or we obtain regulatory approval of and commercialize our product candidates, either on our own or with a third party. Our revenue in recent periods 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 and nine months ended September 30, 2021 and 2020 (in thousands).

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
XIPERE (uveitis program)	\$ 771	\$ 781	\$ 2,646	\$ 2,048
CLS-AX (wet AMD program)	1,341	478	3,382	1,429
Total	2,112	1,259	6,028	3,477
Unallocated	3,035	2,231	8,669	7,124
Total research and development expense	\$ 5,147	\$ 3,490	\$ 14,697	\$ 10,601

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. 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 XIPERE or any of our product candidates that obtain regulatory approval.

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 XIPERE, our product candidates and the SCS Microinjector;
- 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 (Expense)

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 and short-term investments. Interest income is not considered significant to our financial statements.

Other expense consists of interest expense incurred under our loan agreements.

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 nine months ended September 30, 2021, there were no significant changes to our critical accounting policies disclosed in our audited financial statements for the year ended December 31, 2020, which are included in our Annual Report on Form 10-K, as filed with the SEC on March 15, 2021.

Results of Operations for the Three Months Ended September 30, 2021 and 2020

The following table sets forth our results of operations for the three months ended September 30, 2021 and 2020.

	Three Months Ended September 30,		Period-to-Period Change
	2021	2020	
	(in thousands)		
License and other revenue	\$ 3,074	\$ 3,432	\$ (358)
Operating expenses:			
Research and development	5,147	3,490	1,657
General and administrative	2,816	2,374	442
Total operating expenses	7,963	5,864	2,099
Loss from operations	(4,889)	(2,432)	(2,457)
Other income	2	—	2
Other expense	—	(1)	1
Net loss	\$ (4,887)	\$ (2,433)	\$ (2,454)

Revenue. In the three months ended September 30, 2021 and 2020, we recognized \$3.1 million and \$3.4 million, respectively, of revenue associated with our license agreements. License revenue for the three months ended September 30, 2021 was primarily a result of a milestone payments received from Arctic Vision. License revenue for the three months ended September 30, 2020 was primarily a result of a milestone payments received from REGENXBIO.

Research and development. Research and development expense increased by \$1.7 million, from \$3.5 million for the three months ended September 30, 2020 to \$5.1 million for the three months ended September 30, 2021. This increase was due to a \$0.9 million increase in costs for the for CLS-AX program, including costs for OASIS, a Phase 1/2a clinical trial of CLS-AX and a \$0.3 million increase in employee related costs. In addition, there was a \$0.3 million increase in costs in our other programs.

General and administrative. General and administrative expenses increased by \$0.4 million, from \$2.4 million for the three months ended September 30, 2020 to \$2.8 million for the three months ended September 30, 2021. This was primarily attributable to an increase in employee related costs.

Results of Operations for the Nine Months Ended September 30, 2021 and 2020

The following table sets forth our results of operations for the nine months ended September 30, 2021 and 2020.

	Nine Months Ended September 30,		Period-to-Period Change
	2021	2020	
	(in thousands)		
License and other revenue	\$ 3,888	\$ 7,883	\$ (3,995)
Operating expenses:			
Research and development	14,697	10,601	4,096
General and administrative	8,525	8,107	418
Total operating expenses	23,222	18,708	4,514
Loss from operations	(19,334)	(10,825)	(8,509)
Other income	1,001	—	1,001
Other expense	—	(273)	273
Net loss	\$ (18,333)	\$ (11,098)	\$ (7,235)

Revenue. In the nine months ended September 30, 2021 and 2020, we recognized \$3.9 million and \$7.9 million, respectively, of revenue associated with our license agreements. License revenue for the nine months ended September 30, 2021 was primarily a result of milestone payments of \$3.8 million received from Arctic Vision. License revenue for the nine months ended September 30, 2020 was primarily a result of milestone payments of \$4.3 million received from Arctic Vision and \$3.0 million received from REGENXBIO.

Research and development. Research and development expense increased by \$4.1 million, from \$10.6 million for the nine months ended September 30, 2020 to \$14.5 million for the nine months ended September 30, 2021. This increase was primarily due to a \$2.0 million increase in costs for the for CLS-AX program, including costs for OASIS, a Phase 1/2a clinical trial of CLS-AX, and a \$0.6 million increase in costs related drug manufacturing for XIPERE. In addition, employee related costs increased \$1.1 million during the same period.

General and administrative. General and administrative expenses increased by \$0.4 million for the nine months ended September 30, 2021 and 2020. This increase was primarily a result of a \$0.8 million increase in employee related costs, partially offset by a \$0.3 million decrease in patent costs and professional fees.

Other income. Other income for the nine months ended September 30, 2021 was primarily comprised of the gain on the extinguishment of debt from the forgiveness of the PPP Loan and accrued interest.

Other expense. Other expense for the nine months ended September 30, 2020 primarily consisted of interest on long-term debt, the amortization of financing costs, the accretion of warrants and the final payment related to our prior loan agreement.

Liquidity and Capital Resources

Sources of Liquidity

We have funded our operations primarily through the proceeds of public offerings of our common stock, sales of convertible preferred stock and the issuance of long-term debt. As of September 30, 2021, we had cash and cash equivalents of \$25.2 million. We invest any cash in excess of our immediate requirements primarily with a view to liquidity and capital preservation. As of September 30, 2021, 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, we entered into the Arctic License Agreement, pursuant to which Arctic Vision has agreed to pay us up to a total of \$35.5 million. This amount includes an upfront payment of \$4.0 million, which we received in March 2020, as well as an aggregate of up to \$31.5 million in potential development milestone payments for specified events, including \$4.0 million upon regulatory approval of XIPERE in the United States and potential sales milestone payments for achievement of specified levels of net

sales. 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 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 are entitled to receive \$5.0 million from Bausch within 30 days of FDA approval, and we are eligible to receive an additional \$10.0 million upon completion of pre-launch activities for XIPERE. Bausch expects to launch 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. During the nine months ended September 30, 2021, we sold 2.9 million shares of our common stock for net proceeds of \$12.2 million under the ATM agreement. As of September 30, 2021, 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.

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. 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 obtain FDA approval to market and then 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 or restructurings, or potentially entering into additional collaborations, partnerships and other strategic arrangements.

Based on our current plans and forecasted expenses, we expect that our cash and cash equivalents as of the filing date, November 10, 2021, will enable us to fund our planned operating expenses and capital expenditure requirements into 2023. This estimate assumes receipt of the \$9.0 million of milestone payments that we are entitled to receive from our licensees as a result of FDA approval of XIPERE. In addition, the estimate assumes receipt of the \$10.0 million milestone payment that we are entitled to receive from Bausch upon completion of pre-launch activities for XIPERE. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our capital resources sooner than we expect.

Cash Flows

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

	Nine Months Ended September 30,	
	2021	2020
Net cash (used in) provided by:		
Operating activities	\$ (15,787)	\$ (8,684)
Investing activities	—	(55)
Financing activities	23,617	983
Net change in cash and cash equivalents	<u>\$ 7,830</u>	<u>\$ (7,756)</u>

During the nine months ended September 30, 2021 and 2020, our operating activities used net cash of \$15.8 million and \$8.7 million, respectively. The use of cash in each period primarily resulted from our net losses. The increase in net loss to \$18.3 million for the nine months ended September 30, 2021 as compared to \$11.1 million for the nine months ended September 30, 2020 was primarily attributable to higher research and development expenses related to the preclinical and clinical CLS-AX program in the nine months ended September 30, 2021 and higher license revenue in the nine months ended September 30, 2020.

During the nine months ended September 30, 2020, our net cash used in investing activities was \$55,000, due to the purchase of equipment.

During the nine months ended September 30, 2021 our net cash provided by financing activities was \$23.6 million. This primarily consisted of \$11.1 million of net proceeds from the sale of shares of our common stock in a registered direct offering and \$12.2 million of net proceeds from the sale of shares of our common stock under the ATM agreement. During the nine months ended September 30, 2020, our net cash provided by financing activities consisted of \$5.1 million of net proceeds from the sale of shares of our common stock under the ATM agreement and \$1.0 million of proceeds from the PPP Loan, partially offset by a payment of \$5.3 million under our credit facility.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined under SEC rules.

Recent Accounting Pronouncements

See Item 1, “Financial Statements – Note 2, Significant Accounting Policies” for a discussion of recent accounting pronouncements and their effect on us.

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, 2021 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. However, we continue to monitor and assess the potential impact of the COVID-19 pandemic on our control environment.

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. 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, 2020, filed with the Securities and Exchange Commission on March 15, 2021. 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

Exhibit No.	Description
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>
10.1*#	<u>First Amendment to the License Agreement by and between the Registrant and Arctic Vision (Hong Kong) Limited, dated as of August 15, 2021.</u>
10.2*#	<u>Second Amendment to the License Agreement by and between the Registrant and Arctic Vision (Hong Kong) Limited, dated as of September 9, 2021.</u>
10.3*	<u>Second Amendment to the License Agreement by and between the Registrant and Bausch + Lomb Ireland Limited (as assignee of Bausch Health Ireland Limited), dated as of September 27, 2021.</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.

Pursuant to Item 601(b)(10) of Regulation S-K, certain confidential portions of this exhibit have been omitted by means of marking such portions with asterisks [***] as the identified confidential portions (i) are not material and (ii) the Registrant customarily and actually treats that information as private or confidential.

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 10, 2021

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

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.

AMENDMENT NO. 1 TO LICENSE AGREEMENT

This **AMENDMENT NO. 1 TO LICENSE AGREEMENT** (the “**Amendment**”) is effective as of August 15th, 2021 (the “**Amendment Effective Date**”) by and between **CLEARSIDE BIOMEDICAL, INC.**, with a principal place of business at 900 North Point Parkway, Suite 200, Alpharetta, Georgia 30005 United States of America (“**Clearside**”) and **ARCTIC VISION (HONG KONG) LIMITED**, with a principal place of business at 23/F Nan Fung Tower 88 Connaught Road C & 173 Des Voeux Road C, Central, Hong Kong (“**Arctic Vision**”), and solely with respect to **Section 5 (Guaranty)**, Arctic Vision (Cayman) Limited with a principal place of business at Cricket Square, Hutchins Drive, P.O. Box 2681, Grand Cayman KY1-1111 Cayman Islands (“**Arctic Vision Parent**”), and amends that certain License Agreement by and between Clearside and Arctic Vision, dated March 10, 2020 (the “**Agreement**”). Clearside and Arctic Vision may each be referred to individually as a “**Party**” and collectively as the “**Parties**”. Capitalized terms not expressly defined herein shall have the meaning set forth in the Agreement.

RECITALS

WHEREAS, pursuant to the Agreement, Clearside granted to Arctic Vision an exclusive license under Clearside Technology to Develop and Commercialize Licensed Products in the Field in the Territory, and Arctic Vision is obligated to use Commercially Reasonable Efforts to Develop and Commercialize Licensed Products in the Territory for use in an indication associated with uveitis;

WHEREAS, the Parties now desire to expand the Territory; and

WHEREAS, the Parties wish to amend the Agreement in accordance with Section 17.02 thereof.

NOW, THEREFORE, the Parties hereby agree to amend the terms of the Agreement as provided below, effective as of the Amendment Effective Date.

1.AMENDMENT TO SECTION 1.39. Section 1.39 of the Agreement is hereby amended and restated to read in its entirety as follows:

“ **Section 1.39 “Jurisdiction**” means each of the following: (i) Mainland China, (ii) Taiwan, (iii) Hong Kong, (iv) South Korea, (v) Macau, (vi) Brunei, (vii) Cambodia, (viii) India, (ix) Indonesia, (x) Laos, (xi) Malaysia, (xii) Myanmar, (xiii) the Philippines, (xiv) Singapore, (xv) Thailand, and (xvi) Vietnam.”

2.In partial consideration for expansion of the Territory pursuant to the Amendment, Arctic Vision shall pay Clearside:

(a) within [***] of the Amendment Effective Date, a one-time, non-refundable, non-creditable payment of One Million Five Hundred Thousand Dollars (\$1,500,000), by wire transfer; and

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(b) within [***] after the earlier of (1) [***] or (2) [***], in each case in any of [***], a one-time milestone payment of [***]. For clarity, this milestone payment of [***] shall only be payable once, even if [***] occurred or [***] was obtained in more than one of the aforementioned countries.

3.AMENDMENT TO SECTION 8.04(a)(ii). Section 8.04(a)(ii) of the Agreement is hereby amended and restated to read in its entirety as follows:

Milestone Event	Milestone Payment
[***]	[***]

4.EFFECT OF AMENDMENT. Except as amended herein, all other provisions of the Agreement shall remain unchanged and in full force and effect. If there is a conflict between the Agreement and this Amendment, the terms of this Amendment shall prevail solely with respect to the matters set forth in this Amendment.

5.COUNTERPARTS. This Amendment may be executed in counterparts, each such counterpart will be deemed an original agreement, but all such counterparts together will constitute one and the same instrument.

6.GUARANTY. Arctic Vision Parent irrevocably guarantees the performance of all obligations of Arctic Vision under this Amendment. Arctic Vision Parent may engage a qualified Third Party to perform any such obligations, provided that Arctic Vision Parent shall in any case remain responsible for such performance. Arctic Vision Parent acknowledges and agrees that this guarantee is full and unconditional, and no release of Arctic Vision's liabilities (other than in accordance with the terms of this Amendment), whether by decree in any bankruptcy proceeding or otherwise, will affect the continuing validity and enforceability of this guarantee. If and each time that Arctic Vision fails to make any undisputed payment when it is due under or pursuant to this Amendment, Arctic Vision Parent must at Clearside's request (without requiring Clearside first to take steps against Arctic Vision) pay directly to Clearside the relevant amount as if it were the principal obligor in respect of that amount.

7.PATENT RIGHTS AND TECHNOLOGY SHARING. The list of Patent Rights that are Controlled by Clearside as of the Amendment Effective Date and that Cover any Licensed Product, or its Development, Manufacture or Commercialization in the Field in any of (i) Brunei, (ii) Cambodia, (iii) India, (iv) Indonesia, (v) Laos, (vi) Malaysia, (vii) Myanmar, (viii) the Philippines, (ix) Singapore, (x) Thailand, or (xi) Vietnam, are attached hereto as Schedule A, and shall be appended to Exhibit A of the Agreement. The lists of documents attached hereto as Schedule B(i) and Schedule B(ii) shall be appended to Exhibit B(i) and Exhibit B(ii) of the Agreement, respectively.

[Signature Page to Follow]

IN WITNESS WHEREOF, the Parties have caused this Amendment to be executed as of the Amendment Effective Date.

CLEARSIDE BIOMEDICAL, INC.

By: /s/ George Lasezkay

Name: George Lasezkay

Title: Chief Executive Officer

ARCTIC VISION (HONG KONG) LIMITED

By: /s/ Hoi Ti Wu

Name: Hoi Ti Wu

Title: Chief Executive Officer

ARCTIC VISION CAYMAN LIMITED (solely for purposes of Section 6 (Guaranty))

By: /s/ Hoi Ti Wu

Name: Hoi Ti Wu

Title: Chief Executive Officer

Schedule A

[***]

Schedule B

[***]

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AMENDMENT NO. 2 TO LICENSE AGREEMENT

This **AMENDMENT NO. 2 TO LICENSE AGREEMENT** (the “**Amendment**”) is effective as of September 9th, 2021 (the “**Amendment Effective Date**”) by and between **CLEARSIDE BIOMEDICAL, INC.**, with a principal place of business at 900 North Point Parkway, Suite 200, Alpharetta, Georgia 30005 United States of America (“**Clearside**”) and **ARCTIC VISION (HONG KONG) LIMITED**, with a principal place of business at 23/F Nan Fung Tower 88 Connaught Road C & 173 Des Voeux Road C, Central, Hong Kong (“**Arctic Vision**”), and solely with respect to **Section 5 (Guaranty)**, Arctic Vision (Cayman) Limited with a principal place of business at Cricket Square, Hutchins Drive, P.O. Box 2681, Grand Cayman KY1-1111 Cayman Islands (“**Arctic Vision Parent**”), and amends that certain License Agreement by and between Clearside and Arctic Vision, dated March 10, 2020 as well as that certain Amendment No. 1 to the License Agreement, dated August 15, 2021 (collectively, the “**Agreement**”). Clearside and Arctic Vision may each be referred to individually as a “**Party**” and collectively as the “**Parties**”. Capitalized terms not expressly defined herein shall have the meaning set forth in the Agreement.

RECITALS

WHEREAS, pursuant to the Agreement, Clearside granted to Arctic Vision an exclusive license under Clearside Technology to Develop and Commercialize Licensed Products in the Field in the Territory, and Arctic Vision is obligated to use Commercially Reasonable Efforts to Develop and Commercialize Licensed Products in the Territory for use in an indication associated with uveitis;

WHEREAS, the Parties now desire to expand the Territory; and

WHEREAS, the Parties wish to amend the Agreement in accordance with Section 17.02 thereof.

NOW, THEREFORE, the Parties hereby agree to amend the terms of the Agreement as provided below, effective as of the Amendment Effective Date.

1.AMENDMENT TO SECTION 1.39. Section 1.39 of the Agreement is hereby amended and restated to read in its entirety as follows:

“ **Section 1.39 “Jurisdiction**” means each of the following: (i) Mainland China, (ii) Taiwan, (iii) Hong Kong, (iv) South Korea, (v) Macau, (vi) Brunei, (vii) Cambodia, (viii) India, (ix) Indonesia, (x) Laos, (xi) Malaysia, (xii) Myanmar, (xiii) the Philippines, (xiv) Singapore, (xv) Thailand, (xvi) Vietnam, (xvii) Australia, and (xviii) New Zealand.”

2.In partial consideration for expansion of the Territory pursuant to this Amendment, Arctic Vision shall pay Clearside:

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [*], HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.**

(a) within [***] of the Amendment Effective Date, a one-time, non-refundable, non-creditable payment of One Million Five Hundred Thousand Dollars (\$ 1,500,000), by wire transfer; and

(b) within [***] after the earlier of (1) [***] or (2) [***], in each case in any of (i) [***], a one-time milestone payment of [***]. For clarity, this milestone payment of [***] shall only be payable once, even if [***] occurred or [***] was obtained in [***].

3.EFFECT OF AMENDMENT. Except as amended herein, all other provisions of the Agreement shall remain unchanged and in full force and effect. If there is a conflict between the Agreement and this Amendment, the terms of this Amendment shall prevail solely with respect to the matters set forth in this Amendment.

4.COUNTERPARTS. This Amendment may be executed in counterparts, each such counterpart will be deemed an original agreement, but all such counterparts together will constitute one and the same instrument.

5.GUARANTY. Arctic Vision Parent irrevocably guarantees the performance of all obligations of Arctic Vision under this Amendment. Arctic Vision Parent may engage a qualified Third Party to perform any such obligations, provided that Arctic Vision Parent shall in any case remain responsible for such performance. Arctic Vision Parent acknowledges and agrees that this guarantee is full and unconditional, and no release of Arctic Vision's liabilities (other than in accordance with the terms of this Amendment), whether by decree in any bankruptcy proceeding or otherwise, will affect the continuing validity and enforceability of this guarantee. If and each time that Arctic Vision fails to make any undisputed payment when it is due under or pursuant to this Amendment, Arctic Vision Parent must at Clearside's request (without requiring Clearside first to take steps against Arctic Vision) pay directly to Clearside the relevant amount as if it were the principal obligor in respect of that amount.

6.PATENT RIGHTS AND TECHNOLOGY SHARING. The list of Patent Rights that are Controlled by Clearside as of the Amendment Effective Date and that Cover any Licensed Product, or its Development, Manufacture or Commercialization in the Field in any of (i) Australia or (ii) New Zealand, are attached hereto as Schedule A, and shall be appended to Exhibit A of the Agreement. The lists of documents attached hereto as Schedule B(i) and Schedule B(ii) shall be appended to Exhibit B(i) and Exhibit B(ii) of the Agreement, respectively.

[Signature Page to Follow]

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [*], HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.**

IN WITNESS WHEREOF, the Parties have caused this Amendment to be executed as of the Amendment Effective Date.

CLEARSIDE BIOMEDICAL, INC.

ARCTIC VISION (HONG KONG) LIMITED

By: /s/ George Lasezkay

By: /s/ Hoi Ti Wu

Name: George Lasezkay

Name: Hoi Ti Wu

Title: Chief Executive Officer

Title: Chief Executive Officer

ARCTIC VISION CAYMAN LIMITED (solely for purposes of Section 5 (Guaranty))

By: /s/ Hoi Ti Wu

Name: Hoi Ti Wu

Title: Chief Executive Officer

Schedule A

[***]

Schedule B

[***]

SECOND AMENDMENT TO LICENSE AGREEMENT

This Second Amendment to License Agreement (the “**Second Amendment**”), effective as of September 27, 2021 (the “**Second Amendment Effective Date**”) by and between Bausch + Lomb Ireland Limited (as assignee of Bausch Health Ireland Limited) (“**Bausch**”) and Clearside Biomedical, Inc. (“**Clearside**”), amends that certain License Agreement, dated October 22, 2019, by and between Bausch Health and Clearside, as amended by the First Amendment to License Agreement dated as of April 27, 2020 (Collectively, the “**Agreement**”). Each of Bausch and Clearside shall be referred to herein individually as a “**Party**” and collectively as the “**Parties**.”

NOW, THEREFORE, in consideration of the mutual promises set forth herein, the Parties hereby agree as follows:

ARTICLE I. AMENDMENTS

1. Article 1 of the Agreement is hereby amended to add the following new definition:

“**Licensed Domain Names**” means xipere.com and xipere.ca.”

2. The definition of “Licensed IP” is hereby amended to add “Licensed Domain Names” and, as a result, Section 1.61 is hereby deleted in its entirety and replaced with the following:

“**Licensed IP**” means the Licensed Know-How, Licensed Marks, Licensed Patents and Licensed Domain Names.”

3. The following shall be added to the Agreement as new Section 7.8:

“7.8 **Licensed Domain Names.** Bausch shall have the exclusive right, but not the obligation, to use the Licensed Domain Names in connection with the Development and Commercialization of Products in the Field in the Territory; provided that, in its sole discretion, Bausch may also use other domain names in connection with such Development and Commercialization of Products in the Field in the Territory. Clearside shall maintain the registrations for the Licensed Domain Names, at Clearside’s cost and expense, and shall own all rights in and to all Licensed Domain Names; provided that, Bausch shall have the responsibility (but not the obligation) to develop any websites and related content in connection with the Licensed Domain Names and Bausch shall own any and all intellectual property and other rights in and to such websites and contents. Bausch Health shall own all rights in and to all other domain names (other than the Licensed Domain Names) used in the Development and Commercialization of the Products in the Field in the Territory and shall register and maintain such domain names, at Bausch Health’s cost and expense. Notwithstanding Section 2.3, Clearside represents and warrants that it has not granted, and covenants that it shall not grant during the Term, any rights in or to the Licensed Domain Names (or their registrations) to any Third

Party, including for use outside the Territory or outside the Field, and Clearside further covenants that, during the Term, Clearside itself shall not use or otherwise exploit the Licensed Domain Names (or their registrations) to Develop or Manufacture the Products for use outside the Territory or otherwise outside the scope of the license granted to Bausch Health under Section 2.1. Upon the termination or expiration of the Agreement in its entirety, Clearside shall retain all rights to the Licensed Domain Names and the registrations thereto and Bausch shall have no rights therein; provided, however, that Bausch shall retain ownership of any websites and their contents (and any rights thereto) associated with the Licensed Domain Names.”

ARTICLE II. MISCELLANEOUS

1. Capitalized terms not defined herein shall have the same meanings as set forth in the Agreement.
2. Except as set forth herein, all other terms and conditions of the Agreement shall remain in full force and effect.
3. This Second Amendment may be signed in counterparts, each of which shall be an original, with the same effect as if the signatures were upon the same instrument. This Second Amendment shall become binding when each Party shall have received a counterpart of such agreement signed by the other Parties.

[signature page follows]

THIS SECOND AMENDMENT TO LICENSE AGREEMENT IS EXECUTED by the authorized representatives of the Parties as of the Second Amendment Effective Date.

CLEARSIDE BIOMEDICAL, INC. BAUSCH + LOMB IRELAND LIMITED

Signature: /s/ George Lasezkay

Signature: /s/ Roger McGrath

Name: George Lasezkay

Name: Roger McGrath

Title: CEO

Title: Director

Date: September 27, 2021

Date: September 28, 2021

**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, 2021 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 10, 2021

/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, 2021 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 10, 2021

/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, 2021, 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 10th day of November, 2021.

/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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