

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, 2019

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 checked="" type="checkbox"/>
Non-accelerated filer	<input 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 4, 2019, the registrant had 41,149,781 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, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	\$ 22,551	\$ 8,043
Short-term investments	—	32,835
Prepaid expenses	1,468	2,049
Other current assets	27	17
Total current assets	24,046	42,944
Property and equipment, net	655	790
Operating lease right-of-use asset	806	—
Restricted cash	360	360
Other assets	—	26
Total assets	\$ 25,867	\$ 44,120
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 1,429	\$ 6,869
Accrued liabilities	2,698	2,923
Current portion of long-term debt	5,833	556
Current portion of operating lease liabilities	483	—
Current portion of deferred rent	—	128
Other current liabilities	375	—
Total current liabilities	10,818	10,476
Long-term debt	4,329	9,419
Operating lease liabilities	961	—
Deferred rent	—	605
Total liabilities	16,108	20,500
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.001 par value; 10,000,000 shares authorized and no shares issued at September 30, 2019 and December 31, 2018	—	—
Common stock, \$0.001 par value; 100,000,000 shares authorized at September 30, 2019 and December 31, 2018; 41,149,781 and 32,119,227 shares issued and outstanding at September 30, 2019 and December 31, 2018, respectively	41	32
Additional paid-in capital	244,279	230,475
Accumulated deficit	(234,561)	(206,887)
Total stockholders' equity	9,759	23,620
Total liabilities and stockholders' equity	\$ 25,867	\$ 44,120

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,	
	2019	2018	2019	2018
Collaboration revenue	\$ 141	\$ —	\$ 231	\$ —
Operating expenses:				
Research and development	2,728	20,083	14,353	50,805
General and administrative	3,781	3,873	13,169	10,508
Total operating expenses	<u>6,509</u>	<u>23,956</u>	<u>27,522</u>	<u>61,313</u>
Loss from operations	(6,368)	(23,956)	(27,291)	(61,313)
Other (expense) income, net	(168)	84	(383)	133
Net loss	<u>\$ (6,536)</u>	<u>\$ (23,872)</u>	<u>\$ (27,674)</u>	<u>\$ (61,180)</u>
Net loss per share of common stock — basic and diluted	<u>\$ (0.17)</u>	<u>\$ (0.75)</u>	<u>\$ (0.75)</u>	<u>\$ (2.02)</u>
Weighted average shares outstanding — basic and diluted	<u>38,414,751</u>	<u>32,024,223</u>	<u>36,747,314</u>	<u>30,292,909</u>

See accompanying notes to the financial statements.

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

	Three and Nine Months Ended September 30, 2019				
	Common Stock		Additional Paid-In-Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance at December 31, 2018	32,119,227	\$ 32	\$ 230,475	\$ (206,887)	\$ 23,620
Issuance of common shares from at-the-market sales agreement	4,660,966	5	6,622	—	6,627
Exercise of stock options	2,727	—	1	—	1
Share-based compensation expense	—	—	1,247	—	1,247
Net loss	—	—	—	(15,404)	(15,404)
Balance at March 31, 2019	36,782,920	37	238,345	(222,291)	16,091
Issuance of common shares from at-the-market sales agreement	945,974	1	1,272	—	1,273
Issuance of common shares under employee stock purchase plan	17,252	—	15	—	15
Share-based compensation expense	—	—	1,256	—	1,256
Net loss	—	—	—	(5,734)	(5,734)
Balance at June 30, 2019	37,746,146	38	240,888	(228,025)	12,901
Issuance of common shares from at-the-market sales agreement	3,370,000	3	2,416	—	2,419
Exercise of stock options	13,635	—	5	—	5
Vesting of restricted stock units	20,000	—	—	—	—
Share-based compensation	—	—	970	—	970
Net loss	—	—	—	(6,536)	(6,536)
Balance at September 30, 2019	41,149,781	\$ 41	\$ 244,279	\$ (234,561)	\$ 9,759

	Three and Nine Months Ended September 30, 2018					
	Common Stock		Additional Paid-In-Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2017	25,354,651	\$ 25	\$ 145,618	\$ (124,220)	\$ (8)	\$ 21,415
Cumulative effect of accounting change	—	—	—	151	8	159
Issuance of common shares from follow-on public offering	6,538,462	7	79,574	—	—	79,581
Exercise of stock options	53,920	—	237	—	—	237
Share-based compensation expense	—	—	1,138	—	—	1,138
Net loss	—	—	—	(16,607)	—	(16,607)
Balance at March 31, 2018	31,947,033	32	226,567	(140,676)	—	85,923
Issuance of common shares under employee stock purchase plan	7,386	—	45	—	—	45
Exercise of stock options	69,804	—	196	—	—	196
Share-based compensation expense	—	—	1,199	—	—	1,199
Net loss	—	—	—	(20,701)	—	(20,701)
Balance at June 30, 2018	32,024,223	32	228,007	(161,377)	—	66,662
Share-based compensation	—	—	1,286	—	—	1,286
Net loss	—	—	—	(23,872)	—	(23,872)
Balance at September 30, 2018	32,024,223	\$ 32	\$ 229,293	\$ (185,249)	\$ —	\$ 44,076

See accompanying notes to the financial statements.

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

	Nine Months Ended September 30,	
	2019	2018
Operating activities		
Net loss	\$ (27,674)	\$ (61,180)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	160	141
Share-based compensation expense	3,473	3,623
Non-cash interest expense	141	107
Accretion of debt discount	46	95
Amortization and accretion on available-for-sale investments, net	(115)	(514)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	571	(1,686)
Other assets and liabilities	306	(81)
Accounts payable and accrued liabilities	(5,665)	4,554
Net cash used in operating activities	(28,757)	(54,941)
Investing activities		
Maturities of available-for-sale investments	32,950	59,970
Purchase of available-for-sale investments	—	(80,137)
Acquisition of property and equipment	(25)	(34)
Net cash provided by (used in) investing activities	32,925	(20,201)
Financing activities		
Proceeds from at-the-market sales agreement, net of issuance costs	10,319	—
Proceeds from follow-on public offering, net of issuance costs	—	79,581
Proceeds from exercise of stock options	6	433
Proceeds from shares issued under employee stock purchase plan	15	45
Proceeds from long-term debt	—	10,000
Payments made on long-term debt	—	(8,300)
Net cash provided by financing activities	10,340	81,759
Net increase in cash, cash equivalents and restricted cash	14,508	6,617
Cash, cash equivalents and restricted cash, beginning of period	8,403	9,584
Cash, cash equivalents and restricted cash, end of period	\$ 22,911	\$ 16,201

Reconciliation of cash, cash equivalents and restricted cash:

	September 30,	
	2019	2018
Cash and cash equivalents	\$ 22,551	\$ 15,841
Restricted cash	360	360
Cash, cash equivalents and restricted cash at end of period	\$ 22,911	\$ 16,201

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 clinical biopharmaceutical company developing first-in-class pharmacological therapies to restore and preserve vision for people with serious eye diseases. The Company’s current product candidates focus on treatments for diseases affecting the retina and choroid and are injected into the suprachoroidal space (“SCS”) using its proprietary SCS Microinjector™. 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 receives regulatory approval of and successfully commercializes its product candidates. 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, 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 has funded its operations primarily through the sale of convertible preferred stock and common stock and the issuance of long-term debt. On June 30, 2017, the Company entered into an at-the-market sales agreement (“the ATM agreement”) with Cowen and Company LLC (“Cowen”) under which the Company may offer and sell, from time to time at its sole discretion, shares of its common stock having an aggregate offering price of up to \$50.0 million through Cowen acting as sales agent. During the nine months ended September 30, 2019, the Company sold 9.0 million shares of its common stock for net proceeds of \$10.3 million under the ATM agreement. The Company’s registration statement on Form S-3 contemplated under the ATM agreement was declared effective by the SEC on July 13, 2017. The registration statement on Form S-3 includes a prospectus supplement covering the offering up to \$18.5 million of shares of common stock over the 12 months ending March 15, 2020 in accordance with the ATM agreement.

On October 22, 2019, the Company entered into a License Agreement (the “License Agreement”) with Bausch Health Ireland Limited (“Bausch”). Under the License Agreement, the Company has granted an exclusive license to Bausch for the commercialization and development of XIPERE™, the Company’s proprietary suspension of the corticosteroid triamcinolone acetonide formulated for administration to the back of the eye, in the United States and Canada. Under the License Agreement, the Company received an upfront payment of \$5.0 million (see Note 13 *Subsequent Events*).

In connection with the entry by the Company into the License Agreement, on October 18, 2019, the Company entered into a Third Amendment to Second Amended and Restated Loan and Security Agreement (the “3rd Amendment”) with Silicon Valley Bank (“SVB”). Pursuant to the 3rd Amendment, the Company repaid \$5.0 million of the outstanding principal balance of the \$10.0 million term loan. In addition, the Company agreed that if the Company’s cash and cash equivalents balance with SVB falls below \$10.0 million, then the Company will transfer to a pledged account an amount of cash and cash equivalents equal to the sum of the then-outstanding principal balance of the term loan plus an amount for a final payment fee of \$340,441 (see Note 5 *Long-Term Debt*).

The Company will need to obtain additional resources to fund future operations, including to conduct additional clinical trials and to complete the development of its product candidates. If any such products were to receive regulatory approval, the Company may need to prepare for the potential commercialization of its product candidates, which could include additional collaborations with third parties for the commercial launch of the products.

The Company had cash and cash equivalents of \$22.6 million as of September 30, 2019. 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 obtain approval from the U.S. Food and Drug Administration (the “FDA”) to market and then generate significant revenue from any of its product candidates. 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. The Company will need additional resources to fund its operations and may finance future cash needs through public or private equity offerings, license agreements, debt financings, collaborations, strategic alliances and marketing or distribution arrangements.

Based on its current license agreements, research and development plans and forecasted expenses, the Company expects that its existing cash and cash equivalents as of the filing date, November 8, 2019, will enable it to fund its operating expenses and capital expenditure requirements into the third quarter of 2020. The Company's ability to fund its operations into the third quarter of 2020 gives effect to the potential restriction of cash pursuant to the Second Amended and Restated Loan and Security Agreement, as amended by the 3rd Amendment. These conditions raise substantial doubt about the Company's ability to continue as a going concern within one year after the date these financial statements are being issued. Accordingly, the Company has plans to mitigate its going concern risk by raising additional capital, potentially in a combination of equity or debt financings, license agreements or by potentially entering into additional collaborations, partnering and other strategic arrangements. The Company has based this estimate on assumptions that may prove to be wrong, and the Company could exhaust its capital resources sooner than it expects.

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

2. Significant Accounting Policies

Basis of Presentation

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, 2019, statements of operations for the three and nine months ended September 30, 2019 and 2018, statements of stockholders' equity for the three and nine months ended September 30, 2019 and 2018 and statements of cash flows for the nine months ended September 30, 2019 and 2018 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, 2019, its results of its operations for the three and nine months ended September 30, 2019 and 2018, its changes in stockholders' equity for the three and nine months ended September 30, 2019 and 2018 and its cash flows for the nine months ended September 30, 2019 and 2018. The financial data and other information disclosed in these notes related to the three and nine months ended September 30, 2019 and 2018 are unaudited. The results for the nine months ended September 30, 2019 are not indicative of results to be expected for the year ending December 31, 2019, 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, 2018.

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 the accounting for useful lives to calculate depreciation and amortization, clinical expense accruals, share-based compensation expense and income tax valuation allowance. Actual results could differ from these estimates.

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 clinical trials and preclinical studies;
- costs associated with nonclinical 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.

Short-Term Investments

Short-term investments are investments with original maturities of between 90 and 365 days when purchased and are comprised of commercial paper and treasury bills. The Company classifies its short-term investments as available-for-sale securities. Short-term investments are recorded at fair value and unrealized gains and losses are recorded within interest income. In addition, the Company evaluates the short-investments with unrealized losses to determine whether such losses are other-than-temporary.

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

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

Recent Accounting Pronouncements

In February 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2016-02, *Leases (ASC 842)*, and subsequently issued updates as part of ASU 2018-11, *Leases, Targeted Improvements*. The new guidance requires organizations that lease assets with lease terms of more than 12 months to recognize assets and liabilities for the rights and obligations created by those leases on their balance sheets. The Company adopted the ASC 842 effective January 1, 2019 using the optional transition method, did not restate any prior periods and adopted the package of practical expedients. Under the package of practical expedients permitted by the new standard, the Company does not have to reassess whether any expired contracts are or contain leases, the classification of leases or whether initial direct costs should be capitalized. The adoption of the new standard resulted in the recognition of a right-of use asset of \$1.0 million and lease obligations of \$1.7 million on the Company's balance sheet as of January 1, 2019. The adoption did not have a material impact on the Company's statements of operations or cash flows.

In June 2018, the FASB issued ASU 2018-07, *Compensation-Stock Compensation: Improvements to Nonemployee Shared-Based Payment Accounting*. The ASU update expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. The Company adopted ASU 2018-07 effective January 1, 2019, 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, 2019	December 31, 2018
Furniture and fixtures	5	\$ 400	\$ 382
Machinery and equipment	5	121	121
Computer equipment	3	19	19
Leasehold improvements	Lesser of useful life or remaining lease term	684	677
		1,224	1,199
Less: Accumulated depreciation		(569)	(409)
		<u>\$ 655</u>	<u>\$ 790</u>

4. Accrued Liabilities

Accrued liabilities consisted of the following (in thousands):

	September 30, 2019	December 31, 2018
Accrued research and development	\$ 403	\$ 1,263
Accrued employee costs	1,950	1,191
Accrued marketing	31	47
Accrued professional fees	178	63
Accrued interest payable	—	76
Accrued expense	136	283
	<u>\$ 2,698</u>	<u>\$ 2,923</u>

5. Long-Term Debt

Loan and Security Agreements

In September 2016, the Company entered into an amended and restated loan and security agreement, which was subsequently amended on October 31, 2017 (as amended, the "1st A&R loan agreement") with SVB, MidCap Funding XII Trust and MidCap Financial Trust, which amended and restated in its entirety the Company's prior loan and security agreement. The 1st A&R loan agreement provided for new term loans of up to \$15.0 million, with a floating interest rate equal to 7% plus the greater of (i) the 30-day U.S. LIBOR, as reported in the Wall Street Journal on the last business day of the month that immediately precedes the month in which the interest will accrue, or (ii) 0.50%.

Under the terms of the 1st A&R loan agreement, an initial tranche of \$8.0 million was advanced on September 28, 2016. The draw period for the remaining \$7.0 million available under the 1st A&R loan agreement expired on March 31, 2018. The Company was required to pay accrued interest only on the outstanding \$8.0 million balance through December 31, 2017, followed by 30 equal payments of principal and accrued interest. The Company had the option to prepay the outstanding balance of the term loans in full, subject to a prepayment fee of 2% of the original principal amount of the aggregate term loans for any prepayments through May 31, 2020. A final payment of \$0.5 million was due at maturity of the loan on June 1, 2020, or upon the prepayment of the facility or the acceleration of amounts due under the facility as a result of an event of default, and was being accreted in long-term debt over the life of the loan. Of the \$8.0 million borrowed, \$5.3 million was used to repay all amounts outstanding under the original loan agreement.

Closing costs incurred in the refinancing portion of the loan were recorded as expense while the financing costs for the new portion of the loan are recorded in long-term debt and being accreted over the life of the loan. Upon repayment of the original loan agreement, all remaining closing costs associated with the original loan agreement were being accreted to long-term debt over the life of the 1st A&R loan agreement.

On May 14, 2018, the Company entered into a second amended and restated loan and security agreement (the “2nd A&R Loan Agreement”) with SVB, MidCap Funding III Trust and MidCap Financial Trust (together, “MidCap” and collectively with SVB, the “Lenders”), which amended and restated in its entirety the 1st A&R loan agreement. The 2nd A&R Loan Agreement provided for new term loans of up to \$20.0 million, with a floating interest rate equal to 6.50% plus the greater of (i) the 30-day U.S. LIBOR, as reported in the Wall Street Journal on the last business day of the month that immediately precedes the month in which the interest will accrue, or (ii) 1.89%. The 2nd A&R Loan Agreement includes, among other things, the ability of the Lenders to accelerate the payment of the term loan in the event of material adverse change and restrictions on the Company’s ability to sell, assign, license, transfer or otherwise dispose of its assets, including intellectual property assets, without the prior written consent of the Lenders.

The Company borrowed an initial tranche of \$10.0 million on May 14, 2018, of which \$7.0 million was used to repay all amounts outstanding under the 1st A&R loan agreement, including fees associated with the final payment. The prepayment fees were waived. Of the remaining \$10.0 million under the 2nd A&R Loan Agreement, \$5.0 million became available for draw but was not drawn by the Company, and the other \$5.0 million is not available for draw.

As of September 30, 2019, the Company was required to pay accrued interest only on the \$10 million borrowed under the 2nd A&R Loan Agreement through October 31, 2019, followed by consecutive equal monthly payments of principal and interest in arrears continuing through the maturity date of October 1, 2022. The Company had the option to prepay the outstanding balance in full, subject to a prepayment fee of 2% of the original principal amount for any prepayment prior to October 1, 2022. A final payment of 5.50% of the aggregate borrowed amount was due at maturity of the loan on October 1, 2022, or upon the prepayment of the facility or the acceleration of amounts due under the facility as a result of an event of default.

The borrowings under the 2nd A&R Loan Agreement are secured by substantially all of the Company’s assets.

On October 18, 2019, the Company entered into the 3rd Amendment with the Lenders. Pursuant to the 3rd Amendment, the Company repaid \$5.0 million of the outstanding principal balance of the \$10.0 million term loan. The Company did not pay any final payment or termination fees in connection with the \$5.0 million prepayment. In addition, the Company and the Lenders agreed to modify the term loan repayment schedule. As amended, the term loan repayment schedule provides for interest only payments through April 30, 2020, or if the Company completes a specified financial milestone, October 31, 2020, followed by consecutive equal monthly payments of principal and interest in arrears continuing through the maturity date of October 1, 2022. In addition, the Company agreed that if the Company’s cash and cash equivalents balance with SVB falls below \$10.0 million, the Company will transfer to a pledged account an amount of cash and cash equivalents equal to the sum of the then-outstanding principal balance of the term loan plus a final payment fee of \$340,441. As a result of the 3rd Amendment, as of September 30, 2019, the Company has reflected in current liabilities the amount of principal it expects to pay within the next 12 months.

Interest expense on the borrowings under the loan agreements described above was \$223,000 and \$220,000 for the three months ended September 30, 2019 and 2018, respectively, and \$676,000 and \$566,000 for the nine months ended September 30, 2019 and 2018, respectively. Accretion of the scheduled final payment was \$47,000 for each of the three months ended September 30, 2019 and 2018, and \$141,000 and \$107,000 for the nine months ended September 30, 2019 and 2018, respectively. Accretion of the deferred debt issuance costs was \$16,000 for each of the three months ended September 30, 2019 and 2018, and \$47,000 and \$95,000 for the nine months ended September 30, 2019 and 2018, respectively.

As of September 30, 2019, the scheduled payments for the 2nd A&R Loan Agreement, as amended, and the scheduled final payment in 2022, were as follows (in thousands):

Year Ending December 31,	Principal	Interest and Final Payment	Total
2019	\$ 5,000	\$ 107	\$ 5,107
2020	1,333	392	1,725
2021	2,000	234	2,234
2022	1,667	405	2,072
	<u>\$ 10,000</u>	<u>\$ 1,138</u>	<u>\$ 11,138</u>

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, 2019 and December 31, 2018, there were 41,149,781 and 32,119,227 shares of common stock outstanding, respectively.

7. Stock Purchase Warrants

In September 2016, in connection with the 1st A&R loan agreement (see Note 5 *Long-Term Debt*), 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 7.00 years as of September 30, 2019.

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,	
	2019	2018	2019	2018
Research and development	\$ 243	\$ 491	\$ 1,066	\$ 1,365
General and administrative	543	791	2,166	2,246
Total	<u>\$ 786</u>	<u>\$ 1,282</u>	<u>\$ 3,232</u>	<u>\$ 3,611</u>

The following table summarizes the activity related to stock options during the nine months ended September 30, 2019:

	Number of Shares	Weighted Average Exercise Price
Options outstanding at December 31, 2018	3,463,096	\$ 6.62
Granted	1,892,600	1.26
Exercised	(16,362)	0.40
Forfeited	(1,146,450)	5.00
Options outstanding at September 30, 2019	<u>4,192,884</u>	4.67
Options exercisable at December 31, 2018	<u>1,583,749</u>	5.63
Options exercisable at September 30, 2019	<u>2,204,649</u>	5.61

As of September 30, 2019, the Company had \$5.0 million of unrecognized compensation expense related to unvested stock options, which is expected to be recognized over a weighted average period of 2.4 years.

Restricted Stock Units

The Company has granted restricted stock units (“RSUs”) to employees from the 2016 Plan. The shares underlying the RSU awards have vesting terms of eight months to two 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 following table summarizes the activity related to RSUs during the nine months ended September 30, 2019:

	Number of Shares	Weighted Average Exercise Price
Non-vested RSUs outstanding at December 31, 2018	—	\$ —
Granted	1,339,300	0.88
Vested	(20,000)	1.09
Non-vested RSUs outstanding at September 30, 2019	<u>1,319,300</u>	0.88

The Company recorded \$45,000 and \$0.2 million of share-based compensation expense for the three and nine months ended September 30, 2019, respectively, for the RSUs. As of September 30, 2019, the Company had \$1.0 million of unrecognized compensation expense related to the RSUs, which is expected to be recognized over a weighted average period of 1.4 years.

Employee Stock Purchase Plan

In January 2016, the Company’s board of directors adopted and approved, and in January 2016 the Company’s stockholders approved, the Clearside Biomedical, Inc. 2016 Employee Stock Purchase Plan (the “2016 ESPP”) which became effective on June 1, 2016. The first offering period for the 2016 ESPP commenced January 1, 2017. 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 Company has issued a total of 39,539 shares of common stock purchased under the 2016 ESPP. The Company has recorded \$2,000 and \$4,000 of share-based compensation expense for the three months ended September 30, 2019 and 2018, respectively, and \$15,000 and \$12,000 for the nine months ended September 30, 2019 and 2018, respectively, in the statements of operations for the estimated number of shares to be purchased on the next purchase date following the conclusion of the applicable reporting period.

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 relocated to this space in March 2017.

In August 2018, the Company signed an office lease agreement to lease approximately 3,500 square feet of office space in Berkeley, California for its commercial operations. The lease agreement is for a two-year term with a renewal option for an additional one-year term. The Company has determined that it will not exercise the renewal option for the Berkeley lease. Rental payments are \$12,775 per month subject to a 3% increase per year. Rent expense under this lease is recognized on a straight-line basis over the term of the lease. The Company will pay a 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, 2019
Operating lease right-of-use asset	\$ 806
Liabilities	
Current portion of operating lease liabilities	\$ 483
Operating lease liabilities	961
Total operating lease liabilities	\$ 1,444

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, 2019, the Company's weighted average discount rate was 5.3% and the weighted average lease term was 2.4 years.

Total future undiscounted minimum lease payments were as follows at September 30, 2019 (in thousands):

Year Ending December 31,	
2019	\$ 157
2020	574
2021	496
2022	511
2023	393
Total minimum lease payments	\$ 2,131

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

Rent expense was \$100,000 and \$79,000 for the three months ended September 30, 2019 and 2018, respectively, and \$300,000 and \$195,000 for the nine months ended September 30, 2019 and 2018, respectively. Cash payments included in operating activities on the statement of cash flows for operating lease liabilities were \$386,000 for the nine months ended September 30, 2019.

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. Collaboration Agreements

The Company has periodically entered into other short-term collaboration agreements, generally with performance obligations of one to two months, 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 collaboration agreements are recognized as revenue over the term of the agreement. The Company recorded \$141,000 and \$231,000 of revenue from these collaboration agreements during the three and nine months ended September 30, 2019, respectively. In addition, the Company recorded \$0.4 million of deferred revenue in other current liabilities from these collaboration agreements as of September 30, 2019.

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, 2019 and December 31, 2018 consisted primarily of cash and cash equivalents, short-term investments and 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. The Company has determined its short-term investments, comprised of commercial paper, to be Level 2 in the fair value hierarchy. The fair value was determined using a market approach, based on prices and other relevant information generated by market transactions involving similar assets. The short-term investments consist of investments with original maturity dates from date of acquisition of 90 to 365 days and are classified as available-for-sale.

There were no significant transfers between Levels 1, 2 and 3 during the nine months ended September 30, 2019 and the year ended December 31, 2018.

The following tables summarize the fair value of financial assets that are measured at fair value and the classification by level of input within the fair value hierarchy (in thousands):

	September 30, 2019			Recorded Value
	Level 1	Level 2	Level 3	
Financial Assets:				
Cash and money markets	\$ 22,551	\$ —	\$ —	\$ 22,551
Restricted cash money market	360	—	—	360
Total financial assets	<u>\$ 22,911</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 22,911</u>
	December 31, 2018			
	Level 1	Level 2	Level 3	Recorded Value
Financial Assets:				
Cash and money markets	\$ 8,042	\$ —	\$ —	\$ 8,042
Restricted cash money market	360	—	—	360
Treasury bills	7,490	—	—	7,490
Commercial paper	—	25,346	—	25,346
Total financial assets	<u>\$ 15,892</u>	<u>\$ 25,346</u>	<u>\$ —</u>	<u>\$ 41,238</u>

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 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,	
	2019	2018	2019	2018
Outstanding stock options	4,192,884	3,220,500	4,192,884	3,220,500
Non-vested restricted stock units	1,319,300	—	1,319,300	—
Stock purchase warrants	29,796	29,796	29,796	29,796
	<u>5,541,980</u>	<u>3,250,296</u>	<u>5,541,980</u>	<u>3,250,296</u>

13. Subsequent Events

License Agreement

On October 22, 2019, the Company entered into the License Agreement with Bausch. Pursuant to the 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 microneedle (the "Device"), as well as specified other steroids, corticosteroids and NSAIDs in combination with the Device ("Other Products"), subject to specified exceptions, in the United States and Canada for the treatment of ophthalmology indications, including non-infectious uveitis.

Pursuant to the License Agreement, Bausch made an upfront payment of \$5.0 million, which is subject to a refund if the License Agreement is terminated in specified circumstances. In addition, Bausch has agreed to make additional payments of up to \$15.0 million upon the achievement of specified pre-launch development and regulatory milestones and up to an aggregate of \$56.0 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 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 the achievement of certain annual net sales thresholds in the United States and Canada, as well as a lower royalty on annual net sales of Other Products, in each case subject to reductions in specified circumstances; provided that the Company will not receive any royalties on the first \$30.0 million of cumulative net sales of all products.

The Company is responsible for all development expenses for XIPERE until the Company's New Drug Application ("NDA") for XIPERE is approved by the FDA, subject to specified exceptions, as well as manufacturing costs in connection with the NDA. The Company is 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"). If XIPERE is approved by the FDA, Bausch will be responsible for all expenses following such approval; provided that the Company will be responsible for the CRL-related expenses and for one-half of the costs of any post-approval clinical trials required by the FDA, up to a specified maximum amount.

Amendments to Loan and Security Agreement

On October 18, 2019, the Company entered into a 3rd Amendment with its Lenders. Pursuant to the 3rd Amendment, among other things, the Company repaid \$5.0 million of the outstanding principal balance of its \$10.0 million term loan on October 18, 2019. In addition, the Company agreed that if the Company's cash and cash equivalents balance with SVB falls below \$10.0 million, then the Company will transfer to a pledged account an amount of cash and cash equivalents equal to the sum of the then-outstanding principal balance of the term loan plus an amount for a final payment fee of \$340,441 (see Note 5 *Long-Term Debt*).

On October 18, 2019, the Company entered into a Consent and Fourth Amendment to the 2nd A&R Loan Agreement (the “4th Amendment”) with SVB. Pursuant to the 4th Amendment, among other things, SVB consented to the Company’s entry into the License Agreement.

Option and License Agreement

On August 29, 2019, the Company entered into an option and license agreement with REGENXBIO, Inc. (“REGENXBIO”) pursuant to which the Company granted REGENXBIO an exclusive option to enter into a commercial license agreement (the “Option”) granting REGENXBIO an exclusive, worldwide and sublicensable license to the Company’s SCS Microinjector for the delivery of adeno-associated virus-based gene therapies for the treatment of wet age-related macular degeneration, diabetic retinopathy and other conditions for which anti-vascular endothelial growth factor treatment is currently the standard of care. REGENXBIO exercised the Option on October 29, 2019 and has agreed to pay the Company an option fee equal to \$2.0 million, less a credit of \$0.5 million previously received under a technology access agreement, within 30 days. In addition, REGENXBIO has agreed to pay the Company up to an aggregate of \$34.0 million in milestone payments upon the achievement of specified development milestones and up to an aggregate of \$102.0 million in sales-based milestone payments, as well as mid-single digit royalties on net sales of products using the SCS Microinjector during the royalty term.

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, particularly in Part II – Item 1A, "Risk Factors". Statements made herein are as of the date of the filing of this Form 10-Q with the SEC and should not be relied upon as of any subsequent date. Unless otherwise required by applicable law, we do not undertake, and we specifically disclaim, any obligation to update any forward-looking statements to reflect occurrences, developments, unanticipated events or circumstances after the date of such statement.

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited financial statements and related notes that appear in Item 1 of this Quarterly Report on Form 10-Q and with our audited financial statements and related notes for the year ended December 31, 2018 appearing in our Annual Report on Form 10-K filed with the SEC on March 15, 2019.

Overview

We are a clinical biopharmaceutical company developing first-in-class pharmacological therapies to restore and preserve vision for people with serious eye diseases. Our current product candidates focus on diseases affecting the retina, which is the tissue that lines the inside of the eye and is primarily responsible for vision, and the choroid, which is the layer adjacent to the retina that supplies the retina with blood, oxygen and nourishment.

Our suprachoroidal injection platform is a novel, patented non-surgical approach for delivering pharmacotherapy to the back of the eye in the anatomic structure known as the suprachoroidal space, or SCS. The elasticity of the SCS allows for migration when fluid is injected between the choroid and sclera and allows the fluid to spread spherically toward the posterior regions of the eye where it is absorbed into adjacent tissue. We are able to precisely administer drugs into the SCS with our proprietary microinjector that utilizes a needle that is approximately 1 millimeter in length.

Our suprachoroidal injection technology is used in conjunction with our proprietary formulations of existing drugs and novel therapies to create a therapeutic platform of product candidates to treat several serious eye diseases. Our lead product candidate, XIPERE, is a proprietary, preservative-free suspension of the corticosteroid triamcinolone acetonide formulated for administration via suprachoroidal injection. Based in part on the positive results from our Phase 3 PEACHTREE clinical trial, in December 2018, we submitted a New Drug Application, or NDA, to the U.S. Food and Drug Administration, or FDA, for XIPERE for the treatment of macular edema associated with uveitis. On February 19, 2019 we received notification from the FDA that it had accepted the XIPERE NDA for review and had determined that the application was sufficiently complete to permit a substantive review. On October 18, 2019, we received a Complete Response Letter, or CRL, from the FDA regarding the NDA for XIPERE. As part of the complete NDA review, the FDA did not identify any efficacy issues, and there were no requests for further clinical efficacy studies. As anticipated, the CRL included the FDA's request for additional stability data and reinspection of the drug product manufacturer to resolve the FDA's prior observations. The CRL included one new request for additional data on clinical use of the final to-be-marketed SCS Microinjector™ delivery system. We currently expect that this device use assessment will be conducted by at least three physicians in 30 patients, per the FDA's request. We believe that these recommendations cited in the CRL can be addressed in a timely manner that will enable us to resubmit the NDA in the first quarter of 2020. We expect the Prescription Drug User Fee Act, or PDUFA, goal date for the resubmitted NDA will be six months from the FDA's receipt of the resubmission. We will be requesting a meeting with the FDA to discuss and confirm our plans for addressing the recommendations contained in the CRL.

On October 22, 2019, we entered into an exclusive license agreement with Bausch Health Ireland Limited, or Bausch, for the commercialization and development of XIPERE in the United States and Canada, or the License Agreement. Pursuant to the License Agreement, Bausch paid us an upfront payment of \$5.0 million, which is subject to a refund if the License Agreement is terminated in specified circumstances. In addition, Bausch has agreed to make additional payments of up to \$15.0 million upon the achievement of specified pre-launch development and regulatory milestones and up to an aggregate of \$56.0 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 License Agreement). Further, during the applicable royalty term, we 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 United States and Canada, as well as a lower royalty on annual net sales of other products, in each case subject to reductions in specified circumstances; provided that we will not receive any royalties on the first \$30.0 million of cumulative net sales of all products.

We intend to continue discussions with potential collaborators for the commercialization and development of XIPERE in other countries around the world.

On August 29, 2019, we entered into an option and license agreement with REGENXBIO, Inc., or REGENXBIO, pursuant to which we granted REGENXBIO an exclusive option, or the Option, to enter into a commercial license agreement granting REGENXBIO an exclusive, worldwide and sublicensable license to our SCS Microinjector for the delivery of adeno-associated virus-based gene therapies for the treatment of wet age-related macular degeneration, diabetic retinopathy and other conditions for which anti-vascular endothelial growth factor, or anti-VEGF treatment is currently the standard of care. REGENXBIO exercised the Option on October 29, 2019 and has agreed to pay us an option fee equal to \$2.0 million, less a credit of \$0.5 million previously received under a technology access agreement, within 30 days. In addition, REGENXBIO has agreed to make additional payments to us of up to an aggregate of \$34.0 million upon the achievement of specified development milestones and up to \$102.0 million in sales-based milestone payments, as well as mid-single digit royalties on net sales of products using the SCS Microinjector during the royalty term.

In the last several months, our research and development team has performed additional analyses on our proprietary suprachoroidal suspension of axitinib, or CLS-AX, an inhibitor of vascular endothelial growth factor receptor-1, -2 and -3 which may benefit patients who sub-optimally respond to current anti-VEGF therapies. In preclinical testing, we observed the potential for durability benefits which may maintain visual gains and reduce treatment burden in patients with angiogenic retinal diseases. We are advancing CLS-AX as our lead internal development asset and expect to submit an Investigational New Drug application for CLS-AX in mid-2020.

We have incurred net losses since our inception in May 2011. Our operations to date have been limited to organizing and staffing our company, raising capital, undertaking preclinical studies and other research and development initiatives, conducting clinical trials and preparing to commercialize XIPERE for the treatment of macular edema associated with uveitis, prior to entering into the License Agreement with Bausch as described above. To date, we have not generated any revenue, other than license and collaboration 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, 2019, we had an accumulated deficit of \$234.6 million. We recorded net losses of \$6.5 million and \$23.9 million for the three months ended September 30, 2019 and 2018, respectively, and net losses of \$27.7 million and \$61.2 million for the nine months ended September 30, 2019 and 2018, respectively. We anticipate that a substantial portion of our capital resources and efforts in the foreseeable future will be focused on completing the necessary clinical development of, and obtaining regulatory approval of, our product candidates.

We expect to continue to incur significant operating losses at least for the next several years. We do not expect to generate product or license and collaboration revenue unless and until we successfully complete necessary development of, obtain regulatory approval for and successfully commercialize one or more of our 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 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 plans and forecasted expenses, we expect that our existing cash and cash equivalents as of the filing date, November 8, 2019, will enable us to fund our operating expenses and capital expenditure requirements into the third quarter of 2020. Our ability to fund our operations into the third quarter of 2020 gives effect to the potential restriction of cash pursuant to the Loan Agreement, as amended by the 3rd Amendment (each as defined below). This expectation does not give effect to any additional development milestone payments we might receive in connection with our license agreements for XIPERE or any other future license or collaboration agreement.

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 revenue unless or until we obtain regulatory approval of and commercialize our product candidates, either on our own or with a third party.

We have periodically entered into short-term collaboration agreements, generally with performance obligations of one to two months, to evaluate the potential use of our proprietary SCS Microinjector with third-party product candidates for the treatment of

various diseases. Funds received from these collaboration agreements are recognized as revenue generally over the term of the agreement or upon completion of performance obligations within the agreement.

Research and Development

Since our inception, we have focused on our development programs. 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. The costs for some of our development activities, such as clinical trials, 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, such as manufacturing and stability and toxicology studies, that are supportive of a product candidate itself, are classified as direct preclinical costs. Expenses related to clinical trials and similar activities, including costs associated with CROs, are classified as direct clinical costs. Unallocated costs are expenses related to preclinical activities and activities that support more than one development program such as salaries, share-based compensation and depreciation.

For the three and nine months ended September 30, 2018, substantially all of our research and development expenses were related to the preclinical and clinical development of our product candidate.

The following table shows our research and development expenses by program, including those that have been discontinued, for the three and nine months ended September 30, 2019 and 2018 (in thousands).

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
XIPERE (uveitis program)	\$ 427	\$ 2,068	\$ 2,129	\$ 6,649
XIPERE (RVO program)	118	14,148	4,298	33,001
XIPERE (DME program)	3	419	(133)	2,675
Total	548	16,635	6,294	42,325
Unallocated	2,180	3,448	8,059	8,480
Total research and development expense	<u>\$ 2,728</u>	<u>\$ 20,083</u>	<u>\$ 14,353</u>	<u>\$ 50,805</u>

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.

During the nine months ended September 30, 2019, we recorded all estimated remaining accrued expenses reported by our CRO in connection with the termination of our development program for retinal vein occlusion, or RVO.

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 any of our product candidates that obtain regulatory approval. We may never succeed in achieving regulatory approval for any of our product candidates.

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

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

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

General and Administrative

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

Other Income (Expense)

Other income consists of 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 primarily consists of interest expense under our loan agreements for the three and nine months ended September 30, 2019 and 2018.

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, 2019, there were no significant changes to our critical accounting policies disclosed in our audited financial statements for the year ended December 31, 2018, which are included in our Annual Report on Form 10-K, as filed with the SEC on March 15, 2019, other than our adoption of ASU 2016-02, *Leases*, as described in Note 2 to our financial statements included in this report.

Results of Operations for the Three Months Ended September 30, 2019 and 2018

The following table sets forth our results of operations for the three months ended September 30, 2019 and 2018.

	Three Months Ended September 30,		Period-to-Period Change
	2019	2018	
	(in thousands)		
Collaboration revenue	\$ 141	\$ —	\$ 141
Operating expenses:			
Research and development	2,728	20,083	(17,355)
General and administrative	3,781	3,873	(92)
Total operating expenses	6,509	23,956	(17,447)
Loss from operations	(6,368)	(23,956)	17,588
Other (expense) income, net	(168)	84	(252)
Net loss	\$ (6,536)	\$ (23,872)	\$ 17,336

Revenue. In the three months ended September 30, 2019, we recognized \$141,000 of revenue associated with collaboration agreements to evaluate the potential use of our proprietary SCS Microinjector with third-party product candidates for the treatment of various diseases.

Research and development. Research and development expense decreased by \$17.4 million, from \$20.1 million for the three months ended September 30, 2018 to \$2.7 million for the three months ended September 30, 2019. This was primarily attributable to a \$14.0 million decrease due to closing down two late-stage clinical trials, SAPPHIRE and TOPAZ, that were part of our RVO program. Additionally, there was a \$1.0 million decrease due to the completion of the PEACHTREE trial during the first quarter of 2018, a \$0.4 million decrease in costs related to our DME program, as the TYBEE trial was completed in the second quarter of 2018, a \$0.5 million decrease in regulatory expenses as the NDA submission for XIPERE was completed in the fourth quarter of 2018, a \$0.6 million decrease in costs related to device and drug manufacturing and a \$0.5 million decrease in employee related costs.

General and administrative. General and administrative expenses decreased by \$92,000, from \$3.9 million for the three months ended September 30, 2018 to \$3.8 million for the three months ended September 30, 2019. This was primarily attributable to a decrease of \$0.4 million in marketing-related expenses related to the change of our business strategy to seek partners for XIPERE rather than commercialize XIPERE on our own and a decrease of \$0.2 million in patent-related expenses offset by increases of \$0.4 million in professional fees and \$0.2 million in directors and officers insurance premiums.

Other (expense) income, net. Other (expense) income, net for each of the three months ended September 30, 2019 and 2018 primarily consisted of interest on long-term debt, the amortization of financing costs, the accretion of warrants and the final payment related to our loan agreements, offset in part by interest income from our short-term investments. The decline from 2018 to 2019 was

the result of higher interest income on short-term investment balances following our public offering of common stock in the first quarter of 2018, which balances decreased over time.

Results of Operations for the Nine Months Ended September 30, 2019 and 2018

The following table sets forth our results of operations for the nine months ended September 30, 2019 and 2018.

	Nine Months Ended September 30,		Period-to-Period Change
	2019	2018	
	(in thousands)		
Collaboration revenue	\$ 231	\$ —	\$ 231
Operating expenses:			
Research and development	14,353	50,805	(36,452)
General and administrative	13,169	10,508	2,661
Total operating expenses	27,522	61,313	(33,791)
Loss from operations	(27,291)	(61,313)	34,022
Other (expense) income, net	(383)	133	(516)
Net loss	\$ (27,674)	\$ (61,180)	\$ 33,506

Revenue. In the nine months ended September 30, 2019, we recognized \$231,000 of revenue associated with collaboration agreements to evaluate the potential use of our proprietary SCS Microinjector with third-party product candidates for the treatment of various diseases.

Research and development. Research and development expense decreased by \$36.5 million, from \$50.8 million for the nine months ended September 30, 2018 to \$14.4 million for the nine months ended September 30, 2019. This was primarily attributable to a \$28.7 million decrease due to closing down the SAPPHIRE and TOPAZ trials, including the one-time credit of \$2.6 million upon reconciliation of final trial costs. Additionally, there was a \$4.5 million decrease due to the completion of the PEACHTREE trial during the first quarter of 2018, a \$2.8 million decrease in costs related to our DME program, as the TYBEE trial was completed in the second quarter of 2018, and a \$0.9 million decrease in regulatory expenses as the NDA submission for XIPERE was completed in the fourth quarter of 2018. These decreases were partially offset by a \$0.6 million increase in employee-related costs and a \$0.6 million increase in nonclinical activities.

General and administrative. General and administrative expenses increased by \$2.7 million, from \$10.5 million for the nine months ended September 30, 2018 to \$13.2 million for the nine months ended September 30, 2019. The increase was primarily attributable to a \$1.8 million increase in employee-related costs, including accrued expenses related to the resignation of our former CEO, and an increase of \$0.5 million in marketing-related expenses as we prepared for the potential commercialization of XIPERE.

Other (expense) income, net. Other (expense) income, net for each of the nine-month periods ended September 30, 2019 and 2018 primarily consisted of interest on long-term debt, the amortization of financing costs, the accretion of warrants and the final payment related to our loan agreements, offset in part by interest income from our short-term investments. The decline from 2018 to 2019 was the result of higher interest income on short-term investment balances following our public offering of common stock in the first quarter of 2018, which balances decreased over time.

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, 2019, we had cash and cash equivalents of \$22.6 million. On October 22, 2019, we entered into the License Agreement with Bausch, pursuant to which we received an upfront payment of \$5.0 million, which is subject to a refund if the License Agreement is terminated in specified circumstances. On October 29, 2019, REGENXBIO exercised the Option and has agreed to pay us an option fee equal to \$2.0 million, less a credit of \$0.5 million previously received under a technology access agreement, within 30 days. We invest any cash in excess of our immediate requirements primarily with a view to liquidity and capital preservation. As of September 30, 2019, our funds were held in cash and money market funds.

On June 30, 2017, we 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, 2019, we sold 9.0 million shares of our common stock for net proceeds of \$10.3 million under the ATM agreement. Our registration statement on Form S-3 contemplated under the ATM agreement was declared effective by the SEC on July 13, 2017. The registration statement on Form S-3 includes a prospectus supplement covering the offering up to \$18.5 million of shares of common stock over the 12 months ending March 15, 2020 in accordance with the ATM agreement.

On September 28, 2016, we entered into an amended and restated loan and security agreement with Silicon Valley Bank, or SVB, and entities affiliated with MidCap Financial Services, which we refer to collectively with SVB as the Lenders. The amended and restated loan and security agreement provided for new term loans of up to \$15.0 million, with a floating interest rate equal to 7% plus the greater of (i) the 30-day U.S. LIBOR, as reported in the Wall Street Journal on the last business day of the month that immediately preceded the month in which the interest was to accrue, or (ii) 0.50%. We borrowed an initial tranche of \$8.0 million on September 28, 2016, of which \$5.3 million was used to repay all amounts outstanding under our prior loan agreement with SVB. The draw period for the remaining \$7.0 million available under the amended and restated loan and security agreement expired on March 31, 2018. In connection with the amended and restated loan and security agreement, we issued warrants to the Lenders 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 our company, and are immediately exercisable.

On May 14, 2018, we entered into a second amended and restated loan and security agreement with the Lenders, or the Loan Agreement, which amended and restated in its entirety the prior amended and restated loan and security agreement with the Lenders. The Loan Agreement provides for new term loans of up to \$20.0 million, with a floating interest rate equal to 6.5% plus the greater of (i) the 30-day U.S. LIBOR, as reported in the Wall Street Journal on the last business day of the month that immediately precedes the month in which the interest will accrue or (ii) 1.89%.

We borrowed an initial tranche of \$10.0 million on May 14, 2018, of which \$7.0 million was used to repay all amounts outstanding under the amended and restated loan and security agreement, including the fees payable in connection with the final payment. The prepayment fees were waived. Of the remaining \$10.0 million, \$5.0 million became available but we elected not to draw it, and the other \$5.0 million did not become available for draw. On October 18, 2019, we entered into a third amendment to the Loan Agreement, or the 3rd Amendment, with our Lenders. Under the 3rd Amendment, among other things, we repaid \$5.0 million of the outstanding principal balance of the \$10.0 million term loan on October 18, 2019. We did not pay any final payment or termination fees in connection with the \$5.0 million prepayment.

Under the Loan Agreement, as amended, we are required to pay accrued interest only on the \$5.0 million remaining outstanding balance through April 30, 2020, or if we complete a specified financial milestone, October 31, 2020, followed by consecutive equal monthly payments of principal and interest in arrears continuing through the maturity date of October 1, 2022. We have the option to prepay the outstanding balance in full, subject to a prepayment fee of 2% of the original principal amount for any prepayment prior to October 1, 2022. A final payment of 5.50% of the aggregate borrowed amount is due at maturity of the loan on October 1, 2022, or upon the prepayment of the facility or the acceleration of amounts due under the facility as a result of an event of default. In addition, we agreed that if our cash and cash equivalents balance with SVB falls below \$10.0 million, we will transfer to a pledged account an amount of cash and cash equivalents equal to the sum of the then-outstanding principal balance of the term loan plus a final payment fee of \$340,441.

The amounts due under the Loan Agreement are secured by substantially all of our assets.

Funding Requirements

Our primary uses of capital are, and we expect will continue to be, compensation and related expenses, ongoing costs related to our NDA submission for XIPERE, 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 remainder of the development of XIPERE 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 agreements with Bausch and REGENXBIO, 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. 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, 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 revenue from XIPERE. We will need additional financing to fund our operations. These conditions raise substantial doubt about our ability to continue as a going concern within one year after the date of this report. We have plans to mitigate this going concern risk, which primarily consist of raising additional capital, potentially in a combination of equity or debt financings, or potentially entering into additional collaborations, partnerships and other strategic arrangements.

Based on our current plans and forecasted expenses, we expect that our existing cash and cash equivalents as of the filing date, November 8, 2019, will enable us to fund our operating expenses and capital expenditure requirements into the third quarter of 2020. Our ability to fund our operations into the third quarter of 2020 gives effect to the potential restriction of cash pursuant to the Loan Agreement, as amended, by the 3rd Amendment. This expectation does not give effect to any additional development milestone payments we might receive under the agreements with Bausch or REGENXBIO or in connection with any other potential license or collaboration agreement for XIPERE or any future product candidates. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our capital resources sooner than we expect.

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

Cash Flows

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

	Nine Months Ended September 30,	
	2019	2018
Net cash (used in) provided by:		
Operating activities	\$ (28,757)	\$ (54,941)
Investing activities	32,925	(20,201)
Financing activities	10,340	81,759
Net change in cash and cash equivalents	<u>\$ 14,508</u>	<u>\$ 6,617</u>

During the nine months ended September 30, 2019 and 2018, our operating activities used net cash of \$28.8 million and \$54.9 million, respectively. The use of cash in each period primarily resulted from our net losses, offset in part by non-cash share-based compensation expense. The decrease in net loss for the nine months ended September 30, 2019 as compared to the nine months ended September 30, 2018 was primarily attributable to lower research and development expenses as a result of the completion of the PEACHTREE and TYBEE trials in the prior year and the discontinuation of the SAPPHIRE and TOPAZ trials, partially offset by increased commercialization activities related to XIPERE. The nine months ended September 30, 2019 also included a net cash outflow of \$5.4 million from the decrease in our accounts payable balance, which was the result of payments we made in connection with winding down the clinical trials.

During the nine months ended September 30, 2019, our net cash provided by investing activities was \$32.9 million and was due to maturities of short-term, available-for-sale investments. During the nine months ended September 30, 2018, our net cash used in investing activities was \$20.2 million and was due to the net amount of purchases and maturities of short-term, available-for-sale investments.

During the nine months ended September 30, 2019 and 2018, our net cash provided by financing activities was \$10.3 million and \$81.8 million, respectively. The net cash provided by financing activities for the nine months ended September 30, 2019 was comprised of net proceeds of \$10.3 million from the sales of shares of common stock under the ATM agreement. The net cash provided by financing activities for the nine months ended September 30, 2018 was comprised of the net proceeds of \$79.6 million received from our March 2018 public offering of common stock, the net proceeds of \$10.0 million from the second amended and restated loan and security agreement and \$0.4 million of proceeds from the exercise of stock options, offset in part by \$8.3 million paid to satisfy our obligations under the prior loan agreement.

Contractual Obligations

As of September 30, 2019, there were no significant changes to our contractual obligations, other than the Loan Agreement, as amended (see Note 5 *Long-Term Debt*), from those presented as of December 31, 2018 in our Annual Report on Form 10-K.

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.

JOBS Act

We are an “emerging growth company,” as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. Section 107(b) of the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. Thus, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this extended transition period, and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

The market risk inherent in our financial instruments and in our financial position represents the potential loss arising from adverse changes in interest rates. As of September 30, 2019 and December 31, 2018, we had cash and cash equivalents of \$22.6 million and \$8.0 million, respectively. We generally hold our cash in interest-bearing money market accounts. As of September 30, 2019, we had no short-term investments and as of December 31, 2018, we had short-term investments of \$32.8 million. The short-term investments included commercial paper and treasury bills. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. Due to the short-term maturities of our cash equivalents and short-term investments and the low risk profile of our investments, an immediate 100 basis point change in interest rates would not have a material effect on the fair market value of our cash equivalents and short-term investments.

We do not engage in any hedging activities against changes in interest rates. Our outstanding debt instruments carried a floating interest rate that is 6.5% plus the greater of (i) the 30-day U.S. LIBOR, reported in the Wall Street Journal on the last business day of the month that immediately precedes the month in which the interest will accrue or (ii) 1.89%. We estimate that a one percentage point increase in the applicable interest rate under our loan agreements would have resulted in a \$75,000 and \$100,000 increase in interest expense for the nine months ended September 30, 2019 and the year ended December 31, 2018, respectively.

We do not have any foreign currency or other material derivative financial instruments.

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 Controls over Financial Reporting

There has been no change in our internal control over financial reporting during the quarter ended September 30, 2019 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 1. Legal Proceedings

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

Item 1A. Risk Factors

Our business is subject to risks and events that, if they occur, could adversely affect our financial condition and results of operations and the trading price of our securities. 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, 2018, filed with the Securities and Exchange Commission on March 15, 2019. Except as described below, there have been no material changes to the risk factors described in that report.

In light of our receipt of a CRL from the FDA regarding our NDA for XIPERE, the U.S. regulatory requirements and timing for XIPERE approval are uncertain, and we may never obtain regulatory approval in the United States.

In December 2018, we submitted an NDA to the FDA for XIPERE for the treatment of macular edema associated with uveitis. The NDA was accepted for review by the FDA in February 2019, and a PDUFA goal date was assigned for October 19, 2019. In August 2019, we announced that the FDA requested certain items related to chemistry, manufacturing and controls and that we expected to receive a CRL from the FDA. On October 18, 2019, the FDA issued a CRL regarding the NDA, indicating that their review was complete and the NDA was not ready for approval in its present form. As a result, the approval of our NDA for XIPERE has been delayed and may never occur.

In its CRL, the FDA requested additional stability data for the triamcinolone acetonide suspension, reinspection of the drug manufacturer and additional data on clinical use of the final to-be-marketed SCS Microinjector™ delivery system. We [intend to request] [have requested] a meeting with the FDA to discuss and confirm our plans for addressing the recommendations contained in the CRL. While we believe that the recommendations cited in the CRL can be addressed in a timely manner that will enable us to resubmit the NDA in the first quarter of 2020, we cannot predict the outcome of any interactions with the FDA nor can we guarantee when, or if, we will be successful in receiving regulatory approval for XIPERE.

The U.S. regulatory requirements and timing for XIPERE approval are uncertain at this time, and we may never obtain regulatory approval of XIPERE or any of our other product candidates in the United States. If we do not obtain approval for XIPERE or are delayed in obtaining such approval, it would have a material adverse effect on our operations and financial condition.

We have granted an exclusive license to Bausch for the commercialization and development of XIPERE in the United States and Canada, and we intend to seek one or more partners for the commercialization of XIPERE in other jurisdictions around the world. If we are unable to secure additional commercialization partners, or if our partners fail to successfully commercialize XIPERE in their respective markets, our business and prospects will be materially harmed.

Our business prospects and our ability to generate product revenue related to XIPERE, if any, will be heavily dependent on the efforts of third parties with whom we have entered, or will enter, into arrangements to perform sales, marketing and distribution services for XIPERE in the United States and internationally. For instance, we have granted an exclusive license to Bausch for the commercialization and development of XIPERE in the United States and Canada. Pursuant to our agreement with Bausch, we are entitled to receive payments based on the achievement of specified sales and regulatory milestones and tiered royalties based on annual net sales of XIPERE. The successful or timely achievement of many of these milestones is outside of our control because the relevant activities will be conducted by Bausch. We expect to depend to a large degree on the payments from Bausch and future potential commercialization partners in order to fund our operations, and a failure to receive such payments may cause us to:

- delay, reduce or terminate certain research and development programs;
- reduce headcount;
- pursue the raising of additional funds through equity or convertible debt financings that could be dilutive to our stockholders;

- seek funds by entering into agreements that require us to assign rights to technologies or products that we would have otherwise retained;
- enter into new arrangements that may be less favorable than those we would have obtained under different circumstances; or
- consider strategic transactions or engaging in a joint venture with a third party.

We intend to enter into similar arrangements with third parties for the commercialization of XIPERE in other jurisdictions outside of the United States and Canada. We may be unsuccessful in entering into such commercialization arrangements with third parties or may be unable to do so on terms that are favorable to us. Our product revenue related to XIPERE, if any, or the profitability of such product revenue, may be lower, perhaps substantially lower, than if we directly marketed and sold XIPERE. Such revenue will be heavily dependent on the commercialization efforts of our partners, and we may have little or no control over such third parties. Any disputes with our commercialization partners concerning the adequacy of their efforts will substantially divert the attention of our senior management from other business activities and will require us to incur substantial legal costs to fund litigation or arbitration proceedings. If we are unable to establish licensing or collaboration arrangements with additional partners or if our partners fail to exercise commercially reasonable efforts to market and sell XIPERE in their respective licensed jurisdictions or are otherwise ineffective in doing so, our business will be materially harmed, and we may not be able to adequately remedy the harm through negotiation, litigation, arbitration or termination of the commercialization agreements.

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

Our common stock is currently listed on The Nasdaq Global Market. To maintain the listing of our common stock on The Nasdaq Global Market, we are required to meet certain listing requirements, including, among others, either: (i) a minimum closing bid price of \$1.00 per share, a market value of publicly held shares (excluding shares held by our executive officers, directors and 10% or more stockholders) of at least \$5 million and stockholders' equity of at least \$10 million; or (ii) a minimum closing bid price of \$1.00 per share, a market value of publicly held shares (excluding shares held by our executive officers, directors, affiliates and 10% or more stockholders) of at least \$15 million and a total market value of listed securities of at least \$50.0 million.

On October 4, 2019, we received a notice, or the Notice, from the Nasdaq Listing Qualifications Staff that we were not in compliance with Nasdaq Listing Rule 5550(a)(2), or the Rule, as the closing bid price of our common stock was below \$1.00 for the prior 30 consecutive business days. In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we have a period of 180 calendar days from the Notice, or until April 1, 2020, to regain compliance with the Rule. To regain compliance, the closing bid price of our common stock must be at least \$1.00 for a minimum of ten consecutive business days before April 1, 2020. If we do not regain compliance with the Rule during the compliance period, our common stock will be subject to delisting, at which time we may appeal any delisting determination. In addition to our failure to meet the minimum bid price requirement, our stockholders' equity as of September 30, 2019 was below \$10 million.

We may fail to regain compliance with the Rule or to satisfy one or more additional Nasdaq Global Market requirements for continued listing of our common stock in the future. There can be no assurance that we will be successful in maintaining the listing of our common stock on the Nasdaq Global Market, or, if transferred, on the Nasdaq Capital Market. This could impair the liquidity and market price of our common stock. In addition, the delisting of our common stock from a national exchange could have a material adverse effect on our ability to access the capital markets, and any limitation on market liquidity or reduction in the price of our common stock as a result of that delisting could adversely affect our ability to raise capital on terms acceptable to us, or at all.

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

(a) Sales of Unregistered Securities

None.

Item 5. Other Information

On November 8, 2019, we entered into a settlement agreement with NovaMedica LLC, or NovaMedica, to terminate our licensing agreement dated August 29, 2014. Pursuant to the settlement agreement, we and NovaMedica agreed to terminate the licensing agreement, effective immediately, and NovaMedica retained no rights to our intellectual property previously licensed to them. In addition, NovaMedica paid us a termination fee of \$115,000 and we refunded the upfront payment of \$200,000 that we received from NovaMedica in connection with the licensing agreement.

Item 6. Exhibits

Exhibit No.	Description
3.1	Amended and Restated Certificate of Incorporation (incorporated herein by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 001-37783) filed with the SEC on June 7, 2016).
3.2	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).
101.*#	Consent and Second Amendment to Second Amended and Restated Loan and Security Agreement, by and between the Registrant and Silicon Valley Bank, dated as of August 29, 2019.
31.1*	Certification of Principal Executive Officer under Section 302 of the Sarbanes-Oxley Act.
31.2*	Certification of Principal Financial Officer under Section 302 of the Sarbanes-Oxley Act.
32.1**	Certifications of Principal Executive Officer and Principal Financial Officer under Section 906 of the Sarbanes-Oxley Act.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

* 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.

The schedules and exhibits to this agreement have been omitted, but will be furnished to the Securities and Exchange Commission upon request.

CONSENT AND SECOND AMENDMENT TO SECOND AMENDED AND RESTATED LOAN AND SECURITY AGREEMENT

THIS **CONSENT AND SECOND AMENDMENT** to Second Amended and Restated Loan and Security Agreement (this “Amendment”) is entered into as of August 29, 2019, by and among **SILICON VALLEY BANK**, a California corporation (“Bank”), as collateral agent (in such capacity, “Collateral Agent”), Bank in its capacity as a Lender, and the other Lenders party to that certain Second Amended and Restated Loan and Security Agreement dated as of May 14, 2018 (as the same may from time to time be amended, modified, supplemented or restated, including by that certain Consent and First Amendment to Second Amended and Restated Loan and Security Agreement dated as of July 3, 2019, collectively, the “Loan Agreement”) (together with Bank, each a “Lender” and collectively, the “Lenders”), and **CLEARSIDE BIOMEDICAL, INC.**, a Delaware corporation (“Borrower”).

RECITALS

A. Lenders have extended credit to Borrower for the purposes permitted in the Loan Agreement.

B. Borrower has informed Lenders that it desires to grant an exclusive option to enter into the Commercial License (as such term is defined in the Option and License Agreement) to Regenxbio Inc., a Delaware corporation (“Regenxbio”), to develop and commercialize certain products that are administered to patients using a Clearside Device (as such term is defined in the Option and License Agreement) on a worldwide basis, pursuant to the terms of that certain Option and License Agreement by and between Regenxbio and Borrower dated as of August 29, 2019 and attached hereto as Annex I (the “Option and License Agreement”). In connection therewith, Regenxbio has agreed, among other things, to pay to Borrower an option exercise fee in the amount of Two Million Dollars (\$2,000,000) plus various conditional payments and royalties.

C. Section 7.1 of the Loan Agreement provides that Borrower shall not convey, sell, lease, transfer, assign, or otherwise dispose of all or any part of its business or property without Lenders’ prior written consent. Section 7.5 of the Loan Agreement provides that Borrower shall not create, incur allow or suffer any Lien on its property or agree with any Person not to encumber its Intellectual Property except to the extent permitted under Section 7.1 of the Loan Agreement or in the definition of “Permitted Liens” contained therein.

D. Borrower has requested that Lenders consent to Borrower’s entry into and performance of the Option and License Agreement and agree that entry into and performance under the Option and License Agreement will not violate sections 7.1 or 7.5 of the Loan Agreement.

E. Lenders have agreed to so consent to Borrower’s entry into the Option and License Agreement, but only to the extent, in accordance with the terms, subject to the conditions and in reliance upon the representations and warranties set forth below.

AGREEMENT

Now, THEREFORE, in consideration of the foregoing recitals and other good and valuable consideration, the receipt and adequacy of which is hereby acknowledged, and intending to be legally bound, the parties hereto agree as follows:

1. Definitions. Capitalized terms used but not defined in this Amendment shall have the meanings given to them in the Loan Agreement.

2. **Consent.** Subject to the terms of Section 9 below, Lenders hereby consent to Borrower's entry into and performance of the Option and License Agreement attached as Annex I to this Amendment (without giving effect to any subsequent amendments or changes thereto).

3. **Amendments to Loan Agreement.**

3.1 **Section 6.8 (Protection of Intellectual Property Rights).** Section 6.8 of the Loan Agreement hereby is amended in its entirety and replaced with the following:

"6.8 Protection and Registration of Intellectual Property Rights.

(a) (i) Use commercially reasonable efforts to protect, defend and maintain the validity and enforceability of its Intellectual Property; (ii) promptly advise Collateral Agent in writing of material infringements or any other event that could reasonably be expected to materially and adversely affect the value of its Intellectual Property with any material value; and (iii) not allow any Intellectual Property material to Borrower's business to be abandoned, forfeited or dedicated to the public without each Lender's written consent.

(b) To the extent not already disclosed in writing to Collateral Agent, if Borrower (i) obtains any Patent, registered Trademark, registered Copyright, registered mask work, or any pending application for any of the foregoing, whether as owner, licensee or otherwise, or (ii) applies for any Patent or the registration of any Trademark, then Borrower shall immediately provide written notice thereof to Collateral Agent and shall execute such intellectual property security agreements and other documents and take such other actions as Collateral Agent may request in its good faith business judgment to perfect and maintain a first priority perfected security interest in favor of Collateral Agent in such property. If Borrower decides to register any Copyrights or mask works in the United States Copyright Office, Borrower shall: (x) provide Collateral Agent with at least fifteen (15) days prior written notice of Borrower's intent to register such Copyrights or mask works together with a copy of the application it intends to file with the United States Copyright Office (excluding exhibits thereto); (y) execute an intellectual property security agreement and such other documents and take such other actions as Collateral Agent may request in its good faith business judgment to perfect and maintain a first priority perfected security interest in favor of Collateral Agent in the Copyrights or mask works intended to be registered with the United States Copyright Office; and (z) record such intellectual property security agreement with the United States Copyright Office contemporaneously with filing the Copyright or mask work application(s) with the United States Copyright Office. Borrower shall promptly provide to Collateral Agent copies of all applications that it files for Patents or for the registration of Trademarks, Copyrights or mask works, together with evidence of the recording of the intellectual property security agreement required for Collateral Agent to perfect and maintain a first priority perfected security interest in such property.

(c) Provide written notice to Collateral Agent and each Lender within ten (10) days of entering or becoming bound by any Restricted License (other than over-the-counter software that is commercially available to the public). Borrower shall take such commercially reasonable steps as Collateral Agent or any Lender requests to obtain the consent of, or waiver by, any person whose consent or waiver is necessary for (i) any Restricted License to be deemed "Collateral" and for Collateral Agent to have a security interest in it that might otherwise be restricted or prohibited by law or by the terms of any

such Restricted License, whether now existing or entered into in the future, and (ii) Collateral Agent to have the ability in the event of a liquidation of any Collateral to dispose of such Collateral in accordance with Collateral Agent's rights and remedies under this Agreement and the other Loan Documents, provided that the failure to obtain such consent or waiver, after talking the steps set forth above, shall not constitute an Event of Default hereunder."

3.2

Section 14.1 (Definitions). The following defined terms and their respective definitions hereby are added or amended and restated in their entirety, as appropriate, in Section 14.1 of the Loan Agreement to read in their entirety to read as follows:

"Aura License" means that certain License Agreement by and between Aura Biosciences, Inc., a Delaware corporation ("Aura") and Borrower dated as of July 3, 2019 as attached as Annex I to the First Amendment (without giving effect to any subsequent amendments or changes thereto), pursuant to which Borrower has granted Aura an exclusive license to develop and commercialize certain Licensed Products (as such term is defined therein) on a worldwide basis.

"First Amendment" means that certain Consent and First Amendment to Second Amended and Restated Loan and Security Agreement by and among Collateral Agent, Lenders, and Borrower dated as of July 3, 2019.

"Intellectual Property Security Agreement" is collectively (a) that certain Intellectual Property Security Agreement between Collateral Agent and Bank dated as of the Second Amendment Effective Date, as may be amended, modified or restated from time to time and (b) any other intellectual property security agreement(s) between Collateral Agent and Bank at any time thereafter in accordance with Section 6.8(b) hereof.

"Loan Documents" are, collectively, this Agreement, the Warrants, the Intellectual Property Security Agreement, the Perfection Certificate, each Compliance Certificate, each Disbursement Letter, each Loan Payment/Advance Request Form, each Guaranty, any subordination agreements, any note, or notes or guaranties executed by Borrower or any other Person, and any other present or future agreement entered into by Borrower, any Guarantor or any other Person for the benefit of the Lenders and Collateral Agent in connection with this Agreement; all as amended, restated, or otherwise modified.

"Permitted License" is (a) any non-exclusive license of patent rights of Borrower or its Subsidiaries so long as all such Permitted Licenses are granted to third parties in the ordinary course of business, do not result in a legal transfer of title to the licensed property, and have been granted in exchange for fair consideration, (b) any exclusive license of patent rights of Borrower or its Subsidiaries so long as such Permitted Licenses do not result in a legal transfer of title to the licensed property, are exclusive solely as to discrete geographical areas outside of the United States, and have been granted in exchange for fair consideration, (c) the Aura License, and (d) the Regenxbio License.

"Regenxbio License" means that certain Option and License Agreement by and between Regenxbio Inc., a Delaware corporation ("Regenxbio") and Borrower dated as of August 29, 2019 and attached as Annex I to the Second Amendment (without giving effect to any subsequent amendments or changes thereto), pursuant to which Borrower has granted Regenxbio an exclusive option to enter into the Commercial License (as such term is defined in the Regenxbio License) to develop and commercialize certain products that

are administered to patients using a Clearside Device (as such term is defined in the Regenxbio License) on a worldwide basis.

“**Second Amendment**” means that certain Consent and Second Amendment to Second Amended and Restated Loan and Security Agreement by and among Collateral Agent, Lenders, and Borrower dated as of the Second Amendment Effective Date.

“**Second Amendment Effective Date**” is August 29, 2019.

3.3 Exhibit A (Collateral Description). Exhibit A of the Loan Agreement hereby is replaced in its entirety by Exhibit A attached hereto.

4. Grant of Lien in Intellectual Property. Borrower understands and agrees that the effect of the amendments set forth in Section 3 above serve to create a Lien in favor of Collateral Agent in Borrower’s Intellectual Property, and, without limiting in any respect Borrower’s grant of a Lien and security interest to Collateral Agent for the ratable benefit of the Lenders in the Collateral pursuant to Section 4.1 of the Loan Agreement, to secure the payment and performance in full of all of the Obligations, Borrower hereby grants Collateral Agent, for the ratable benefit of the Lenders, a continuing security interest in, and pledges to Collateral Agent, for the ratable benefit of the Lenders, all of its Intellectual Property, wherever located, whether now owned or hereafter acquired or arising, and all proceeds and products thereof. Borrower hereby authorizes Collateral Agent to (a) file a UCC-3 financing statement amendment reflecting the change in Collateral and (b) record the Intellectual Property Security Agreement with the United States Patent and Trademark Office.

5. Representations and Warranties. To induce Lenders to enter into this Amendment, Borrower hereby represents and warrants to Lenders as follows:

5.1 Immediately after giving effect to this Amendment (a) the representations and warranties contained in the Loan Documents are true, accurate and complete in all material respects as of the date hereof (except to the extent such representations and warranties relate to an earlier date, in which case they are true and correct as of such date), and (b) no Event of Default has occurred and is continuing;

5.2 Borrower has the power and authority to execute and deliver this Amendment and to perform its obligations under the Loan Agreement, as amended by this Amendment;

5.3 The organizational documents of Borrower delivered to Lenders on the Effective Date remain true, accurate and complete and have not been amended, supplemented or restated and are and continue to be in full force and effect.

6. Integration. This Amendment and the Loan Documents represent the entire agreement about this subject matter and supersede prior negotiations or agreements. All prior agreements, understandings, representations, warranties, and negotiations between the parties about the subject matter of this Amendment and the Loan Documents merge into this Amendment and the Loan Documents.

7. Ratification of Perfection Certificate. Borrower hereby ratifies, confirms and reaffirms, all and singular, the terms and disclosures contained in a certain Perfection Certificate dated on or prior to the Effective Date and acknowledges, confirms and agrees that the disclosures and information Borrower provided to Lenders in such Perfection Certificate have not changed, as of the date hereof.

8. Counterparts. This Amendment may be executed in any number of counterparts and all of such counterparts taken together shall be deemed to constitute one and the same instrument.

9. Effectiveness. This Amendment shall be deemed effective upon (a) the due execution and delivery to Lenders of (i) this Amendment by each party hereto, (ii) an Intellectual Property Security Agreement by each party thereto, and (iii) a fully-executed copy of the Option and License Agreement together with all other documents entered into in connection therewith, and (b) Borrower's payment to Lenders of all Lenders' Expenses due and owing as of the date hereof, which may be debited from any of Borrower's accounts at Bank.

10. Governing Law. This Amendment and the rights and obligations of the parties hereto shall be governed by and construed in accordance with the laws of the State of California.

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IN WITNESS WHEREOF, the parties hereto have caused this Amendment to be duly executed and delivered as of the date first written above.

BORROWER:

CLEARSIDE BIOMEDICAL, INC.

By /s/ George Lasezkay
Name: George Lasezkay
Title: CEO

COLLATERAL AGENT AND LENDER:

SILICON VALLEY BANK

By /s/ Scott McCarty
Name: Scott McCarty
Title: Director

LENDERS:

ELM 2016-1 TRUST

By: MidCap Financial Services Capital
Management, LLC, as Servicer

By /s/ John O'Dea
Name: John O'Dea
Title: Authorized Signatory

ELM 2018-2 TRUST, as Assignee

By: MidCap Financial Services Capital
Management, LLC, as Servicer

By /s/ John O'Dea
Name: John O'Dea
Title: Authorized Signatory

[Signature Page to Consent and Second Amendment to Second Amended and Restated Loan and Security Agreement]

EXHIBIT A

COLLATERAL DESCRIPTION

The Collateral consists of all of Borrower's right, title and interest in and to the following personal property:

All goods, Accounts (including health-care receivables), Equipment, Inventory, contract rights or rights to payment of money, leases, License Agreements, franchise agreements, General Intangibles, commercial tort claims, documents, instruments (including any promissory notes), chattel paper (whether tangible or electronic), cash, deposit accounts, fixtures, letters of credit rights (whether or not the letter of credit is evidenced by a writing), securities, and all other investment property, supporting obligations, and financial assets, whether now owned or hereafter acquired, wherever located; and

all Borrower's Books relating to the foregoing, and any and all claims, rights and interests in any of the above and all substitutions for, additions, attachments, accessories, accessions and improvements to and replacements, products, proceeds and insurance proceeds of any or all of the foregoing.

ANNEX 1

OPTION AND LICENSE AGREEMENT

[See attached]

**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, 2019 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 8, 2019

/s/ George Lasezkay, Pharm.D., J.D.
George Lasezkay, Pharm. D., J.D.
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, 2019 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 8, 2019

/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, 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, 2019, 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 8th day of November 2019.

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

George Lasezkay, Pharm. D., J.D.

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.