

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, DC 20549**

**FORM 10-Q**

(Mark One)

**QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**  
For the quarterly period ended March 31, 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)

45-2437375  
(I.R.S. Employer  
Identification No.)

**900 North Point Parkway, Suite 200**  
**Alpharetta, GA**  
(Address of principal executive offices)

**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)

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

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

As of May 6, 2019, the registrant had 37,595,551 shares of common stock, \$0.001 par value per share, outstanding.

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## PART I – FINANCIAL INFORMATION

## Item 1. Financial Statements

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

	March 31, 2019	December 31, 2018
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 32,950	\$ 8,043
Short-term investments	1,988	32,835
Prepaid expenses	497	2,049
Other current assets	33	17
Total current assets	35,468	42,944
Property and equipment, net	755	790
Operating lease right-of-use asset	925	—
Restricted cash	360	360
Other assets	26	26
Total assets	\$ 37,534	\$ 44,120
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 5,258	\$ 6,869
Accrued liabilities	4,520	2,923
Current portion of long-term debt	1,389	556
Current portion of operating lease liabilities	499	—
Current portion of deferred rent	—	128
Total current liabilities	11,666	10,476
Long-term debt	8,647	9,419
Operating lease liabilities	1,130	—
Deferred rent	—	605
Total liabilities	21,443	20,500
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.001 par value; 10,000,000 shares authorized and no shares issued at March 31, 2019 and December 31, 2018	—	—
Common stock, \$0.001 par value; 100,000,000 shares authorized at March 31, 2019 and December 31, 2018; 36,782,920 and 32,119,227 shares issued and outstanding at March 31, 2019 and December 31, 2018, respectively	37	32
Additional paid-in capital	238,345	230,475
Accumulated deficit	(222,291)	(206,887)
Total stockholders' equity	16,091	23,620
Total liabilities and stockholders' equity	\$ 37,534	\$ 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 March 31,	
	2019	2018
Collaboration revenue	\$ 45	\$ —
Operating expenses:		
Research and development	10,967	13,379
General and administrative	4,384	3,074
Total operating expenses	15,351	16,453
Loss from operations	(15,306)	(16,453)
Other expense, net	(98)	(154)
Net loss	\$ (15,404)	\$ (16,607)
Net loss per share of common stock — basic and diluted	\$ (0.45)	\$ (0.62)
Weighted average shares outstanding — basic and diluted	34,144,209	26,818,137

*See accompanying notes to the financial statements.*

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

	<b>Three Months Ended March 31, 2019</b>					
	<b>Common Stock</b>		<b>Additional Paid-In-Capital</b>	<b>Accumulated Deficit</b>	<b>Accumulated Other Comprehensive Loss</b>	<b>Total Stockholders' Equity</b>
	<b>Shares</b>	<b>Amount</b>				
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	<u>36,782,920</u>	<u>\$ 37</u>	<u>\$ 238,345</u>	<u>\$ (222,291)</u>	<u>\$ —</u>	<u>\$ 16,091</u>

	<b>Three Months Ended March 31, 2018</b>					
	<b>Common Stock</b>		<b>Additional Paid-In-Capital</b>	<b>Accumulated Deficit</b>	<b>Accumulated Other Comprehensive Loss</b>	<b>Total Stockholders' Equity</b>
	<b>Shares</b>	<b>Amount</b>				
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	<u>31,947,033</u>	<u>\$ 32</u>	<u>\$ 226,567</u>	<u>\$ (140,676)</u>	<u>\$ —</u>	<u>\$ 85,923</u>

*See accompanying notes to the financial statements.*

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

	Three Months Ended March 31,	
	2019	2018
<b>Operating activities</b>		
Net loss	\$ (15,404)	\$ (16,607)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	53	47
Share-based compensation expense	1,247	1,138
Non-cash interest expense	46	49
Accretion of debt discount	15	49
Amortization and accretion on available-for-sale investments, net	(103)	(43)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	1,536	(613)
Other assets and liabilities	(29)	12
Accounts payable and accrued liabilities	(14)	341
Deferred rent	—	(26)
Net cash used in operating activities	(12,653)	(15,653)
<b>Investing activities</b>		
Maturities of available-for-sale investments	30,950	20,970
Purchase of available-for-sale investments	—	(8,725)
Acquisition of property and equipment	(18)	—
Net cash provided by investing activities	30,932	12,245
<b>Financing activities</b>		
Proceeds from at-the-market sales agreement, net of issuance costs	6,627	—
Proceeds from follow-on public offering, net of issuance costs	—	79,581
Proceeds from exercise of stock options	1	237
Payments made on long-term debt	—	(800)
Net cash provided by financing activities	6,628	79,018
Net increase in cash, cash equivalents and restricted cash	24,907	75,610
Cash, cash equivalents and restricted cash, beginning of period	8,403	9,584
Cash, cash equivalents and restricted cash, end of period	\$ 33,310	\$ 85,194

**Reconciliation of cash, cash equivalents and restricted cash:**

	March 31,	
	2019	2018
Cash and cash equivalents	\$ 32,950	\$ 84,834
Restricted cash	360	360
Cash, cash equivalents and restricted cash shown on the statements of cash flows	\$ 33,310	\$ 85,194

*See accompanying notes to the financial statements.*

**Notes to the Financial Statements  
(unaudited)**

**1. The Company**

Clearside Biomedical, Inc. (the “Company”) is a late-stage 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. As of March 31, 2019, the Company had sold 4.7 million shares of its common stock for net proceeds of \$6.6 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.

The Company will need to obtain additional financing to fund future operations, including completing the development and commercialization of its primary product candidates. The Company will need to obtain additional financing to conduct additional trials for the regulatory approval of its product candidates if requested by regulatory bodies, and to complete the development of any additional product candidates. If such products were to receive regulatory approval, the Company may need to prepare for the potential commercialization of its product candidates and fund the commercial launch of the products, if the Company decides to commercialize the products on its own. Moreover, the Company’s fixed expenses such as rent and other contractual commitments are substantial and are expected to increase in the future.

The Company had cash, cash equivalents and short-term investments of \$34.9 million as of March 31, 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 sales of its lead product candidate, XIPERE™. In the absence of product or other revenues, the amount, timing, nature or source of which cannot be predicted, the Company’s losses will continue as it conducts its research and development activities and prepares for the anticipated commercial launch of XIPERE. The Company will need additional financing to fund its operations and to commercialize XIPERE 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 research and development plans, including the discontinuation of clinical development of XIPERE together with an anti-vascular endothelial growth factor agent for the treatment of retinal vein occlusion, its plans to reduce certain administrative expenses and its timing expectations related to the approval of its New Drug Application (“NDA”) submission, the Company expects that its existing cash, cash equivalents and short-term investments will enable it to fund its operating expenses and capital expenditure requirements into the first quarter of 2020. Accordingly, the Company has plans to mitigate its going concern risk by raising additional capital, potentially in a combination of equity or debt financings, or by entering into potential 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. 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.

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 March 31, 2019, statements of operations for the three months ended March 31, 2019 and 2018, statements of stockholders' equity for the three months ended March 31, 2019 and 2018 and statements of cash flows for the three months ended March 31, 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 March 31, 2019, its results of its operations for the three months ended March 31, 2019 and 2018, its changes in stockholders' equity for the three months ended March 31, 2019 and 2018 and its cash flows for the three months ended March 31, 2019 and 2018. The financial data and other information disclosed in these notes related to the three months ended March 31, 2019 and 2018 are unaudited. The results for the three months ended March 31, 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. No material adjustments to these estimates have been recorded in these financial statements.



### ***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 awards granted to non-employees is re-measured each period until the related service is complete. 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 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)	March 31, 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	677	677
		1,217	1,199
Less: Accumulated depreciation		(462)	(409)
		<u>\$ 755</u>	<u>\$ 790</u>

### 4. Accrued Liabilities

Accrued liabilities consisted of the following (in thousands):

	March 31, 2019	December 31, 2018
Accrued research and development	\$ 3,268	\$ 1,263
Accrued marketing	366	47
Accrued bonuses	405	1,088
Accrued professional fees	129	63
Accrued vacation	169	103
Accrued interest payable	—	76
Accrued expense	183	283
	<u>\$ 4,520</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 “1<sup>st</sup> A&R loan agreement”) with Silicon Valley Bank (“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 1<sup>st</sup> 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 1<sup>st</sup> 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 1<sup>st</sup> 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 1<sup>st</sup> A&R loan agreement.

On May 14, 2018, the Company entered into a second amended and restated loan and security agreement (the “2<sup>nd</sup> 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 1<sup>st</sup> A&R loan agreement. The 2<sup>nd</sup> A&R Loan Agreement provides 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 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 1<sup>st</sup> A&R loan agreement, including fees associated with the final payment. The prepayment fees were waived. Of the remaining \$10.0 million under the 2<sup>nd</sup> 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.

The Company is required to pay accrued interest only on the \$10 million borrowed under the 2<sup>nd</sup> 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 has the option to prepay the outstanding balance in full, subject to a prepayment fee of 3% of the original principal amount for any prepayment prior to May 14, 2019 or 2% of the original principal amount for any prepayment on or after May 14, 2019 but 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.

The borrowings under the 2<sup>nd</sup> A&R Loan Agreement are secured by substantially all of the Company’s assets, except that the collateral does not include any of the Company’s intellectual property. However, pursuant to the terms of a negative pledge arrangement, the Company has agreed not to encumber any of its intellectual property.

Interest expense on the borrowings under the loan agreements described above was \$225,000 and \$161,000 for the three months ended March 31, 2019 and 2018, respectively. Accretion of the scheduled final payment was \$46,000 and \$49,000 for the three months ended March 31, 2019 and 2018, respectively. Accretion of the deferred debt issuance costs was \$15,000 and \$49,000 for the three months ended March 31, 2019 and 2018, respectively.

As of March 31, 2019, the scheduled payments for the 2<sup>nd</sup> A&R Loan Agreement, including the scheduled final payment in 2022, were as follows (in thousands):

Year Ending December 31,	Principal	Interest and Final Payment	Total
2019	\$ 556	\$ 635	\$ 1,191
2020	3,333	651	3,984
2021	3,333	366	3,699
2022	2,778	638	3,416
	<u>\$ 10,000</u>	<u>\$ 2,290</u>	<u>\$ 12,290</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 March 31, 2019 and December 31, 2018, there were 36,782,920 and 32,119,227 shares of common stock outstanding, respectively.

## 7. Stock Purchase Warrants

In September 2016, in connection with the 1<sup>st</sup> A&R loan agreement (see Note 5), 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 7.5 years as of March 31, 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 March 31,	
	2019	2018
Research and development	\$ 462	\$ 431
General and administrative	775	702
Total	<u>\$ 1,237</u>	<u>\$ 1,133</u>

The following table summarizes the activity related to stock options during the three months ended March 31, 2019:

	Number of Shares	Weighted Average Exercise Price
Options outstanding at January 1, 2019	3,463,096	\$ 6.62
Granted	1,532,600	1.24
Exercised	(2,727)	0.40
Forfeited	(160,080)	6.25
Options outstanding at March 31, 2019	<u>4,832,889</u>	6.62
Options exercisable at December 31, 2018	<u>1,583,749</u>	5.63
Options exercisable at March 31, 2019	<u>1,593,506</u>	5.77

As of March 31, 2019, the Company had \$10.3 million of unrecognized compensation expense related to unvested stock options, which is expected to be recognized over a weighted average period of 2.7 years.

### *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 22,287 shares of common stock purchased under the 2016 ESPP. The Company has recorded \$9,800 and \$5,000 of share-based compensation expense for the three months ended March 31, 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. 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):

	<b>March 31, 2019</b>
Operating lease right-of-use asset	\$ 925
<b>Liabilities</b>	
Current portion of operating lease liabilities	\$ 499
Operating lease liabilities	1,130
Total operating lease liabilities	<u>\$ 1,629</u>

The Company recognizes a right-of-use asset for the right to use the underlying asset for the lease term, and a lease liability, which represents the present value of the Company's obligation to make payments over the lease term. The renewal option is not included in the calculation of the right-of-use asset and the lease liabilities as the Company has not yet determined if the leases will be renewed. The present value of the lease payments is calculated using an incremental borrowing rate as the Company's leases do not provide an implicit interest rate. At March 31, 2019, the Company's weighted average discount rate was 5.3% and the weighted average lease term was 2.9 years.

Total future undiscounted minimum lease payments were as follows at March 31, 2019 (in thousands):

<b>Year Ending December 31,</b>	
2019	\$ 471
2020	574
2021	496
2022	511
2023	393
Total minimum lease payments	<u>\$ 2,445</u>

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

Rent expense was \$100,000 and \$58,000 for the three months ended March 31, 2019 and 2018, respectively. Cash payments included in operating activities on the statement of cash flows for operating lease liabilities was \$129,000 for the three months ended March 31, 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 \$45,000 of revenue from these collaboration agreements during the three months ended March 31, 2019.

## 11. Available-for-Sale Investments

The following table summarizes the Company's available-for-sale investments (in thousands):

	March 31, 2019		
	Amortized Cost	Unrealized Losses	Fair Value
Commercial paper	\$ 1,988	\$ —	\$ 1,988
Total available-for-sale investments	<u>\$ 1,988</u>	<u>\$ —</u>	<u>\$ 1,988</u>

## 12. 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 March 31, 2019 and December 31, 2018 consisted primarily of cash and cash equivalents, short-term investments and long-term debt. The fair value of cash and cash equivalents, government bonds, 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 is classified as Level 1 in the fair value hierarchy. The Company has determined its short-term investments, comprised of treasury bills and 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 three months ended March 31, 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):

	March 31, 2019			Recorded Value
	Level 1	Level 2	Level 3	
<b>Financial Assets:</b>				
Cash and money markets	\$ 32,950	\$ —	\$ —	\$ 32,950
Restricted cash money market	360	—	—	360
Commercial paper	—	1,988	—	1,988
Total financial assets	<u>\$ 33,310</u>	<u>\$ 1,988</u>	<u>\$ —</u>	<u>\$ 35,298</u>

**December 31, 2018**

	Level 1	Level 2	Level 3	Recorded Value
<b>Financial Assets:</b>				
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>

**13. 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 March 31,	
	2019	2018
Outstanding stock options	4,832,889	3,135,929
Stock purchase warrants	29,796	29,796
	<u>4,862,685</u>	<u>3,165,725</u>

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

*Certain statements contained in this Quarterly Report on Form 10-Q may constitute forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. The words or phrases "would be," "will allow," "intends to," "will likely result," "are expected to," "will continue," "is anticipated," "estimate," "project," or similar expressions, or the negative of such words or phrases, are intended to identify "forward-looking statements." We have based these forward-looking statements on our current expectations and projections about future events. Because such statements include risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Factors that could cause or contribute to these differences include those below and elsewhere in this Quarterly Report on Form 10-Q and our other filings with the Securities and Exchange Commission, or SEC, 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 late-stage 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 two major components of the eye: 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, formerly known as CLS-TA, 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. The Prescription Drug User Fee Act, or PDUFA, goal date has been assigned for October 19, 2019. If approved, we anticipate launching XIPERE in the first quarter of 2020.

In May 2018, we completed a Phase 2 clinical trial, which we refer to as TYBEE, evaluating the safety and efficacy of administering XIPERE in combination with intravitreal EYLEA® (aflibercept), an anti-VEGF agent, in patients with diabetic macular edema, or DME. Based upon a review of our Phase 2 TYBEE clinical trial data, we have decided to cease clinical development of XIPERE in combination with an anti-VEGF therapy for the treatment of DME. We believe there is a path forward with XIPERE in DME and are evaluating options for clinical trials that can demonstrate the potential benefit from XIPERE as a monotherapy. We intend to discuss this strategy with appropriate regulatory authorities and, subject to the availability of additional funding, to pursue the development of XIPERE as monotherapy in DME and other potential indications outside of uveitis. We are also evaluating the potential to develop therapeutic candidates based on the administration of gene therapy and novel small molecules through the SCS using our SCS Microinjector.

If XIPERE or any of our other product candidates are approved, we currently plan to commercialize them with a specialty team of approximately 20 sales and medical marketing professionals to target the approximately 1,900 uveitis and retina specialists in the United States. If we commercialize any of our product candidates ourselves, we will require significant additional funding. We may pursue collaborations with third parties to commercialize any of our drugs approved for marketing, including XIPERE, in the United States. We do not expect to commercialize any products approved outside the United States ourselves, but instead would likely seek third-party collaborations for commercialization internationally.



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 of our most advanced product candidates and preparing to commercialize XIPIERE for the treatment of macular edema associated with uveitis if approved by the FDA. 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 March 31, 2019, we had an accumulated deficit of \$222.3 million. We recorded net losses of \$15.4 million and \$16.6 million for the three months ended March 31, 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 and preparing for potential commercialization of, our product candidates, including commercializing XIPIERE for the treatment of macular edema associated with uveitis, if approved, either on our own or in collaboration with third parties.

We expect to continue to incur significant operating losses at least for the next several years. We do not expect to generate product revenue unless and until we successfully complete necessary development of, and obtain regulatory approval for, one or more of our product candidates. 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. We anticipate that our clinical trial expenses will decrease over the near term as we have discontinued late-stage clinical trials of XIPIERE 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 for XIPIERE for the treatment of macular edema associated with uveitis and other developmental efforts necessary to seek such approvals. We anticipate that our general and administrative expenses will increase substantially as we:

- establish sales and distribution infrastructure and scale up external manufacturing capabilities to commercialize XIPIERE for the treatment of macular edema associated with uveitis, if approved;
- maintain, expand and protect our intellectual property portfolio; and
- add operational, financial and management information systems and personnel, including personnel to support our development and potential future commercialization efforts.

Based on our current plans and forecasted expenses we expect that our existing cash, cash equivalents and short-term investments will enable us to fund our operating expenses and capital expenditure requirements into the first quarter of 2020.

## **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.

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 over the term of the agreement.

We may enter into additional collaboration agreements to evaluate the potential use of our proprietary SCS Microinjector with third-party product candidates for the treatment of various eye diseases.

### ***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. Expenses related to activities that support more than one development program or activity, such as salaries, share-based compensation and depreciation, are not classified as direct clinical costs or preclinical costs and are separately classified as unallocated.

For the three months ended March 31, 2019 and 2018, substantially all of our research and development expenses were related to the clinical development of our product candidates.

The following table shows our research and development expenses by program, including those that have been discontinued, for the three months ended March 31, 2019 and 2018 (in thousands).

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2019</b>	<b>2018</b>
XIPERE (uveitis program)	\$ 1,183	\$ 2,573
XIPERE (RVO program)	6,802	7,376
XIPERE (DME program)	3	1,177
Total	7,988	11,126
Unallocated	2,979	2,253
Total research and development expense	<u>\$ 10,967</u>	<u>\$ 13,379</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. Historically, any such modifications have not been material.

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 include the following:

- the costs associated with process development, scale-up and manufacturing of XIPERE and the SCS Microinjector for clinical trials and for requirements associated with regulatory filings associated with 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 include facility related costs not otherwise included in research and development expenses, professional fees for legal, patent, consulting, and accounting and audit services.

We anticipate that our general and administrative expenses will increase in the future to support our continued research and development activities and the potential commercialization of our product candidates. Additionally, we anticipate increased costs related to services associated with maintaining compliance with Nasdaq listing rules and SEC requirements, including compliance with the Sarbanes-Oxley Act, director and officer insurance, and investor and public relations costs.

#### ***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 months ended March 31, 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 three months ended March 31, 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 March 31, 2019 and 2018

The following table sets forth our results of operations for the three months ended March 31, 2019 and 2018.

	Three Months Ended March 31,		Period-to-Period Change
	2019	2018	
	(in thousands)		
Collaboration revenue	\$ 45	\$ —	\$ 45
Operating expenses:			
Research and development	10,967	13,379	(2,412)
General and administrative	4,384	3,074	1,310
Total operating expenses	15,351	16,453	(1,102)
Loss from operations	(15,306)	(16,453)	1,147
Other expense, net	(98)	(154)	56
Net loss	\$ (15,404)	\$ (16,607)	\$ 1,203

*Revenue.* In the three months ended March 31, 2019, we recognized \$45,000 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 \$2.4 million, from \$13.4 million for the three months ended March 31, 2018 to \$11.0 million for the three months ended March 31, 2019. This was primarily attributable to a \$1.4 million decrease due the completion of the PEACHTREE trial during the first quarter of 2018, a \$1.2 million decrease in costs related to our DME program, as the TYBEE trial was completed in the second quarter of 2018, and a \$0.6 million decrease due to closing down two late-stage clinical trials, SAPPHIRE and TOPAZ. These decreases were partially offset by a \$0.8 million increase in employee-related costs and a \$0.5 million increase in manufacturing costs for XIPERE.

*General and administrative.* General and administrative expenses increased by \$1.3 million, from \$3.1 million for the three months ended March 31, 2018 to \$4.4 million for the three months ended March 31, 2019. The increase was primarily attributable to a \$0.6 million increase in employee-related costs and an increase of \$0.6 million in marketing-related expenses as we prepare for potential commercialization of XIPERE.

*Other expense, net.* Other expense, net for each of the three months ended March 31, 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.

## Liquidity and Capital Resources

### Sources of Liquidity

We have funded our operations primarily through the proceeds of public offerings of our common stock, sales of convertible preferred stock and the issuance of long-term debt. As of March 31, 2019, we had cash, cash equivalents and short-term investments of \$34.9 million. We invest any cash in excess of our immediate requirements primarily with a view to liquidity and capital preservation. As of March 31, 2019, our funds were held in cash, money market funds and commercial paper.

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. As of March 31, 2019, we have sold 4.7 million shares of our common stock for net proceeds of \$6.6 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.

We are required to pay accrued interest only on the \$10.0 million outstanding balance 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. We have the option to prepay the outstanding balance in full, subject to a prepayment fee of 3% of the original principal amount for any prepayment prior to May 14, 2019 or 2% of the original principal amount for any prepayment on or after May 14, 2019 but 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.

The amounts due under the Loan Agreement are secured by substantially all of our assets, except that the collateral does not include any of our intellectual property. However, pursuant to the terms of a negative pledge arrangement, we have agreed not to encumber any of our intellectual property.

### ***Funding Requirements***

Our primary uses of capital are, and we expect will continue to be, compensation and related expenses, costs related to our NDA submission, preparation for XIPERE's anticipated commercial launch in the first quarter of 2020, 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. We do not currently have any committed external source of funds, and, 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 additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable 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 increased costs and expenses for fees to members of our board of directors, increased personnel costs, increased 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 sales of XIPERE. We will need additional financing to fund our operations and commercialize XIPERE.

Based on our current research and development plans, including the discontinuation of clinical development of XIPERE together with an anti-VEGF agent for the treatment of retinal vein occlusion, or RVO, our plans to reduce certain administrative expenses and our timing expectations related to the approval of our NDA submission, we expect that our existing cash, cash equivalents and short-term investments will enable us to fund our operating expenses and capital expenditure requirements into the first quarter of 2020. Accordingly, 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 entering into potential collaborations, partnerships and other strategic arrangements. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our capital resources sooner than we expect. These conditions raise substantial doubt about our ability to continue as a going concern within one year after the date of this report.

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):

	Three Months Ended March 31,	
	2019	2018
Net cash (used in) provided by:		
Operating activities	\$ (12,653)	\$ (15,653)
Investing activities	30,932	12,245
Financing activities	6,628	79,018
Net change in cash and cash equivalents	<u>\$ 24,907</u>	<u>\$ 75,610</u>

During the three months ended March 31, 2019 and 2018, our operating activities used net cash of \$12.7 million and \$15.7 million, respectively. The use of cash in each period primarily resulted from our net losses. The decrease in net loss for the three months ended March 31, 2019 as compared to the three months ended March 31, 2018 was primarily attributable to the lower research and development expenses as a result of the completion of the PEACHTREE and TYBEE trials in the prior year and the shut-down of the SAPPHIRE and TOPAZ trials, partially offset by commercialization activities described above.

During the three months ended March 31, 2019 and 2018, our net cash provided by investing activities was \$30.9 million and \$12.2 million, respectively. In each period, cash flows from investing activities were related primarily to maturities of short-term, available-for-sale investments.

During the three months ended March 31, 2019 and 2018, our net cash provided by financing activities was \$6.6 million and \$79.0 million, respectively. The net cash provided by financing activities for the three months ended March 31, 2019 was comprised of net proceeds from the sales of shares of common stock under the ATM agreement. The net cash provided by financing activities for the three months ended March 31, 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, offset by \$8.3 million paid to satisfy our obligations under the prior loan agreement, and \$0.4 million of proceeds from the exercise of stock options.

### **Contractual Obligations**

As of March 31, 2019, there were no significant changes to our contractual obligations 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 March 31, 2019 and December 31, 2018, we had cash and cash equivalents of \$33.0 million and \$8.0 million, respectively. We generally hold our cash in interest-bearing money market accounts. As of March 31, 2019 and December 31, 2018, we had short-term investments of \$2.0 million and \$32.8 million, respectively. 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 \$25,000 and \$100,000 increase in interest expense for the three months ended March 31, 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 Interim Chief Executive Officer and 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 Interim Chief Executive Officer and 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 March 31, 2019 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.



## PART II – OTHER INFORMATION

### Item 1. Legal Proceedings

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

### Item 1A. Risk Factors

Our business is subject to risks and events that, if they occur, could adversely affect our financial condition and results of operations and the trading price of our securities. In addition to the other information set forth in this quarterly report on Form 10-Q, you should carefully consider the factors described 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. There have been no material changes to the risk factors described in that report.

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

(a) *Sales of Unregistered Securities*

None.

**Item 6. Exhibits**

<u>Exhibit No.</u>	<u>Description</u>
3.1	<a href="#"><u>Amended and Restated Certificate of Incorporation (incorporated herein by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 001-37783) filed with the SEC on June 7, 2016).</u></a>
3.2	<a href="#"><u>Amended and Restated Bylaws (incorporated herein by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K (File No. 001-37783) filed with the SEC on June 7, 2016).</u></a>
10.1	<a href="#"><u>Letter agreement, dated April 16, 2019, by and between the Company and George Lasezkay (incorporated herein by to reference Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-37783) filed with the SEC on April 17, 2019).</u></a>
31.1*	<a href="#"><u>Certification of Principal Executive Officer under Section 302 of the Sarbanes-Oxley Act.</u></a>
31.2*	<a href="#"><u>Certification of Principal Financial Officer under Section 302 of the Sarbanes-Oxley Act.</u></a>
32.1**	<a href="#"><u>Certifications of Principal Executive Officer and Principal Financial Officer under Section 906 of the Sarbanes-Oxley Act.</u></a>
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.



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

I, George Lasezkay, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the period ended March 31, 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: May 10, 2019

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

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

I, Charles A. Deignan, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the period ended March 31, 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: May 10, 2019

/s/ Charles A. Deignan  
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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, Interim Chief Executive Officer of Clearside Biomedical, Inc. (the "Company"), and Charles A. Deignan, Chief Financial Officer of the Company, each hereby certifies that, to the best of his knowledge:

1. The Company's Quarterly Report on Form 10-Q for the period ended March 31, 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 10th day of May 2019.

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

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