

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 June 30, 2019

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Commission File Number: 001-37783

**Clearside Biomedical, Inc.**

(Exact Name of Registrant as Specified in its Charter)

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

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

30005  
(Zip Code)

(678) 270-3631

Registrant's telephone number, including area code

N/A

(Former name, former address and former fiscal year, if changed since last report)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.001 per share	CLSD	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input checked="" type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input checked="" type="checkbox"/>

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  No

As of August 5, 2019, the registrant had 37,759,781 shares of common stock, \$0.001 par value per share, outstanding.

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## PART I – FINANCIAL INFORMATION

## Item 1. Financial Statements

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

	June 30, 2019	December 31, 2018
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 26,174	\$ 8,043
Short-term investments	—	32,835
Prepaid expenses	1,659	2,049
Other current assets	60	17
Total current assets	27,893	42,944
Property and equipment, net	708	790
Operating lease right-of-use asset	867	—
Restricted cash	360	360
Other assets	26	26
Total assets	\$ 29,854	\$ 44,120
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 2,227	\$ 6,869
Accrued liabilities	2,863	2,923
Current portion of long-term debt	2,222	556
Current portion of operating lease liabilities	504	—
Current portion of deferred rent	—	128
Other current liabilities	225	—
Total current liabilities	8,041	10,476
Long-term debt	7,877	9,419
Operating lease liabilities	1,035	—
Deferred rent	—	605
Total liabilities	16,953	20,500
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.001 par value; 10,000,000 shares authorized and no shares issued at June 30, 2019 and December 31, 2018	—	—
Common stock, \$0.001 par value; 100,000,000 shares authorized at June 30, 2019 and December 31, 2018; 37,746,146 and 32,119,227 shares issued and outstanding at June 30, 2019 and December 31, 2018, respectively	38	32
Additional paid-in capital	240,888	230,475
Accumulated deficit	(228,025)	(206,887)
Total stockholders' equity	12,901	23,620
Total liabilities and stockholders' equity	\$ 29,854	\$ 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 June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Collaboration revenue	\$ 45	\$ —	\$ 90	\$ —
Operating expenses:				
Research and development	658	17,343	11,625	30,722
General and administrative	5,004	3,561	9,388	6,635
Total operating expenses	5,662	20,904	21,013	37,357
Loss from operations	(5,617)	(20,904)	(20,923)	(37,357)
Other (expense) income, net	(117)	203	(215)	49
Net loss	\$ (5,734)	\$ (20,701)	\$ (21,138)	\$ (37,308)
Net loss per share of common stock — basic and diluted	\$ (0.15)	\$ (0.65)	\$ (0.59)	\$ (1.27)
Weighted average shares outstanding — basic and diluted	37,636,053	31,979,158	35,899,777	29,412,904

*See accompanying notes to the financial statements.*

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

	Six Months Ended June 30, 2019				
	Common Stock		Additional Paid-In-Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance at December 31, 2018	32,119,227	\$ 32	\$ 230,475	\$ (206,887)	\$ 23,620
Issuance of common shares from at-the-market sales agreement	4,660,966	5	6,622	—	6,627
Exercise of stock options	2,727	—	1	—	1
Share-based compensation expense	—	—	1,247	—	1,247
Net loss	—	—	—	(15,404)	(15,404)
Balance at March 31, 2019	36,782,920	37	238,345	(222,291)	16,091
Issuance of common shares from at-the-market sales agreement	945,974	1	1,272	—	1,273
Issuance of common shares under employee stock purchase plan	17,252	—	15	—	15
Share-based compensation expense	—	—	1,256	—	1,256
Net loss	—	—	—	(5,734)	(5,734)
Balance at June 30, 2019	<u>37,746,146</u>	<u>\$ 38</u>	<u>\$ 240,888</u>	<u>\$ (228,025)</u>	<u>\$ 12,901</u>

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

*See accompanying notes to the financial statements.*

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

	Six Months Ended June 30,	
	2019	2018
<b>Operating activities</b>		
Net loss	\$ (21,138)	\$ (37,308)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	107	94
Share-based compensation expense	2,503	2,337
Non-cash interest expense	93	60
Accretion of debt discount	31	79
Amortization and accretion on available-for-sale investments, net	(115)	(244)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	347	(830)
Other assets and liabilities	164	(50)
Accounts payable and accrued liabilities	(4,702)	640
Net cash used in operating activities	(22,710)	(35,222)
<b>Investing activities</b>		
Maturities of available-for-sale investments	32,950	31,870
Purchase of available-for-sale investments	—	(52,446)
Acquisition of property and equipment	(25)	—
Net cash provided by (used in) investing activities	32,925	(20,576)
<b>Financing activities</b>		
Proceeds from at-the-market sales agreement, net of issuance costs	7,900	—
Proceeds from follow-on public offering, net of issuance costs	—	79,581
Proceeds from exercise of stock options	1	433
Proceeds from shares issued under employee stock purchase plan	15	45
Proceeds from long-term debt	—	10,000
Payments made on long-term debt	—	(8,300)
Net cash provided by financing activities	7,916	81,759
Net increase in cash, cash equivalents and restricted cash	18,131	25,961
Cash, cash equivalents and restricted cash, beginning of period	8,403	9,584
Cash, cash equivalents and restricted cash, end of period	\$ 26,534	\$ 35,545

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

	June 30,	
	2019	2018
Cash and cash equivalents	\$ 26,174	\$ 35,185
Restricted cash	360	360
Cash, cash equivalents and restricted cash at end of period	\$ 26,534	\$ 35,545

*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. During the six months ended June 30, 2019, the Company sold 5.6 million shares of its common stock for net proceeds of \$7.9 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, which could include collaborating with third parties for the commercial launch of the products.

The Company had cash and cash equivalents of \$26.2 million as of June 30, 2019. The Company has suffered recurring losses and negative cash flows from operations since inception and anticipates incurring additional losses until such time, if ever, that it can obtain approval from the U.S. Food and Drug Administration (the “FDA”) to market and then generate significant sales of any of its product candidates. In the absence of product or other revenues, the amount, timing, nature or source of which cannot be predicted, the Company’s losses will continue. The Company will need additional financing to fund its operations and may finance future cash needs through public or private equity offerings, license agreements, debt financings, collaborations, strategic alliances and marketing or distribution arrangements.

Based on its current research and development plans, its plans to reduce certain administrative expenses, its timing expectations related to the approval of its New Drug Application (“NDA”) submission and its intention to seek a licensing or collaboration agreement with one or more partners for the commercialization of its lead product candidate, XIPERE, the Company expects that its existing cash and cash equivalents will enable it to fund its operating expenses and capital expenditure requirements into the third 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 June 30, 2019, statements of operations for the three and six months ended June 30, 2019 and 2018, statements of stockholders' equity for the three and six months ended June 30, 2019 and 2018 and statements of cash flows for the six months ended June 30, 2019 and 2018 are unaudited. The unaudited interim financial statements have been prepared on the same basis as the annual financial statements and, in the opinion of management, reflect all adjustments, which include normal recurring adjustments, necessary for the fair presentation of the Company's financial position as of June 30, 2019, its results of its operations for the three and six months ended June 30, 2019 and 2018, its changes in stockholders' equity for the three and six months ended June 30, 2019 and 2018 and its cash flows for the six months ended June 30, 2019 and 2018. The financial data and other information disclosed in these notes related to the three and six months ended June 30, 2019 and 2018 are unaudited. The results for the six months ended June 30, 2019 are not indicative of results to be expected for the year ending December 31, 2019, any other interim periods or any future year or period. These unaudited financial statements should be read in conjunction with the audited financial statements and related footnotes, which are included in the Company's Annual Report on Form 10-K for the year ended December 31, 2018.

### ***Use of Estimates***

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

### ***Research and Development Costs***

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

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

Costs for certain development activities, such as clinical trials, are recognized based on an evaluation of the progress to completion of specific tasks using data such as patient enrollment, clinical site activations, or information provided to the Company by its vendors on their actual costs incurred. Payments for these activities are based on the terms of the individual arrangements, which may differ from the patterns of costs incurred, and are reflected in the financial statements as prepaid or accrued expense. In connection with the termination of the Company's development program for retinal vein occlusion ("RVO"), the research and development expenses related to the RVO program for the second quarter of 2019 reflect a credit of \$2.6 million upon reconciliation with the CRO of final trial costs for the RVO program. The 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 restricted stock units granted is measured based on the market value of the Company's common stock on the date of grant. Share-based compensation costs are expensed on a straight-line basis over the relevant vesting period.

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

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

### ***Cash Equivalents***

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

### ***Short-Term Investments***

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

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

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

### ***Recent Accounting Pronouncements***

In February 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2016-02, *Leases (ASC 842)*, and subsequently issued updates as part of ASU 2018-11, *Leases, Targeted Improvements*. The new guidance requires organizations that lease assets with lease terms of more than 12 months to recognize assets and liabilities for the rights and obligations created by those leases on their balance sheets. The Company adopted the ASC 842 effective January 1, 2019 using the optional transition method, did not restate any prior periods and adopted the package of practical expedients. Under the package of practical expedients permitted by the new standard, the Company does not have to reassess whether 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)	June 30, 2019	December 31, 2018
Furniture and fixtures	5	\$ 400	\$ 382
Machinery and equipment	5	121	121
Computer equipment	3	19	19
Leasehold improvements	Lesser of useful life or remaining lease term	684	677
		1,224	1,199
Less: Accumulated depreciation		(516)	(409)
		<u>\$ 708</u>	<u>\$ 790</u>

### 4. Accrued Liabilities

Accrued liabilities consisted of the following (in thousands):

	June 30, 2019	December 31, 2018
Accrued research and development	\$ 777	\$ 1,263
Accrued employee costs	1,610	1,191
Accrued marketing	185	47
Accrued professional fees	79	63
Accrued interest payable	—	76
Accrued expense	212	283
	<u>\$ 2,863</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 2% of the original principal amount for any prepayment prior to October 1, 2022. A final payment of 5.50% of the aggregate borrowed amount is due at maturity of the loan on October 1, 2022, or upon the prepayment of the facility or the acceleration of amounts due under the facility as a result of an event of default.

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 \$227,000 and \$186,000 for the three months ended June 30, 2019 and 2018, respectively, and \$452,000 and \$346,000 for the six months ended June 30, 2019 and 2018, respectively. Accretion of the scheduled final payment was \$47,000 and \$11,000 for the three months ended June 30, 2019 and 2018, respectively, and \$93,000 and \$60,000 for the six months ended June 30, 2019 and 2018, respectively. Accretion of the deferred debt issuance costs was \$16,000 and \$30,000 for the three months ended June 30, 2019 and 2018, respectively, and \$31,000 and \$79,000 for the six months ended June 30, 2019 and 2018, respectively.

As of June 30, 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	\$ 423	\$ 979
2020	3,333	651	3,984
2021	3,333	366	3,699
2022	2,778	638	3,416
	<u>\$ 10,000</u>	<u>\$ 2,078</u>	<u>\$ 12,078</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 June 30, 2019 and December 31, 2018, there were 37,746,146 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 7.25 years as of June 30, 2019.

## 8. Share-Based Compensation

Share-based compensation is accounted for in accordance with the provisions of ASC 718, *Compensation-Stock Compensation*.

### Stock Options

The Company has granted stock option awards to employees, directors and consultants from its 2011 Stock Incentive Plan (the “2011 Plan”) and its 2016 Equity Incentive Plan (the “2016 Plan”). The estimated fair value of options granted is determined as of the date of grant using the Black-Scholes option pricing model. The resulting fair value is recognized ratably over the requisite service period, which is generally the vesting period of the awards.

Share-based compensation expense for options granted under the 2011 Plan and the 2016 Plan is reflected in the statements of operations as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Research and development	\$ 361	\$ 443	\$ 823	\$ 873
General and administrative	848	753	1,623	1,456
Total	<u>\$ 1,209</u>	<u>\$ 1,196</u>	<u>\$ 2,446</u>	<u>\$ 2,329</u>

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

	Number of Shares	Weighted Average Exercise Price
Options outstanding at December 31, 2018	3,463,096	\$ 6.62
Granted	1,882,600	1.26
Exercised	(2,727)	0.40
Forfeited	(760,999)	4.38
Options outstanding at June 30, 2019	<u>4,581,970</u>	4.79
Options exercisable at December 31, 2018	<u>1,583,749</u>	5.63
Options exercisable at June 30, 2019	<u>2,092,661</u>	5.84

As of June 30, 2019, the Company had \$6.6 million of unrecognized compensation expense related to unvested stock options, which is expected to be recognized over a weighted average period of 2.6 years.

### Employee Stock Purchase Plan

In January 2016, the Company’s board of directors adopted and approved, and in January 2016 the Company’s stockholders approved, the Clearside Biomedical, Inc. 2016 Employee Stock Purchase Plan (the “2016 ESPP”) which became effective on June 1, 2016. The first offering period for the 2016 ESPP commenced January 1, 2017. The 2016 ESPP is considered a compensatory plan and the fair value of the discount and the look-back period are estimated using the Black-Scholes option pricing model and expense is recognized over the six month withholding period prior to the purchase date. The Company has issued a total of 39,539 shares of common stock purchased under the 2016 ESPP. The Company has recorded \$3,000 of share-based compensation expense for each of the three months ended June 30, 2019 and 2018, and \$12,000 and \$8,000 for the six months ended June 30, 2019 and 2018, respectively, in the statements of operations for the estimated number of shares to be purchased on the next purchase date following the conclusion of the applicable reporting period.

### Restricted Stock Units

The Company has granted 485,900 restricted stock units (“RSUs”) to employees from its 2016 Plan at a fair value of \$1.09 per share. The shares underlying the RSU awards will vest in full one year from the date of grant subject to the employees’ continuous service and subject to accelerated vesting in specified circumstances. The Company recorded \$45,000 of share-based compensation expense for both the three months and six months ended June 30, 2019 for the RSUs. As of June 30, 2019, the Company had \$0.5

million of unrecognized compensation expense related to the RSUs, which is expected to be recognized over a weighted average period of 0.9 years.

## 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>June 30, 2019</b>
Operating lease right-of-use asset	\$ 867
<b>Liabilities</b>	
Current portion of operating lease liabilities	\$ 504
Operating lease liabilities	1,035
Total operating lease liabilities	<u>\$ 1,539</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 June 30, 2019, the Company's weighted average discount rate was 5.3% and the weighted average lease term was 2.6 years.

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

<b>Year Ending December 31,</b>	
2019	\$ 314
2020	574
2021	496
2022	511
2023	393
Total minimum lease payments	<u>\$ 2,288</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 June 30, 2019 and 2018, respectively, and \$200,000 and \$116,000 for the six months ended June 30, 2019 and 2018, respectively. Cash payments included in operating activities on the statement of cash flows for operating lease liabilities were \$257,000 for the six months ended June 30, 2019.

## Contract Service Providers

In the course of the Company's normal business operations, it has agreements with contract service providers to assist in the performance of its research and development, clinical research and manufacturing. Substantially all of these contracts are on an as needed basis.

## 10. Collaboration Agreements

The Company has periodically entered into other short-term collaboration agreements, generally with performance obligations of one to two months, to evaluate the potential use of its proprietary SCS Microinjector with third-party product candidates for the treatment of various diseases. Funds received from these collaboration agreements are recognized as revenue over the term of the agreement. The Company recorded \$45,000 and \$90,000 of revenue from these collaboration agreements during the three and six months ended June 30, 2019, respectively. In addition, the Company recorded \$0.2 million of deferred revenue in other current liabilities from these collaboration agreements during the three and six months ended June 30, 2019.

## 11. Fair Value Measurements

The Company records certain financial assets and liabilities at fair value in accordance with the provisions of ASC Topic 820, *Fair Value Measurements and Disclosures*, on fair value measurements. As defined in the guidance, fair value, defined as an exit price, represents the amount that would be received to sell an asset or pay to transfer a liability in an orderly transaction between market participants. As a result, fair value is a market-based approach that should be determined based on assumptions that market participants would use in pricing an asset or a liability. As a basis for considering these assumptions, the guidance defines a three-tier value hierarchy that prioritizes the inputs used in the valuation methodologies in measuring fair value.

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

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

The Company's material financial instruments at June 30, 2019 and December 31, 2018 consisted primarily of cash and cash equivalents, short-term investments and long-term debt. The fair values of cash and cash equivalents, other current assets and accounts payable approximate their respective carrying values due to the short term nature of these instruments and are classified as Level 1 in the fair value hierarchy. The fair value of long-term debt approximates the carrying value due to variable interest rates that correspond to market rates and is classified as Level 1 in the fair value hierarchy. The Company has determined its short-term investments, comprised of commercial paper, to be Level 2 in the fair value hierarchy. The fair value was determined using a market approach, based on prices and other relevant information generated by market transactions involving similar assets. The short-term investments consist of investments with original maturity dates from date of acquisition of 90 to 365 days and are classified as available-for-sale.

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

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

	June 30, 2019			Recorded Value
	Level 1	Level 2	Level 3	
<b>Financial Assets:</b>				
Cash and money markets	\$ 26,174	\$ —	\$ —	\$ 26,174
Restricted cash money market	360	—	—	360
Total financial assets	<u>\$ 26,534</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 26,534</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>

**12. Net Loss Per Share**

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Outstanding stock options	4,581,970	3,220,500	4,581,970	3,220,500
Non-vested restricted stock units	485,900	—	485,900	—
Stock purchase warrants	29,796	29,796	29,796	29,796
	<u>5,097,666</u>	<u>3,250,296</u>	<u>5,097,666</u>	<u>3,250,296</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 the retina, which is the tissue that lines the inside of the eye and is primarily responsible for vision; and the choroid, which is the layer adjacent to the retina that supplies the retina with blood, oxygen and nourishment.

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

Our suprachoroidal injection technology is used in conjunction with our proprietary formulations of existing drugs and novel therapies to create a therapeutic platform of product candidates to treat several serious eye diseases. Our lead product candidate, XIPERE, is a proprietary, preservative-free suspension of the corticosteroid triamcinolone acetonide formulated for administration via suprachoroidal injection. Based in part on the positive results from our Phase 3 PEACHTREE clinical trial, in December 2018, we submitted a New Drug Application, or NDA, to the U.S. Food and Drug Administration, or FDA, for XIPERE for the treatment of macular edema associated with uveitis. On February 19, 2019 we received notification from the FDA that it had accepted the XIPERE NDA for review and had determined that the application was sufficiently complete to permit a substantive review. The Prescription Drug User Fee Act, or PDUFA, goal date has been assigned for October 19, 2019. If it is approved for marketing, we intend to pursue collaborations with third parties to commercialize XIPERE in the United States and internationally.

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 either alone or with a partner. 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.

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 XIPERE for the treatment of macular edema associated with uveitis, if it is 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 June 30, 2019, we had an accumulated deficit of \$228.0 million. We recorded net losses of \$5.7 million and \$20.7 million for the three months ended June 30, 2019 and 2018, respectively, and net losses of \$21.1 million and \$37.3 million for the six months ended June 30, 2019 and 2018, respectively. We anticipate that a substantial portion of our capital resources and efforts in the foreseeable future will be focused on completing the necessary clinical development of, and obtaining regulatory approval and preparing for potential commercialization of, our product candidates, including commercializing XIPERE for the treatment of macular edema associated with uveitis, if approved, 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. Our clinical trial expenses have decreased significantly following our decision to discontinue late-stage clinical trials of XIPERE for indications other than uveitis. However, we will continue our efforts to seek to discover, research and develop additional product candidates and seek regulatory approvals in additional regions for XIPERE for the treatment of macular edema associated with uveitis.

## **Business Strategy Update**

We have decided not to commercialize XIPERE on our own but instead to seek a licensing or collaboration agreement with one or more partners for its commercialization. We have completed pre-launch preparations, including branding, injection training development, distribution reimbursement support and pricing evaluations, but we do not intend to spend significant additional amounts on commercialization preparations.

We are currently in discussions with multiple potential partners for XIPERE in the United States and internationally. While there can be no guarantee that we will be successful in partnering XIPERE, or as to the structure of any such transaction, we expect that any partnering agreement could provide for upfront payments and milestone payments, as well as royalties on product sales if XIPERE receives regulatory approval and has a successful commercial launch.

Based on our current plans and forecasted expenses, and our decision not to commercialize XIPERE ourselves, we expect that our existing cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements into the third quarter of 2020. This expectation does not give effect to any payments we might receive in connection with a license or collaboration agreement for XIPERE or any other potential license agreement.

## **Components of Operating Results**

### **Revenue**

We have not generated any revenue from the sale of any drugs, and we do not expect to generate any revenue unless or until we obtain regulatory approval of and commercialize our product candidates, or successfully enter into licensing or collaboration arrangements with third parties to 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.

### **Research and Development**

Since our inception, we have focused on our development programs. Research and development expenses consist primarily of costs incurred for the research and development of our preclinical and clinical product candidates, which include:

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

- costs associated with technology and intellectual property licenses;
- costs for our research and development facility; and
- depreciation expense for assets used in research and development activities.

We expense research and development costs to operations as incurred. The costs for some of our development activities, such as clinical trials, are recognized based on the terms of underlying agreements, as well as an evaluation of the progress to completion of specific tasks using data such as patient enrollment, clinical site activations and additional information provided to us by our vendors about their actual costs occurred.

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

For the three and six months ended June 30, 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 and six months ended June 30, 2019 and 2018 (in thousands).

	<b>Three Months Ended</b>		<b>Six Months Ended</b>	
	<b>June 30,</b>		<b>June 30,</b>	
	<b>2019</b>	<b>2018</b>	<b>2019</b>	<b>2018</b>
XIPERE (uveitis program)	\$ 519	\$ 2,008	\$ 1,702	\$ 4,581
XIPERE (RVO program)	(2,622)	11,477	4,180	18,853
XIPERE (DME program)	(139)	1,079	(136)	2,256
Total	(2,242)	14,564	5,746	25,690
Unallocated	2,900	2,779	5,879	5,032
Total research and development expense	<u>\$ 658</u>	<u>\$ 17,343</u>	<u>\$ 11,625</u>	<u>\$ 30,722</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.

During the first quarter of 2019, we recorded all remaining accrued expenses reported by our CRO in connection with the termination of our development program for retinal vein occlusion, or RVO. Our research and development expenses related to the RVO program for the second quarter of 2019 reflect a credit of \$2.6 million upon reconciliation with our CRO of final trial costs for the RVO program.

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

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

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

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

#### ***General and Administrative***

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

## Other Income (Expense)

Other income consists of interest income earned on our cash and cash equivalents and short-term investments. Interest income is not considered significant to our financial statements.

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

## Critical Accounting Policies and Significant Judgments and Estimates

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

We define our critical accounting policies as those accounting principles generally accepted in the United States of America that require us to make subjective estimates and judgments about matters that are uncertain and are likely to have a material impact on our financial condition and results of operations, as well as the specific manner in which we apply those principles. During the six months ended June 30, 2019, there were no significant changes to our critical accounting policies disclosed in our audited financial statements for the year ended December 31, 2018, which are included in our Annual Report on Form 10-K, as filed with the SEC on March 15, 2019, other than our adoption of ASU 2016-02, *Leases*, as described in Note 2 to our financial statements included in this report.

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

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

	Three Months Ended		Period-to-Period Change
	2019	2018	
	June 30,		
	(in thousands)		
Collaboration revenue	\$ 45	\$ —	\$ 45
Operating expenses:			
Research and development	658	17,343	(16,685)
General and administrative	5,004	3,561	1,443
Total operating expenses	<u>5,662</u>	<u>20,904</u>	<u>(15,242)</u>
Loss from operations	(5,617)	(20,904)	15,287
Other (expense) income, net	(117)	203	(320)
Net loss	<u>\$ (5,734)</u>	<u>\$ (20,701)</u>	<u>\$ 14,967</u>

*Revenue.* In the three months ended June 30, 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 \$16.7 million, from \$17.3 million for the three months ended June 30, 2018 to \$0.7 million for the three months ended June 30, 2019. This was primarily attributable to a \$14.1 million decrease due to closing down two late-stage clinical trials, SAPPHIRE and TOPAZ, that were part of our RVO program. Research and development expenses for the three months ended June 30, 2019 reflect the one-time credit of \$2.6 million upon reconciliation of final trial costs for the RVO program. Additionally, there was a \$1.6 million decrease due to 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 \$0.3 million decrease in regulatory expenses as the NDA submission for XIPERE was completed in the fourth quarter of 2018. These decreases were partially offset by a \$0.3 million increase in employee-related costs and a \$0.7 million increase in nonclinical activities.

*General and administrative.* General and administrative expenses increased by \$1.4 million, from \$3.6 million for the three months ended June 30, 2018 to \$5.0 million for the three months ended June 30, 2019. The increase was primarily attributable to a \$1.2 million increase in employee-related costs, including accrued expenses related to the resignation of our former CEO, and an increase of \$0.2 million in marketing-related expenses as we prepared for potential commercialization of XIPERE.

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

## Results of Operations for the Six Months Ended June 30, 2019 and 2018

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

	Six Months Ended June 30,		Period-to-Period Change
	2019	2018	
	(in thousands)		
Collaboration revenue	\$ 90	\$ —	\$ 90
Operating expenses:			
Research and development	11,625	30,722	(19,097)
General and administrative	9,388	6,635	2,753
Total operating expenses	<u>21,013</u>	<u>37,357</u>	<u>(16,344)</u>
Loss from operations	(20,923)	(37,357)	16,434
Other (expense) income, net	(215)	49	(264)
Net loss	<u>\$ (21,138)</u>	<u>\$ (37,308)</u>	<u>\$ 16,170</u>

*Revenue.* In the six months ended June 30, 2019, we recognized \$90,000 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 \$19.1 million, from \$30.7 million for the six months ended June 30, 2018 to \$11.6 million for the six months ended June 30, 2019. This was primarily attributable to a \$14.7 million decrease due to closing down the SAPPHIRE and TOPAZ trials, including the one-time credit of \$2.6 million upon reconciliation of final trial costs. Additionally, there was a \$3.5 million decrease due to the completion of the PEACHTREE trial during the first quarter of 2018, a \$2.4 million decrease in costs related to our DME program, as the TYBEE trial was completed in the second quarter of 2018, and a \$0.3 million decrease in regulatory expenses as the NDA submission for XIPERE was completed in the fourth quarter of 2018. These decreases were partially offset by \$0.6 million increase in costs related to device and drug manufacturing, a \$1.0 million increase in employee-related costs and a \$0.7 million increase in nonclinical activities.

*General and administrative.* General and administrative expenses increased by \$2.8 million, from \$6.6 million for the six months ended June 30, 2018 to \$9.4 million for the six months ended June 30, 2019. The increase was primarily attributable to a \$1.8 million increase in employee-related costs, including accrued expenses related to the resignation of our former CEO, and an increase of \$0.8 million in marketing-related expenses as we prepared for the potential commercialization of XIPERE.

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

## Liquidity and Capital Resources

### Sources of Liquidity

We have funded our operations primarily through the proceeds of public offerings of our common stock, sales of convertible preferred stock and the issuance of long-term debt. As of June 30, 2019, we had cash and cash equivalents of \$26.2 million. We invest

any cash in excess of our immediate requirements primarily with a view to liquidity and capital preservation. As of June 30, 2019, our funds were held in cash and money market funds.

On June 30, 2017, we entered into an at-the-market sales agreement, or the ATM agreement, with Cowen and Company LLC, or Cowen, under which we may offer and sell, from time to time at our sole discretion, shares of our common stock having an aggregate offering price of up to \$50.0 million through Cowen acting as our sales agent. During the six months ended June 30, 2019, we sold 5.6 million shares of our common stock for net proceeds of \$7.9 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 2% of the original principal amount for any prepayment prior to October 1, 2022. A final payment of 5.50% of the aggregate borrowed amount is due at maturity of the loan on October 1, 2022, or upon the prepayment of the facility or the acceleration of amounts due under the facility as a result of an event of default.

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, research and development costs to build our product candidate pipeline, legal and other regulatory expenses and general overhead costs.

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

- successful enrollment in, and completion of, clinical trials;
- receipt of marketing approvals from applicable regulatory authorities;
- establishing commercial manufacturing capabilities or making arrangements with third-party manufacturers;

- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our product candidates; and
- launching commercial sales of the products, if and when approved, whether alone or in collaboration with others.

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

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity offerings, debt financings and potential collaboration, license and development agreements. 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, including any collaboration or licensing arrangement for XIPERE, 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 costs and expenses for fees to members of our board of directors, accounting and finance personnel costs, directors and officers insurance premiums, audit and legal fees, investor relations fees and expenses for compliance with reporting requirements under the Exchange Act and rules implemented by the SEC and Nasdaq.

### Outlook

We have suffered recurring losses and negative cash flows from operations since inception and anticipate incurring additional losses until such time, if ever, that we can obtain FDA approval to market and then generate significant sales of XIPERE. We will need additional financing to fund our operations. These conditions raise substantial doubt about our ability to continue as a going concern within one year after the date of this report. We have plans to mitigate this going concern risk, which primarily consist of raising additional capital, potentially in a combination of equity or debt financings, or entering into potential collaborations, partnerships and other strategic arrangements.

Based on our current plans and forecasted expenses, and our decision not to commercialize XIPERE ourselves, we expect that our existing cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements into the third quarter of 2020. This expectation does not give effect to any payments we might receive in connection with a license or collaboration agreement for XIPERE or any other potential license or collaboration agreement for any future product candidates. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our capital resources sooner than we expect.

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

### Cash Flows

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

	Six Months Ended	
	June 30,	
	2019	2018
Net cash (used in) provided by:		
Operating activities	\$ (22,710)	\$ (35,222)
Investing activities	32,925	(20,576)
Financing activities	7,916	81,759
Net change in cash and cash equivalents	<u>\$ 18,131</u>	<u>\$ 25,961</u>

During the six months ended June 30, 2019 and 2018, our operating activities used net cash of \$22.7 million and \$35.2 million, respectively. The use of cash in each period primarily resulted from our net losses, offset in part by non-cash share-based compensation expense. The decrease in net loss for the six months ended June 30, 2019 as compared to the six months ended June 30, 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. The six months ended June 30, 2019 also included a net cash outflow of \$4.6 million from the decrease in our accounts payable balance, which was the result of payments for the winding down of the clinical trials.

During the six months ended June 30, 2019, our net cash provided by investing activities was \$32.9 million and was due to maturities of short-term, available-for-sale investments. During the six months ended June 30, 2018, our net cash used in investing activities was \$20.6 million and was due to the net amount of purchases and sales of short-term, available-for-sale investments.

During the six months ended June 30, 2019 and 2018, our net cash provided by financing activities was \$7.9 million and \$81.8 million, respectively. The net cash provided by financing activities for the six months ended June 30, 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 six months ended June 30, 2018 was comprised of the net proceeds of \$79.6 million received from our March 2018 public offering of common stock, the net proceeds of \$10.0 million from the second amended and restated loan and security agreement, 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 June 30, 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 June 30, 2019 and December 31, 2018, we had cash and cash equivalents of \$26.2 million and \$8.0 million, respectively. We generally hold our cash in interest-bearing money market accounts. As of June 30, 2019, we had no short-term investments and as of December 31, 2018, we had short-term investments of \$32.8 million. The short-term investments included commercial paper and treasury bills. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. Due to the short-term maturities of our cash equivalents and short-term investments and the low risk profile of our investments, an immediate 100 basis point change in interest rates would not have a material effect on the fair market value of our cash equivalents and short-term investments.

We do not engage in any hedging activities against changes in interest rates. Our outstanding debt instruments carried a floating interest rate that is 6.5% plus the greater of (i) the 30-day U.S. LIBOR, reported in the Wall Street Journal on the last business day of the month that immediately precedes the month in which the interest will accrue or (ii) 1.89%. We estimate that a one percentage point increase in the applicable interest rate under our loan agreements would have resulted in a \$50,000 and \$100,000 increase in interest expense for the six months ended June 30, 2019 and the year ended December 31, 2018, respectively.

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

#### **Item 4. Controls and Procedures**

##### ***Evaluation of Disclosure Controls and Procedures***

The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the “Exchange Act”), refers to controls and procedures that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that such information is accumulated and communicated to a company’s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure.

In designing and evaluating our disclosure controls and procedures, management recognizes that disclosure controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the disclosure controls and procedures are met. Additionally, in designing disclosure controls and procedures, our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible disclosure controls and procedures. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a control system, misstatements due to error or fraud may occur and not be detected.

Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures as of the end of the period covered by this report. Based on that evaluation, our Chief Executive Officer and our Chief Financial Officer concluded that our disclosure controls and procedures were effective as of the end of the period covered by this report at the reasonable assurance level.

##### ***Changes in Internal Controls over Financial Reporting***

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

**Item 1. Legal Proceedings**

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

**Item 1A. Risk Factors**

Our business is subject to risks and events that, if they occur, could adversely affect our financial condition and results of operations and the trading price of our securities. In addition to the other information set forth in this quarterly report on Form 10-Q, you should carefully consider the factors described below and in “Part I, Item 1A. Risk Factors” of our Annual Report on Form 10-K for the fiscal year ended December 31, 2018, filed with the Securities and Exchange Commission on March 15, 2019. Except as described below, there have been no material changes to the risk factors described in that report.

***We intend to seek one or more partners for the commercialization of XIPERE in the United States and internationally. If we are unable to secure commercialization partners, or if those partners fail to successfully commercialize XIPERE in their respective markets, our business and prospects will be materially harmed.***

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

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

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

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

**Item 2. Unregistered Sales of Equity Securities and Use of Proceeds***(a) Sales of Unregistered Securities*

None.

**Item 5. Other Information**

On August 6, 2019, we entered into an amendment to the offer letter agreement with George Lasezkay, originally dated April 16, 2019, setting forth the terms of Dr. Lasezkay's employment as our Chief Executive Officer. Pursuant to the amendment, we and Dr. Lasezkay agreed to extend the initial term of the offer letter agreement to March 31, 2020. Other than as set forth in the amendment, the other terms and conditions of the offer letter agreement continued in full force and effect.

The foregoing description of the amendment to the offer letter agreement is not complete and is qualified in its entirety by reference to the amendment to the offer letter agreement, which is filed as an exhibit to this Quarterly Report on Form 10-Q and is incorporated herein by reference.

In connection with entering into the amendment extending the initial term of the offer letter agreement, we granted Dr. Lasezkay a restricted stock unit for 100,000 shares of our common stock. The shares underlying this restricted stock unit will vest in full on March 31, 2020, subject to Dr. Lasezkay's continuous service through such date. In addition, all of the then unvested shares underlying the restricted stock unit will vest upon the earliest of (i) immediately prior to a change in control, (ii) Dr. Lasezkay's termination by us without cause, (iii) upon request by us that Dr. Lasezkay resign without cause following the receipt of any indication of interest from a third party for a change in control or (iv) upon commencement of employment of a new Chief Executive Officer of our company.

**Item 6. Exhibits**

Exhibit No.	Description
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>Third Amendment to License Agreement, by and among the Registrant, Emory University and Georgia Tech Research Corporation, dated April 1, 2018.</u></a>
10.2*#	<a href="#"><u>Consent and First Amendment to Second Amended and Restated Loan and Security Agreement, by and between the Registrant and Silicon Valley Bank, dated as of July 3, 2019.</u></a>
10.3*	<a href="#"><u>Amendment to offer letter agreement, by and between the Registrant and George Lasezkay, dated as of August 6, 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.

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



## THIRD AMENDMENT TO LICENSE AGREEMENT

This Third Amendment (the “**Third Amendment**”) to the License Agreement (the “**Agreement**”) dated July 4, 2012, by and among Clearside Biomedical, Inc., a Delaware corporation having a principal place of business at 900 North Point Parkway, Suite 200, Alpharetta, Georgia 30005 (“**Clearside**” or “**COMPANY**”), Emory University, a nonprofit Georgia corporation having offices located at 1599 Clifton Road NE, 4th Floor, Mailstop 1599/001/ 1 AZ, Atlanta, Georgia 30322 (“**Emory**”) and the Georgia Tech Research Corporation, a nonprofit corporation with offices located at offices located at 505 10th Street NW, Atlanta, Georgia 30332-0415 (“**GTRC**” and together with Emory, “**LICENSOR**”) is effective this 1st day of April, 2018 (the “**Third Amendment Effective Date**”).

WHEREAS, Emory and/or GTRC have made joint advances to the technology licensed pursuant to the Agreement;

WHEREAS the parties have made prior amendment to the Agreement on or around April 2, 2014 (the “**First Amendment**”), and on or around December 12, 2016 (the “**Second Amendment**”), in order to include patents that may issue based on U.S. Provisional Patent Application Serial No. 61/918,992 (the “**2014 Patent Application**”) and U.S. Provisional Patent Application Serial No. 62/364,470 (the “**2016 Patent Application**”) as “Licensed Patents” under the Agreement;

WHEREAS, the parties also desire to treat any patent applications and patents that may be Prosecuted and Maintained by LICENSOR claiming any invention (the “**2017 Invention**”) described in that certain Georgia Tech Research Corporation Invention Disclosure Form, titled “Targeted drug delivery methods using a microneedle”, attached hereto as Appendix A and incorporated herein by reference (collectively, the “**2017 IDF-Related Patents**”) as “Licensed Patents” under the Agreement; and

WHEREAS, in connection with such advances, the parties hereto wish to make certain changes to the Agreement.

NOW THEREFORE, in consideration of the promises, undertakings and covenants set forth in this Third Amendment, the receipt and sufficiency of which are hereby agreed and acknowledged, the parties agree as follows:

1. 2017 Invention Know-How and 2017 IDF-Related Patents.

- a. Any techniques, technology, prototypes, data, methods, and other information known to the Inventors of the 2017 IDF-Related Patents and owned by LICENSOR as of the Third Amendment Effective Date that is reasonably necessary to practice the 2017 IDF-Related Patents and that is disclosed but not claimed in a patent or patent application shall, promptly following the Third Amendment Effective Date, be (i) disclosed to COMPANY, and (ii) included as “Licensed Know-How” under the Agreement.
  - b. Any and all 2017 IDF-Related Patents and any rights, titles, or interests in or to such 2017 IDF-Related Patents shall constitute “Licensed Patents” under the Agreement. Appendix B of the Agreement (as amended by the First Amendment and Second Amendment) shall, without the need for any subsequent signatures by any of the parties, be amended to include reference(s) to
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the 2017 IDF-Related Patents promptly following each applicable patent office assigning a patent application serial number or patent serial number to such 2017 IDF-Related Patents.

2. Additional License Fee. As consideration for the license granted to COMPANY with respect to the 2017 IDF-Related Patents, COMPANY shall pay LICENSOR a license fee in the amount of fifteen thousand (\$15,000) Dollars within thirty (30) days of the Third Amendment Effective Date.
  3. Deletion of Section 2.5.6. The parties (i) acknowledge and agree that COMPANY has fully and satisfactorily performed all of its obligations pursuant to Section 2.5.6 of the Agreement, and (ii) agree that section 2.5.6 of the Agreement is hereby deleted in its entirety.
  4. Representations and Warranties. Subject to the disclaimers under the Agreement (including, without limitation, the disclaimer set forth in Section 9.2 of the Agreement), GTRC hereby represents that the representations set forth in Section 9.1 of the Agreement are complete and accurate with respect to the 2017 IDF-Related Patents and the Licensed Know-How described in Section 1.a of this Third Amendment, as of the Third Amendment Effective Date.
  5. No Default. Each Party acknowledges and agrees that as of the Third Amendment Effective Date, to its actual knowledge, no event has occurred, is continuing, or would result from the execution of this Third Amendment that constitutes a breach of the Agreement.
  6. Miscellaneous.
    - 6.1. Defined Terms. Capitalized terms undefined herein shall have the meaning ascribed to them in the Agreement.
    - 6.2. No Other Amendment; Effectiveness. Except as expressly amended herein, the Agreement, as amended by the First Amendment and the Second Amendment, remain in full force and effect according to their original terms.
    - 6.3. Governing Law. This Third Amendment shall be construed under and governed by the laws of the State of Georgia and the United States of America.
    - 6.4. Severability. All rights and restrictions contained herein may be exercised and shall be applicable and binding only to the extent that they do not violate any applicable laws and are intended to be limited to the extent necessary so that they will not render the Agreement, as amended by this Third Amendment, illegal, invalid, or unenforceable. If any provision or portion of any provision of this Third Amendment, not essential to the commercial purpose of the Agreement, as amended by this Third Amendment, shall be held to be, or to cause the Agreement, as amended by this Third Amendment, to be illegal, invalid, or unenforceable by a court of competent jurisdiction, it is the intention of the parties that the remaining provisions or portions thereof shall constitute their agreement with respect to the subject matter hereof, and all such remaining provisions, or portions thereof, shall remain in full force and effect. To the extent legally permissible, any illegal, invalid or unenforceable provision of the Agreement, as amended by this Third Amendment, shall be replaced by a valid provision which shall implement the commercial purpose of the illegal, invalid, or unenforceable provision.
    - 6.5. Counterparts. This Third Amendment may be executed electronically and in counterparts, each of which is deemed an original, but all of which together shall constitute one and the same instrument.
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*Signature page follows*

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IN WITNESS WHEREOF, the parties have caused this Third Amendment to be executed by their duly authorized representatives as of the Third Amendment Effective Date.

EMORY UNIVERSITY

GEORGIA TECH RESEARCH CORPORATION

By: /s/ Todd Sherer, PhD, CLP  
Name: Todd Sherer, PhD, CLP  
Title: Asst VP Research & Exec Dir  
Date: March 29, 2018

By: /s/ Lauren Maclanahan  
Name: Lauren Maclanahan  
Title: Sr Director  
Date: March 26, 2018

By: /s/ Kevin Wozniak  
Name: Kevin Wozniak  
Title: Asst Sec, GTRC  
Date: March 26, 2018

CLEARSIDE BIOMEDICAL, INC.

By: /s/ Daniel H. White  
Name: Daniel H. White  
Title: President & CEO  
Date: March 30, 2018

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**APPENDIX A**

**Information Disclosure Form**

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

THIS **CONSENT AND FIRST AMENDMENT** to Second Amended and Restated Loan and Security Agreement (this “Amendment”) is entered into as of July \_\_, 2019, by and among **SILICON VALLEY BANK**, a California corporation (“**Bank**”), as collateral agent (in such capacity, “Collateral Agent”), Bank in its capacity as a Lender, **MIDCAP FUNDING III TRUST**, and **MIDCAP FINANCIAL TRUST** (individually and collectively, jointly and severally, “MidCap”) (together with Bank, each a “Lender” and collectively, the “Lenders”), and **CLEARSIDE BIOMEDICAL, INC.**, a Delaware corporation (“Borrower”).

**RECITALS**

**A.** Lenders and Borrower have entered into that certain Second Amended and Restated Loan and Security Agreement dated as of May 14, 2018 (as the same may from time to time be amended, modified, supplemented or restated, the “Loan Agreement”). Lenders have extended credit to Borrower for the purposes permitted in the Loan Agreement.

**B.** Borrower has informed Lenders that it desires to grant an exclusive license to Aura Biosciences, Inc., a Delaware corporation (“Aura”), to develop and commercialize certain Licensed Products (as such term is defined in the License Agreement) on a worldwide basis, pursuant to the terms of that certain License Agreement by and between Aura and Borrower dated as of July \_\_, 2019 and attached hereto as Annex I (the “License Agreement”). In connection therewith, Aura has agreed, among other things, to pay to Borrower an upfront payment in the amount of Fifty Thousand Dollars (\$50,000) plus various conditional payments and royalties.

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

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

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

**AGREEMENT**

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

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

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2. **Consent.** Subject to the terms of Section 7 below, Lenders hereby consent to Borrower's entry into and performance of the License Agreement.

3. **Amendments to Loan Agreement.**

3.1 **Section 14.1 (Definitions).** The following defined term and its respective definition hereby is added to Section 14.1 of the Loan Agreement to read in its entirety as follows:

"**Aura License**" means that certain License Agreement by and between Aura Biosciences, Inc., a Delaware corporation ("Aura") and Borrower dated as of July \_\_, 2019, pursuant to which Borrower has granted Aura an exclusive license to develop and commercialize certain Licensed Products (as such term is defined therein) on a worldwide basis.

3.2 **Section 14.1 (Definitions).** The defined term "Permitted License" set forth in Section 14.1 of the Loan Agreement hereby is amended and restated in its entirety to read as follows:

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

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

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

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

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

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

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

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

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

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

*[Balance of Page Intentionally Left Blank]*

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

**BORROWER:**

CLEARSIDE BIOMEDICAL, INC.

By /s/ Leslie Zacks  
Name: Leslie Zacks  
Title: General Counsel

**COLLATERAL AGENT AND LENDER:**

SILICON VALLEY BANK

By: /s/ Myron O. Jensen  
Name: Myron O. Jensen  
Title: Vice President

**LENDERS:**

ELM 2016-1 TRUST

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

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

ELM 2018-2 TRUST, as Assignee

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

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

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

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**ANNEX 1**

**LICENSE AGREEMENT**

August 6, 2019

George Lasezkay  
XXXX

Re: Amendment to Offer of Executive Employment

Dear George:

This letter (the "**Amendment**") serves to partially amend your original Offer of Executive Employment by Clearside Biomedical, Inc. (the "**Company**") dated April 16, 2019 (the "**Employment Offer**," attached hereto as **Exhibit A**). This Amendment will become effective immediately upon your signature below. In consideration for your continued employment with the Company, your Employment Offer is amended as follows:

The first sentence in the Employment Term section is amended and restated in its entirety to read "The initial term of this Agreement will end on March 31, 2020 (the "**Initial Term**"), unless terminated prior thereto by either you or the Company."

All other terms and conditions of the Employment Offer shall continue in full force and effect. This Amendment may be executed in any number of counterparts, each of which when so executed and delivered will be deemed an original and all of which together shall constitute one and the same instrument.

Please sign this letter below to indicate your acceptance of these terms.

Sincerely,

CLEARSIDE BIOMEDICAL, INC.

/s/ Charles A. Deignan  
Name: Charles A. Deignan  
Title: Chief Financial Officer

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I have read and understood this amendment to my offer letter and hereby acknowledge, accept and agree to the terms as set forth above and further acknowledge that no other commitments were made to me as part of my employment except as specifically set forth herein.

Accepted: /s/ George Lasezkay  
George Lasezkay

Date: August 6, 2019

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**EXHIBIT A**  
**OFFER OF EXECUTIVE EMPLOYMENT**

**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 June 30, 2019 of Clearside Biomedical, Inc. (the “registrant”);
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant’s other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrant’s most recent fiscal quarter (the registrant’s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting.
5. The registrant’s other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant’s auditors and the audit committee of the registrant’s board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant’s ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant’s internal control over financial reporting.

Date: August 8, 2019

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

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

I, Charles A. Deignan, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the period ended June 30, 2019 of Clearside Biomedical, Inc. (the “registrant”);
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant’s other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrant’s most recent fiscal quarter (the registrant’s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting.
5. The registrant’s other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant’s auditors and the audit committee of the registrant’s board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant’s ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant’s internal control over financial reporting.

Date: August 8, 2019

/s/ Charles A. Deignan  
\_\_\_\_\_  
Charles A. Deignan  
Chief Financial Officer  
(principal financial officer)

**CERTIFICATIONS OF  
PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL OFFICER  
PURSUANT TO 18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the “Exchange Act”) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), George Lasezkay, Chief Executive Officer of Clearside Biomedical, Inc. (the “Company”), and Charles A. Deignan, Chief Financial Officer of the Company, each hereby certifies that, to the best of his knowledge:

1. The Company’s Quarterly Report on Form 10-Q for the period ended June 30, 2019, to which this Certification is attached as Exhibit 32.1 (the “Periodic Report”), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and
2. The information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

**IN WITNESS WHEREOF**, the undersigned have set their hands hereto as of the 8th day of August 2019.

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

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

Chief Executive Officer

(principal executive officer)

/s/ Charles A. Deignan

Charles A. Deignan

Chief Financial Officer

(principal financial officer)

- \* This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.