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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2018

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	**45-2437375**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
900 North Point Parkway, Suite 200 Alpharetta, GA	**30005**
(Address of principal executive offices)	**(Zip Code)**

(678) 270-3631

Registrant's telephone number, including area code

N/A

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

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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	☐	Accelerated filer	☒
Non-accelerated filer	☐	Smaller reporting company	☒
Emerging growth company	☒		

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

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

As of November 2, 2018, the registrant had 32,024,223 shares of common stock, $0.001 par value per share, outstanding.

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PART I – FINANCIAL INFORMATION

Item 1. Financial Statements

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

	September 30, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 15,841	$ 9,224
Short-term investments	49,101	28,416
Prepaid expenses	3,247	1,445
Other current assets	—	116
Total current assets	68,189	39,201
Property and equipment, net	778	885
Restricted cash	360	360
Other assets	54	47
Total assets	$ 69,381	$ 40,493
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 11,910	$ 5,384
Accrued liabilities	2,744	4,716
Current portion of long-term debt	—	3,200
Current portion of deferred rent	211	199
Other current liabilities	—	20
Total current liabilities	14,865	13,519
Long-term debt	9,911	4,809
Deferred rent	524	610
Deferred revenue	—	140
Total liabilities	25,300	19,078
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized and no shares issued at September 30, 2018 and December 31, 2017	—	—
Common stock, $0.001 par value; 100,000,000 shares authorized at September 30, 2018 and December 31, 2017; 32,024,223 and 25,354,651 shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively	32	25
Additional paid-in capital	229,293	145,618
Accumulated deficit	(185,240)	(124,220)
Accumulated other comprehensive loss	(4)	(8)
Total stockholders' equity	44,081	21,415
Total liabilities and stockholders' equity	$ 69,381	$ 40,493

See accompanying notes to the financial statements

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
License and collaboration revenue	$ —	$ 155	$ —	$ 290
Operating expenses:				
Research and development	20,083	16,050	50,805	35,118
General and administrative	3,873	2,298	10,508	7,259
Total operating expenses	23,956	18,348	61,313	42,377
Loss from operations	(23,956)	(18,193)	(61,313)	(42,087)
Other income (expense), net	84	(143)	133	(395)
Net loss	$ (23,872)	$ (18,336)	$ (61,180)	$ (42,482)
Net loss per share of common stock — basic and diluted	$ (0.75)	$ (0.72)	$ (2.02)	$ (1.68)
Weighted average shares outstanding — basic and diluted	32,024,223	25,338,462	30,292,909	25,299,910
Net loss	$ (23,872)	$ (18,336)	$ (61,180)	$ (42,482)
Unrealized (loss) gain on available-for-sale investments	(5)	15	4	5
Comprehensive loss	$ (23,877)	$ (18,321)	$ (61,176)	$ (42,477)

See accompanying notes to the financial statements.

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

	Nine Months Ended September 30,	
	2018	**2017**
Operating activities		
Net loss	$ (61,180)	$ (42,482)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	141	135
Share-based compensation expense	3,623	2,420
Non-cash interest expense	107	159
Accretion of debt discount	95	158
Amortization and accretion on available-for-sale investments, net	(514)	6
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(1,686)	(125)
Other assets	(7)	(61)
Accounts payable and accrued liabilities	4,554	3,694
Deferred revenue	—	(15)
Deferred rent	(74)	121
Net cash used in operating activities	(54,941)	(35,990)
Investing activities		
Purchase of available-for-sale investments	(80,137)	(40,614)
Maturities of available-for-sale investments	59,970	53,082
Acquisition of property and equipment	(34)	(306)
Net cash (used in) provided by investing activities	(20,201)	12,162
Financing activities		
Proceeds from follow-on public offering, net of issuance costs	79,581	5,057
Proceeds from exercise of stock options	433	196
Proceeds from shares issued under employee stock purchase plan	45	40
Proceeds from long-term debt	10,000	—
Payments made on long-term debt	(8,300)	—
Net cash provided by financing activities	81,759	5,293
Net increase (decrease) in cash, cash equivalents and restricted cash	6,617	(18,535)
Cash, cash equivalents and restricted cash, beginning of period	9,584	35,184
Cash, cash equivalents and restricted cash, end of period	$ 16,201	$ 16,649
Supplemental schedule of noncash investing and financing activities		
Tenant improvements paid by landlord	$ —	$ 637

See accompanying notes to the financial statements.

1. The Company

Clearside Biomedical, Inc. (the "Company") is a late-stage clinical biopharmaceutical company developing first-in-class drug therapies to treat blinding diseases of the eye. The Company's current product candidates are injected into the suprachoroidal space ("SCS") using its proprietary SCS Microinjector, and focus on the treatment of diseases affecting the retina and choroid, especially diseases associated with macular edema. 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 proceeds of its public offerings of common stock, sale of convertible preferred stock and the issuance of long-term debt. On March 12, 2018, the Company closed a follow-on public offering in which it sold 6,538,462 shares of common stock at a public offering price of $13.00 per share, resulting in net proceeds of $79.6 million after deducting underwriting discounts and commissions and estimated offering expenses. On May 14, 2018, the Company entered into a second amended and restated loan agreement, which provides for up to $20.0 million in term loans, of which the Company borrowed $10.0 million on May 14, 2018 (see Note 5). The Company will continue to need to obtain additional financing to fund future operations, including completing the development and commercialization of its primary product candidates. The Company will also 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 that might be acquired. If such products were to receive regulatory approval, the Company would need to prepare for the potential commercialization of its product candidates and fund the commercial launch of the products, if the Company decides to commercialize the products on its own. Moreover, the Company's fixed expenses such as rent and other contractual commitments are substantial and are expected to increase in the future.

The Company had cash, cash equivalents and short-term investments of $64.9 million as of September 30, 2018. In the absence of product or other revenues, the amount, timing, nature or source of which cannot be predicted, the Company's losses will continue as it conducts its research and development activities. Until the Company can generate a sufficient amount of revenue, the Company may finance future cash needs through public or private equity offerings, license agreements, debt financings, collaborations, strategic alliances and marketing or distribution arrangements. The Company has incurred losses and negative cash flows since inception and expects operating losses and negative cash flows to continue into the foreseeable future. Absent raising additional funds, based on the Company's current research and development plans, including the discontinuation of its clinical development program for combination therapy in retinal vein occlusion, planned reductions of certain administrative expenses and the Company's timing expectations with respect to the submission of a New Drug Application ("NDA") for its product candidate XIPERE for the treatment of patients with macular edema associated with non-infectious uveitis, the Company's existing cash, cash equivalents and short-term investments, combined with anticipated available borrowing capacity under its debt facility as of the filing date, November 8, 2018, will be sufficient to fund its operations into the first quarter of 2020.

2. Significant Accounting Policies

Basis of Presentation

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

Unaudited Interim Financial Information

The accompanying balance sheet as of September 30, 2018, statements of operations and comprehensive loss for the three and nine months ended September 30, 2018 and 2017 and statements of cash flows for the nine months ended September 30, 2018 and 2017 are unaudited. The unaudited interim financial statements have been prepared on the same basis as the annual financial statements and, in the opinion of management, reflect all adjustments, which include normal recurring adjustments, necessary for the fair presentation of the Company's financial position as of September 30, 2018 and its results of its operations for the three and nine months ended September 30, 2018 and 2017 and its cash flows for the nine months ended September 30, 2018 and 2017. The financial data and other information disclosed in these notes related to the three and nine months ended September 30, 2018 and 2017 are unaudited. The results for the three and nine months ended September 30, 2018 are not indicative of results to be expected for the year ending December 31, 2018, 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, 2017.

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 trial estimates and related accrued liabilities, 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, but are not limited to:

- 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 technology and intellectual property licenses;
- costs for the Company's research and development facility; and
- depreciation expense for assets used in research and development activities.

Costs for certain development activities, such as clinical trials, are recognized based on an evaluation of the progress to completion of specific tasks using data such as patient enrollment, clinical site activations, or information provided to the Company by its vendors on their actual costs incurred. Payments for these activities are based on the terms of the individual arrangements, which may differ from the patterns of costs incurred, and are reflected in the financial statements as prepaid or accrued expense. No material adjustments to these estimates have been recorded in these financial statements.

Share-Based Compensation

Compensation cost related to share-based awards granted to employees is measured based on the estimated fair value of the award at the grant date. The Company estimates the fair value of stock options using a Black-Scholes option pricing model. Compensation expense for options granted to non-employees is determined as the fair value of consideration received or the fair value of the equity instruments issued, whichever is more reliably measured. The fair value of awards granted to non-employees is re-measured each period until the related service is complete. Share-based compensation costs are expensed on a straight-line basis over the relevant vesting period.

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

All share-based compensation costs are recorded in general and administrative or research and development costs in the statements of operations and comprehensive loss 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 accumulated other comprehensive income (loss) until realized. 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

Accounting Pronouncements Recently Adopted

In May 2014, the Financial Accounting Standards Board ("FASB") issued ASU 2014-09, *Revenue from Contracts with Customers*. Under ASU 2014-09, companies are required to recognize revenue to depict the transfer of goods or services to customers in amounts that reflect the consideration (that is, payment) to which the company expects to be entitled in exchange for those goods or services. The new standard also results in enhanced disclosures about revenue, provide guidance for transactions that were not previously addressed comprehensively (for example, service revenue and contract modifications) and modifies guidance for multiple-element arrangements.

The Company adopted the standard effective January 1, 2018 using the modified retrospective transition method. After evaluating its current and prior license agreements, as well as its other collaboration agreements, the Company recorded the remaining $160,000 of deferred revenue under those agreements as a cumulative adjustment to accumulated deficit. The adoption of the new standard did not have a material impact on the Company's financial statements and related disclosures.

In August 2016, the FASB issued ASU 2016-15, *Statement of Cash Flows Classification of Certain Cash Receipts and Cash Payments*. The update addresses eight specific cash flow matters with the objective of reducing diversity in practice in how certain cash receipts and payments are classified in the statement of cash flows. The update is effective for annual periods beginning after December 15, 2017, and interim periods within the period. The Company adopted the standard effective January 1, 2018, and the adoption did not have a material impact on its financial statements and related disclosures.

In November 2016, the FASB issued ASU 2016-18, *Restricted Cash*, which addresses diversity in practice in the classification and presentation of a change in restricted cash on the statement of cash flows. The amendments in this update require that a statement of cash flows explain the change during the period in the total of cash, cash equivalents, and amounts generally described as restricted cash or restricted cash equivalents. The Company adopted the standard effective January 1, 2018, resulting in a change to the presentation of restricted cash on the statements of cash flows.

The following table is a reconciliation of cash and cash equivalents and restricted cash reported within the balance sheets that sum to the total amounts in the statements of cash flows (in thousands).

	September 30,	
	2018	2017
Cash and cash equivalents	$ 15,841	$ 16,289
Restricted cash	360	360
Cash, cash equivalents and restricted cash shown on the statements of cash flows	$ 16,201	$ 16,649

Restricted cash consists of amounts held by a financial institution under a contractual agreement.

In May 2017, the FASB issued ASU 2017-9, *Compensation-Stock Compensation: Scope of Stock Compensation Modification Accounting*. The ASU was issued to provide clarity and reduce both (1) diversity in practice and (2) cost and complexity when applying the guidance in Topic 718, Compensation—Stock Compensation, to a change to the terms or conditions of a share-based payment award. The amendments in this update provide guidance about which changes to the terms or conditions of a share-based

payment award require an entity to apply modification accounting in Topic 718. The update is effective for annual periods beginning after December 15, 2017, and interim periods thereafter. The Company adopted ASU 2017-9 effective January 1, 2018, and the impact on its financial statements and related disclosure would depend on any future modifications to its share-based awards.

Recent Accounting Pronouncements Not Yet Adopted

In February 2016, the FASB issued ASU 2016-02, *Leases (ASC 842)*, which requires lessees to recognize most leases on the balance sheet. This is expected to increase both reported assets and liabilities. For public companies, the standard will be effective for the first interim reporting period within annual periods beginning after December 15, 2018, although early adoption is permitted. Lessees and lessors will be required to apply the new standard at the beginning of the earliest period presented in the financial statements in which they first apply the new guidance, using a modified retrospective transition method. The requirements of this standard include a significant increase in required disclosures. The Company is currently assessing the impact that adopting this new accounting standard will have on its financial statements and related disclosures.

In June 2018, the FASB issued ASU No. 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 new standard is effective for fiscal years and interim periods beginning after December 15, 2018. Early adoption is permitted, but no earlier than an entity's adoption date of ASU 2014-09, *Revenue from Contracts with Customers*. The Company is currently assessing the impact that adopting this new accounting standard will have on its financial statements and related disclosures.

3. Property and Equipment, Net

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

	Estimated Useful Lives (Years)	September 30, 2018	December 31, 2017
Furniture and fixtures	5	$ 338	$ 303
Machinery and equipment	5	121	121
Computer equipment	3	32	41
Leasehold improvements	Lesser of useful life or remaining lease term	667	667
		1,158	1,132
Less: Accumulated depreciation		(380)	(247)
		$ 778	$ 885

4. Accrued Liabilities

Accrued liabilities consisted of the following (in thousands):

	September 30, 2018	December 31, 2017
Accrued research and development	$ 1,109	$ 3,360
Accrued bonuses	875	920
Accrued professional fees	40	62
Accrued vacation	118	113
Accrued interest payable	72	58
Accrued expense	530	203
	$ 2,744	$ 4,716

5. Long-Term Debt

Loan and Security Agreements

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

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

On May 14, 2018, the Company entered into a second amended and restated loan and security agreement (the "2nd A&R Loan Agreement") with SVB, MidCap Funding III Trust and MidCap Financial Trust (together, "MidCap" and collectively with SVB, the "Lenders"), which amended and restated in its entirety the 1st A&R loan agreement. The 2nd A&R Loan Agreement 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 the 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 1st A&R loan agreement, including fees associated with the final payment. The prepayment fees were waived. Of the remaining $10.0 million available under the 2nd A&R Loan Agreement, $5.0 million is no longer available for draw as the SAPPHIRE clinical trial did not meet its primary endpoint. The other $5.0 million (the "Term C Loan") will become available when the Lenders have received evidence, in form and substance reasonably satisfactory to them, that the U.S. Food and Drug Administration (the "FDA") has accepted the Company's NDA for its product candidate XIPERE for the treatment of patients with macular edema associated with non-infectious uveitis. Once the draw period for the Term C Loan has commenced, the Company may draw funds at its discretion until the earlier of (i) March 31, 2019 and (ii) the occurrence of an event of default. The Company is required to pay accrued interest only on all amounts outstanding under the 2nd A&R Loan Agreement through October 31, 2019 (or if the Term C Loan is made during the applicable draw period, through December 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 of the term loans in full, subject to a prepayment fee of 3% of the original principal amount of each term loan for any prepayment prior the first anniversary of the date such term loan is funded or 2% of the original principal amount of each term loan for any prepayment on or after the first anniversary of the date such term loan is funded but prior to October 1, 2022. A final payment of 5.50% of the aggregate borrowed amount is due at maturity of the loan on October 1, 2022, or upon the prepayment of the facility or the acceleration of amounts due under the facility as a result of an event of default.

The Company accounted for the 2nd A&R Loan Agreement as a modification in accordance with the guidance in ASC 470-50, *Debt*. Amounts paid to lenders and 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, which consists of the final payment, are being accreted over the life of the loan and recorded in long-term debt. Upon repayment of the 1st A&R loan agreement, all remaining closing costs associated with the 1st A&R loan agreement are being accreted to long-term debt over the life of the 2nd A&R Loan Agreement.

The term loans under the 2nd 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 $220,000 and $168,000 for the three months ended September 30, 2018 and 2017, respectively, and $566,000 and $486,000 for the nine months ended September 30, 2018 and

2017, respectively. Accretion of the scheduled final payment was $47,000 and $53,000 for the three months ended September 30, 2018 and 2017, respectively, and $107,000 and $159,000 for the nine months ended September 30, 2018 and 2017, respectively. Accretion of the deferred debt issuance costs was $16,000 and $53,000 for the three months ended September 30, 2018 and 2017, respectively, and $95,000 and $158,000 for the nine months ended September 30, 2018 and 2017, respectively.

As of September 30, 2018, the scheduled payments for the 2nd 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
2018	$ —	$ 214	$ 214
2019	556	845	1,401
2020	3,333	651	3,984
2021	3,333	365	3,698
2022	2,778	638	3,416
	$ 10,000	$ 2,713	$ 12,713

6. Common Stock

The Company's amended and restated certificate of incorporation authorizes the Company to issue 100,000,000 shares of $0.001 par value common stock. As of September 30, 2018 and December 31, 2017, there were 32,024,223 and 25,354,651 shares of common stock outstanding, respectively.

7. Stock Purchase Warrants

In September 2016, in connection with the 1st A&R loan agreement (see Note 5), the Company 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 the Company, and are immediately exercisable. The warrants were recorded in equity and had a weighted average remaining life of 8.0 years as of September 30, 2018.

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. Options granted to non-employees are re-measured at each financial reporting period until required services are performed.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Research and development	$ 491	$ 345	$ 1,405	$ 1,002
General and administrative	791	539	2,206	1,395
Total	$ 1,282	$ 884	$ 3,611	$ 2,397

The following table summarizes the activity related to stock options during the nine months ended September 30, 2018:

	Number of Shares	Weighted Average Exercise Price
Options outstanding at January 1, 2018	3,075,349	$ 6.17
Granted	679,500	8.32
Exercised	(123,724)	3.51
Forfeited	(64,875)	8.72
Options outstanding at September 30, 2018	3,566,250	6.62
Options exercisable at December 31, 2017	1,114,286	3.94
Options exercisable at September 30, 2018	1,393,998	5.15

As of September 30, 2018, the Company had $12.0 million of unrecognized compensation expense related to unvested stock options, which is expected to be recognized over a weighted average period of 2.8 years.

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 17,078 shares of common stock purchased under the 2016 ESPP. The Company has recorded $4,000 and $5,000 of share-based compensation expense for the three months ended September 30, 2018 and 2017, respectively, and $12,000 and $23,000 for the nine months ended September 30, 2018 and 2017, respectively, in the statements of operations and comprehensive loss for the estimated number of shares to be purchased on the next purchase date following the conclusion of the applicable reporting period.

9. Commitments and Contingencies

Lease Commitment Summary

In November 2016, the Company signed an office lease agreement to lease approximately 20,000 square feet of office space in Alpharetta, Georgia for its corporate headquarters. The lease agreement is for a 6.5 year term with a renewal option for one additional five-year term. Rental payments are $35,145 per month subject to an increase of 3% per year. Rent expense under this lease is recognized on a straight-line basis over the term of the lease. In addition, the lease agreement requires payment of the pro-rata share of the annual operating expenses associated with the premises. The Company relocated to this new 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.

Total future minimum lease payments were as follows at September 30, 2018 (in thousands):

Year Ending December 31,	
2018	$ 147
2019	600
2020	550
2021	472
Thereafter	860
Total minimum lease payments	$ 2,629

Rent expense was $79,000 and $58,000 for the three months ended September 30, 2018 and 2017, respectively, and $195,000 and $156,000 for the nine months ended September 30, 2018 and 2017, respectively.

Contract Service Providers

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

10. License and Collaboration Agreements

In August 2014, the Company entered into a royalty-bearing license agreement with NovaMedica LLC ("NovaMedica"). Under this agreement, the Company granted to NovaMedica the right to use the Company's intellectual property to develop and commercialize the intended products (the "Covered Products") and to have the exclusive right to sell those products in Russia and specified adjacent territories involving the use of the corticosteroid triamcinolone acetonide as the sole active pharmaceutical ingredient for administration in the SCS. In connection with this royalty-bearing license, NovaMedica made an upfront payment to the Company of $200,000. The Company is currently developing product candidates that, when completed, would be subject to this license giving NovaMedica the exclusive right to then sell the products in the specified geographic territories. In mid-December 2015, the Company received positive results from the Phase 2 clinical trial relating to the product candidate and determined, based on these results, that the intellectual property could become commercially feasible. Beginning in the first quarter of 2016, the Company began recognizing the $200,000 to revenue over the period of time estimated to complete clinical development and commercialization of the Covered Products and the beginning of the first set of patent expirations in 2027. On January 1, 2018, upon the adoption of ASU 2014-09, the Company accelerated the recognition of the deferred revenue and recorded the remaining balance of $160,000 as a cumulative adjustment to accumulated deficit. The Company recorded $5,000 and $15,000 of license revenue during the three and nine months ended September 30, 2017, respectively, from this license agreement. NovaMedica is jointly owned by Rusnano MedInvest LLC and Domain Russia Investments Limited.

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 $150,000 and $275,000 of revenue from these collaboration agreements during the three and nine months ended September 30, 2017, respectively.

11. Available-for-Sale Investments

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

	September 30, 2018		
	Amortized Cost	Unrealized Losses	Fair Value
Commercial paper	$ 37,160	$ —	$ 37,160
Treasury bills	11,945	(4)	11,941
Total available-for-sale investments	$ 49,105	$ (4)	$ 49,101

12. Fair Value Measurements

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

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

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

The Company's material financial instruments at September 30, 2018 and December 31, 2017 consisted primarily of cash and cash equivalents, short-term investments and long-term debt. The fair value of cash and cash equivalents, government bonds, other current assets and accounts payable approximate their respective carrying values due to the short term nature of these instruments and are classified as Level 1 in the fair hierarchy. The fair value of long-term debt approximates the carrying value due to variable interest rates that correspond to market rates. The Company has determined its short-term investments, comprised of commercial paper, certificates of deposit, and corporate bonds, to be Level 2 in the fair value hierarchy. The fair value was determined using a market approach, based on prices and other relevant information generated by market transactions involving similar assets. The short-term investments consist of investments with original maturity dates from date of acquisition of 90 to 365 days and are classified as available-for-sale.

There were no significant transfers between Levels 1, 2 and 3 during the nine months ended September 30, 2018 and the year ended December 31, 2017.

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

	September 30, 2018			
	Level 1	Level 2	Level 3	Recorded Value
Financial Assets:				
Cash and money markets	$ 15,841	$ —	$ —	$ 15,841
Restricted cash money market	360	—	—	360
Treasury bills	11,941	—	—	11,941
Commercial paper	—	37,160	—	37,160
Total financial assets	$ 28,142	$ 37,160	$ —	$ 65,302

	December 31, 2017			
	Level 1	Level 2	Level 3	Recorded Value
Financial Assets:				
Cash and money markets	$ 9,224	$ —	$ —	$ 9,224
Restricted cash money market	360	—	—	360
Government bonds	11,238	—	—	11,238
Certificates of deposit	—	1,960	—	1,960
Corporate bonds	—	5,064	—	5,064
Commercial paper	—	10,154	—	10,154
Total financial assets	$ 20,822	$ 17,178	$ —	$ 38,000

13. Net Loss Per Share

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Outstanding stock options	3,566,250	2,274,290	3,566,250	2,274,290
Stock purchase warrants	29,796	29,796	29,796	29,796
	3,596,046	2,304,086	3,596,046	2,304,086

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, particularly in Part II – Item 1A, "Risk Factors," and our other filings with the Securities and Exchange Commission, or SEC. 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, 2017 appearing in our Annual Report on Form 10-K filed with the SEC on March 16, 2018.

Overview

We are a late-stage clinical biopharmaceutical company developing first-in-class drug therapies to treat blinding diseases of the eye. Our current product candidates are injected into the suprachoroidal space, or SCS, using our proprietary SCS Microinjector, and focus on the treatment of diseases affecting the retina and choroid, especially diseases associated with macular edema. With the suprachoroidal injection procedure, our product candidates are more directly administered to the retina and choroid as compared to other ocular drug administration techniques such as intravitreal injections. We believe treatment of eye disease via suprachoroidal injection may provide a number of benefits, including lower frequency of administration and faster onset of therapeutic effect. We hold the exclusive rights to develop and commercialize drugs for treatment via injection into the SCS. Our most advanced product candidates are based on commonly used ophthalmic drugs, which we believe will allow us to more efficiently and predictably pursue the regulatory approval of these product candidates under Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act.

We are developing our lead product candidate, XIPERE™, a proprietary, preservative-free formulation of the corticosteroid triamcinolone acetonide, to be administered suprachoroidally for the treatment of patients with macular edema associated with non-infectious uveitis. In March 2018, we announced positive topline results from our PEACHTREE Phase 3 clinical trial of XIPERE for the treatment of macular edema associated with non-infectious uveitis. We enrolled 160 patients in the trial, of which 96 patients were randomized to the treatment arm to receive two 4.0 mg doses of XIPERE 12 weeks apart, and 64 patients were randomized to the control arm to undergo two sham procedures at the same 12-week intervals. Patients were evaluated every four weeks for a total of 24 weeks, and a total of 155 patients, or 97% of those enrolled, completed the full evaluation period of the trial. The trial met the primary endpoint with 47% of XIPERE patients gaining at least 15 letters in best corrected visual acuity, or BCVA, as measured using the Early Treatment of Diabetic Retinopathy Study, or ETDRS, scale, from baseline at week 24, compared to 16% of patients in the control arm. This improvement was statistically significant, with a p-value of less than 0.001. The improvement in BCVA from baseline was better in the treatment arm than the control arm at each monthly evaluation. The mean improvement from baseline was maintained throughout the evaluation period, with 9.6 letters gained at week 4 and 13.8 letters gained at week 24 in the treatment arm, compared to 1.3 letters gained at week 4 and 3.0 letters gained at week 24 in the control arm. These differences in mean improvement in BCVA between the XIPERE arm and the control arm at week 24 were also statistically significant with a p-value of less than 0.001.

Suprachoroidal administration of XIPERE resulted in a mean reduction from baseline of 153 microns in central subfield thickness, or CST, of the retina at week 24 in the treatment arm compared to an 18 micron mean reduction in the control arm, a result that was also statistically significant with a p-value of less than 0.001.

XIPERE was generally well tolerated in the trial, with no treatment-related serious adverse events reported. Through 24 weeks, corticosteroid-related elevated intraocular pressure, or IOP, adverse events were reported for approximately 11.5% (11/96) of patients in the XIPERE treatment arm, compared to 15.6% (10/64) of patients in the control arm, when including patients who received corticosteroid rescue medication. Specifically, 72% (46/64) of patients in the control arm were administered rescue medication, with 38 of the 46 receiving various forms of local corticosteroid treatments, such as intravitreal OZURDEX (dexamethasone intravitreal implant) and periocular and intravitreal triamcinolone acetonide. Of those 38 control arm patients receiving local corticosteroid rescue medication, 10 patients, or 26.3%, experienced elevated IOP adverse events. In addition, over the course of this 24-week trial, adverse events involving changes in cataract grading from baseline were similar in each arm, with approximately 7.3% and 6.3% of patients in

the XIPERE treatment arm and control arm showing adverse event changes in cataract grading, respectively. Further, no cataract surgeries resulted from this trial.

Additionally, commonly evaluated signs of inflammation using the Standardization of Uveitis Nomenclature, or SUN, scales resolved in at least two-thirds of treatment arm patients. For example, 68% of patients in the treatment arm with any level of vitreous haze at baseline had vitreous haze scores of zero by the final visit at week 24, compared to 23% of patients in the control arm. Resolution of anterior chamber cells and anterior chamber flare was 72% and 74%, respectively, for patients in the XIPERE treatment arm compared to 17% and 20%, respectively, for patients in the control arm. For patients with baseline scores of 2+ vitreous haze based on the SUN scale, 40.9% of patients experienced resolution in the XIPERE treatment arm compared to 0% of patients in the control arm at week 24. Resolution on the SUN scales is defined as achieving a score of zero on the applicable SUN scale, implying no measurable inflammation was present.

With respect to durability of treatment effect, approximately 85% of the patients in the treatment arm did not receive rescue therapy, remaining on XIPERE treatment over the 24 weeks of the trial, compared to approximately 28% of patients in the control arm.

In the treatment arm, 52% of patients could read 70 or more ETDRS letters, the minimum legal limit to qualify for a driver's license in most states, at week 24, compared to 22% of patients in the control arm.

Based on the results from PEACHTREE and all of the other information from our development related to XIPERE for the treatment of uveitis, we intend to submit a New Drug Application, or NDA, to the U.S. Food and Drug Administration, or FDA, for XIPERE for the treatment of patients with macular edema associated with non-infectious uveitis by the end of 2018.

We have also been developing XIPERE in combination with an anti-vascular endothelial growth factor, or anti-VEGF, agent for the treatment of retinal vein occlusion, or RVO, a sight-threatening disorder resulting from the blockage of a retinal vein. We have been exploring whether suprachoroidal XIPERE together with an intravitreal injection of an anti-VEGF agent can provide earlier improved visual acuity, reduced macular edema and reduced injection frequency, in each case as compared to administration of an intravitreal anti-VEGF agent alone.

We completed a Phase 2 clinical trial, which we refer to as TANZANITE, in 46 patients with RVO. In this trial, 23 patients in the combination arm initially received suprachoroidal XIPERE together with an intravitreal injection of the anti-VEGF agent Eylea, or intravitreal Eylea, and 23 patients in the control arm initially received intravitreal Eylea alone. The objective of the trial was to determine whether patients receiving suprachoroidal XIPERE together with intravitreal Eylea could sustain improvements in visual acuity and reductions in macular edema over the three months of the clinical trial while requiring fewer additional Eylea treatments than patients receiving intravitreal Eylea alone. Patients in each arm were evaluated at months one, two and three after the initial treatment using pre-specified criteria to determine if they continued to experience macular edema or reductions in visual acuity and therefore required additional intravitreal Eylea treatments. The primary objective of the trial was met, with patients in the combination arm requiring an aggregate of 60% fewer additional Eylea treatments than patients in the Eylea alone control arm over three months, a result that was statistically significant ($p=0.013$). In addition, based on a post-hoc analysis, 18 of the 23 patients, or 78%, in the combination arm of the trial did not require additional treatments during the three-month trial compared to 7 of the 23 patients, or 30%, in the control arm, a result that was also statistically significant ($p=0.003$). In the same Phase 2 trial, patients in the combination arm experienced greater improvement in visual acuity than those in the Eylea alone control arm, with a mean BCVA improvements at months one, two and three of 16, 20 and 19 letters, respectively, compared to improvements of 11, 12 and 11 letters, respectively. In addition, 52% of patients receiving XIPERE together with intravitreal Eylea recovered three lines of vision by month 1, compared to 39% of patients receiving intravitreal Eylea alone. We also extended our evaluation of the patients who participated in the trial and did not receive any additional Eylea treatment during the initial three-month evaluation period to further assess the durability of suprachoroidal XIPERE in combination with intravitreal Eylea for an additional six months following completion of the trial. Of the 32 eligible patients, the medical records of 31 patients were obtained for review. Based on combined data from TANZANITE and the extended evaluation period, 17 of the 23 patients in the combination arm, or 74%, did not receive any additional treatment over the nine-month period, compared to only 4 of 23 patients, or 17%, in the control arm.

Based on the results of TANZANITE and after incorporating feedback from an end-of-Phase 2 meeting with the FDA held in late 2016, we began to enroll patients in a Phase 3 clinical trial, which we refer to as SAPPHIRE, in the first quarter of 2017. In June 2018, we completed enrollment of 460 patients in SAPPHIRE, a multicenter, randomized, masked, controlled trial, to assess the efficacy and safety of suprachoroidal XIPERE together with intravitreal Eylea in patients with RVO. Patients in the combination treatment arm received suprachoroidal XIPERE together with intravitreal Eylea at the beginning of the trial, intravitreal Eylea alone at week 4 and suprachoroidal XIPERE together with intravitreal Eylea at weeks 12 and 24. Patients in the control arm received intravitreal Eylea alone at the beginning of the trial and follow-up intravitreal Eylea alone every four weeks through and including week 24. The primary endpoint of this trial was to determine the proportion of patients in each arm with a BCVA improvement of at

least 15 letters from baseline at eight weeks after initial treatment. Several secondary efficacy and safety endpoints were also evaluated.

In addition, in the third quarter of 2017, we began the start-up activities for a second Phase 3 clinical trial in patients with RVO, which we refer to as TOPAZ. We enrolled the first patient in TOPAZ in March 2018. Similar to the SAPPHIRE trial, TOPAZ is a multicenter, randomized, masked, controlled Phase 3 trial to assess the efficacy and safety of suprachoroidal XIPERE together with an intravitreal anti-VEGF agent (either Lucentis or Avastin) in patients with RVO. Patients in the combination treatment arm would receive suprachoroidal XIPERE together with an intravitreal anti-VEGF agent at the beginning of the trial, intravitreal anti-VEGF agent alone at week 4 and suprachoroidal XIPERE together with intravitreal anti-VEGF agent at weeks 12 and 24. Patients in the control arm would receive intravitreal anti-VEGF agent alone at the beginning of the trial and follow-up intravitreal anti-VEGF agent alone every four weeks through and including week 24.

On November 5, 2018, we announced that the primary endpoint of SAPPHIRE was not achieved, as approximately 50% of patients in both the combination arm and the control arm experienced a BCVA improvement of at least 15 letters from baseline at eight weeks after initial treatment. In light of the 8-week topline data, we plan to discontinue SAPPHIRE and TOPAZ, as well as the clinical development of XIPERE in combination with anti-VEGF agent for the treatment of RVO.

We are also developing XIPERE for the treatment of diabetic macular edema, or DME. In April 2017, we completed enrollment of 20 patients with DME in an open-label, multi-center Phase 1/2 clinical trial, which we refer to as HULK, to obtain safety data and to observe efficacy outcomes from administering a combination of intravitreal Eylea and suprachoroidal XIPERE, as well as suprachoroidal XIPERE alone, over a six-month evaluation period. In November 2017, we announced preliminary results from the HULK trial. In the trial, we observed a mean change in visual acuity improvement from baseline for patients receiving XIPERE, with a greater improvement in treatment naïve eyes. Anatomic improvement was observed in all treated eyes, with more than two-thirds of those eyes achieving a greater than 50% reduction in excess central retinal thickness from baseline, based on monthly measurements through six months after initial treatment. In the treatment naïve group, 40% of patients did not require retreatment over the entire six months, with an additional 20% requiring only one retreatment. XIPERE was well tolerated in the trial, including in patients who received multiple injections, with a low incidence of ocular side effects such as elevated IOP.

In May 2018, we completed a Phase 2 clinical trial, which we refer to as TYBEE, evaluating the safety and efficacy of administering a combination of intravitreal Eylea and suprachoroidal XIPERE to patients with DME, as compared to intravitreal Eylea alone. A total of 71 patients were randomly assigned on a 1:1 basis to receive either quarterly treatments of suprachoroidal XIPERE together with intravitreal Eylea at months 0 and 3 in the combination arm or four monthly treatments of intravitreal Eylea plus a sham suprachoroidal procedure at months 0, 1, 2 and 3 in the control arm, with patients in both arms receiving intravitreal Eylea treatment at months 4 and 5 as needed. Patient follow-up in TYBEE was six months after initial treatment.

Patients in each arm of this trial achieved a statistically significant mean improvement in BCVA as measured by the ETDRS letter scale from baseline over six months with an average of 12.3 and 13.5 ETDRS letters gained in the combination arm and in the control arm, respectively, each with a p-value of less than 0.001. When comparing the two arms, the difference in improvement in BCVA was not statistically significant.

Patients receiving suprachoroidal XIPERE together with intravitreal Eylea achieved a mean reduction from baseline of 208 microns in CST of the retina at six months. There was a 177 micron mean reduction in CST from baseline in the control arm. Each of these changes from baseline were statistically significant with p-values less than 0.001. In addition, 93% of patients in the combination arm had a greater than 50% reduction in excess CST at six months, compared to 73% of patients in the control arm. Patients in the combination arm also achieved a significantly greater resolution in their macular edema at week 4 as compared to the control arm at week 4 ($p<0.03$), an improvement that was maintained throughout the remainder of the 24-week trial.

Suprachoroidal XIPERE in combination with intravitreal Eylea was generally well tolerated in the TYBEE trial, with no treatment-related serious adverse events reported through the 24-week evaluation period. Elevated IOP adverse events were reported for 8.3% (3/36) of patients in the combination arm, compared to 2.9% (1/35) of patients in the control arm. Both the combination and control arms reported cataract adverse events, with approximately 5.6% (2/36) of patients in the combination arm and 2.9% (1/35) of patients in the control arm developing cataracts.

We have consulted with our scientific and medical advisors to evaluate a path forward in our DME program. Based on their advice, and in light of the results of SAPPHIRE in RVO, we have decided to cease any clinical development of XIPERE in combination with an anti-VEGF therapy. We believe there is a potential role for XIPERE as monotherapy in DME, RVO and other potential indications outside of uveitis, similar to the approval and use of other steroids for these indications.

Finally, we continue nonclinical efforts, both internally and with multiple collaborators, in other ocular diseases and technologies, such as gene therapy, that may benefit from a suprachoroidal treatment approach, and expect to report additional results from preclinical studies next year.

If any of our product candidates are approved, we plan to commercialize them with a specialty team of 30 to 40 sales and medical marketing professionals to target the approximately 1,900 uveitis and retina specialists in the United States, and we may also pursue collaborations with third parties to commercialize any of our drugs approved for marketing outside the United States.

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 and, beginning in 2013, conducting clinical trials of our most advanced drug candidates. To date, we have not generated any revenue, other than license and collaboration revenue, and we have primarily financed our operations through public offerings and private placements of our equity securities, issuances of convertible promissory notes and loan agreements. As of September 30, 2018, we had an accumulated deficit of $185.2 million. We recorded net losses of $23.9 million and $18.3 million for the three months ended September 30, 2018 and 2017, respectively, and $61.2 million and $42.5 million for the nine months ended September 30, 2018 and 2017, respectively. We anticipate that a substantial portion of our capital resources and efforts in the foreseeable future will be focused on completing the necessary development for and obtaining regulatory approval and preparing for potential commercialization of our product candidates.

We expect to continue to incur significant and increasing operating losses at least for the next several years. We do not expect to generate product revenue unless and until we successfully complete necessary development of, and obtain regulatory approval for, one or more of our product candidates. Our net losses may fluctuate significantly from quarter to quarter and year to year, depending on the timing of our clinical trials and our expenditures on other research and development activities. We anticipate that our clinical trial expenses will decrease as we discontinue our SAPPHIRE and TOPAZ clinical trials. However, we will however continue our efforts to seek to discover, research and develop additional product candidates and seek regulatory approvals for XIPERE for the treatment of non-infectious uveitis and other developmental efforts necessary to seek such approvals. We anticipate that our general and administrative expenses will increase substantially as we:

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

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. In 2014, we executed a license agreement with NovaMedica LLC, or NovaMedica. In connection with this agreement, we received an up-front payment of $200,000 from NovaMedica. We deferred recognizing these payments through 2015. In the first quarter of 2016, we began recognizing revenue related to the NovaMedica payment. In the first quarter of 2018, upon our adoption ASU 2014-09, *Revenue from Contracts with Customers*, the remaining $160,000 of deferred revenue was recorded as a cumulative adjustment to our accumulated deficit.

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

Research and Development

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

- employee-related expenses, including salaries, benefits, travel and share-based compensation expense for research and development personnel;
- expenses incurred under agreements with contract research organizations, or CROs, as well as contract manufacturing organizations and consultants that conduct clinical trials and preclinical studies;
- costs associated with preclinical activities and development activities;
- costs associated with technology and intellectual property licenses;
- costs for our research and development facility; and

- depreciation expense for assets used in research and development activities.

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

Expenses related to activities, such as manufacturing and stability and toxicology studies, that are supportive of a product candidate itself, are classified as direct preclinical costs. Expenses related to clinical trials and similar activities, including costs associated with CROs, are classified as direct clinical costs. Expenses related to activities that support more than one development program or activity, such as salaries, share-based compensation and depreciation, are not classified as direct clinical costs or preclinical costs and are separately classified as unallocated.

For the three and nine months ended September 30, 2018 and 2017, 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 for the three and nine months ended September 30, 2018 and 2017 (in thousands).

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
XIPERE (uveitis program)	$ 2,068	$ 3,331	$ 6,650	$ 9,534
XIPERE (RVO program)	14,148	8,593	33,001	16,292
XIPERE (DME program)	419	1,909	2,674	2,853
Wet AMD program	—	—	—	247
Total	16,635	13,833	42,325	28,926
Unallocated	3,448	2,217	8,480	6,192
Total research and development expense	$ 20,083	$ 16,050	$ 50,805	$ 35,118

Our expenses related to clinical trials are based on estimates of patient enrollment and related expenses at clinical investigator sites as well as estimates for the services received and efforts expended under contracts with research institutions, consultants and CROs that conduct and manage clinical trials on our behalf. We generally accrue expenses related to clinical trials based on contracted amounts applied to the level of patient enrollment and activity according to the protocol. If future timelines or contracts are modified based upon changes in the clinical trial protocol or scope of work to be performed, we would modify our estimates of accrued expenses accordingly on a prospective basis. Historically, any such modifications have not been material.

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

The duration, costs and timing of clinical trials and development of our product candidates will depend on a variety of factors that include, but are not limited to, the following:

- the costs associated with process development, scale-up and manufacturing of XIPERE and the SCS Microinjector for clinical trials and for requirements associated with regulatory filings associated with approval;
- the number of trials required for approval and any requirement for extension trials;
- per patient trial costs;
- the number of patients that participate in the trials;
- the number of sites included in the trials;
- the countries in which the trials are conducted;
- the length of time required to enroll eligible patients;

- the number of doses that patients receive;
- the drop-out or discontinuation rates of patients;
- potential additional safety monitoring or other studies requested by regulatory agencies;
- the duration of patient follow-up; and
- the efficacy and safety profiles of the product candidates.

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

General and Administrative

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

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

Other Income (Expense)

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

Other expense primarily consists of interest expense under our loan agreements for the three and nine months ended September 30, 2018 and 2017.

Critical Accounting Policies and Significant Judgments and Estimates

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

We define our critical accounting policies as those accounting principles generally accepted in the United States of America that require us to make subjective estimates and judgments about matters that are uncertain and are likely to have a material impact on our financial condition and results of operations, as well as the specific manner in which we apply those principles. During the nine months ended September 30, 2018, there were no significant changes to our critical accounting policies disclosed in our audited financial statements for the year ended December 31, 2017, which are included in our Annual Report on Form 10-K, as filed with the SEC on March 16, 2018, other than our adoption of ASU 2014-09, *Revenue from Contracts with Customers*, as described in Note 2 to our financial statements included in this report.

Results of Operations for the Three Months Ended September 30, 2018 and 2017

The following table sets forth our results of operations for the three months ended September 30, 2018 and 2017.

	Three Months Ended September 30,		Period-to-Period Change
	2018	2017	
	(in thousands)		
License and collaboration revenue	$ —	$ 155	$ (155)
Operating expenses:			
Research and development	20,083	16,050	4,033
General and administrative	3,873	2,298	1,575
Total operating expenses	23,956	18,348	5,608
Loss from operations	(23,956)	(18,193)	(5,763)
Other income (expense), net	84	(143)	227
Net loss	$ (23,872)	$ (18,336)	$ (5,536)

Revenue. In the three months ended September 30, 2017, we recognized $5,000 of revenue associated with our agreement with NovaMedica and $150,000 of revenue associated with other collaboration agreements.

Research and development. Research and development expense increased by $4.0 million, from $16.1 million for the three months ended September 30, 2017 to $20.1 million for the three months ended September 30, 2018. This was primarily attributable to an increase in costs related to our clinical program in RVO. Costs for our RVO program increased $5.6 million, which included purchases of clinical drug supply for SAPPHIRE and TOPAZ. We also incurred a $0.5 million increase in regulatory costs in preparation for an NDA submission, a $0.5 million increase in employee-related costs due to an increase in headcount and a $0.4 million increase in other research and development activities. These increases were partially offset by a $1.5 million decrease in clinical costs for our uveitis program, as PEACHTREE was completed during the first quarter of 2018, and a $1.5 million decrease in costs related to our DME program, as TYBEE was completed in the second quarter of 2018.

General and administrative. General and administrative expenses increased by $1.6 million, from $2.3 million for the three months ended September 30, 2017 to $3.9 million for the three months ended September 30, 2018. The increase was primarily attributable to a $0.7 million increase in employee-related costs, an increase of $0.5 million in marketing-related expenses as we prepare for potential commercialization of XIPERE and an increase of $0.2 million in patent-related expenses.

Other income (expense), net. Other income (expense), net for each of the three months ended September 30, 2018 and 2017 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 by interest income from our short-term investments.

Results of Operations for the Nine Months Ended September 30, 2018 and 2017

The following table sets forth our results of operations for the nine months ended September 30, 2018 and 2017.

	Nine Months Ended September 30,		Period-to-Period Change
	2018	2017	
	(in thousands)		
License and collaboration revenue	$ —	$ 290	$ (290)
Operating expenses:			
Research and development	50,805	35,118	15,687
General and administrative	10,508	7,259	3,249
Total operating expenses	61,313	42,377	18,936
Loss from operations	(61,313)	(42,087)	(19,226)
Other income (expense), net	133	(395)	528
Net loss	$ (61,180)	$ (42,482)	$ (18,698)

Revenue. In the nine months ended September 30, 2017, we recognized $15,000 of revenue associated with our agreement with NovaMedica and $275,000 of revenue associated with other collaboration agreements.

Research and development. Research and development expense increased by $15.7 million, from $35.1 million for the nine months ended September 30, 2017 to $50.8 million for the nine months ended September 30, 2018. This was primarily attributable to an increase in costs related to our clinical program in RVO. Costs for our RVO program increased $16.7 million, which included purchases of clinical drug supply for SAPPHIRE and start-up costs and purchases of clinical drug supply for TOPAZ. We also incurred a $0.9 million increase in regulatory costs in preparation for an NDA submission, a $1.0 million increase in employee-related costs due to an increase in headcount and a $0.7 million increase for other research and development activities. These increases were partially offset by a $2.3 million decrease in clinical costs for our uveitis program, as PEACHTREE was completed during the first quarter of 2018, a $0.6 million decrease in costs related to device and drug manufacturing and a $0.2 million decrease in our wet AMD program, which was discontinued in the first quarter of 2017.

General and administrative. General and administrative expenses increased by $3.2 million, from $7.3 million for the nine months ended September 30, 2017 to $10.5 million for the nine months ended September 30, 2018. The increase was primarily attributable to a $1.8 million increase in employee-related costs, an increase of $1.1 million in marketing-related expenses as we prepare for potential commercialization of XIPERE and an increase of $0.2 million in professional fees.

Other income (expense), net. Other income (expense), net for each of the nine months ended September 30, 2018 and 2017 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 by interest income from our short-term investments. The improvement for 2018 compared to 2017 was the result of higher short-term investment balances with the net proceeds of our public offering of common stock in the first quarter of 2018.

Liquidity and Capital Resources

Sources of Liquidity

We have funded our operations primarily through the proceeds of public offerings of our common stock, sales of convertible preferred stock and the issuance of long-term debt. As of September 30, 2018, we had cash, cash equivalents and short-term investments of $64.9 million. We invest any cash in excess of our immediate requirements primarily with a view to liquidity and capital preservation. As of September 30, 2018, our funds were held in cash, money market funds, commercial paper and treasury bills.

On March 12, 2018, we closed a follow-on public offering in which we sold 6,538,462 shares of common stock at a public offering price of $13.00 per share, resulting in net proceeds of $79.6 million after deducting underwriting discounts and commissions and estimated offering expenses.

On June 30, 2017, we entered into an at-the-market sales agreement with Cowen and Company LLC, or Cowen, under which we may offer and sell, from time to time at our sole discretion, shares of our common stock having an aggregate offering price of up to $50.0 million through Cowen acting as our sales agent. As of the date of this report, we have not sold any shares of our common stock under the at-the-market facility.

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 is no longer available for draw as the SAPPHIRE clinical trial did not meet its primary endpoint. The other $5.0 million, or the Term C

Loan, will become available for draw when the Lenders have received evidence, in form and substance reasonably satisfactory to them, that the FDA has accepted our NDA for XIPERE for the treatment of patients with macular edema associated with non-infectious uveitis. Once the draw period for the Term C Loan has commenced, we may draw funds at our discretion until March 31, 2019 or, if earlier, an event of default. We are required to pay accrued interest only on outstanding amounts through October 31, 2019, or if the Term C Loan is made during the applicable draw period, through December 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 of the term loans in full, subject to a prepayment fee of 3% of the original principal amount of each term loan for any prepayment prior the first anniversary of the date such term loan is funded or 2% of the original principal amount of each term loan for any prepayment on or after the first anniversary of the date such term loan is funded but prior to October 1, 2022. A final payment of 5.50% of the aggregate borrowed amount is due at maturity of the loan on October 1, 2022, or upon the prepayment of the facility or the acceleration of amounts due under the facility as a result of an event of default.

The term loans 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 upcoming NDA submission, commercial launch preparation for XIPERE, 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 up to $50.0 million of our common stock under the at-the-market sales agreement with Cowen subject to the terms of that agreement and depending on market conditions. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our drug development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

We also incur costs as a public company that we have not previously incurred or have previously incurred at lower rates, including increased costs and expenses for fees to members of our board of directors, increased personnel costs, increased directors and officers insurance premiums, audit and legal fees, investor relations fees and expenses for compliance with reporting requirements under the Exchange Act and rules implemented by the SEC and Nasdaq.

Outlook

Based on our current research and development plans, including the discontinuation of clinical development of XIPERE together with an anti-VEGF agent for the treatment of RVO, our plans to reduce certain administrative expenses and our timing expectations related to the progress of our upcoming NDA submission, we expect that our existing cash, cash equivalents and short-term investments, combined with anticipated available borrowing capacity under our second amended and restated loan and security agreement, will enable us to fund our operating expenses and capital expenditure requirements into the first quarter of 2020. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our capital resources sooner than we expect.

Cash Flows

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

	Nine Months Ended September 30,	
	2018	**2017**
Net cash (used in) provided by:		
Operating activities	$ (54,941)	$ (35,990)
Investing activities	(20,201)	12,162
Financing activities	81,759	5,293
Net change in cash and cash equivalents	$ 6,617	$ (18,535)

During the nine months ended September 30, 2018 and 2017, our operating activities used net cash of $54.9 million and $36.0 million, respectively. The use of cash in each period primarily resulted from our net losses. The increase in net loss for the nine months ended September 30, 2018 as compared to the nine months ended September 30, 2017 was primarily attributable to the higher research and development expenses and commercialization activities described above.

During the nine months ended September 30, 2018 and 2017, our net cash (used in) provided by investing activities was $(20.2) million and $12.2 million, respectively. In each period, cash flows used in investing activities related primarily to purchases and maturities of short-term, available-for-sale investments.

During the nine months ended September 30, 2018 and 2017, our net cash provided by financing activities was $81.8 million and $5.3 million, respectively. The net cash provided by financing activities for the nine months ended September 30, 2018 was comprised of the net proceeds of $79.6 million received from our March 2018 public offering of common stock, the net proceeds of $10.0 million from the second amended and restated loan and security agreement, 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. During the nine months ended September 30, 2017, our net cash provided by financing activities was primarily comprised of the net proceeds received from the underwriters' exercise of their option to purchase additional shares in January 2017 as part of our public offering of common stock that initially closed in December 2016.

Contractual Obligations

The following table summarizes our significant contractual obligations as of September 30, 2018, which consisted of obligations under the leases for our corporate headquarters in Alpharetta, Georgia and additional office space in Berkeley, California, obligations under the Loan Agreement and the obligations under a manufacturing supply agreement, or the Supply Agreement, with Gerresheimer Regensburg GmbH, a company incorporated under the laws of Germany, or Gerresheimer.

	Payments due by period (in thousands)				
	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Operating lease obligations	$ 2,629	$ 147	$ 1,150	$ 957	$ 375
Long-term debt obligations	12,713	214	5,385	7,114	—
Manufacturing supply agreement(1)	519	519	—	—	—
Total	$ 15,861	$ 880	$ 6,535	$ 8,071	$ 375

(1) On May 8, 2018, we entered into the Supply Agreement, pursuant to which Gerresheimer will manufacture and supply our proprietary SCS Microinjector. We will provide Gerresheimer with a rolling forecast schedule of our projected purchase orders for at least the next four calendar quarters. The agreement contains an initial five-year term that will automatically renew for successive periods of three years, unless terminated by either party at least 12 months prior to the end of the applicable term.

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. In addition, the JOBS Act defers the requirement to have the independent auditor assess the internal controls over financial reporting under Section 404(b) of the Sarbanes-Oxley Act. However, we still must comply with the Section 404(a) requirement that management assess our internal controls over financial reporting, and we began compliance with this requirement in our annual report on Form 10-K for the year ended December 31, 2017, filed with the SEC on March 16, 2018.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

The market risk inherent in our financial instruments and in our financial position represents the potential loss arising from adverse changes in interest rates. As of September 30, 2018 and December 31, 2017, we had cash and cash equivalents of $15.8 million and $9.2 million, respectively. We generally hold our cash in interest-bearing money market accounts. As of September 30, 2018 and December 31, 2017, we had short-term investments of $49.1 million and $28.4 million, respectively. The short-term investments included commercial paper, certificates of deposit, treasury bills, corporate bonds and government bonds. 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. As of September 30, 2018, 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%. As of December 31, 2017, our outstanding debt instruments carried a floating interest rate that is 7.0% 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) 0.50%. We estimate that a one percentage point increase in the applicable interest rate under our loan agreements would have resulted in a $75,000 and $60,000 increase in interest expense for the nine months ended September 30, 2018 and the year ended December 31, 2017, 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 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 Chief Financial Officer concluded that our disclosure controls and procedures were effective as of the end of the period covered by this report at the reasonable assurance level.

Changes in Internal Controls over Financial Reporting

There has been no change in our internal control over financial reporting during the quarter ended September 30, 2018 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II – OTHER INFORMATION

Item 1. Legal Proceedings

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

Item 1A. Risk Factors

Our business is subject to risks and events that, if they occur, could adversely affect our financial condition and results of operations and the trading price of our securities. Except for the updated risk factor set forth immediately below, our risk factors have not changed materially from those described in "Part I, Item 1A. Risk Factors" of our Annual Report on Form 10-K for the fiscal year ended December 31, 2017, filed with the Securities and Exchange Commission on March 16, 2018.

We contract with third parties for the manufacture of XIPERE, including our SCS Microinjector, for preclinical and clinical studies and expect to continue to do so for commercialization. This reliance on third parties increases the risk that we will not have sufficient quantities of XIPERE, including our SCS Microinjector, or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We do not have any manufacturing facilities or personnel. We currently procure the active pharmaceutical ingredient in XIPERE on a purchase order basis from a third-party manufacturer, but we do not have a commercial supply agreement in place with that manufacturer. In addition, we have entered into a supply agreement with Gerresheimer, pursuant to which we obtain each of the components of our SCS Microinjector. Some of our current suppliers, including Gerresheimer, are based outside of the United States. In addition, some of the facilities of our third-party manufacturers have only undergone a limited number of FDA inspections or no inspections. We expect to continue to rely on third parties as we proceed with preclinical and clinical studies using XIPERE with our SCS Microinjector, as well as for commercial manufacture, if any of our product candidates receives marketing approval. This reliance on third parties increases the risk that we will not have sufficient quantities of XIPERE including our SCS Microinjector or such quantities at an acceptable cost or quality, which could delay, prevent or impair our ability to timely conduct our clinical trials or our other development or commercialization efforts.

We also expect to rely on third-party manufacturers or collaborators for the manufacture of commercial supply of any other product candidates for which we obtain marketing approval. We may be unable to establish any agreements with third-party manufacturers or collaborators or to do so on acceptable terms.

Reliance on third-party manufacturers or collaborators entails additional risks, including:

- reliance on the third party for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreement by the third party;
- the possible misappropriation of our proprietary information, including our trade secrets and know-how; and
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us.

Our product candidates, including our proprietary drug formulations packaged together with our SCS Microinjector, are regulated under the drug regulations of the Federal Food, Drug, and Cosmetic Act, or FDCA. Third-party manufacturers may not be able to comply with current good manufacturing practices, or cGMP, regulations, regulations applicable to drug/device combination products, including applicable provisions of the FDA's drug cGMP regulations, device cGMP requirements embodied in the Quality System Regulation, or QSR, or similar regulatory requirements outside the United States. For example, in preparation for NDA submission for XIPERE for the treatment of patients with macular edema associated with non-infectious uveitis, we conducted audits of our third-party manufacturers, which identified items that require correction prior to the FDA's Pre-Approval Inspection of those manufacturing facilities. While we are working with these manufacturers to remediate those issues, there can be no assurance that we or they will be able to remediate those issues in a timely manner or at all. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, a refusal to file determination by the FDA, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates, operating restrictions and criminal prosecutions, any of which could significantly affect our ability to achieve regulatory approval of our product candidates.

Our product candidates that we may develop may compete with other drugs and devices for access to manufacturing facilities. There are a limited number of manufacturers that operate under the drug and device cGMP regulations applicable to our product candidates and that might be capable of manufacturing for us. Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval. We do not currently have arrangements in place for redundant supply or a second source for bulk drug substance or our SCS Microinjector. If our current contract manufacturers cannot perform as agreed, we may be required to replace such manufacturers. Although we believe that there are several potential alternative manufacturers who could manufacture our drugs and the components of our SCS Microinjector, we may incur added costs and delays in identifying and qualifying any such replacement. For example, the FDA could require supplemental data if a new supplier is relied upon for the active pharmaceutical ingredient used in our products. Any interruption or delay in the supply of components and materials, or our inability to obtain components or materials from alternate sources at acceptable prices in a timely manner, could impair our ability to meet the demand of our customers and cause them to cancel orders.

Our current and anticipated future dependence upon others for the manufacture of our product candidates may compromise our future profit margins and our ability to commercialize any product candidates that receive marketing approval on a timely and competitive basis.

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

(a) Sales of Unregistered Securities

None.

Item 6. Exhibits

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

* Filed herewith.

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

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Clearside Biomedical, Inc.

Date: November 8, 2018

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

Exhibit 31.1

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

I, Daniel H. White, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the period ended September 30, 2018 of Clearside Biomedical, Inc. (the "registrant");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 8, 2018

/s/ Daniel H. White
Daniel H. White
President and Chief Executive Officer
(principal executive officer)

Exhibit 31.2

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

I, Charles A. Deignan, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the period ended September 30, 2018 of Clearside Biomedical, Inc. (the "registrant");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 8, 2018

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

Exhibit 32.1

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

1. The Company's Quarterly Report on Form 10-Q for the period ended September 30, 2018, to which this Certification is attached as Exhibit 32.1 (the "Periodic Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

2. The information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

IN WITNESS WHEREOF, the undersigned have set their hands hereto as of the 8th day of November, 2018.

/s/ Daniel H. White
Daniel H. White
President and Chief Executive Officer
(principal executive officer)

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

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