# **UNITED STATES** SECURITIES AND EXCHANGE COMMISSION

**WASHINGTON, DC 20549** 

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QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934  $\boxtimes$ 

For the quarterly period ended June 30, 2018

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

Commission File Number: 001-37783

# Clearside Biomedical, Inc.

(Exact Name of Registrant as Specified in its Charter)

**Delaware** (State or other jurisdiction of incorporation or organization)

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

30005 (Zip Code)

45-2437375

(I.R.S. Employer Identification No.)

(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)

	hether the registrant (1) has filed all reports required to be filed by Secnths (or for such shorter period that the registrant was required to file so. Yes $\boxtimes$ No $\square$	` '	,
required to be submitted and post	hether the registrant has submitted electronically and posted on its corped pursuant to Rule 405 of Regulation S-T ( $\S$ 232.405 of this chapter) wired to submit and post such files). Yes $\boxtimes$ No $\square$		ſ
ž .	the the registrant is a large accelerated filer, an accelerated filer, and the definitions of "large accelerated filer," "accelerated filer," "smaller act.		
Large accelerated filer		Accelerated filer	$\boxtimes$
Non-accelerated filer	$\square$ (Do not check if a small reporting company)	Small reporting company	
Emerging growth company	$\boxtimes$		
0 00	npany, indicate by check mark if the registrant has elected not to use the	1 158	y

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

As of August 6, 2018, the registrant had 32,024,223 shares of common stock, \$0.001 par value per share, outstanding,

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### **Item 1. Financial Statements**

# CLEARSIDE BIOMEDICAL, INC.

# **Balance Sheets**

(in thousands, except share and per share data) (unaudited)

		June 30, 2018	December 31, 2017		
Assets					
Current assets:					
Cash and cash equivalents	\$	35,185	\$	9,224	
Short-term investments		49,245		28,416	
Prepaid expenses		2,391		1,445	
Other current assets		_		116	
Total current assets		86,821		39,201	
Property and equipment, net		791		885	
Restricted cash		360		360	
Other assets		44		47	
Total assets	\$	88,016	\$	40,493	
Liabilities and stockholders' equity					
Current liabilities:					
Accounts payable	\$	8,372	\$	5,384	
Accrued liabilities		2,368		4,716	
Current portion of long-term debt		_		3,200	
Current portion of deferred rent		206		199	
Other current liabilities		_		20	
Total current liabilities		10,946		13,519	
Long-term debt		9,848		4,809	
Deferred rent		550		610	
Deferred revenue		_		140	
Total liabilities		21,344		19,078	
Commitments and contingencies					
Stockholders' equity:					
Preferred stock, \$0.001 par value; 10,000,000 shares authorized and no shares issued at					
June 30, 2018 and December 31, 2017		_		_	
Common stock, \$0.001 par value; 100,000,000 shares authorized at June 30, 2018 and					
December 31, 2017; 32,024,223 and 25,354,651 shares issued and outstanding at June 30, 2018 and December 31, 2017, respectively		32		25	
Additional paid-in capital		228,007		25 145,618	
Accumulated deficit				,	
Accumulated other comprehensive gain (loss)		(161,368)		(124,220)	
		66 672		(8)	
Total stockholders' equity	Φ.	66,672	Φ.	21,415	
Total liabilities and stockholders' equity	\$	88,016	\$	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 June 30,				ıded			
	2018 2017			2018		2017		
License and collaboration revenue	\$	_	\$	130	\$	_	\$	135
Operating expenses:								
Research and development		17,343		11,478		30,722		19,068
General and administrative		3,561		2,290		6,635		4,961
Total operating expenses		20,904		13,768		37,357		24,029
Loss from operations		(20,904)		(13,638)		(37,357)		(23,894)
Other income (expense), net		203		(135)		49		(252)
Net loss	\$	(20,701)	\$	(13,773)	\$	(37,308)	\$	(24,146)
Net loss per share of common stock — basic and diluted	\$	(0.65)	\$	(0.54)	\$	(1.27)	\$	(0.96)
Weighted average shares outstanding — basic and diluted		31,979,158		25,309,966		29,412,904		25,280,314
							-	
Net loss	\$	(20,701)	\$	(13,773)	\$	(37,308)	\$	(24,146)
Unrealized gain (loss) on available-for-sale investments		2		(2)		9		(10)
Comprehensive loss	\$	(20,699)	\$	(13,775)	\$	(37,299)	\$	(24,156)

 $See\ accompanying\ notes\ to\ the\ financial\ statements.$ 

# CLEARSIDE BIOMEDICAL, INC. Statements of Cash Flows

(in thousands) (unaudited)

	Six Months Ended June 30,				
	2018		2017		
Operating activities					
Net loss	\$ (37,308)	\$	(24,146)		
Adjustments to reconcile net loss to net cash used in operating activities:					
Depreciation	94		87		
Share-based compensation expense	2,337		1,531		
Non-cash interest expense	60		105		
Accretion of debt discount	79		105		
Amortization and accretion on available-for-sale investments, net	(244)		30		
Changes in operating assets and liabilities:					
Prepaid expenses and other current assets	(830)		(239)		
Other assets	3		(48)		
Accounts payable and accrued liabilities	640		(14)		
Deferred revenue	_		(10)		
Deferred rent	 (53)		70		
Net cash used in operating activities	(35,222)		(22,529)		
Investing activities					
Purchase of available-for-sale investments	(52,446)		(25,603)		
Maturities of available-for-sale investments	31,870		25,010		
Acquisition of property and equipment	 _		(319)		
Net cash used in investing activities	(20,576)		(912)		
Financing activities					
Proceeds from follow-on public offering, net of issuance costs	79,581		5,057		
Proceeds from exercise of stock options	433		195		
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)		<u> </u>		
Net cash provided by financing activities	81,759		5,292		
Net increase (decrease) in cash, cash equivalents and restricted cash	 25,961		(18,149)		
Cash, cash equivalents and restricted cash, beginning of period	9,584		35,184		
Cash, cash equivalents and restricted cash, end of period	\$ 35,545	\$	17,035		
Supplemental schedule of noncash investing and financing activities					
Tenant improvements paid by landlord	\$ <del></del>	\$	637		

See accompanying notes to the financial statements.

#### CLEARSIDE BIOMEDICAL, INC.

# Notes to the Financial Statements (unaudited)

#### 1. The Company

Clearside Biomedical, Inc. (the "Company") is a 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 need to expend substantial resources for research and development, including costs associated with the clinical testing of its 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 \$84.4 million as of June 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, the Company expects that it will be able to delay, reduce or eliminate certain research and development programs or reduce administrative expense while still advancing clinical trials for key product candidates in order that the cash on hand as of the filing date, August 8, 2018, will be sufficient to fund its operations into the fourth quarter of 2019.

#### 2. Significant Accounting Policies

#### **Basis of Presentation**

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

#### **Unaudited Interim Financial Information**

The accompanying balance sheet as of June 30, 2018, statements of operations and comprehensive loss for the three and six months ended June 30, 2018 and 2017 and statements of cash flows for the six months ended June 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 June 30, 2018 and its results of its operations for the three and six months ended June 30, 2018 and 2017. The financial data and other information disclosed in these notes related to the three and six months ended June 30, 2018 and 2017 are unaudited. The results for the three and six months ended June 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 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).

	June 30,				
	2018		2017		
Cash and cash equivalents	\$ 35,185	\$	16,675		
Restricted cash	 360		360		
Cash, cash equivalents and restricted cash shown on the statements of cash flows	\$ 35,545	\$	17,035		

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)	June 30, 2018		De	ecember 31, 2017
Furniture and fixtures	5	\$	303	\$	303
Machinery and equipment	5		121		121
Computer equipment	3		32		41
Leasehold improvements	Lesser of useful life or remaining				
	lease term		667		667
			1,123		1,132
Less: Accumulated depreciation			(332)		(247)
		\$	791	\$	885

#### 4. Accrued Liabilities

Accrued liabilities consisted of the following (in thousands):

	ıne 30, 2018	<b>December</b> 3 <b>2017</b>		
Accrued research and development	\$ 1,208	\$	3,360	
Accrued bonuses	554		920	
Accrued professional fees	68		62	
Accrued vacation	88		113	
Accrued interest payable	71		58	
Accrued expense	379		203	
	\$ 2,368	\$	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 2<sup>nd</sup> A&R Loan Agreement, \$5.0 million (the "Term B Loan") will become available for draw beginning on the later of (i) October 31, 2018 and (ii) the date on which the Lenders have received evidence, in form and substance reasonably satisfactory to them, that the Company has produced positive Phase 3 data meeting the primary endpoints from its ongoing SAPPHIRE clinical trial. An additional \$5.0 million (the "Term C Loan") will become available for draw beginning on the later of (i) October 31, 2018 or (ii) the date on which 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 New Drug Application ("NDA") for its product candidate CLS-TA for the treatment of patients with non-infectious uveitis. Once the draw period for the Term B Loan or the Term C Loan, as applicable, has commenced, the Company may draw funds under the applicable loan 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 2<sup>nd</sup> 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 1<sup>st</sup> A&R loan agreement, all remaining closing costs associated with the 1<sup>st</sup> A&R loan agreement are being accreted to long-term debt over the life of the 2<sup>nd</sup> A&R Loan Agreement.

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

Interest expense on the borrowings under the loan agreements was \$186,000 and \$162,000 for the three months ended June 30, 2018 and 2017, respectively, and \$346,000 and \$317,000 for the six months ended June 30, 2018 and 2017, respectively. Accretion of the scheduled final payment was \$11,000 and \$53,000 for the three months ended June 30, 2018 and 2017, respectively, and \$60,000 and \$105,000 for the six months ended June 30, 2018 and 2017, respectively. Accretion of the deferred debt issuance costs was \$9,000 and \$53,000 for the three months ended June 30, 2018 and 2017, respectively, and \$23,000 and \$105,000 for the six months ended June 30, 2018 and 2017, respectively.

As of June 30, 2018, the scheduled payments for the 2<sup>nd</sup> A&R Loan Agreement, including the scheduled final payment in 2022, were as follows (in thousands):

	Interest and							
Year Ending December 31,	Principal Final Payment		Principal Final Payment		Principal Final Payment		yment Total	
2018	\$ —	\$ 429	\$	429				
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	\$ 2,928	\$	12,928				

#### 6. Common Stock

The Company's amended and restated certificate of incorporation authorizes the Company to issue 100,000,000 shares of \$0.001 par value common stock. As of June 30, 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 8.25 years as of June 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 June 30,			Six Months Ended June 30,				
		2018		2017		2018		2017
Research and development	\$	443	\$	332	\$	873	\$	657
General and administrative		753		438		1,456		856
Total	\$	1,196	\$	770	\$	2,329	\$	1,513

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

	Number of	Weighted Average
	Shares	Exercise Price
Options outstanding at January 1, 2018	3,075,349	\$ 6.17
Granted	318,750	8.93
Exercised	(123,724)	3.51
Forfeited	(49,875)	8.12
Options outstanding at June 30, 2018	3,220,500	6.51
Options exercisable at December 31, 2017	1,114,286	3.94
Options exercisable at June 30, 2018	1,278,725	4.90

As of June 30, 2018, the Company had \$11.3 million of unrecognized compensation expense related to unvested stock options, which is expected to be recognized over a weighted average period of 2.7 years.

#### Employee Stock Purchase Plan

In January 2016, the Company's board of directors adopted and approved, and in January 2016 the Company's stockholders approved, the Clearside Biomedical, Inc. 2016 Employee Stock Purchase Plan (the "2016 ESPP") which became effective on June 1, 2016. The first offering period for the 2016 ESPP commenced January 1, 2017. The 2016 ESPP is considered a compensatory plan and the fair value of the discount and the look-back period are estimated using the Black-Scholes option pricing model and expense is recognized over the six month withholding period prior to the purchase date. The Company has issued a total of 17,078 shares of common stock purchased under the 2016 ESPP. The Company has recorded \$3,000 and \$9,000 of share-based compensation expense for the three months ended June 30, 2018 and 2017, respectively, and \$9,000 and \$18,000 for the six months ended June 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.

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

Year Ending December 31,	
2018	\$ 217
2019	444
2020	458
2021	472
Thereafter	 860
Total minimum lease payments	\$ 2,451

Rent expense was \$58,000 for each of the three months ended June 30, 2018 and 2017 and \$116,000 and \$98,000 for the six months ended June 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 \$10,000 of license revenue during the three and six months ended June 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 \$125,000 of revenue from these collaboration agreements during the three and six months ended June 30, 2017.

#### 11. Available-for-Sale Investments

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

	June 30, 2018							
	Amortized Un			Amortized Unrealized				Fair
		Cost		Losses	Value			
Commercial paper	\$	40,784	\$		\$	40,784		
Treasury bills		8,461		_		8,461		
Total available-for-sale investments	\$	49,245	\$		\$	49,245		

#### 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 June 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 six months ended June 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):

	June 30, 2018									
	I	Level 1	I	Level 2	L	evel 3		ecorded Value		
Financial Assets:										
Cash and money markets	\$	20,913	\$	_	\$	_	\$	20,913		
Restricted cash money market		360		_		_		360		
Treasury bills		8,462		_		_		8,462		
Commercial paper		_		55,055		_		55,055		
Total financial assets	\$	29,735	\$	55,055	\$	_	\$	84,790		

	December 31, 2017									
	L	evel 1	1	Level 2	1	Level 3		ecorded 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 Montl June 3		Six Months Ended June 30,		
	2018	2017	2018	2017	
Outstanding stock options	3,220,500	2,235,378	3,220,500	2,235,378	
Stock purchase warrants	29,796	29,796	29,796	29,796	
	3,250,296	2,265,174	3,250,296	2,265,174	

#### 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 suprachoroidally injected CLS-TA, our proprietary, preservative-free formulation of the corticosteroid triamcinolone acetonide, or TA, to be administered suprachoroidally for the treatment of patients with non-infectious uveitis. On March 5, 2018, we announced positive topline results from our PEACHTREE Phase 3 clinical trial of CLS-TA 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 suprachoroidal CLS-TA 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 suprachoroidal CLS-TA 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 control arm.

Administration of suprachoroidal CLS-TA 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.

Suprachoroidal CLS-TA was generally well tolerated, with no treatment-related serious adverse events reported in the trial. Through 24 weeks, corticosteroid-related elevated intraocular pressure, or IOP, adverse events were reported for approximately 11.5% (11/96) of patients in the CLS-TA 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 subtenon and intravitreal triamcinolone acetonide. Of those 38 control arm patients, ten, or 26.3%, experienced elevated IOP. 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 CLS-TA 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 resolved in at least two-thirds of treatment arm patients. For example, 67% 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 whose vitreous haze resolved by week 24. Resolution of anterior chamber cells and anterior chamber flare was 72% and 79%, respectively, of patients in the CLS-TA treatment arm compared to 17% and 20%, respectively, of patients in the control arm.

With respect to durability of treatment effect, approximately 85% of the patients in the treatment arm did not receive rescue therapy, remaining on CLS-TA 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 CLS-TA for the treatment of uveitis, we intend to submit a New Drug Application, or NDA, for CLS-TA for the treatment of patients with non-infectious uveitis by the end of 2018.

We are also developing CLS-TA 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 are exploring whether suprachoroidal CLS-TA together with an intravitreal injection of an anti-VEGF agent can provide earlier improved visual acuity and reduced macular edema, and reduced injection frequency 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 CLS-TA 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 CLS-TA 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 CLS-TA 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 CLS-TA 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 CLS-TA together with intravitreal Eylea in patients with RVO. Patients in the combination treatment arm will receive suprachoroidal CLS-TA together with intravitreal Eylea at the beginning of the trial, intravitreal Eylea alone at week 4 and suprachoroidal CLS-TA together with intravitreal Eylea at weeks 12 and 24. Patients in the control arm will receive intravitreal Eylea alone at the beginning of the trial and follow-up intravitreal Eylea alone every four weeks through and including week 24. After 24 weeks, patients will be followed for approximately an additional six months. While safety and efficacy analyses will be conducted at week 24 and at the end of the study after the additional six-month period, the primary endpoint of this trial will be 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 will also be evaluated. We expect to report topline 8-week results from SAPPHIRE in the fourth quarter of 2018.

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 CLS-TA together with an intravitreal anti-VEGF agent (either Lucentis or Avastin) in patients with RVO. Patients in the combination treatment arm will receive suprachoroidal CLS-TA together with an intravitreal anti-VEGF agent at the beginning of the trial, intravitreal anti-VEGF agent at week 4 and suprachoroidal CLS-TA together with intravitreal anti-VEGF agent at weeks 12 and 24. Patients in the control arm will 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. After 24 weeks, patients will be followed for approximately an additional six months, with patients in each arm having the opportunity to receive treatment as needed based on monthly evaluations. The primary objective of this trial will be 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 will also be evaluated. We anticipate total enrollment of approximately 460 patients in the trial.

We are also developing suprachoroidal CLS-TA 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 CLS-TA, as well as suprachoroidal CLS-TA 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 suprachoroidal CLS-TA, 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. Suprachoroidal CLS-TA, including in patients who received multiple injections, was well tolerated, with a low incidence of ocular side effects, including IOP elevations.

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 CLS-TA to patients with DME, as compared to intravitreal Eylea alone. A total of 71 patients were randomly assigned 1:1 to receive either quarterly treatments of suprachoroidal CLS-TA 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.

Each arm in this trial showed a statistically significant mean improvement in BCVA as measured by the ETDRS letter scale from baseline over six months (p=0.001). The improvements in BCVA in each arm were clinically and statistically similar with the combination arm and the Eylea alone arm gaining an average of 12.3 and 13.5 ETDRS letters respectively (p=0.664).

Additionally, administration of suprachoroidal CLS-TA together with intravitreal Eylea showed a mean reduction from baseline of 208 microns in CST of the retina at six months, compared to a 177 micron mean reduction in the control arm (p=0.156). Further, 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. There was significantly greater resolution in macular edema in the combination arm compared to the Eylea only arm at week 4, and this additional resolution was maintained through the 24-week trial.

Suprachoroidal CLS-TA in combination with intravitreal Eylea was generally well tolerated, with no treatment-related serious adverse events reported in the TYBEE trial 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 are continuing to analyze data from the TYBEE trial along with expertise from our scientific advisors.

Finally, multiple nonclinical studies, both internally and with multiple collaborators, are underway in preclinical development areas such as gene therapy for inherited retinal disorders, neovascular age-related macular degeneration, also known as wet AMD, and other ocular diseases that may benefit from suprachoroidal administration of investigational product candidates.

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 revenue, and we have primarily financed our operations through public offerings and private placements of our equity securities, issuances of convertible promissory notes and loan agreements. As of June 30, 2018, we had an accumulated deficit of \$161.4 million. We recorded net losses of \$20.7 million and \$13.8 million for the three months ended June 30, 2018 and 2017, respectively, and \$37.3

million and \$24.1 million for the six months ended June 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 expenses will increase as we:

- complete our ongoing SAPPHIRE and TOPAZ clinical trials;
- initiate and conduct our planned future clinical trials;
- seek to discover, research and develop additional product candidates;
- seek regulatory approvals for any product candidates that successfully complete clinical trials and other developmental efforts necessary to seek such approvals;
- establish sales, marketing and distribution infrastructure and scale up external manufacturing capabilities to commercialize any product candidates for which we may obtain regulatory approval;
- maintain, expand and protect our intellectual property portfolio;
- hire additional clinical, manufacturing, medical and scientific personnel;
- 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 six months ended June 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 six months ended June 30, 2018 and 2017 (in thousands).

		Three Months Ended June 30,					ths Ended ne 30,													
		2018		2018		2018		2018		2018		2018		2018 2017		2017	2018			2017
CLS-TA (uveitis program)	\$	2,008	\$	2,623	\$	4,581	\$	6,203												
CLS-TA (RVO program)		11,477		5,764		18,852		7,699												
CLS-TA (DME program)		1,079		805		2,256		945												
Wet AMD program		_		_		_		247												
Total		14,564		9,192		25,689		15,094												
Unallocated		2,779		2,286		5,033		3,974												
Total research and development expense	\$	17,343	\$	11,478	\$	30,722	\$	19,068												

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. We expect our research and development expenses to increase over the next several years as we progress our product candidates through clinical development. 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 CLS-TA 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 six months ended June 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 six months ended June 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 June 30, 2018 and 2017

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

	Three Mon	ths Ended			
	 June	30,	Period-to-Period		
	2018	2017		Change	
		(in thousands)			
License and collaboration revenue	\$ _	\$ 130	\$	(130)	
Operating expenses:					
Research and development	17,343	11,478		5,865	
General and administrative	3,561	2,290		1,271	
Total operating expenses	20,904	13,768		7,136	
Loss from operations	(20,904)	(13,638)		(7,266)	
Other income (expense), net	203	(135)		338	
Net loss	\$ (20,701)	\$ (13,773)	\$	(6,928)	

*Revenue*. In the three months ended June 30, 2017, we recognized \$5,000 of revenue associated with our agreement with NovaMedica and \$125,000 of revenue associated with other collaboration agreements.

Research and development. Research and development expense increased by \$5.9 million, from \$11.5 million for the three months ended June 30, 2017 to \$17.3 million for the three months ended June 30, 2018. This was primarily attributable to an increase in costs related to our clinical programs. Costs for our RVO program increased \$5.7 million, which included purchases of Eylea for SAPPHIRE and start-up costs and purchases of Lucentis and Avastin for TOPAZ, and costs for our DME program increased \$0.3 million. We also incurred a \$0.2 million increase in regulatory costs in preparation for an NDA submission and a \$0.3 million increase in employee-related costs due to an increase in headcount to support our increased clinical trial activities. These increases were partially offset by a \$0.2 million decrease in clinical costs for our uveitis program, as PEACHTREE was completed during the first quarter of 2018, and a \$0.4 million decrease in costs related to device and drug manufacturing.

General and administrative. General and administrative expenses increased by \$1.3 million, from \$2.3 million for the three months ended June 30, 2017 to \$3.6 million for the three months ended June 30, 2018. The increase was primarily attributable to a \$0.6 million increase in employee-related costs, an increase of \$0.4 million in marketing-related expenses as we prepare for potential commercialization of CLS-TA and an increase of \$0.1 million in patent-related expenses.

Other income (expense), net. Other income (expense), net for each of the three months ended June 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 Six Months Ended June 30, 2018 and 2017

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

Six Months Ended							
	June	2 30,	Period-to-Period				
	2018	2017		Change			
		(in thousands)					
\$	_	\$ 135	\$	(135)			
	30,722	19,068		11,654			
	6,635	4,961		1,674			
	37,357	24,029		13,328			
	(37,357)	(23,894)		(13,463)			
	49	(252)		301			
\$	(37,308)	\$ (24,146)	\$	(13,162)			
	\$	\$ — 30,722 6,635 37,357 (37,357) 49	June 30,       2018     2017       (in thousands)       \$     —     \$ 135       30,722     19,068       6,635     4,961       37,357     24,029       (37,357)     (23,894)       49     (252)	June 30,     Pe       2018     2017       (in thousands)     \$       \$ — \$ 135     \$       30,722     19,068       6,635     4,961       37,357     24,029       (37,357)     (23,894)       49     (252)			

*Revenue*. In the six months ended June 30, 2017, we recognized \$10,000 of revenue associated with our agreement with NovaMedica and \$125,000 of revenue associated with other collaboration agreements.

Research and development. Research and development expense increased by \$11.7 million, from \$19.1 million for the six months ended June 30, 2017 to \$30.7 million for the six months ended June 30, 2018. This was primarily attributable to an increase in costs related to our clinical programs. Costs for our RVO program increased \$11.2 million, which included purchases of Eylea for SAPPHIRE and start-up costs and purchases of Lucentis and Avastin for TOPAZ, and costs for our DME program increased \$1.3 million. We also incurred a \$0.4 million increase in regulatory costs in preparation for an NDA submission and a \$0.4 million increase in employee-related costs due to an increase in headcount to support our increased clinical trial activities. These increases were partially offset by a \$0.8 million decrease in clinical costs for our uveitis program, as PEACHTREE was completed during the first quarter of 2018, and a \$0.9 million decrease in costs related to device and drug manufacturing.

General and administrative. General and administrative expenses increased by \$1.7 million, from \$5.0 million for the six months ended June 30, 2017 to \$6.6 million for the six months ended June 30, 2018. The increase was primarily attributable to a \$1.1 million increase in employee-related costs, an increase of \$0.5 million in marketing-related expenses as we prepare for potential commercialization of CLS-TA and an increase of \$0.1 million in professional fees.

Other income (expense), net. Other income (expense), net for each of the six months ended June 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.

#### **Liquidity and Capital Resources**

#### Sources of Liquidity

We have funded our operations primarily through the proceeds of public offerings of our common stock, sales of convertible preferred stock and the issuance of long-term debt. As of June 30, 2018, we had cash, cash equivalents and short-term investments of \$84.4 million. We invest any cash in excess of our immediate requirements primarily with a view to liquidity and capital preservation. As of June 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, or the Term B Loan, will become available for draw beginning on the later of (i) October 31, 2018 and (ii) the date on which the Lenders have received evidence, in form and substance reasonably satisfactory to them, that we have produced positive Phase 3 data meeting primary endpoints from the SAPPHIRE trial. An additional \$5.0 million, or the Term C Loan, will become available for draw beginning on the later of (i) October 31, 2018 and (ii) the date on which the Lenders have received evidence, in form and substance reasonably satisfactory to them, that the FDA has accepted the NDA for CLS-TA for the treatment of patients with non-infectious uveitis. Once the draw period for the Term B Loan or the Term C Loan, as applicable, has commenced, we may draw funds under the

applicable term loan at our discretion until the earlier of (i) March 31, 2019 or (ii) the occurrence of 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, third-party clinical research and development services, laboratory and related supplies, clinical costs, 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 CLS-TA or any future product candidates, although we will require additional funding to complete our Phase 3 clinical program for CLS-TA as a potential treatment, together with an anti-VEGF agent, for RVO. 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 research and development plans and our timing expectations related to the progress of our programs, including our ability to control spending by delaying, reducing or eliminating research and development programs or reducing administrative expense while still advancing clinical trials for our most advanced product candidates, we expect that our existing cash, cash equivalents and short-term investments, combined with anticipated available borrowing capacity under our 2nd A&R Loan Agreement, will enable us to fund our operating expenses and capital expenditure requirements into the fourth quarter of 2019. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our capital resources sooner than we expect. Additionally, the process of testing product candidates in clinical trials is costly, and the timing of progress in these trials is uncertain.

#### Cash Flows

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

	 Six Months Ended June 30,				
	2018				
Net cash (used in) provided by:					
Operating activities	\$ (35,222)	\$	(22,529)		
Investing activities	(20,576)		(912)		
Financing activities	81,759		5,292		
Net change in cash and cash equivalents	\$ 25,961	\$	(18,149)		

During the six months ended June 30, 2018 and 2017, our operating activities used net cash of \$35.2 million and \$22.5 million, respectively. The use of cash in each period primarily resulted from our net losses. The increase in net loss for the six months ended June 30, 2018 as compared to the six months ended June 30, 2017 was primarily attributable to the higher research and development expenses described above.

During the six months ended June 30, 2018 and 2017, our net cash used in investing activities was \$20.6 million and \$0.9 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 six months ended June 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 six months ended June 30, 2018 was comprised of the net proceeds of \$79.6 million received from our March 2018 public offering of common stock, the net proceeds of \$10.0 million from the 2nd A&R Loan 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 six months ended June 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 June 30, 2018, which consisted of obligations under the lease for our corporate headquarters in Alpharetta, Georgia, 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)										
	Less than							More than			
	Total		1 year		1 year		3 years	3-	5 years	5 ;	years
Operating lease obligations	\$ 2,451	\$	217	\$	902	\$	957	\$	375		
Long-term debt obligations	12,928		429		5,385		7,114		_		
Manufacturing supply agreement(1)	519		519		_		_		_		
Total	\$ 15,898	\$	1,165	\$	6,287	\$	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 our annual report on Form 10-K for the year ended December 31, 2017.

#### Item 3. Quantitative and Qualitative Disclosures about Market Risk

The market risk inherent in our financial instruments and in our financial position represents the potential loss arising from adverse changes in interest rates. As of June 30, 2018 and December 31, 2017, we had cash and cash equivalents of \$35.2 million and \$9.2 million, respectively. We generally hold our cash in interest-bearing money market accounts. As of June 30, 2018 and December 31, 2017, we had short-term investments of \$49.2 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 June 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 \$50,000 and \$80,000 increase in interest expense for the six months ended June 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 June 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. In addition to the other information set forth in this quarterly report on Form 10-Q, you should carefully consider the factors described in "Part I, Item 1A. Risk Factors" of our Annual Report on Form 10-K for the fiscal year ended December 31, 2017, filed with the Securities and Exchange Commission on March 16, 2018. There have been no material changes to the risk factors described in that report.

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

(a) Sales of Unregistered Securities

None.

#### Item 6. Exhibits

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).
10.1*#	Supply Agreement, by and between Registrant and Gerresheimer Regensburg GMBH, dated as of May 8, 2018.
10.2*	Change in Control Equity Acceleration Plan, amending the Registrant's 2016 Equity Incentive Plan.
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

 <sup>\*</sup> Filed herewith.

# Confidential treatment has been requested with respect to portions of this exhibit, indicated by asterisks, which has been filed separately with the SEC.

<sup>\*\*</sup> 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: August 8, 2018

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

n behalf of the Registrant and as Principal Financial Officer)

CLEARSIDE BIOMEDICAL, INC.				
and				
GERRESHEIMER REGENSBURG GMBH				
SUPPLY AGREEMENT				
FOR				
PRODUCTS				

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#### SUPPLY AGREEMENT FOR PRODUCTS

THIS AGREEMENT is made the 8th day of May, 2018 (the "Effective Date") BETWEEN:

**Clearside Biomedical, Inc.** a company incorporated under laws of the State of Delaware, USA and having its registered office at 900 North Point Parkway, Suite 200, Alpharetta 30005, USA, for and on behalf of itself and its Affiliates ("**CLEARSIDE BIOMEDICAL**")

**Gerresheimer Regensburg GmbH,** a company incorporated under laws of Germany and having its registered office at Kumpfmühler Straße 2, 93047 Regensburg, Germany ("**GERRESHEIMER**").

CLEARSIDE BIOMEDICAL and GERRESHEIMER may be hereinafter referred to as a/one "Party" and collectively as the "Parties".

**WHEREAS** GERRESHEIMER develops, manufactures, distributes and sells plastic dispensing systems, components and devices for use in pharmaceutical and other healthcare products;

WHEREAS CLEARSIDE BIOMEDICAL develops, manufactures, distributes and sells pharmaceuticals and medical devices;

WHEREAS GERRESHEIMER has agreed to manufacture and supply the Products to CLEARSIDE BIOMEDICAL as stipulated in the Product Schedules, and CLEARSIDE BIOMEDICAL has agreed to purchase the Products in accordance with the terms of this Agreement.

#### NOW, IT IS HEREBY AGREED as follows:

### 1. <u>DEFINITIONS</u>

1.1 In this Agreement, each of the following terms shall have the respective meaning set forth below:

"Affiliate" means in relation to one Party, any other corporation, firm, partnership or other entity or person which is directly or indirectly controlled by, in control of or under common control with the other. For the purposes of this definition, control shall consist of the ownership of more than fifty percent (50%) of the voting stock of any organisation or the legal power to direct or cause the direction of the general management of the organisation as appropriate. In case of GERRESHEIMER, the term Affiliates shall apply only to Affiliates of GERRESHEIMER Regensburg GmbH, which comprises companies which are directly or indirectly controlled by Gerresheimer Regensburg GmbH.

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- "Agreed Defective Product" has the meaning set forth in Clause 10.5.
- "Agreement" means this supply agreement together with all its Schedules (the "Schedules").
- "Annual Price Review" has the meaning set forth in Clause 7.2.
- "Applicable Law" means applicable laws, regulations, certification requirements and agreed standards in the European Union and the United States of America.
- "Background IP" has the meaning set forth in Clause 15.1.
- "Business Day(s)" means any day other than a Saturday, Sunday, or any other day which is a statutory public holiday in the United States of America and/or GERRESHEIMER's country of manufacture of the applicable Product (as defined in the applicable Product Schedule).
- "Calendar Quarter" has the meaning set forth in Clause 4.1.
- "Certificate of Analysis" a document identified as such and provided by GERRESHEIMER to CLEARSIDE BIOMEDICAL that (i) sets forth the analytical test results for a specified lot of Product shipped to CLEARSIDE BIOMEDICAL or its designee hereunder and includes a certified quality control protocol, (ii) states that such Product is in conformance with the Specifications, and (iii) states that such Product is manufactured in accordance with the Specifications and cGMPs.
- **"cGMP"** means the principles detailed in the U.S. Current Good Manufacturing Practices, 21 C.F.R. Parts 210 and 211 being implemented within the pharmaceutical manufacturing industry for such products; in each case as amended, promulgated or accepted from time to time.
- "Change of Control" means either the ownership of more than fifty percent (50 %) of the ordinary share capital of the applicable Party carrying the right to vote at general meetings or the power to nominate a majority of the board of directors of such Party. The aforementioned shall not apply to a change in the legal or beneficial ownership or control if such change is part of a reorganisation or restructuring process between Affiliates of the Party, provided such Affiliate is not a direct competitor of the other Party.
- "CLEARSIDE BIOMEDICAL Results" has the meaning set forth in Clause 15.5.
- "Commercial Launch Anniversary" has the meaning set forth in Clause 4.1.
- "Confidential Information" means without limitation any information disclosed to the Receiving Party in the course of or as a result of this Agreement by or on behalf of the Disclosing Party or any other person being involved in the exchange of information or learned or observed by the Receiving Party relating to (i) the Disclosing Party's business or business plans, including, but not limited to, suppliers, customers, prospective customers, contractors, utilization data, cost and pricing data, software products, all proprietary information, Know-How, trade secrets, technical and non-technical materials, products, specifications, processes, sales and marketing

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plans and strategies, and designs; (ii) information of any Third Parties for which the Disclosing Party has an obligation of confidentiality; (iii) any discussions and proceedings relating to any of the foregoing information, whether disclosed in oral, electronic, visual, written or any other form; and (iv) any information developed or derived by the Receiving Party from the information described in the foregoing clauses (i) – (iii), whether or not for or on behalf of the Disclosing Party. Confidential Information includes, without limitation, the existence and terms and conditions of this Agreement. The fact that the Disclosing Party may have marked or identified as confidential or proprietary any specific information shall be indicative that the Disclosing Party believes such information to be confidential or proprietary, but the failure to so mark information shall not conclusively determine that such information is or is not considered confidential information by the Disclosing Party.

"Consents" has the meaning set forth in Clause 14.2.

"Defective Product" means Product not in compliance with the Specifications.

"**Delivery**" means a delivery of Products made in accordance with the terms of this Agreement and the relevant Firm Order and any applicable Purchase Order (and "**Deliver**" and "**Delivered**" shall be construed accordingly).

"**Delivery Terms**" means the terms for delivery of a Product as specified in the relevant Product Schedule. For each Delivery, GERRESHEIMER shall provide to CLEARSIDE BIOMEDICAL or its Affiliates, as applicable, the agreed Delivery documentation, but in any event, a Certificate of Analysis.

"Direct Labour Costs" mean the cost for personnel directly involved in the manufacturing process.

"Disclosing Party" means the Party or any of its Affiliates that discloses or causes to be disclosed Confidential Information to the Receiving Party.

"Dispute" has the meaning set forth in Clause 38.1.

"Documentation" has the meaning set forth in Clause 13.2.

"Equipment" means the CLEARSIDE BIOMEDICAL owned Product specific injection mould tooling and other equipment listed in the Product Schedules.

"Firm Order" has the meaning set forth in Clause 4.3.

"Forecast Schedule" has the meaning set forth in Clause 4.1.

"GERRESHEIMER Results" has the meaning set forth in Clause 15.5.

"Indemnified Party" has the meaning set forth in Clause 22.7.

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"Indemnifying Party" has the meaning set forth in Clause 22.7.

"Initial Term" has the meaning set forth in Clause 2.

"Intellectual Property" or "IP" means Know-How, patent rights, trademarks, service marks, trade names, design rights, copyright (including rights in computer software) and any rights or property similar to any of the foregoing in any part of the world, whether registered or not, together with the right to apply for the registration of any such rights, and all rights or forms of protection having equivalent or similar effect, in any part of the world.

"Know-How" means a package of non-patented practical information, resulting from experience and testing, which is (i) secret, that is to say, not generally known or easily accessible, (ii) substantial, that is to say, significant and useful for the production of the Products, and (iii) identified, that is to say, described in a sufficiently comprehensive manner so as to make it possible to verify that it fulfils the criteria of secrecy and substantiality.

"Latent Defect" has the meaning set forth in Clause 10.2.

"Manufacturing Site" means the manufacturing facilities of GERRESHEIMER or its Affiliates as detailed in the applicable Product Schedule or such other manufacturing facilities of GERRESHEIMER (or of any duly authorised sub-contractor under this Agreement) as approved by CLEARSIDE BIOMEDICAL in writing.

"Materials" means the raw materials and components used in the manufacture of the Product, excluding the Pharmaceutical Component, which will be provided by CLEARSIDE BIOMEDICAL.

"Month" means a calendar month.

"Notice of Dispute" has the meaning set forth in Clause 38.1.

"Permitted User" means an individual who: (i) is a director, officer, consultant, contractor, agent or employee of the Receiving Party or any such person or legal entity directly engaged in this Agreement on behalf of the Receiving Party; (ii) is bound by confidentiality, nondisclosure and nonuse obligations no less restrictive than those contained herein; and (iii) has a need to know the Confidential Information in connection with the Agreement. In clarification of the foregoing, companies and/or agents covering the Receiving Party's risks resulting out of this Agreement or insurance companies and/or agents to which the Receiving Party applies for such cover shall also be deemed as Permitted User, provided that they are party to an effective agreement with the Receiving Party protecting the Confidential Information on terms no less restrictive than those contained herein.

"Product" means such products as will be specified in the Product Schedules.

"Product Schedule" means a schedule in the form set out in Schedule 1. The initial Product Schedule is appended to this Agreement as Schedule 2.

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- "Pharmaceutical Component" means, in case the Parties have agreed on such proceedings, the pharmaceutical product to be incorporated into the Product as identified in the applicable Product Schedule.
- "Purchase Order" has the meaning set forth in Clause 4.3.
- "Quality Agreement" means the Quality Agreement as set forth in Schedule 3 between the Parties as amended from time to time.
- "Quality Managers" means the person nominated in writing by CLEARSIDE BIOMEDICAL and the person nominated in writing by GERRESHEIMER who will be responsible for quality matters relating to this Agreement (and such persons as may from time to time be substituted by either Party for such persons).
- "Recall" has the meaning set forth in Clause 16.3.
- "Receiving Party" means the Party or any of its Affiliates who receives Confidential Information from the Disclosing Party.
- "Refurbishment Program" has the meaning set forth in Clause 13.7.
- "Regulator" means any relevant authority in the country of manufacture of the Product, and/or the country of sale and/or marketing of the Product, which regulates any aspect of the manufacture of the Product and/or the sale or marketing of the Product.
- "Selling Price" means in respect of each Product, the price of the Product as set out in the relevant Product Schedule, as may be adjusted from time to time in accordance with this Agreement.
- "Senior Representatives' Meeting" has the meaning set forth in Clause 38.1.
- "Specifications" means the specifications for the Product identified in the applicable Product Schedule as such specifications may be amended from time to time by written agreement of the Parties in accordance with this Agreement.
- "Sprint Capacity" has the meaning set forth in Clause 4.4.
- "Third Party" means any party other than CLEARSIDE BIOMEDICAL or GERRESHEIMER.
- **"Tooling & Equipment Warranty Period"** has the meaning set forth in Clause 13.6.
- "Year" means a calendar year.
  - 1.2 In this Agreement unless it is inconsistent with the context:

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- (A) Words denoting the singular include the plural and vice versa; words denoting one gender include all genders; words denoting persons include corporations and vice versa.
- (B) References to the word "including" are to be construed without limitation.
- (C) The Schedules attached hereto shall form part of this Agreement and a reference to a particular Clause, Sub-Clause, paragraph or Schedule shall be a reference to the Clause, Sub-Clause, paragraph or Schedule in or to this Agreement.
- (D) The headings are inserted for convenience only and are to be ignored for the purposes of construction.

# 2. <u>DURATION</u>

This Agreement will commence on the Effective Date and will remain in force until the end of the Year containing the fifth (5th) anniversary of the Effective Date (the "**Initial Term**"), unless terminated by either Party in its sole discretion upon at least twelve (12) month written notice to the other Party prior to the end of the Initial Term. Thereafter, this Agreement will automatically renew for successive periods of three (3) Years, until terminated in accordance with this Clause 2 (i.e., with at least twelve (12) month written notice to the other Party prior to the end of the renewal term). The Initial Term, together with any renewal terms is referred to herein as the Term.

### 3. GERRESHEIMER'S AND CLEARSIDE BIOMEDICAL'S OBLIGATIONS

- 3.1 In accordance with the terms of this Agreement, GERRESHEIMER shall manufacture and supply to CLEARSIDE BIOMEDICAL and/or CLEARSIDE BIOMEDICAL Affiliates such quantities of Product as ordered in accordance with the terms of this Agreement. For the avoidance of doubt, (i) CLEARSIDE BIOMEDICAL may re-sell Product purchased hereunder to its Third Party licensees or collaboration partners, and (ii) all purchase of Product pursuant to this Agreement shall be made directly by CLEARSIDE BIOMEDICAL or its Affiliates.
- 3.2 GERRESHEIMER undertakes to ensure that it has at all times sufficient manufacturing capacity at the Manufacturing Site to satisfy the Sprint Capacity and Product requirements set out in each Firm Order and Forecast Schedule.
- Each Party shall be entitled to request changes and modifications to the Specifications and/or Products. The Party proposing a change shall make a proposal to the other Party in writing explaining the objectives of the change and expected cost and other impacts. The Parties shall discuss the proposed change including the allocation of cost and the impact of supply of the Product. Any change should only be implemented upon prior mutual written agreement of the scope, cost and impact of the change; PROVIDED, HOWEVER, that in no event may

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GERRESHEIMER refuse to make a change for which CLEARSIDE BIOMEDICAL agrees to pay for the mutually agreed upon costs and impacts.

3.4 Subject to Clause 3.3, (i) the Specifications and Third Party Material suppliers may only be changed by GERRESHEIMER with the prior written consent of CLEARSIDE BIOMEDICAL and the approval of any applicable Regulator (if applicable), (ii) CLEARSIDE BIOMEDICAL shall not unreasonably withhold its agreement to any change in the Specifications or Third Party Material suppliers requested by GERRESHEIMER, (iii) any amendment to the Specifications shall be subject to the rules regarding confidentiality as expressed in this Agreement, and (iv) any change in the Specifications or Third Party Material suppliers should only be implemented upon prior mutual written agreement of the scope, cost and impact of the change.

### 4. <u>FORECASTS AND ORDERS</u>

Beginning no later than six (6) Months prior to placing its initial Purchase Order for Product (it being understood that a 4.1 forecast for a Calendar Quarter may be zero), prior to the first day of each calendar quarter (beginning each 1st January, 1st April, 1st July and 1st October and each referred to herein as a "Calendar Quarter"), CLEARSIDE BIOMEDICAL shall provide GERRESHEIMER with a rolling forecast schedule of its projected orders for the Products for at least the following four (4) Calendar Quarters ("Forecast Schedule"). The initial forecast will be provided by July 1, 2018 and is expected to reflect projected orders of between [\*\*\*] units of Product for the following (4) Calendar Quarters. Beginning with the first Forecast Schedule submitted after the one year anniversary of the first commercial sale of the Product to a Third Party (the "Commercial Launch Anniversary"), with CLEARSIDE BIOMEDICAL to notify GERRESHEIMER forthwith in writing of the date of the Commercial Launch. Subject to Clause 4.4, CLEARSIDE BIOMEDICAL can only vary the forecast amounts for the second Calendar Quarter of a Forecast Schedule in the next subsequent Forecast Schedule by +/- [\*\*\*], and can only vary the forecast amounts for the third Calendar Quarter of a Forecast Schedule in the next subsequent Forecast Schedule by +/- [\*\*\*]. If CLEARSIDE BIOMEDICAL desires to vary the forecasted amounts by an additional [\*\*\*] up to [\*\*\*] or up to [\*\*\*] respectively, then (i) in case of an increase, GERRESHEIMER agrees to notify Buyer within five (5) Business Days after receipt of such request, whether the ordered additional quantities of Products set forth in the request are exceeding the Sprint Capacity and whether such exceeding quantities can be delivered or not. In any event GERRESHEIMER will use reasonable efforts to fulfill this additional demand. In the event such excess quantities of Product directly results in additional costs, such costs shall be documented by GERRESHEIMER and the Parties shall discuss in good faith such costs and what part thereof CLEARSIDE BIOMEDICAL may need to reimburse before any such costs are incurred and/or committed. If GERRESHEIMER, despite using reasonable efforts, cannot meet such excess quantities, the failure to supply the excess quantities shall not be regarded as a Failure to Supply; or (ii) in case of a decrease, if such decrease directly results in additional costs, such costs shall be documented by GERRESHEIMER and the CLEARSIDE BIOMEDICAL shall reimburse to GERRESHEIMER all such documented costs. For the avoidance of doubt, the maximum quantities of Products to be supplied by GERRESHEIMER during any six (6) Month period prior to the Commercial

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Launch Anniversary shall be [\*\*\*] units of Product and GERRESHEIMER shall be under no obligation whatsoever to supply any quantities of Product beyond that amount.

- 4.2 In addition to the Forecast Schedule, prior to the 1st September of each Year after the commencement of the issuance of Forecast Schedules, CLEARSIDE BIOMEDICAL shall provide on an annual basis a two (2) Year non-binding forecast of projected orders for the Products to be used by GERRESHEIMER solely for planning purposes.
- The Products detailed in the first Calendar Quarter of each Forecast Schedule ("Firm Order") will be binding on both Parties. CLEARSIDE BIOMEDICAL shall issue purchase orders against each Firm Order (each a "Purchase Order"), which Purchase Order shall include the requested delivery dates. GERRESHEIMER shall respond to each Purchase Order received from CLEARSIDE BIOMEDICAL within ten (10) Business Days of receipt. The response of GERRESHEIMER shall include confirmation of the delivery dates; PROVIDED, HOWEVER, that GERRESHEIMER may not reject any quantities forecasted in a Firm Order or any delivery date that is more than thirty (30) days from the date the applicable Purchase Order is submitted. GERRESHEIMER's failure to reject any portion of a Purchase Order within the applicable ten (10) Business Day period shall be deemed to be GERRESHEIMER's acceptance thereof. In the event that either Party requires amendments to the quantities ordered, the timing of production and/or delivery, the relevant planning personnel from both Parties shall within ten (10) Business Days of receipt of a Forecast Schedule, Firm Order or Purchase Order discuss in good faith and agree amendments to the Forecast Schedule, Firm Order or Purchase Order.
- CLEARSIDE BIOMEDICAL and/or its Affiliates shall use commercially reasonable endeavours not to, at any one time, collectively place Firm Orders at a level that would require an aggregate capacity at GERRESHEIMER greater than the maximum manufacturing capacity of the Manufacturing Site as set forth in the applicable Product Schedule ("Sprint Capacity") and GERRESHEIMER shall not be obliged to supply Products in excess of the Sprint Capacity. In the event that the aggregate CLEARSIDE BIOMEDICAL demand is greater than the Sprint Capacity CLEARSIDE BIOMEDICAL shall promptly instruct GERRESHEIMER the order of preference for the deliveries.
- 4.5 It is understood that the remaining three (3) Calendar Quarters of the Forecast Schedule constitutes an estimate of the future Product requirement of CLEARSIDE BIOMEDICAL and its Affiliates and does not constitute a binding commitment by CLEARSIDE BIOMEDICAL or its Affiliates to order or purchase such Product.
- 4.6 For certain long lead time materials, as defined in good faith between the Parties, which requires GERRESHEIMER to place orders with a minimum lead time longer than three (3) Months in advance of manufacturing, GERRESHEIMER will be entitled to place those orders based on the projections set forth in a Forecast

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Schedule, and CLEARSIDE BIOMEDICAL agrees to pay for any such Materials which are not used in Firm Orders of Products placed by CLEARSIDE BIOMEDICAL and/or its Affiliates and cannot otherwise be used by GERRESHEIMER.

- 4.7 CLEARSIDE BIOMEDICAL may from time to time provide GERRESHEIMER with individual purchase orders for Products in addition to the quantities set forth in Firm Orders. GERRESHEIMER shall respond to each such individual purchase order received from CLEARSIDE BIOMEDICAL or an Affiliate of CLEARSIDE BIOMEDICAL within ten (10) Business Days of receipt. The response shall include confirmation or not of the Delivery dates and quantity as set out in such individual purchase order. GERRESHEIMER's failure to reject any portion of such Purchase Order within the applicable ten (10) Business Day period shall be deemed to be GERRESHEIMER's acceptance thereof.
- If a CLEARSIDE BIOMEDICAL Affiliate desires to purchase the Product from GERRESHEIMER under the terms of this Agreement the Parties will consider the appropriate contractual mechanisms for the CLEARSIDE BIOMEDICAL Affiliate to receive Product from GERRESHEIMER or its Affiliates (as the case may be) and benefit from the terms of this Agreement, taking into account the CLEARSIDE BIOMEDICAL Affiliate may need to enter into separate legal agreements with GERRESHEIMER. For the avoidance of doubt, before the aforementioned contractual mechanism has been agreed by the Parties, GERRESHEIMER shall not be obliged to sell (and/or deliver) any Products to CLEARSIDE BIOMEDICAL Affiliates or fulfil or accept purchase orders from CLEARSIDE BIOMEDICAL Affiliates. GERRESHEIMER shall confirm promptly to CLEARSIDE BIOMEDICAL whether such CLEARSIDE BIOMEDICAL Affiliate is covered by GERRESHEIMER's trade credit insurance. If such COMPANY Affiliate is not covered by GERRESHEIMERs trade credit insurance, then GERRESHEIMER shall only provide such CLEARSIDE BIOMEDICAL Affiliate with the named Product upon receipt of a payment security from CLEARSIDE BIOMEDICAL by means of a payment guarantee of CLEARSIDE BIOMEDICAL or a bank guarantee of an internationally business bank rated with triple B.

### 5. IDLE COSTS

- 5.1 CLEARSIDE BIOMEDICAL understands that GERRESHEIMER may have plant space and equipment established for the purpose of manufacturing and supplying the Product to CLEARSIDE BIOMEDICAL. In the event CLEARSIDE BIOMEDICAL fails to purchase a Firm Order which leads to equipment to become idle through no fault of GERRESHEIMER, and such plant and equipment are otherwise ready for production, except in the case of a Force Majeure the following proposal shall be considered upon notification:
  - (i) To compensate GERRESHEIMER for Direct Labour Costs associated with the planned manufacturing of the Firm Order, and to the extent such direct labour is not assignable to other GERRESHEIMER projects, CLEARSIDE BIOMEDICAL shall pay GERRESHEIMER all direct labour associated with the planned manufacturing of Products pursuant to the then-applicable Firm Order not

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purchased;

- (ii) Notwithstanding any other provisions in this Agreement, after production readiness (i.e. being after successful qualification of the equipment), CLEARSIDE BIOMEDICAL shall pay GERRESHEIMER [\*\*\*] per square foot of clean room space dedicated to CLEARSIDE BIOMEDICAL's equipment per Month in which CLEARSIDE BIOMEDICAL fails to purchase more than [\*\*\*] units of Products per Month.
- 5.2 In the event that CLEARSIDE BIOMEDICAL fails to purchase Product for [\*\*\*] following the Commercial Launch Anniversary CLEARSIDE BIOMEDICAL shall purchase all Materials purchased by GERRESHEIMER and all work in process and finished Product manufactured by GERRESHEIMER, in each case as purchased or manufactured in reasonable reliance on the previously submitted Forecast Schedules.
- 5.3 GERRESHEIMER will use reasonable efforts to mitigate expenses, including reasonable efforts to secure business sufficient to reactivate the idle plant space as soon as practicable and/or reassignment of direct labour. CLEARSIDE BIOMEDICAL shall not reimburse GERRESHEIMER for any period while such plant space and direct labour are in use for the benefit of a third party

# 6. <u>DELIVERY, PASSING OF TITLE AND RISK IN THE PRODUCT</u>

- Delivery shall be made in accordance with the applicable Delivery Terms. The risk for each shipment of the Product, as for destruction or any case of deterioration or change in quality or loss of shipment, shall pass to CLEARSIDE BIOMEDICAL in accordance with the agreed Delivery Terms. [\*\*\*]. Notwithstanding anything to the contrary in the applicable Delivery Terms to the contrary, GERRESHEIMER shall at all times arrange for shipment of the Product, including clearing the Product for export and import. To the extent CLEARSIDE BIOMEDICAL is financially responsible for shipment, GERRESHEIMER shall include the cost thereof as a separate line item.
- GERRESHEIMER retains title to all Products until Delivery in accordance with the Delivery Terms. CLEARSIDE BIOMEDICAL shall have the right to dispose of the PRODUCTS delivered by GERRESHEIMER in the ordinary course of business, including reselling Products to Third Party licensees or collaboration partners of CLEARSIDE BIOMEDICAL. CLEARSIDE BIOMEDICAL shall also have the right to process the Products delivered by GERRESHEIMER.

### 7. PRICES

7.1 GERRESHEIMER will supply to CLEARSIDE BIOMEDICAL the Product at the Selling Price. GERRESHEIMER shall invoice CLEARSIDE BIOMEDICAL at the Selling Price. New Products may be added to this Agreement from time to time and will be supplied at the Selling Price set out in the respective Product Schedule.

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- 7.2 On or before 1<sup>st</sup> October each Year, the Parties will meet and discuss in good faith any applicable adjustment to the Selling Price (an "Annual Price Review"). [\*\*\*].
- 7.3 Irrespective of the aforementioned, (i) GERRESHEIMER shall be entitled to adjust the Selling Price effective as the beginning of a Year by providing no less than sixty (60) days prior written notice in the event and to the extent of a cost increase with respect to labour and energy that exceeds, [\*\*\*]; PROVIDED, HOWEVER, that such Selling Price adjustments described in subsection (iii) will be limited to twice annually.
- In case CLEARSIDE BIOMEDICAL reasonably believes that an adjustment to the Selling Price pursuant to Clause 7.3 is not accurate and proper, CLEARSIDE BIOMEDICAL may request, and GERRESHEIMER shall provide, additional documentation supporting the adjustment. If CLEARSIDE BIOMEDICAL reasonably considers such response as not being reasonably satisfactory, the Parties shall endeavour to resolve any dispute that may arise pursuant to this Clause. If the Parties fail to agree, [\*\*\*] of being notified pursuant to this Clause 7.4, whether the adjustment to the Selling Price in question is accurate and proper, CLEARSIDE BIOMEDICAL will have the right, acting reasonable, during regular business hours and upon reasonable [\*\*\*]. The Third Party independent accounting firm shall only be entitled to disclose in its audit report to CLEARSIDE BIOMEDICAL whether the reported adjustment to the Selling Price pursuant to Clause 7.3 is accurate and proper and the amount of any inaccuracies. Within thirty (30) days after both Parties have received a copy of such audit report, which has to be forwarded simultaneously to both Parties by the Third Party independent accounting firm, GERRESHEIMER or CLEARSIDE BIOMEDICAL, as applicable, will compensate the other Party for payment errors or omissions revealed by the audit.

### 8. <u>INVOICE AND PAYMENT</u>

- 8.1 The Selling Price shall be in USD. GERRESHEIMER shall invoice CLEARSIDE BIOMEDICAL or CLEARSIDE BIOMEDICAL Affiliates (as appropriate, depending on who placed the order for the relevant Product) in USD
- 8.2 Each invoice issued by GERRESHEIMER hereunder shall specify:
  - (i) The Selling Price in respect of the Product Delivered;
  - (ii) The quantity of Product Delivered;
  - (iii) The applicable order number;
  - (iv) The amount of VAT due in respect of the Product Delivered (if any); and
  - (v) Any other amounts reimbursable to GERRESHEIMER pursuant to this Agreement.

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- 8.3 CLEARSIDE BIOMEDICAL shall pay all invoices not disputed in good faith within [\*\*\*] days after date of receipt of such invoice. In the event that CLEARSIDE BIOMEDICAL defaults on payment of amounts not disputed in good faith, interest is to be paid on the invoiced amount with [\*\*\*] per Year.
- 8.4 The Selling Price, and any other amounts payable pursuant to this Agreement, shall be as stated and are exclusive of VAT (or equivalent).
- 8.5 For the purpose of a potential risk of payment default by CLEARSIDE BIOMEDICAL CLEARSIDE BIOMEDICAL shall be obliged to provide an adequate bank guarantee of an internationally business bank rated with triple B upon GERRESHEIMER written request if CLEARSIDE BIOMEDICAL cannot be covered by GERRESHEIMER's trade credit insurance. In the event such bank guarantee is limited in time, CLEARSIDE BIOMEDICAL shall provide the subsequent bank guarantee under the same conditions no later than thirty (30) days before the expiry of the bank guarantee in place. The Parties agree to evaluate on an annual basis and in good faith GERRESHEIMER's requirement that CLEARSIDE BIOMEDICAL continue the bank guarantee.

# 9. <u>FAILURE TO SUPPLY</u>

- 9.1 Save Force Majeure, if GERRESHEIMER is unable, or anticipates that it will be unable to Deliver in whole or in part the quantities of Product required under any Firm Order or any other Purchase Order accepted by GERRESHEIMER, the following provisions shall apply:
  - (i) GERRESHEIMER shall, as soon as it becomes aware of that fact and in any event not less than fifteen (15) Business Days prior to the Delivery date, give written notice to CLEARSIDE BIOMEDICAL or CLEARSIDE BIOMEDICAL Affiliates (as the case may be) setting out the reasons for such shortfall or failure.
  - (ii) Without prejudice to CLEARSIDE BIOMEDICAL's other rights and remedies under this Agreement, at law or in equity, the Parties shall use reasonable endeavours to negotiate an alternative Delivery schedule for the shortfall or failed Delivery.
  - (iii) Without prejudice to CLEARSIDE BIOMEDICAL's other rights and remedies under this Agreement, at law or in equity with respect to GERRESHEIMER missing the original Delivery Date, in the event that an alternative Delivery schedule is agreed pursuant to paragraph (ii) above GERRESHEIMER shall Deliver the Product in accordance with such alternative Delivery schedule.
- 9.2 Save Force Majeure, without prejudice to GERRESHEIMERs obligations under this Agreement, in the event that the Parties fail to agree on alternative Delivery schedule pursuant to Clause 9.1 (ii) above, whether it be due to a disruption in the manufacture of the Product at the Manufacturing Site or otherwise CLEARSIDE BIOMEDICAL's Firm Order commitment shall be deemed to be cancelled with

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respect to the affected amount of the shortfall or failed Delivery and CLEARSIDE BIOMEDICAL would be relieved of its obligation to purchase any of such quantities.

9.3 CLEARSIDE BIOMEDICAL shall, within fifteen (15) Business Days from Delivery inform GERRESHEIMER if it determines, acting reasonably, that the wrong Product has been delivered or if there is any visible external Defects or damage to the pallets and/or outer packaging or if there is a quantitative deficiency in any shipment with respect to the Product volumes indicated on the applicable Firm Order (i.e. the number of pallets delivered does not correspond to the number of pallets on the relevant delivery note). If GERRESHEIMER is notified by telephone or in person then such notification shall be confirmed by CLEARSIDE BIOMEDICAL or CLEARSIDE BIOMEDICAL Affiliates (as appropriate) in writing. Subject to Force Majeure and without prejudice to CLEARSIDE BIOMEDICAL's other rights and remedies under this Agreement, at law or in equity with respect to the failure to Delivery conforming Product, GERRESHEIMER shall then be obliged to rectify the incomplete Delivery within thirty (30) Business Days, running from the respective first date of notification.

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- [\*\*\*]. GERRESHEIMER shall promptly issue to CLEARSIDE BIOMEDICAL a detailed written explanation for the delay and actions taken to remedy any delay in the supply of Product reasonably acceptable to CLEARSIDE BIOMEDICAL.
  - [\*\*\*], GERRESHEIMER shall, where relevant, promptly notify CLEARSIDE BIOMEDICAL thereof and GERRESHEIMER shall perform best efforts to resolve the Failure to Supply and to resume its supply obligations as soon as possible to the best interest of CLEARSIDE BIOMEDICAL; GERRESHEIMER shall continuously keep CLEARSIDE BIOMEDICAL informed of the status and the corrective actions performed by it with respect thereto.

In the event the Failure to Supply lasts or is anticipated by the GERRESHEIMER to last for more than [\*\*\*] or such longer timeframe as agreed between the Parties, then GERRESHEIMER shall, at its costs (unless the Failure to Supply is solely due to CLEARSIDE BIOMEDICAL in which event such shall be at the cost of CLEARSIDE BIOMEDICAL; in the event the Failure to Supply is at least partly the responsibility of CLEARSIDE BIOMEDICAL, Parties shall share such costs at a ratio to be agreed between the Parties and in proportion to either Party's contribution to the Failure to Supply), promptly submit a CAPA plan to CLEARSIDE BIOMEDICAL, for CLEARSIDE BIOMEDICAL's approval. The CAPA plan shall set forth in detail the actions to be taken by GERRESHEIMER to solve the Failure to Supply and the anticipated timelines for implementing these actions. This plan shall also state which percentage of quantities of Product requested by CLEARSIDE BIOMEDICAL can continue to be delivered by GERRESHEIMER in accordance with this Agreement and the anticipated timelines for resuming full compliance. In the event CLEARSIDE BIOMEDICAL approves the CAPA plan, GERRESHEIMER shall forthwith implement such plan and continuously keep CLEARSIDE BIOMEDICAL updated on the status thereof.

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Subject to Force Majeure, in the event that GERRESHEIMER does not adhere to the actions and/or timelines assigned to GERRESHEIMER in the agreed CAPA plan and the Parties have not agreed on an amendment to the CAPA plan regarding such non-adherence, then GERRESHEIMER shall, upon CLEARSIDE's reasonable request, provide reasonable assistance to CLEARSIDE BIOMEDICAL to qualify a THIRD PARTY manufacturer of PRODUCT. Parties shall bear any actual and duly documented costs incurred in providing such assistance at a ratio to be agreed between the Parties and in proportion to either Party's contribution to the failure to adhere to the CAPA plan. If such THIRD PARTY manufacturer utilizes Gerresheimer Results licensed pursuant to Section 15.3 or 25.10 in the manufacture of Product, CLEARSIDE BIOMEDICAL shall pay GERRESHEIMER the royalty or license fee as agreed in accordance with Sections 15.3 or 25.10.

## 10. QUALITY

- 10.1 GERRESHEIMER shall comply with the terms of the Quality Agreement.
  - CLEARSIDE BIOMEDICAL shall promptly examine each Delivery and shall have the right, exercisable within five (5) Business Days after Delivery, to reject such Product that it determines to be Defective Product as a result of the exercise of careful diligence upon such examination. For the avoidance of doubt Product shall not be Defective Product if non-compliance with the Specification is attributed to operating instructions, maintenance regulations or installation regulations not having been adhered to by CLEARSIDE BIOMEDICAL or Third Parties. However, the foregoing rejection time limit shall not apply to Defective Product not reasonably detectable or discoverable during the examination by CLEARSIDE BIOMEDICAL as defined above ("Latent Defect"). Where CLEARSIDE BIOMEDICAL and CLEARSIDE BIOMEDICAL Affiliates (as the case may be) do not reject any such Product but such Product becomes a Defective Product subject to Latent Defects as defined above within a period of [\*\*\*\*] after Delivery, CLEARSIDE BIOMEDICAL shall inform GERRESHEIMER of such Defective Product within five (5) Business Days from detecting the Latent Defect. Failing the notification deadlines outlined above, CLEARSIDE BIOMEDICAL shall be deemed to have accepted the relevant shipment of Product.
  - 10.3 In case the CLEARSIDE BIOMEDICAL rejects a Product according to Clause 10.2 above:
    - (i) CLEARSIDE BIOMEDICAL shall issue a written complaint to GERRESHEIMER (detailing any asserted Defective Product and, if applicable, submitting a sufficient number of affected Product samples);
    - (ii) the Parties shall promptly use good faith efforts to agree whether or not the Delivery in question complies with the Firm Order, Quality Agreement, the

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Specifications, cGMP and any other requirements set forth in this Agreement (or any one of them); and

- (iii) GERRESHEIMER shall be entitled at all reasonable times to inspect and/or analyse the Delivery in question.
- The Parties shall use their commercially reasonable endeavours to resolve any dispute that may arise pursuant to this Clause. If the Parties fail to agree, within thirty (30) days of being notified pursuant to Clause 10.3 (i) whether the applicable Product in question is non-compliant with the Specifications, this dispute shall be resolved by a mutually agreed independent laboratory/expert and the decision of the independent laboratory/expert shall be final and binding on the Parties. For the avoidance of doubt, the independent laboratory/expert shall not decide on any other question or matter other than whether the Product is a Defective Product. Unless agreed otherwise, the independent laboratory/expert's fees shall be borne by the Party against whom the independent laboratory/expert's decision is given. In case of a split decision, costs shall be split between the Parties accordingly.
- In the event that GERRESHEIMER acknowledges the Product to be a Defective Product pursuant to Clause 10.4 ("Agreed Defective Product") or the independent laboratory/expert concludes it is Defective Product (in which case, it shall be deemed to be "Agreed Defective Product" for purposes of this Agreement), GERRESHEIMER shall at CLEARSIDE BIOMEDICAL's option, either (a) replace or rework the Agreed Defective Product at GERRESHEIMER's risk and expense to the extent possible and reasonable; or (b) refund such portion of the price attributable to the Agreed Defective Product. In the first former case (replacement according to (a)), GERRESHEIMER shall be entitled to require CLEARSIDE BIOMEDICAL to dispose of the Agreed Defective Product according to Applicable Law with any expenses or costs reasonably incurred by CLEARSIDE BIOMEDICAL to be borne by GERRESHEIMER. The remedy described in this Clause 10.5 shall be in addition to, and not in lieu of, any other remedies available under this Agreement, at law or in equity. For the avoidance of doubt, (i) in the event CLEARSIDE BIOMEDICAL elects a refund with respect to the Agreed Defective Product, CLEARSIDE BIOMEDICAL shall have no obligation to purchase the quantity of Product in relation thereof and the Firm Order and any applicable Purchase Order shall be reduced accordingly, and (ii) the remedies set forth herein shall not be applied against the limitation of liability provisions of this Agreement, including Clause 23.3.
- If the independent laboratory/expert finds that the Product is not an Agreed Defective Product, CLEARSIDE BIOMEDICAL shall pay any expenses or costs reasonably incurred by GERRESHEIMER in connection with the rejection in accordance with the payment provisions contained in this Agreement. In no event shall GERRESHEIMER be responsible for non-compliances with Specification in the Product if such non-compliances are caused (partly or in whole) by deficiencies in the design or Specifications provided by CLEARSIDE BIOMEDICAL.

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#### 11. SUPPLY AND STORAGE OF MATERIALS AND PRODUCTS

- GERRESHEIMER shall be solely responsible for the ordering and supply of the relevant quantities of Materials necessary in order to manufacture the Products, and for the timely delivery of such Materials, in accordance with CLEARSIDE BIOMEDICAL'S Forecast Schedules and Firm Orders.
- CLEARSIDE BIOMEDICAL may during the Term of this Agreement and after mutual agreement, provide certain Pharmaceutical Components to GERRESHEIMER. In such case, as gesture of goodwill on a voluntary basis and without acknowledging any legal obligations on behalf of GERRESHEIMER in connection therewith, GERRESHEIMER will visually inspect deliveries of Pharmaceutical Component as advised by CLEARSIDE MEDICAL and within three (3) Business Days notify CLEARSIDE BIOMEDICAL in writing (with email being sufficient) of visual defects detected during such visual inspection, and will not use any Pharmaceutical Component that is subject to such visual defects without the prior written consent of CLEARSIDE BIOMEDICAL.

In case of any defect of such Pharmaceutical Component, GERRESHEIMER shall not be deemed to be in breach of this Agreement or otherwise be liable in any manner whatsoever for any failure or delay in performing its obligations under this Agreement caused by such defect. Any timeframes agreed and affected will be consequently postponed.

Notwithstanding anything else in this Agreement, the warranties in Clause 22.1 do not apply to, GERRESHEIMER makes no warranties with respect to, and GERRESHEIMER shall have no liability whatsoever to CLEARSIDE BIOMEDICAL for the Pharmaceutical Component (except to the extent that such are damaged or impaired during manufacture or due to GERRESHEIMER's non-adherence to the agreed storage conditions regarding Pharmaceutical Component as set forth in the mutually agreed packaging specification due to GERRESHEIMER's gross negligence or willful misconduct).

Notwithstanding anything else in this Agreement, CLEARSIDE BIOMEDICAL shall indemnify and hold GERRESHEIMER harmless from and against any and all claims of third parties arising out of the usage of the Pharmaceutical Component. For the sake of clarification this in particular includes without limitation claims and/or damages incurred by a third party due to a non-compliance with the standards set forth in this Agreement as well as liability for health damage or for loss or damage to any third party's property and all claims, demands, proceedings and causes of action resulting directly therefrom. This indemnity also applies irrespective of the legal basis of a claim. The limitations of Clause 23.4 shall expressly not apply to this Clause 11.2

GERRESHEIMER shall at all times store and warehouse all Materials and Product manufactured by GERRESHEIMER pursuant to this Agreement (including the Quality Agreement) in premises that are secure, clean, and in line with industry

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standard, Applicable Law, including cGMP, and the conditions mutually agreed between the Parties.

11.4 If GERRESHEIMER, acting reasonably, considers that a delivery of Materials which has been supplied by any supplier is Defective, GERRESHEIMER acting reasonably shall reject such delivery, and shall procure that substitute Materials complying with the Specification are promptly supplied by the relevant supplier in substitution.

### 12. RESPONSIBLE PERSON

GERRESHEIMER shall employ a person accountable for approval and release of batches of Product as notified by GERRESHEIMER in writing to CLEARSIDE BIOMEDICAL. Any such person will be suitably trained, qualified and experienced in order to perform the role in accordance with Applicable Laws, including cGMPs.

#### 13. TOOLING AND EQUIPMENT

- The Parties shall agree on any new Equipment reasonably required for the manufacture the Product at the Manufacturing Site that shall be purchased. Where GERRESHEIMER sources new Equipment from a Third Party, CLEARSIDE BIOMEDICAL shall pay GERRESHEIMER for the actual cost of such Equipment on the same terms offered by the Third Party plus an additional sum for GERRESHEIMER's time and resources in sourcing such Equipment, such additional sum to be agreed in advance in writing between the Parties in advance of GERRESHEIMER carrying out any such work in relation to such Equipment. Where Equipment is to be provided by GERRESHEIMER and not sourced from a Third Party, CLEARSIDE BIOMEDICAL shall reimburse GERRESHEIMER for the actual costs of GERRESHEIMER's time and materials in creating such Equipment, such costs again to be agreed in advance in writing between the Parties in advance of GERRESHEIMER carrying out any such work or making any commitment to any Third Party in relation to such materials
- Title in the Equipment purchased or created by GERRESHEIMER shall pass to CLEARSIDE BIOMEDICAL on completion of payment due by CLEARSIDE BIOMEDICAL and GERRESHEIMER will mark all Equipment with appropriate plates identifying it as being owned by CLEARSIDE BIOMEDICAL, and maintain an asset register containing details of the Equipment. For the avoidance of doubt, as between CLEARSIDE BIOMEDICAL and GERRESHEIMER, CLEARSIDE BIOMEDICAL shall own all drawings and specifications for the Equipment necessary to effectively use, maintain, repair and/or modify the Tooling and Equipment (hereinafter referred to as "Documentation") and as set forth in Schedule 4 to this Agreement.
- GERRESHEIMER shall be obligated to deliver the Documentation upon the physical transfer of the Tooling and Equipment to CLEARSIDE BIOMEDICAL only to the extent they are in GERRESHEIMER's possession; PROVIDED, HOWEVER, that GERRESHEIMER is not making any representation or warranty that, as between

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CLEARSIDE BIOMEDICAL and the Equipment manufacturer that CLEARSIDE BIOMEDICAL will become the owner of such Documentation.

- GERRESHEIMER will maintain a lifetime record for each item of Equipment detailing all procedures carried out on the Equipment (including, without limitation, servicing, maintenance and parts changes) during the period of use by GERRESHEIMER at the Manufacturing Site.
- 13.4 GERRESHEIMER will use the Equipment exclusively for the manufacture and supply of the Product to CLEARSIDE BIOMEDICAL and CLEARSIDE BIOMEDICAL Affiliates, unless otherwise agreed in writing between the Parties. Without limiting the foregoing, the manufacturing line that incorporates the Equipment shall be dedicated to the use of manufacturing Product for and on behalf of CLEARSIDE BIOMEDICAL.
- GERRESHEIMER will conduct at CLEARSIDE BIOMEDICAL's sole cost routine maintenance of the Equipment and shall also be responsible for repair of the Equipment with all proven costs to be borne by CLEARSIDE BIOMEDICAL. For the avoidance of doubt GERRESHEIMER shall replace any wear parts and repair any damage caused by GERRESHEIMER's negligent act or omission at its own cost. GERRESHEIMER undertakes to follow the technical specification for the use of the CLEARSIDE BIOMEDICAL Equipment and to use the CLEARSIDE BIOMEDICAL Equipment with all due and reasonable care.
- Notwithstanding Clause 13.5, GERRESHEIMER will take responsibility for all repairs and relationship with the supplier of the Equipment for the period under which the Equipment is covered by a warranty, as specified in the respective Product Schedule ("Tooling & Equipment Warranty Period"). CLEARSIDE BIOMEDICAL expressly authorises GERRESHEIMER to exercise its rights with the supplier of the CLEARSIDE BIOMEDICAL Equipment in respect of such warranty. If repairs or changes to the Equipment need to be made that are not covered under the warranty or if the supplier of the Equipment rejects a warranty claim, CLEARSIDE BIOMEDICAL will discuss with the GERRESHEIMER what costs are payable.
- Following expiry of the Tooling & Equipment Warranty Period, by the end of second quarter of each Year GERRESHEIMER agrees to make a proposal to CLEARSIDE BIOMEDICAL to address any complete overhauls and repairs ("Refurbishment Program") to the CLEARSIDE BIOMEDICAL Equipment to be carried out specifying their respective cost, lead-time and capacity impact. Any agreed repair and/or refurbishment program shall be carried out by GERRESHEIMER at CLEARSIDE BIOMEDICAL's sole cost, except where the repairs or refurbishment is necessitated by GERRESHEIMER's wilful negligence or omission, in which case GERRESHEIMER shall be responsible for such costs. GERRESHEIMER shall not be deemed to be at fault as defined above if the repairs or refurbishments in question were a result of an explicit instruction from CLEARSIDE BIOMEDICAL to use such Equipment outside of its intended use or recommended purpose.

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13.8 Spare parts for the Equipment shall be ordered by GERRESHEIMER before commercial production starts and shall be funded by CLEARSIDE BIOMEDICAL. Any spare parts used shall be replaced by GERRESHEIMER during the Tooling & Equipment Warranty Period at GERRESHEIMER's cost and thereafter at CLEARSIDE BIOMEDICAL's cost, in accordance with Clauses 13.6 and 13.7. Following expiry of the Tooling & Equipment Warranty Period, spare parts inventory shall be maintained at the same levels as prior to commercial production.

#### 14. <u>REGULATORY COMPLIANCE</u>

- GERRESHEIMER shall respond in an effective and prompt manner to any questions of a regulatory nature relating to the Product, its manufacture or the Manufacturing Site raised either by CLEARSIDE BIOMEDICAL, its Affiliates (PROVIDED, HOWEVER, that such Affiliate is supplied with Products pursuant to Clause 4.8), or by a Regulator. GERRESHEIMER shall within twenty-four (24) hours deliver to CLEARSIDE BIOMEDICAL any documentation received by Regulators alleging the Products, its manufacture or the Manufacturing Site is not in compliance with Applicable Laws, including cGMP. GERRESHEIMER shall within twenty-four (24) hours notify CLEARSIDE BIOMEDICAL in writing of any proposed investigation or inspection by a Regulator of the Manufacturing Site and keep CLEARSIDE BIOMEDICAL reasonably updated about the progress of such investigation or inspection. GERRESHEIMER shall within twenty-four (24) hours notify CLEARSIDE BIOMEDICAL if it receives any adverse event reports related to the Product.
- GERRESHEIMER shall, at its sole cost and expense, obtain and hold all consents, authorizations, permits, certificates, licenses or approvals of, exemptions by, or filings or registrations with, any Regulator required for the performance of its obligations under this Agreement ("Consents"). At all times, GERRESHEIMER shall maintain and comply with all the Consents to permit the performance of its then current obligations under this Agreement.
- GERRESHEIMER shall provide to CLEARSIDE BIOMEDICAL all documents and information requested by a Regulator in support of CLEARSIDE BIOMEDICAL's regulatory filings. Upon the reasonable prior written request, GERRESHEIMER may in its sole discretion reasonably assist CLEARSIDE BIOMECIAL with regulatory filings of CLEARSIDE BIOMEDICAL's licensees and Third Party collaboration partners, with all proven costs to be borne by CLEARSIDE BIOMEDICAL. For the avoidance of doubt, GERRESHEIMER shall have no obligation whatsoever to assist CLEARSIDE BIOMEDICAL with respect of the aforementioned licensees and Third Party collaboration partners.
- GERRESHEIMER shall maintain, in accordance with and for the period required cGMPs, complete and adequate records pertaining to all activities in connection with, and facilities used for, the manufacture, generation, storage, testing, treatment, holding, transportation, distribution, or other handling or receiving of the Product or Materials.

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- If GERRESHEIMER is notified that Product or the portion of the Manufacturing Site will be subject to an inspection by any Regulator including as part of the pre-approval inspection for the Product, GERRESHEIMER shall:
  - within twenty-four (24) hours advise CLEARSIDE BIOMEDICAL by telephone and email and provide all relevant information known to GERRESHEIMER regarding such investigation;

Fully cooperate with and allow any such inspection;

All inquiries related to Product or manufacturing process shall be copied to CLEARSIDE BIOMEDICAL within twenty-four (24) hours;

within twenty-four (24) hours send CLEARSIDE BIOMEDICAL a summary of any inspection report observations issued by any Regulator directly related to the manufacture, generation, processing, storage, transportation, distribution, treatment, disposal or other management of Product.

Respond to all inspection report observations by any Regulator and take all appropriate corrective actions required by such Regulator, in each case, within the timelines required by the Regulator.

### 15. <u>INTELLECTUAL PROPERTY RIGHTS</u>

- 15.1 Each Party shall continue to own and/or control (as the case may be) its own Intellectual Property and Know-How existing prior to the Effective Date or generated independently of the services under this Agreement ("Background IP").
- For the term and sole purpose of this Agreement and solely to the extent necessary to fulfil the obligations arising out of this Agreement, CLEARSIDE BIOMEDICAL shall grant GERRESHEIMER and its Affiliates a worldwide, royalty free, fully-paid up and irrevocable for the term of this Agreement, non-exclusive licence to Background IP of CLEARSIDE BIOMEDICAL and its Affiliates.
- 15.3 The Parties agree that the manufacture of the initial Product specified on Schedule 2 in accordance with the Specifications referred to in Schedule 2 does not incorporate or otherwise involve the use of any GERRESHEIMER Results. GERRESHEIMER undertakes all reasonable efforts not to incorporate any GERRESHEIMER Results into the Products.

However, if during the performance of the Agreement, GERRESHEIMER and CLEARSIDE BIOMEDICAL come to the conclusion that specific and specifically defined GERRESHEIMER Results might be useful in or for the manufacturing of the Product, GERRESHEIMER shall inform CLEARSIDE BIOMEDICAL and shall comprehensively disclose to CLEARSIDE BIOMEDICAL if and to what extent GERRESHEIMER wants to include into or use such GERRESHEIMER Results for the manufacture of the

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Product including conditions suggested for its use (including but not limited to the purpose and the amount of the license fee to be paid by CLEARSIDE BIOMEDICAL). CLEARSIDE BIOMEDICAL shall review such suggested conditions and if necessary discuss with GERRESHEIMER what would be the consequences of not using such specific GERRESHEIMER Results. If then CLEARSIDE BIOMEDICAL decides, in its own and sole discretion, that specific and specifically defined GERRESHEIMER Results shall be used in or for the manufacturing of the Product, then the Parties shall promptly negotiate in good faith an amendment to this Agreement which sets forth the licensed Gerresheimer Results, the license fee payable for the use of GERRESHEIMER Results and other reasonable and customary agreed-upon terms and conditions. If Gerresheimer incorporates GERRESHEIMER Results into a Product without such written agreement, CLEARSIDE BIOMEDICAL shall have an irrevocable, transferable, royalty-free license to utilize those GERRESHEIMER Results as necessary or helpful to commercialize the affected Product or Products.

15.4Without regard to inventorship GERRESHEIMER or its Affiliates (as the case may be) shall become the sole owner of all right, title and interest in and to all Intellectual Property relating to improvements to GERRESHEIMER Background IP and/or to any new manufacturing and/or production processes (or parts thereof) that is discovered in the course of this Agreement ("GERRESHEIMER Results"). CLEARSIDE BIOMEDICAL hereby agrees to, and does hereby assign all right, title and interest to GERRESHEIMER Results to GERRESHEIMER. For the avoidance of doubt CLEARSIDE BIOMEDICAL shall have no right to patent any of the GERRESHEIMER Results. For the avoidance of doubt, GERRESHEIMER Results shall not include any CLEARSIDE BIOMEDICAL Results.

- Without regard to inventorship, CLEARSIDE BIOMEDICAL shall become sole owner of all right, title and interest in and to all Intellectual Property relating to improvements to CLEARSIDE BIOMEDICAL Background IP and/or the Product discovered and/or generated in the course of this Agreement and that are not GERRSHEIMER Results ("CLEARSIDE BIOMEDICAL Results"). GERRESHEIMER hereby agrees to, and does hereby assign all right, title and interest to CLEARSIDE BIOMEDICAL Results to CLEARSIDE BIOMEDICAL. For the avoidance of doubt GERRESHEIMER shall have no right to patent any of the CLEARSIDE BIOMEDICAL Results.
- GERRESHEIMER will promptly notify CLEARSIDE BIOMEDICAL in writing and with full details of any CLEARSIDE BIOMEDICAL Results or Product- specific GERRESHEIMER RESULTS generated or acquired. Same applies vice versa in case CLEARSIDE BIOMEDICAL generates or acquires GERRESHEIMER Results.

### 16. CUSTOMER COMPLAINTS AND RECALL

GERRESHEIMER shall notify CLEARSIDE BIOMEDICAL's Quality Manager by telephone and in writing without undue delay upon becoming aware of any problem relating to

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the Product which could reasonably have negative effects on CLEARSIDE BIOMEDICAL, including, but not limited to:

- (a) where any Product or its labelling may have been mistaken for or applied to another product;
- (b) where any Product may be affected by significant contamination, significant chemical, physical or any other change or deterioration;
- (c) where any Product is the subject of a complaint by a Third Party or customer; or
- (d) where any Product may not comply with the Specification.
- Notwithstanding the provisions and procedures set forth in Clause 10 but in no way limiting CLEARSIDE BIOMEDICAL rights thereunder, CLEARSIDE BIOMEDICAL shall without undue delay notify GERRESHEIMER about any Products that are subject to a complaint by Third Parties including customers and, if available, send a reasonable quantity of the relevant suspected Products to GERRESHEIMER and issue a written report of this suspected non-conformance.
- If any of the circumstances described in Clause 16.1 above arise, whether notified to CLEARSIDE BIOMEDICAL or not, 16.3 GERRESHEIMER shall take, at CLEARSIDE BIOMEDICAL's written request and, except as otherwise stated herein, at CLEARSIDE BIOMEDICALs cost, all such reasonable acts as CLEARSIDE BIOMEDICAL may direct. If CLEARSIDE BIOMEDICAL deems that a recall of or other corrective action with respect to the Product or the Pharmaceutical Component (a "Recall") is required, CLEARSIDE BIOMEDICAL shall notify GERRESHEIMER immediately in advance and without delay and both Parties shall promptly develop the Recall strategy and GERRESHEIMER shall provide all reasonably necessary cooperation to support the implementation of the Recall strategy. In the event that a Recall is caused by Agreed Defective Product, all reasonable direct costs of such Recall shall be borne by GERRESHEIMER. To the extent a Recall is caused in party by Agreed Defective Product and in part by some other reasons, the portion of the cost of the Recall shall be allocated to GERRESHIEMER based on its comparative fault. For the avoidance of doubt where the Recall is not caused by Agreed Defective Product, CLEARSIDE BIOMEDICAL shall bear all costs of such Recall. For the avoidance of doubt CLEARSIDE BIOMEDICAL shall be obliged to use commercially reasonable efforts to mitigate any expenses or costs of such Recall. For the avoidance of doubt GERRESHEIMER's compensation obligation pursuant to this Clause 16.3 shall be subject to the limitations on liability as set out in Clause 23.3. Notwithstanding anything in this Clause to the contrary, the strategy with respect to, and any communications with the Regulators or other Third Parties associated with, any Recall of Product or the Pharmaceutical Component shall be conducted solely by CLEARSIDE BIOMEDICAL.

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Upon notification from CLEARSIDE BIOMEDICAL that it has received a complaint as described in Clause 16.1 (c) in respect of the Product, GERRESHEIMER will promptly and at its own expense conduct all such necessary internal investigations as may be reasonably necessary to determine the validity of such complaint. The initial findings of such investigations shall be reported in writing to CLEARSIDE BIOMEDICAL within fifteen (15) Business Days of the detailed original notification. In the case of a more detailed investigation being necessary, GERRESHEIMER shall promptly submit with due consideration a final report indicating the root cause and corrective/preventative actions. GERRESHEIMER. For the avoidance of doubt, CLEARSIDE BIOMEDICAL shall have the sole right and authority to respond to any complaint made by a Third Party, and GERRESHEIMER shall not communicate with such Third Party without the prior written consent of CLEARSIDE BIOMEDICAL.

# 17. <u>DOCUMENTATION AND REPORTS</u>

GERRESHEIMER shall complete the documentation relating to the manufacture of the Product in accordance with cGMP and any other agreed requirements of CLEARSIDE BIOMEDICAL.

### 18. <u>CONFIDENTIALITY</u>

- Any Confidential Information to be disclosed by the Disclosing Party to the Receiving Party in or as a result of the Agreement shall remain the Disclosing Party's property.
- The Receiving Party shall not disclose (directly or indirectly) any Confidential Information of the Disclosing Party to, or permit it to be accessed by, any person except a Permitted User.
- Each Party shall cause its Affiliates and Permitted Users to abide by the terms of this Agreement. Each Party shall be liable for the breach of this Agreement by any of its Affiliates and Permitted Users. In the event the Receiving Party becomes aware of any breach of this Agreement by it, its Affiliates or any of its Permitted Users, the Receiving Party shall promptly notify the Disclosing Party of such breach and all facts known to the Receiving Party regarding same.
- The Receiving Party shall use, and shall cause its Affiliates and Permitted Users to use, the Confidential Information only for the purpose of this Agreement and for no other purpose whatsoever.
- The duty of confidentiality, nondisclosure and non-use under this Clause owed in relation to the Confidential Information of the Disclosing Party shall not extend to any information which:
  - (a) the Receiving Party thereof can show by competent proof that it knew prior to disclosure; or

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- (b) is or comes into the public domain other than in breach of this Clause; or
- (c) is obtained from a Third Party that is lawfully entitled to possession of such Confidential Information and is under no obligation of confidentiality to the Disclosing Party; or
- (d) was independently developed by or for the Receiving Party without any reference to, aid from or reliance upon the Confidential Information of the Disclosing Party.
- If the Receiving Party is legally compelled to disclose Confidential Information of the Disclosing Party or the substance of this Agreement in connection with a legal or administrative proceeding with a requirement under Applicable Law, the U.S. Securities and Exchange Commission, the Nasdaq market or any other securities exchange or market, the Receiving Party shall give the Disclosing Party prompt notice of such request so that the Disclosing Party may seek an appropriate protective order or other remedy. If the Disclosing Party seeks a protective order or other remedy, the Receiving Party shall reasonably cooperate with and assist the Disclosing Party in such efforts, at the Disclosing Party's expense. Subject to any protective order obtained, the Receiving Party shall be permitted to disclose only that portion of Confidential Information which its legal counsel determines it is required to disclose.
- 18.7 The obligations of each Party in this Clause 18 shall survive for a term of five (5) Years the expiration or earlier termination, for any reason, of this Agreement.
- Upon termination of this Agreement or earlier if requested by the Disclosing Party, the Receiving Party shall return or destroy, at the Disclosing Party's own choice and at its sole discretion, all Confidential Information which it has in its possession or under its control, save that the Receiving Party can keep one (1) copy for compliance purposes. Notwithstanding anything to the contrary in this Agreement, the Receiving Party shall not be required to destroy any computer files stored securely by the Receiving Party that are created during automatic system back-up.

#### 19. <u>INTENTIONALLY LEFT BLANK</u>

## 20. FORCE MAJEURE

Force Majeure shall mean any event beyond the control of the Party claiming the Force Majeure, which could not be reasonably foreseen at the time of the Effective Date of the Agreement. Force Majeure therefore may include without limitation any Act of God including, but not limited to, fire, earthquake, flood or other natural disaster, accidents or equipment failure which are not the fault of the Party relying upon such circumstances; act of any sovereign including, but not limited to, riot, war, invasion; acts of terrorism and any measures to combat terrorism; imposing of government sanctions embargo or similar action; law, judgment, order, decree, blockade; labour dispute including, but not limited to, strike, lockout or boycott;

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interruption or failure of utility service including, but not limited to, electric power, gas, water or telephone service; failure of the transportation of any personnel, equipment, machinery, supply of materials required by GERRESHEIMER for the purposes of this Agreement; other similar events.

- 20.2 If any Force Majeure occurs in relation to either Party which affects or may affect the performance of any of its obligations under this Agreement, it shall promptly notify the other Party in writing forthwith as to the nature and extent of the circumstances in question.
- 20.3 Neither Party shall be deemed to be in breach of this Agreement, or shall be otherwise liable to the other Party, by reason of any delay in performance, or the non-performance of any of its obligations hereunder, to the extent that the delay or non-performance is due to any Force Majeure of which it has duly notified the other Party, and the time for performance of that obligation shall be extended accordingly and reasonably (and in any event equal to the period of Force Majeure).
- If the performance by either Party of any of its obligations under this Agreement is prevented or delayed by Force Majeure for a continuous period in excess of fifteen (15) Business Days, the Parties shall enter into *bona fide* discussions with a view to alleviating its effects, or to agreeing upon such alternative arrangements as may be fair and reasonable in the circumstances.
- If the performance by either Party of any of its obligations under this Agreement is prevented or delayed by Force Majeure for three (3) Months or more, consecutively during any one (1) Year period, then the other Party shall in its discretion have the right to terminate the Agreement forthwith upon written notice.

### 21. <u>INSPECTION / AUDIT RIGHTS</u>

CLEARSIDE BIOMEDICAL shall have the right to inspect the Manufacturing Site from time to time with at least a six (6) month hiatus during the first two (2) full Years during the Term and at least a twelve (12) Month hiatus between such inspections (which can be shortened for critical issues) at normal business hours, upon at least fifteen (15) Business Days prior written notice (which can be shortened for critical issues) to GERRESHEIMER to ensure GERRESHEIMERs compliance with the terms of this Agreement and the Quality Agreement. Where CLEARSIDE BIOMEDICAL requires the inspection is to be undertaken by a designated Third Party GERRESHEIMER agrees to arrange for the audit to take place but CLEARSIDE BIOMEDICAL shall pay all the fees of the designated Third Party for such inspection; PROVIDED, HOWEVER, that such Third Party shall be duly authorized and shall be bound by the same confidentiality obligations as CLEARSIDE BIOMEDICAL and provided that such Third Party is not a competitor of GERRESHEIMER. Time of such inspections shall be mutually agreed upon by both Parties. For the avoidance of doubt, CLEARSIDE BIOMEDICAL shall be entitled

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to perform additional inspections in the event GERRESHIEMER has delivered Defective Product in two (2) or more deliveries in any consecutive twelve (12) Month period, or it has received reports from Regulator(s) that said Regulator(s) have audited GERRESHEIMER with respect to the Product and after such audit have concluded that the Manufacturing Site is not in compliance with Applicable Laws.

- 21.2 If after such inspections, CLEARSIDE BIOMEDICAL reasonably believes that GERRESHEIMER is in material violation of any of its obligations, warranties, covenants or representations under this Agreement, CLEARSIDE BIOMEDICAL may request additional information from GERRESHEIMER and if CLEARSIDE BIOMEDICAL reasonably considers such response as not being reasonably satisfactory, CLEARSIDE BIOMEDICAL may request GERRESHEIMER to implement certain changes or provide a written explanation of its unwillingness to implement such changes. GERRESHEIMER shall be required to consider implementing any requested changes but not to actually act upon or implement any changes that may have been requested. It shall be a satisfactory explanation either that GERRESHEIMER demonstrates that its processes comply with cGMP requirements, the relevant regulations and/or the Specifications.
- GERRESHEIMER shall use reasonable efforts to cause its sub-contractors to provide the same access as set forth in Clause 21.1 In the event access is not granted to CLEARSIDE BIOMEDICALS, GERRESHEIMER may perform the audit on CLEARSIDE BIOMEDICALs behalf, with all incurring proven costs to be borne by CLEARSIDE BIOMEDIAL, and shall share the results of the audit with CLEARSIDE BIOMEDICAL, subject to compliance with confidentiality obligations.

# 22. <u>WARRANTIES AND INDEMNITY</u>

- 22.1 GERRESHEIMER hereby represents and warrants that:
  - (i) it is a corporation duly organised and validly existing and in good standing under the laws of its jurisdiction of organisation;
  - (ii) it has the corporate power and authority to negotiate, execute, deliver and perform its obligations under this Agreement;
  - (iii) the Product supplied hereunder shall conform to the Specifications;
  - (iv) [\*\*\*];
  - (v) that the Product will be delivered free from any security, interest, lien or encumbrance;
  - (vi) it shall comply with Applicable Laws;

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- (vii) [\*\*\*]
- (viii) GERRESHEIMER has not used, and will not use, in any capacity associated with or related to the manufacture of the Product, the services of any Persons who have been, or are in the process of being, (i) debarred under 21 U.S.C. § 335a(a) or (b) or any comparable laws of a foreign jurisdiction, or (c) excluded from participation in the Medicare program, any state Medicaid program or any other health care program. Furthermore, neither GERRESHEIMER nor any of its officers, employees, or consultants has been convicted of an offense under (a) either a federal or state law that is cited in 21 U.S.C. § 335(a) as a ground for debarment, denial of approval or suspension, (b) any other law cited in any comparable Applicable Laws as a ground for debarment, denial of approval or suspension. GERRESHIEMER shall notify CLEARSIDE BIOMEDICAL immediately upon learning of any circumstance that would cause this certification under this Clause 22.1(viii) to become false or inaccurate.
- 22.2 [\*\*\*].
- 22.3 The warranties set forth in Clause 22.1 above shall not apply to any Product that has been misused, neglected, improperly handled, stored, abused or used for any purpose other than the one for which it was manufactured.
- THE WARRANTIES EXPRESSLY SET FORTH IN THIS AGREEMENT ARE IN LIEU OF ALL OTHER WARRANTIES, AND TO THE EXTENT ALLOWED BY APPLICABLE LAW GERRESHEIMER DISCLAIMS ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. GERRESHEIMER EXPRESSLY DISCLAIMS ANY REPRESENTATIONS AND WARRANTIES REGARDING THE PERFORMANCE, SAFETY OR EFFICACY OF THE PRODUCT IN COMBINATION WITH ANY PRODUCTS, AGENTS, DRUGS, COMPOUNDS OR COMPONENTS OF CLEARSIDE BIOMEDICAL IN THE FINAL PHARMACEUTICAL PRODUCT OR THE PHARMCEUTICAL COMPONENT. CLEARSIDE BIOMEDICAL EXPRESSLY ACCEPTS THESE DISCLAIMERS.
- GERRESHEIMER shall indemnify, defend, release and hold harmless CLEARSIDE BIOMEDICAL, its Affiliates, and their respective directors, employees, contractors and agents, from and against any and all actual Third Party claims, judgments, damages, losses, liabilities, penalties, suits, costs and expenses (including reasonable attorney's fees and court costs) incurred after the Effective Date and to the extent arising out of or relating to: (a) a breach of this Agreement or the Quality Agreement by GERRESHEIMER; (b) the negligent or willful misconduct of by GERRESHEIMER, its Affiliates, or their respective employees, agents or contractors. For the sake of clarity, GERRESHEIMER shall not be responsible to indemnify, defend, release or hold harmless CLEARSIDE BIOMEDICAL as provided for above for that portion of any claims, judgments, damages, losses, liabilities, penalties, suits, costs or expenses for which CLEARSIDE bears contributory liability as agreed to by the Parties or determined by a court of competent jurisdiction.

- Subject to Clause 11.2, CLEARSIDE BIOMEDICAL shall indemnify, defend, release and hold harmless GERRESHEIMER, its Affiliates, directors, employees and agents or sub-contractors from and against any and all actual Third Party claims, judgments, damages, losses, liabilities, penalties, suits, costs and expenses (including reasonable attorney's fees and court costs) incurred after the Effective Date and to the extent arising out of or relating to: (a); a breach of this Agreement or the Quality Agreement by CLEARSIDE BIOMEDICAL, or (b) the sale, distribution, supply, use or operation of the Product including, but not limited to, any claims resulting from filling, storing, packaging, testing, using or selling Product or relating to the adequacy of the labelling, warnings and instructions. For the sake of clarity, CLEARSIDE BIOMEDICAL shall not be responsible to indemnify, defend, release or hold harmless GERRESHEIMER as provided for above for that portion of any claims, judgments, damages, losses, liabilities, penalties, suits, costs or expenses for which GERRESHEIMER bears contributory liability as agreed to by the Parties or determined by a court of competent jurisdiction.
- 22.7 In the event that a Party (the "Indemnified Party") receives a claim or demand from a Third Party in respect of a matter which is the subject of an indemnity under this Clause it shall give the other Party (the "Indemnifying Party") written notice thereof as soon as reasonably practicable and shall permit the Indemnifying Party and its insurers the opportunity to assume direction and control of the defence against such claims, at its sole expense, including without limitation, the selection of counsel to the extent that the Indemnified Parties' liability is not thereby invoked.
- 22.8 The Parties shall cooperate with one-another and their insurers in the disposition of any such matter.
- 22.9 [\*\*\*].
- 22.10 [\*\*\*].

### 23. <u>LIMITATIONS ON LIABILITY</u>

- 23.1 Neither Party excludes or limits liability to the other Party for:
  - (a) fraud or fraudulent misrepresentation;
  - (b) death or personal injury caused by negligence or willful misconduct; or
  - (c) any matter in respect of which it would be unlawful for the Parties to exclude liability.
- 23.2 [\*\*\*].

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- Subject to Clause 23.1, in no event shall the collective and aggregate liability of GERRESHEIMER and its Affiliates to CLEARSIDE BIOMEDICAL and its Affiliates for all claims under this Agreement, and any renewals or extensions thereof, whether in connection with a warranty claim, a Recall, an indemnity claim, a combination thereof, or otherwise, and whether arising under contract, warranty, tort (including negligence), strict liability, product liability, a combination thereof, or any other theory of liability or indemnification [\*\*\*].
- Subject to Clause 23.1 and subject to Clause 11.2, in no event shall the collective and aggregate liability of CLEARSIDE BIOMEDICAL or CLEARSIDE BIOMEDICAL Affiliates to GERRESHEIMER and its Affiliates for all claims under this Agreement, and any renewals or extensions thereof, whether in connection with a warranty claim, a Recall, an indemnity claim, a combination thereof, or otherwise, and whether arising under contract, warranty, tort (including negligence), strict liability, product liability, a combination thereof, or any other theory of liability or indemnification [\*\*\*].

### 24. <u>INSURANCE</u>

GERRESHEIMER shall maintain at its own cost full and sufficient Third Party, product liability, product recall insurance with a reputable insurance company for a value of at least [\*\*\*] and on written request shall provide to CLEARSIDE BIOMEDICAL a copy of the certificate of the said insurance.

### 25. TERMINATION AND CONSEQUENCES OF TERMINATION

- In the event that either Party should be in material breach of this Agreement (being a single event or series of events that are together defined as a material breach) and either:
  - (a) the breach is capable of remedy and the breaching Party has failed to substantially remedy the breach within sixty (60) days of written notice specifying the breach and requiring the same to be remedied; or
  - (b) the breach is not capable of remedy within sixty (60) days from the receipt of written notice specifying the breach and requiring the same to be remedied; then

the non-breaching Party may without prejudice to any other rights or remedies which may be available to it terminate this Agreement with immediate effect by giving written notice of termination to the breaching Party.

25.2 If one Party shall compound or make any arrangement with its creditors, or an insolvency administrator is appointed over all or any part of its assets or goes into liquidation (whether voluntary or otherwise) save as part of a *bona fide* reconstruction not involving insolvency or shall take or suffer to be taken any

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similar action as a result of its inability to pay its debts or its insolvency it shall promptly so notify the other Party in writing giving particulars of the circumstances whereupon the other Party may terminate the Agreement immediately by written notice. For the avoidance of doubt the other Party may terminate the Agreement upon the occurrence of any of the circumstances described in this Clause 25.2 notwithstanding that Party may not have given notice to the other Party as required.

- 25.3 If at any time during the term of the Agreement there shall be any Change of Control of a Party or in case of Clearside, of an Affiliate party to an Affiliate Agreement pursuant to Clause 4.8:
  - (i) The Party shall immediately so notify the other Party in writing. GERRESHEIMER shall confirm promptly after receipt of a Change of Control notification whether CLEARSIDE BIOMEDICAL is still covered by GERRESHEIMER's trade credit insurance after such Change of Control. If CLEARSIDE BIOMECDICAL is not covered by GERRESHEIMER's trade credit insurance, then GERRESHEIMER shall sell (and/or Deliver) any Products to CLEARSIDE BIOMEDICAL or fulfil or accept any Purchase Orders only upon receipt of a payment security from CLEARSIDE BIOMEDICAL by means of a payment guarantee of CLEARSIDE BIOMEDICAL or a bank guarantee of an internationally business bank rated with triple B; and
  - Either Party may upon receiving notice or otherwise becoming aware of a Change of Control of the Party have the right, exercisable within ten (10) days after receipt of notice or becoming aware, to terminate the Agreement by notice in writing to the Party; PROVIDED, HOWEVER, that such Party may only terminate this Agreement upon a Change of Control of the other Party if it considers, acting reasonable, that such Change of Control is prejudicial to its interests; PROVIDED FURTHER, HOWEVER, that such termination shall become effective twenty four (24) Months from the date of the Change of Control notice, unless the Parties mutually agree in writing on a shorter period of time. With respect to GERRESHEIMER, such Change of Control shall always be deemed prejudicial, if CLEARSIDE BIOMEDICAL's acquiror's primary business is in direct competition with GERRESHEIMER (it being understood that for the avoidance of doubt, such acquirer of CLEARSIDE BIOMEDICAL shall not be construed as having a primary business in direct competition with GERRESHEIMER by virtue of the fact that it manufactures the Product by itself for use with its own pharmaceutical products). The same terms and conditions shall apply to agreements pursuant to Clause 4.8.
  - 25.4 If CLEARSIDE BIOMEDICAL ceases to sell the final pharmaceutical product which incorporates Product supplied under this Agreement, CLEARSIDE BIOMEDICAL may terminate this Agreement on giving thirty (30) days prior written notice if it is ceasing to sell the Product as a result of a market withdrawal in the USA by requirement of a Regulator, and three (3) Month prior written notice in any other circumstances. In case CLEARSIDE BIOMEDICAL's decision is due to significant

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technical, or any regulatory reasons with respect to the Product, CLEARSIDE BIOMEDICAL shall notify GERRESHEIMER immediately upon learning of such technical or regulatory impact, and, as appropriate, work together with GERRESHEIMER to remedy such impact during the notice period.

- 25.5 The applicable Party may terminate this Agreement in accordance with Clause 20.5 (Force Majeure).
- 25.6 Either Party may terminate this Agreement by electing not to renew the Agreement in accordance with Clause 2.
- For the avoidance of doubt in the event of any termination of this Agreement, the respective Product Schedules will terminate, unless the Parties expressly agree in writing that the terms of this Agreement shall continue to apply to a Product Schedule following termination of this Agreement.
- On termination of the Agreement, GERRESHEIMER shall, not later than forty five (45) Business Days after CLEARSIDE BIOMEDICAL's prior written request but at CLEARSIDE BIOMEDICALs cost deliver to CLEARSIDE BIOMEDICAL (or as CLEARSIDE BIOMEDICAL shall direct) all quantities of the Product already produced (based on the agreed Selling Prices in the Product Schedule), semi- finished Products (based on the purchase price of the Materials plus manufacturing costs, and where available such costs shall be those identified in the cost breakdown in the Product Schedule), the Material and consumables (purchase price of the Materials plus [\*\*\*\*] where available such price can be that identified in the cost breakdown in the Product Schedule), in its possession for the binding quantities for the next six (6) Months in the most recent Forecast Schedule or as otherwise agreed.
- 25.9 For the avoidance of doubt, upon termination of this Agreement by GERRESHEIMER pursuant to Clauses 25.1 or 25.2 or by CLEARSIDE BIOMEDICAL pursuant to Clause 25.4, CLEARSIDE BIOMEDICAL shall be obliged to reimburse GERRESHEIMER for all binding quantities for the next six (6) Months in the most recent Forecast Schedule or as otherwise agreed, provided they are not Agreed Defective Products.
- In the event CLEARSIDE BIOMEDICAL terminates this Agreement pursuant to Clause 25.1, GERRESHEIMER shall, at its sole cost, provide reasonable assistance to CLEARSIDE BIOMEDICAL in the technical transfer of the manufacturing equipment to CLEARSIDE BIOMEDICAL's or a Third Party's manufacturing facility designated by CLEARSIDE BIOMEDICAL and shall grant to CLEARSIDE BIOMEDICAL a fully paid up non-exclusive worldwide license, with the limited right to grant sub-license to only such THIRD PARTY manufacturer, under the licensed GERRESHEIMER Results pursuant to Clause 15.3, or if not applicable, to new manufacturing and/or production processes relating directly to the Product required to use, sell, make and have made the affected Products (hereinafter

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referred to as "Licensed IP"); PROVIDED, HOWEVER, that the license granted hereunder shall be effective only during the period of time of the supply of Products by said THIRD PARTY manufacturer (such period is hereinafter referred to as a "License Period") and CLEARSIDE BIOMEDICAL shall not exercise its rights to use, sell, make or have made the Products or to utilize the Gerresheimer Results pursuant to such license other than during such a License Period. In all other cases and after the License Period if CLEARSIDE BIOMEDICAL desires that a THIRD PARTY manufacturer shall manufacture the Product by using Gerresheimer Results licensed pursuant to this Clause or pursuant to Section 15.3, CLEARSIDE BIOMEDICAL shall pay to GERRESHEIMER the licence fee, royalties or other amounts as negotiated between the Parties pursuant to Section 15.3 for as long as such manufacture continues.

- In all other cases of CLEARSIDE BIOMEDICAL terminating this Agreement for whatever reasons GERRESHEIMER shall in general provide reasonable assistance to CLEARSIDE BIOMEDICAL to effect a complete transfer of the process of the manufacturing of the Product to another manufacturing site of CLEARSIDE BIOMEDICEAL's choice. CLEARSIDE BIOMEDICAL shall reimburse GERRESHEIMER for any actual and duly documented costs incurred in providing such assistance on a time and material basis.
- 25.11 With effect from termination of the Agreement, the Parties shall not make any use for any purpose whatsoever of any Intellectual Property which is the property of other Party except as it is expressly mentioned in this Agreement.
- For the avoidance of doubt the Parties expressly acknowledge that any termination of this Agreement for whatever reason shall not affect the effectiveness of any corresponding agreement pursuant to Clause 4.8 unless as otherwise agreed by the Parties in writing.
- 25.13 Following effectiveness of termination of the Agreement, CLEARSIDE BIOMEDICAL may remove the CLEARSIDE BIOMEDICAL Equipment from the Manufacturing Site (Removal). GERRESHEIMER shall, at the request of CLEARSIDE BIOMEDICAL, after prior written notification and without interruption of GERRESHEIMER's business operations exceeding what is reasonably necessary to perform such Removal:
  - (A) grant CLEARSIDE BIOMEDICAL access to the Manufacturing Site during normal business hours;
  - (B) identify the CLEARSIDE BIOMEDICAL Equipment located within the Manufacturing Site; and
- (C) permit CLEARSIDE BIOMEDICAL to remove such Equipment.
  - 25.14 The costs incurred by CLEARSIDE BIOMEDICAL in any removal of the CLEARSIDE BIOMEDICAL Equipment pursuant to this Clause 25 and, should the removal

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directly result in any material damage to the Manufacturing Site or the CLEARSIDE BIOMEDICAL Equipment, the costs relating to the repair of the Manufacturing Site or the CLEARSIDE BIOMEDICAL Equipment (excluding damages caused by the negligence of a Party which shall be borne by that Party), shall be borne as follows:

- (a) in cases where CLEARSIDE BIOMEDICAL terminates pursuant to Clauses 25.1 (GERRESHEIMER material breach);25.2 (GERRESHEIMER insolvency); 25.3 (GERRESHEIMER Change of Control), by GERRESHEIMER; or
- (b) in cases where either Party terminates in accordance with Clause 20.5 (Force Majeure) equally by both Parties; or
- (c) in cases where GERRESHEIMER terminates pursuant to Clause 25.1 (CLEARSIDE BIOMEDICAL material breach); 25.2 (CLEARSIDE BIOMEDICAL insolvency); 25.3 (CLEARSIDE BIOMEDICAL Change of Control), by CLEARSIDE BIOMEDICAL.

The Parties shall use their reasonable endeavours to minimise all such costs.

#### 26. WAIVER

No waiver or forbearance by either Party in enforcing any of its rights under this Agreement shall prejudice or affect the ability of the said Party to enforce such rights or any of its other rights at any time in the future. No waiver shall be effective unless in writing and signed by the Party concerned. For the avoidance of doubt it is agreed that a waiver of a right on one occasion shall not constitute a waiver of the same right in the future.

#### 27. NOTICE

Other than as expressly provided for herein or in the Quality Agreement, any notice given in accordance with this Agreement shall be in writing in English and shall be properly served if sent by registered mail, email, or delivered by hand to the address of either Party as set out in this Agreement. Notices shall be deemed to have been served: (a) seven (7) Business Days after the date of deposit if sent by registered mail; or (b) on the next Business Day after being sent by email; or (c) if delivered by hand, on the date of delivery.

#### **GERRESHEIMER Contacts:**

GerresheimerRegensburg GmbH ### ### Medical Systems Oskar-von-Miller-Strasse 6 92442 Wackersdorf Germany

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#### Copy to

Gerresheimer Regensburg GmbH Head of Legal Affairs Kumpfmuehler Strasse 2 93047 Regensburg Germany

#### **COMPANY Contacts:**

Clearside Biomedical, Inc. 900 North Point Parkway, Suite 200 Alpharetta, GA 30005 Attention: Chief Executive Officer

email: daniel.white@clearsidebio.com

#### Copy to:

Hutchison PLLC 3110 Edwards Mill Road, Suite 300 Raleigh, NC 27612

Attn: William N. Wofford email: bwofford@hutchlaw.com

### 28. SURVIVAL OF RIGHTS DUTIES AND OBLIGATIONS

- 28.1 Termination or expiry of this Agreement shall not release either Party hereto from any liability or right of action which at the time of termination has already accrued to either Party hereto or which may thereafter accrue in respect of any act or omission prior to such termination. Such rights shall include but not be limited to the recovery of any monies due hereunder,
- Any provision of this Agreement which by its very nature imposes an obligation after termination or expiration of this Agreement shall survive the termination or expiration of this Agreement. Without limiting the foregoing, expiration or earlier termination of the Agreement shall be without prejudice to the continuation in force of Clauses 10, 14, 15, 16, 17, 18, 22, 23, 25, 26, 27, 28, 38 and 39.

### 29. RELATIONSHIP OF THE PARTIES

Each Party is an independent contractor and neither is the agent of the other. Except as is specifically provided in this Agreement neither Party is authorised to incur any expenditure or cost for the other without the written consent of that Party.

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#### 30. ASSIGNMENT

The Parties' rights and obligations under this Agreement may not be assigned in whole or in part without the prior written consent of the other Party (such consent not to be unreasonably withheld). Notwithstanding the foregoing, either Party may, even without the consent of the other Party, assign this Agreement or any of its rights or obligations (i) to any of its Affiliates, or (ii) in connection with a sale or transfer of all or substantially all of such Party's business or assets relating to the subject matter of this Agreement, whether by merger, sale of assets or otherwise; PROVIDED, HOWEVER, that such Party's rights and obligations under this Agreement shall be assumed in writing by its successor in interest in any such transaction and PROVIDED FURTHER that if in case of CLEARSIDE BIOMEDICAL said Affiliate or Third Party's primary business is in direct competition with GERRESHEIMER, then GERRESHEIMER is entitled to terminate this Agreement in its sole discretion upon at least twenty four (24) Month written notice to CLEARSIDE BIOMEDICAL.

#### 31. <u>SUB-CONTRACTORS</u>

GERRESHEIMER may not delegate or otherwise sub-contract its obligations under this Agreement without the prior written consent of CLEARSIDE BIOMEDICAL, such consent not to be unreasonably withheld or delayed. For the avoidance of doubt GERRESHEIMER may, in its sole discretion, sub-contract its rights and obligations under this Agreement to any of its Affiliates in which case GERRESHEIMER shall remain responsible for the performance of its Affiliates.

### 32. SOLE AGREEMENT

- This Agreement represents the entire agreement between the Parties and supersedes and extinguishes all previous agreements and negotiations between the Parties in respect of the subject matter hereof and shall apply to the exclusion of all other standard conditions of sale or purchase, whether written, oral, express or implied which the Parties may purport to apply or which are endorsed upon any correspondence or documents issued by one Party irrespective of their date of communication to the other Party.
- Each Party acknowledges that in entering into this Agreement, it is not relying upon any statement, draft, agreement, undertaking, warranty, promise, assurance or arrangement of any nature whatsoever, whether written or otherwise, relating to the subject matter of this Agreement made by any person prior to the date of this Agreement which is not set out in this Agreement. Except in the case of fraud, no Party shall have any right of action against the other Party arising out of or in connection with any such statement, except to the extent it is repeated in this Agreement.

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32.3 In the event of any conflict with, or inconsistency between any term or provision of this Agreement and any term or provision of its Schedules or other agreements entered into pursuant to it, the term or provision of this Agreement shall prevail.

### 33. EXPENSES

Each Party shall pay all of its own fees and expenses (including all legal, accounting and other advisory fees) incurred in connection with the negotiation and execution of this Agreement.

#### 34. AMENDMENTS

No modification or amendment of this Agreement shall be valid or binding upon the Parties hereto unless made in writing and duly executed on behalf of both of the Parties by their respective duly authorised officers. This also applies to any waiver of the aforementioned written form requirement. Any modifications to the Specifications shall be agreed to in writing by both Parties. The last agreed version shall automatically supersede the previous one.

# 35. <u>SEVERABILITY</u>

Each clause of this Agreement is a distinct and severable clause and if any clause is deemed illegal, void or unenforceable, the validity, legality, or enforceability of any other clause or portion of this Agreement shall not be affected thereby to the exclusion of all other remedies.

If any provision of this Agreement is held to be invalid, illegal or unenforceable, in any respect, then such provision will be given no effect by the Parties and shall not form part of this Agreement. To the fullest extent permitted by Applicable Law and if the rights and obligations of any Party will not be materially and adversely affected all other provisions of this Agreement shall remain in full force and effect and the Parties shall use their commercially reasonable efforts to negotiate a provision in replacement of the provision held invalid, illegal or unenforceable that is consistent with Applicable Law and achieves, as nearly as possible, the original intention of the Parties.

### 36. ETHICAL STANDARDS AND HUMAN RIGHTS

- 36.1 Unless otherwise required or prohibited by law, GERRESHEIMER warrants, to the best of its knowledge, in relation to the supply of Product or services under the terms of this Agreement to:
  - (i) provide employees with at least an amount of income necessary to meet their basic needs;
  - (ii) provide employees with the right to rest;

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- (iii) protect employees against discrimination in the workplace;
- (iv) protect employees against coercion and degrading treatment;
- (V) respect employees' right to freedom of association;
- (vi) uphold the effective abolition of child labour;
- (vii) provide employees safe and healthy working conditions;
- (viii) protect and improve the environment; and
- (ix) work against corruption in any form.
- GERRESHEIMER is responsible for controlling its own supply chain and will encourage compliance with ethical standards and human rights by any subsequent supplier of goods and services that are used by GERRESHEIMER when performing its obligations under this Agreement.

#### 37. COUNTERPARTS

- 37.1 This Agreement may be executed in any number of counterparts, and by the Parties in separate counterparts, but shall not be effective until each Party has executed at least one counterpart.
- 37.2 Each counterpart shall constitute an original of this Agreement, but all counterparts shall together constitute but one and the same instrument.

#### 38. DISPUTE RESOLUTION

- 38.1 If either Party believes that there is a dispute between the Parties arising out of or in connection with this Agreement, including, without limitation, any non-contractual disputes or claims or any question regarding its existence, validity or termination (a "**Dispute**"), such Party may serve written notice on the other Party setting out details of the Dispute and the reasons why the Party serving the notice believes that the Dispute has arisen (a "**Notice of Dispute**"). Upon service of a Notice of Dispute, the Dispute shall be referred:
  - (i) first to representatives of each Party with day-to-day responsibility for the management of matters relating to this Agreement, who shall discuss by phone or meeting at a mutually acceptable time and place and endeavour to resolve the Dispute (each acting reasonably and in good faith) within 5 (five) Business Days after service of the Notice of Dispute; and
  - (ii) failing resolution of the Dispute in accordance with the abovementioned, to the XXXXXXXX for GERRESHEIMER and the Chief Executive Officer for CLEARSIDE

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BIOMEDICAL, who shall discuss by phone or meeting at a mutually acceptable time and place (the "Senior Representatives' Meeting") and endeavour to resolve the Dispute (each acting reasonably and in good faith) within 20 (twenty) days after the proceedings in accordance with Clause 38.1 (i).

If a Dispute has not been resolved within 20 (twenty) days after the Senior Representatives' Meeting, the Parties may, subject to Clause 39 below, take any action available to them at law, provided that the Parties may at any time seek a injunctive injunctive relief or other preliminary measures from a competent court provided that the final settlement is reserved for the court of arbitration pursuant to Clause 39.2.

### 39. GOVERNING LAW AND JURISDICTION

- 39.1 This Agreement and any dispute or claim arising out of or in connection with it or its subject matter or formation (including non-contractual disputes or claims) shall be governed by and construed in all respects in accordance with the laws of [\*\*\*], excluding any conflicts or choice of law rules or principle that might otherwise refer construction or interpretation of this Agreement to the substantive law of another jurisdiction. For the avoidance of doubt the provisions of the United Nations Convention for the International Sale of Goods (CISG) are explicitly excluded.
- In relation to any legal action or proceedings to enforce this Agreement or any agreement pursuant thereto the Parties agree that all disputes arising out of or in connection with the present contract shall be finally settled under the Rules of Arbitration of the International Chamber of Commerce (ICC) by one or more arbitrators appointed in accordance with the said Rules of Arbitration. The procedural law of [\*\*\*] shall apply where the Rules of ICC are silent. The place of arbitration shall be [\*\*\*], and the language of correspondence and the proceedings shall be conducted in English language. The costs of the arbitration court shall be borne by the unsuccessful Party, and each Party shall bear in full its own part of all other costs however arising. The Parties agree to accept the decision of the court of arbitration as final and binding on both of them, to the exclusion of all other remedies. Nothing in this Clause 39.2 shall be construed as limiting the right of the Parties to seek an injunctive relief or other preliminary measures from a competent court, provided that the final settlement is reserved for the court of arbitration.

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**IN WITNESS WHEREOF** the Parties hereto have caused their duly authorised representatives to sign this Agreement on their behalf the day and year first before written.

SIGNED BY for and on behalf of Clearside Biomedical, Inc

for and on behalf of **Gerresheimer Regensburg GmbH** 

Date May 8, 2018

Date May 8, 2018

Signed /s/ Daniel H. White

Signed <u>/s/ Illegible</u>

Daniel H. White

Illegible

Title President and CEO

TitleIllegible

SIGNED BY

Date May 8, 2018

Signed <u>/s/</u>Illegible Illegible

TitleIllegible

#### **SCHEDULES**

Schedule 1 – Product Schedule Template

Schedule 2 - Product Schedule

Schedule 3 – Quality Agreement

Schedule 4 – Documentation Regarding Tooling and Equipment

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#### Schedule 1

# PRODUCT SCHEDULE TEMPLATE

- 1. LEGAL ENTITIES (CLEARSIDE BIOMEDICAL & GERRESHEIMER) FOR ORDERS
- 2. DEVICE NAME
- 3. CLEARSIDE BIOMEDICAL PHARMA PRODUCT IN WHICH PRODUCT/DEVICE IS USED
- 4. GERRESHEIMER MANUFACTURING SITE(S)
- 5. CLEARSIDE BIOMEDICAL DELIVERY SITE(S)
- 6. DELIVERY TERMS / INCO TERMS
- 7. DEVICE SHELF LIFE
- 8. LEAD-TIME FOR DELIVERIES
- 9. PRODUCT SPECIFICATION
  - Description
  - b. Manufacturing standards
  - c. Packaging (if applicable), storage
  - d. Specific quality standards (in addition to those set out in the general QA)

# 10. PERFORMANCE STANDARDS

- a. Quality
- b. Delivery

# 11. CLEARSIDE BIOMEDICAL EQUIPMENT

- a. List of CLEARSIDE BIOMEDICAL Equipment
- b. Payment schedule for CLEARSIDE BIOMEDICAL Equipment
- c. Tooling & Equipment Warranty period (inc wear parts not covered by the piece cost)
- d. Annual / Sprint Capacity (including lead time for capacity changes)

### 12. PRICING

- Currency of orders and invoices
- b. Exchange Rate

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- c. Selling Price
- d. Raw Material prices
- e. Minimum order quantities
- f. Idle Costs
- 13. CLEARSIDE BIOMEDICAL Purchase Commitment (if different from standard 3 months Firm Orders)

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#### Schedule 2

#### PRODUCT SCHEDULE

1. LEGAL ENTITIES (CLEARSIDE BIOMEDICAL & GERRESHEIMER) FOR ORDERS

Clearside Biomedical, LLC 900 North Point Parkway Suite 200 Alpharetta, GA 30005

Gerresheimer Peachtree City (USA), L.P. 650 Highway 74 South Georgia 30269 Peachtree City, USA

2. DEVICE NAME

Clearside Microinjector Kit.

- 3. CLEARSIDE BIOMEDICAL Device Description and Use
  - a. [\*\*\*]
  - b. Device Use The final device is used to deliver pharmaceutical agents to the Suprachoroidal space of the eye.
- 4. CRITICAL MANUFACTURING SITE(S)

[\*\*\*]

5. CLEARSIDE BIOMEDICAL DELIVERY SITE(S)

[\*\*\*]

6. DELIVERY TERMS / INCO TERMS

[\*\*\*]

7. DEVICE SHELF LIFE

[\*\*\*]

45

8.	LEAD-TIME FOR DELIVERIES
	[***]

- 9. PRODUCT SPECIFICATION
  - a. Description

The Microinjector is a sterile, hand-held device [\*\*\*] designed for Suprachoroidal injection of Clearside Biomedical drug products. [\*\*\*].

b. Manufacturing standards

ISO 14644-1 Class 8

c. Packaging, storage,

[\*\*\*]

d. Specific quality standards (in addition to those set out in the general QA)

NA

#### 10. PERFORMANCE STANDARDS

[\*\*\*

As per the Supply Agreement Section #6

- 11. CLEARSIDE BIOMEDICAL EQUIPMENT
  - a. List of CLEARSIDE BIOMEDICAL Equipment to be updated by an attachment as additional equipment is received
    - i. [\*\*\*]
    - ii. [\*\*\*]
    - iii.[\*\*\*]
  - b. Payment schedule for CLEARSIDE BIOMEDICAL Equipment
    - i. [\*\*\*]
    - ii. Automation Complete per Quotation
      - 1. [\*\*\*]
      - 2. [\*\*\*]
      - 3. [\*\*\*

46

4. [\*\*\*

Payment terms set forth above are under the condition prerequisite that proper credit insurance is approved or a bank guarantee has been provided by Clearside. In the case that Clearside does not meet Gerresheimer Credit Requirements; all project costs will be pre-payment in advance of work performed or assets ordered.

c. Tooling & Equipment Warranty period (including wear parts not covered by the piece cost to be quoted and detailed)

[\*\*\*]

d. Annual / Sprint Capacity (including lead time for capacity changes)

[\*\*\*]

#### 12. PRICING

a. Currency of orders and invoices

i. USD

- b. Exchange Rate
  - i. Fixed on a monthly basis; no change if FX rate changes [\*\*\*] or less
- c. Selling Price

[\*\*\*]

#### 13. Volume Forecast

i. [\*\*\*

a. [\*\*\*]

b. [\*\*\*

Note: [\*\*\*]

Exchange rate: 1.00 Euro = \$1.1993 USD (Jan2018)

[\*\*\*]

[\*\*\*]

Additional packaging or alternate shipper totes etc. are not included.

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Current	shipping configuration: [***]
[***]	
	To be updated once all PQs have been passed and serial production has started for all parts, including purchased parts
Minimum order qu	antities [***]
	48
CONFIDENTIAL TREA CONFIDENTIALITY R AND EXCHANGE COI	ITMENT HAS BEEN REQUESTED FOR PORTIONS OF THIS EXHIBIT. THE COPY FILED HEREWITH OMITS THE INFORMATION SUBJECT TO A EQUEST. OMISSIONS ARE DESIGNATED [***]. A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECURITIES MMISSION.

#### Schedule 3

## **QUALITY AGREEMENT**

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This Quality Agreement ("Agreement") is made and entered into this 8th day of May, 2018 (the "Effective Date") by and between Clearside Biomedical, Inc. (herein, "CLEARSIDE BIOMEDICAL") a Delaware incorporated company with offices at 900 North Point Parkway, Suite 200, Alpharetta, GA 30005 and Gerresheimer Regensburg GmbH (herein referred to as "GERRESHEIMER") a company incorporated under laws of Germany and having its registered office at Kumpfmühler Straße 2, 93047 Regensburg, Germany.

#### 1. PURPOSE

This Agreement defines certain quality assurance requirements and establishes certain roles and responsibilities of the participating parties. It is being entered into pursuant to the Supply Agreement.

#### 2. SCOPE

This Agreement covers the manufacturing, packaging, testing, storage, and release for each clinical or commercially saleable Product made for CLEARSIDE BIOMEDICAL by GERRESHEIMER pursuant to the Supply Agreement.

GERRESHEIMER and CLEARSIDE BIOMEDICAL shall have shared responsibility for the performance of activities under their respective Quality Management Systems (QMS) as expressly defined within this Agreement.

#### 3. TERMS OF AGREEMENT

In the event of conflict between the terms of this Agreement and the terms of the Supply Agreement, the Supply Agreement controls. The terms and duties created herein shall supplement, but never supersede, those of the Supply Agreement.

#### 4. **DEFINITIONS**

"Supply Agreement" means that agreement entered into by the parties and made effective 8th day of May, 2018

Capitalized terms used but not otherwise defined herein shall have the meaning given to them in the Supply Agreement. All other terms used but not defined in the Supply Agreement or this Agreement shall have the meaning given to them according to cGMP or in the standard promulgated by the International Organization for Standardization (the "ISO Standards"), as applicable.

### 5. GENERAL RESPONSIBILITIES

CLEARSIDE BIOMEDICAL and GERRESHEIMER shall adhere to the terms as specified in this Agreement. Both parties shall promptly inform the other of any conflicts with the commitments, as stated, and work amicably towards resolution.

All manufacturing, quality assurance and quality control operations shall be according to cGMP and ISO 13485. The Parties agree that compliance with certain aspects of ISO 13485 is a matter of interpretation and that the Parties will work together in good faith to resolve any differences in interpretation of the regulations. This Agreement covers certain quality assurance aspects of manufacturing, packaging, testing, storage and release for Product made for CLEARSIDE BIOMEDICAL by GERRESHEIMER.

### 6. QUALITY SYSTEMS

## **6.1** Establishment of Quality Systems

Quality systems shall be established, documented and maintained by and at GERRESHEIMER as a means of ensuring that Product conforms to Specifications.

#### **6.2** Technology Changes / Change Control

GERRESHEIMER shall have a system for changes that shall be approved in writing by CLEARSIDE BIOMEDICAL. These changes include components, primary packaging materials, labeling, suppliers (manufacturer of components/primary packaging materials), product formulation, manufacturing process, in-process and finished product requirements, CLEARSIDE BIOMEDICAL specific analytical test methods, and release requirements. See Sections 3.3 and 3.4 of the Supply Agreement for further obligations with respect to changes.

#### **6.3** Deviations

CLEARSIDE BIOMEDICAL must be notified within 2 business days of deviations and /or non-conformances and CLEARSIDE BIOMEDICAL must approve any deviations and/or non-conformance that will affect the process or product quality if Gerresheimer wants to use deviated Product. Such approval shall be in CLEARSIDE BIOMEDICAL's sole discretion. If deviated or non-conforming Product is rejected, returned, or disposed, CLEARSIDE BIOMEDICAL will not be notified; however any delay in delivery of finished Product will be communicated.

#### **6.4** Qualifications and Training

Procedures shall be established by GERRESHEIMER to ensure that all personnel have adequate combination of education, experience and training to perform job functions.

#### **6.5** Identification & Traceability

GERRESHEIMER shall maintain a system to assure the proper acceptance and identification of components, packaging materials, inprocess materials and finished Product throughout manufacturing, packaging and warehousing. Records shall be maintained to allow for the traceability of the specific lots of components and packaging materials used in a particular finished Product lot.

#### 7. REGULATORY

#### **7.1** Manufacture

GERRESHEIMER shall manufacture, package and/or test products in accordance with the obligations of the Supply Agreement and this Agreement, and in accordance with 21 CFR Part 820 and ISO 13485 to meet the defined specifications provided by CLEARSIDE BIOMEDICAL.

#### **7.2** Regulatory Documentation

CLEARSIDE BIOMEDICAL is responsible for defining the regulatory documentation to be maintained at GERRESHEIMER and what will be required to be sent to CLEARSIDE BIOMEDICAL.

### **7.3** Regulatory Filings

CLEARSIDE BIOMEDICAL is responsible for submission, maintenance, approvals and updates/ amendments to regulatory filings for finished Product.

#### 7.4 Label Copy Approval / Label Usage

CLEARSIDE BIOMEDICAL shall have responsibility for Label Copy approval. CLEARSIDE BIOMEDICAL shall provide GERRESHEIMER Purchasing with approved label copy. GERRESHEIMER shall use only labels and labeling in compliance with standards/Specifications provided by CLEARSIDE BIOMEDICAL.

#### **7.5** Audits

(a) CLEARSIDE BIOMEDICAL Audits for assessment of GERRESHEIMER Quality Systems - See Section 21 of the Supply Agreement.

- (b) Regulatory Audits See Section 14 of the Supply Agreement.
- **7.6** Recalls- See Section 16.3 of the Supply Agreement.
- 7.7 Product Complaints See Section 16 of the Supply Agreement.
- **7.8** Medical Device Reporting

CLEARSIDE BIOMEDICAL shall have responsibility for and shall process all Medical Device Reports (MDRs) or Incidents received on the Product in accordance with federal and/ or international regulations. GERRESHEIMER is responsible for notifying CLEARSIDE BIOMEDICAL immediately of any MDRs they may receive directly.

**7.9** Device Listing/Registration

CLEARSIDE BIOMEDICAL shall be responsible for meeting all Device Listing filing requirements related to the product.

#### 8. SUBCONTRACTING

- **8.1** GERRESHEIMER shall not to transfer or give its activity listed within the Quality Agreement, including the Checklist, to a subcontractor without a prior written approval from CLEARSIDE BIOMEDICAL.
- **8.2** If authorised by CLEARSIDE BIOMEDICAL in writing, GERRESHEIMER may only sub-contract activities to sub-contractors approved and regularly evaluated. Requirements described in this Quality Agreement are applicable to GERRESHEIMER authorized subcontractors.

#### 9. DOCUMENTATION CONTROL

- 9.1 GERRESHEIMER must develop, maintain and adhere to all of the Product control documentation including, but not limited to, manufacturing records, packaging instructions, drawings, specifications, and test methods. Any deviations from GERRESHEIMER's pre-established documentation must be pre-approved and agreed to by both Parties in writing, as defined in this Agreement and the Supply Agreement. GERRESHEIMER must ensure that these requirements are governed by the GERRESHEIMER change control policy and are thoroughly understood, prior to production.
- 9.2 GERRESHEIMER shall conform its Product control documentation to be in compliance with the latest 21 CFR Part 820 and ISO 13485 requirements. IF CLEARSIDE BIOMEDICAL has reason to believe GERRESHEIMER's control does not so conform, CLEARSIDE BIOMEDICAL shall direct such concerns in writing to GERRESHEIMER who shall either remedy instances of non-conformance or respond to address such concerns.
- **9.3** Neither GERRESHEIMER nor CLEARSIDE BIOMEDICAL shall make changes to this Quality Agreement without prior notification and approval of the other party. All changes must be in writing and signed by both parties.
- **9.4** As supplied by CLEARSIDE BIOMEDICAL, GERRESHEIMER shall maintain official copies of CLEARSIDE BIOMEDICAL provided documentation as agreed upon herein or in the Supply Agreement.

#### 10. FACILITY / EQUIPMENT CONTROLS

- **10.1** GERRESHEIMER shall have facilities, work flow and material handling such that components, packaging materials and products are protected from damage, contamination, or mix-up during production or storage.
- **10.2** GERRESHEIMER shall maintain all equipment used in the manufacture, packaging, testing, and supply of Products hereunder in good operating condition and shall maintain

the Manufacturing Site and such equipment in accordance with current Quality System Regulations (QSR) (21 CFR Part 820), specifications, and ISO 13485. As deemed appropriate, equipment shall be qualified prior to use by performing Installation Qualification, Operation Qualification and Performance Qualification using protocols in accordance with 21 CFR Part 820 and ISO 13485.

- 10.3 GERRESHEIMER shall have a cleaning / sanitization program to assure that all equipment that has substantial contact with CLEARSIDE BIOMEDICAL's product is controlled for contamination. GERRESHEIMER shall have written procedures in place supporting this program.
- GERRESHEIMER shall assure that any equipment used in connection with the manufacture of other product(s) containing highly potent or hazardous products shall have no contact with the CLEARSIDE BIOMEDICAL Product. GERRESHEIMER shall perform specific validation studies for equipment cleaning processes for products containing highly potent or hazardous components to demonstrate their cleaning effectiveness. However, all non-product contact parts and equipment may be used in common for both the Product and highly potent or hazardous products.
- 10.5 GERRESHEIMER shall maintain an environmental monitoring program for the evaluation of bioburden in areas of possible product exposure as necessary based on the susceptibility of the CLEARSIDE BIOMEDICAL products manufactured unless otherwise justified by historical data and the validated process.
- 10.6 Equipment and instruments used to produce or test the Product or components thereof shall be calibrated, where appropriate, at suitable intervals in accordance with an established written program.

#### 11. PURCHASING CONTROLS

- Approve Components / Packaging Materials & Suppliers pursuant to the Supply Agreement
  GERRESHEIMER is responsible for the qualification of new or alternate components/packaging materials or
  suppliers. GERRESHEIMER shall communicate any proposed change to CLEARSIDE BIOMEDICAL in writing prior to
  implementing the change. CLEARSIDE BIOMEDICAL has the authority to restrict the proposed change. To the extent the new or
  alternate components/packaging materials or suppliers are requested by CLEARSIDE BIOMEDICAL, the cost of such qualifications
- 11.2 Incoming Inspection
  GERRESHEIMER is responsible for the incoming identification, sampling, testing and disposition of components and packaging materials according to written specifications and procedures agreed to by the supplier and CLEARSIDE BIOMEDICAL.

#### 12. MATERIAL CONTROL & SPECIFICATIONS

**12.1** Components / Packaging Materials

shall be the responsibility of CLEARSIDE BIOMEDICAL. .

GERRESHEIMER shall be responsible for using components / primary materials from vendors approved by CLEARSIDE BIOMEDICAL and as stated on the specification sheets for each component.

Prior to use, all components / materials must be found by GERRESHEIMER to be acceptable against reasonable pre-established standards.

Changes to test methods, component/primary material specifications or vendors must be evaluated against pre-established requirements such as regulatory requirements,

compendia, etc. and must be documented with change control history and approvals by CLEARSIDE BIOMEDICAL and GERRESHEIMER

Deviation from existing component/material specifications must be documented and approved by CLEARSIDE BIOMEDICAL and GERRESHEIMER.

All testing and inspection must be documented.

#### 12.2 Storage

All materials (components, packaging materials, product, in-process Product and finished Product) must be stored under conditions appropriate to maintain material integrity.

#### 12.3 Product

It is GERRESHEIMER's responsibility to assure only components meeting the Specifications are used in Product manufacturing.

It is GERRESHEIMER's responsibility to assure that the Product is tested per procedures, specifications and sampling plans approved between CLEARSIDE BIOMEDICAL and GERRESHEIMER..

No changes to CLEARSIDE BIOMEDICAL specific test methods or product specification shall be made without evaluation and CLEARSIDE BIOMEDICAL approval. Changes to process specification outside of the validated process limits will also require CLEARSIDE BIOMEDICAL evaluation and approval.

Except as noted otherwise, GERRESHEIMER must notify CLEARSIDE BIOMEDICAL immediately or as soon as identifiable, the occurrence of a confirmed out-of-specification or questionable result, product failure or major testing deviation for products outside of the control from GERRESHEIMER.

Final release of Product is the responsibility of CLEARSIDE BIOMEDICAL.. GERRESHEIMER will forward a Certificate of Conformance and to CLEARSIDE BIOMEDICAL prior to CLEARSIDE BIOMEDICAL's release of each shipment.

#### 12.4 Labels / Labeling

CLEARSIDE BIOMEDICAL is responsible for the issuance of label copy control documents of all printed packaging components. CLEARSIDE BIOMEDICAL is responsible for providing the approved master label documents to GERRESHEIMER Purchasing.

GERRESHEIMER shall be responsible for the inspection of all receipts of printed copy against a master label through GERRESHEIMER's normal receiving and inspection procedures.

GERRESHEIMER shall be responsible for print verification of all first receipts of new versions of printed copy.

All labels/labeling material shall be stored in a limited access area, controlled, and reconciled as required by QSRs.

GERRESHEIMER shall be responsible for segregating and quarantining any obsolete printed components. Disposition of excess or obsolete material shall be performed with the approval of CLEARSIDE BIOMEDICAL unless otherwise agreed upon.

#### 13. PRODUCTION CONTROLS

13.1 It is the responsibility of GERRESHEIMER to adopt the necessary techniques and/or controls during all phases of manufacturing / packaging to control the quality of the Product. GERRESHEIMER shall maintain records of test performance sufficient to meet regulatory requirements.

- 13.2 As defined by the validated process, the Product will be evaluated throughout production to ensure Specifications are met.
- 13.3 GERRESHEIMER will reconcile all Product components and all finished Product labels in accordance with its standard operating procedures.
- 13.4 All Defective Product must be quarantined and the deviation investigated appropriately per GERRESHEIMER standard procedures.

#### 14. QUALITY CONTROL

#### **14.1** Sampling Plans

GERRESHEIMER shall use established and agreed upon sampling plans. CLEARSIDE BIOMEDICAL shall provide assistance when requested by GERRESHEIMER for classifying defects.

#### **14.2** Verification of Quality

The finished Product must meet final product Specifications.

#### **14.3** Records and Reports

The following are the minimal records that should be maintained for the Product:

- Component receiving and test records
- Manufacturing Records
- Packaging Records
- Quality Control Records (e.g., In-process checks, line clearance, etc.)
- Label Reconciliation Records
- Non-Conformance / Deviation Reports
- Batch Release
- Certificate of Compliance
- Certificate of Analysis

#### 15. VALIDATION

GERRESHEIMER is responsible for validation of appropriate equipment used and activities performed, unless otherwise agreed pursuant to the Supply Agreement or protocol. This includes but is not limited to installation, operation and performance qualification of equipment for manufacturing, packaging and testing the product, unless otherwise agreed upon. Additionally, computer systems, purified water systems and HVAC systems shall be adequately qualified/validated. Cleaning/sanitizing procedures shall be validated to prevent Product contamination. Analytical and microbiological methods shall be appropriately validated to test the quality, safety, efficacy and purity of components and Product. Manufacturing and packaging processes will be appropriately validated.

#### 16. TECHNOLOGY CHANGES

GERRESHEIMER is responsible for notifying CLEARSIDE BIOMEDICAL on any technology changes that impact the Product, manufacturing and packaging process. Notification shall be done prior to change implementation. Reasonable exceptions to prior notification will be allowed to support immediate on-going production.

## 17. RECORDS

All records must be retained by GERRESHEIMER for the later of five (5) years or the retention period prescribed by 21 CFR Part 820 and ISO 13485. If CLEARSIDE BIOMEDICAL desires that any records be retained for a longer period, then it shall either take possession of the records from GERRESHEIMER, or request from GERRESHEIMER a proposal for extended retention.

GERRESHEMER is responsible for maintaining a disaster contingency plan to ensure that record requirements can be met.

## 18. LIFE CYCLE and TERMINATION

This Quality Agreement shall be reviewed annually by both parties. This annual review does not preclude changes or amendments in the interim as needed.

This Quality Agreement will survive the Supply Agreement and extend the term of the Quality Agreement through the usable life of the product and/or until all regulatory obligations of the Contract Facility have been met.

CONFIDENTIAL TREATMENT HAS BEEN REQUESTED FOR PORTIONS OF THIS EXHIBIT. THE COPY FILED HEREWITH OMITS THE INFORMATION SUBJECT TO A CONFIDENTIALITY REQUEST. OMISSIONS ARE DESIGNATED [\*\*\*]. A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

Page 7 of 10

Sup	plier	Agreemen	11

## **Quality Agreement Checklist<sub>1</sub>**

	Requirements		Responsibility
		GERRE\$HEIMER	Responsibility CLEAR\$IDE BIOMEDICAL
		<u> </u>	
[***]		[***]	[***]
		<u> </u>	
		<u> </u>	
		-	
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Requirements	Respons	ibility
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Supplier Agreemen
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Requirements		Responsibility	
	Requirements	Requirements Respons	

1In the event of conflict between the foregoing checklist and the terms of this Agreement and/or the Supply Agreement, the terms of the Supply Agreement shall govern.

The parties hereby agree to the foregoing as of the Effective Date hereof.

gnature:	/s/ Illegible
ite:	April 25, 2018
inted Name:	Illegible
tle:	Illegible
gnature:	/s/ Illegible
ite:	April 25, 2018
inted Name:	Illegible
tle:	Illegible
gnature:	/s/ Daniel H. White
ite:	May 9, 2018
inted Name:	Daniel H. White
tle:	President & Chief Executive Officer - Clearside Biomedical, Inc
gnature:	/s/ Glenn Noronha
ite:	April 12, 2018
inted Name:	Glenn Noronha
tle:	Chief Scientific Officer - Clearside Biomedical, Inc
gnature:	/s/ Keleigh Mahn
ite:	April 11, 2018
inted Name:	Keleigh Mahn
tle:	Sr. Director, Quality - Clearside Biomedical, Inc

<sup>&</sup>lt;sup>2</sup>Responsibilities including consultations and document approvals are delineated within the Global Project RACI Matrix (*responsibility assignment chart: Responsible/ Accountable/ Consulted/ Informed*)

#### Schedule 4

## DOCUMENTATION REGARDING TOOLING AND EQUIPMENT

The following Documentation is necessary to effectively use, maintain, repair and/or modify the Tooling and Equipment pursuant to Clause 13 of this Agreement.

[\*\*\*]

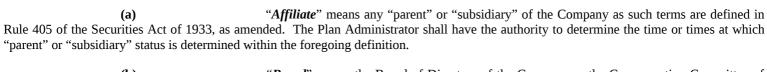
## CLEARSIDE BIOMEDICAL, INC.

## CHANGE IN CONTROL EQUITY ACCELERATION PLAN

#### **Section 1.** Introduction.

The Clearside Biomedical, Inc. Change in Control Equity Acceleration Plan (the "*Plan*") is hereby established effective June 20, 2018 (the "*Effective Date*"). The purpose of the Plan is to provide for equity acceleration for certain eligible employees of Clearside Biomedical, Inc. (the "*Company*") upon certain events in connection with an acquisition of the Company.

For purposes of the Plan, the following terms are defined as follows:



- **(b)** "Board" means the Board of Directors of the Company or the Compensation Committee of the Board of Directors of the Company.
  - (c) "Cause" has the meaning ascribed to such term in the Equity Plan.
- **(d)** "*Change in Control*" has the meaning ascribed to such term in the Equity Plan. Once a Change in Control has occurred, no future events shall constitute a Change in Control for purposes of the Plan.
- **(e)** "*Closing*" means the initial closing of the Change in Control as defined in the definitive agreement executed in connection with the Change in Control. In the case of a series of transactions constituting a Change in Control, "Closing" means the first closing that satisfies the threshold of the definition for a Change in Control.
  - **(f)** "*Code*" means the Internal Revenue Code of 1986, as amended.
- **(g)** "*Company*" means Clearside Biomedical, Inc. or, following a Change in Control, the surviving Entity resulting from such event.
  - **(h)** "*Continuous Service*" has the meaning ascribed to such term in the Equity Plan.
- **(i)** "*Covered Period*" means the period commencing immediately prior to the Closing of a Change in Control and continuing through the date that is twelve (12) months following the Closing of a Change in Control.
- **(j)** "Covered Termination" means an employee's Involuntary Termination that occurs within the Covered Period. For such purposes, if the event giving rise to an employee's right to resign as a result of a Constructive Termination arises within the Covered Period, and the employee's resignation occurs not later than thirty (30) days after the expiration of the Company's thirty-day cure period, such termination shall be a Covered Termination.

agreement that an El		"Employment Agreement" means any individual employment offer letter, contract or e Company or any of its Affiliates.
	(m)	"Entity" means a corporation, partnership, limited liability company or other entity.
ime to time.	(n)	"Equity Plan" means the Company's 2016 Equity Incentive Plan, as it may be amended from
severance benefits to Plan.	(o) an Eligible Employee or an	"Individual Severance Arrangement" means any Employment Agreement providing for by other severance arrangement between the Eligible Employee and the Company other than the
	-	" <i>Involuntary Termination</i> " means the termination of the Eligible Employee's Continuous without Cause and other than as a result of death or disability, which constitutes a "separation tion Section 1.409A-1(h) without regard to any alternative definition thereunder).
following the Closin	<b>(q)</b> g.	"Plan Administrator" means the Board prior to the Closing and the Representative upon and
	(r) pard prior to or in connection osing as provided in Section	<b>"Representative"</b> means one or more members of the Board or other persons or Entities on with a Change in Control that will have authority to administer and interpret the Plan upon a 5(a).
Section 2.	Eligibility For Beni	EFITS.
the Securities Exchar Service with the Co Involuntary Termina	nge Act of 1934, as amende mpany or any of its Affiliate tion immediately prior to the	<b>Eligible Employee</b> . An employee of the Company is eligible to participate in the Plan and h employee is not an executive officer of the Company (as that term is defined in Section 16 of d from time to time and Rule 16a-1 thereunder); and (ii) such employee remains in Continuous es through immediately prior to the Closing of the Change in Control (or such employee has an e Closing of the Change in Control). The determination of whether an employee is an Eligible tor, in its sole discretion, and such determination shall be binding and conclusive on all persons.
Arrangement.	(b)	No Change. This Plan does not supersede the terms of any Individual Severance
Section 3.	Amount Of Benefit.	
Eligible Employee as	(a) s follows:	Accelerated Vesting of Stock Awards. Benefits under the Plan shall be provided to an
	B) any time-based reacquisi	To the extent not previously vested: (A) the vesting and exercisability of nase the Company's common stock that are held by the Eligible Employee on such date shall be tion or repurchase rights held by the Company in respect of common stock issued pursuant to
		2

**(k)** "*Eligible Employee*" means an active employee of the Company who meets all the requirements to be eligible to receive Plan benefits as set forth in Section 2.

to the Eligible Employee by the Company shall lapse in full, and (C) the vesting of any other time-based stock awards granted to the Eligible Employee by the Company, and any issuance of shares triggered by the time-based vesting of such stock awards, shall be accelerated in full, in each case effective as of (x) if such options or stock awards are not assumed or substantially equivalent awards are not substituted by the acquiring or succeeding corporation in the Change in Control, immediately prior to the Closing of a Change in Control and (y) if such options or stock awards are assumed or substantially equivalent awards are substituted by the acquiring or succeeding corporation in the Change in Control, immediately upon the Eligible Employee's Covered Termination. In addition, with respect to any performance based vesting award held by the Eligible Employee that has vesting levels depending upon the level of performance, upon such events vesting acceleration shall occur with respect to the number of shares subject to the award as if the applicable performance criteria had been attained at a 100% level.

In order to give effect to the intent of the foregoing provision, notwithstanding anything to the contrary set forth in the Eligible Employee's stock award agreements or the stock incentive or equity incentive plan or arrangement under which such stock award was granted that provides that any then unvested portion of the award will immediately expire upon the Eligible Employee's termination of service, no unvested portion of the Eligible Employee's stock award shall generally terminate any earlier than the effective date of the acceleration of vesting set forth in Section 3(a)(1); provided, however that after giving effect to the vesting acceleration provisions set forth above, the Eligible Employee's stock awards shall remain subject to earlier termination in connection with a Change in Control or a Corporate Transaction (as each term is defined in the Equity Plan) in which the Eligible Employee's stock award is not assumed, substituted or continued by the acquiring or surviving entity.

**(b) Additional Benefits.** Notwithstanding the foregoing, the Company may, in its sole discretion, provide benefits to employees who are not Eligible Employees ("*Non-Eligible Employees*") chosen by the Plan Administrator, in its sole discretion, and the provision of any such benefits to a Non-Eligible Employee shall in no way obligate the Company to provide such benefits to any other Non-Eligible Employee, even if similarly situated. If benefits under the Plan are provided to a Non-Eligible Employee, references in the Plan to "Eligible Employee" (and similar references) shall be deemed to refer to such Non-Eligible Employee.

**(c) Parachute Payments.** The following provisions shall not supersede any provisions to the contrary provided under any Individual Severance Arrangement, if applicable:

Any provision of the Plan to the contrary notwithstanding, if any payment or benefit an Eligible Employee would receive from the Company pursuant to the Plan or otherwise ("Payment") would (i) constitute a "parachute payment" within the meaning of Section 280G of the Code, and (ii) but for this sentence, be subject to the excise tax imposed by Section 4999 of the Code (the "Excise Tax"), then such Payment will be equal to the Reduced Amount (defined below). The "Reduced Amount" shall be either (x) the largest portion of the Payment that would result in no portion of the Payment being subject to the Excise Tax or (y) the largest portion, up to and including the total, of the Payment, whichever amount, after taking into account all applicable federal, state and local employment taxes, income taxes, and the Excise Tax (all computed at the highest applicable marginal rate), results in the Eligible Employee's receipt, on an after-tax basis, of the greater economic benefit notwithstanding that all or some portion of the Payment may be subject to the Excise Tax. If a reduction in payments or benefits constituting "parachute payments" is necessary so that the Payment equals the Reduced Amount, reduction shall occur in the manner that results in the greatest economic benefit for the Eligible Employee. If more than one method of reduction will result in the same economic benefit, the items so reduced will be reduced pro rata.

(2) In the event it is subsequently determined by the Internal Revenue Service that some portion of the Reduced Amount as determined pursuant to clause (x) in the preceding paragraph

is subject to the Excise Tax, the Eligible Employee agrees to promptly return to the Company a sufficient amount of the Payment so that no portion of the Reduced Amount is subject to the Excise Tax. For the avoidance of doubt, if the Reduced Amount is determined pursuant to clause (y) in the preceding paragraph, the Eligible Employee will have no obligation to return any portion of the Payment pursuant to the preceding sentence.

Unless the Eligible Employee and the Company agree on an alternative accounting firm, the accounting firm engaged by the Company for general tax compliance purposes as of the day prior to the effective date of the Change in Control shall perform the foregoing calculations. If the accounting firm so engaged by the Company is serving as accountant or auditor for the individual, entity or group effecting the Change in Control, the Company shall appoint a nationally recognized accounting firm to make the determinations required hereunder. The Company shall bear all expenses with respect to the determinations by such accounting firm required to be made hereunder.

#### Section 4. Transfer and Assignment.

The rights and obligations of an Eligible Employee under this Plan may not be transferred or assigned without the prior written consent of the Company. The Plan shall be binding upon any entity or person who is a successor by merger, acquisition, consolidation or otherwise to the business formerly carried on by the Company without regard to whether or not such entity or person actively assumes the obligations hereunder and without regard to whether or not a Change in Control occurs

#### Section 5. RIGHT TO INTERPRET AND ADMINISTER PLAN; AMENDMENT AND TERMINATION.

shall be the Plan Administrator and shall have the exclusive discretion and authority to establish rules, forms, and procedures for the administration of the Plan and to construe and interpret the Plan and to decide any and all questions of fact, interpretation, definition, computation or administration arising in connection with the operation of the Plan, including, but not limited to, the eligibility to participate in the Plan and amount of benefits paid under the Plan. The rules, interpretations, computations and other actions of the Board shall be binding and conclusive on all persons. Upon and after the Closing, the Plan will be interpreted and administered in good faith by the Representative who shall be the Plan Administrator during such period. All actions taken by the Representative in interpreting the terms of the Plan and administering the Plan upon and after the Closing will be final and binding on all Eligible Employees. Any references in this Plan to the "Board" or "Plan Administrator" with respect to periods following the Closing of a Change in Control shall mean the Representative.

**(b) Amendment and Termination.** The Plan Administrator reserves the right to amend or terminate the Plan or the benefits provided hereunder at any time in its discretion. In addition, the Plan will automatically terminate following the satisfaction of all the Company's obligations under the Plan.

#### Section 6. No Implied Employment Contract.

The Plan shall not be deemed (i) to give any employee or other person any right to be retained in the employ of the Company or (ii) to interfere with the right of the Company to discharge any employee or other person at any time, with or without cause, which right is hereby reserved.

## Section 7. Legal Construction.

This Plan is intended to be governed by and shall be construed in accordance with the laws of the State of Delaware.

# 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 June 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: August 8, 2018

/s/ Daniel H. White

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

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

#### I, Charles A. Deignan, certify that:

- 1. I have reviewed this Quarterly Report on Form 10-Q for the period ended June 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: August 8, 2018

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

## **CERTIFICATIONS OF** PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL OFFICER PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), 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:

- The Company's Quarterly Report on Form 10-Q for the period ended June 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
- The information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the 2. Company.

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

/s/ Daniel H. White /s/ Charles A. Deignan Daniel H. White Charles A. Deignan President and Chief Executive Officer Chief Financial Officer (principal executive 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.