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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-Q

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

For the quarterly period ended June 30, 2018

OR

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

For the transition period from _____ to _____

Commission file number: 001-37500

Chiasma, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**76-0722250**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

460 Totten Pond Road, Suite 530
Waltham, Massachusetts 02451
(Address of principal executive office) (Zip Code)

Registrant's telephone number, including area code:
(617) 928-5300

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

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

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

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒ (Do not check if a smaller reporting company)	Smaller reporting company	☐
		Emerging growth company	☒

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

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

As of August 6, 2018, there were 24,386,383 shares of the registrant's Common Stock, $0.01 par value per share, outstanding.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements. These statements include all matters that are not related to present facts or current conditions or that are not historical facts, including statements regarding our strategy, future operations, future financial position, future revenue, projected costs, prospects, plans, objectives of management and expected market growth. The words "anticipate," "believe," "could," "continue," "should," "predict," "estimate," "expect," "intend," "may," "plan," "potentially," "will," "would," or the negative of these terms or other similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements include, but are not limited to, statements about:

- the U.S. regulatory review process of our New Drug Application, or NDA, for octreotide capsules in acromegaly, and our efforts to conduct and complete a Phase 3 clinical trial of octreotide capsules in adult acromegaly patients per our agreement with the FDA under a Special Protocol Assessment, or SPA, to potentially enable us to resubmit our NDA to the U.S. Food and Drug Administration, or the FDA, in order to secure regulatory approval of octreotide capsules in acromegaly;
- our ability to preserve patients, sites and other resources necessary to enable us to simultaneously conduct two Phase 3 clinical trials in adult patients with acromegaly and to produce data packages from each trial that could be suitable for submission in both the United States and the European Union;
- any regulatory approvals that may be issued or denied by the FDA, the European Medicines Agency, or EMA, or other regulatory agencies for octreotide capsules in acromegaly or other indications;
- the therapeutic benefits, effectiveness and safety of octreotide capsules;
- our estimates of the size and characteristics of the markets that may be addressed by octreotide capsules;
- the commercial success and market acceptance of octreotide capsules or any future product candidates that are approved for marketing in the United States or other countries;
- our ability to generate future revenue;
- the number, designs, results and timing of our clinical trials of octreotide capsules and the timing of the commencement and availability of data from these trials;
- our ability to randomize at least 80 patients who are responders to octreotide capsules from the 135 adult acromegaly patients enrolled in the run-in phase of our MPOWERED clinical trial;
- the safety and efficacy of therapeutics marketed by our competitors that are targeted to indications which octreotide capsules have been developed to treat;
- our ability to leverage our Transient Permeability Enhancer, or TPE, platform to develop and commercialize novel oral product candidates incorporating peptides that are currently only available in injectable or other non-absorbable forms;
- the possibility that competing products or technologies may make octreotide capsules, other product candidates we may develop and commercialize or our TPE technology obsolete;
- our ability to manufacture sufficient amounts of octreotide capsules for clinical trials and commercialization activities;
- our ability to secure collaborators to license, manufacture, market and sell octreotide capsules or any products for which we receive regulatory approval in the future;
- our ability to protect our intellectual property and operate our business without infringing upon the intellectual property rights of others;
- our product development and operational plans generally; and
- our estimates and expectations regarding our capital requirements, cash and expense levels and liquidity sources.

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our financial

condition, results of operations, business strategy and financial needs. These forward-looking statements are subject to a number of risks, uncertainties and assumptions described in the section titled "Risk Factors" and elsewhere in this Quarterly Report on Form 10-Q and our prior filings with the SEC. Moreover, we operate in a very competitive and rapidly changing environment. New risk factors emerge from time to time, and it is not possible for our management to predict all risk factors nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in, or implied by, any forward-looking statements. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

Unless the context requires otherwise, references in this Quarterly Report on Form 10-Q to "we," "us", "our" and "Chiasma" refer to Chiasma, Inc. and our subsidiaries. We own various U.S. federal trademark registrations and applications, and unregistered trademarks and service marks, including "Chiasma," "TPE", "MYCAPSSA" and our corporate logo. Other trademarks or service marks that may appear in this Quarterly Report on Form 10-Q are the property of their respective holders. For convenience, we do not use the ® and ™ symbols in each instance in which one of our trademarks appears throughout this Quarterly Report on Form 10-Q, but this should not be construed as any indication that we will not assert, to the fullest extent under applicable law, our rights thereto. We do not intend to use or display other companies' trademarks and trade names to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

Chiasma, Inc.

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PART I — FINANCIAL INFORMATION

Item 1. Financial Statements

Chiasma, Inc.
Condensed Consolidated Balance Sheets

	June 30, 2018 (Unaudited)	December 31, 2017
	(in thousands except share data)	
Assets		
Current assets		
Cash and cash equivalents	$ 13,844	$ 14,603
Marketable securities	40,781	52,336
Prepaid expenses and other current assets	1,175	1,768
Total current assets	55,800	68,707
Property and equipment, net	153	193
Other assets	982	983
Total assets	$ 56,935	$ 69,883
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 2,529	$ 1,017
Accrued expenses	5,648	4,033
Other current liabilities	—	1,695
Total current liabilities	8,177	6,745
Long-term liabilities	558	664
Total liabilities	8,735	7,409
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Common stock, $0.01 par value; authorized 125,000,000 shares at June 30, 2018 and December 31, 2017; issued and outstanding 24,386,383 shares at June 30, 2018 and 24,381,605 shares at December 31, 2017	244	244
Preferred stock, $0.01 par value; authorized 5,000,000 shares; none outstanding	—	—
Additional paid-in capital	269,058	267,642
Accumulated other comprehensive loss	(33)	(59)
Accumulated deficit	(221,069)	(205,353)
Total stockholders' equity	48,200	62,474
Total liabilities and stockholders' equity	$ 56,935	$ 69,883

See accompanying notes to these unaudited condensed consolidated financial statements.

Chiasma, Inc.
Condensed Consolidated Statements of Operations
(Unaudited)

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2018	2017	2018	2017
	(in thousands except share and per share data)			
Operating expenses:				
General and administrative	$ 2,627	$ 2,641	$ 5,061	$ 5,101
Research and development	6,305	4,279	11,168	8,934
Total operating expenses	8,932	6,920	16,229	14,035
Loss from operations	(8,932)	(6,920)	(16,229)	(14,035)
Other income, net	(280)	(204)	(510)	(364)
Loss before income taxes	(8,652)	(6,716)	(15,719)	(13,671)
Provision (benefit) for income taxes	21	138	(3)	203
Net loss	(8,673)	(6,854)	(15,716)	(13,874)
Earnings per share attributable to common stockholders				
Basic	$ (0.36)	$ (0.28)	$ (0.64)	$ (0.57)
Diluted	$ (0.36)	$ (0.28)	$ (0.64)	$ (0.57)
Weighted-average shares outstanding:				
Basic	24,384,283	24,359,584	24,383,123	24,359,584
Diluted	24,384,283	24,359,584	24,383,123	24,359,584

See accompanying notes to these unaudited condensed consolidated financial statements.

Chiasma, Inc.
Condensed Consolidated Statements of Comprehensive Loss
(Unaudited)

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2018	2017	2018	2017
	(in thousands)			
Net loss	$ (8,673)	$ (6,854)	$ (15,716)	$ (13,874)
Other comprehensive income (loss):				
Unrealized gains (losses) on available for sale securities, net	62	7	26	(15)
Total other comprehensive income (loss)	62	7	26	(15)
Comprehensive loss	$ (8,611)	$ (6,847)	$ (15,690)	$ (13,889)

See accompanying notes to these unaudited condensed consolidated financial statements.

Chiasma, Inc.
Condensed Consolidated Statements of Cash Flows
(Unaudited)

	Six Months Ended June 30,	
	2018	2017
	(in thousands)	
Operating Activities:		
Net loss	$ (15,716)	$ (13,874)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation	46	79
Stock-based compensation	1,365	2,215
Amortization of discount on marketable securities, net	(130)	(134)
Provision (benefit) for deferred income taxes	(5)	63
Non-cash interest expense	5	67
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	593	833
Accounts payable and accrued expenses	3,127	(670)
Other assets	6	(10)
Other current and long-term liabilities	(56)	139
Net cash used in operating activities	(10,765)	(11,292)
Investing Activities:		
Purchase of marketable securities	(17,565)	(55,831)
Maturities of marketable securities	29,277	50,182
Purchases of property and equipment	(6)	(3)
Net cash provided by (used in) investing activities	11,706	(5,652)
Financing Activities:		
Payment under license termination agreement	(1,700)	(1,700)
Net cash used in financing activities	(1,700)	(1,700)
Net decrease in cash and cash equivalents	(759)	(18,644)
Cash and cash equivalents, beginning of period	14,603	37,013
Cash and cash equivalents, end of period	$ 13,844	$ 18,369

See accompanying notes to these unaudited condensed consolidated financial statements.

CHIASMA, INC.
Notes to Unaudited Condensed Consolidated Financial Statements
June 30, 2018

1. Description of Business and Summary of Significant Accounting Policies

Chiasma, Inc. is a clinical-stage biopharmaceutical company incorporated in 2001 under the laws of the State of Delaware. Chiasma, Inc. is headquartered in Massachusetts and has two wholly owned subsidiaries; Chiasma (Israel) Ltd., and Chiasma Securities Corp, collectively referred to as "the Company," "we," "us," "our" or "Chiasma". We are a clinical-stage biopharmaceutical company focused on improving the lives of patients who face challenges associated with their existing treatments for rare and serious chronic disease. Employing our proprietary Transient Permeability Enhancer ("TPE") technology platform, we seek to develop oral medications that are currently available only as injections. We are currently developing oral octreotide capsules, conditionally trade-named "MYCAPSSA", our sole TPE platform-based clinical product candidate, in two Phase 3 clinical trials in adult patients for the treatment of acromegaly to potentially support regulatory approval in the United States and European Union. Acromegaly is a rare and debilitating condition that results in the body's production of excess growth hormone. Octreotide is an analog of somatostatin, a natural inhibitor of growth hormone secretion. Octreotide capsules have been granted orphan designation in the United States and the European Union for the treatment of acromegaly. We retain worldwide rights to develop and commercialize octreotide capsules with no royalty obligations to third parties.

In September 2017, we initiated a third Phase 3 clinical trial for oral octreotide capsules for the maintenance therapy of adult patients with acromegaly following our agreement with the United States Food and Drug Administration ("FDA") on the design of the trial, reached through a Special Protocol Assessment in August 2017. The trial, referred to as CHIASMA OPTIMAL, is a randomized, double-blind, placebo-controlled, nine-month trial expected to enroll 50 adult acromegaly patients designed to support regulatory approval of octreotide capsules in the United States. We are also currently conducting an international Phase 3 clinical trial, referred to as MPOWERED, of oral octreotide capsules for the maintenance treatment of adult patients with acromegaly to support regulatory approval in the European Union by the European Medicines Agency ("EMA"). The MPOWERED trial is a global, randomized, open-label and active-controlled 15-month trial which completed enrollment in July 2018 with 135 adult acromegaly patients entered into the run-in phase, of which we expect to randomize at least 80 patients who are responders to octreotide capsules following a six-month run-in to either octreotide capsules or injectable somatostatin receptor ligands (octreotide or lanreotide), and then followed for an additional nine months.

Liquidity

We have incurred significant losses from operations since our inception and expect losses to continue for at least the next several years. We are heavily dependent on the regulatory approval and subsequent commercial success of our product candidate, octreotide capsules for the treatment of acromegaly in the United States and European Union, both of which may never occur.

We expect to continue with our ongoing international Phase 3 CHIASMA OPTIMAL clinical trial of octreotide capsules in acromegaly to support potential regulatory approval in the United States and ongoing international Phase 3 MPOWERED clinical trial of octreotide capsules in acromegaly to support potential regulatory approval in the European Union. In June and August 2016, we announced two separate corporate restructuring plans, which were completed in 2017, intended to focus our resources on the continued development of octreotide capsules for the maintenance treatment of adult acromegaly patients. We currently expect our existing cash, cash equivalents and marketable securities to fund our operations for at least one year after the date these condensed consolidated financial statements are issued. We expect to continue to incur significant operating losses for the foreseeable future.

Successful transition to attaining profitable operations is dependent upon achieving a level of revenues adequate to support our cost structure. We plan to continue to fund our losses from operations and capital funding needs from existing balances of cash, cash equivalents and marketable securities and potentially through the issuance of debt and/or equity or through collaborations or license agreements with other companies. Debt or equity financing may not be available on a timely basis on terms acceptable to us, or at all. If we are not able to secure adequate additional funding, we may be forced to make further reductions in spending, extend payment terms with suppliers, liquidate assets where possible, suspend or curtail our planned development of octreotide capsules, or delay our commercial preparations or launch readiness even if the CHIASMA OPTIMAL trial achieves its primary endpoint or if octreotide capsules are approved by the FDA or EMA. Any of

these actions could materially harm our business, results of operations and future prospects. Failure to obtain regulatory approval of octreotide capsules in acromegaly will prevent us from commercializing the product candidate, which could raise significant concerns about our continued viability as a business.

Basis of Presentation

We have prepared the accompanying unaudited condensed consolidated financial statements pursuant to the rules and regulations of the U.S. Securities and Exchange Commission ("SEC") regarding interim financial reporting. Accordingly, certain information and footnote disclosures required by accounting principles generally accepted in the United States ("U.S. GAAP") for annual financial statements have been condensed or omitted. The information included in this quarterly report on Form 10-Q should be read in conjunction with our Annual Report on Form 10-K for the year ended December 31, 2017. The year-end condensed consolidated balance sheet data presented for comparative purposes was derived from our audited financial statements, but does not include all disclosures required by U.S. GAAP. In the opinion of management, we have prepared the accompanying unaudited condensed consolidated financial statements on the same basis as our audited financial statements, and these financial statements include all adjustments, consisting only of normal recurring adjustments, necessary for a fair presentation of the results of the interim periods presented. Interim results are not necessarily indicative of results for a full year or for any other subsequent interim period.

Cash Equivalents

Cash equivalents consist of highly liquid instruments purchased with an original maturity of three months or less at the date of purchase.

Marketable Securities

Our investments primarily consist of commercial paper and corporate and government debt securities. These marketable securities are classified as available-for-sale, and as such, are reported at fair value on our condensed consolidated balance sheets. Unrealized holding gains and losses are reported within accumulated other comprehensive income as a separate component of stockholders' equity. The amortized cost of debt securities is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization, together with interest on securities, are included in other income, net, on our condensed consolidated statements of operations.

If a decline in the fair value of a marketable security below our cost basis is determined to be other than temporary, such marketable security is written down to its estimated fair value as a new cost basis and the amount of the write-down is included in earnings as an impairment charge. The cost of securities sold is based on the specific identification method.

Concentrations of credit risk

Financial instruments that potentially subject us to significant concentration of credit risk consist primarily of cash, cash equivalents and marketable securities. We routinely maintain deposits in financial institutions in excess of government insured limits. Management believes that we are not exposed to significant credit risk as our deposits are held at financial institutions that management believes to be of high credit quality and we have not experienced any significant losses in these deposits. We regularly invest excess operating cash in deposits with major financial institutions and money market funds and in notes issued by the U.S. government, as well as in fixed income investments and U.S. bond funds, both of which can be readily purchased and sold using established markets. We believe that the market risk arising from our holdings of these financial instruments is mitigated based on the fact that many of these securities are either government backed or of high credit rating.

Use of Estimates

The preparation of condensed consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenue, and expenses, and the disclosure of contingent assets and liabilities as of and during the reporting period. We base these estimates and assumptions on historical experience when available, and on various factors that we believe to be reasonable under the specific circumstances. Significant estimates relied upon in preparing the accompanying condensed consolidated financial statements include, but are not limited to, accounting for stock-based compensation, present value of long-term purchase obligation, income taxes, and accounting for certain accruals. We assess the above estimates on an ongoing basis; however, actual results could materially differ from those estimates.

Recently Issued Accounting Pronouncements

In February 2016, the Financial Accounting Standards Board ("FASB") issued new guidance which establishes a right-of-use model that requires a lessee to record an asset and a lease liability on the balance sheet for all leases with terms longer than 12 months. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement. The new standard is effective for annual periods beginning after December 15, 2018, including interim periods within those annual reporting periods. A modified retrospective transition approach, which includes a number of optional practical expedients that we may elect to apply, is required for lessees for capital and operating leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements. We are currently evaluating the impact the standard may have on our condensed consolidated financial statements and we currently expect that most of our operating lease commitments will be subject to the new standard and recognized as operating lease liabilities and right-of-use assets upon adoption.

In June 2018, the FASB issued new guidance which changes certain aspects of the accounting for share-based payments granted to nonemployees. Under this guidance, most of the treatment for share-based payments granted to nonemployees would be aligned with the requirements for share-based payments granted to employees. The new standard is effective beginning January 1, 2019. Early adoption of this standard is permitted. We are currently evaluating the impact the standard may have on our condensed consolidated financial statements.

2. Investments

Our investments consisted of the following as of June 30, 2018 and December 31, 2017:

	As of June 30, 2018			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
	($ in thousands)			
Money market funds	$ 13,210	$ —	$ —	$ 13,210
Corporate notes	19,453	—	(23)	19,430
Commercial paper	21,361	1	(11)	21,351
Total	$ 54,024	$ 1	$ (34)	$ 53,991

	As of December 31, 2017			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
	($ in thousands)			
Money market funds	$ 12,399	$ —	$ —	$ 12,399
Corporate notes	29,788	—	(35)	29,753
Commercial paper	22,607	1	(25)	22,583
Total	$ 64,794	$ 1	$ (60)	$ 64,735

As of June 30, 2018, we do not consider those securities that are in an unrealized loss position to be other-than-temporarily impaired, as we have the ability to hold such investments until recovery of the fair value. We utilize the specific identification method in computing realized gains and losses. We had no realized gains and losses on our available-for-sale securities for the three and six months ended June 30, 2018 or 2017.

The fair values of our investments by classification in our condensed consolidated balance sheets as of June 30, 2018 and December 31, 2017 were as follows:

	June 30, 2018	December 31, 2017
	($ in thousands)	
Cash and cash equivalents	$ 13,210	$ 12,399
Marketable securities	40,781	52,336
Total	$ 53,991	$ 64,735

Cash and cash equivalents in the table above exclude cash of $0.6 million and $2.2 million as of June 30, 2018 and December 31, 2017, respectively. The contractual maturity dates of all of our investments are less than one year.

3. Fair Value Measurements of Financial Instruments

Certain assets and liabilities are reported at fair value on a recurring basis. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants at the measurement date. The fair value accounting guidance requires that assets and liabilities carried at fair value be classified and disclosed in one of the following three categories:

- *Level 1* — Quoted prices in active markets for identical assets or liabilities that we have the ability to access at the measurement date.
- *Level 2* — Inputs other than quoted prices in active markets that are observable for the asset or liability, either directly or indirectly.
- *Level 3* — Inputs that are unobservable for the asset or liability.

To the extent that valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by us in determining fair value is greatest for instruments categorized in Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

The fair value measurements of our financial instruments are summarized in the table below:

	Fair Value Measurements at June 30, 2018			
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
		($ in thousands)		
Cash equivalents:				
Money market funds	$ 13,210	$ —	$ —	$13,210
Total cash equivalents	$ 13,210	$ —	$ —	$13,210
Marketable securities:				
Corporate notes	$ —	$ 19,430	$ —	$19,430
Commercial paper	—	21,351	—	21,351
Total marketable securities	—	40,781	—	40,781
Total	$ 13,210	$ 40,781	$ —	$53,991

	Fair Value Measurements at December 31, 2017			
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
		($ in thousands)		
Cash equivalents:				
Money market funds	$ 12,399	$ —	$ —	$12,399
Total cash equivalents	$ 12,399	$ —	$ —	$12,399
Marketable securities:				
Corporate notes	$ —	$ 29,753	$ —	$29,753
Commercial paper	—	22,583	—	22,583
Total marketable securities	—	52,336	—	52,336
Total	$ 12,399	$ 52,336	$ —	$64,735

Our cash equivalents are classified as Level 1 assets under the fair value hierarchy as these assets have been valued using quoted market prices in active markets and do not have any restrictions on redemption. Our marketable securities are classified as Level 2 assets under the fair value hierarchy as these assets were primarily determined from independent pricing services, which normally derive security prices from recently reported trades for identical or similar securities, making adjustments based upon other significant observable market transactions. At the end of each reporting period, we perform quantitative and qualitative analysis of prices received from third parties to determine whether prices are reasonable estimates of fair value. After completing our analysis, we did not adjust or override any fair value measurements provided by our pricing services as of June 30, 2018 or December 31, 2017. We did not have any Level 3 assets being measured at fair value on a recurring basis as of June 30, 2018 and December 31, 2017.

4. Earnings per Share of Common Stock

All common stock warrants and stock options have been excluded from the computation of diluted weighted-average shares outstanding because such securities would have an anti-dilutive impact due to net losses reported during the three and six months ended June 30, 2018 and 2017.

5. Accrued Expenses

As of June 30, 2018 and December 31, 2017, accrued expenses consisted of the following:

	June 30, 2018	December 31, 2017
	($ in thousands)	
Accrued general and administrative expenses	$ 1,390	$ 752
Accrued research and development expenses	3,537	2,501
Accrued payroll and employee benefits	721	780
Total accrued expenses	$ 5,648	$ 4,033

6. License Agreement

In December 2012, we signed a license agreement with F. Hoffmann-La Roche Ltd. and Hoffmann-La Roche Inc. (collectively “Roche”), which was effective in January 2013, and granted Roche an exclusive, non-transferable license to our intellectual property related to octreotide capsules.

In July 2014, Roche terminated the license agreement. Upon termination, Roche returned all rights and documentation granted under the agreement to us. Following the termination of the license agreement, we are not entitled to further payments from Roche, Roche has no remaining rights to octreotide capsules and we retain all rights to octreotide capsules and all related intellectual property. Subsequent to the termination, we purchased from Roche active pharmaceutical ingredient (“API”) supplies to continue the development and manufacturing of octreotide capsules as well as Roche’s

proposed trade name for octreotide capsules for an aggregate amount of $5.1 million payable in three equal annual installments of $1.7 million beginning in 2016. We made the $1.7 million annual payments in each of March 2018, 2017, and 2016. The difference between the aggregate purchase price and the present value of the installment payments represented the interest component of the financing arrangement and was recorded as interest expense over the payment term. We have no further financial or operational obligations to Roche.

7. Warrants

As of December 31, 2017, there were 3,567,015 common stock warrants outstanding with exercise prices ranging from $0.09 per share to $9.13 per share. The warrants were issued at various points between October 2012 and February 2015 with expiration dates ranging from October 2022 through February 2025. There were no warrants exercised during the six months ended June 30, 2018. There were 3,567,015 outstanding warrants as of June 30, 2018.

8. Stock Incentive Plans

In 2008, our board of directors adopted the 2008 Stock Incentive Plan (the "2008 Plan"), which provided for the grant of incentive stock options, nonqualified stock options, and restricted stock to employees, directors, and nonemployees of the Company up to 3,547,741 shares of common stock. Option awards expire 10 years from the grant date and generally vest over four years, but vesting conditions can vary at the discretion of our board of directors.

In July 2015, the Company approved the 2015 Stock Option and Incentive Plan (the "2015 Plan"), which became effective upon our initial public offering ("IPO"). The 2015 Plan allows the grant of incentive stock options, nonqualified stock options, and restricted stock to employees, directors, and nonemployees of the Company up to 3,566,296 shares of common stock. In connection with the adoption of the 2015 Plan, no further option grants are permitted under the 2008 Plan and any expirations, cancellations, or terminations under the 2008 Plan are available for issuance under the 2015 Plan. On January 1, 2016, the number of shares reserved and available for issuance under the 2015 Stock Plan increased by 960,504 shares of common stock pursuant to a provision in the 2015 Stock Plan that provides that the number of shares reserved and available for issuance will automatically increase each January 1, beginning on January 1, 2016, by 4% of the number of shares of common stock issued and outstanding on the immediately preceding December 31 or such lesser number as determined by the compensation committee of the board of directors. The compensation committee of the board of directors determined there would be no increase to the shares reserved and available under the 2015 Stock Plan on January 1, 2018 and 2017. As of June 30, 2018, the total number of shares authorized for stock award plans is 7,114,037 of which 2,357,616 remain available for grant. There are 4,437,387 stock options outstanding as of June 30, 2018.

Stock-based compensation for the three and six months ended June 30, 2018 and 2017 consisted of the following:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
	($ in thousands)			
General and administrative	$ 378	$ 510	$ 701	$ 865
Research and development	350	986	664	1,350
Total	$ 728	$ 1,496	$ 1,365	$ 2,215

We issued approximately 5,000 shares of common stock following the exercise of stock options in the three and six months ended June 30, 2018. There were no exercises of stock options in the six months ended June 30, 2017.

The fair value of each stock option issued was estimated at the date of grant using the Black-Scholes option model with the following weighted-average assumptions:

	Six Months Ended June 30,	
	2018	2017
Expected volatility	76.6%	74.0%
Expected term (years)	6.19	5.63
Risk-free interest rate	2.72%	1.79%
Expected dividend yield	0%	0%

We issued approximately 840,000 stock option grants in the six months ended June 30, 2018. The weighted-average grant date fair value per share of stock options granted during the six months ended June 30, 2018 was $1.04. We issued approximately 104,000 option grants in the six months ended June 30, 2017. The weighted-average grant date fair value per share of options granted during the six months ended June 30, 2017 was $0.86.

9. Commitments and Contingencies

We conduct certain of our operations in leased facilities, which are accounted for as operating leases. Certain leases include renewal options. In addition, we lease automobiles and equipment under operating leases. There were no assets held under capital leases at June 30, 2018 and December 31, 2017. At June 30, 2018, the minimum rental commitments under all non-cancelable operating leases with initial or remaining terms of more than one year was approximately $0.3 million through 2020.

Legal Proceedings

On June 9, 2016, Chiasma, Inc. and certain of our current and former officers were named as defendants in a federal securities class action lawsuit filed in the United States District Court for the District of Massachusetts, styled *Gerneth v. Chiasma, Inc., et al*. This lawsuit challenges our public statements regarding our Phase 3 clinical trial methodology for octreotide capsules and our ability to obtain FDA approval for the marketing and sale of octreotide capsules. In December 2016, a lead plaintiff was appointed in the case. An amended complaint was filed by the lead plaintiff on February 10, 2017 similarly challenging our statements regarding the Phase 3 clinical trial methodology and results, and our ability to obtain FDA approval for octreotide capsules, purportedly in violation of Sections 11 and 15 of the Securities Act of 1933. The amended complaint adds as defendants current and former members of our board of directors, as well as the investment banks that underwrote our initial public offering ("IPO") on July 15, 2015. The lead plaintiff seeks to represent a class of all purchasers of our stock in our IPO. The plaintiff is seeking an unspecified amount of compensatory damages on behalf of himself and members of a putative shareholder class, including interest and reasonable costs and expenses incurred in litigating the action, and any other relief the court determines is appropriate. The defendants filed a motion to dismiss the amended complaint on March 27, 2017 and on February 15, 2018, the court denied defendants' motion to dismiss. The defendants filed an answer to the amended complaint on March 30, 2018. We believe this lawsuit is meritless and intend to vigorously defend against it. At this time, no assessment can be made as to the likely outcome of this lawsuit or whether the outcome will be material to us.

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited condensed consolidated financial statements and the accompanying notes thereto included elsewhere in this Quarterly Report on Form 10-Q and the audited financial information and the notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2017. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report on Form 10-Q, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of this Quarterly Report on Form 10-Q and our prior filings with the SEC, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a clinical-stage biopharmaceutical company focused on improving the lives of patients who face challenges associated with their existing treatments for rare and serious chronic disease. Employing our proprietary Transient Permeability Enhancer, or TPE, technology platform, we seek to develop oral medications that are currently available only as injections. We are currently developing oral octreotide capsules, conditionally trade-named "MYCAPSSA", our sole TPE platform-based clinical product candidate, in two Phase 3 clinical trials in adult patients for the treatment of acromegaly to potentially support regulatory approval in the United States and European Union. Acromegaly is a rare and debilitating condition that results in the body's production of excess growth hormone. Octreotide is an analog of somatostatin, a natural inhibitor of growth hormone secretion. We believe that octreotide capsules, if approved by regulatory authorities, will be the first somatostatin analog available for oral administration. Octreotide capsules have been granted orphan designation in the United States and the European Union for the treatment of acromegaly. The worldwide market for injectable somatostatin analogs is approximately $2.5 billion annually, of which we estimate approximately $775 million represents annual sales for the treatment of acromegaly. We retain worldwide rights to develop and commercialize octreotide capsules with no royalty obligations to third parties.

In September 2017, we initiated a third Phase 3 clinical trial for oral octreotide capsules for the maintenance therapy of adult patients with acromegaly following our agreement with the United States Food and Drug Administration, or the FDA, on the design of the trial, reached through a Special Protocol Assessment, or SPA, in August 2017. The trial, referred to as CHIASMA OPTIMAL, is a randomized, double-blind, placebo-controlled, nine-month trial expected to enroll 50 adult acromegaly patients designed to support regulatory approval of octreotide capsules in the United States. In June 2018, we announced that we had achieved 50% of target patient enrollment in the trial. We expect to complete randomization by the end of 2018 and anticipate the release of top-line data from this trial in the fourth quarter of 2019. In May 2018, we reached further agreement with the FDA under a SPA Agreement Modification letter providing that the hierarchical secondary endpoints that will be considered by the FDA in evaluating the totality of evidence for octreotide capsules treatment effect now are:

- Proportion of patients who maintain GH response at week 36 compared to screening;
- Time to loss of response: IGF-1 > 1.0×ULN;
- Time to loss of response: IGF-1 > 1.3×ULN; and
- Proportion of patients requiring rescue treatment.

We are also currently conducting an international Phase 3 clinical trial, referred to as MPOWERED, of oral octreotide capsules for the maintenance treatment of adult patients with acromegaly to support regulatory approval in the European Union. The MPOWERED trial is a global, randomized, open-label and active-controlled 15-month trial which completed enrollment in July 2018 with 135 adult acromegaly patients entered into the run-in phase, of which we expect to randomize at least 80 patients who are responders to octreotide capsules following a six-month run-in to either octreotide capsules or injectable somatostatin receptor ligands (octreotide or lanreotide), and then followed for an additional nine months. We currently expect to complete the MPOWERED trial in the fourth quarter of 2019 and release top-line data from this trial by early 2020.

We were incorporated in 2001 and commenced active operations in the same year. Our operations to date have been limited to organizing and staffing our company, business planning, raising capital, developing our TPE technology, identifying potential drug candidates, undertaking nonclinical studies and, beginning in 2010, conducting clinical trials, preparing for regulatory submissions and conducting pre-commercial activities. To date, we have financed our operations primarily through private placements, funding received from a licensing agreement, a loan agreement and our initial public offering. We have no products approved for sale and all of our historical revenue has been related to one license agreement, which was terminated in 2014. Since our inception and through June 30, 2018, we have raised an aggregate of $366.2 million to fund our operations, of which $86.3 million was through our license agreement with F. Hoffmann-La Roche Ltd. and Hoffmann-La Roche Inc., collectively Roche, $106.5 million was from issuing shares of common stock in our initial public offering, or IPO, $161.4 million was from the issuance of private securities and $12.0 million was from borrowings under a loan agreement. In 2013, using proceeds from the Roche license agreement, we repaid all outstanding borrowings under our loan agreement and paid an aggregate of $55.0 million in cash as partial consideration for the redemption of certain shares of our redeemable preferred stock. As of June 30, 2018, our consolidated cash, cash equivalents and marketable securities were $54.6 million, of which $0.3 million was held by Chiasma (Israel) Ltd., our wholly owned Israeli subsidiary.

We have incurred significant operating losses since our inception. Our net loss was $15.7 million for the six months ended June 30, 2018 and $26.8 million for the year ended December 31, 2017. As of June 30, 2018, we had an accumulated deficit of $221.1 million. We expect to incur significant operating losses over the next several years. These losses, combined with prior losses, will continue to have an adverse effect on our cash resources, stockholders' equity and working capital. We expect to continue to conduct the international Phase 3 MPOWERED clinical trial of octreotide capsules in acromegaly that we initiated in March 2016 to support potential regulatory approval in the European Union and our Phase 3 CHIASMA OPTIMAL clinical trial of octreotide capsules in acromegaly that we initiated in September 2017 to support potential regulatory approval in the United States. We expect the release of top-line CHIASMA OPTIMAL data in the fourth quarter of 2019 and we expect to complete the MPOWERED trial in the fourth quarter of 2019 and release top-line data from this trial by early 2020. Clinical development timelines, the probability of success and development costs can differ materially from expectations.

In June and August 2016, we announced two separate corporate restructuring plans intended to focus our resources on the continued development of octreotide capsules for the maintenance treatment of adult acromegaly patients. As a result of the August 2016 reduction in workforce, we eliminated our research and discovery functions and are currently not investing in those areas. Because of the numerous risks and uncertainties facing our company and associated with developing and commercializing pharmaceutical products generally, we are unable to predict the extent of any future losses or when we will become profitable, if at all.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings and debt financings, and we may also opportunistically consider license and collaboration agreements with potential partners. We may be unable to raise capital when needed or on attractive terms, or to enter into collaboration agreements, which could force us to delay, limit, reduce or terminate our product development or future commercialization efforts. We will need to generate significant revenues to achieve profitability, which we may not be able to achieve.

Roche License Agreement

In December 2012, we executed a license agreement with Roche, which went into effect on January 2013. Pursuant to the license agreement, we granted Roche an exclusive, non-transferable license to all intellectual property related to octreotide capsules. Under the terms of the license, Roche obtained worldwide rights to research, develop, make, import, export, sell, market or distribute the commercial product. We retained certain responsibilities for research and development activities under a joint development plan.

In July 2014, Roche terminated the license agreement. Pursuant to the termination of the license agreement, we are not entitled to further payments from Roche, Roche has no remaining rights to octreotide capsules and we retain all rights to octreotide capsules and all related intellectual property. Subsequent to the termination, we purchased from Roche active

pharmaceutical ingredient, or API, supplies to continue the development and manufacturing of octreotide capsules, together with Roche's proposed trade name, "MYCAPSSA" for octreotide capsules, for an aggregate amount of $5.1 million, payable in three annual installments of $1.7 million beginning in 2016. We made the $1.7 million annual payments in each of March 2018, 2017, and 2016. We have no further financial or operational obligations to Roche.

Financial Overview

Research and Development

Research and development expenses consist of expenses incurred in performing research and development activities, including compensation and benefits for full-time research and development employees, an allocation of facilities expenses, overhead expenses, nonclinical pharmacology studies, manufacturing process-development and scale-up activities, clinical trial and related clinical manufacturing expenses, fees paid to contract research organizations, or CROs, investigative sites, and other external expenses. In the early phases of development, our research and development costs included expanding our technology platform as well as early development of specific product candidates. The majority of our research and development expenses has been spent on the development of octreotide capsules, including the manufacturing of clinical trial material, manufacturing process development and validation, regulatory and clinical activities, and our TPE platform. We expense research and development costs as incurred.

As a result of the August 2016 reduction in workforce, we eliminated our research and discovery functions and are currently not investing in those areas. We continue to invest in the clinical development of octreotide capsules. Product candidates in late stages of development generally have higher development costs than those in earlier stages of development, primarily due to the increased size and duration of late-stage clinical trials. We plan to continue our international Phase 3 CHIASMA OPTIMAL clinical trial of octreotide capsules in acromegaly that we initiated in September 2017 to support potential regulatory approval in the United States. We also expect to continue to conduct our international Phase 3 MPOWERED clinical trial of octreotide capsules in acromegaly that we initiated in March 2016 to support potential regulatory approval in the European Union. The successful development of octreotide capsules is highly uncertain.

General and Administrative

General and administrative expenses consist primarily of salaries and related benefits, including stock-based compensation, related to our executive, finance, and support functions. Other general and administrative expenses include facility-related costs not otherwise allocated to research and development expenses, travel expenses for our general and administrative personnel and professional fees for auditing, tax, and corporate and intellectual property legal services.

Our marketing expenses in the six months ended June 30, 2018 and the year ended December 31, 2017 were immaterial and are expected to continue to be immaterial while our primary business activity involves the conduct of clinical trials.

Restructuring Charges

Restructuring charges consist of employee severance benefits and related costs, contract termination fees, asset write-offs resulting from restructuring plans, suspension fees associated with commercial manufacturing agreements, and other expenses associated with restructuring our operations.

Other Income, Net

Other income, net consists mainly of interest income earned on our investments, net of interest incurred on our obligation related to the acquisition of API and trade name MYCAPSSA from Roche.

Provision for Income Taxes

We are subject to federal and state income taxes for earnings generated in the United States, and foreign taxes on earnings of our wholly-owned Israeli subsidiary. Our consolidated tax expense is primarily affected by the mix of our foreign subsidiary permanent items, discrete items, and unrecognized tax benefits and to a lesser extent our taxable income (loss) in the United States.

Critical Accounting Policies and Use of Estimates

We have adopted various accounting policies to prepare our consolidated financial statements in accordance with accounting principles generally accepted in the United States, or U.S. GAAP. Our most significant accounting policies are described in Note 1 to our consolidated financial statements included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2017. There have been no material changes in our critical accounting policies during the three and six months ended June 30, 2018. The preparation of our consolidated financial statements in conformity with U.S. GAAP requires us to make estimates and assumptions that affect the amounts reported in our consolidated financial statements and accompanying notes. Our estimates and assumptions, include those related to the accounting for stock-based compensation, present value of long-term purchase obligation, income taxes, and accounting for certain accruals. We assess the above estimates on an ongoing basis; however, actual results could materially differ from those estimates.

Results of Operations for the Three and Six Months ended June 30, 2018 and 2017

Research and Development

The following is a comparison of research and development expenses for the three and six months ended June 30, 2018 and 2017:

	Three Months Ended June 30,				Six Months Ended June 30,			
	2018	2017	$ Change	% Change	2018	2017	$ Change	% Change
	($ in thousands)							
Research and development	$6,305	$4,279	$2,026	47%	$11,168	$8,934	$2,234	25%

For the three months ended June 30, 2018, our total research and development expenses increased by $2.0 million to $6.3 million. For the six months ended June 30, 2018, our total research and development expenses increased by $2.2 million to $11.2. These increases were primarily due to costs related to the CHIASMA OPTIMAL clinical trial which we initiated in September 2017, and the MPOWERED trial which completed enrollment into its six-month run-in phase in July 2018 and were partially offset by reduced personnel costs associated with the transition of our former Chief Development Officer from a full-time employee to a member of the board of directors of both our company and our Israeli subsidiary.

General and Administrative

The following is a comparison of general and administrative expenses for the three and six months ended June 30, 2018 and 2017:

	Three Months Ended June 30,				Six Months Ended June 30,			
	2018	2017	$ Change	% Change	2018	2017	$ Change	% Change
	($ in thousands)							
General and administrative	$2,627	$2,641	$ (14)	(1%)	$5,061	$5,101	$ (40)	(1%)

For the three and six months ended June 30, 2018, our general and administrative expenses were relatively flat compared to the same periods in the prior year at $2.6 million and $5.1 million, respectively. In 2018, we incurred increased legal fees which were primarily offset by a reduction in costs following the November 2017 termination of our office facility lease in Waltham.

Other Income, net

Other income totaled $0.5 million for the six months ended June 30, 2018 compared to other income of $0.4 million for the same period in 2017, an increase of approximately $0.1 million. The increase was driven by interest income generated from increased yields on our cash equivalents and marketable securities and a decrease in the imputed interest expense associated with the obligation related to the acquisition of API and trade name MYCAPSSA from Roche.

Provision (Benefit) for Income Taxes

Our total tax benefit was approximately $3,000 for the six months ended June 30, 2018, representing an effective tax rate of 0.0%, as compared to a tax provision of $0.2 million for the six months ended June 30, 2017, representing an effective tax rate of (1.5%).

Our effective tax rate differs from the statutory rate each year mainly due to a full valuation allowance maintained against U.S. deferred tax assets and due to lower tax rates applied to income of our Israeli subsidiary.

Liquidity and Capital Resources

Since our inception and through June 30, 2018, we have raised an aggregate of $366.2 million to fund our operations, of which $86.3 million was through our license agreement with Roche, approximately $106.5 million was from selling shares of common stock in our IPO, $161.4 million was from the issuance of private securities, and $12.0 million was from borrowings under a loan agreement. In March 2013, using proceeds from the Roche license agreement, we repaid all outstanding borrowings under our loan agreement and paid an aggregate of $55.0 million in cash as partial consideration for the redemption of certain shares of our preferred stock.

As of June 30, 2018, our cash and cash equivalents were $13.8 million, of which $0.3 million was held by our Israeli subsidiary. In addition, as of June 30, 2018, we have $40.8 million invested in short-term marketable securities.

Plan of Operations and Future Funding Requirements

We expect that our primary uses of capital will be associated with seeking regulatory approval of octreotide capsules in the United States and European Union, including clinical trial costs (including our international Phase 3 CHIASMA OPTIMAL clinical trial that we initiated in September 2017 to support regulatory approval of octreotide capsules in the United States and our international Phase 3 MPOWERED clinical trial which completed enrollment into its six-month run-in phase in July 2018 to support regulatory approval of octreotide capsules in the European Union), manufacturing of octreotide capsules for market consumption, if approved, legal and regulatory expenses related to seeking regulatory approval of octreotide capsules in the United States and European Union, compensation and related expenses, third-party clinical development services, pre-commercialization activities, legal and other regulatory expenses, and other general operating costs.

We currently expect our existing cash, cash equivalents and marketable securities will be sufficient to fund our operations through the anticipated release of top-line data from our Phase 3 CHIASMA OPTIMAL trial in the fourth quarter of 2019 while supporting our Phase 3 MPOWERED trial in parallel. We cannot estimate the actual amounts necessary to successfully complete the development and commercialization of octreotide capsules, if at all, or whether, or when, we may achieve profitability. Our future capital requirements will depend on many factors, including, but not limited to:

- the costs, timing and outcome of the development and regulatory review of octreotide capsules;
- the progress and results of our ongoing clinical trials of octreotide capsules or any future clinical trials or studies we may conduct;
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for octreotide capsules and any other future product candidates for which we receive marketing approval;
- proceeds, if any, received from commercial sales of octreotide capsules and any future product candidates for which we receive marketing approval;

- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims; and
- the extent to which we develop, acquire or in-license other product candidates and technologies or explore or consummate other strategic transactions.

Until such time, if ever, as we can generate substantial product sales, we expect to finance our cash needs through a combination of equity offerings and debt financings and we may opportunistically consider license and collaboration arrangements. We believe that shelf registration statements can contribute, when used, to greater financial flexibility. To that end, we filed a shelf registration statement on Form S-3 with the Securities and Exchange Commission in March 2018, which was declared effective in May 2018. To the extent that we raise additional capital through future issuance of equity or debt, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our existing common stockholders. If we raise additional funds through collaboration arrangements, we may have to relinquish valuable rights to our current or future product candidates, exploratory programs, technologies or future revenue streams 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 product development or future commercialization efforts of octreotide capsules or grant rights to others to develop and market future potential product candidates that we would otherwise prefer to develop and market ourselves.

Cash Flows

The following is a summary of cash flows for the six months ended June 30, 2018 and 2017:

	Six Months Ended June 30,	
	2018	2017
	($ in thousands)	
Cash flows provided by (used in):		
Operating activities	$ (10,765)	$ (11,292)
Investing activities	11,706	(5,652)
Financing activities	(1,700)	(1,700)

Operating Activities

Net cash used in operating activities was $10.8 million for the six months ended June 30, 2018, and primarily consisted of $15.7 million in net loss, adjusted for non-cash items of $1.3 million (primarily stock-based compensation) and working capital increases of $3.7 million (primarily due to the increase in accounts payable and accrued expenses and decreases in prepaid expenses and other current assets). Net cash used in operating activities was $11.3 million for the six months ended June 30, 2017, and primarily consisted of $13.9 million in net loss, adjusted for non-cash items of $2.3 million (primarily stock-based compensation). The primary driver for the decrease in our cash used in our operating activities during the six months ended June 30, 2018 compared to the six months ended June 30, 2017 was the timing of clinical trial related payments driving our net working capital increases in 2018 and employee severance payments made in the six months ended June 30, 2017.

Investing Activities

Net cash provided by investing activities was $11.7 million for the six months ended June 30, 2018, primarily related to the net maturities of marketable securities, compared to $5.7 million in cash used in investing activities for the six months ended June 30, 2017, primarily related to the net purchases of marketable securities.

Financing Activities

Net cash used in financing activities was $1.7 million during the six months ended June 30, 2018, primarily related to the final $1.7 million installment payment related to the termination of the Roche license agreement. For the six months ended June 30, 2017, net cash used in financing activities was $1.7 million, related to the second $1.7 million installment payment related to the termination of the Roche license agreement.

Contractual Obligations

We conduct our operations in leased facilities, which are accounted for as operating leases. Certain leases include renewal options. In addition, we lease automobiles and equipment under operating leases. There were no assets held under capital leases at June 30, 2018 or December 31, 2017. At June 30, 2018, the minimum rental commitments under all non-cancelable operating leases with initial or remaining terms of more than one year was approximately $0.3 million through 2020.

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 in the rules and regulations of the SEC.

JOBS Act

In April 2012, the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, was enacted. Section 107 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 public companies.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

The market risk inherent in our financial instruments and in our financial position represents the potential loss arising from adverse changes in interest rates. As of June 30, 2018, we had $13.8 million in cash and cash equivalents, consisting of cash in checking accounts at U.S. and Israeli banking institutions as well as money market funds. In addition, as of June 30, 2018, we had $40.8 million of marketable securities consisting of short-term corporate notes and commercial paper. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. An immediate 100 basis point change in interest rates would cause a decrease in the value of our short-term investments of $0.1 million. As of June 30, 2018, we did not have any outstanding borrowings, and as a result we are not exposed to interest rate risk associated with credit facilities.

In addition, we are subject to currency risk for balances held, or denominated, in currencies other than U.S. dollars. We seek to maintain all balances in U.S. dollars until payment in other currencies is required to minimize this currency risk. Fluctuations in the exchange rate between the U.S. dollar and each of the Euro, GBP and NIS over the past 24 months have been approximately 5%, (2%) and 5%, respectively. As of June 30, 2018, we held $0.3 million in Israeli banks and petty cash funds to support our Israeli operations, approximately half of which is denominated in U.S. dollars. We contract with CROs internationally, primarily for the execution of clinical trials and manufacturing activities. Transactions with these providers are settled in U.S. dollars, Euros or GBP and, therefore, we believe that we have only minimal exposure to foreign currency exchange risks. We do not hedge against foreign currency risks.

We do not believe that inflation and changing prices had a significant impact on our results of operations for any periods presented herein.

Item 4. Controls and Procedures

Management's Evaluation of our Disclosure Controls and Procedures

We maintain disclosure controls and procedures (as defined in Rules 13a-15(e) or 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act) that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act is (1) recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms and (2) accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure.

Based on this evaluation, our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures as of the end of the period covered by this report. In designing and evaluating our disclosure controls and procedures, our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our principal executive officer and principal financial officer has concluded based upon the evaluation described above that, as of June 30, 2018, our disclosure controls and procedures were effective at the reasonable assurance level.

We continue to review and document our disclosure controls and procedures, including our internal controls and procedures for financial reporting, and may from time to time make changes aimed at enhancing their effectiveness and to ensure that our systems evolve with our business.

Changes in Internal Control Over Financial Reporting

During the three months ended June 30, 2018, there have been no changes in our internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15(d)-15(f) promulgated under the Exchange Act, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II — OTHER INFORMATION

Item 1. Legal Proceedings

On June 9, 2016, Chiasma, Inc. and certain of our current and former officers were named as defendants in a federal securities class action lawsuit filed in the United States District Court for the District of Massachusetts, styled *Gerneth v. Chiasma, Inc., et al*. This lawsuit challenges our public statements regarding our Phase 3 clinical trial methodology for octreotide capsules and our ability to obtain FDA approval for the marketing and sale of octreotide capsules. In December 2016, a lead plaintiff was appointed in the case. An amended complaint was filed by the lead plaintiff on February 10, 2017 similarly challenging our statements regarding the Phase 3 clinical trial methodology and results, and our ability to obtain FDA approval for octreotide capsules, purportedly in violation of Sections 11 and 15 of the Securities Act of 1933. The amended complaint adds as defendants current and former members of our board of directors, as well as the investment banks that underwrote our initial public offering ("IPO") on July 15, 2015. The lead plaintiff seeks to represent a class of all purchasers of our stock in our IPO. The plaintiff is seeking an unspecified amount of compensatory damages on behalf of himself and members of a putative shareholder class, including interest and reasonable costs and expenses incurred in litigating the action, and any other relief the court determines is appropriate. The defendants filed a motion to dismiss the amended complaint on March 27, 2017 and on February 15, 2018, the court denied defendants' motion to dismiss. The defendants filed an answer to the amended complaint on March 30, 2018. We believe this lawsuit is meritless and intend to vigorously defend against it. At this time, no assessment can be made as to the likely outcome of this lawsuit or whether the outcome will be material to us.

Item 1A. Risk Factors

We operate in a rapidly changing environment that involves a number of risks that could materially affect our business, financial condition or future results, some of which are beyond our control. In addition to the other information set forth in this Quarterly Report on Form 10-Q, you should carefully consider the factors discussed in Part I, "Item 1A. Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2017, as filed with the Securities and Exchange Commission, which could materially affect our business, financial condition or future results. The following risk factor includes a material change from the risk factor set forth in our Annual Report on Form 10-K for the year ended December 31, 2017. You should carefully review this risk factor and the risks factors described in our Annual Report on Form 10-K and in other reports we file with the Securities and Exchange Commission in evaluating our business.

Even though our Phase 3 CHIASMA OPTIMAL trial is being conducted under a SPA agreed to with the FDA, we cannot guarantee that the design of, or data collected from, this trial or any of our clinical trials will be sufficient to support filing or approval of an NDA.

In the context of a Phase 3 clinical trial, the purpose of a SPA is to reach agreement with the FDA on the protocol design and size of the trial that may form the primary basis of an efficacy claim in support of an NDA. In requesting a SPA agreement, a sponsor asks focused questions on specific issues relating to the protocol, protocol design, study conduct, study goals and data analysis. However, according to draft regulatory guidance, a SPA agreement does not indicate FDA concurrence on every protocol detail. Absence of an FDA comment on a particular aspect of a trial does not necessarily indicate agreement if the sponsor did not specifically ask about that aspect. Moreover, a SPA is not a guarantee of approval, even if the trial is successful. A SPA is not binding on the FDA and may be rescinded if, for example, the FDA identifies a safety concern related to the product or its pharmacological class, if the FDA and the scientific community recognize a paradigm shift in disease diagnosis or management, if the relevant data, assumptions or information provided by the sponsor in the SPA submission are found to be false or misstated or omit relevant facts, or if the sponsor fails to follow the protocol that was agreed upon with the FDA. A SPA may be modified with the written agreement of the FDA and the trial sponsor and, according to draft regulatory guidance, minor issues can be resolved through additional correspondence and protocol amendments after the trial begins. However, the FDA retains significant latitude and discretion in interpreting the terms of a SPA agreement, the significance of protocol amendments, if necessary after the trial begins, and the data and results from the applicable clinical trial.

Further, the results from the CHIASMA OPTIMAL trial, a double-blind, placebo controlled clinical trial, may not be sufficiently robust to support the filing or approval of an NDA. In particular, the CHIASMA OPTIMAL trial is also expected to have a relatively small sample size, 50 patients enrolled, and therefore the FDA has indicated that missing data, which might be only a few measurements, may raise questions about data quality and may, ultimately, invalidate the trial results. It should also be noted that the design of the CHIASMA OPTIMAL trial is different in important ways from the design of both our current MPOWERED clinical trial and our completed Phase 3 clinical trial. For example, in contrast to our completed Phase 3 clinical trial, which did not have a placebo arm, the CHIASMA OPTIMAL trial design calls for the randomization of 50% of study patients to placebo capsules, the effect of which we cannot predict. We believe conducting a randomized, double-blind and controlled trial, with a placebo control may be particularly challenging. For example, it may be difficult to identify patients with acromegaly willing to enroll in a placebo controlled trial. In our completed Phase 3 clinical trial we used IGF-1 < 1.3 times the upper limit of normal as a screening eligibility criteria and the threshold for response whereas in our CHIASMA OPTIMAL trial we use IGF-1 ≤ 1.0 times the upper limit of normal. In light of these new trial design elements, even if we achieve a clinical response consistent with or similar to what we believe we achieved in our completed Phase 3 clinical trial, we may fail to achieve the primary or secondary endpoints of the CHIASMA OPTIMAL trial.

We anticipate that both primary and secondary endpoints in the CHIASMA OPTIMAL trial, as well as data from our other clinical trials of octreotide capsules, will be taken into account by the FDA in evaluating the totality of evidence for octreotide capsules treatment effect. Therefore, achievement of the primary endpoint in the CHIASMA OPTIMAL trial alone may not be sufficient to support approval. Not all endpoints measured may be supportive of octreotide capsules' efficacy or safety.

We anticipate that the FDA will review the totality of the data collected from the CHIASMA OPTIMAL trial, including both primary and secondary endpoints and whether the data collected are sufficiently robust to support the interpretability of these analyses, in determining whether to approve our NDA, if resubmitted, for the marketing and sale of octreotide capsules. There can be no assurance that the data collected from the CHIASMA OPTIMAL trial will be sufficient to support approval of our NDA, if resubmitted, for the marketing and sale of octreotide capsules.

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

Recent Sales of Unregistered Securities

None.

Issuer Purchases of Equity Securities

In the quarter ended June 30, 2018, we did not repurchase any shares of our common stock.

Use of Proceeds from Initial Public Offering of Common Stock

On July 21, 2015, we completed the sale of 7,319,750 shares of our common stock (inclusive of 954,750 shares of common stock sold by us pursuant to the full exercise of an option granted to the underwriters) in our IPO at a price to the public of $16.00 per share. The offer and sale of the shares in our IPO was registered under the Securities Act pursuant to registration statements on Form S-1 (File No. 333-204949), which was filed with the SEC on June 15, 2015 and amended subsequently and declared effective by the SEC on July 15, 2015, and Form S-1MEF (File No. 333-205691), which was filed with the SEC on July 15, 2015 and automatically effective upon filing. Following the sale of the shares in connection with the closing of our IPO, the offering terminated. The offering did not terminate before all the securities registered in the registration statements were sold. Barclays Capital Inc. and Cowen and Company, LLC acted as joint book-running managers for the offering. William Blair & Company, L.L.C. and Oppenheimer & Co. Inc. acted as co-managers.

We raised approximately $106.5 million in net proceeds after deducting underwriting discounts and commissions and offering expenses payable by us. We invested the funds received in cash equivalents and other short-term investments in accordance with our investment policy.

In June 2016 and August 2016, we announced two separate corporate restructuring plans intended to focus our resources on the continued development of octreotide capsules for the maintenance treatment of adult acromegaly patients. As a result of the August 2016 reduction in workforce, we eliminated our research and discovery functions and are currently not investing in those areas.

We expect that our primary uses of capital will be associated with seeking regulatory approval of octreotide capsules in the United States and European Union, including clinical trial costs (including the international Phase 3 MPOWERED clinical trial which completed enrollment into its six-month run-in phase in July 2018 to support anticipated European Union regulatory approval of octreotide capsules and our international Phase 3 CHIASMA OPTIMAL clinical trial that we initiated in September 2017 to support United States regulatory approval of octreotide capsules), manufacturing of octreotide capsules for market consumption, if approved, legal and regulatory expenses related to seeking regulatory approval of octreotide capsules in the United States and European Union, compensation and related expenses, third-party clinical development services, legal and other regulatory expenses, pre-commercialization activities, and other general operating costs.

Item 6. Exhibits

The following exhibits are filed as part of this Quarterly Report on Form 10-Q:

Exhibit No.	Description
31.1*	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Exchange Act rules 13a-14 or 15d-14, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1+	Certification of Principal Executive Officer and Principal Financial Officer pursuant 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS*	XBRL Instance Document.

Exhibit No.	Description
101.SCH*	XBRL Taxonomy Extension Schema Document.
101.CAL*	XBRL Taxonomy Extension Calculation Document.
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB*	XBRL Taxonomy Extension Labels Linkbase Document.
101.PRE*	XBRL Taxonomy Extension Presentation Link Document.

* Filed herewith.
† Indicates a management contract or compensation plan, contract or arrangement.
+ The certification furnished in Exhibit 32.1 hereto is deemed to be furnished with this Quarterly Report on Form 10-Q and will not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, except to the extent that the Registrant specifically incorporates it by reference.

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.

CHIASMA, INC.

August 9, 2018

By: */s/ Mark J. Fitzpatrick*
Mark J. Fitzpatrick
President, Chief Executive Officer and Director
(Principal Executive Officer and Principal Financial Officer)

Exhibit 31.1

Certification

I, Mark J. Fitzpatrick, certify that:

1. I have reviewed this quarterly report on Form 10-Q for the period ended June 30, 2018 of Chiasma, Inc.;

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. I am 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; and

5. I have disclosed, based on my 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 9, 2018

/s/ Mark J. Fitzpatrick
Mark J. Fitzpatrick
President, Chief Executive Officer and Director
(Principal Executive Officer and Principal Financial Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the quarterly report on Form 10-Q of Chiasma, Inc. (the "Company") for the period ended June 30, 2018, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Mark J. Fitzpatrick, President, Chief Executive Officer and Director (Principal Executive Officer and Principal Financial Officer) of the Company, hereby certifies, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. Section 1350, that to his knowledge:

1) the Report which this statement accompanies fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company at the dates and for the periods indicated in the Report.

Date: August 9, 2018

/s/ Mark J. Fitzpatrick
Mark J. Fitzpatrick
President, Chief Executive Officer and Director
(Principal Executive Officer and Principal Financial Officer)