ChemoCentryx, Inc. Form 10-Q November 08, 2018 Table of Contents

# UNITED STATES

#### SECURITIES AND EXCHANGE COMMISSION

**WASHINGTON, DC 20549** 

Form 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2018

or

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

For the transition period from\_\_\_\_\_\_ to \_\_\_\_\_

Commission File Number: 001-35420

ChemoCentryx, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware (State or Other Jurisdiction of

94-3254365 (I.R.S. Employer

**Incorporation or Organization**)

**Identification No.)** 

850 Maude Avenue

Mountain View, California (Address of Principal Executive Offices)

94043 (Zip Code)

(650) 210-2900

(Registrant s Telephone Number, Including Area Code)

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

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

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

Large accelerated filer Accelerated filer

Non-accelerated filer Smaller reporting company

Emerging growth company

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

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

The number of outstanding shares of the registrant s common stock, par value \$0.001 per share, as of October 31, 2018 was 50,525,716.

# CHEMOCENTRYX, INC.

# **QUARTERLY REPORT ON FORM 10-Q**

# For the quarterly period ended September 30, 2018

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## PART I. FINANCIAL INFORMATION

## **Item 1. Financial Statements**

## CHEMOCENTRYX, INC.

## CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands, except share and par value data)

(unaudited)

	Sep	tember 30, 2018	Dec	ember 31, 2017
Assets				
Current assets:	φ.		Φ.	40.000
Cash and cash equivalents	\$	24,114	\$	40,020
Short-term investments		149,004		87,271
Accounts receivable		336		51,090
Prepaid expenses and other current assets		2,613		1,449
Total current assets		176,067		179,830
Property and equipment, net		1,594		1,210
Long-term investments		12,878		7,929
Other assets		222		359
Total assets	\$	190,761	\$	189,328
Liabilities and Stockholders Equity				
Current liabilities:				
Accounts payable	\$	576	\$	1,400
Accrued liabilities		11,727		8,575
Deferred revenue		49,025		22,962
Total current liabilities		61,328		32,937
Long-term debt, net		14,727		4,676
Noncurrent deferred revenue		92,809		72,197
Other non-current liabilities		425		251
Total liabilities		169,289		110,061
Commitments				
Stockholders equity:				
Preferred stock, \$0.001 par value, 10,000,000 shares authorized; no shares issued and outstanding				
		50		49

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Common stock, \$0.001 par value, 200,000,000 shares authorized; 50,428,507 and 48,837,060 shares issued and outstanding at September 30, 2018 and		
December 31, 2017, respectively		
Additional paid-in capital	385,339	368,553
Note receivable	(16)	(16)
Accumulated other comprehensive loss	(189)	(119)
Accumulated deficit	(363,712)	(289,200)
Total stockholders equity	21,472	79,267
Total liabilities and stockholders equity	\$ 190,761	\$ 189,328

See accompanying notes.

## CHEMOCENTRYX, INC.

## CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except per share data)

(unaudited)

	Three Months Ended September 30, 2018 2017				Nine Months Ender September 30, 2018 2017			30,
Revenue:								
Collaboration and license revenue	\$	8,975	\$	9,029	\$	33,543	\$	26,196
Total revenue		8,975		9,029		33,543		26,196
Operating expenses:								
Research and development		15,135		12,315		47,636		36,614
General and administrative		5,373		3,624		14,781		12,381
Total operating expenses		20,508		15,939		62,417		48,995
Loss from operations		(11,533)		(6,910)		(28,874)	(	22,799)
Other income (expense):								
Interest income		1,066		350		2,471		1,003
Interest expense		(423)				(778)		
Total other income, net		643		350		1,693		1,003
Net loss	\$	(10,890)	\$	(6,560)	\$	(27,181)	\$ (	21,796)
Basic and diluted net loss per common share	\$	(0.22)	\$	(0.13)	\$	(0.55)	\$	(0.45)
Shares used to compute basic and diluted net loss per common share		50,341		48,602		49,579		48,314

See accompanying notes.

# CHEMOCENTRYX, INC.

## CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(in thousands)

(unaudited)

	End	Three Months Ended September 30,		ths Ended ber 30,
	2018	2017	2018	2017
Net loss	\$ (10,890)	\$ (6,560)	\$ (27,181)	\$ (21,796)
Unrealized gain (loss) on available-for-sale securities	48	45	(70)	(18)
Comprehensive loss	\$ (10,842)	\$ (6,515)	\$ (27,251)	\$ (21,814)

See accompanying notes.

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## CHEMOCENTRYX, INC.

## CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

# (in thousands)

# (unaudited)

	I	Ended 30, 2017		
Operating activities				
Net loss	\$	(27,181)	\$	(21,796)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:				
Depreciation of property and equipment		371		311
Stock-based compensation		7,969		6,841
Noncash interest (income) expense, net		(714)		63
Changes in assets and liabilities:				
Accounts receivable		50,754		29,675
Prepaids and other current assets		(1,164)		(577)
Other assets		137		(102)
Accounts payable		(824)		682
Other liabilities		3,053		(347)
Deferred revenue		(656)		(15,667)
Net cash provided by (used in) operating activities		31,745		(917)
Investing activities				` ′
Purchases of property and equipment, net		(755)		(376)
Purchases of investments	(	(173,739)	(	104,201)
Maturities of investments		108,050		109,050
Net cash provided by (used in) investing activities		(66,444)		4,473
Financing activities				
Proceeds from exercise of stock options and employee stock purchase plan		9,291		2,678
Employees tax withheld and paid for restricted stock units		(473)		(297)
Borrowings under credit facility agreement, net of issuance costs		9,975		` ′
				2 201
Net cash provided by financing activities		18,793		2,381
Net increase (decrease) in cash and cash equivalents		(15,906)		5,937
Cash and cash equivalents at beginning of period		40,020		12,024
Cash and cash equivalents at end of period	\$	24,114	\$	17,961
Supplemental disclosures of cash flow information				
Cash paid for interest	\$	426	\$	
ı				

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See accompanying notes.

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#### CHEMOCENTRYX, INC.

#### NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

**September 30, 2018** 

(unaudited)

#### 1. Description of Business

ChemoCentryx, Inc. (the Company) commenced operations in 1997. The Company is a clinical-stage biopharmaceutical company focused on developing new medications targeted at inflammatory disorders, autoimmune diseases and cancer. The Company s principal operations are in the United States and it operates in one segment.

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

The financial information filed is unaudited. The Condensed Consolidated Financial Statements included in this report reflect all adjustments (consisting only of normal recurring adjustments) that the Company considers necessary for the fair statement of the results of operations for the interim periods covered and of the financial condition of the Company at the date of the interim balance sheet. The December 31, 2017 Condensed Consolidated Balance Sheet was derived from audited financial statements. The results for interim periods are not necessarily indicative of the results for the entire year or any other interim period. The Condensed Consolidated Financial Statements should be read in conjunction with the Company s financial statements and the notes thereto included in the Company s Annual Report on Form 10-K for the year ended December 31, 2017, filed with the Securities and Exchange Commission on March 12, 2018.

# 2. Summary of Significant Accounting Policies Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States (GAAP) requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. Actual results could differ from these estimates.

#### **Concentration of Credit Risk**

The Company invests in a variety of financial instruments and, by its policy, limits the amount of credit exposure with any one issuer, industry or geographic area.

Accounts receivable are typically unsecured and are concentrated in the pharmaceutical industry and government sector. Accordingly, the Company may be exposed to credit risk generally associated with pharmaceutical companies and government funded entities. The Company has not historically experienced any significant losses due to concentration of credit risk.

Accounts receivable consists of the following (in thousands):

	Sept	ember 30, 2018	Dec	ember 31, 2017
Vifor (1)	\$	336	\$	51,090

(1) As of December 31, 2017, accounts receivable excluded the \$10.0 million cash commitment received from Vifor (International) Ltd. and/or its affiliates (collectively, Vifor) in February 2018 in connection with the agreement that harmonized the geographic commercialization rights underlying the agreements for both avacopan and CCX140 drug candidates, which we refer to as the Avacopan Amendment. See Note 8. Collaboration and License Agreements for a detailed discussion.

#### **Net Loss Per Share**

Basic net loss per common share is computed by dividing net loss attributable to common stockholders by the weighted-average number of common shares outstanding during the period, without consideration for common stock equivalents.

Diluted net loss per share is computed by dividing net loss attributable to common stockholders by the sum of the weighted-average number of common shares outstanding and dilutive common stock equivalent shares outstanding for the period. The Company s potentially dilutive common stock equivalent shares, which include incremental common shares issuable upon (i) the exercise of outstanding stock options and warrants, (ii) vesting of restricted stock units (RSUs) and restricted stock awards (RSAs), and (iii) the purchase from contributions to the 2012 Employee Stock Purchase Plan (the ESPP), (calculated based on the treasury stock method), are only included in the calculation of diluted net loss per share when their effect is dilutive.

For the nine months ended September 30, 2018 and 2017, the following potentially dilutive securities were excluded from the calculation of diluted net loss per share due to their anti-dilutive effect:

	Nine Months Ended September 30,			
	2018	2017		
Options to purchase common stock, including purchases				
from contributions to ESPP	10,816,005	10,131,143		
Restricted stock units	473,687	456,346		
Restricted stock awards	37,713	95,866		
Warrants to purchase common stock	150,000	150,000		
	11,477,405	10,833,355		

### **Comprehensive Loss**

Comprehensive loss comprises net loss and other comprehensive income (loss). For the periods presented other comprehensive income (loss) consists of unrealized gains and losses on the Company savailable-for-sale securities. For the three and nine months ended September 30, 2018 and 2017, there were no sales of investments, and therefore there were no reclassifications.

#### **Revenue Recognition**

Effective January 1, 2018, the Company adopted Accounting Standards Codification (ASC) Topic 606, Revenue from Contracts with Customers (ASC 606) using the modified retrospective transition method. This standard applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments. Under ASC 606, the Company recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the Company expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that the Company determines are within the scope of ASC 606, the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the Company satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that Company will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, the Company assesses the goods or services promised within each contract and determines those that are performance obligations and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

The Company enters into corporate collaborations under which it may obtain upfront license fees, research and development funding and development and regulatory and commercial milestone payments and royalty payments. The Company s performance obligations under these arrangements may include licenses of intellectual property, distribution rights, research and development services, delivery of manufactured product, and/or participation on joint steering committees.

Licenses of intellectual property: If the license to the Company s intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenue from upfront license fees allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license. For licenses that are bundled with other promises, the Company utilizes judgement to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring proportional performance for purposes of recognizing revenue from non-refundable, up-front fees. The Company evaluates the measure of proportional performance each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

Milestone payments: At the inception of each arrangement that includes development, regulatory or commercial milestone payments, the Company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price. ASC 606 suggests two alternatives to use when estimating the amount of variable consideration: the expected value method and the most likely amount method. Under the expected value method, an entity considers the sum of

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probability-weighted amounts in a range of possible consideration amounts. Under the most likely amount method, an entity considers the single most likely amount in a range of possible consideration amounts. Whichever method is used, it should be consistently applied throughout the life of the contract; however, it is not necessary for the Company to use the same approach for all contracts. The Company expects to use the most likely amount method for development and regulatory milestone payments. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the Company s or the licensee s control, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. The transaction price is then allocated to each performance obligation on a relative stand-alone selling price basis. The Company recognizes revenue as or when the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, the Company re-evaluates the probability or achievement of each such milestone and any related constraint, and if necessary, adjusts its estimates of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenues and earnings in the period of adjustment.

Commercial milestones and royalties: For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and in which the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue when the related sales occur. To date, the Company has not recognized any royalty revenue resulting from its collaboration arrangements.

Up-front payments and fees are recorded as deferred revenue upon receipt or when due, and may require deferral of revenue recognition to a future period until the Company performs its obligations under these arrangements. Amounts payable to the Company are recorded as accounts receivable when the Company s right to consideration is unconditional.

Upon adoption of ASC 606 under the modified retrospective transition method, the Company recognized the cumulative effect of initially applying the new revenue standard of \$47.3 million as an adjustment to the opening balance of accumulated deficit and an increase in deferred revenue. The comparative information has not been restated and continues to be reported under the accounting standards in effect for those periods. Before the adoption of ASC 606, the Company recognized upfront fees straight-line under ASC 605 over the estimated performance period and recognized milestones when earned under the milestone method of accounting. See Note 2. Summary of Significant Accounting Policies Revenue Recognition in the Company s Annual Report on Form 10-K for the fiscal year ended December 31, 2017, filed with the SEC on March 12, 2018 for a detailed discussion.

The impact of adoption on the Company s consolidated statement of operations and balance sheet was as follows (in thousands):

	For	the Three	В	Ended Septem alances Vithout	ber 3	0, 2018
	Re	As eported	Adoption of ASC606			fect of hange
Statement of Operations		-				
Collaboration and license revenue	\$	8,975	\$	4,727	\$	4,248
Loss from operations		(11,533)		(15,781)		4,248
Net loss		(10,890)		(15,138)		4,248

			F	or the				
	Nine Months Ended September 30, 2018							
		As Balances Without			F	Effect		
	Re	ported	Adoptio	on of ASC606	of (	Change		
Statement of Operations								
Collaboration and license revenue	\$	33,543	\$	23,849	\$	9,694		
Loss from operations		(28,874)		(38,568)		9,694		
Net loss	(	(27,181)		(36,875)		9,694		

	As Reported	Balan	ber 30, 2018 ces Without on of ASC606	Effect of Change
Balance Sheet				
Liabilities:				
Deferred revenue	\$ 49,025	\$	19,382	\$ 29,643
Noncurrent deferred revenue	92,809		84,815	7,994
Stockholders equity:				
Accumulated deficit	(363,712)		(326,075)	(37,637)

## **Recent Accounting Pronouncements**

In June 2018, the Financial Accounting Standard Board issued Accounting Standards Update No. 2018-07, Compensation Stock Compensation (Topic 718). The new standard simplifies the accounting for share-based payments to nonemployees by aligning it with the accounting for share-based payments to employees, with certain exceptions. The new standard will be effective for the Company on January 1, 2019. The Company is currently evaluating the impact of the adoption of this standard on its financial statements and does not expect the adoption of this accounting guidance to have a material impact on the consolidated financial statements.

On December 22, 2017, the Tax Cuts and Jobs Act (the Act ) was enacted into law. Accounting Standards Codification (ASC) 740, Income Taxes, requires companies to recognize the effect of the tax law changes in the period of enactment. Shortly after the enactment of the Act, the SEC staff issued Staff Accounting Bulletin No. 118 (SAB 118) to address the application of U.S. GAAP in situations when a registrant does not have the necessary information available, prepared, or analyzed (including computations) in reasonable detail to complete the accounting for certain income tax effects of the Act. The Company has adjusted its deferred tax assets and liabilities based on the reduction of the U.S. federal corporate tax rate from 34% to 21% and assessed the realizability of its deferred tax assets based on its current understanding of the provisions of the new law. The Company considers its accounting for the impacts of the new law to be provisional and the Company will continue to assess the impact of the recently enacted tax law (and expected further guidance from federal and state tax authorities as well as further guidance for the associated income tax accounting) on its business and consolidated financial statements for the remainder of 2018. No adjustments were made to the provisional estimate during the three and nine months ended September 30, 2018.

In February 2016, the Financial Accounting Standard Board issued Accounting Standards Update No. 2016-02, Leases (Topic 842). The new standard requires that all lessees recognize the assets and liabilities that arise from leases on the balance sheet and disclose qualitative and quantitative information about their leasing arrangements. The new standard will be effective for the Company on January 1, 2019. The Company is currently evaluating the impact of the adoption of this standard on its financial statements. However, the Company expects the adoption of this accounting guidance to result in an increase in lease assets and a corresponding increase in lease liabilities on its balance sheets.

The Company has reviewed other recent accounting pronouncements and concluded they are either not applicable to the business or that no material effect is expected on the consolidated financial statements as a result of future adoption.

In August 2018, the SEC adopted amendments to certain disclosure requirements in Securities Act Release No. 33-10532, Disclosure Update and Simplification. These amendments eliminate, modify, or integrate into other SEC requirements certain disclosure rules. Among the amendments is the requirement to present an analysis of changes in stockholders—equity in the interim financial statements included in quarterly reports on Form 10-Q. The analysis, which can be presented as a footnote or separate statement, is required for the current and comparative

quarter and year-to-date interim periods. The amendments are effective for the Company in its interim financial statements for the quarter ended March 31, 2019. The Company does not anticipate that the adoption of these SEC amendments will have a material effect to the Company s financial position, results of operations, cash flows or stockholders equity.

## 3. Cash Equivalents and Investments

The amortized cost and fair value of cash equivalents and investments at September 30, 2018 and December 31, 2017 were as follows (in thousands):

	Amortized Cost	Septem Gross Gains	Unre Lo	Fair Value	
Money market fund	\$ 21,152	\$	\$		\$ 21,152
U.S. treasury securities	22,919			(31)	22,888
Commercial paper	39,690				39,690
Asset-backed securities	29,037			(8)	29,029
Corporate debt securities	70,399			(150)	70,249
Total available-for-sale securities	\$ 183,197	\$	\$	(189)	\$ 183,008
Classified as:					
Cash equivalents					\$ 21,126
Short-term investments					149,004
Long-term investments					12,878
Total available-for-sale securities					\$ 183,008
		December 31, 2017 Gross Unrealized			
	Amortized			*	Fair
	Amortized Cost		Unre	*	Fair Value
Money market fund		Gross	Unre	alized	
Money market fund U.S. treasury securities	Cost	Gross Gains	Unre Lo	alized	Value
•	<b>Cost</b> \$ 29,848	Gross Gains	Unre Lo	ealized osses	<b>Value</b> \$ 29,848
U.S. treasury securities	Cost \$ 29,848 29,005	Gross Gains	Unre Lo	ealized osses	<b>Value</b> \$ 29,848 28,953
U.S. treasury securities Commercial paper	Cost \$ 29,848 29,005 46,184	Gross Gains	Unre Lo	ealized osses (52)	<b>Value</b> \$ 29,848 28,953 46,184
U.S. treasury securities  Commercial paper  Corporate debt securities	Cost \$ 29,848 29,005 46,184 27,095	Gross Gains	Unre Lo \$	ealized osses (52) (67)	Value \$ 29,848 28,953 46,184 27,028
U.S. treasury securities  Commercial paper  Corporate debt securities  Total available-for-sale securities	Cost \$ 29,848 29,005 46,184 27,095	Gross Gains	Unre Lo \$	ealized osses (52) (67)	Value \$ 29,848 28,953 46,184 27,028
U.S. treasury securities  Commercial paper  Corporate debt securities  Total available-for-sale securities  Classified as:	Cost \$ 29,848 29,005 46,184 27,095	Gross Gains	Unre Lo \$	ealized osses (52) (67)	Value \$ 29,848 28,953 46,184 27,028 \$ 132,013
U.S. treasury securities  Commercial paper  Corporate debt securities  Total available-for-sale securities  Classified as:  Cash equivalents	Cost \$ 29,848 29,005 46,184 27,095	Gross Gains	Unre Lo \$	ealized osses (52) (67)	Value \$ 29,848 28,953 46,184 27,028 \$ 132,013

Cash equivalents in the tables above exclude cash of \$3.0 million and \$3.2 million as of September 30, 2018 and December 31, 2017, respectively. All available-for-sale securities held as of September 30, 2018 had contractual maturities of less than two years. There have been no significant realized gains or losses on available-for-sale securities for the periods presented. No significant available-for-sale securities held as of September 30, 2018 have

been in a continuous unrealized loss position for more than 12 months. As of September 30, 2018, unrealized losses on available-for-sale investments are not attributed to credit risk and are considered to be temporary. The Company believes that it is more likely than not that investments in an unrealized loss position will be held until maturity or the recovery of the cost basis of the investment. The Company believes it has no other-than-temporary impairments on its securities because it does not intend to sell these securities and it believes it is not more likely than not that it will be required to sell these securities before the recovery of their amortized cost basis. To date, the Company has not recorded any impairment charges on marketable securities related to other-than-temporary declines in market value.

#### 4. Fair Value Measurements

The Company determines the fair value of financial assets and liabilities using three levels of inputs as follows:

Level 1 Inputs which include quoted prices in active markets for identical assets and liabilities.

Level 2 Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3 Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

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## **Recurring Fair Value Measurements**

The Company s financial assets subject to fair value measurements on a recurring basis and the level of inputs used in such measurements were as follows as of September 30, 2018 and December 31, 2017 (in thousands):

		<b>September 30, 2018</b>					
Description	Level 1	Level 2	Level 3	Total			
Money market fund	\$ 21,152	\$	\$	\$ 21,152			
U.S. treasury securities		22,888					
Commercial paper		39,690		39,690			
Asset-backed securities		29,029 29,0					
Corporate debt securities		70,249		70,249			
Total assets	\$ 21,152	\$ 161,856  December	\$ • 31, 2017	\$ 183,008			
Description	Level 1	Level 2	Level 3	Total			
Money market fund	\$ 29,848	\$	\$	\$ 29,848			
U.S. treasury securities		28,953		28,953			
Commercial paper		46,184		46,184			
Corporate debt securities		27,028		27,028			
Total assets	\$ 29,848	\$ 102,165	\$	\$ 132,013			

During the nine months ended September 30, 2018, there were no transfers between Level 1 and Level 2 financial assets. When the Company uses observable market prices for identical securities that are traded in less active markets, the Company classifies its marketable debt instruments as Level 2. When observable market prices for identical securities are not available, the Company prices its marketable debt instruments using non-binding market consensus prices that are corroborated with observable market data; quoted market prices for similar instruments; or pricing models, such as a discounted cash flow model, with all significant inputs derived from or corroborated with observable market data. Non-binding market consensus prices are based on the proprietary valuation models of pricing providers or brokers. These valuation models incorporate a number of inputs, including non-binding and binding broker quotes; observable market prices for identical or similar securities; and the internal assumptions of pricing providers or brokers that use observable market inputs and, to a lesser degree, unobservable market inputs. The Company corroborates non-binding market consensus prices with observable market data using statistical models when observable market data exists. The discounted cash flow model uses observable market inputs, such as LIBOR-based yield curves, prime rate, currency spot and forward rates, and credit ratings.

#### **Other Fair Value Measurements**

The carrying amount and estimated fair value of financial instruments not recorded at fair value at September 30, 2018 and December 31, 2017 were as follows (in thousands):

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	Septen	September 30, 2018		nber 31,
	20			2017
	Carrying	<b>Estimated</b>	Carrying	<b>Estimated</b>
	Amount	Fair Value	Amount	Fair Value
Long-term debt, net (1)	\$ 14,727	\$ 14,867	\$4,676	\$ 4,812

<sup>(1)</sup> Carrying amounts of long-term debt were net of unamortized debt discounts of \$273,000 and \$324,000 as of September 30, 2018 and December 31, 2017, respectively.

The fair value of the Company s long-term debt is estimated using the net present value of future debt payments, discounted at an interest rate that is consistent with market interest rates, which is a Level 2 input.

#### 5. Accrued Liabilities

Accrued liabilities consist of the following (in thousands):

	_	September 30, 2018		December 31, 2017	
Research and development related	\$	7,590	\$	4,962	
Compensation related		2,419		2,345	
Consulting and professional services		1,086		1,012	
Other		632		256	
	\$	11,727	\$	8,575	

### 6. Long-term Debt

On December 28, 2017 (the Closing Date), the Company entered into a Loan and Security Agreement with Hercules Capital, Inc. (Hercules) pursuant to which term loans in an aggregate principal amount of up to \$50.0 million (the Credit Facility) are available to the Company in three tranches, subject to certain terms and conditions. As of September 30, 2018, the Company had borrowed \$15.0 million under the Credit Facility, which is the full amount available under the first tranche. The Company may borrow up to an additional \$10.0 million through December 15, 2018 under the second tranche. The third tranche, which would allow the Company to borrow up to an additional \$25.0 million, would be available upon Hercules approval through June 15, 2019.

Advances under the Credit Facility will bear an interest rate equal to the greater of (i) 8.05% plus the prime rate as reported from time to time in The Wall Street Journal minus 4.75%, and (ii) 8.05%. For advances under the first tranche, the Company will make interest-only payments through July 1, 2020, and will then repay the principal balance and interest on the advances in equal monthly installments after the interest-only period and continuing through December 1, 2021. For advances made under the second and third tranches, the Company will make interest-only payments for the first 30 months, and will then repay the principal balance and interest on the advances in equal monthly installments after the interest-only period with each advance repaid 48 months after it is drawn.

The Company may prepay advances under the Credit Facility, in whole or in part, at any time, subject to a prepayment charge equal to: (a) 2.0% of amounts so prepaid, if such prepayment occurs during the first year following the Closing Date; (b) 1.5% of the amount so prepaid, if such prepayment occurs during the second year following the Closing Date; and (c) 1.0% of the amount so prepaid, if such prepayment occurs after the second year following the Closing Date. The Credit Facility is secured by substantially all of the Company s assets, excluding intellectual property.

In addition, Hercules has the right to participate, in an amount up to \$2.0 million, in any subsequent equity financing broadly marketed to multiple investors in an amount greater than \$20.0 million. The Credit Facility also includes customary affirmative and negative covenants, including restrictions on the payment of dividends, and events of default, the occurrence and continuance of which provide Hercules with the right to demand immediate repayment of all principal and unpaid interest under the Credit Facility, and to exercise remedies against the Company and the collateral securing the Credit Facility. The Company was in compliance with all loan covenants for all periods presented.

The Company will pay an end-of-term charge for each tranche which will occur on the earliest of (i) the applicable tranche maturity date; (ii) the date that the Company prepays all of the outstanding principal under each tranche in full, or (iii) the date the loan payments are accelerated due to an event of default. For the first tranche, the end of term charge is \$0.9 million. In the case of the second and third tranches, the charge is 6.25% of the aggregate amount of the advances applicable to such tranche.

In addition, the Company pays a commitment charge of 1% of the advances made under the Credit Facility, with a minimum charge of \$162,500 paid on the Closing Date. Also, the Company reimbursed Hercules for costs incurred related to the Credit Facility. These charges were recorded as discounts to the carrying value of the loan and are amortized over the term of the loan using the effective interest method.

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As of September 30, 2018, the Company had outstanding borrowings under the Credit Facility of \$14.7 million, net of discounts of \$0.3 million. Future minimum principal payments, which exclude the end of term charge, related to the Credit Facility as of September 30, 2018 are as follows (in thousands):

	<b>Amounts</b>
Year ending December 31:	
Remaining of fiscal year 2018	\$
2019	
2020	4,785
2021	10,215
Total minimum payments	15,000
Less: amount representing debt discount	(273)
Present value of remaining debt payments	14,727
Less: current portion	
-	
Noncurrent portion	\$ 14,727

# 7. Related-Party Transactions Bio-Techne

Bio-Techne Corporation, formerly Techne Corporation, is one of the Company's principal stockholders. In connection with the Company's initial public offering (IPO) in February 2012, Bio-Techne received a warrant with a ten-year term to purchase 150,000 shares of the Company's common stock at an exercise price per share equal to \$20.00 per share, or 200% of the IPO price of its common stock, which was outstanding as of September 30, 2018. The Company had an accounts payable balance due to Bio-Techne for the purchases of research materials of approximately \$460 and \$6,000 as of September 30, 2018 and December 31, 2017, respectively.

## 8. Collaboration and License Agreements Avacopan Agreements

In May 2016, the Company entered into an exclusive collaboration and license agreement with Vifor pursuant to which the Company granted Vifor exclusive rights to commercialize avacopan in Europe and certain other markets (the Avacopan Agreement). Avacopan is the Company s lead drug candidate for the treatment of patients with anti-neutrophil cytoplasmic auto-antibody associated vasculitis (AAV) and other rare diseases. The Avacopan Agreement also provided Vifor with an exclusive option to negotiate during 2016 a worldwide license agreement for one of the Company s other drug candidates, CCX140, an orally-administered inhibitor of the chemokine receptor known as CCR2. In connection with the Avacopan Agreement, the Company received a non-refundable upfront payment of \$85.0 million, comprising \$60.0 million in cash and \$25.0 million in the form of an equity investment to purchase 3,333,333 shares of the Company s common stock at a price of \$7.50 per share.

In February 2017, Vifor and the Company expanded the Vifor territories under the Avacopan Agreement to include all markets outside the United States and China (the Avacopan Amendment). In connection with this February 2017 arrangement, the Company received a \$20.0 million upfront payment for the expanded rights. In June 2018, Vifor and the Company further expanded the Vifor territories under the Avacopan Agreement to provide Vifor with exclusive commercialization rights in China (the Avacopan Letter Agreement). The Company retains control of ongoing and future development of avacopan (other than country-specific development in the licensed territories) and all commercialization rights to avacopan in the United States. In consideration for this June 2018 arrangement, the Company received a \$5.0 million payment for the expanded rights.

Upon achievement of certain regulatory and commercial milestones with avacopan, the Company will receive additional payments of up to \$460.0 million under the Avacopan Agreement. In addition, the Company will receive royalties, with rates ranging from the low teens to the mid-twenties, on future potential net sales of avacopan by Vifor in the licensed territories. In December 2017, the Company achieved a \$50.0 million regulatory milestone when the European Medicines Agency (EMA) validated the Company s Conditional marketing authorisation (CMA) application for avacopan for the treatment of AAV.

The Company identified the following material promises under the Avacopan Agreement, the Avacopan Amendment, and the Avacopan Letter Amendment: (1) the license related to avacopan; (2) the development and regulatory services for the submission of the marketing authorisation application (MAA); and (3) an exclusive option to negotiate a worldwide license agreement for CCX140, which expired in 2016. The Company considered that the license has standalone functionality and is capable of being distinct. However, the Company determined that the license is not distinct from the development and regulatory services within the context of the agreement because Vifor is dependent on the Company to execute the development and regulatory activities in order for Vifor to benefit from the license. As such, the license is combined with the development and regulatory services into a single performance obligation. The exclusive option related to CCX140 is a separate performance obligation and the Company determined that its transaction price is not material. As such, the transaction price under this arrangement will be allocated to the license and the development and regulatory services.

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As of September 30, 2018, the transaction price of \$153.0 million consists of the following:

\$78.0 million upfront payment under the May 2016 Avacopan Agreement. Of the total \$85.0 million upfront payment received under the May 2016 Avacopan Agreement, \$7.0 million was allocated to the issuance of 3,333,333 shares of the Company s common stock valued at \$2.10 per share, the closing stock price on the effective date of the agreement, May 9, 2016. The remaining \$78.0 million was allocated to the transaction price under this arrangement;

\$20.0 million upfront payment under the February 2017 Avacopan Amendment;

\$50.0 million regulatory milestone payment achieved upon the validation of the Company s CMA application by the EMA, for avacopan for the treatment of AAV in December 2017; and

\$5.0 million payment under the Avacopan Letter Agreement.

The Company will re-evaluate the transaction price in each reporting period and as uncertain events are resolved or other changes in circumstances occur.

The Company determined that the combined performance obligation will be performed over the duration of the contract, which began on the effective date of May 9, 2016 and ends upon completion of development and regulatory services. The Company will use a cost-based input method to measure proportional performance and to calculate the corresponding amount of revenue to recognize. The Company believes this is the best measure of progress because other measures do not reflect how the Company transfers its performance obligation to Vifor. In applying the cost-based input method of revenue recognition, the Company measures actual costs incurred relative to budgeted costs to fulfill the combined performance obligation. These costs consist primarily of third-party contract costs. Revenue will be recognized based on actual costs incurred as a percentage of total budgeted costs as the Company completes its performance obligations.

For the three and nine months ended September 30, 2018, the Company recognized \$7.6 million and \$28.8 million of collaboration and license revenue under the Avacopan Agreement, the Avacopan Amendment, and the Avacopan Letter Agreement, respectively.

Prior to the adoption of ASC 606 on January 1, 2018, the Company accounted for its performance obligations under the Avacopan Agreement and Avacopan Amendment as one combined unit of accounting with the upfront fees being recognized over the estimated period of performance. See Note 10. Collaboration and License Agreements Avacopan Agreements in the Company s Annual Report on Form 10-K for the fiscal year ended December 31, 2017, filed with the SEC on March 12, 2018, for further discussion. For the three and nine months ended September 30, 2017, the Company recognized \$6.2 million and \$18.2 million of collaboration and license revenue under the Avacopan Agreement and Avacopan Amendment under ASC 605, respectively.

## CCX140 Agreement

In December 2016, the Company entered into a second collaboration and license agreement with Vifor pursuant to which the Company granted Vifor exclusive rights to commercialize CCX140 (the CCX140 Agreement) in markets

outside the United States and China. CCX140 is an orally-administered inhibitor of the chemokine receptor known as CCR2. The Company retains marketing rights in the United States and China, while Vifor has commercialization rights in the rest of the world. Pursuant to the CCX140 Agreement, the Company is responsible for the clinical development of CCX140 in rare renal diseases and is reimbursed for Vifor s equal share of such development cost. Vifor retains an option to solely develop and commercialize CCX140 in more prevalent forms of chronic kidney disease (CKD). Should Vifor later exercise the CKD option, the Company would receive co-promotion rights for CKD in the United States. Under the terms of the CCX140 Agreement, the Company received a non-refundable upfront payment of \$50.0 million in 2017.

In June 2018, the Company and Vifor entered into a letter agreement to expand Vifor s rights to include the right to exclusively commercialize CCX140 in China (the CCX140 Letter Agreement). In connection with the CCX140 Letter Agreement, the Company received a payment of \$5.0 million. The Company and Vifor also entered into an amendment to the CCX140 Agreement (the CCX140 Amendment) to clarify the timing of certain payments with respect to development funding of the CCX140 program by Vifor, and the Company received a non-refundable payment of \$11.5 million. The Company retains control of ongoing and future development of CCX140 (other than country-specific development in the licensed territories), and all commercialization rights to CCX140 in the United States.

Upon achievement of certain regulatory and commercial milestones with CCX140, the Company will receive additional payments of up to \$625.0 million under the CCX140 Agreement. In addition, the Company will receive tiered royalties, with rates ranging from ten to the mid-twenties, on net sales of CCX140 in the licensed territories.

The Company identified the following material promises under the CCX140 Agreement, the CCX140 Amendment, and CCX140 Letter Agreement: (1) the license related to CCX140; and (2) the development and regulatory services for the submission of the MAA. The Company considered that the license has standalone functionality and is capable of being distinct. However, the

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Company determined that the license is not distinct from the development and regulatory services within the context of the agreement because Vifor is dependent on the Company to execute the development and regulatory activities in order for Vifor to benefit from the license. As such, the license is combined with the development and regulatory services into a single performance obligation.

As of September 30, 2018, the transaction price of \$113.5 million consists of the following:

\$50.0 million upfront payment under the CCX140 Agreement;

\$58.5 million of CCX140 development funding by Vifor; and

\$5.0 million upfront payment under the CCX140 Letter Agreement.

The Company will re-evaluate the transaction price in each reporting period and as uncertain events are resolved or other changes in circumstances occur.

The Company determined that the combined performance obligation will be performed over the duration of the contract, which began on the effective date of December 22, 2016 and ends upon completion of development and regulatory services. The Company will use a cost-based input method to measure proportional performance and to calculate the corresponding amount of revenue to recognize. The Company believes this is the best measure of progress because other measures do not reflect how the Company transfers its performance obligation to Vifor. In applying the cost-based input method of revenue recognition, the Company measures actual costs incurred relative to budgeted costs to fulfill the combined performance obligation. These costs consist primarily of third-party contract costs. Revenue will be recognized based on actual costs incurred as a percentage of total budgeted costs as the Company completes its performance obligations. For the three and nine months ended September 30, 2018, the Company recognized \$1.5 million and \$4.8 million of collaboration and license revenue under the CCX140 Agreement, the CCX140 Amendment, and the CCX140 Letter Agreement, respectively.

Prior to the adoption of ASC 606 on January 2, 2018, the Company accounted for its performance obligations under the CCX140 Agreement as one combined unit of accounting with the upfront fee of \$50.0 million being recognized over the estimated period of performance. See Note 10. Collaboration and License Agreements CCX140 Agreement in the Company s Annual Report on Form 10-K for the fiscal year ended December 31, 2017, filed with the SEC on March 12, 2018, for further discussion. For the three and nine months ended September 30, 2017, the Company recognized \$2.8 million and \$8.0 million of collaboration and license revenue under the CCX140 Agreement under ASC 605, respectively.

The following table presents the contract assets and liabilities for all of the Company s revenue contracts as of the following dates (in thousands):

	September 30, 2018		December 31, 2017	
Contract asset:				
Accounts receivable	\$	336	\$	51,090

Contract liability:		
Deferred revenue (1)	(141,834)	(95,159)

(1) Upon adoption of ASC 606 under the modified retrospective transition method, the Company recognized the cumulative effect of initially applying the new revenue standard of \$47.3 million as an adjustment to the opening balance of accumulated deficit and an increase in deferred revenue. See Note 2. Summary of Significant Accounting Policies Revenue Recognition for a detailed discussion.

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During the three and nine months ended September 30, 2018, the Company recognized the following revenue as a result of changes in the contract asset and the contract liability balances (in thousands):

	Three Months Ended September 30, 2018		 onths Ended ember 30, 2018
Revenue recognized in the period from:			
Amount included in contract liability at the beginning of the period	\$	8,719	\$ 30,960
Performance obligations satisfied (or partially satisfied) in previous periods	\$	(2,604)	\$ (2,867)

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# 9. Equity Incentive Plans Stock Options

During the nine months ended September 30, 2018, the Company had the following activities under its equity incentive plans:

					Weighted	
			**	7 • 1 4 1	Average	
				Veighted	Remaining	
	Available for		Avera	U	iseContractual	Aggregate
	Grant	Shares		Price	Term (in years	Intrinsic Value
Balance at December 31, 2017	2,028,880	10,203,571	\$	7.68		
Shares authorized	1,940,000					
Granted (1)	(2,420,772)	2,191,912		9.92		
Exercised (2)	79,585	(1,439,754)		6.23		
Forfeited and expired	162,686	(162,686)		7.77		
Outstanding at September 30, 2018	1,790,379	10,793,043	\$	8.32	6.50	\$ 49,384,541
	, ,	, ,				. , ,
Vested and expected to vest, net of estimated forfeiture at						
September 30, 2018		10,504,655	\$	8.32	6.43	\$ 48,192,358
Exercisable at September 30, 2018		6,824,579	\$	8.47	5.13	\$ 31,173,388

During the nine months ended September 30, 2018, the activity for restricted stock is summarized as follows:

	Shares	Fai	r Value
Balance at December 31, 2017	508,444	\$	5.79
Granted	228,860		11.32
Vested	(225,904)		5.78
Canceled			
Unvested at September 30, 2018	511,400	\$	8.26

<sup>(1)</sup> The difference between shares granted in the number of shares available for grant and outstanding options represents the RSUs and RSAs granted for the period.

<sup>(2)</sup> Shares presented as available for grant represents shares repurchased for tax withholding upon vesting of RSUs. **Restricted Stock** 

## **Stock-based Compensation**

Total stock-based compensation expense was \$2.8 million and \$8.0 million during the three and nine months ended September 30, 2018, respectively, and \$1.9 million and \$6.8 million during the same periods ended September 30, 2017. As of September 30, 2018, \$16.0 million, \$2.5 million, and \$31,000 of total unrecognized compensation expenses associated with outstanding employee stock options, unvested restricted stock, and the ESPP, net of estimated forfeitures, were expected to be recognized over a weighted-average period of 2.59, 1.33, and 0.12 years, respectively.

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

The following discussion and analysis should be read in conjunction with our financial statements and accompanying notes included in this Quarterly Report on Form 10-Q and the financial statements and accompanying notes thereto and Management s Discussion and Analysis of Financial Condition and Results of Operations included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2017, filed with the Securities and Exchange Commission, or SEC, on March 12, 2018.

#### **Forward-Looking Statements**

This Quarterly Report on Form 10-Q contains forward-looking statements that involve risks and uncertainties. All statements other than statements of historical facts contained in this Quarterly Report on Form 10-Q are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as may, could, will, would, should, expect, plan, aim, anticipate, believe, estimate, predict, or continue or the negative of these terms or other comparable terminology. These forward-looking statements include, but are not limited to, statements about:

the initiation, timing, progress and results of our preclinical studies and clinical trials, and our research and development programs;

our ability to advance drug candidates into, and successfully complete, clinical trials;

the commercialization of our drug candidates;

the implementation of our business model, strategic plans for our business, drug candidates and technology;

the scope of protection we are able to establish and maintain for intellectual property rights covering our drug candidates and technology;

estimates of our expenses, future revenues, capital requirements and our needs for additional financing;

the timing or likelihood of regulatory filings and approvals;

our ability to maintain and establish collaborations or obtain additional government grant funding;

our financial performance; and

developments relating to our competitors and our industry.

These statements relate to future events or to our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Factors that may cause actual results to differ materially from current expectations include, among other things, those included in Item 1A. Risk Factors in our Annual Report on Form 10-K for the fiscal year ended December 31, 2017, filed with the SEC on March 12, 2018 and in this Quarterly Report on Form 10-Q.

Any forward-looking statement in this Quarterly Report on Form 10-Q reflects our current views with respect to future events and is subject to these and other risks, uncertainties and assumptions relating to our operations, results of operations, industry and future growth. Given these uncertainties, you should not place undue reliance on these forward-looking statements. For all forward-looking statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995. 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.

ChemoCentryx®, the ChemoCentryx logo, Traficet and Traficet-EN are our trademarks in the United States, the European Community, Australia and Japan. EnabaLink® and RAM® are our trademarks in the United States. Each of the other trademarks, trade names or service marks appearing in this Quarterly Report on Form 10-Q belongs to its respective holder.

Unless the context requires otherwise, in this Quarterly Report on Form 10-Q the terms ChemoCentryx, we, us and our refer to ChemoCentryx, Inc., a Delaware corporation, and our subsidiary taken as a whole unless otherwise noted.

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#### Overview

ChemoCentryx is a biopharmaceutical company developing new medications targeted at inflammatory disorders, autoimmune diseases and cancer. Each of our drug candidates is designed to selectively block a specific chemoattractant receptor, leaving the rest of the immune system intact. Our drug candidates are small molecules, which are orally administered, and, if approved, could address unmet medical needs, including improved efficacy, and offer significant quality of life benefits, since patients swallow a capsule or pill instead of having to visit a clinic for an infusion or undergo an injection.

In 2016, we executed on our strategy to form an alliance with a partner that could provide upfront fees and milestone payments to support the clinical development of our two leading drug candidates, avacopan and CCX140, to registration and pay us royalties upon sales in international markets, while we develop our own commercial infrastructure to sell directly in the United States.

To help communicate the breadth of our drug discovery platform, we have segmented our pipeline into early stage and late stage drug candidates.

#### **Late Stage Drug Candidates**

We have chosen to focus initially on orphan indications, where drug candidates tend to enjoy a faster path to market and better reimbursement. Our leading drug candidates address areas of clear unmet need, where the current standard of care, or SOC, is insufficient to halt progression of the disease and/or where today s treatment options come with serious side effects, such as those which accompany the prolonged use of steroids:

#### Avacopan (CCX168) Complement Inhibition in Orphan Diseases

Avacopan (formerly CCX168) is an orally-administered complement inhibitor targeting the C5a receptor, or C5aR, and is being developed for orphan diseases, including (i) anti-neutrophil cytoplasmic auto-antibody associated vasculitis, or AAV, a devastating autoimmune disease that damages blood vessels and can lead to kidney failure; (ii) complement 3 glomerulopathy, or C3G, a debilitating disease that can lead to kidney failure; and (iii) hidradenitis suppurativa, or HS, a chronic, inflammatory, debilitating skin disease characterized by recurrent, painful, nodules and abscesses, ultimately leading to the formation of draining fistulas (also known as sinus tracts) as well as scarring.

Avacopan has been granted orphan drug designation by the U.S. Food and Drug Administration, or FDA, for the treatment of AAV and C3G and by the European Medicines Agency, or EMA, for the treatment of C3G and microscopic polyangiitis and granulomatosis with polyangiitis, both forms of AAV. Additionally, avacopan has been granted PRIority MEdicines, or PRIME, designation from the EMA, to expedite its clinical development, and to potentially accelerate its marketing authorization.

Following completion of two Phase II clinical trials in patients with AAV, in which avacopan was well-tolerated and provided effective steroid-free control of the disease, we launched the Phase III ADVOCATE trial in December 2016. The FDA and the EMA concurred with the design of the study. ADVOCATE is a randomized, double-blind two-arm study which enrolled 316 patients at approximately 200 sites in the United States, Canada, Europe, Australia, New Zealand and Japan. Patient enrollment of the Phase III ADVOCATE trial was completed in July 2018 and we expect to report topline data from this study in the fourth quarter of 2019. Additionally, we launched a registration-supporting clinical trial to study avacopan for the treatment of patients with C3G and plan to initiate a large placebo-controlled Phase II clinical study for the treatment of patients with HS in late 2018.

# CCX140 Chronic and Orphan Kidney Diseases

CCX140, an orally-administered inhibitor of the chemokine receptor known as CCR2, has been in development for diabetic nephropathy, or DN, a form of chronic kidney disease, or CKD, and is now being developed for focal segmental glomerulosclerosis, or FSGS, a rare renal disease characterized by progressive proteinuria, excess protein in the urine, and impaired renal function. CCX140 has been granted orphan drug designation by the FDA for the treatment of FSGS.

A global Phase II clinical trial of CCX140 in patients with DN met its primary endpoint by demonstrating that CCX140 given orally once daily added to a SOC renin-angiotensin-aldosterone system inhibitor treatment resulted in a statistically significant reduction in proteinuria, beyond that achieved with SOC alone, with the most pronounced effect shown in the highest proteinuric patients. Based on the safety and efficacy data related to reduction in proteinuria observed in the Phase II trial in DN, we launched our clinical development program of CCX140 for the treatment of patients with primary FSGS, for which there are currently no FDA-approved treatments.

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## **Kidney Health Alliance with Vifor**

In May 2016, we announced a partnership, which we refer to as the Avacopan Agreement, with Vifor (International) Ltd., and/or its affiliates, or collectively, Vifor, a European-based world leader specializing in kidney disease. While under this agreement we retained all rights to the United States and China, we granted Vifor exclusive commercialization rights to avacopan in Europe and certain other international markets. In December 2016, we entered into an additional agreement with Vifor, which we refer to as the CCX140 Agreement, relating to CCX140, our other late stage drug candidate. Under this second agreement, we again retained all rights to the United States and China and we granted Vifor exclusive worldwide commercialization rights outside of the United States and China. In February 2017, we announced a further agreement with Vifor that harmonized the geographic commercialization rights underlying the agreements for both drug candidates, which we refer to as the Avacopan Amendment. In June 2018, we entered into additional agreements with Vifor to further expand Vifor s exclusive commercialization rights to include China under the Avacopan Agreement and the CCX140 Agreement.

We have secured \$215 million in upfront cash payments and milestones pursuant to our agreements with Vifor and are eligible for additional substantial milestone payments. Through our alliance, we maintain the commercialization rights to avacopan and CCX140 in the United States, and also retain control of the clinical development programs for orphan renal disease. Vifor gained the exclusive commercialization rights for all other international markets, and is obligated to pay us tiered royalties, with rates ranging from ten to the mid-twenties, on potential net sales.

At a future time defined in the CCX140 Agreement, Vifor has an option to solely develop and commercialize CCX140 in more prevalent forms of CKD. Should Vifor later exercise the CKD option, we would receive co-promotion rights for CKD in the United States, and we estimate that the clinical development and registration process for CKD would end at approximately the same time as Orphan Drug exclusivity.

# **Early Stage Drug Candidates**

While we have focused initially on kidney disease, our target specific and selective approach designed to stop the spread of inflammatory disease-inducing cells shows promise in other disease areas. Over time we plan to bring forward drug candidates to treat other inflammatory and autoimmune disorders, as well as cancer, where our drug candidate CCX872 has shown promise in a Phase Ib trial for advanced pancreatic cancer. We expect that our ability to do so will grow as we increase our scale and to the extent that we start to earn revenues and royalties from the commercialization of our late stage kidney disease franchise.

Since commencing our operations in 1997, our efforts have focused on research, development and the advancement of our drug candidates into and through clinical trials. As a result, we have incurred significant losses. We have funded our operations primarily through the sale of convertible preferred and common stock, contract revenue under our collaborations, government contracts and grants and borrowings under equipment financing arrangements.

As of September 30, 2018, we had an accumulated deficit of \$363.7 million. We expect to continue to incur net losses as we develop our drug candidates, expand clinical trials for our drug candidates currently in clinical development, expand our research and development activities, expand our systems and facilities, seek regulatory approvals and engage in commercialization preparation activities in anticipation of FDA approval of our drug candidates. In addition, if a product is approved for commercialization, we will need to expand our organization. Significant capital is required to launch a product and many expenses are incurred before revenues are received. We are unable to predict the extent of any future losses or when we will become profitable, if at all.

# Critical Accounting Policies and Significant Judgments and Estimates

There have been no material changes in our critical accounting policies during the nine months ended September 30, 2018, as compared to those disclosed in Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operations Critical Accounting Policies and Significant Judgments and Estimates in our Annual Report on Form 10-K for the fiscal year ended December 31, 2017, filed with the SEC on March 12, 2018, other than the following:

Effective January 1, 2018, we adopted Accounting Standards Codification, or ASC, Topic 606, *Revenue from Contracts with Customers*, or ASC 606, using the modified retrospective transition method. This standard applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments. Under ASC 606, we recognize revenue when our customer obtains control of promised goods or services, in an amount that reflects the consideration which we expect to receive in exchange for those goods or services. To determine revenue recognition for arrangements that we determine are within the scope of ASC 606, we perform the following five steps: (i) identify the contract(s)

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with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) we satisfy a performance obligation. We only apply the five-step model to contracts when it is probable that we will collect the consideration we are entitled to in exchange for the goods or services we transfer to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, we assess the goods or services promised within each contract and determine those that are performance obligations and assess whether each promised good or service is distinct. We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

We enter into corporate collaborations under which we may obtain upfront license fees, research and development funding and development and regulatory and commercial milestone payments and royalty payments. Our performance obligations under these arrangements may include licenses of intellectual property, distribution rights, research and development services, delivery of manufactured product, and/or participation on joint steering committees.

Licenses of intellectual property: If the license to our intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, we recognize revenue from upfront license fees allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license. For licenses that are bundled with other promises, we utilize judgement to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring proportional performance for purposes of recognizing revenue from non-refundable, up-front fees. We evaluate the measure of proportional performance each reporting period and, if necessary, adjust the measure of performance and related revenue recognition.

Milestone payments: At the inception of each arrangement that includes development, regulatory or commercial milestone payments, we evaluate whether the milestones are considered probable of being reached and estimate the amount to be included in the transaction price. ASC 606 suggests two alternatives to use when estimating the amount of variable consideration: the expected value method and the most likely amount method. Under the expected value method, an entity considers the sum of probability-weighted amounts in a range of possible consideration amounts. Under the most likely amount method, an entity considers the single most likely amount in a range of possible consideration amounts. Whichever method is used, it should be consistently applied throughout the life of the contract; however, it is not necessary for us to use the same approach for all contracts. We expect to use the most likely amount method for development and regulatory milestone payments. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within our or the licensee s control, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. The transaction price is then allocated to each performance obligation on a relative stand-alone selling price basis. We recognize revenue as or when the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, we re-evaluate the probability or achievement of each such milestone and any related constraint, and if necessary, adjust our estimates of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenues and earnings in the period of adjustment.

Commercial milestones and royalties: For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and in which the license is deemed to be the predominant item to which the royalties relate, we recognize revenue when the related sales occur. To date, we have not recognized any royalty revenue resulting from our collaboration arrangements.

Up-front payments and fees are recorded as deferred revenue upon receipt or when due, and may require deferral of revenue recognition to a future period until we perform our obligations under these arrangements. Amounts payable to

us are recorded as accounts receivable when our right to consideration is unconditional.

## **Results of Operations**

### Revenue

We have not generated any revenue from product sales. For the periods presented, our revenue was derived from collaboration and license revenue related to the Avacopan Agreement and CCX140 Agreement, in each case, as amended, and the related letter agreements. Total revenues for the periods as compared to the same periods in the prior year were as follows (in thousands):

	Three Mon	ths Ended	Nine Mont	ths Ended
	September 30,		September 30,	
	2018	2017	2018	2017
Collaboration and license revenue	\$ 8,975	\$ 9,029	\$ 33,543	\$ 26,196
Dollar increase (decrease)	\$ (54)		\$ 7,347	
Percentage increase (decrease)	(1)%		28%	

On January 1, 2018, we adopted ASC 606 under the modified retrospective transition method and recognized the cumulative effect of initially applying the new revenue standard of \$47.3 million as an adjustment to the opening balance of accumulated deficit and an increase in deferred revenue. Revenue recognized prior to January 1, 2018 has not been restated and continues to be reported under the accounting standards in effect for those periods.

For the three and nine months ended September 30, 2018, we use a cost-based input method to measure proportional performance and to calculate the corresponding amount of revenue to recognize. In applying the cost-based input method of revenue recognition, we measure actual costs incurred relative to budgeted costs to fulfill the combined performance obligation. These costs consist primarily of third-party contract costs. Revenue is recognized based on actual costs incurred as a percentage of total budgeted costs as we complete our performance obligations.

Before the adoption of ASC 606, we recognized upfront fees straight-line under ASC 605 over the estimated performance period and recognized milestone when earned under the milestone method of accounting. For the three and nine months ended September 30, 2017, revenue recognized represents amortization of the upfront license fee commitments from Vifor pursuant to the Avacopan Agreement and CCX140 Agreement, in each case, as amended.

## Research and development expenses

Research and development expenses represent costs incurred to conduct basic research, the discovery and development of novel small molecule therapeutics, development of our suite of proprietary drug discovery technologies, preclinical studies and clinical trials of our drug candidates. We recognize all research and development expenses as they are incurred. These expenses consist primarily of salaries and related benefits, including stock-based compensation, third-party contract costs relating to research, formulation, manufacturing, preclinical study and clinical trial activities, laboratory consumables, and allocated facility costs. Total research and development expenses for the three and nine months ended September 30, 2018, as compared to the same periods in the prior year, were as follows (in thousands):

Three Months Ended September 30,

Nine Months Ended September 30,

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	2018	2017	2018	2017
Research and development expenses	\$ 15,135	\$ 12,315	\$47,636	\$ 36,614
Dollar increase	\$ 2,820		\$ 11,022	
Percentage increase	23%		30%	

The increase in research and development expenses from 2017 to 2018 for the three month period was primarily due to the advancement of the avacopan ADVOCATE Phase III pivotal trial which completed enrollment in July 2018. The increase in research and development expenses from 2017 to 2018 for the nine month period was primarily due to initiation and patient enrollment of the avacopan Phase II clinical trial in patients with C3G and start-up, initiation and patient enrollment of the CCX140 Phase II clinical trials in patients with FSGS. Continued patient enrollment of the avacopan Phase III ADVOCATE trial in patients with AAV also contributed to the increase in research and development expenses for the nine month period.

The following table summarizes our research and development expenses (in thousands):

	E	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017	
Phase I	\$ 104	\$ 218	\$ 1,183	\$ 962	
Phase II	3,536	3,760	11,554	6,476	
Phase III	7,480	5,067	23,171	19,069	
Research and drug discovery	4,015	3,270	11,728	10,107	
Total R&D	\$ 15,135	\$ 12,315	\$47,636	\$ 36,614	

We track development expenses that are directly attributable to our clinical development candidates by phase of clinical development. Such development expenses include third-party contract costs relating to formulation, manufacturing, preclinical studies and clinical trial activities. We allocate research and development salaries, benefits or indirect costs to our development candidates and we have included such costs in research and development expenses. All remaining research and development expenses are reflected in Research and drug discovery which represents early stage drug discovery programs. Such expenses include allocated employee salaries and related benefits, stock-based compensation, consulting and contracted services to supplement our in-house laboratory activities, laboratory consumables and allocated facility costs associated with these earlier stage programs.

At any given time, we typically have several active early stage research and drug discovery projects. Our internal resources, employees and infrastructure are not directly tied to any individual research or drug discovery project and are typically deployed across multiple projects. As such, we do not maintain information regarding these costs incurred for our early stage research and drug discovery programs on a project specific basis. We expect our research and development expenses to increase as we advance our development programs further and increase the number and size of our clinical trials. The process of conducting preclinical studies and clinical trials necessary to obtain regulatory approval is costly and time consuming. We or our partners may never succeed in achieving marketing approval for any of our drug candidates. The probability of success for each drug candidate may be affected by numerous factors, including preclinical data, clinical data, competition, manufacturing capability and commercial viability. Our strategy includes entering into additional partnerships with third parties for the development and commercialization of some of our independent drug candidates.

The successful development of our drug candidates is highly uncertain and may not result in approved products. Completion dates and completion costs can vary significantly for each drug candidate and are difficult to predict for each product. Given the uncertainty associated with clinical trial enrollments and the risks inherent in the development process, we are unable to determine the duration and completion costs of the current or future clinical trials of our drug candidates or if, or to what extent, we will generate revenues from the commercialization and sale of any of our drug candidates. We anticipate we will make determinations as to which programs to pursue and how much funding to direct to each program on an ongoing basis in response to the scientific and clinical success of each drug candidate, as well as ongoing assessment as to each drug candidate s commercial potential. We will need to raise additional capital or may seek additional strategic alliances in the future in order to complete the development and commercialization of our drug candidates, including avacopan, CCX140 and CCX872.

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## General and administrative expenses

Total general and administrative expenses for the three and nine months ended September 30, 2018, as compared to the same periods in the prior year, were as follows (in thousands):

		Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017	
General and administrative expenses	\$ 5,373	\$ 3,624	\$ 14,781	\$ 12,381	
Dollar increase	\$ 1,749		\$ 2,400		
Percentage increase	48%		19%		

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

The increases from 2017 to 2018 for the three and nine month periods were primarily due to higher employee-related expenses, including those associated with our commercialization planning efforts, and higher professional fees.

We anticipate that our general and administrative expenses will increase substantially in the future primarily because of increased pre-commercial activities and personnel costs to support the potential launch of avacopan for the treatment of AAV in the United States.

## Other income, net

Other income, net primarily consists of interest income earned on our marketable securities. Total other income, net for the three and nine month periods, as compared to the same periods in the prior year, were as follows (in thousands):

			Nine N	<b>Months</b>	
	Three M	Ionths Ended	En	ded	
	Septo	September 30,		September 30,	
	2018	2017	2018	2017	
Interest income	\$ 1,066	\$ 350	\$ 2,471	\$ 1,003	
Interest expense	(423	5)	(778)		
Total other income, net	\$ 643	\$ 350	\$ 1,693	\$ 1,003	
Dollar increase	\$ 293	}	\$ 690		
Percentage increase	84	-%	69%		

The increases in total other income, net from 2017 to 2018 for the three and nine month periods were primarily due to increased interest income resulting from higher cash and investment balances and a higher return on the investment portfolio in 2018, partially offset by interest expense related to the loan and security agreement with Hercules Capital,

Inc., or the Credit Facility. We expect that interest expense to increase in the future if we borrow additional amounts under the Credit Facility or if interest rates continue to rise.

# **Liquidity and Capital Resources**

As of September 30, 2018, we had approximately \$186.0 million in cash, cash equivalents and investments. The following table shows a summary of our cash flows for the nine months ended September 30, 2018 and 2017 (in thousands):

	Nine Montl	Nine Months Ended		
	Septemb	er 30,		
	2018	2017		
Cash provided by (used in)				
Operating activities	\$ 31,745	\$ (917)		
Investing activities	\$ (66,444)	\$4,473		
Financing activities	\$ 18,793	\$2,381		

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Operating activities. Net cash provided by operating activities was \$31.7 million for the nine months ended September 30, 2018, compared to net cash used in operating activities of \$0.9 million for the same period in 2017. This increase was primarily due to changes in working capital items, which was partially offset by a higher net loss. For the nine months ended September 30, 2018, changes in working capital included the receipt of \$50.0 million milestone payment in connection with the Avacopan Agreement, \$10.0 million upfront commitment under the Avacopan Amendment, \$10.0 million of aggregate payments under the June 2018 Avacopan Letter Agreement and the CCX140 Letter Agreement and \$11.5 million payment for CCX140 development funding by Vifor. For the same period in 2017, changes in working capital included \$30.0 million from the first installment of the upfront commitment under the CCX140 Agreement.

*Investing activities*. Net cash used in investing activities for the periods presented primarily relate to the purchases of investments and maturities of investments used to fund the day-to-day needs of our business.

Financing activities. Net cash provided by financing activities was \$18.8 million for the nine months ended September 30, 2018, compared to \$2.4 million for the same period in 2017. Net cash provided by financing activities for both periods presented included proceeds from the exercise of stock options and stock purchases from contributions to our 2012 Employee Stock Purchase Plan, and cash used for tendered ChemoCentryx, Inc. common stock to satisfy employee tax withholding requirements upon vesting of restricted stock units. For the nine months ended September 30, 2018, net cash provided by financing activities also included \$10.0 million received under the Credit Facility.

In December 2017, we entered into the Credit Facility with Hercules, under which we may borrow up to \$50.0 million in three tranches, subject to certain terms and conditions. Under the first tranche, we may borrow up to \$15.0 million, of which we borrowed \$5.0 million in December 2017 and \$10.0 million in June 2018. Upon satisfaction of certain milestones, the second tranche is available under the Credit Facility, which would allow us to borrow up to an additional \$10.0 million through December 15, 2018. The third tranche, which would allow us to borrow up to an additional \$25.0 million, will be available upon Hercules approval through June 15, 2019. We intend to use the net proceeds from the Credit Facility for general corporate purposes, which may include the repayment of debt and working capital. We were in compliance with all loan covenants as of September 30, 2018. See Note 6. Long-term Debt in the Notes to Condensed Consolidated Financial Statements included in Item 1 of this Quarterly Report on Form 10-Q for additional information regarding our borrowings.

As of September 30, 2018, we had approximately \$186.0 million in cash, cash equivalents and investments. We believe that our available cash, cash equivalents and investments will be sufficient to fund our anticipated level of operations for at least 12 months following our financial statement issuance date, November 8, 2018. However, our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially.

Our future capital requirements are difficult to forecast and will depend on many factors, including:

the terms and timing of any other collaborative, licensing and other arrangements that we may establish;

the initiation, progress, timing and completion of preclinical studies and clinical trials for our drug candidates and potential drug candidates;

the number and characteristics of drug candidates that we pursue;

the progress, costs and results of our clinical trials;

the outcome, timing and cost of regulatory approvals;

delays that may be caused by changing regulatory approvals;

the cost and timing of hiring new employees to support continued growth;

the costs involved in filing and prosecuting patent applications and enforcing and defending patent claims;

the cost and timing of procuring clinical and commercial supplies of our drug candidates;

the cost and timing of establishing sales, marketing and distribution capabilities; and

the extent to which we acquire or invest in businesses, products or technologies.

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## **Contractual Obligations and Commitments**

Except for the additional borrowing of \$10.0 million under the Credit Facility in June 2018, there have been no material changes outside the ordinary course of our business to the contractual obligations we reported in our Annual Report on Form 10-K for the fiscal year ended December 31, 2017, filed with the SEC on March 12, 2018. See Note 6. Long-term Debt in the Notes to Condensed Consolidated Financial Statements included in Item 1 of this Quarterly Report on Form 10-Q for additional information regarding our borrowings.

## **Recent Accounting Pronouncements**

See Note 2. Summary of Significant Accounting Policies in the Notes to Condensed Consolidated Financial Statements included in Item 1 of this Quarterly Report on Form 10-Q for a full description of recently issued accounting pronouncements, including the respective expected dates of adoption and effects on our consolidated financial position and results of operations.

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

Our market risks at September 30, 2018 have not changed significantly from those discussed in Item 7A. Quantitative and Qualitative Disclosures About Market Risk of our Annual Report on Form 10-K for the fiscal year ended December 31, 2017, filed with the SEC on March 12, 2018, other than the following:

Advances under the Credit Facility will bear an interest rate equal to the greater of (i) 8.05% plus the prime rate as reported from time to time in The Wall Street Journal minus 4.75%, and (ii) 8.05%. We are affected by market risk exposure primarily through the effect of changes in interest rates on amounts payable under the Credit Facility. At September 30, 2018, borrowings under the Credit Facility totaled \$15.0 million with an interest rate of 8.55%. The Company will make interest-only payments through July 1, 2020, and will then repay the principal balance and interest on the advances in equal monthly installments after the interest-only period and continuing through December 1, 2021. If the amount outstanding under the Credit Facility remained at this level for an entire year and interest rate increased by 1%, our annual interest expense would increase by an additional \$150,000. See Note 6. Long-term Debt in the Notes to Condensed Consolidated Financial Statements included in Item 1 of this Quarterly Report on Form 10-Q for additional information regarding our borrowings.

# Item 4. Controls and Procedures Conclusions Regarding the Effectiveness of Disclosure Controls and Procedures

As of September 30, 2018, management, with the participation of our Disclosure Committee, performed an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act. Our disclosure controls and procedures are designed to ensure that information required to be disclosed in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission s rules and forms, and that such information is accumulated and communicated to our management, including the Chief Executive Officer and the Chief Financial and Administrative Officer, to allow timely decisions regarding required disclosures.

Any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objective. Based on this evaluation, our Chief Executive Officer and Chief Financial and Administrative Officer concluded that, as of September 30, 2018, the design and operation of our disclosure controls and procedures were effective.

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

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

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## PART II. OTHER INFORMATION

## **Item 1. Legal Proceedings**

Not Applicable.

### **Item 1A. Risk Factors**

There have been no material changes to the risk factors included in Item 1A. Risk Factors in our Annual Report on Form 10-K for the fiscal year ended December 31, 2017, filed with the SEC on March 12, 2018, other than the risk factors below.

## **Risks Related to Our Business**

The development of new drugs is a highly risky undertaking which involves a lengthy process, and our drug discovery and development activities therefore may not result in products that are approved for marketing and sale by the applicable regulatory authorities on the time schedule we have planned, or at all, or result in substantial payments to us.

Our drug candidates are in the early stages of drug discovery or clinical trials and are prone to the risks of failure inherent in drug development. As of September 30, 2018, nine of our drug candidates have been tested in human beings. We will need to conduct significant additional preclinical studies and clinical trials before we can demonstrate that any of our drug candidates is safe and effective to the satisfaction of the FDA, the EMA and other regulatory authorities. Preclinical studies and clinical trials are expensive and uncertain processes that take years to complete. For example, we incurred significant expenses related to the IND filing and the completed single ascending dose Phase I clinical trial for CCX915, our first generation CCR2 drug candidate, which did not advance into Phase II clinical trials because its pharmacokinetic, or PK, properties in humans did not meet our expectations. Failure can occur at any stage of the process, and we cannot assure you that any of our drug candidates will demonstrate safety and efficacy in clinical trials or result in commercially successful products. For example, we have a Conditional Marketing Authorization, or CMA, application pending for avacopan for the treatment of patients with anti-neutrophil cytoplasmic AAV, which is under review by the EMA s Committee for Medicinal Products for Human Use, or CHMP, and for which, as part of its standard review protocol, we have received the CHMP s Day 120 list of questions. These questions raise a number of issues with respect to our CMA application within the categories of quality, clinical and non-clinical that fit within the CHMP s categorization scheme as major objections and as such will need to be resolved to the satisfaction of the CHMP before it would be able to make a recommendation for conditional marketing authorization in the European Union. While we believe that the issues raised by the CHMP in its Day 120 list of questions are all potentially addressable and that we will be able to provide adequate responses, we can provide no assurance regarding if or when we will be able to address these issues to the satisfaction of the CHMP, whether we will ultimately be successful in obtaining a CMA or, if successful, that the indication for which we ultimately receive a CMA will not be narrower than the indication for which we are currently seeking conditional approval.

We cannot assure you that our ongoing clinical trials or any future clinical trial of any of our other drug candidates will be completed on schedule, or at all, or whether our planned clinical trials will start in a timely manner. The commencement of our planned clinical trials could be substantially delayed or prevented by a number of factors, including:

delays or failures in obtaining sufficient quantities of the active pharmaceutical ingredient, or API, and/or drug product;

delays or failures in reaching agreement on acceptable clinical trial agreement terms or clinical trial protocols with prospective sites;

delays or failures in obtaining institutional review board, or IRB, or ethics committee approval to conduct a clinical trial at a prospective site;

the need to successfully complete, on a timely basis, preclinical safety pharmacology or toxicology studies;

the limited number of, and competition for, suitable sites to conduct the clinical trials;

the limited number of, and competition for, suitable patients for enrollment in the clinical trials; and

delays or failures in obtaining regulatory approval to commence a clinical trial.

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The completion of our clinical trials could also be substantially delayed or prevented by a number of factors, including:

slower than expected rates of patient recruitment and enrollment;

failure of patients to complete the clinical trials;

failure of our third party vendors to timely or adequately perform their contractual obligations relating to the clinical trials;

inability or unwillingness of patients or medical investigators to follow our clinical trial protocols;

inability to monitor patients adequately during or after treatment;

termination of the clinical trials by one or more clinical trial sites;

unforeseen safety issues;

lack of efficacy demonstrated during clinical trials;

lack of adequate funding to continue the clinical trials;

the need for unexpected discussions with the FDA, EMA or other foreign regulatory agencies regarding the scope or design of our clinical trials or the need to conduct additional trials;

unforeseen delays by the FDA, EMA or other foreign regulatory agencies after submission of our results;

an unfavorable FDA or EMA inspection of our contract manufacturers of API or drug product; and

inspection of the clinical trial preliminary results, operations or trial sites by the FDA or other regulatory authorities resulting in the imposition of a clinical hold.

Any failure or significant delay in completing clinical trials for our drug candidates would harm the commercial prospects for our drug candidates and adversely affect our financial results.

Additionally, changes in regulatory requirements and guidance may occur and we may need to amend clinical trial protocols to reflect these changes. Amendments may require us to resubmit our clinical trial protocols to regulatory agencies and ethics committees for reexamination, which may impact the costs, timing or successful completion of a clinical trial. If we experience delays in completion of, or if we terminate, any of our clinical trials, the commercial prospects for our drug candidates may be harmed and our ability to generate product revenues will be delayed. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of a drug candidate.

Our clinical trials may be suspended or terminated at any time for a number of safety-related reasons. For example, we may voluntarily suspend or terminate our clinical trials if at any time we believe that our drug candidates present an unacceptable safety risk to the clinical trial patients. In addition, IRBs or regulatory agencies may order the temporary discontinuation or termination of our clinical trials at any time if they believe that the clinical trials are not being conducted in accordance with applicable regulatory requirements, including if they present an unacceptable safety risk to patients. Administering any drug candidate to humans may produce undesirable side effects. The existence of undesirable side effects resulting from our drug candidates could cause us or regulatory authorities, such as the FDA, to interrupt, delay or halt clinical trials of our drug candidates and could result in the FDA or other regulatory agencies denying further development or approval of our drug candidates for any or all targeted indications.

Further, chemokine receptors and chemoattractant receptors are a novel class of targets. As a result, we may experience unforeseen adverse side effects with our existing and future drug candidates, including CCX140 and avacopan. Although we have not observed significant harmful side effects in prior studies of our drug candidates, later trials could reveal such side effects. The PK profile of preclinical studies may not be indicative of results in any clinical trial. For example, prior to commencing our preclinical studies of our CCX140 drug candidate, we studied another drug candidate that targeted CCR2, which we abandoned after PK results were not as favorable in humans as in earlier preclinical animal studies. We have not completed studies on the long-term effects associated with the use of our drug candidates. Completion of studies of these long-term effects may be required for regulatory approval and would delay our introduction of our drug candidates into the market. These studies could also be required at any time after regulatory approval of any of our drug candidates. Absence of long-term data may also limit the approved uses of our products, if any, to short-term use. Some or all of our drug candidates may prove to be unsafe for human use.

In addition, we are party to collaboration and license agreements with Vifor, the Avacopan Agreement and the CCX140 Agreement, which require Vifor to make substantial payments to us upon achievement of certain regulatory and commercial milestones. However, Vifor has the right to terminate the Avacopan Agreement and the CCX140 Agreement at its convenience, in which case we would not receive such payments.

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# **Item 2.** Unregistered Sales of Equity Securities and Use of Proceeds Not Applicable.

# Item 3. Defaults Upon Senior Securities

Not Applicable.

# Item 4. Mine Safety Disclosures

Not Applicable.

# Item 5. Other Information

Not Applicable.

# Item 6. Exhibits

A list of exhibits is set forth on the Exhibit Index immediately preceding the signature page of this Quarterly Report on Form 10-Q, and is incorporated herein by reference.

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# **EXHIBIT INDEX**

Exhibit Number	Description
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101	The following information from the Registrant s Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2018, formatted in XBRL (Extensible Business Reporting Language): (i) Condensed Consolidated Balance Sheets, (ii) Condensed Consolidated Statements of Operations, (iii) Condensed Consolidated Statements of Comprehensive Loss, (iv) Condensed Consolidated Statements of Cash Flows, and (v) the Notes to Condensed Consolidated Financial Statements.

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# **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.

## CHEMOCENTRYX, INC.

Date: November 8, 2018 /s/ Thomas J. Schall, Ph.D.

Thomas J. Schall, Ph.D. President and Chief Executive Officer (Principal Executive Officer)

Date: November 8, 2018 /s/ Susan M. Kanaya

Susan M. Kanaya Executive Vice President, Chief Financial and Administrative Officer and Secretary (Principal Financial Officer)

Date: November 8, 2018 /s/ Pui San Kwan

Pui San Kwan Vice President, Finance (Principal Accounting Officer)

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