

**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, 2021

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
Incorporation or Organization)

835 Industrial Road, Suite 600
San Carlos, California
(Address of Principal Executive Offices)

94-3254365
(I.R.S. Employer
Identification No.)

94070
(Zip Code)

(650) 210-2900

(Registrant's Telephone Number, Including Area Code)

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

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

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

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

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

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

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

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

The number of outstanding shares of the registrant's common stock, par value \$0.001 per share, as of October 29, 2021 was 70,031,462.

CHEMOCENTRYX, INC.

QUARTERLY REPORT ON FORM 10-Q
For the quarterly period ended September 30, 2021

Table of Contents

PART I. FINANCIAL INFORMATION

	<u>Page</u>
Item 1. Financial Statements (Unaudited)	3
Condensed Consolidated Balance Sheets – September 30, 2021 and December 31, 2020	3
Condensed Consolidated Statements of Operations – Three and Nine Months Ended September 30, 2021 and 2020	4
Condensed Consolidated Statements of Comprehensive Loss – Three and Nine Months Ended September 30, 2021 and 2020	5
Condensed Consolidated Statements of Stockholders' Equity – Three and Nine Months Ended September 30, 2021 and 2020	6
Condensed Consolidated Statements of Cash Flows – Nine Months Ended September 30, 2021 and 2020	8
Notes to Condensed Consolidated Financial Statements	9
Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations	20
Item 3. Quantitative and Qualitative Disclosures About Market Risk	26
Item 4. Controls and Procedures	26
<u>PART II. OTHER INFORMATION</u>	
Item 1. Legal Proceedings	28
Item 1A. Risk Factors	28
Item 2. Unregistered Sales of Equity Securities and Use of Proceeds	43
Item 3. Defaults Upon Senior Securities	43
Item 4. Mine Safety Disclosures	43
Item 5. Other Information	43
Item 6. Exhibits	43
<u>EXHIBIT INDEX</u>	44
<u>SIGNATURES</u>	45

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

**CHEMOCENTRYX, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS**

(in thousands, except share and par value data)

	September 30, 2021 (unaudited)	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	\$ 93,726	\$ 32,297
Short-term investments	175,701	404,273
Accounts receivable from related party	20,005	32
Accounts receivable, other	52	137
Prepaid expenses and other current assets	3,899	4,831
Total current assets	293,383	441,570
Property and equipment, net	33,002	25,160
Long-term investments	102,030	23,800
Operating lease right-of-use assets	25,035	26,911
Other assets	1,395	1,458
Total assets	<u>\$ 454,845</u>	<u>\$ 518,899</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 4,414	\$ 12,875
Accrued and other current liabilities	25,984	19,794
Long-term debt, current	14,013	6,302
Deferred revenue from related party	15,618	12,587
Total current liabilities	60,029	51,558
Long-term debt, net	9,560	18,099
Non-current deferred revenue from related party	21,423	24,000
Non-current lease liabilities	46,672	38,671
Other non-current liabilities	1,267	958
Total liabilities	138,951	133,286
Commitments (Note 7)		
Stockholders' equity:		
Preferred stock, \$0.001 par value, 10,000,000 shares authorized; no shares issued and outstanding	—	—
Common stock, \$0.001 par value, 200,000,000 shares authorized; 69,937,510 and 69,452,466 shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively	70	69
Additional paid-in capital	892,446	870,788
Note receivable	(16)	(16)
Accumulated other comprehensive (loss) income	(37)	114
Accumulated deficit	(576,569)	(485,342)
Total stockholders' equity	315,894	385,613
Total liabilities and stockholders' equity	<u>\$ 454,845</u>	<u>\$ 518,899</u>

See accompanying notes.

CHEMOCENTRYX, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Revenue:				
Collaboration and license revenue from related party	\$ 17,691	\$ 5,027	\$ 29,613	\$ 60,165
Grant revenue	52	58	296	368
Total revenue	17,743	5,085	29,909	60,533
Operating expenses:				
Research and development	19,948	18,582	64,219	56,655
General and administrative	19,598	10,362	55,558	29,474
Total operating expenses	39,546	28,944	119,777	86,129
Loss from operations	(21,803)	(23,859)	(89,868)	(25,596)
Other expense:				
Interest income	164	499	693	2,059
Interest expense	(668)	(700)	(2,052)	(1,943)
Total other (expense) income, net	(504)	(201)	(1,359)	116
Net loss	\$ (22,307)	\$ (24,060)	\$ (91,227)	\$ (25,480)
Basic and diluted net loss per common share	\$ (0.32)	\$ (0.35)	\$ (1.31)	\$ (0.40)
Shares used to compute net loss per common share	69,894	68,922	69,764	64,500

See accompanying notes.

CHEMOCENTRYX, INC.
CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(in thousands)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Net loss	\$ (22,307)	\$ (24,060)	\$ (91,227)	\$ (25,480)
Unrealized gain (loss) on available-for-sale securities	44	(216)	(151)	(46)
Comprehensive loss	<u>\$ (22,263)</u>	<u>\$ (24,276)</u>	<u>\$ (91,378)</u>	<u>\$ (25,526)</u>

See accompanying notes.

CHEMOCENTRYX, INC.
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

(in thousands, except share data)
(unaudited)

	Common Stock		Additional Paid-In Capital	Note Receivable	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount					
Balance as of June 30, 2021	69,885,975	\$ 70	\$ 884,559	\$ (16)	\$ (81)	\$ (554,262)	\$ 330,270
Net loss	—	—	—	—	—	(22,307)	(22,307)
Unrealized gain on investments	—	—	—	—	44	—	44
Issuance of common stock under equity incentive plans	51,535	—	463	—	—	—	463
Employee stock-based compensation	—	—	7,165	—	—	—	7,165
Compensation expense related to options granted to consultants	—	—	259	—	—	—	259
Balance as of September 30, 2021	<u>69,937,510</u>	<u>\$ 70</u>	<u>\$ 892,446</u>	<u>\$ (16)</u>	<u>\$ (37)</u>	<u>\$ (576,569)</u>	<u>\$ 315,894</u>

	Common Stock		Additional Paid-In Capital	Note Receivable	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount					
Balance as of December 31, 2020	69,452,466	\$ 69	\$ 870,788	\$ (16)	\$ 114	\$ (485,342)	\$ 385,613
Net loss	—	—	—	—	—	(91,227)	(91,227)
Unrealized loss on investments	—	—	—	—	(151)	—	(151)
Issuance of common stock under equity incentive plans	571,387	1	3,724	—	—	—	3,725
Repurchased shares upon vesting of restricted stock units for tax withholdings	(86,343)	—	(5,273)	—	—	—	(5,273)
Employee stock-based compensation	—	—	22,459	—	—	—	22,459
Compensation expense related to options granted to consultants	—	—	748	—	—	—	748
Balance as of September 30, 2021	<u>69,937,510</u>	<u>\$ 70</u>	<u>\$ 892,446</u>	<u>\$ (16)</u>	<u>\$ (37)</u>	<u>\$ (576,569)</u>	<u>\$ 315,894</u>

See accompanying notes.

CHEMOCENTRYX, INC.
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

(in thousands, except share data)
(unaudited)

	Common Stock		Additional Paid-In Capital	Note Receivable	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount					
Balance as of June 30, 2020	68,803,400	\$ 69	\$ 852,006	\$ (16)	\$ 488	\$ (431,406)	\$ 421,141
Net loss	—	—	—	—	—	(24,060)	(24,060)
Unrealized loss on investments	—	—	—	—	(216)	—	(216)
Issuance of common stock under equity incentive plans	305,173	—	2,005	—	—	—	2,005
Employee stock-based compensation	—	—	5,721	—	—	—	5,721
Compensation expense related to options granted to consultants	—	—	228	—	—	—	228
Balance as of September 30, 2020	<u>69,108,573</u>	<u>\$ 69</u>	<u>\$ 859,960</u>	<u>\$ (16)</u>	<u>\$ 272</u>	<u>\$ (455,466)</u>	<u>\$ 404,819</u>

	Common Stock		Additional Paid-In Capital	Note Receivable	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount					
Balance as of December 31, 2019	60,234,784	\$ 60	\$ 495,624	\$ (16)	\$ 318	\$ (429,986)	\$ 66,000
Net loss	—	—	—	—	—	(25,480)	(25,480)
Unrealized loss on investments	—	—	—	—	(46)	—	(46)
Issuance of common stock upon follow-on offering, net of issuance costs	5,980,000	6	325,648	—	—	—	325,654
Issuance of common stock under equity incentive plans	2,986,248	3	26,495	—	—	—	26,498
Repurchased shares upon vesting of restricted stock units for tax withholdings	(92,459)	—	(3,709)	—	—	—	(3,709)
Employee stock-based compensation	—	—	15,171	—	—	—	15,171
Compensation expense related to options granted to consultants	—	—	731	—	—	—	731
Balance as of September 30, 2020	<u>69,108,573</u>	<u>\$ 69</u>	<u>\$ 859,960</u>	<u>\$ (16)</u>	<u>\$ 272</u>	<u>\$ (455,466)</u>	<u>\$ 404,819</u>

CHEMOCENTRYX, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)
(unaudited)

	Nine Months Ended September 30,	
	2021	2020
Operating activities		
Net loss	\$ (91,227)	\$ (25,480)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	23,207	15,902
Depreciation of property and equipment	2,123	402
Non-cash lease expense	1,375	1,402
Non-cash interest expense, net	3,713	822
Changes in assets and liabilities:		
Accounts receivable, other	85	132
Accounts receivable due from related party	(19,973)	(58)
Prepays and other current assets	640	(770)
Other assets	63	(5)
Accounts payable	68	213
Operating lease liabilities	10,364	6,255
Other liabilities	4,374	(701)
Deferred revenue from related party	454	(60,033)
Net cash used in operating activities	(64,734)	(61,919)
Investing activities		
Purchases of property and equipment, net	(18,527)	(6,136)
Purchases of investments	(246,166)	(391,942)
Maturities of investments	393,453	124,220
Net cash provided by (used in) investing activities	128,760	(273,858)
Financing activities		
Proceeds from issuance of common stock	—	325,654
Proceeds from exercise of stock options and employee stock purchase plan	3,725	26,472
Employees' tax withheld and paid for with restricted stock units	(5,273)	(3,709)
Borrowings under credit facility agreement, net of issuance costs	—	4,358
Payments of long-term debt	(1,049)	—
Net cash (used in) provided by financing activities	(2,597)	352,775
Net increase in cash, cash equivalents and restricted cash	61,429	16,998
Cash, cash equivalents and restricted cash at beginning of period	33,377	40,259
Cash, cash equivalents and restricted cash at end of period	\$ 94,806	\$ 57,257
Supplemental disclosures of cash flow information		
Cash paid for interest	\$ 1,534	\$ 1,433
Purchases of property and equipment, net recorded in accounts payable and accrued liabilities	\$ 8,562	\$ 7,175
Right-of-use assets obtained in exchange for lease obligations	\$ 501	\$ 27,365

See accompanying notes.

CHEMOCENTRYX, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
September 30, 2021
(unaudited)

1. Description of Business

ChemoCentryx, Inc. (the Company) commenced operations in 1997. The Company is a biopharmaceutical company focused on the development and commercialization of new medications targeting inflammatory disorders, autoimmune diseases and cancer. The Company discovered, developed and is now commercializing TAVNEOSTM (avacopan) in the United States as an adjunctive treatment for adult patients with severe active anti-neutrophil cytoplasmic autoantibody-associated vasculitis (ANCA-associated vasculitis) in combination with standard therapy. 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, 2020 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, 2020 filed with the Securities and Exchange Commission on March 1, 2021.

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.

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 income (loss) per share when their effect is dilutive.

For the three and nine months ended September 30, 2021 and 2020, the following potentially dilutive securities were excluded from the calculation of diluted net loss per share due to their anti-dilutive effect (in thousands):

	Three and Nine Months Ended September 30,	
	2021	2020
Options to purchase common stock, including purchases from contributions to ESPP	7,240	7,416
Restricted stock units	432	389
Restricted stock awards	15	14
Warrants to purchase common stock	150	150
	7,837	7,969

Comprehensive Loss

Comprehensive loss comprises net loss and other comprehensive loss. For the periods presented, other comprehensive loss consists of unrealized gains (losses) on the Company's available-for-sale securities. For the three and nine months ended September 30, 2021 and 2020, there were no significant sales of investments and therefore there were no reclassifications of comprehensive loss.

Recent Accounting Pronouncements

The Company has reviewed 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.

3. Cash Equivalents, Restricted Cash and Investments

Cash, Cash Equivalents and Restricted Cash

The following table provides a reconciliation of cash, cash equivalents and restricted cash shown in the Condensed Consolidated Statements of Cash Flows (in thousands):

	September 30, 2021	December 31, 2020
Cash and cash equivalents	\$ 93,726	\$ 32,297
Restricted cash included in Other assets	1,080	1,080
Total cash, cash equivalents and restricted cash	\$ 94,806	\$ 33,377

Restricted cash as of September 30, 2021 and December 31, 2020 was held as collateral for stand-by letters of credit issued by the Company to its landlord in connection with the lease of the Company's facility in San Carlos, California. See "Note 7. Commitments" for additional information on this lease.

Cash Equivalents and Investments

The amortized cost and fair value of cash equivalents and investments at September 30, 2021 and December 31, 2020 were as follows (in thousands):

	September 30, 2021			
	Amortized	Gross Unrealized		Fair
	Cost	Gains	Losses	Value
Money market fund	\$ 88,364	\$ —	\$ —	\$ 88,364
U.S. treasury securities	40,484	6	(3)	40,487
Non-U.S. government securities	16,900	—	(9)	16,891
Commercial paper	82,933	—	—	82,933
Asset-backed securities	25,002	3	(20)	24,985
Corporate debt securities	112,449	15	(29)	112,435
Total available-for-sale securities	\$ 366,132	\$ 24	\$ (61)	\$ 366,095

Classified as:	
Cash equivalents	\$ 88,364
Short-term investments	175,701
Long-term investments	102,030
Total available-for-sale securities	\$ 366,095

	December 31, 2020			
	Amortized	Gross Unrealized		Fair
	Cost	Gains	Losses	Value
Money market fund	\$ 30,139	\$ —	\$ —	\$ 30,139
U.S. treasury securities	176,625	60	—	176,685
Government-sponsored agencies	12,500	—	—	12,500
Commercial paper	140,364	—	—	140,364
Asset-backed securities	25,706	23	—	25,729
Corporate debt securities	72,764	38	(7)	72,795
Total available-for-sale securities	\$ 458,098	\$ 121	\$ (7)	\$ 458,212

Classified as:	
Cash equivalents	\$ 30,139
Short-term investments	404,273
Long-term investments	23,800
Total available-for-sale securities	\$ 458,212

Cash equivalents in the tables above exclude cash of \$5.4 million and \$2.2 million as of September 30, 2021 and December 31, 2020, respectively. All available-for-sale securities held as of September 30, 2021 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. The Company applies the specific identification method to determine the cost basis of the securities sold. No available-for-sale securities held as of September 30, 2021 have been in a continuous unrealized loss position for more than 12 months. As of September 30, 2021, unrealized losses on available-for-sale investments are not attributed to credit risk. 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 that an allowance for credit losses is unnecessary because the unrealized losses on certain of the Company's marketable securities are due to market factors. To date, the Company has not recorded any impairment charges on marketable securities.

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.

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, 2021 and December 31, 2020 (in thousands):

Description	September 30, 2021			
	Level 1	Level 2	Level 3	Total
Money market fund	\$ 88,364	\$ —	\$ —	\$ 88,364
U.S. treasury securities	—	40,487	—	40,487
Non-U.S. government securities	—	16,891	—	16,891
Commercial paper	—	82,933	—	82,933
Asset-backed securities	—	24,985	—	24,985
Corporate debt securities	—	112,435	—	112,435
Total available-for-sale securities	\$ 88,364	\$ 277,731	\$ —	\$ 366,095

Description	December 31, 2020			
	Level 1	Level 2	Level 3	Total
Money market fund	\$ 30,139	\$ —	\$ —	\$ 30,139
U.S. treasury securities	—	176,685	—	176,685
Government-sponsored agencies	—	12,500	—	12,500
Commercial paper	—	140,364	—	140,364
Asset-backed securities	—	25,729	—	25,729
Corporate debt securities	—	72,795	—	72,795
Total available-for-sale securities	\$ 30,139	\$ 428,073	\$ —	\$ 458,212

During the three and nine months ended September 30, 2021, 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, 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, 2021 and December 31, 2020 were as follows (in thousands):

	September 30, 2021		December 31, 2020	
	Carrying Amount	Estimated Fair Value	Carrying Amount	Estimated Fair Value
Long-term debt, net ⁽¹⁾	\$ 23,573	\$ 23,722	\$ 24,401	\$ 25,332

- (1) Carrying amounts of long-term debt were net of unamortized debt discounts of \$378 and \$599 as of September 30, 2021 and December 31, 2020, 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 and Other Current Liabilities

Accrued and other current liabilities consist of the following (in thousands):

	September 30, 2021	December 31, 2020
Research and development related	\$ 9,805	\$ 11,062
Compensation related	10,356	5,498
Consulting and professional services	1,640	1,690
Current portion of operating lease liability	2,707	845
Other	1,476	699
	<u>\$ 25,984</u>	<u>\$ 19,794</u>

6. Long-term Debt

In December 2017, 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 (as amended, the Credit Facility) were available to the Company. As of September 30, 2021, the Company had borrowed \$20.0 million under the Credit Facility, with an interest rate of 8.05% per annum and the remaining available amount had expired. Advances under the Credit Facility bear an interest rate equal to the greater of either (i) 8.05% plus the prime rate as reported from time to time in The Wall Street Journal (the Prime Rate) minus 4.75%, and (ii) 8.05%. The Company made interest-only payments through June 2021 and the first principal and interest payment on July 1, 2021. The Credit Facility was subsequently amended in July 2021 to extend the interest-only payment period through December 2021, and at which point the Company will then be obligated to repay the principal balance and interest on the advances in equal monthly installments through December 1, 2022. The Company is obligated to pay an end of term charge of \$1.3 million in December 2022.

On January 8, 2020, the Company entered into an Amended and Restated Loan and Security Agreement (the Amended Loan Agreement) with Hercules, which amended and restated the agreement between the parties, and pursuant to which an additional term loan in an aggregate principal amount of up to \$100.0 million (the Restated Credit Facility) is available to the Company at its discretion in three tranches. The first tranche of the Restated Credit Facility of up to \$40.0 million was available to the Company through December 15, 2020, of which \$20.0 million became available upon submission of the TAVNEOS New Drug Application (NDA). The second tranche of up to an additional \$30.0 million became available to the Company through December 15, 2021 upon NDA approval of TAVNEOS for the treatment of ANCA-associated vasculitis. The third tranche of up to an additional \$30.0 million would be available through December 15, 2022, subject to certain conditions.

Under the Restated Credit Facility, the Company borrowed \$5.0 million from the first tranche with an interest rate of 8.50% per annum as of September 30, 2021. Advances under the Restated Credit Facility bear an initial interest rate equal to the greater of either (i) 8.50% plus the Prime Rate minus 5.25%, and (ii) 8.50%, which may be reduced upon the Company achieving certain cumulative net TAVNEOS revenue levels. For advances under the Restated Credit Facility, the Company will make interest only payments through September 1, 2022 and will then be obligated to repay the principal balance and interest on the advances in equal monthly installments through February 1, 2024. Upon satisfaction of certain conditions, the interest-only payment period and the principal balance repayment period may be extended. In addition, the Company is obligated to pay an end of term charge of 7.15% of the aggregate amount of the advances under the Restated Credit Facility.

The Company paid a commitment fee of 1% of the advances made by Hercules, with a minimum charge of \$162,500 for the Credit Facility and a minimum charge of \$520,000 for the Restated Credit Facility. Also, the Company reimbursed Hercules for costs incurred related to the Restated 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.

In addition, the Company may prepay advances under the Amended Loan Agreement, in whole or in part, at any time, subject to a prepayment charge that ranges from 1.0% to 2.0%, depending on the timing of the prepayment. The Amended Loan Agreement is secured by substantially all of the Company's assets, excluding intellectual property. The Amended Loan Agreement also includes customary loan covenants, with which the Company was in compliance for all periods presented.

In connection with the Restated Credit Facility, the Company also entered into a Right to Invest Agreement with Hercules, pursuant to which Hercules shall have the right to participate, in an amount up to \$3.0 million, in any subsequent equity financing broadly marketed to multiple investors in an amount greater than \$30.0 million. Hercules purchased \$1.0 million of the Company's common stock during the June 2020 equity follow-on offering.

As of September 30, 2021, the Company had outstanding borrowings under the Amended Loan Agreement of \$23.6 million, net of discounts of \$0.4 million. Future minimum principal payments, which exclude the end of term charge, as of September 30, 2021 are as follows (in thousands):

	<u>Amounts</u>
Year ending December 31:	
Remaining of fiscal year 2021	\$ —
2022	20,006
2023	3,353
2024	<u>592</u>
Total minimum payments	23,951
Less: amount representing debt discount	<u>(378)</u>
Present value of remaining debt payments	23,573
Less: current portion	<u>(14,013)</u>
Non-current portion	<u>\$ 9,560</u>

7. Commitments

Operating Leases

In May 2004, the Company entered into a noncancelable operating lease for its previous office and primary research facility located in Mountain View, California. In May 2019, the Company entered into a third amendment to the lease agreement for the same facility to extend the term of the lease through April 2021. In July 2020, the Company entered into a letter agreement to further extend the lease term through June 2021.

In July 2019, the Company entered into a ten-year operating lease for a 96,463 square foot facility in San Carlos, California to replace its previous headquarters located in Mountain View, California. Upon execution of the lease agreement, the Company provided the landlord an approximately \$1.1 million security deposit in the form of a letter of credit. The lease commenced in June 2020 and is anticipated to expire in February 2031 with an option to extend the lease for five years. The lease extension option was not considered in the right-of-use asset or the lease liability as the Company did not consider it reasonably certain the option would be exercised. Monthly rent payments began in March 2021. Following a six-month period of discounted rent, the Company is obligated to pay an initial annual base rent at a rate of approximately \$6.5 million, which is subject to scheduled 3% annual increases, plus certain operating expenses. The Company moved its headquarters to this new facility in April 2021.

The Company was provided a tenant improvement allowance of \$15.4 million plus an additional allowance of \$4.8 million for the same. The additional allowance will be repaid by the Company as additional rent in equal monthly payments at a rate of 7% per annum through the initial term of the lease. As of September 30, 2021, the Company has received a tenant improvement allowance of \$19.2 million. The Company has the right to sublease the facility, subject to landlord consent.

The balance sheet classification of the Company's operating lease assets and liabilities was as follows (in thousands):

	<u>September 30, 2021</u>	<u>December 31, 2020</u>
Balance Sheet		
Assets:		
Operating lease right-of-use assets	\$ 25,035	\$ 26,911
Liabilities:		
Operating lease liabilities:		
Accrued and other current liabilities ⁽¹⁾	\$ 2,707	\$ 845
Non-current lease liabilities	46,672	38,671

(1) Includes current portion of operating lease liabilities as of September 30, 2021 and December 31, 2020.

The component of lease costs, which was included in operating expenses in the Company's Condensed Consolidated Statements of Operations, was as follows (in thousands):

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2021</u>	<u>2020</u>	<u>2021</u>	<u>2020</u>
Operating lease cost	\$ 1,375	\$ 1,743	\$ 4,857	\$ 2,905

During the nine-months ended September 30, 2021 and 2020, cash paid for amounts included in the measurement of lease liabilities was \$3.1 million, excluding the \$10.0 million tenant improvement allowance received, and \$1.2 million, respectively. These amounts were included in net cash used in operating activities in the Company's Condensed Consolidated Statements of Cash Flows.

Future minimum lease payments under all noncancelable operating leases as of September 30, 2021 are as follows (in thousands):

	<u>Operating leases</u>
Year ending December 31:	
Remaining of fiscal year 2021	\$ 1,816
2022	7,336
2023	7,535
2024	7,741
2025	7,952
Thereafter	44,686
Total minimum payments	77,066
Less: interest	(26,797)
Less: future tenant improvement reimbursements	(890)
Present value of lease liabilities	<u>\$ 49,379</u>

As of September 30, 2021, the weighted-average remaining lease term was 9.42 years and the weighted-average operating discount rate used to determine the operating lease liability was 9.5%.

8. Related-Party Transactions

Vifor

Vifor held 9,194,085 shares of the Company's common stock as of September 30, 2021. The Company has collaboration agreements with Vifor: the Avacopan Agreements and the CCX140 Agreements (each as described below). See "Note 2. Summary of Significant Accounting Policies – Concentration of Credit Risk" for additional information on accounts receivable balance due from Vifor

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 ANCA-associated vasculitis 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 amendment, 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, and together with the Avacopan Agreement and the Avacopan Amendment, the Avacopan Agreements). 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 the Avacopan Letter Agreement, the Company received a \$5.0 million payment for the expanded rights.

In December 2017, the Company achieved a \$50.0 million regulatory milestone when the European Medicines Agency (EMA) validated the Company's conditional marketing authorization (CMA) application for avacopan for the treatment of ANCA-associated vasculitis. In February 2021, the Company achieved a \$10.0 million regulatory milestone when the Japanese NDA (JNDA) for TAVNEOS in the treatment of ANCA-associated vasculitis was filed with the Japanese Pharmaceuticals and Medical Device Agency (PMDA) by Vifor, through its sublicensee Kissei Pharmaceutical, Co., Ltd. (Kissei). In September 2021, the Japanese Ministry of Health, Labor and Welfare (MHLW) approved the JNDA for TAVNEOS for the treatment of patients with microscopic polyangiitis (MPA) and granulomatosis with polyangiitis (GPA), the two main forms of ANCA-associated vasculitis. As a result, the Company achieved a \$20.0 million regulatory milestone. Upon further achievement of certain regulatory and commercial milestones with

TAVNEOS, the Company will receive additional payments of up to \$430.0 million under the Avacopan Agreements. In addition, the Company will receive royalties, with rates ranging from the low teens to the mid-twenties, on future potential net sales of TAVNEOS by Vifor in the licensed territories.

The Company identified the following material promises under the Avacopan Agreements: (1) the license related to avacopan; (2) the development and regulatory services for the submission of the marketing authorization 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. Therefore, the transaction price under this arrangement is allocated to the license and the development and regulatory services.

As of September 30, 2021, the transaction price of \$183.0 million comprised 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 ANCA-associated vasculitis in December 2017;
- \$10.0 million regulatory milestone payment achieved upon the acceptance of the JNDA for TAVNEOS in the treatment of ANCA-associated vasculitis filed by Vifor, through its Japanese sublicensee Kissei with the PMDA in February 2021;
- \$20.0 million regulatory milestone payment achieved upon the MHLW approval of the JNDA for TAVNEOS in the treatment of ANCA-associated vasculitis by Vifor, through its Japanese sublicensee Kissei in September 2021; and
- \$5.0 million non-refundable upfront payment under the Avacopan Letter Agreement.

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 uses 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 is 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, 2021, the Company recognized \$17.9 million and \$28.2 million, respectively, of collaboration and license revenue under the Avacopan Agreements, as compared to \$2.9 million and \$9.9 million, respectively, during the same periods in 2020.

Avacopan Commercial Supply Agreement

In October 2020, the Company entered into a Manufacturing and Supply Agreement with Vifor (the Avacopan Commercial Supply Agreement). Under the Avacopan Commercial Supply Agreement, the Company will supply and sell avacopan drug product to Vifor for commercial use outside of the United States. Vifor will purchase avacopan drug product at a certain percentage mark up to the Company's cost of goods, in accordance with the Avacopan Agreements. Vifor's purchase of avacopan drug product is subject to certain binding forecast periods. The Avacopan Commercial Supply Agreement will expire upon the termination of the Avacopan Agreements or under certain circumstances as specified in the Avacopan Commercial Supply Agreement. In connection with the Avacopan Commercial Supply Agreement, the Company also entered into a letter agreement with Vifor, pursuant to which the \$6.2 million previously received from Vifor under the CCX140 Agreement (discussed below) is creditable to Vifor's purchase of avacopan drug product. For the nine months ended September 30, 2021, the Company recognized \$0.6 million of collaboration and license revenue under the Avacopan Commercial Supply Agreement.

CCX140 Agreements

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. 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 non-refundable payment of \$5.0 million. The Company and Vifor also entered into an amendment to the CCX140 Agreement (the CCX140 Amendment, and together with the CCX140 Agreement and the CCX140 Letter Agreement, the CCX140 Agreements) 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.

The Company identified the following material promises under the CCX140 Agreements: (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 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, 2021, the transaction price of \$66.5 million comprised the following:

- \$50.0 million upfront payment under the CCX140 Agreement;
- \$11.5 million of CCX140 development funding by Vifor; and
- \$5.0 million non-refundable 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 services. The Company uses 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 is recognized based on actual costs incurred as a percentage of total budgeted costs as the Company completes its performance obligations.

In May 2020, the Company announced topline data from a 46 patient Phase II dose-ranging trial in the orphan kidney disorder, primary Focal Segmental Glomerulosclerosis (FSGS), called the LUMINA-1 trial. In the study, CCX140 did not demonstrate a meaningful reduction in proteinuria relative to the control group after 12 weeks of blinded treatment. As such, CCX140 will not be further developed in FSGS. As a result, the Company reduced the total anticipated FSGS budgeted costs and the corresponding transaction price related to development funding under the CCX140 Agreement by \$47.2 million and recognized \$46.7 million of contract revenue during the three months ended June 30, 2020. In addition, \$6.2 million of deferred revenue previously received from Vifor under the CCX140 Agreements is creditable against Vifor's purchases of avacopan drug product under the Avacopan Commercial Supply Agreement. 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.

For the three and nine months ended September 30, 2021, the Company recognized \$7,000 and \$0.8 million of collaboration and license revenue under the CCX140 Agreements, respectively, compared to \$2.1 million and \$50.2 million during the same periods in 2020, respectively. As of September 30, 2021, deferred revenue under the CCX140 Agreement, representing the Company's remaining estimated performance obligation under these agreements has been fully recognized.

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, 2021	December 31, 2020
Contract asset:		
Accounts receivable	\$ 20,005	\$ 32
Contract liability:		
Deferred revenue	\$ (37,041)	\$ (36,587)

During the three and nine months ended September 30, 2021, 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, 2021	Nine Months Ended September 30, 2021
Revenue recognized in the period from:		
Amount included in contract liability at the beginning of the period	\$ 17,682	\$ 29,546
Performance obligations satisfied (or partially satisfied) in previous periods	\$ 16,313	\$ 24,391

9. Government Grant

In September 2019, the Company was awarded a two-year \$1.0 million grant from the orphan drug office of the U.S. Food and Drug Administration to support the clinical development of avacopan in patients with the rare kidney disease complement 3 glomerulopathy. The grant was extended for an additional four months in August 2021. For the three and nine months ended September 30, 2021, the Company recognized \$0.1 million and \$0.4 million of grant revenue, respectively. As of September 30, 2021 and December 31, 2020, \$52,000 and \$0.1 million, respectively, was recorded as accounts receivable.

10. Stockholders' Equity

Stock Options

During the nine months ended September 30, 2021, the Company had the following activities under its equity incentive plans:

	Available for Grant	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Balance at December 31, 2020	3,170,577	7,114,225	\$ 14.61		
Shares authorized	2,950,000	—			
Granted ⁽¹⁾	(1,198,068)	945,534	53.64		
Exercised ⁽²⁾	86,343	(324,204)	10.30		
Forfeited and expired	537,592	(537,592)	27.75		
Outstanding at September 30, 2021	<u>5,546,444</u>	<u>7,197,963</u>	\$ 18.95	5.89	\$ 243,375,474
Vested and expected to vest, net of estimated forfeiture at September 30, 2021		<u>6,988,419</u>	\$ 18.23	5.81	\$ 240,345,856
Exercisable at September 30, 2021		<u>5,099,071</u>	\$ 11.17	4.89	\$ 204,903,335

(1) 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.

(2) Shares presented as available for grant represents shares repurchased for tax withholding upon vesting of RSUs.

Restricted Stock

During the nine months ended September 30, 2021, the activity for restricted stock is summarized as follows:

	Shares	Weighted Average Grant-Date Fair Value
Balance at December 31, 2020	420,030	\$ 34.73
Granted	229,356	54.58
Vested	(202,342)	30.60
Canceled	—	—
Unvested at September 30, 2021	<u>447,044</u>	<u>\$ 46.79</u>

Stock-based Compensation

Total stock-based compensation expense was \$7.4 million and \$23.2 million during the three and nine months ended September 30, 2021, respectively, and \$5.9 million and \$15.9 million during the same periods ended September 30, 2020, respectively. As of September 30, 2021, \$42.3 million, \$11.6 million and \$84,000 of total unrecognized compensation expenses associated with outstanding employee stock options, unvested restricted stock, and the ESPP, net of estimated forfeitures, respectively, were expected to be recognized over a weighted-average period of 2.34, 1.43 and 0.12 years, respectively.

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, 2020, filed with the Securities and Exchange Commission, or SEC, on March 1, 2021.

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,” “intend,” “predict,” “seek,” “contemplate,” “potential” 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 anticipated impact of the novel coronavirus disease 2019, or COVID-19, pandemic on our business, preclinical studies, clinical trials and ability to commercialize any of our drug candidates;
- the commercialization of TAVNEOS™ (avacopan) and our other 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;
- the impact or outcome of putative shareholder class action litigation;
- 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, 2020, filed with the SEC on March 1, 2021.

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, and TAVNEOS™ 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 subsidiaries taken as a whole unless otherwise noted.

Overview

ChemoCentryx is a biopharmaceutical company focused on the development and commercialization of new medications targeting inflammatory disorders, autoimmune diseases and cancer. We have commercially launched TAVNEOS in the United States in anti-neutrophil cytoplasmic autoantibody-associated vasculitis, or ANCA-associated vasculitis.

In October 2021, the U.S. Food and Drug Administration, or FDA, approved TAVNEOS, an orally administered selective complement 5a receptor inhibitor, as an adjunctive treatment for adult patients with severe active ANCA-associated vasculitis, specifically granulomatosis with polyangiitis, or GPA, and microscopic polyangiitis, or MPA, the two main forms of ANCA-associated vasculitis, in combination with standard therapy. ANCA-associated vasculitis is a systemic autoimmune disease in which over-activation of the complement system further activates neutrophils, leading to inflammation and eventual destruction of small blood vessels. This results in organ damage and failure, with the kidney as the major target, and is often fatal if not treated.

TAVNEOS is the first FDA approved orally-administered inhibitor of the complement 5a receptor. The approval in ANCA-associated vasculitis was supported by the results of the pivotal Phase III ADVOCATE trial, which were highlighted in the February 2021 edition of The New England Journal of Medicine. We have developed TAVNEOS Connect, a patient support program designed to assist patients who are prescribed TAVNEOS.

We also plan to commercialize TAVNEOS internationally through our kidney health alliance with Vifor Fresenius Medical Care Renal Pharma Ltd. and its affiliates and sublicensees, or collectively, Vifor. In November 2020, Vifor announced that the Marketing Authorisation Application, or MAA, for TAVNEOS in the treatment of ANCA-associated vasculitis was accepted for review (validated) by the European Medicines Agency, or EMA. Decision on the MAA filing is expected by the end of 2021. In September 2021, the Japanese Ministry of Health, Labor and Welfare, or MHLW, approved the Japanese NDA, or JNDA, filed by Vifor and Kissei for TAVNEOS for the treatment of patients with MPA and GPA.

Our drug candidates are designed to selectively block a specific chemoattractant receptor, leaving the rest of the immune system intact. These drug candidates are small molecules, orally-administered inhibitors that 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, our drug candidates may improve patient compliance. Our pipeline includes the following programs:

TAVNEOS:

- We are also developing TAVNEOS for the treatment of severe (Hurley Stage III) hidradenitis suppurativa, or HS. In October 2020, we announced topline data with positive results in a subgroup analysis of severe HS patients (Hurley Stage III) from the Phase II AURORA trial of TAVNEOS. We plan to advance TAVNEOS into Phase III clinical development for the treatment of severe HS in the first half of 2022.
- In December 2020, we announced topline data from the Phase II ACCOLADE trial of TAVNEOS for the treatment of patients with complement 3 glomerulopathy, or C3G. We plan to discuss the evidence of clinical benefit of TAVNEOS in C3G with the FDA in the first half of 2022.
- Based on the renal improvement results observed with TAVNEOS treatment in both the ADVOCATE trial in ANCA-associated vasculitis and the ACCOLADE trial in C3G, as measured by an increase in estimated glomerular filtration rate, we plan to develop TAVNEOS in additional complement-mediated renal indications such as lupus nephritis, or LN. We plan to initiate a clinical development towards registration of TAVNEOS for the treatment of LN in mid-2022.

Immuno-Oncology:

- CCX559 is our orally-administered small molecule checkpoint (PD-1/PD-L1) inhibitor, which we are developing for the treatment of various cancers. We initiated a Phase I clinical trial of CCX559 in the second quarter of 2021.

Our Strategy

The key elements to our commercial and scientific strategy are to:

- Commercialize TAVNEOS in the United States on our own, where we believe a company of our size can effectively compete in rare disease markets. We have deployed a specialty sales force primarily targeting that subset of nephrologists and rheumatologists treating ANCA-associated vasculitis patients in the United States;

- Support our international commercialization partner Vifor and its Japanese sublicensee Kissei Pharmaceutical, Co., Ltd., or Kissei, in their regulatory approval applications. TAVNEOS was approved in Japan in September 2021;
- Develop and commercialize TAVNEOS for additional indications, including C3G, severe HS, and additional complement-mediated renal indications such as LN;
- Develop our other drug candidates and establish collaborations with pharmaceutical and biotechnology companies to further develop and market our drug candidates; and
- Discover and validate new drug candidates.

As of September 30, 2021, we had an accumulated deficit of \$576.6 million. We expect to continue to incur net losses as we launch TAVNEOS in the United States, develop our other drug candidates, expand clinical trials for our drug candidates currently in clinical development, and expand our research and development activities, organization, systems and facilities. Significant capital is required to launch a drug 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.

COVID-19

In December 2019, a disease caused by a novel strain of coronavirus, COVID-19, was identified in Wuhan, China. This virus has spread globally, including countries in which we have active clinical trial sites or contract manufacturing sites. The length of the pandemic and its related restrictions and their consequences for us remain subject to a number of risks and uncertainties, including disease resurgence and variants. We experienced a delay in topline clinical data from our ongoing AURORA trial to the fourth quarter of 2020, due to COVID-19, impacting certain sites where the trial was being conducted. We do not currently anticipate any material delays in the continued commercial launch of TAVNEOS in ANCA-associated vasculitis, nor are we currently anticipating any material disruption in our clinical drug supply as a result of the pandemic.

Critical Accounting Policies and Significant Judgments and Estimates

There have been no material changes in significant judgments and estimates for our critical accounting policies during the nine months ended September 30, 2021, 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, 2020, filed with the SEC on March 1, 2021.

Results of Operations

Revenue

We have not generated any revenue from drug product sales. For the periods presented, our revenues were derived from collaboration and license revenue related to the Avacopan Agreement, the Avacopan Commercial Supply Agreement and the CCX140 Agreement, in each case, as amended, and the related letter agreements. Total revenue for the three and nine months ended September 30, 2021, as compared to the same periods in the prior year, was as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Collaboration and license revenue from related party	\$ 17,691	\$ 5,027	\$ 29,613	\$ 60,165
Grant revenue	52	58	296	368
Total revenue	<u>\$ 17,743</u>	<u>\$ 5,085</u>	<u>\$ 29,909</u>	<u>\$ 60,533</u>
Dollar increase (decrease)	\$ 12,658		\$ (30,624)	
Percentage increase (decrease)	249%		(51%)	

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 primarily consist 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.

The increase in total revenue during the three months ended September 30, 2021 from the same period of 2020 was attributable to the \$20.0 million milestone earned from Vifor for the September 2021 JNDA, approval by the MHLW, for TAVNEOS in the

treatment of ANCA-associated vasculitis. The decrease in total revenue for the nine months ended September 30, 2021 was primarily due to the acceleration of revenue recognized under the CCX140 Agreement, reflecting the decision to discontinue development of CCX140 in FSGS in the second quarter of 2020. This decrease was partially offset by the \$30.0 million milestones from Vifor for the February 2021 JNDA acceptance and the September 2021 JNDA approval of TAVNEOS. In addition, during the nine months ended September 30, 2021, we recognized \$0.6 million of collaboration and license revenue related to sales of TAVNEOS to Vifor for anticipated commercial use outside of the United States.

Research and development expenses

Research and development expenses represent costs incurred to conduct basic research, 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, 2021, 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,	
	2021	2020	2021	2020
Research and development expenses	\$ 19,948	\$ 18,582	\$ 64,219	\$ 56,655
Dollar increase	\$ 1,366		\$ 7,564	
Percentage increase	7%		13%	

The increases from 2020 to 2021 for the three and nine month periods ended September 30 were primarily attributable to the manufacture of commercial drug supply in anticipation of the launch of TAVNEOS for the treatment of ANCA-associated vasculitis and higher research and drug discovery expenses, including those associated with the development of CCX559, our orally-available small molecule checkpoint (PD-1/PD-L1) inhibitor. These increases were partially offset by lower Phase II related expenses due to the completion of the TAVNEOS AURORA Phase IIb clinical trial in patients with HS and the discontinuation of further clinical development of CCX140 in FSGS in 2020.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Phase I	\$ 3,239	\$ 25	\$ 9,301	\$ 455
Phase II	3,813	5,335	11,336	20,160
Phase III	7,825	5,769	27,212	18,995
Research and drug discovery	5,071	7,453	16,370	17,045
Total research and development expenses	\$ 19,948	\$ 18,582	\$ 64,219	\$ 56,655

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, as we did with TAVNEOS, for any of our other 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 drug products. Completion dates and completion costs can vary significantly for each drug candidate and are difficult to predict for each drug 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 may 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 TAVNEOS, CCX559 and CCX507.

General and administrative expenses

Total general and administrative expenses for the three-and nine-months ended September 30, 2021, 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,	
	2021	2020	2021	2020
General and administrative expenses	\$ 19,598	\$ 10,362	\$ 55,558	\$ 29,474
Dollar increase	\$ 9,236		\$ 26,084	
Percentage increase	89 %		88 %	

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 2020 to 2021 for the three and nine month periods ended September 30 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 due to commercialization-related activities and personnel costs to support the launch of TAVNEOS in ANCA-associated vasculitis in the United States.

Other (expense) income, net

Other (expense) income, net primarily consists of interest income earned on our marketable securities and interest expense for our long-term debt. Total other (expense) income, net for the three and nine month periods ended September 30, 2021, 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,	
	2021	2020	2021	2020
Interest income	\$ 164	\$ 499	\$ 693	\$ 2,059
Interest expense	(668)	(700)	(2,052)	(1,943)
Total other (expense) income, net	\$ (504)	\$ (201)	\$ (1,359)	\$ 116
Dollar increase	\$ 303		\$ 1,475	
Percentage increase	151 %		1272 %	

The increases in total other expense, net from 2020 to 2021 for the three and nine month periods ended September 30 were primarily due to less interest income earned from our investment portfolio under the continued low interest rate environment during the current COVID-19 pandemic and increased interest expense due to additional borrowings under the Credit Facility and the Restated Credit Facility (as defined below) in March 2020.

Liquidity and Capital Resources

As of September 30, 2021, we had approximately \$372.5 million in cash, cash equivalents, restricted cash and investments. The following table shows a summary of our cash flows for the three and nine months ended September 30, 2021 and 2020 (in thousands):

	Nine Months Ended September 30,	
	2021	2020
Cash provided by (used in)		
Operating activities	\$ (64,734)	\$ (61,919)
Investing activities	\$ 128,760	\$ (273,858)
Financing activities	\$ (2,597)	\$ 352,775

Operating activities. Net cash used in operating activities was \$64.7 million for the nine months ended September 30, 2021, compared to \$61.9 million for the same period in 2020. This increase was primarily due to changes in working capital items.

Investing activities. Net cash provided by (used in) investing activities for periods presented primarily relate to the purchase, sale and maturity of investments used to fund the day-to-day needs of our business. Following our equity follow-on offering in June 2020, we invested the majority of our net proceeds received in short and long term investments.

Financing activities. Net cash used in financing activities was \$2.6 million for the nine months ended September 30, 2021, compared to cash provided of \$352.8 million for the same period in 2020. Net cash used in financing activities for both periods presented included proceeds from the exercise of stock options and cash used for tendered ChemoCentryx, Inc. common stock to satisfy employee tax withholding requirements upon vesting of restricted stock units. Net cash provided by financing activities for the nine months ended September 30, 2020 included net proceeds of \$325.7 million from the issuance of common stock from our June 2020 equity follow-on offering and \$4.4 million received under the Restated Credit Facility.

As of September 30, 2021, we had borrowed \$20.0 million under the loan and security agreement, or Credit Facility, with Hercules Capital, Inc., or Hercules. In January 2020, we entered into an amended and restated credit facility, or the Restated Credit Facility, with Hercules, which provides for borrowings of up to an additional \$100.0 million in three tranches, subject to certain terms and conditions. As of September 30, 2021, we had borrowed \$5.0 million under the Restated Credit Facility. The Credit Facility was subsequently amended in July 2021 to extend the interest-only payment period through December 2021, and at which point we will then repay the principal balance and interest on the advances in equal monthly installments through December 1, 2022. 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, 2021, we had approximately \$372.5 million in cash, cash equivalents, restricted cash 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 9, 2021. 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 commercialization of TAVNEOS as an adjunctive treatment for adult patients with severe active ANCA-associated vasculitis;
- 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, including any delays as a result of the COVID-19 pandemic on our business, preclinical studies or clinical trials;
- the number and characteristics of drug candidates that we pursue;
- the progress, costs and results of our clinical trials;
- delays that may be caused by changing regulatory approvals;
- the outcome, timing and cost of regulatory approvals;
- the cost and timing of hiring new employees to support continued growth and expansion;
- 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, drug products or technologies.

Contractual Obligations and Commitments

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, 2020, filed with the SEC on March 1, 2021.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements (as defined by applicable SEC regulations) that are reasonably likely to have a current or future material effect on our financial condition, results of operations, liquidity, capital expenditures or capital resources, except warrants and stock options.

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.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Our market risks at September 30, 2021 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, 2020, filed with the SEC on March 1, 2021, other than the following:

We are affected by market risk exposure primarily through the effect of changes in interest rates on amounts payable under the Credit Facility and Restated Credit Facility. At September 30, 2021, borrowings under the Credit Facility totaled \$20.0 million with an interest rate of 8.05%. Advances under the Credit Facility 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, or Prime Rate, minus 4.75%, and (ii) 8.05%. We made interest-only payments on our borrowings under the Credit Facility through June 2021 and the first principal and interest payment on July 1, 2021. The Credit Facility was subsequently amended in July 2021 to extend the interest-only payment period through December 2021, at which point we will then be obligated to repay the principal balance and interest on the advances in equal monthly installments through December 1, 2022.

In addition, borrowings under the Restated Credit Facility totaled \$5.0 million at September 30, 2021 with an interest rate equal to the greater of (i) 8.50% plus the Prime Rate minus 5.25%, and (ii) 8.50%, which may be reduced upon the Company achieving certain cumulative net TAVNEOS revenue levels. We are obligated to make interest-only payments on our borrowings under the Restated Credit Facility through September 1, 2022, at which point we will then be obligated to repay the principal balance and interest on the advances in equal monthly installments after the interest-only period and continuing through February 1, 2024. If the total amounts outstanding under the Credit Facility and the Restated Credit Facility remained at this level for an entire year and the interest rates increased by 1%, our annual interest expense would increase by an additional \$250,000. 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, 2021, 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, 2021, 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, 2021, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. As a result of the COVID-19 pandemic, including the related stay-at-home and shelter-in-place orders mandated by state and local governments in which we operate, many of our employees have been working remotely since March 2020. As part of our Company's transition to a temporary remote workforce, we took precautionary actions to re-evaluate our financial reporting process to provide assurance that we could report our financial results accurately and timely. We will continue to monitor and assess new potential impacts of the COVID-19 pandemic, including those related to any stay-at-home and shelter-in-place requirements, on the design and operating effectiveness of our internal controls going forward.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

The Company and its Chief Executive Officer were named as defendants in two putative shareholder class actions filed on May 5, 2021, and June 8, 2021, in the U.S. District Court for the Northern District of California. These cases have been consolidated into the lead case, *Homyk v. ChemoCentryx, Inc.*, No. 4:21-cv-03343-JST (N.D. Cal.). The action alleges violations of Sections 10(b) and 20(a) of the Securities Exchange Act in connection with statements regarding our New Drug Application, or NDA, for TAVNEOS, and seeks an award of damages, interest and attorneys' fees. A lead plaintiff has not yet been selected. We intend to file a motion to dismiss the complaint, and to vigorously defend against these claims. Given the early stages of these cases, we are unable to estimate a reasonably possible range of loss, if any, that may result from the litigation.

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, 2020, filed with the SEC on March 1, 2021, except the following:

Risks Related to Our Business

We are substantially dependent on our ability to successfully commercialize TAVNEOS™ (avacopan), which is currently our only approved drug product. If we are unable to successfully commercialize TAVNEOS, our ability to generate revenue and our financial condition will be adversely affected.

We have invested a substantial amount of capital resources on the development, registration and commercialization of TAVNEOS, which was approved in the United States in October as an adjunctive treatment for adult patients with severe active ANCA-associated vasculitis, specifically granulomatosis with polyangiitis, or GPA, and microscopic polyangiitis, or MPA, the two main forms of ANCA-associated vasculitis, in combination with standard therapy including glucocorticoids, and not for the elimination of glucocorticoid use, and was approved in Japan in September for the treatment of patients with MPA and GPA. We cannot be certain that TAVNEOS will be successfully commercialized.

Our ability to generate revenue from drug product sales depends heavily on our success in many areas, including but not limited to:

- successfully commercializing TAVNEOS, either independently or with marketing service providers;
- the effectiveness of our sales and marketing strategy and operations, and obtaining market acceptance of TAVNEOS, including garnering market share from existing and future treatment alternatives;
- maintaining compliance with all regulatory requirements applicable to TAVNEOS and our commercial activities, including the post-marketing requirements and post-marketing commitments required by the FDA;
- obtaining coverage and adequate reimbursement from third-party payors for each of our drug products;
- the continued acceptability of the safety profile of TAVNEOS and the occurrence of any unexpected side effects, adverse reactions or misuse, including potential business impact such as the need to withdraw the drug product (either voluntarily or as mandated by the FDA), loss of support by the advocacy communities or loss of positive corporate reputation resulting in related unfavorable media coverage in these areas;
- successfully managing third-party service providers involved in the manufacturing and development of TAVNEOS;
- successfully completing the development of TAVNEOS in other indications by demonstrating safety, tolerability and efficacy profiles that are satisfactory to the FDA and other regulatory bodies in other territories;
- obtaining regulatory approvals to market TAVNEOS for other indications;
- negotiating favorable terms in any collaboration, licensing or other arrangements into which we may enter;
- maintaining, protecting and expanding the portfolio of intellectual property rights, including patents, trade secrets and know how; and
- attracting, hiring and retaining qualified personnel.

In our efforts to market TAVNEOS in the United States for the adjunctive treatment for adult patients with severe active ANCA-associated vasculitis, our revenue will be dependent, in part, on the size of the markets in the United States, or in other territories where we may seek and obtain regulatory approval, the number of competitors in such markets, the acceptance of the price of the drug

product in those markets and the ability to obtain reimbursement at any price. If the number of our addressable patients is not as large as we estimate or the reasonably accepted population for treatment is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such drug products. If we are not able to generate substantial revenue from the sale of approved drug product, we may never become profitable.

The commercial adoption of TAVNEOS and any other drug candidates we develop will depend on the degree of their market acceptance.

Even with the requisite approvals from the FDA and other regulatory authorities, the commercial adoption of TAVNEOS in the United States for the adjunctive treatment for adult patients with severe active ANCA-associated vasculitis, specifically GPA and MPA in combination with standard therapy including glucocorticoids, and not for the elimination of glucocorticoid use, and in Japan for the treatment of patients with MPA and GPA, and any other indications and drug candidates we may develop, will depend on the degree of their acceptance by physicians, patients, third-party payors and others in the medical community. If TAVNEOS or any other drug candidates we develop do not achieve an adequate level of market acceptance, we may not generate significant product revenues or any profits from operations. The degree of market acceptance of TAVNEOS or any other drug candidates we develop, if approved for commercial sale, will depend on a number of factors, some of which are beyond our control, including:

- the safety and efficacy of the drug candidate as demonstrated in clinical trials;
- the perception of physicians, patients, third-party payors and others in the medical community of the relative safety, efficacy, convenience, effect on quality-of-life and cost-effectiveness of the drug product, compared to those of other available treatments;
- the drug product's approved labeling, including the description of the drug product's approved indications, the description of its efficacy, including the endpoints in which it showed an improvement, and the prevalence and severity of any side effects, including any associated limitations or warnings;
- the cost of treatment in relation to alternative treatments, including any similar generic treatments;
- our ability to differentiate TAVNEOS or other approved drug products from other treatments in the same space;
- the prevalence and severity of any side effects, including those that may be discovered following approval and commercialization;
- the willingness of the target patient population to try new treatments and of physicians to prescribe these treatments;
- the strength of marketing and distribution support and timing of market introduction of competitive drug products;
- the publicity concerning our drug products or competing drug products and treatments;
- drug product liability litigation alleging injuries relating to our drug products or similar classes of drugs;
- any post-approval study requirements for our drug products and the results thereof; and
- sufficient third-party insurance coverage and reimbursement.

Our continuing efforts to educate physicians, patients, third-party payors and others in the medical community on the benefits and risks of TAVNEOS may require significant resources and may never be successful. Physicians may opt to prescribe the drug products of our competitors for a variety of reasons. If TAVNEOS fails to achieve an adequate level of acceptance by physicians, patients, third-party payors and others in the medical community, we will not be able to generate sufficient revenue to become or remain profitable.

We cannot guarantee that TAVNEOS or any other drug candidates we may seek to develop will ever be commercially successful, and to the extent they are not commercially successful, such drug candidates would incur significant expense with lower than expected or no corresponding revenue. Because we expect the sales of TAVNEOS to generate substantially all of our revenue for the foreseeable future, the failure of TAVNEOS to find market acceptance would substantially harm our business and could require us to seek additional financing.

The market opportunity for TAVNEOS or any future drug candidate we develop may be smaller than we estimate.

The potential market opportunity for TAVNEOS and any future drug candidate is difficult to precisely estimate. Our estimates of the potential market opportunity for our drug candidates include several key assumptions of the current market size and current pricing for commercially available drug products and are based on industry and market data obtained from industry publications, studies conducted by us, our industry knowledge, third-party research reports and other surveys. While we believe our estimates are reasonable and reliable, they may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of diseases and disorders. The number of patients may turn out to be lower than expected. Additionally, the potentially addressable patient population for TAVNEOS or any future drug candidate we develop may be limited or may not be amenable to treatment with

TAVNEOS or such future drug candidate, and new patients may become increasingly difficult to identify or gain access to, which would adversely affect our results of operations and our business.

We have only recently begun product sales and anticipate that we will continue to incur significant losses for the foreseeable future, and if we are unable to achieve and sustain profitability, the market value of our common stock will likely decline.

Other than TAVNEOS, we do not currently have any drug products approved for sale, and we continue to incur significant research and development and general and administrative expenses related to our operations. Our net loss for the years ended December 31, 2020, 2019 and 2018 was \$55.4 million, \$55.5 million and \$38.0 million, respectively. As of December 31, 2020, we had an accumulated deficit of \$485.3 million. We expect to continue to incur significant losses for the foreseeable future. We expect these losses and our cash utilization to increase in the near term as we continue to conduct clinical trials for CCX559 and CCX507 and conduct research and development of our other drug candidates. To date, substantially all of our revenues has been derived from upfront fees and milestone payments, other payments pursuant to our collaboration agreements and government grants and contracts for research and development. For example, in May 2016 and December 2016, we entered into collaboration and license agreements with Vifor (International) Ltd. and/or its affiliates, or collectively, Vifor, for the commercialization of avacopan and CCX140, respectively. In addition, if approved, we expect to incur significant costs to commercialize our drug products and our drug products may never gain market acceptance. If our drug candidates fail to demonstrate safety and efficacy in clinical trials, do not gain regulatory approval, or do not achieve market acceptance, we may never become profitable. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. If we are unable to achieve and sustain profitability, the market value of our common stock will likely decline. Because of the numerous risks and uncertainties associated with developing pharmaceutical drugs, we are unable to predict the extent of any future losses or whether we will become profitable.

If we are unable to obtain regulatory approval to market our drug products in the United States and foreign jurisdictions, we will not be permitted to commercialize such drug products.

We have received regulatory approval for TAVNEOS as an adjunctive treatment for adult patients with severe active ANCA-associated vasculitis, specifically GPA and MPA in combination with standard therapy including glucocorticoids, and not for the elimination of glucocorticoid use, pursuant to a new drug application, or NDA, that was approved by the FDA in October 2021. Before receiving regulatory approval to market any other drug product, we must demonstrate with substantial clinical evidence to the satisfaction of the FDA or other regulatory authority that the drug product is safe and effective in the patient population and the indication that will be treated. Data obtained from preclinical and clinical activities are susceptible to varying interpretations that could delay, limit or prevent regulatory approvals. In addition, delays or rejections may be encountered based upon additional government regulation from future legislation or administrative action or changes in FDA policy during the period of drug development, clinical trials and FDA regulatory review. Failure to comply with applicable FDA or other applicable regulatory requirements may result in criminal prosecution, civil penalties, recall or seizure of drug products, total or partial suspension of production or injunction, adverse publicity, as well as other regulatory action against our potential drug products or us.

If regulatory approval of a drug product is granted, such approval will be limited to those indications or disease states and conditions for which the drug product is demonstrated through clinical trials to be safe and effective. For example, TAVNEOS has only been approved in the United States as an adjunctive treatment for adult patients with severe active ANCA-associated vasculitis, and our marketing of TAVNEOS must be consistent with the approved indication. We cannot assure you that any drug product developed by us, alone or with others, will be demonstrated to be safe and efficacious in clinical trials and will meet all of the applicable regulatory requirements needed to receive regulatory approval.

Outside the United States, our ability, or that of our collaborative partners, to market a drug product is contingent upon receiving a marketing authorization from the appropriate regulatory authorities. This foreign regulatory approval process typically includes all of the risks and costs associated with FDA approval described above and may also include additional risks and costs, such as the risk that such foreign regulatory authorities, which often have different regulatory and clinical trial requirements, interpretations and guidance from the FDA, may require additional clinical trials or results for approval of a drug candidate, any of which could result in delays, significant additional costs or failure to obtain such regulatory approval. For example, there can be no assurance that we or our collaborative partners will not have to provide additional information or analysis, or conduct additional clinical trials, before receiving approval to market drug candidates.

TAVNEOS has been approved by the FDA as an adjunctive treatment for adult patients with severe active ANCA-associated vasculitis in combination with standard therapy including glucocorticoids, and not for the elimination of glucocorticoid use. Regulatory approval is limited by the FDA to the specific indication for which approval has been granted and, unless we seek regulatory approval for additional indications, we will be prohibited from marketing TAVNEOS for other indications. We may be subject to fines, penalties or injunctions if we are determined to have promoted or be promoting the use of TAVNEOS for unapproved, or “off-label” uses, resulting in damage to our reputation and business.

While we received approval for TAVNEOS from the FDA for the indication of adjunctive treatment for adult patients with severe active ANCA-associated vasculitis in combination with standard therapy including glucocorticoids, and not for the elimination of glucocorticoid use. TAVNEOS is not indicated to treat any other conditions. We are prohibited from promoting TAVNEOS for any

other indication unless we are granted FDA approval for such indication. The FDA strictly regulates the promotional claims that may be made about prescription drug products, and TAVNEOS may not be promoted for uses that are not approved by the FDA as reflected in its approved labeling. If we are not able to obtain FDA approval for any desired future indications for our drug products and drug candidates, our ability to effectively market and sell our drug products may be reduced and our business may be adversely affected.

While physicians may choose to prescribe drug products for uses that are not described in the drug product's labeling and for uses that differ from those tested in clinical trials and approved by the regulatory authorities, we are prohibited from marketing and promoting the drug products for indications that are not specifically approved by the FDA. These "off-label" uses are common across medical specialties and may constitute an appropriate treatment for some patients in varied circumstances. Regulatory authorities in the United States generally do not restrict or regulate the behavior of physicians in their choice of treatment within the practice of medicine. Regulatory authorities do, however, restrict communications by biotechnology or pharmaceutical companies on unapproved uses. If the FDA determines that our promotional activities constitute promotion of an unapproved use of our products, it could request that we modify our promotional materials and subject us to FDA regulatory or enforcement actions as well as actions by other agencies, including issuance of warning letters or untitled letters, suspension or withdrawal of an approved drug product from the market, mandatory or voluntary recalls, civil fines, disgorgement of money, operating restrictions, additional reporting requirements and/or oversight if we become subject to a corporate integrity agreement or similar agreement, injunctions or criminal prosecution, any of which could significantly harm our business.

Even though we have obtained regulatory approval for TAVNEOS, and even if we obtain approval for any of our other drug candidates, we or our collaborative partners will still face extensive regulatory requirements and our drug products may face future development and regulatory difficulties.

Even though we have obtained regulatory approval for TAVNEOS, and even if we obtain regulatory approval for any of our other drug candidates, our drugs and manufacturing operations will remain subject to continual review by the FDA, the EMA and EU Member State Competent Authorities, and/or non-U.S./non-EU regulatory authorities. Any regulatory approval that we receive for our drug candidates may be subject to limitations on the indicated uses for which the drug product may be marketed or contain requirements for potentially costly post-marketing follow-up studies to monitor the safety and efficacy of the drug product. The FDA and the EMA also have authority to require a risk evaluation and mitigation strategy, or REMS, or risk management plan, as part of an NDA, CMA, marketing authorization application, or MAA, or after approval, which may impose further requirements or restrictions on the distribution or use of an approved drug, such as limiting prescribing to certain physicians or medical centers that have undergone specialized training, limiting treatment to patients who meet certain safe-use criteria or requiring treated patients to enroll in a registry. In addition, upon approval by the FDA, the EMA, EU Member State Competent Authorities, and/or non-U.S./non-EU regulatory authorities of any of our drug candidates, we will be subject to extensive and ongoing regulatory requirements by the FDA, the EMA, EU Member State Competent Authorities, and other regulatory authorities with regard to the labeling, packaging, adverse event reporting, storage, advertising, promotion and recordkeeping for our drug products. The FDA and the EMA, the European institutions and the EU Member State Competent Authorities, strictly regulate the promotional claims that may be made about prescription drug products. In particular, a drug product may not be promoted for uses that are not approved by the FDA or the European Commission as reflected in the drug product's approved labeling. For example, TAVNEOS was approved by the FDA in October 2021 as an adjunctive treatment for adult patients with severe active ANCA-associated vasculitis in combination with standard therapy including glucocorticoids, and not for the elimination of glucocorticoid use. Even though we have obtained approved for TAVNEOS in this indication, and even if we receive regulatory approval for any of our other drug candidates, physicians may nevertheless prescribe our drugs to their patients in a manner that is inconsistent with the approved label. However, if we are found to have promoted such unapproved uses, we may become subject to significant liability and government fines.

In addition, manufacturers of drug products are required to comply with cGMP regulations, which include requirements related to quality control and quality assurance as well as the corresponding maintenance of records and documentation. Further, regulatory authorities must authorize manufacturing facilities before they can be used to manufacture our drug products, and such facilities will remain subject to continual review and periodic inspections by the FDA, the EMA, EU Member State Competent Authorities, and other regulatory authorities for compliance with cGMP regulations.

If we or a regulatory authority discovers previously unknown problems with a drug, such as adverse events of unanticipated severity or frequency, or problems with the facility where the drug product is manufactured, a regulatory authority may impose restrictions on that drug product, the manufacturer or us, including imposition of a REMS, or similar risk management measures, or requesting recall or withdrawal of the drug product from the market or suspension of manufacturing. If we, our drug products or the manufacturing facilities for our drug products fail to comply with regulatory requirements of the FDA, the EMA, the EU institutions, the EU Member State Competent Authorities and/or other non-U.S./non-EU regulatory authorities, we could be subject to administrative or judicially imposed sanctions, including:

- warning letters, untitled letters or other communications asserting that we are in violation of law;
- injunctions, civil or criminal penalties or monetary fines;

- suspension or withdrawal of regulatory approvals;
- suspension of ongoing clinical trials;
- restrictions on operations, including costly new manufacturing requirements;
- refusal to approve pending applications seeking regulatory approval for new drugs or supplements to approved applications submitted by us;
- product recalls;
- drug product detentions or seizures; or
- refusal to allow us to enter into supply contracts, including government contracts.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may delay or inhibit our ability to successfully commercialize our drug products and generate revenues.

The regulatory requirements and policies may change and additional government regulations may be enacted for which we may also be required to comply. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States, the EU or in other countries or jurisdictions. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we will not be permitted to market our future drug products and our business will suffer.

Undesirable side effects caused by TAVNEOS could impact our ability to market and derive revenue from TAVNEOS, and such side effects or adverse events associated with any drug candidate could compromise our ability to develop our drug candidates.

As we commercialize TAVNEOS or conduct additional clinical trials on TAVNEOS or our other drug candidates, these efforts could reveal a high and unacceptable incidence and severity of undesirable side effects. Undesirable side effects could adversely affect patient enrollment in clinical studies, cause us or regulatory authorities to interrupt, delay or halt clinical studies or result in the delay, denial or withdrawal of regulatory approval by the FDA or other regulatory authorities. Undesirable or adverse side effects also could result in regulatory authorities mandating a more restrictive prescribing label for the drug product, which, in turn, could limit the market acceptance of the drug product even if approved for marketing and commercialization.

Drug-related side effects could result in potential product liability claims. A successful product liability claim or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations, business and financial condition. In addition, regardless of merit or eventual outcome, product liability claims may result in impairment of our business reputation, significant negative media attention, withdrawal of clinical study participants, costs due to related litigation, distraction of management's attention from our primary business, initiation of investigations by regulators, substantial monetary awards to patients or other claimants, the inability to commercialize our current drug candidate or any future drug candidate, product recalls, restrictions on labeling, marketing or promotion, decreased demand for our drug candidates, if approved for marketing, and loss of revenue.

Additionally, if we or others later identify undesirable side effects caused by either TAVNEOS or any other drug candidate, either in the post-marketing setting or in clinical trials, a number of potentially significant negative consequences could result, including but not limited to:

- the delay, prevention or withdrawal of approvals by regulatory authorities;
- the requirement of additional warnings on the prescribing label;
- the requirement of a REMS plan, which could include a medication guide outlining the risks of such side effects for distribution to patients, a communication plan for healthcare providers and/or other elements to assure safe use;
- litigation and the potential to be held liable for harm caused to patients;
- the recall or withdrawal of the drug product;
- fines, injunctions, or imposition of civil or criminal penalties; and
- an adverse effect on our reputation.

Any of these events could prevent us from achieving or maintaining market acceptance of TAVNEOS or any other drug candidate for which we obtain approval, and could significantly harm our business, results of operations, financial condition and prospects.

We are in the early stages of developing our commercialization infrastructure in the United States. If we are unable to develop a sales and marketing and distribution capability on our own or through collaborations with marketing partners, we will not be successful in commercializing our future drug products.

We are in the early stages of developing our commercialization infrastructure in the United States and have no history of selling, marketing or distributing therapeutic drugs. In order to market any drugs that may be approved by the FDA, EMA or other comparable regulatory authorities, we must build our sales, marketing, managerial and other non-technical capabilities, or make arrangements with third parties to perform these services. We have entered into the Avacopan Agreement with Vifor for development and commercialization of avacopan outside of the United States and Vifor has in turn sublicensed its right to commercialize avacopan in Japan to its sublicensee Kissei. We retain commercialization rights to avacopan in the United States. To the extent we rely directly or indirectly on third parties such as Vifor for marketing and distributing our approved drug products, any revenue we receive will depend upon the efforts of third parties, which may not be successful and are only partially within our control and our drug product revenue is likely to be lower than if we directly marketed or sold our drug products. Future collaborators may fail to develop or effectively commercialize our drug candidates because they cannot obtain necessary regulatory approvals, development or commercialization is not commercially reasonable, they elect to pursue competitive drug products outside of the collaboration, or for other reasons. If we are unable to enter into arrangements with third parties to commercialize any approved drug products on acceptable terms or at all, we may not be able to successfully commercialize our future drug products or we will have to market these drug products ourselves, which will be expensive and require us to build our own commercial infrastructure, which we do not have experience doing. We cannot assure you we will be successful in any of these initiatives. If we are not successful in commercializing our future drug products, either on our own or through collaborations with third parties, any future drug product revenue will be materially adversely affected.

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 drug 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.

Although we have obtained regulatory approval for TAVNEOS in the United States, many of our drug candidates are in the early stages of drug discovery or clinical trials or, with respect to TAVNEOS, are in research programs for potential additional indications, and are prone to the risks of failure inherent in drug development. We will need to conduct significant additional preclinical studies and clinical trials for many of our drug candidates before we can demonstrate that such drug candidates are 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 drug products. While we have filed integrated regulatory submissions in 2020 with the EMA and FDA for regulatory approval of TAVNEOS, and while we received approval from the FDA in October 2021, we can provide no assurance we will receive such approval in Europe.

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 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;
- the FDA or comparable foreign regulatory authorities disagreeing as to the design or implementation of our clinical studies; or
- obtaining regulatory authorizations to commence a trial.

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

- changes to clinical trial protocols;

- 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 or in accordance with regulatory requirements;
- 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;
- occurrence of serious adverse events in trials of the same class of agents conducted by other companies;
- subjects choosing an alternative treatment for the indication for which we are developing our drug candidates, or participating in competing clinical trials;
- selection of clinical end points that require prolonged periods of clinical observation or analysis of the resulting data;
- 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;
- a facility manufacturing our drug candidates or any of their components being ordered by the FDA or comparable foreign regulatory authorities to temporarily or permanently shut down; any changes to our manufacturing process that may be necessary or desired;
- any changes to our manufacturing process that may be necessary or desired; or
- third-party contractors becoming debarred or suspended or otherwise penalized by the FDA or other government or regulatory authorities for violations of regulatory requirements, in which case we may need to find a substitute, and we may not be able to use some or all of the data produced by such contractors in support of our marketing applications.

We could also encounter delays if a clinical trial is suspended or terminated by us, the IRBs or ethics committees of the institutions in which such trials are being conducted, the Data Safety Monitoring Board, or DSMB, for such trial or the FDA or other regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

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 drug 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.

If we are required to suspend or discontinue clinical trials due to side effects or other safety risks, or if we obtain unfavorable results in our post-marketing studies of TAVNEOS or any future studies of the long-term effects associated with the use of our drug candidates, our efforts to commercialize our drug products could be delayed or halted.

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 for such targets, including TAVNEOS and CCX507. As of the date of this Quarterly Report on Form 10-Q, nine of our drug candidates have been tested in human beings. Although we have not observed material safety concerns in prior studies of our drug candidates, later trials could reveal unforeseen adverse events. The safety PK results from preclinical studies may not be indicative of results observed in subsequent clinical trials. 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 drugs, if any, to short-term use. Some or all of our drug candidates may prove to be unsafe for human use.

Undesirable side effects caused by our drug candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA, EMA or other comparable regulatory authorities. Drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete a trial or result in potential drug product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly. Given the serious nature of the conditions we are treating in our clinical trials, and the multiple concomitant medications including our active drug candidates that our patients are treated with, side effects (such as nausea, diarrhea, infections, hepatic enzyme elevations, and possible allergic reactions) have been reported in our clinical studies. While such disorders may be found to be not related to our drug candidates, such events may create a negative safety perception. Even if any of our drug candidates receives regulatory approval, as greater numbers of patients use a drug following its approval, an increase in the incidence or severity of side effects or the incidence of other post-approval problems that were not seen or anticipated during pre-approval clinical trials could result in a number of potentially significant negative consequences, including that regulatory authorities may withdraw their approval of the drug, regulatory authorities may require the addition of labeling statements, such as “black box” warnings or contraindications, or impose additional safety monitoring or reporting requirements, we may be required to change the way the drug is administered or conduct additional clinical trials, we may be required to implement a REMS or create a medication guide outlining the risks of such side effects for distribution to patients, we could be sued and held liable for harm caused to patients, and our reputation may suffer. Any of these events could substantially increase the costs and expenses of developing, commercializing and marketing any such drug candidates or could harm or prevent sales of any approved drug products.

Interim, “topline,” and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose preliminary or topline data from our preclinical studies and clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial.

We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the topline or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, topline data should be viewed with caution until the final data are available.

From time to time, we may also disclose interim data from our preclinical studies and clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular drug candidate or drug product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure.

If the interim, topline, or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for and commercialize our drug products may be harmed, which could harm our business, operating results, prospects or financial condition.

Even though we have obtained orphan drug designation to TAVNEOS in the United States, Japan and Europe, we may not be able to obtain or maintain orphan drug exclusivity for this drug candidate or any other drug candidates for which we obtain orphan drug designation.

In the United States, under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biological product intended to treat a rare disease or condition. Such diseases and conditions are those that affect fewer than 200,000 individuals in the United States, or if they affect more than 200,000 individuals in the United States, there is no reasonable expectation that the cost of developing and making a drug available in the United States for these types of diseases or conditions will be recovered from sales of the drug. Orphan drug designation must be requested before submitting an NDA. If the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by that agency. Orphan drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process, but it can lead to financial incentives, such as opportunities for grant funding toward clinical trial costs, tax advantages and user-fee waivers.

If a drug that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the drug is entitled to orphan drug marketing exclusivity for a period of seven years. Orphan drug marketing exclusivity generally prevents the FDA from approving another application, including a full NDA, to market the same drug or biological product for the same indication for seven years, except in limited circumstances, including if the FDA concludes that the later drug is safer, more effective or makes a major contribution to patient care. For purposes of small molecule drugs, the FDA defines “same drug” as a drug that contains the same active chemical entity and is intended for the same use as the drug in question. A designated orphan drug may not receive orphan drug marketing exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. Orphan drug marketing exclusivity rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition.

The criteria for designating an orphan medicinal drug in the EU are similar in principle to those in the United States. Under Article 3 of Regulation (EC) 141/2000, a medicinal drug may be designated as orphan if (i) it is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition; (ii) either (a) such condition affects no more than five in 10,000 persons in the EU when the application is made, or (b) the drug, without the benefits derived from orphan status, would not generate sufficient return in the EU to justify investment; and (iii) there exists no satisfactory method of diagnosis, prevention or treatment of such condition authorized for marketing in the EU, or if such a method exists, the drug product will be of significant benefit to those affected by the condition, as defined in Regulation (EC) 847/2000. Orphan medicinal products are eligible for financial incentives such as reduction of fees or fee waivers and are, upon grant of a marketing authorization, entitled to ten years of market exclusivity for the approved therapeutic indication. The application for orphan designation must be submitted before the application for marketing authorization. The applicant will receive a fee reduction for the MAA if the orphan designation has been granted, but not if the designation is still pending at the time the marketing authorization is submitted. Orphan designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

The ten-year market exclusivity in the EU may be reduced to six years if, at the end of the fifth year, it is established that the drug product no longer meets the criteria for orphan designation, for example, if the drug product is sufficiently profitable not to justify maintenance of market exclusivity. Additionally, marketing authorization may be granted to a similar drug product for the same indication at any time if:

- the second applicant can establish that its drug product, although similar, is safer, more effective or otherwise clinically superior;
- the applicant consents to a second orphan medicinal application; or
- the applicant cannot supply enough orphan medicinal product.

The FDA granted orphan drug designation for TAVNEOS for the treatment of C3G and ANCA-associated vasculitis, including GPA, formerly known as Wegener’s granulomatosis, MPA and Churg-Strauss syndrome. Upon approval of TAVNEOS by the FDA as an adjunctive treatment for adult patients with severe active ANCA-associated vasculitis in combination with standard therapy including glucocorticoids, and not for the elimination of glucocorticoid use, the FDA granted us orphan drug exclusivity in this indication, which means that the FDA cannot approve the same drug for the same indication for a period of seven years, except where a subsequent applicant for the same drug demonstrates that its product is clinically superior to TAVNEOS or we otherwise are unable to assure sufficient quantities. In November 2014, the European Commission granted orphan drug designation for avacopan for the treatment of GPA and MPA, and, in June 2017, for the treatment of C3G. However, we cannot assure you that we will be able to maintain orphan drug exclusivity for TAVNEOS or that we will be able to obtain or maintain orphan drug exclusivity for any of our other drug candidates, if they are approved for any orphan-designated use in any jurisdiction, in a timely manner or at all, or that a competitor will not obtain orphan drug exclusivity that could block the regulatory approval of any of our drug candidates for several years. If we are unable to maintain or obtain orphan drug exclusivity, our ability to generate sufficient revenues may be negatively affected. If a competitor is able to obtain orphan drug exclusivity that would block our drug candidates’ regulatory approval, our

ability to generate revenues would be significantly reduced, which would harm our business prospects, financial condition and results of operations.

We rely on third party contract manufacturing organizations to manufacture and supply TAVNEOS and our drug candidates for us. If one of our suppliers or manufacturers fails to perform adequately or fulfill our needs, we may be required to incur significant costs and devote significant efforts to find new suppliers or manufacturers. We may also face delays in the development and commercialization TAVNEOS or any of our drug candidates.

We currently have limited experience in, and we do not own facilities for, manufacturing TAVNEOS or our drug candidates. We rely upon third party contract manufacturing organizations to manufacture and supply larger quantities of TAVNEOS and these other drug candidates. The manufacture of pharmaceutical products in compliance with cGMP requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of pharmaceutical products often encounter difficulties in production, including difficulties with production costs and yields, quality control, including stability of the drug candidate and quality assurance testing, shortages of qualified personnel, as well as compliance with strictly enforced FDA cGMP requirements, other federal and state regulatory requirements, and foreign regulations. Raw materials for the synthesis of our API are sourced globally. If the manufacturers of our raw materials and pharmaceutical products were to encounter any difficulties or otherwise fail to comply with their obligations to us or under applicable regulations, our ability to provide study drugs in our preclinical studies and clinical trials would be jeopardized. Any delay or interruption in the supply of preclinical study or clinical trial materials could delay the completion of our preclinical studies and clinical trials, increase the costs associated with maintaining our preclinical study and clinical trial programs and, depending upon the period of delay, require us to commence new trials at significant additional expense or terminate the studies and trials completely.

All manufacturers of our drug candidates must comply with cGMP requirements enforced by the FDA through its facilities inspection program. These requirements include, among other things, quality control, quality assurance and the maintenance of records and documentation. Manufacturers of our component materials may be unable to comply with these cGMP requirements and with other FDA, state and foreign regulatory requirements. The FDA or similar foreign regulatory agencies at any time may also implement new standards, or change their interpretation and enforcement of existing standards for manufacture, packaging or testing of drug products. We have little control over our manufacturers' compliance with these regulations and standards. A failure to comply with these requirements may result in fines and civil penalties, suspension of production, suspension or delay in drug product approval, product seizure or recall, or withdrawal of drug product approval. If the safety of any drug product supplied is compromised due to our manufacturers' failure to adhere to applicable laws or for other reasons, we may not be able to obtain regulatory approval for or successfully commercialize our drug products, and we may be held liable for any injuries sustained as a result. Any of these factors could cause a delay of clinical trials, regulatory submissions, approvals or commercialization of our drug candidates or entail higher costs or impair our reputation.

We currently rely on a single source supplier for API and drug product for each of our drug candidates. In the event that we and our suppliers cannot agree to the terms and conditions for them to provide some or all of our API clinical and commercial supply needs, or if any single source supplier terminates the agreement in response to a breach by us, or if a supplier is not able to timely provide us with API and drug product, we would not be able to manufacture the API on a commercial scale until a qualified alternative supplier is identified, which could also delay the development of, and impair our ability to commercialize, TAVNEOS and our other drug candidates. For example, public health epidemics, such as the ongoing coronavirus outbreak, may impact the ability of our existing or future suppliers to provide us with preclinical study or clinical trial materials.

Although alternative sources of supply exist, the number of third-party suppliers with the necessary manufacturing and regulatory expertise and facilities is limited, and it could be expensive and take a significant amount of time to arrange for alternative suppliers, which could have a material adverse effect on our business. New suppliers of any API would be required to qualify under applicable regulatory requirements and would need to have sufficient rights under applicable intellectual property laws to the method of manufacturing such ingredients. Obtaining the necessary FDA approvals or other qualifications under applicable regulatory requirements and ensuring non-infringement of third-party intellectual property rights could result in a significant interruption of supply and could require the new manufacturer to bear significant additional costs which may be passed on to us.

Risks Related to Government Regulation

The regulatory approval process is expensive, time-consuming and uncertain and may prevent us from obtaining approvals for the commercialization of some or all of our drug candidates.

The research, testing, manufacturing, labeling, approval, selling, import, export, marketing and distribution of drugs and drug candidates are subject to extensive regulation by the FDA and other regulatory authorities in the United States, the EMA, the EU institutions (e.g., the European Commission) and the EU Member State Competent Authorities, as well as equivalent authorities and regulatory bodies in other countries, which regulations differ from country to country. We are not permitted to market our drug candidates in the United States until we receive approval of an NDA from the FDA and in the EU until we have received approval from the European Commission or EU Member State Competent Authorities. Obtaining approval of an NDA, MAA or CMA can be

an expensive, time-consuming and uncertain process. In addition, failure to comply with FDA, EMA and other applicable U.S., EU and foreign regulatory requirements may subject us to administrative or judicially imposed sanctions, including:

- warning letters;
- civil and criminal penalties;
- injunctions;
- withdrawal of approved drug products;
- drug product seizure or detention;
- drug product recalls;
- total or partial suspension of production; and
- refusal to approve pending NDAs or supplements to approved NDAs, pending CMA or MAAs.

Prior to receiving approval to commercialize any of our drug candidates in the United States, the EU, or in other countries, we must demonstrate with substantial evidence from well controlled clinical trials, and to the satisfaction of the FDA, the EMA, and other regulatory authorities abroad, that such drug candidates are safe and effective for their intended uses. Results from preclinical studies and clinical trials can be interpreted in different ways. Even if we believe the preclinical or clinical data for our drug candidates are promising, such data may not be sufficient to support approval by the FDA, the EMA, and other regulatory authorities. Administering any of our drug candidates to humans may produce undesirable side effects, which could interrupt, delay or halt clinical trials of our drug candidates and result in the FDA, the EMA, or other regulatory authorities denying approval of our drug candidates for any or all targeted indications.

Regulatory approval of an NDA or NDA supplement, or of a CMA, MAA, or of their respective extensions and variations, is not guaranteed, and the approval process is expensive and may take several years. The FDA and the EMA also have substantial discretion in the approval process. Despite the time and expense exerted, failure can occur at any stage, and we could encounter problems that cause us to abandon or repeat clinical trials, or perform additional preclinical studies and clinical trials. The number of preclinical studies and clinical trials that will be required for FDA or EMA approval varies depending on the drug candidate, the disease or condition that the drug candidate is designed to address, and the regulations applicable to any particular drug candidate. The FDA or EMA can delay, limit or deny approval of a drug candidate for many reasons, including, but not limited to, the following:

- a drug candidate may not be deemed safe or effective;
- FDA or EMA officials may not find the data from preclinical studies and clinical trials sufficient;
- the FDA or EMA might not approve our or our third-party manufacturer's processes or facilities; or
- the FDA or EMA may change its approval policies or adopt new regulations.

If any of our drug candidates fails to demonstrate safety and efficacy in clinical trials or does not gain regulatory approval, our business and results of operations will be materially and adversely harmed.

Changes in funding for the FDA and other government agencies could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new drug products and services from being developed or commercialized in a timely manner, which could negatively impact our business.

The ability of the FDA to review and approve new drugs can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Separately, in response to the COVID-19 pandemic, on March 10, 2020 the FDA announced its intention to postpone most inspections of foreign manufacturing facilities, and on March 18, 2020, the FDA temporarily postponed routine surveillance inspections of domestic manufacturing facilities. On July 10, 2020, the FDA announced its intention to resume certain on-site

inspections of domestic manufacturing facilities subject to a risk-based prioritization system. The FDA intends to use this risk-based assessment system to identify the categories of regulatory activity that can occur within a given geographic area, ranging from mission critical inspections to resumption of all regulatory activities. Additionally, on April 15, 2021, the FDA issued a guidance document in which the FDA described its plans to conduct voluntary remote interactive evaluations of certain drug manufacturing facilities and clinical research sites. According to the guidance, the FDA intends to request such remote interactive evaluations in situations where an in-person inspection would not be prioritized, deemed mission-critical, or where direct inspection is otherwise limited by travel restrictions, but where the FDA determines that remote evaluation would still be appropriate. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

New healthcare reform measures, or changes to existing laws and regulations, could hinder or prevent our drug candidates' commercial success by making it difficult or impossible for us to obtain adequate prices or insurance coverage.

In the United States, there have been and we expect there will continue to be a number of legislative and regulatory changes to the healthcare system in ways that could affect our future revenues and profitability and the future revenues and profitability of our potential customers. Federal and state lawmakers regularly propose and, at times, enact legislation that would result in significant changes to the healthcare system, some of which are intended to contain or reduce the costs of medical products and services. For example, in March 2010, the Affordable Care Act was signed into law. It contained a number of provisions, including those governing enrollment in federal healthcare programs, reimbursement changes and fraud and abuse measures, all of which impacted existing government healthcare programs and resulted in the development of new programs. The Affordable Care Act, among other things:

- imposed a non-deductible annual fee on pharmaceutical manufacturers or importers who sell “branded prescription drugs” to specified federal government programs;
- increased the minimum level of Medicaid rebates payable by manufacturers of brand-name drugs from 15.1% to 23.1%;
- required collection of rebates for drugs paid by Medicaid managed care organizations;
- required manufacturers to participate in a coverage gap discount program, under which they must agree to offer 70% (in 2021) point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer’s outpatient drugs to be covered under Medicare Part D; and
- mandated a further shift in the burden of Medicaid payments to the states.

Since its enactment, there have been judicial, executive and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Prior to the Supreme Court’s decision, President Biden had issued an executive order to initiate a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is unclear how the healthcare reform measures of the Biden administration, or other efforts to challenge the ACA, if any, will impact the ACA or our business.

Other legislative changes have been adopted since the Affordable Care Act was enacted. These changes include aggregate reductions to Medicare payments to providers of 2% per fiscal year, which went into effect in April 2013 and, due to subsequent legislative amendments, will remain in effect through 2030, with the exception of a temporary suspension from May 1, 2020 through December 31, 2021, unless additional Congressional action is taken. In January 2013, the ATRA was enacted, which, among other things, further reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Recently, there has also been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed drug products, in part informed by the current atmosphere of mounting criticism of prescription drug costs in the U.S., which has resulted in several Congressional inquiries and proposed bills designed to, among other things, reform government program reimbursement methodologies. We expect there will continue to be legislative and regulatory proposals to change the healthcare system in ways that could impact our ability to sell TAVNEOS profitably, as governmental oversight and scrutiny of pharmaceutical companies is increasing. We anticipate that the U.S. Congress, state legislatures, and regulators may adopt or accelerate adoption of new healthcare policies and reforms intended to curb healthcare costs, such as federal and state controls on reimbursement for drugs (including under Medicare, Medicaid and commercial health plans), new or increased requirements to pay prescription drug rebates and penalties to government health care programs, and additional pharmaceutical cost transparency policies that aim to require drug companies to justify their prices through required disclosures. For example, measures have been introduced in Congress that would

impose caps on prescription drug prices and would require manufacturers to negotiate drug pricing with the government. These new laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on our potential customers and accordingly, our financial operations.

There likely will continue to be legislative and regulatory proposals at the federal and state levels directed at containing or lowering the cost of health care. We cannot predict the initiatives that may be adopted in the future or their full impact, particularly in light of the current presidential administration and U.S. Congress. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of health care may adversely affect:

- our ability to set a price we believe is fair for our drug products;
- our ability to generate revenues and achieve or maintain profitability; and
- the availability of capital.

Further, 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 IRBs for reexamination, which may impact the costs, timing or successful completion of a clinical trial. In light of widely publicized events concerning the safety risk of certain drug products, regulatory authorities, members of Congress, the Governmental Accounting Office, medical professionals and the general public have raised concerns about potential drug safety issues. These events have resulted in the recall and withdrawal of drug products, revisions to drug labeling that further limit use of the drug products and establishment of risk management programs that may, for instance, restrict distribution of drug products or require safety surveillance and/or patient education. The increased attention to drug safety issues may result in a more cautious approach by the FDA to clinical trials and the drug approval process. Data from clinical trials may receive greater scrutiny with respect to safety, which may make the FDA or other regulatory authorities more likely to terminate or suspend clinical trials before completion, or require longer or additional clinical trials that may result in substantial additional expense and a delay or failure in obtaining approval or approval for a more limited indication than originally sought.

Even if we are able to commercialize TAVNEOS or our other drug candidates, if approved, the drugs may become subject to unfavorable pricing regulations or third party reimbursement practices, which could harm our business.

Successful sales of TAVNEOS and our drug candidates, if approved, depend on the availability of adequate coverage and reimbursement from third-party payors. Patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid in the United States, and commercial payors are critical to new drug acceptance.

Our ability to commercialize any drugs successfully also will depend in part on the extent to which coverage and reimbursement for these drugs and related treatments will be available from government health administration authorities, private health insurers and other organizations. The regulations that govern regulatory approvals, pricing and reimbursement for new therapeutic drugs vary widely from country to country. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or licensing approval is granted. In some non-U.S. markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain regulatory approval for a drug in a particular country, but be subject to price regulations that delay our commercial launch of the drug and negatively impact the revenues we are able to generate from the sale of the drug in that country. Adverse pricing limitations may hinder our ability to recover our investment in TAVNEOS or our drug candidates, even if our drug candidates obtain regulatory approval. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a drug is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

We cannot be sure that reimbursement will be available for TAVNEOS or any other drug that we commercialize and, if coverage and reimbursement are available, what the level of reimbursement will be. Reimbursement may impact the demand for, or the price of, any drug for which we obtain regulatory approval. Obtaining reimbursement for our drugs may be difficult because of the higher prices often associated with branded drugs and drugs administered under the supervision of a physician. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize any drug candidate that we successfully develop.

In the United States, no uniform policy of coverage and reimbursement for drugs exists among third-party payors. As a result, obtaining coverage and reimbursement approval of a drug from a government or other third-party payor is a time-consuming and costly process that could require us to provide to each payor supporting scientific, clinical and cost-effectiveness data for the use of our drugs on a payor-by-payor basis, with no assurance that coverage and adequate reimbursement will be obtained. Even if we obtain coverage for a given drug, the resulting reimbursement payment rates might not be adequate for us to achieve or sustain profitability or may require co-payments that patients find unacceptably high. Additionally, third-party payors may not cover, or provide adequate reimbursement for, long-term follow-up evaluations required following the use of our drugs.

If we obtain approval in one or more non-U.S. jurisdictions for our drug candidates, we will be subject to rules and regulations in those jurisdictions. In some non-U.S. jurisdictions, the reimbursement of drugs and biologics is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after obtaining regulatory approval of a drug candidate. In addition, market acceptance and sales of our drug candidates will depend significantly on the availability of adequate coverage and reimbursement from third-party payors for our drug candidates and may be affected by existing and future health care reform measures.

If we fail to comply with healthcare laws and regulations, we could face investigations, substantial civil or criminal penalties and our business, operations and financial condition could be adversely affected. Additionally, any challenge to or investigation into our practices under these laws could cause adverse publicity and be costly to respond to, and thus could harm our business.

Certain federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our business. We could be subject to healthcare fraud and abuse rules by both the federal government and the states in which we conduct our business. The laws and regulations that may affect our ability to operate include, without limitation:

- the federal Anti-Kickback Statute, which prohibits, among other things, any person from knowingly and willfully offering, soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act. Violations of the federal Anti-Kickback Statute may result in significant civil monetary penalties or criminal fines and imprisonment. Violations can result in exclusion from participation in government healthcare programs, including Medicare and Medicaid;
- the federal False Claims Act, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, false claims, or knowingly using false statements, to obtain payment from the federal government including the Medicare and Medicaid or other federal healthcare programs. For example, pharmaceutical companies have been prosecuted under the False Claims Act in connection with alleged "off-label" promotion of drugs, misstated government pricing information, or provision of free drug product or other items of value to customers, among other things. Private individuals can bring False Claims Act "qui tam" actions, on behalf of the government and such individuals, commonly known as "whistleblowers," may share in amounts paid by the entity to the government in fines or settlement. When an entity is determined to have violated the federal civil False Claims Act, the government may impose significant civil fines and penalties, and exclude the entity from participation in Medicare, Medicaid and other federal healthcare programs;
- federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the federal Civil Monetary Penalties law, which prohibits, among other things, offering or transferring remuneration to a federal healthcare beneficiary that a person knows or should know is likely to influence the beneficiary's decision to order or receive items or services reimbursable by the government from a particular provider or supplier;
- the federal Physician Payments Sunshine Act, which requires pharmaceutical companies to submit annual reports to CMS. In the annual reports, pharmaceutical companies must report information related to payments and other transfers of value to teaching hospitals, physicians, and, beginning in 2022, certain other health care professionals. Failure to submit required information, or failure to submit information in a timely, accurate and complete manner, may result in significant civil monetary penalties;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers or competitors; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by the government or, in some states, any payor including commercial insurers; state laws

that require pharmaceutical companies to comply with the industry’s voluntary compliance guidelines and the applicable compliance guidance published by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; and state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and drug product pricing information.

In addition, certain states mandate that we comply with a state code of conduct, adopt a company code of conduct under state criteria, disclose marketing payments made to physicians and other healthcare providers, and/or report compliance information to the state authorities. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply in multiple jurisdictions with different compliance and reporting requirements increases the possibility that a pharmaceutical company may run afoul of one or more of the requirements.

If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, the exclusion from participation in U.S. federal or state health care programs and the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment or restructuring of our operations could adversely affect our ability to operate our business and our financial results. Any action against us for violation of these laws, even if we successfully defend against it or reach a settlement agreement, could cause us to incur significant legal expenses and divert our management’s attention from the operation of our business.

Risks Related to the Securities Markets and an Investment in Our Stock

There may not be a viable market for our common stock or the price of our common stock may be volatile, and stockholders may not be able to sell their shares at prices that are attractive to them.

There was no public market for our common stock prior to our initial public offering in February 2012, the trading volume of our common stock on the Nasdaq Global Select Market has been limited and there can be no assurance that an active and liquid trading market for our common stock will develop or be sustained. We cannot predict the extent to which investor interest in our company will lead to the development or maintenance of an active trading market on the Nasdaq Global Select Market or otherwise or how liquid that market might become. If an active public market does not develop or is not sustained, it may be difficult for stockholders to sell their shares of common stock at prices that are attractive to them, or at all. Further, an inactive market may also impair our ability to raise capital by selling shares of our common stock and may impair our ability to enter into strategic partnerships or acquire companies or drugs, drug candidates or technologies by using our shares of common stock as consideration.

Stockholders may also be unable to sell their shares of common stock at prices that are attractive to them due to fluctuations in the market price of our common stock. The market prices for securities of biotechnology and pharmaceutical companies have historically been highly volatile. Since the commencement of trading in connection with our initial public offering in February 2012, the publicly traded shares of our common stock have themselves experienced significant price and volume fluctuations. During the nine-month period ended September 30, 2021, the price per share for our common stock on the Nasdaq Global Select Market ranged from a low sale price of \$9.53 to a high sale price of \$70.29. This market volatility is likely to continue. These and other factors could reduce the market price of our common stock, regardless of our operating performance. In addition, the trading price of our common stock could change significantly, both over short periods of time and the longer term, due to many factors, including, but not limited to, those described elsewhere in this “Risk Factors” section and the following:

- results from, and any delays in, clinical trial programs relating to our drug candidates, including the ongoing and planned clinical trials for TAVNEOS, CCX559, CCX507 and other drug candidates;
- announcements of regulatory approvals or disapprovals of our drug candidates, or delays in any regulatory agency review or approval processes;
- failure or discontinuation of any of our research programs;
- announcements relating to future collaborations;
- general economic conditions in the United States and abroad;
- acquisitions and sales of new drug products, technologies or business;
- delays in the commercialization of any of our drug candidates;
- market conditions in the pharmaceutical, biopharmaceutical and biotechnology sectors;
- the issuance of new or changed securities analysts’ reports or recommendations regarding us, our competitors or our industry in general;
- actual and anticipated fluctuations in our quarterly operating results;

- disputes concerning our intellectual property or other proprietary rights;
- introduction of technological innovations or new drug products by us or our competitors;
- manufacturing issues related to our drug candidates for clinical trials or future drug products for commercialization;
- market acceptance of TAVNEOS or our future drug products;
- the level of underlying demand for TAVNEOS and customers' buying patterns
- deviations in our operating results from the estimates of analysts, or other analyst comments;
- third-party payor coverage and reimbursement policies;
- new legislation in the United States relating to the sale or pricing of pharmaceuticals;
- FDA, EMA or other U.S. or foreign regulatory actions affecting us or our industry;
- drug product liability claims or other litigation or public concern about the safety of our drug candidates or future drugs;
- our ability to obtain necessary intellectual property licenses;
- the outcome of any future legal actions to which we are party;
- sales of our common stock by our officers, directors or significant stockholders;
- additions or departures of key personnel; and
- other external factors, including natural disasters and other crises.

In addition, the stock markets in general, and the markets for pharmaceutical, biopharmaceutical and biotechnology stocks in particular, have experienced extreme volatility that have been often unrelated to the operating performance of the issuer. These broad market fluctuations may adversely affect the trading price or liquidity of our common stock. As of the date of this filing, a consolidated securities class action lawsuit has been filed against us (*Homyk v. ChemoCentryx, Inc.*, 4:21-cv-03343-JST (N.D. Cal.)), and other litigation may be filed in the future. Given the early stage of this case, we are unable to estimate a range of potential loss. Furthermore, we may incur substantial costs defending the lawsuit and the attention of our management may be diverted from the operation of our business.

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.

EXHIBIT INDEX

Exhibit Number	Description
10.1	First Amendment to Amended and Restated Loan and Security Agreement.
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.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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 9, 2021

/s/ Thomas J. Schall, Ph.D.

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

Date: November 9, 2021

/s/ Susan M. Kanaya

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

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

THIS **FIRST AMENDMENT TO AMENDED AND RESTATED LOAN AND SECURITY AGREEMENT** (this “Amendment”), dated as of July 23, 2021 (the “First Amendment Effective Date”), is entered into by and between CHEMOCENTRYX, INC., a Delaware corporation, and each of its Qualified Subsidiaries (hereinafter collectively referred to as the “Borrower”), the several banks and other financial institutions or entities from time to time party to the Loan and Security Agreement (hereinafter defined) (collectively, referred to as “Lender”), and HERCULES CAPITAL, INC., a Maryland corporation, in its capacity as administrative agent and collateral agent for itself and the Lender (in such capacity, together with its successors and assigns in such capacity, “Agent”).

Borrower, Lender and Agent are parties to that certain Amended and Restated Loan and Security Agreement dated as of January 8, 2020 (as amended, restated or modified from time to time, the “Loan and Security Agreement”). Borrower has requested that Agent and Lender agree to certain amendments to the Loan and Security Agreement. Agent and Lender have agreed to such requests, subject to the terms and conditions hereof.

Accordingly, the parties hereto agree as follows:

SECTION 1 Definitions; Interpretation.

(a) **Terms Defined in Loan and Security Agreement.** All capitalized terms used in this Amendment (including in the recitals hereof) and not otherwise defined herein shall have the meanings assigned to them in the Loan and Security Agreement as amended by this Amendment.

(b) **Interpretation.** The rules of interpretation set forth in Section 1.1 of the Loan and Security Agreement as amended by this Amendment shall be applicable to this Amendment and are incorporated herein by this reference.

SECTION 2 Amendments to the Loan and Security Agreement. The Loan and Security Agreement shall be amended as follows effective as of the First Amendment Effective Date:

(a) **New Definition.** The following definition is added to Section 1.1 in its proper alphabetical order:

“First Amendment Effective Date” means July 23, 2021.

(b) **Amended Definitions.** The following definitions are hereby amended and restated as follows:

“Tranche 1 Amortization Date” means January 1, 2022.

“Tranche 2 Amortization Date” means January 1, 2022.

(c) **Section 2.2(d).** The second sentence of Section 2.2(d) is hereby amended and restated as follows:

“Commencing on the First Amendment Effective Date, Borrower shall repay the aggregate Tranche principal balance that is outstanding on the day immediately preceding the applicable Amortization Date of such Tranche, in equal monthly installments of principal

and interest (mortgage style) beginning on such Amortization Date and continuing on the first Business Day of each month thereafter until the Secured Obligations (other than inchoate indemnity obligations) with respect to such Tranche are repaid.”

(d) **References Within Loan and Security Agreement.** Each reference in the Loan and Security Agreement to “this Agreement” and the words “hereof,” “herein,” “hereunder,” or words of like import, shall mean and be a reference to the Loan and Security Agreement as amended by this Amendment.

SECTION **Conditions of Effectiveness.** The effectiveness of this Amendment shall be subject to the satisfaction of each of the following
3 conditions precedent:

(a) **Fees and Expenses.** Borrower shall have paid (i) all attorney fees and other costs and expenses then due in accordance with Section 5(e) of this Amendment, and (ii) all other fees, costs and expenses, if any, due and payable as of the First Amendment Effective Date under the Loan and Security Agreement as amended by this Amendment.

(b) **This Amendment.** Agent shall have received this Amendment, executed by Agent, Lender and Borrower.

(c) **Representations and Warranties; No Default.** On the First Amendment Effective Date, after giving effect to the amendment of the Loan and Security Agreement contemplated hereby:

(i) The representations and warranties contained in Section 4 shall be true and correct on and as of the First Amendment Effective Date as though made on and as of such date; and

(ii) There exist no Events of Default or events that with the passage of time would result in an Event of Default.

SECTION **Representations and Warranties.** To induce Agent and Lender to enter into this Amendment, Borrower hereby confirms, as of
4 the date hereof, (a) that the representations and warranties made by it in the Loan and Security Agreement and in the other Loan Documents are true and correct in all material respects; *provided, however,* that such materiality qualifier shall not be applicable to any representations and warranties that already are qualified or modified by materiality in the text thereof; (b) that there has not been and there does not exist a Material Adverse Effect; and (c) that the information included in the Perfection Certificate delivered to Agent on the New Loan Effective Date remains true and correct in all material respects. For the purposes of this Section 4, (i) each reference in Section 5 of the Loan and Security Agreement to “this Agreement,” and the words “hereof,” “herein,” “hereunder,” or words of like import in such Section, shall mean and be a reference to the Loan and Security Agreement as amended by this Amendment, and (ii) any representations and warranties which relate solely to an earlier date shall not be deemed confirmed and restated as of the date hereof (provided that such representations and warranties shall be true, correct and complete in all material respects as of such earlier date).

SECTION 5 **Miscellaneous.**

(a) **Loan Documents Otherwise Not Affected; Reaffirmation; No Novation.**

(i) Except as expressly amended pursuant hereto or referenced herein, the Loan and Security Agreement and the other Loan Documents shall remain unchanged and in full force and effect and are hereby ratified and confirmed in all respects. Lender’s and Agent’s execution and delivery of, or acceptance of, this Amendment shall not be deemed to create a course of dealing or otherwise create any express or implied duty by any of them to provide any other or further amendments, consents or waivers in the future.

(ii) Borrower hereby reaffirms the grant of security under Section 3.1 of the Loan and Security Agreement and hereby reaffirms that such grant of security in the Collateral secures all Secured Obligations under the Loan and Security Agreement, including without limitation any Advance funded on or after the First Amendment Effective Date.

(i) This Amendment is not a novation and the terms and conditions of this Amendment shall be in addition to and supplemental to all terms and conditions set forth in the Loan Documents. Nothing in this Amendment is intended, or shall be construed, to constitute an accord and satisfaction of any Loan Party's Secured Obligations under or in connection with the Loan and Security Agreement and any other Loan Document or to modify, affect or impair the perfection or continuity of Agent's security interest in, (on behalf of itself and the Lenders) security titles to or other liens on any Collateral for the Secured Obligations.

(b) **Conditions.** For purposes of determining compliance with the conditions specified in Section 3, each Lender that has signed this Amendment shall be deemed to have consented to, approved or accepted or to be satisfied with, each document or other matter required thereunder to be consented to or approved by or acceptable or satisfactory to a Lender unless Agent shall have received notice from such Lender prior to the First Amendment Effective Date specifying its objection thereto.

(c) **Release.** In consideration of the agreements of Agent and each Lender contained herein and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Borrower, on behalf of itself and its successors, assigns, and other legal representatives, hereby fully, absolutely, unconditionally and irrevocably releases, remises and forever discharges Agent and each Lender, and its successors and assigns, and its present and former shareholders, affiliates, subsidiaries, divisions, predecessors, directors, officers, attorneys, employees, agents and other representatives (Agent, Lender and all such other persons being hereinafter referred to collectively as the "**Releasees**" and individually as a "**Releasee**"), of and from all demands, actions, causes of action, suits, covenants, contracts, controversies, agreements, promises, sums of money, accounts, bills, reckonings, damages and any and all other claims, counterclaims, defenses, rights of set-off, demands and liabilities whatsoever of every name and nature, known or unknown, suspected or unsuspected, both at law and in equity, which Borrower, or any of its successors, assigns, or other legal representatives may now or hereafter own, hold, have or claim to have against the Releasees or any of them for, upon, or by reason of any circumstance, action, cause or thing whatsoever which arises at any time on or prior to the day and date of this Amendment under the Loan and Security Agreement or any of the other Loan Documents or transactions thereunder or related thereto. Borrower understands, acknowledges and agrees that the release set forth above may be pleaded as a full and complete defense and may be used as a basis for an injunction against any action, suit or other proceeding which may be instituted, prosecuted or attempted in breach of the provisions of such release. Borrower agrees that no fact, event, circumstance, evidence or transaction which could now be asserted or which may hereafter be discovered shall affect in any manner the final, absolute and unconditional nature of the release set forth above. Borrower waives the provisions of California Civil Code Section 1542, which states:

A GENERAL RELEASE DOES NOT EXTEND TO CLAIMS THAT THE CREDITOR OR RELEASING PARTY DOES NOT KNOW OR SUSPECT TO EXIST IN HIS OR HER FAVOR AT THE TIME OF EXECUTING THE RELEASE AND THAT, IF KNOWN BY HIM OR HER, WOULD HAVE MATERIALLY AFFECTED HIS OR HER SETTLEMENT WITH THE DEBTOR OR RELEASED PARTY.

The provisions of this section shall survive payment in full of the Secured obligations, full performance of all the terms of this Amendment and the other Loan Documents.

(d) **No Reliance.** Borrower hereby acknowledges and confirms to Agent and Lender that Borrower is executing this Amendment on the basis of its own investigation and for its own reasons without reliance upon any agreement, representation, understanding or communication by or on behalf of any other Person.

(e) **Costs and Expenses.** Borrower agrees to pay to Agent the date hereof the reasonable out-of-pocket costs and expenses of Agent and Lender party hereto, and the fees and disbursements of counsel to Agent and Lender party hereto (including allocated costs of internal counsel), in connection with the negotiation, preparation, execution and delivery of this Amendment and any other documents to be delivered in connection herewith on the First Amendment Effective Date or after such date.

(f) **Binding Effect.** This Amendment binds and is for the benefit of the successors and permitted assigns of each party.

(g) **Governing Law.** This Amendment shall be governed by, and construed and enforced in accordance with, the laws of the State of California, excluding conflict of laws principles that would cause the application of laws of any other jurisdiction.

(h) **Complete Agreement; Amendments.** This Amendment and the Loan Documents represent the entire agreement about this subject matter and supersede prior negotiations or agreements with respect to such subject matter. All prior agreements, understandings, representations, warranties, and negotiations between the parties about the subject matter of this Amendment and the Loan Documents merge into this Amendment and the Loan Documents.

(i) **Severability of Provisions.** Each provision of this Amendment is severable from every other provision in determining the enforceability of any provision.

(j) **Counterparts.** This Amendment may be executed in any number of counterparts and by different parties on separate counterparts, each of which, when executed and delivered, is an original, and all taken together, constitute one Amendment. Delivery of an executed counterpart of a signature page of this Amendment by facsimile, portable document format (.pdf) or other electronic transmission will be as effective as delivery of a manually executed counterpart hereof.

(k) **Loan Documents.** This Amendment and the documents related thereto shall constitute Loan Documents.

(a) **Electronic Execution of Certain Other Documents.** The words “execution,” “execute”, “signed,” “signature,” and words of like import in or related to any document to be signed in connection with this Amendment and the transactions contemplated hereby (including without limitation assignments, assumptions, amendments, waivers and consents) shall be deemed to include electronic signatures, the electronic matching of assignment terms and contract formations on electronic platforms approved by Agent, or the keeping of records in electronic form, each of which shall be of the same legal effect, validity or enforceability as a manually executed signature or the use of a paper-based recordkeeping system, as the case may be, to the extent and as provided for in any applicable law, including the Federal Electronic Signatures in Global and National Commerce Act, the California Uniform Electronic Transaction Act, or any other similar state laws based on the Uniform Electronic Transactions Act..

[Balance of Page Intentionally Left Blank; Signature Pages Follow]

IN WITNESS WHEREOF, the parties hereto have duly executed this Amendment, as of the date first above written.

BORROWER:

CHEMOCENTRYX, INC.

Signature: /s/ Thomas J. Schall, Ph.D. _____

Print Name: Thomas J. Schall, Ph.D.

Title: President and Chief Executive Officer

AGENT:

HERCULES CAPITAL, INC.

Signature: /s/ Jennifer Choe _____
Print Name: Jennifer Choe
Title: Associate General Counsel

LENDER:

HERCULES CAPITAL, INC.

Signature: /s/ Jennifer Choe _____
Print Name: Jennifer Choe
Title: Associate General Counsel

HERCULES CAPITAL FUNDING TRUST 2018-1

Signature: /s/ Jennifer Choe _____
Print Name: Jennifer Choe
Title: Associate General Counsel

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

I, Thomas J. Schall, Ph.D., certify that:

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

/s/ Thomas J. Schall, Ph.D.

Thomas J. Schall, Ph.D.

Chief Executive Officer

Date: November 9, 2021

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

I, Susan M. Kanaya, certify that:

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

/s/ Susan M. Kanaya

Susan M. Kanaya

Chief Financial and Administrative Officer

Date: November 9, 2021

CERTIFICATION
Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
(Subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code)

In connection with the Quarterly Report on Form 10-Q of ChemoCentryx, Inc. (the "Company") for the period ended September 30, 2021, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Thomas J. Schall, Ph.D., as Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 9, 2021

/s/ Thomas J. Schall, Ph.D.

Thomas J. Schall, Ph.D.

Chief Executive Officer

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. § 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing. A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

CERTIFICATION
Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
(Subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code)

In connection with the Quarterly Report on Form 10-Q of ChemoCentryx, Inc. (the "Company") for the period ended September 30, 2021, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Susan M. Kanaya, as Chief Financial and Administrative Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 9, 2021

/s/ Susan M. Kanaya

Susan M. Kanaya

Chief Financial and Administrative Officer

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. § 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing. A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.
