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, 2020

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	**94-3254365**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification No.)**
850 Maude Avenue Mountain View, California	**94043**
(Address of Principal Executive Offices)	**(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	☐	Accelerated filer	☒
Non-accelerated filer	☐	Smaller reporting company	☐
		Emerging growth company	☐

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

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

The number of outstanding shares of the registrant's common stock, par value $0.001 per share, as of October 31, 2020 was 69,208,414.

CHEMOCENTRYX, INC.

QUARTERLY REPORT ON FORM 10-Q
For the quarterly period ended September 30, 2020

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

CHEMOCENTRYX, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands, except share and par value data)
(unaudited)

	September 30, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 56,177	$ 39,179
Short-term investments	415,207	133,607
Accounts receivable, other	44	176
Accounts receivable from related party	58	—
Prepaid expenses and other current assets	2,956	1,400
Total current assets	474,442	174,362
Property and equipment, net	15,063	2,154
Long-term investments	14,456	29,454
Operating lease right-of-use assets	27,667	1,704
Other assets	1,414	1,409
Total assets	$ 533,042	$ 209,083
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 8,868	$ 1,532
Accrued and other current liabilities	18,938	19,806
Long-term debt, current	3,066	—
Other current liabilities to related party	6,173	—
Deferred revenue from related party	9,817	37,742
Total current liabilities	46,862	59,080
Long-term debt, net	21,260	19,786
Non-current deferred revenue from related party	24,814	63,095
Non-current lease liabilities	34,436	566
Other non-current liabilities	851	556
Total liabilities	128,223	143,083
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; 69,108,573 and 60,234,784 shares issued and outstanding at September 30, 2020 and December 31, 2019, respectively	69	60
Additional paid-in capital	859,960	495,624
Note receivable	(16)	(16)
Accumulated other comprehensive income	272	318
Accumulated deficit	(455,466)	(429,986)
Total stockholders' equity	404,819	66,000
Total liabilities and stockholders' equity	$ 533,042	$ 209,083

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,	
	2020	2019	2020	2019
Revenue:				
Collaboration and license revenue from related party	$ 5,027	$ 10,581	$ 60,165	$ 26,081
Grant revenue	58	—	368	—
Total revenue	5,085	10,581	60,533	26,081
Operating expenses:				
Research and development	18,582	18,096	56,655	51,074
General and administrative	10,362	6,116	29,474	17,187
Total operating expenses	28,944	24,212	86,129	68,261
Loss from operations	(23,859)	(13,631)	(25,596)	(42,180)
Other income (expense):				
Interest income	499	1,311	2,059	3,850
Interest expense	(700)	(542)	(1,943)	(1,631)
Total other income (expense), net	(201)	769	116	2,219
Net loss	$ (24,060)	$ (12,862)	$ (25,480)	$ (39,961)
Basic and diluted net loss per common share	$ (0.35)	$ (0.22)	$ (0.40)	$ (0.71)
Shares used to compute basic and diluted net loss per common share	68,922	58,205	64,500	56,219

See accompanying notes.

CHEMOCENTRYX, INC.
CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(in thousands)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Net loss	$ (24,060)	$ (12,862)	$ (25,480)	$ (39,961)
Unrealized gain (loss) on available-for-sale securities	(216)	56	(46)	607
Comprehensive loss	$ (24,276)	$ (12,806)	$ (25,526)	$ (39,354)

See accompanying notes.

CHEMOCENTRYX, INC.
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

(in thousands, except share data)
(unaudited)

	Common Stock		Additional Paid-In	Note	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Receivable	Income	Deficit	Equity
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	69,108,573	$ 69	$ 859,960	$ (16)	$ 272	$ (455,466)	$ 404,819

	Common Stock		Additional Paid-In	Note	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Receivable	Income	Deficit	Equity
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	69,108,573	$ 69	$ 859,960	$ (16)	$ 272	$ (455,466)	$ 404,819

See accompanying notes.

CHEMOCENTRYX, INC.
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

(in thousands, except share data)
(unaudited)

	Common Stock		Additional Paid-In	Note	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Receivable	Income (Loss)	Deficit	Equity
Balance as of June 30, 2019	58,209,745	$ 58	$ 472,661	$ (16)	$ 353	$ (401,596)	$ 71,460
Net loss	—	—	—	—	—	(12,862)	(12,862)
Unrealized gain on investments	—	—	—	—	56	—	56
Issuance of common stock under equity incentive and employee stock purchase plans	43,395	—	269	—	—	—	269
Employee stock-based compensation	—	—	2,856	—	—	—	2,856
Compensation expense related to options granted to consultants	—	—	83	—	—	—	83
Balance as of September 30, 2019	58,253,140	$ 58	$ 475,869	$ (16)	$ 409	$ (414,458)	$ 61,862

	Common Stock		Additional Paid-In	Note	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Receivable	Income (Loss)	Deficit	Equity
Balance as of December 31, 2018	50,652,238	$ 51	$ 389,398	$ (16)	$ (198)	$ (374,497)	$ 14,738
Net loss	—	—	—	—	—	(39,961)	(39,961)
Unrealized gain on investments	—	—	—	—	607	—	607
Issuance of common stock under Equity Distribution Agreement, net of issuance costs	6,491,196	6	73,270	—	—	—	73,276
Issuance of common stock under equity incentive and employee stock purchase plans	1,217,325	1	5,836	—	—	—	5,837
Repurchased shares upon vesting of restricted stock units for tax withholdings	(107,619)	—	(1,174)	—	—	—	(1,174)
Employee stock-based compensation	—	—	8,359	—	—	—	8,359
Compensation expense related to options granted to consultants	—	—	180	—	—	—	180
Balance as of September 30, 2019	58,253,140	$ 58	$ 475,869	$ (16)	$ 409	$ (414,458)	$ 61,862

See accompanying notes.

CHEMOCENTRYX, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)
(unaudited)

	Nine Months Ended September 30,	
	2020	2019
Operating activities		
Net loss	$ (25,480)	$ (39,961)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	15,902	8,539
Depreciation of property and equipment	402	413
Non-cash lease expense	1,402	803
Non-cash interest expense (income), net	822	(1,394)
Changes in assets and liabilities:		
Accounts receivable, other	132	—
Accounts receivable due from related party	(58)	2,058
Prepaids and other current assets	(770)	756
Other assets	(5)	116
Accounts payable	213	(29)
Operating lease liabilities	6,255	(801)
Other liabilities	(701)	3,460
Deferred revenue from related party	(60,033)	(23,853)
Net cash used in operating activities	(61,919)	(49,893)
Investing activities		
Purchases of property and equipment, net	(6,136)	(465)
Purchases of investments	(391,942)	(189,404)
Sales of investments	—	4,967
Maturities of investments	124,220	165,770
Net cash used in investing activities	(273,858)	(19,132)
Financing activities		
Proceeds from issuance of common stock	325,654	73,276
Proceeds from exercise of stock options and employee stock purchase plan	26,472	5,837
Employees' tax withheld and paid for restricted stock units	(3,709)	(1,174)
Borrowings under credit facility agreement, net of issuance costs	4,358	—
Net cash provided by financing activities	352,775	77,939
Net increase in cash, cash equivalents and restricted cash	16,998	8,914
Cash, cash equivalents and restricted cash at beginning of period	40,259	28,088
Cash, cash equivalents and restricted cash at end of period	$ 57,257	$ 37,002
Supplemental disclosures of cash flow information		
Cash paid for interest	$ 1,433	$ 1,317
Right-of-use assets obtained in exchange for lease obligations (1)	$ 27,365	$ 2,796
Purchases of property and equipment, net recorded in accounts payable and accrued liabilities	$ 7,175	$ —

(1) Amount for the nine months ended September 30, 2019 includes the transition adjustment of $1,301 for the adoption of Accounting Standards Update (ASU) No. 2016-02, Leases (Topic 842).

See accompanying notes.

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 targeted at inflammatory disorders, autoimmune diseases and cancer. The Company's principal operations are in the United States and it operates in one segment.

Unaudited Interim Financial Information

The financial information filed is unaudited. The Condensed Consolidated Financial Statements included in this report reflect all adjustments (consisting only of normal recurring adjustments) that the Company considers necessary for the fair statement of the results of operations for the interim periods covered and of the financial condition of the Company at the date of the interim balance sheet. The December 31, 2019 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, 2019 filed with the Securities and Exchange Commission on March 10, 2020.

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.

Total accounts receivable consists of the following (in thousands):

	September 30, 2020	December 31, 2019
U.S. Food and Drug Administration	$ 44	$ 176
Vifor (International) Ltd., and/or its affiliates, or collectively, Vifor	58	—
	$ 102	$ 176

Net Loss Per Share

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

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

For the three and nine months ended September 31, 2020 and 2019, 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,	
	2020	2019
Options to purchase common stock, including purchases from contributions to ESPP	7,416	11,059
Restricted stock units	389	402
Restricted stock awards	14	41
Warrants to purchase common stock	150	150
	7,969	11,652

Comprehensive Loss

Comprehensive loss comprises net loss and other comprehensive gain (loss). For the periods presented, other comprehensive gain (loss) consists of unrealized gains (losses) on the Company's available-for-sale securities. For the three and nine months ended September 30, 2020, there were no significant sales of investments and therefore there were no reclassifications of comprehensive loss. For the three and nine months ended September 30, 2019, amounts reclassified from accumulated other comprehensive income to net loss for unrealized gains (losses) on available-for-sale securities were not significant, and were recorded as part of other income, net in the Condensed Consolidated Statements of Operations.

Recent Accounting Pronouncements

In June 2016, the Financial Accounting Standard Board issued ASU 2016-13, Financial Instruments – Credit Losses: Measurement of Credit Losses on Financial Instruments. The new standard replaces the incurred loss impairment methodology under the current standard with a methodology that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information to inform credit loss estimates. The Company is required to use a forward-looking expected credit loss model for accounts receivable and other financial instruments. Credit losses relating to available-for-sale debt securities will also be recorded through an allowance for credit losses rather than as a reduction in the amortized cost basis of the securities. The new standard became effective for the Company on January 1, 2020. The Company's adoption on January 1, 2020 did not have a material impact on the consolidated financial statements.

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

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, 2020	December 31, 2019
Cash and cash equivalents	$ 56,177	$ 39,179
Restricted cash included in Other assets	1,080	1,080
Total cash, cash equivalents and restricted cash	$ 57,257	$ 40,259

Restricted cash as of September 30, 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 of this lease.

Cash Equivalents and Investments

The amortized cost and fair value of cash equivalents and investments at September 30, 2020 and December 31, 2019 were as follows (in thousands):

	September 30, 2020			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Money market fund	$ 50,473	$ —	$ —	$ 50,473
U.S. treasury securities	200,899	104	—	201,003
Government-sponsored agencies	12,495	2	—	12,497
Commercial paper	120,809	—	—	120,809
Asset-backed securities	22,218	68	—	22,286
Corporate debt securities	72,970	109	(11)	73,068
Total available-for-sale securities	$ 479,864	$ 283	$ (11)	$ 480,136
Classified as:				
Cash equivalents				$ 50,473
Short-term investments				415,207
Long-term investments				14,456
Total available-for-sale securities				$ 480,136

	December 31, 2019			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Money market fund	$ 30,353	$ —	$ —	$ 30,353
U.S. treasury securities	40,245	47	—	40,292
Commercial paper	12,429	—	—	12,429
Asset-backed securities	25,436	50	—	25,486
Corporate debt securities	84,605	225	(4)	84,826
Total available-for-sale securities	$ 193,068	$ 322	$ (4)	$ 193,386
Classified as:				
Cash equivalents				$ 30,325
Short-term investments				133,607
Long-term investments				29,454
Total available-for-sale securities				$ 193,386

Cash equivalents in the tables above exclude cash of $5.7 million and $8.9 million as of September 30, 2020 and December 31, 2019, respectively. All available-for-sale securities held as of September 30, 2020 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 significant available-for-sale securities held as of September 30, 2020 have been in a continuous unrealized loss position for more than 12 months. As of September 30, 2020, 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, 2020 and December 31, 2019 (in thousands):

	September 30, 2020			
Description	**Level 1**	**Level 2**	**Level 3**	**Total**
Money market fund	$ 50,473	$ —	$ —	$ 50,473
U.S. treasury securities	—	201,003	—	201,003
Government-sponsored agencies	—	12,497	—	12,497
Commercial paper	—	120,809	—	120,809
Asset-backed securities	—	22,286	—	22,286
Corporate debt securities	—	73,068	—	73,068
Total assets	$ 50,473	$ 429,663	$ —	$ 480,136

	December 31, 2019			
Description	**Level 1**	**Level 2**	**Level 3**	**Total**
Money market fund	$ 30,353	$ —	$ —	$ 30,353
U.S. treasury securities	—	40,292	—	40,292
Commercial paper	—	12,429	—	12,429
Asset-backed securities	—	25,486	—	25,486
Corporate debt securities	—	84,826	—	84,826
Total assets	$ 30,353	$ 163,033	$ —	$ 193,386

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, 2020 and December 31, 2019 were as follows (in thousands):

	September 30, 2020		December 31, 2019	
	Carrying Amount	Estimated Fair Value	Carrying Amount	Estimated Fair Value
Long-term debt, net (1)	$ 24,326	$ 25,153	$ 19,786	$ 20,253

(1) Carrying amounts of long-term debt were net of unamortized debt discounts of $674 and $214 as of September 30, 2020 and December 31, 2019, 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, 2020	December 31, 2019
Research and development related	$ 10,988	$ 13,100
Compensation related	4,337	3,608
Consulting and professional services	1,397	1,094
Current portion of operating lease liability	1,253	1,503
Other	963	501
	$ 18,938	$ 19,806

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, 2020, 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 will make interest-only payments through July 1, 2021, and will then repay the principal balance and interest on the advances in equal monthly installments continuing through December 1, 2022. The Company will pay an end of term charge of $1.3 million.

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 is available to the Company through December 15, 2020, of which $20.0 million became available upon submission of the avacopan New Drug Application (NDA) for the treatment of patients with anti-neutrophil cytoplasmic auto-antibody associated vasculitis (ANCA vasculitis). The second tranche of up to an additional $30.0 million would be available to the Company through December 15, 2021 upon NDA approval of avacopan for the treatment of ANCA 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 had borrowed $5.0 million from the first tranche with an interest rate of 8.50% per annum as of September 30, 2020. 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 avacopan revenue levels. For advances under the Restated Credit Facility, the Company will make interest only payments through September 1, 2022 and will then 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 will 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 charge of 1% of the advances made under the Amended Loan Agreement, 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 Amended Loan Agreement. 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 Amended Loan Agreement, 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. See "Note 10. Stockholders' Equity" for additional information.

As of September 30, 2020, the Company had outstanding borrowings under the Amended Loan Agreement of $24.3 million, net of discounts of $0.7 million. Future minimum principal payments, which exclude the end of term charge, related to the Restated Credit Facility as of September 30, 2020 are as follows (in thousands):

	Amounts
Year ending December 31:	
Remaining of fiscal year 2020	$ —
2021	6,389
2022	14,666
2023	3,353
2024	592
Total minimum payments	25,000
Less: amount representing debt discount	(674)
Present value of remaining debt payments	24,326
Less: current portion	(3,066)
Non-current portion	$ 21,260

7. Commitments

Operating Leases

In May 2004, the Company entered into a noncancelable operating lease for its current 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 current 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 are anticipated to begin in March 2021. Following a six month period of discounted rent, the Company will 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 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, 2020, the Company has received a tenant improvement allowance of $6.0 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):

	September 30, 2020	December 31, 2019
Balance Sheet		
Assets:		
Operating lease right-of-use assets	$ 27,667	$ 1,704
Liabilities:		
Operating lease liabilities:		
Accrued and other current liabilities (1)	$ 1,253	$ 1,503
Non-current lease liabilities	34,436	566

(1) Includes current portion of operating lease liabilities as of September 30, 2020 and December 31, 2019.

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):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Operating lease cost	$ 1,743	$ 351	$ 2,905	$ 943

During the nine months ended September 30, 2020 and 2019, cash paid for amounts included in the measurement of lease liabilities was $1.2 million, excluding the $6.0 million tenant improvement allowance received, and $0.9 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, 2020 are as follows (in thousands):

	Operating leases
Year ending December 31:	
Remaining of fiscal year 2020	$ 434
2021	5,210
2022	7,316
2023	7,516
2024	7,721
Thereafter	52,518
Total minimum payments	80,715
Less: interest	(31,472)
Less: future tenant improvement reimbursements	(13,554)
Present value of lease liabilities	$ 35,689

As of September 30, 2020, the weighted-average remaining lease term was 10.2 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, 2020. 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 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.

Upon achievement of certain regulatory and commercial milestones with avacopan, the Company will receive additional payments of up to $460.0 million under the Avacopan 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 avacopan by Vifor in the licensed territories. In December 2017, the Company achieved a $50.0 million regulatory milestone when the European Medicines Agency (EMA) validated the Company's conditional marketing authorization (CMA) application for avacopan for the treatment of ANCA vasculitis.

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. As such, the transaction price under this arrangement is allocated to the license and the development and regulatory services.

As of September 30, 2020, the transaction price of $153.0 million comprises 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 vasculitis in December 2017; and
- $5.0 million non-refundable upfront payment under the Avacopan Letter Agreement.

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

The Company determined that the combined performance obligation will be performed over the duration of the contract, which began on the effective date of May 9, 2016 and ends upon completion of development and regulatory services. The Company 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, 2020, the Company recognized $2.9 million and $9.9 million of collaboration and license revenue under the Avacopan Agreements, respectively, as compared to $8.8 million and $20.9 million during the same respective periods in 2019.

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, 2020, the transaction price of $66.5 million comprises 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, the Company reclassified $6.2 million of deferred revenue previously received from Vifor to other current liabilities to related party. 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, 2020, the Company recognized $2.1 million and $50.2 million of collaboration and license revenue under the CCX140 Agreements, respectively, compared to $1.8 million and $5.2 million during the same respective periods in 2019. As of September 30, 2020, deferred revenue under the CCX140 Agreement was $2.0 million, representing the Company's remaining estimated performance obligation under these agreements.

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, 2020	December 31, 2019
Contract asset:		
Accounts receivable	$ 58	$ -
Contract liability:		
Deferred revenue	(34,631)	(100,837)

During the three and nine months ended September 30, 2020, 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, 2020	Nine Months Ended September 30, 2020
Revenue recognized in the period from:		
Amount included in contract liability at the beginning of the period	$ 4,967	$ 60,033
Performance obligations satisfied (or partially satisfied) in previous periods	$ 1,825	$ 39,502

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. For the three and nine months ended September 30, 2020, the Company recognized $0.1 million and $0.4 million of grant revenue, respectively. As of September 30, 2020, $44,000 was recorded as accounts receivable.

10. Stockholders' Equity

Stock Options

During the nine months ended September 30, 2020, 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, 2019	2,192,545	9,287,901	$ 9.44		
Shares authorized	2,000,000	-			
Granted (1)	(1,179,578)	934,218	49.08		
Exercised (2)	92,459	(2,704,469)	9.61		
Forfeited and expired (3)	122,135	(110,468)	23.90		
Outstanding at September 30, 2020	3,227,561	7,407,182	$ 14.16	6.75	$ 301,653,026
Vested and expected to vest, net of estimated forfeiture at September 30, 2020		7,136,579	$ 13.70	6.67	$ 293,912,662
Exercisable at September 30, 2020		4,434,932	$ 8.46	5.49	$ 205,536,129

(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.
(3) The difference between shares forfeited and expired in the number of shares available for grant and those outstanding represents RSUs canceled during the period.

Restricted Stock

During the nine months ended September 30, 2020, the activity for restricted stock is summarized as follows:

	Shares	Weighted Average Grant-Date Fair Value
Balance at December 31, 2019	399,823	$ 10.54
Granted	245,360	48.08
Vested	(230,986)	9.98
Canceled	(11,667)	10.95
Unvested at September 30, 2020	402,530	$ 33.74

Stock-based Compensation

Total stock-based compensation expense was $5.9 million and $15.9 million during the three and nine months ended September 30, 2020, respectively, and $2.9 million and $8.5 million during the same respective periods ended September 30, 2019. As of September 30, 2020, $35.7 million, $7.7 million and $107,000 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 2.40, 1.65 and 0.12 years, respectively.

Equity Follow-On Offering

In June 2020, the Company completed an equity follow-on offering of 5,980,000 shares of its common stock at a sale price of $58.00 per share. The Company received net proceeds of $325.7 million, after deducting underwriting discounts, commissions and offering expenses.

11. Subsequent Event

In October 2020, the Company entered into a Manufacturing and Supply Agreement with Vifor (the "Vifor Avacopan Commercial Supply Agreement"). Under the Vifor 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 Vifor Avacopan Commercial Supply Agreement will expire upon the termination of the Avacopan Agreements or under certain circumstances as specified in the agreement.

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, 2019, filed with the Securities and Exchange Commission, or SEC, on March 10, 2020.

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 and clinical trials;
- the commercialization of our drug candidates;
- the implementation of our business model, strategic plans for our business, drug candidates and technology;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our drug candidates and technology;
- estimates of our expenses, future revenues, capital requirements and our needs for additional financing;
- the timing or likelihood of regulatory filings and approvals, including whether the U.S. Food and Drug Administration, or FDA, will act by the Prescription Drug User Fee Act, or PDUFA, target goal date for a decision of July 7, 2021 for the avacopan New Drug Application, or NDA;
- our ability to maintain and establish collaborations or obtain additional government grant funding;
- our financial performance; and
- developments relating to our competitors and our industry.

These statements relate to future events or to our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Factors that may cause actual results to differ materially from current expectations include, among other things, those included in "Item 1A. Risk Factors" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2019, filed with the SEC on March 10, 2020.

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

In November 2019, we announced positive topline data from the pivotal Phase III ADVOCATE trial of avacopan, our lead drug candidate that is an orally-administered selective complement 5a receptor inhibitor, for the treatment of patients with anti-neutrophil cytoplasmic antibody-associated vasculitis, or ANCA vasculitis. The ADVOCATE trial compared avacopan with the currently used standard of care regimen which consists of high doses of glucocorticoid (most commonly prednisone) which is administered to patients for months. The prednisone standard of care, or SOC, was the active comparator (prednisone active comparator SOC) against which avacopan was assessed in a two-arm, randomized, controlled, and blinded trial. Subjects in both study arms received background therapy with rituximab or cyclophosphamide. The trial met both of its primary endpoints, showing that avacopan therapy without the need for daily prednisone could achieve disease remission at 26 weeks and sustained remission at 52 weeks, as assessed by the Birmingham Vasculitis Activity Score, or BVAS. BVAS remission at week 26 in the avacopan treated subjects was numerically superior and statistically non-inferior to the prednisone active comparator SOC control group, where BVAS remission was achieved in 72.3% of the avacopan treated subjects vs. 70.1% of subjects in the prednisone active comparator SOC control group ($p<0.0001$ for non-inferiority). Sustained remission at 52 weeks was observed in 65.7% of the avacopan treated subjects vs. 54.9% in the prednisone active comparator SOC control group, achieving both non-inferiority and superiority to prednisone active comparator SOC ($p=0.0066$ for superiority of avacopan). Reduction in overall burden of disease management and improvement in quality of life was also demonstrated through key secondary endpoints, including improved kidney function and reduction of adverse events and illnesses associated with steroids, such as prednisone.

In September 2020, we announced that the FDA had accepted for review the avacopan NDA for the treatment of ANCA vasculitis in the United States and had set July 7, 2021 as the PDUFA target goal date for the avacopan NDA. Following the mid-cycle review meeting with the FDA, the Company intends to provide an update regarding the FDA's plans to conduct an advisory committee meeting. If the NDA is approved, we plan to commercialize avacopan in the United States on our own and internationally through our kidney health alliance with Vifor Fresenius Medical Care Renal Pharma Ltd. and its affiliates and sublicensees, or collectively, Vifor. We are also developing avacopan in other indications, including complement 3 glomerulopathy, or C3G, and hidradenitis suppurativa, or HS, and plan to expand indications to include lupus nephritis in the first half of 2021.

Avacopan (CCX168)—Inhibition of Complement-Mediated Pathways in Orphan Diseases

Avacopan (formerly CCX168) is our lead drug candidate. It is a potential first-in-class, orally-administered molecule that employs a novel, highly targeted mode of action in the treatment of ANCA vasculitis and other complement-driven autoimmune and inflammatory diseases. ANCA vasculitis is an orphan, severe, and often fatal autoimmune disease that is characterized by elevated levels of autoantibodies called anti-neutrophil cytoplasmic autoantibodies and by inflammation that can affect many different organ systems, and commonly involves the kidneys. ANCA vasculitis affects approximately 40,000 to 75,000 people in the United States, with 4,000 to 9,000 new cases each year; similarly, ANCA vasculitis affects approximately 50,000 to 100,000 people in Europe, with 5,000 to 10,000 new cases each year.

We have successfully completed and reported positive topline clinical data from our pivotal Phase III clinical trial of avacopan for the treatment of ANCA vasculitis, known as the ADVOCATE trial. ADVOCATE was a randomized, double-blind, active-controlled worldwide clinical trial which enrolled 331 patients with newly diagnosed or relapsing ANCA vasculitis at approximately 200 sites in the United States, Canada, Europe, Australia, New Zealand and Japan. The aim of the trial was to assess the safety and efficacy of avacopan in inducing and sustaining remission in patients with ANCA vasculitis.

Avacopan has been granted orphan drug designation by the FDA for the treatment of ANCA vasculitis and by the European Medicines Agency, or EMA, for the treatment of microscopic polyangiitis and granulomatosis with polyangiitis, both forms of ANCA vasculitis. Based on the success of the avacopan clinical studies in ANCA vasculitis, we filed an NDA with the FDA in July 2020, which is currently under review by the FDA. Our alliance partner, Vifor, announced in November 2020 that the Marketing Authorization Application, MAA, was accepted for review (validated) by the EMA. We will further support Vifor with their filing of applications for regulatory approval internationally.

We are building a commercial infrastructure and plan to deploy an appropriately sized specialty field force in the United States to commercialize avacopan in ANCA vasculitis, if approved. We expect that our future field force will focus primarily on a subset of rheumatologists and nephrologists who treat this disease. In territories outside of the United States, our partner Vifor would be responsible for the commercialization of avacopan.

Additionally, we launched a registration-supporting clinical trial, the ACCOLADE trial, to study avacopan for the treatment of patients with C3G. C3G is an ultra-rare disease of the kidney that is characterized by deposition of the complement fragment known as C3 in the glomeruli, or filtration units of the kidney, leading to inflammatory cell accumulation, potentially leading to significant kidney damage and eventual renal failure. The incidence of C3G is estimated at one to three per million people in the United States. The prevalence in the United States is estimated to be as low as five cases per million people. We expect to report topline data from the ACCOLADE trial in the fourth quarter of 2020.

We also initiated a large placebo-controlled Phase IIb clinical trial, the AURORA trial, for the treatment of patients with moderate-to-severe HS. HS is a chronic, inflammatory, debilitating skin disease characterized by recurrent, painful, nodules and abscesses, ultimately leading to the formation of draining fistulas (also known as sinus tracts) as well as scarring. The disease originates from inflammation and occlusion of the hair follicle. Apart from pain, the nodules may rupture, and often extrude a purulent, foul-smelling discharge leading to substantial social embarrassment for these patients. Due to its chronic nature and frequently occurring relapses of the skin lesions, HS has a great impact on the patient's quality of life, deeply affecting social, working, and psychological aspects. In the United States, the estimated prevalence of HS is 0.1%, of which 5% to 15% are severe Hurley Stage III patients. In Europe, the number of affected patients is believed to be greater, with higher prevalence. In October 2020, we announced positive data in the Hurley Stage III patients from the AURORA trial and plan to advance avacopan into Phase III development for the treatment of severe HS.

Kidney Health Alliance with Vifor

In May 2016, we announced a partnership, which we refer to as the Avacopan Agreement, with Vifor. While under this agreement we retained all rights to avacopan in the United States and China, we granted Vifor exclusive commercialization rights to avacopan in Europe and certain other international markets. In December 2016, we entered into an additional agreement with Vifor, which we refer to as the CCX140 Agreement, relating to CCX140, an orally-administered selective inhibitor of the chemokine receptor known as CCR2. Under the CCX140 Agreement, we again retained all rights to CCX140 in the United States and China and we granted Vifor exclusive worldwide commercialization rights to CCX140 outside of the United States and China. In February 2017, we announced a further agreement with Vifor that harmonized the geographic commercialization rights underlying the agreements for both drug candidates, which we refer to as the Avacopan Amendment. In June 2018, we entered into additional agreements with Vifor to further expand Vifor's exclusive commercialization rights to include China under the Avacopan Agreement and the CCX140 Agreement. In May 2020, we announced topline data from a 46 patient Phase II dose-ranging trial in the orphan kidney disorder, primary Focal Segmental Glomerulosclerosis, or 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.

We have secured $215.0 million in upfront cash and milestone payments pursuant to our agreements with Vifor and are eligible for additional substantial milestone payments. Through our alliance, we maintain the commercialization rights to avacopan and CCX140 in the United States, and also retain control of the clinical development programs for orphan renal disease. Vifor gained the exclusive commercialization rights for all other international markets, and is obligated to pay us tiered royalties, with percentage rates ranging from ten to the mid-twenties, on potential net sales.

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

Early Stage Drug Candidates

While we have focused initially on kidney and dermatological diseases, our target-specific and selective approach designed to stop the spread of inflammatory disease-inducing cells shows promise in other disease areas. Over time we plan to bring forward drug candidates to treat a range of inflammatory and autoimmune disorders, as well as cancer, where we plan to advance our orally-available checkpoint (PD-L1/PD-1) inhibitor, CCX559, into clinical development in the first half of 2021. We expect that our ability to advance our drug candidates into clinical development will grow as we increase our scale and to the extent that we start to earn revenues and royalties from the commercialization of avacopan.

We have incurred significant losses since commencing our operations in 1997. We have funded our operations primarily through the sale of convertible preferred and common stock, contract revenue under our collaborations, government contracts and grants and borrowings under loan and equipment financing arrangements.

As of September 30, 2020, we had an accumulated deficit of $455.5 million. We expect to continue to incur net losses as we develop our drug candidates, expand clinical trials for our drug candidates currently in clinical development, expand our research and development activities, expand our systems and facilities, seek regulatory approvals and engage in commercialization preparation activities in anticipation of FDA approval of our drug candidates. In addition, if a product is approved for commercialization, we will need to expand our organization. Significant capital is required to launch a product and many expenses are incurred before revenues are received. We are unable to predict the extent of any future losses or when we will become profitable, if at all.

Recent Developments

In December 2019, a disease caused by a novel strain of coronavirus, COVID-19, was identified in Wuhan, China. This virus continues to spread globally and, as of November 2020, has spread to nearly every country and region in the world, including those in which we have active clinical trial sites. While the length of the pandemic and its related restrictions and their consequences on the Company remain subject to a number of risks and uncertainties, as a result of the completion of certain clinical work and collection of certain blinded endpoint data prior to the start of the crisis, we are not currently expecting any material delays in when we intend to report topline clinical data from our ongoing clinical trials. Similarly, we do not currently anticipate any material delays in our preparation for commercial readiness to launch avacopan for the treatment of ANCA vasculitis, if approved, nor are we currently anticipating any material disruption in our clinical drug supply as a result of the pandemic.

In October 2020, we announced positive data in the Hurley Stage III patients from the avacopan Phase II AURORA trial in patients with HS. The Phase II AURORA clinical trial randomized 398 patients to one of three treatment arms. The study population included patients with moderate HS (Hurley Stage II) or severe HS (Hurley Stage III), which were stratified evenly across the treatment groups. The primary endpoint of the proportion of all patients (both moderate HS plus severe HS achieving Hidradenitis Suppurativa Clinical Response (HiSCR), as assessed evaluating 10 mg twice-daily (BID) and 30 mg BID dosing regimens of avacopan against placebo after 12 weeks of treatment in the combined study population, was not achieved with statistical significance at either dose level, although a numerical improvement was noted at the 30mg BID dose. Importantly, avacopan 30mg BID demonstrated a statistically significant higher response than placebo in the most severe (Hurley Stage III) HS patients; we plan to advance avacopan into Phase III development for the treatment of severe HS.

In November 2020, Vifor announced that the MAA for avacopan in the treatment of ANCA vasculitis was accepted for review (validated) by the EMA.

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, 2020, 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, 2019, filed with the SEC on March 10, 2020.

Results of Operations

Revenue

We have not generated any revenue from product sales. For the periods presented, our revenues were derived from collaboration and license revenue related to the Avacopan 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, 2020, 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,	
	2020	2019	2020	2019
Collaboration and license revenue from related party	$ 5,027	$ 10,581	$ 60,165	$ 26,081
Grant revenue	58	—	368	—
Total revenue	$ 5,085	$ 10,581	$ 60,533	$ 26,081
Dollar increase (decrease)	$ (5,496)		$ 34,452	
Percentage increase (decrease)	(52%)		132%	

We use a cost-based input method to measure proportional performance and to calculate the corresponding amount of revenue to recognize. In applying the cost-based input method of revenue recognition, we measure actual costs incurred relative to budgeted costs to fulfill the combined performance obligation. These costs consist primarily of third-party contract costs. Revenue is recognized based on actual costs incurred as a percentage of total budgeted costs as we complete our performance obligations. The decrease in total revenue from 2019 to 2020 for the three month period was primarily attributable to lower costs incurred in 2020 due to the completion of the avacopan ADVOCATE Phase III pivotal trial in 2020. The increase in total revenue from 2019 to 2020 for the nine month period was primarily due to the acceleration of revenue recognition of the transaction price associated with the CCX140 Agreement with Vifor. Following the decision to discontinue development of CCX140 in FSGS, $46.7 million of deferred revenue was recognized as contract revenue in the second quarter of 2020. This increase was partially offset by lower costs incurred due to the completion of the avacopan ADVOCATE Phase III pivotal trial in 2020.

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 month periods ended September 30, 2020, 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,	
	2020	2019	2020	2019
Research and development expenses	$ 18,582	$ 18,096	$ 56,655	$ 51,074
Dollar increase	$ 486		$ 5,581	
Percentage increase	3%		11%	

The increases from 2019 to 2020 for the three and nine month periods were primarily attributable to patient enrollment of the avacopan AURORA Phase IIb clinical trial in patients with HS, professional fees associated with the preparation of our NDA submission for avacopan for the treatment of ANCA vasculitis and higher research and drug discovery expenses, including those associated with the development of CCX559, our orally-available checkpoint (PD-L1/PD-1) inhibitor. These increases were partially offset by decreases in expenses due to the completion of the avacopan ADVOCATE Phase III pivotal trial in 2020 and the CCX140 LUMINA-1 Phase II clinical trial in 2019.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Phase I	$ 25	$ 116	$ 455	$ 444
Phase II	5,335	6,997	20,160	18,273
Phase III	5,769	7,701	18,995	22,422
Research and drug discovery	7,453	3,282	17,045	9,935
Total research and development expenses	$ 18,582	$ 18,096	$ 56,655	$ 51,074

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

At any given time, we typically have several active early stage research and drug discovery projects. Our internal resources, employees and infrastructure are not directly tied to any individual research or drug discovery project and are typically deployed across multiple projects. As such, we do not maintain information regarding these costs incurred for our early stage research and drug discovery programs on a project specific basis. We expect our research and development expenses to increase as we advance our

development programs further and increase the number and size of our clinical trials. The process of conducting preclinical studies and clinical trials necessary to obtain regulatory approval is costly and time consuming. We or our partners may never succeed in achieving marketing approval for any of our drug candidates. The probability of success for each drug candidate may be affected by numerous factors, including preclinical data, clinical data, competition, manufacturing capability and commercial viability. Our strategy includes entering into additional partnerships with third parties for the development and commercialization of some of our independent drug candidates.

The successful development of our drug candidates is highly uncertain and may not result in approved products. Completion dates and completion costs can vary significantly for each drug candidate and are difficult to predict for each product. Given the uncertainty associated with clinical trial enrollments and the risks inherent in the development process, we are unable to determine the duration and completion costs of the current or future clinical trials of our drug candidates or if, or to what extent, we will generate revenues from the commercialization and sale of any of our drug candidates. We anticipate we will make determinations as to which programs to pursue and how much funding to direct to each program on an ongoing basis in response to the scientific and clinical success of each drug candidate, as well as ongoing assessment as to each drug candidate's commercial potential. We 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 avacopan, CCX559 and CCX872.

General and administrative expenses

Total general and administrative expenses for the three and nine months ended September 30, 2020, 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,	
	2020	2019	2020	2019
General and administrative expenses	$ 10,362	$ 6,116	$ 29,474	$ 17,187
Dollar increase	$ 4,246		$ 12,287	
Percentage increase	69%		71%	

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 2019 to 2020 for the three and nine month periods were primarily due to higher employee-related expenses, including those associated with our commercialization planning efforts, and higher professional fees.

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

Other income (expense), net

Other income (expense), net primarily consists of interest income earned on our marketable securities and interest expense for our long-term debt. Total other income (expense), net for the three and nine month periods ended September 30, 2020, 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,	
	2020	2019	2020	2019
Interest income	$ 499	$ 1,311	$ 2,059	$ 3,850
Interest expense	(700)	(542)	(1,943)	(1,631)
Total other income (expense), net	$ (201)	$ 769	$ 116	$ 2,219
Dollar decrease	$ (970)		$ (2,103)	
Percentage decrease	(126%)		(95%)	

The decreases in total other income (expense), net from 2019 to 2020 for the three and nine month periods were primarily due to decreased interest income earned from our investment portfolio in a 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), partially offset by interest income from higher cash and investment balances.

Liquidity and Capital Resources

As of September 30, 2020, we had approximately $486.9 million in cash, cash equivalents, restricted cash and investments. The following table shows a summary of our cash flows for the nine months ended September 30, 2020 and 2019 (in thousands):

	Nine Months Ended September 30,	
	2020	2019
Cash provided by (used in)		
Operating activities	$ (61,919)	$ (49,893)
Investing activities	$ (273,858)	$ (19,132)
Financing activities	$ 352,775	$ 77,939

Operating activities. Net cash used in operating activities was $61.9 million for the nine months ended September 30, 2020, compared to $49.9 million for the same period in 2019. This increase was primarily due to higher operating expenses and changes in working capital items.

Investing activities. Net cash 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. We expect cash used in investing activities through the end of 2020 and into the first half of 2021 to continue to increase as we build out our new headquarters in San Carlos, California. See “Note 7. Commitments” for a detailed discussion.

Financing activities. Net cash provided by financing activities was $352.8 million for the nine months ended September 30, 2020, compared to $77.9 million for the same period in 2019. 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. Net cash provided by financing activities for the nine months ended September 30, 2019 included net proceeds of $73.3 million from the issuance of common stock under an equity distribution agreement. Net cash provided by financing activities for both periods presented included proceeds from the exercise of stock options and stock purchases from contributions to our 2012 Employee Stock Purchase Plan, and cash used for tendered ChemoCentryx, Inc. common stock to satisfy employee tax withholding requirements upon vesting of restricted stock units.

As of September 30, 2020, 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 with Hercules, or the Restated Credit Facility, 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, 2020, we had borrowed $5.0 million under the Restated Credit Facility. 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, 2020, we had approximately $486.9 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, 2020. However, our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially.

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

- the terms and timing of any other collaborative, licensing and other arrangements that we may establish;
- the initiation, progress, timing and completion of preclinical studies and clinical trials for our drug candidates and potential drug candidates, 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;

- the outcome, timing and cost of regulatory approvals;
- delays that may be caused by changing regulatory approvals;
- the cost and timing of hiring new employees to support continued growth;
- the costs involved in filing and prosecuting patent applications and enforcing and defending patent claims;
- the cost and timing of procuring clinical and commercial supplies of our drug candidates;
- the cost and timing of establishing sales, marketing and distribution capabilities; and
- the extent to which we acquire or invest in businesses, products or technologies.

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, 2019, filed with the SEC on March 10, 2020, other than as set forth below.

In March 2020, we made an additional borrowing of $5.0 million under the Restated Credit Facility. 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.

In July 2019, we entered into a ten-year operating lease for a 96,463 square foot facility in San Carlos, California to replace our then-current headquarters located in Mountain View, California. The lease commenced in June 2020 and monthly rent payments are anticipated to begin in March 2021. In July 2020, we entered into a letter agreement to further extend the lease term of the Mountain View, California facility through June 2021. See “Note 7. Commitments” in the Notes to Condensed Consolidated Financial Statements included in Item 1 of this Quarterly Report on Form 10-Q for additional information of this lease.

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, 2020 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, 2019, filed with the SEC on March 10, 2020, 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, 2020, 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 are obligated to make interest-only payments on our borrowings under the Credit Facility through July 1, 2021, 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 December 1, 2022. In addition, borrowings under the Restated Credit Facility totaled $5.0 million at September 30, 2020 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 avacopan 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, 2020, 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, 2020, 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, 2020, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. As a result of COVID-19, 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 COVID-19, 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

Not Applicable.

Item 1A. Risk Factors

The outbreak of the novel coronavirus disease 2019, or COVID-19, could adversely impact our business, manufacturing operations, preclinical studies and clinical trials.

In December 2019, a disease caused by a novel strain of coronavirus, COVID-19, was identified in Wuhan, China. This virus continues to spread globally and, as of November 2020, has spread to nearly every country and region in the world, including those in which we have active clinical trial sites. The outbreak and government measures taken in response have also had a significant impact, both direct and indirect, on businesses and commerce, as worker shortages have occurred; supply chains have been disrupted; facilities and production have been suspended; and demand for certain goods and services, such as medical services and supplies, has spiked, while demand for other goods and services, such as travel, has fallen. In response to the spread of COVID-19 and in accordance with direction from state and local government authorities, we have limited the number of essential staff in our corporate headquarters. As the COVID-19 pandemic continues to spread around the globe, we may experience disruptions that could severely impact our business, manufacturing operations, preclinical studies and clinical trials, including:

- delays or difficulties in enrolling patients in our clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- interruption of key clinical trial activities, such as (i) clinical trial site monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others, (ii) interruption of clinical trial subject visits and study procedures, or (iii) difficulties in collecting study data in accordance with clinical trial protocols due to patients' inability to travel or site closures, which may impact the integrity of subject data and clinical study endpoints;
- interruption or delays in the operations of the FDA or other regulatory authorities, which may impact review and approval timelines;
- interruption of, or delays in receiving, supplies of our drug candidates from our contract manufacturing organizations due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems;
- delays in clinical sites receiving the supplies and materials needed to conduct our clinical trials and interruption in global shipping that may affect the transport of clinical trial materials;
- increases in the costs of clinical trials due to the impact of COVID-19;
- interruptions in preclinical studies due to restricted or limited operations at our laboratory facility or those of our outsourced service providers;
- limitations on employee resources that would otherwise be focused on the conduct of our preclinical studies or clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people;
- business disruptions caused by potential workplace, laboratory and office closures and an increased reliance on employees working from home, staffing shortages, travel limitations, cyber security and data accessibility, or communication or mass transit disruptions;
- delays in receiving approval from local regulatory authorities to initiate our planned clinical trials;
- changes in local regulations as part of a response to COVID-19 which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue the clinical trials altogether;

- delays in necessary interactions with local regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees;
- refusal of the FDA to accept data from clinical trials in affected geographies outside the United States;
- delays or impacts on the successful commercial launch of our product candidates due to decreases in business travel or live customer interactions;
- interruption or delays to our discovery and development pipeline;
- continued volatility in our and other biopharmaceutical companies' shares of common stock, which may result in difficulties raising capital through sales of our common stock or equity linked to our common stock, to the extent needed, and the terms of sales may be on unfavorable terms or unavailable, which may impact our short-term and long-term liquidity; and
- interruption or delays to, or increased costs associated with, our planned move to our new corporate headquarters.

The COVID-19 pandemic continues to rapidly evolve and as a result of the COVID-19 resurgence impacting certain sites where we have been conducting our AURORA trial, topline data from that trial has been delayed until early in the fourth quarter of 2020. The extent to which the COVID-19 pandemic may further impact our business, including our manufacturing operations, preclinical studies, clinical trials and financial condition, will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the pandemic, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease.

To the extent the COVID-19 pandemic adversely affects our business and results of operations, it may also have the effect of heightening many of the other risks described in "Item 1A. Risk Factors" of our Annual Report on Form 10-K for the year ended December 31, 2019, filed with the SEC on March 10, 2020.

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†	Commercial Manufacturing Agreement, dated as of August 26, 2020, by and between the Registrant and Hovione LLC.
10.2	Lease Extension Letter, dated July 1, 2020, by and between Google Inc. and the Registrant.
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)
†	Portions of this exhibit have been omitted pursuant to Item 601 (b)(10)(iv) of Regulation S-K.

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, 2020

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

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

Date: November 9, 2020

/s/ Susan M. Kanaya

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

Date: November 9, 2020

/s/ Pui San Kwan

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

Exhibit 10.1

[***] CERTAIN INFORMATION IN THIS DOCUMENT HAS BEEN OMITTED FROM THIS EXHIBIT BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.

COMMERCIAL MANUFACTURING AGREEMENT (AVACOPAN)

Between

CHEMOCENTRYX, INC.

and

HOVIONE LLC

THIS AGREEMENT ("**Agreement**") is made and entered into as of August 17, 2020 (the "**Effective Date**") by and between ChemoCentryx, Inc. a Delaware corporation, with offices at 850 Maude Avenue, Mountain View, CA 94043 ("**Customer**"), and Hovione LLC, with a mailing address at 40 Lake Drive, East Windsor, New Jersey 08520 ("**Hovione**").

RECITALS

WHEREAS, Hovione has expertise, available facilities and experience related to the development, synthesis, formulation, testing and production of active pharmaceutical ingredients, has both pilot plant and commercial scale facilities to manufacture same, and is interested in providing such development and manufacturing services to Customer; and

WHEREAS, Customer has engaged the manufacturing development and clinical supply services of Hovione pursuant to the Master Services Agreement dated as of May 21, 2014 (the "**MSA**") pursuant to which Hovione previously confirmed, validated and scaled up Customer technology to manufacture the active pharmaceutical ingredient "AVACOPAN"; and

WHEREAS, Customer now wishes to engage the services of Hovione to manufacture of commercial quantities of the active pharmaceutical ingredient using the validated technology on a commercial scale in Hovione's facility and may wish to engage Hovione in post-submission development activities.

NOW, THEREFORE, in consideration of the acknowledgements, confirmations, representations, warranties, and covenants contained herein, Customer and Hovione hereby agree as follows:

*** Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

1. **Definitions.** For the purposes of this Agreement, unless this Agreement will expressly provide otherwise or unless the context otherwise requires, the following initially capitalized terms in this Agreement, whether used in the singular or plural, will have the respective meanings set forth below:

1.1 "**Acquisition Costs**" shall mean the actual invoiced price paid by a Hovione to any Third Party for acquiring any raw materials, packaging components and intermediates used exclusively in the Manufacture of the Product under this Agreement, including direct out-of-pocket shipping and handling costs, customs duties and taxes incurred and paid by Hovione in connection with the acquisition of such materials, packaging components and intermediates.

1.2 "**Affiliate**" shall mean, with respect to a Party, any corporation, company, partnership, joint venture and/or firm that controls, is controlled by or is under common control with such Party. As used in this Agreement, "**control**" means (a) in the case of a corporate entity, direct or indirect ownership of at least fifty percent (50%) of the stock or shares having the right to vote for the election of directors, and (b) in the case of a non-corporate entity, the direct or indirect power to manage, direct or cause the direction of the management and policies of the non-corporate entity or the power to elect at least fifty percent (50%) of the members of the governing body of such non-corporate entity.

1.3 "**API**" shall mean the active pharmaceutical ingredient "AVACOPAN", the details of which are set forth in Exhibit 2 (Specifications).

1.4 "**Applicable Law**" shall mean all applicable court orders, ordinances, rules, regulations, laws, guidelines, guidances, statutes and requirements of any kind whatsoever, as amended from time to time, including the bodies of law, regulations (including without limitation, cGMP or its equivalent) applicable to the Manufacturing activities for each Product in the Territory, including, but not limited to, in the US, the FDA, in Europe, the EMA, and in Japan, the PMDA.

1.5 "**Approval**" shall mean regulatory approval by the FDA or EMA that enables Customer to market and sell a final product containing the Product in the United States of America or Europe, as the case may be.

1.6 "**Batch**" shall mean a specific quantity or lot of the Product, as further described in Exhibit 2 hereto, that is intended to be of uniform character and quality, within specified limits, and is produced during the same cycle of Manufacture as defined by the Batch Record.

1.7 "**Batch Record(s)**" shall mean the final executed batch production and control record(s) for each Batch of the Product Manufactured under this Agreement in accordance with 21 CFR § 211.188.

1.8 "**Business Day**" shall mean a day other than a Saturday, Sunday or a day on which commercial banks located in Ireland, Portugal or the United States of America shall be authorized or required by Applicable Law to close.

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1.9 "**Calendar Year**" shall mean the twelve (12) month period commencing on January 1 and ending on December 31 of each year during the Term.

1.10 "**cGMP**" shall mean current good manufacturing practices as established by the FDA, or Regulatory Authorities in European Union or Japan, relating to the manufacture of medicinal products for human use, including, without limitation, current good manufacturing practices as specified in the ICH guidelines, including without limitation, ICH Q7, Guidance on Good Manufacturing Practices of the International Conference on Harmonization of Technical Requirements of Pharmaceuticals for Human Use and the Guide to Good Manufacturing Practices for Medicinal Products as promulgated under European Directive 91/356/EEC.

1.11 "**Certificate of Analysis**" shall mean, as further specified in Section 6.2, with respect to each Product, a controlled document, prepared by Hovione that (a) lists all analytical tests and/or standards Hovione uses to evaluate a Product in order for such Product to be considered Manufactured in accordance with the terms of this Agreement and acceptable for release, and (b) certifies the accuracy of each of the foregoing.

1.12 "**Certificate of Compliance**" shall mean a document prepared by Hovione (a) listing the Manufacturing date, unique Batch number, and quantity of Product in such Batch; and (b) certifying that such Batch was Manufactured in accordance with the Master Batch Record and cGMP, if applicable.

1.13 "**Change Order**" has the meaning assigned it in Section 5.2.

1.14 "**Commercially Reasonable**" and "**Commercially Reasonable Efforts**" shall mean the level of diligence and/or efforts and commitment of resources consistent with the past practice of similarly situated pharmaceutical manufacturers with respect to comparable pharmaceutical products.

1.15 "**Completion Date**" shall mean the date of Batch Release for the Manufacture of Batches, or the date of report completion for analytical, lab and other Services.

1.16 "**Confidential Information**" has the meaning set forth in Section 12.1.

1.17 "**Customer Indemnitee**" has the meaning set forth in Section 14.1.

1.18 "**Customer Improvements**" shall mean all Improvements other than Hovione Improvements. Notwithstanding anything to the contrary in this Agreement, "Customer Improvements" shall include any and all Improvements that [***].

1.19 "**Customer Materials**" shall mean any and all materials provided by Customer for Hovione's use in the performance of Manufacturing and Services under this Agreement.

1.20 "**Customer Technology**" shall mean the Technology either (a) owned or controlled by Customer prior to the Effective date or (b) developed or acquired by Customer independent of this Agreement and without the use of the Confidential Information of Hovione.

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1.21 "**Deliverable(s)"** shall mean any deliverable required to be provided to Customer by Hovione as set forth in the applicable Work Plan.

1.22 "**Delivery Date"** shall mean the date on which the Product or other Services under this Agreement are designated to be ready for pick-up at the Hovione Facility as set forth in the applicable Purchase Order.

1.23 "**Drug Master File**" or "**DMF**" shall mean a drug master file providing detailed information about the Facility, the equipment and the Manufacturing Processes relating to the Product and such other information as required by Applicable Laws, including 21 C.F.R. Section 314.420, and to the extent applicable of any equivalent requirement under Applicable Laws.

1.24 "**Effective Date**" shall mean the date first appearing at the beginning of this Agreement.

1.25 "**EMA**" shall mean the European Medicines Agency and any successor agency having substantially the same functions.

1.26 "**Facility**" shall mean (a) the primary Manufacturing facility of Hovione located in [***], (b) any secondary Manufacturing facility established by Hovione at the request of Customer pursuant to Section 3.1 (each of which may be referred to in the Agreement as a "**Site**"), and (c) [***].

1.27 "**FDA**" shall mean the United States Food and Drug Administration, and any successor agency having substantially the same functions.

1.28 "**FDCA**" shall mean the United States Federal Food, Drug and Cosmetic Act, including all regulations, guidelines, and guidances arising thereunder, as any of the same may be amended from time to time.

1.29 "**Governmental Authority**" shall mean any national, multinational, regional, state or local regulatory agency in the United States, the European Union, Japan, or any other country in the Territory.

1.30 "[***]" shall mean [***].

1.31 "**Hovione Improvements**" shall mean [***]. "Hovione Improvements" shall include [***].

1.32 "**Hovione Indemnitees**" shall have the meaning set forth in Section 14.2.

1.33 "**Hovione Technology**" shall mean the Technology either (a) owned or controlled by Hovione prior to the Effective Date or (b) developed or acquired by Hovione independent of this Agreement and without the use of the Confidential Information of Customer or Customer Technology.

1.34 "**Improvements**" shall mean all Technology, discoveries, inventions, and/or developments, modifications, innovations, updates, enhancements and/or improvements to Technology (whether or not protectable under patent, trademark, copyright or similar laws)

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that are conceived, discovered, invented, developed, created, made and/or reduced to practice in the performance of the Parties' obligations under this Agreement.

1.35 "**Initial Term**" shall have the meaning set forth in Section 10.1.

1.36 "**Inspection Period**" shall have the meaning set forth in Section 6.3(a).

1.37 "**Latent Defect**" shall mean a failure of the applicable Product to comply with cGMP or the Specifications that (a) couldn't reasonably have been identified through review of the Records or the initial testing and inspection of the applicable Product, and (b) is the fault of Hovione. "**Latent Defect**" does not include any such failure of Product to comply with cGMP or the Specifications that [***]. For the avoidance of doubt, if any Product [***].

1.38 "**Losses**" shall have the meaning set forth in Section 14.1.

1.39 "**Manufacture**", "**Manufactured**" and "**Manufacturing**" shall mean all operations of Hovione in the scheduling, production, packaging, labeling, warehousing, quality control testing (including as requested all in-process, release and stability testing), release, and shipping of the Product to meet the Specifications and other requirements for the Product hereunder.

1.40 "**Minimum Annual Commitment**" shall have the meaning set forth in Section 3.7.

1.41 "**MSA**" shall have the meaning set forth in the preamble.

1.42 "**NDA**" shall have the meaning set forth in Section 10.5.

1.43 "**Parties**" shall mean Customer and Hovione together.

1.44 "**Party**" shall mean either Customer or Hovione, as the context requires.

1.45 "**Person**" shall mean an individual natural person, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, incorporated associated, joint venture or similar entity or organization, including a government or political subdivision, department or agency of a government.

1.46 "**PMDA**" shall mean the Japanese Pharmaceuticals and Medical Devices Agency and any successor agency having substantially the same functions

1.47 "**Process**" shall mean the series of operations needed to convert the Starting Materials to the Product, including the testing thereof.

1.48 "**Product**" shall mean the API to be Manufactured by Hovione for Customer under this Agreement pursuant to a validated Process.

1.49 "**Product Licensees**" shall mean Customer's licensees and sublicensees of the Product in the Territory.

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1.50 "**Project Specific Raw Materials**" shall mean the certain raw materials that are necessary for the Manufacture of the Product identified on Exhibit 5 and include the Starting Materials identified on Exhibit 6. For clarity and pursuant to Section 4.1, the Project Specific Raw Materials set forth on Exhibit 5 shall be supplied by Customer [***], all other Project Specific Raw Materials will be planned, procured and managed through Hovione's supplier quality and purchasing departments.

1.51 "**Purchase Order**" shall have the meaning set forth in Section 3.3.

1.52 "**Quality Agreement**" shall mean a separate quality agreement signed by each of the Parties that applies to Services to be performed under cGMP requirements and sets forth the mutual responsibilities of the Parties with respect to quality assurance and cGMP guidelines applicable to Services performed by Hovione. Such responsibilities of Hovione and Customer are defined in the Quality Agreement.

1.53 "**Recalls**" shall have the meaning set forth in Section 6.6.

1.54 "**Records**" shall have the meaning set forth in Section 2.9.

1.55 "**Regulatory Application**" shall mean the new drug application or other submission made by Customer to the FDA, or any equivalent regulatory agency in the Territory, seeking allowance to market, distribute, and sell the Product in the United States and/or elsewhere in the Territory, as such application may be amended or supplemented.

1.56 "**Regulatory Authority(ies)**" shall mean the regulatory entities with regulatory authority over the manufacture, storage, testing, or use of pharmaceutical products (including the Product), as well as any successor entity thereto, in the Territory. In the United States, "Regulatory Authority" includes the FDA. In the European Union, "Regulatory Authority" includes the EMA. In Canada, "Regulatory Authority" includes the Canadian Therapeutic Products Directorate. In Japan, "Regulatory Authority" includes the PMDA.

1.57 "**Sale**" shall mean the commercialization and marketing of Product by Customer.

1.58 "**Services**" shall mean the activities to be performed by Hovione related to the Manufacture of Product hereunder pursuant to this Agreement, and/or as further described in the relevant Work Plan, where applicable as described in Section 2.1.

1.59 "**Specifications**" shall mean the specifications, quality standards and testing methods for Product that are set forth in Exhibit 2 (as may be amended from time to time by written agreement of the Parties) or are otherwise mutually agreed to by the Parties in writing.

1.60 "**Starting Materials**" shall mean those materials identified in Exhibit 6. Starting Materials are certain Project Specific Raw Materials that have additional requirements as set forth in the Quality Agreement and shall meet the specifications set forth in the Regulatory Application. For clarity and pursuant to Section 4, [***].

1.61 "**Supply Failure**" shall have the meaning set forth in Section 7.3.

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1.62 "**Technology**" shall mean all methods, techniques, trade secrets, copyrights, know-how, data, documentation, hardware, software and other intellectual property of any kind, whether or not protectable under patent, trademark, copyright or similar laws.

1.63 "**Term**" shall have the meaning set forth in Section 10.1.

1.64 "**Territory**" shall mean [***].

1.65 "**Third Party**" shall mean any Person other than the Parties and their respective Affiliates.

1.66 "**Work Plan**" shall mean an individual contract agreed to by the Parties and executed under this Agreement that references this Agreement as containing the governing terms and conditions, to conduct additional Services related to the Manufacturing of Product.

2. Performance of Services.

2.1 Services. Customer appoints Hovione to perform the Manufacturing of the Product under the terms and conditions set forth in this Agreement. In addition, Hovione may provide additional services related to the development and Manufacturing of the Product under the terms and conditions of this Agreement and the relevant individual Work Plans executed under this Agreement (the "**Services**"). If Services are requested, this Agreement will serve as a general form of contract under which the Parties can contract individual Work Plans, substantially in the form as Exhibit 1, without having to renegotiate the basic terms and conditions contained in this Agreement. Each Work Plan shall be consecutively numbered beginning with C1 (*e.g.*, "**Work Plan C1**").

2.2 As of the Effective Date, Hovione commits to make available a defined capacity at its Facility sufficient to meet Customer's forecasted demand for the Product and, following Approval as set forth in Section 3.7, Customer commits to pay the Minimum Annual Commitment in consideration for Customer's reservation of such capacity. For the avoidance of doubt, the commercial Manufacture and supply of Product shall be ordered through a Purchase Order in accordance with Section 3.3 and shall not require an additional Work Plan.

2.3 Hovione Responsibilities. Hovione, or its Affiliates, shall diligently carry out the Services as provided in this Agreement and shall, subject to Hovione's representation and warranties set forth in Section 8.2(b), use Commercially Reasonable Efforts to perform the Manufacturing and any Services without any material defect and according to the established timelines set forth and agreed between the Parties in a signed writing (including, if and as applicable, in a Work Plan or meeting minutes). Hovione shall retain appropriately qualified and trained personnel with the requisite knowledge and experience to perform the Services in accordance with this Agreement.

2.4 As more specifically provided below, Hovione responsibilities shall include, as applicable, the following:

(a) Storing Customer Materials and/or Project Specific Raw Materials at the Facility up to the earlier of the expiration date of the Customer Materials or the Project Specific Raw Materials (as the case may be) or the termination of this Agreement;

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Following the earlier of the referred dates, Hovione shall provide [***] days' prior written notice to Customer requesting instructions on whether to return or destroy such Customer Materials and/or Project Specific Raw Materials, at Customer's reasonable cost. If Customer has not provided instructions within such [***] day period, Hovione shall have the right to destroy all unused quantities of Customer Materials and unused but fully paid-up Project Specific Raw Materials.

(b) Keeping Records and reporting data to Customer and applicable Regulatory Authorities, as may be required by Applicable Law and this Agreement;

(c) Following standard industry procedures and the applicable Hovione SOP(s) established for the keeping of laboratory notebooks, and establishing systems for securing data, Deliverables, Customer Technology and Customer Materials from loss or damage (copies of such Hovione SOPs will be available on site at Hovione for review by Customer);

(d) Compliance with cGMP requirements, at Hovione's own expense, thereby filing and maintaining all necessary governmental and regulatory approvals, licenses, and permits to operate the Facility as a cGMP Manufacturing site for the Product;

(e) Immediately notifying Customer of any notification from a Governmental Authority or Regulatory Authority regarding a cGMP inspection of a Facility that is directly related to the Product. Customer shall have the option to have up to [***] individuals on-site during any inspection that is directly related to the Product as well as to have a person present during preapproval inspection preparations and overall site readiness that is directly related to the Product, at Customer's expense. Any Customer personnel shall be required to follow all rules and procedures established by Hovione when on Hovione's site. Hovione shall correct any cGMP deficiencies identified by any Governmental Authority or Regulatory Authority at Hovione's expense; and

(f) Ensure that Customer has access (subject to customary system down-time) to Hovione's NavStream® system, in which Customer can access the inventory of the Customer Materials and Product to assist in Customer's planning and reporting processes.

2.5 Customer Responsibilities. Unless otherwise specified, Customer will:

(a) Transfer to Hovione, at its expense, the Customer Materials, analytical methods, samples and other materials or information necessary or reasonably useful for Hovione to perform the Services;

(b) Provide Customer Technology and any other material information pertaining to any special handling conditions for the Product or other Customer Materials supplied to Hovione by Customer, including information regarding storage and use of such Product or other Customer Materials;

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(c) Provide Hovione with access to knowledgeable Customer personnel for consultation regarding the Product, Customer Technology, Customer Confidential Information, Customer Materials and the Services; and

(d) File and maintain all necessary regulatory approvals for the Product.

(e) Drug Master File. Except as specifically agreed to by the Parties in writing, Hovione will neither prepare nor file the Drug Master File ("**DMF**"), which shall be Customer's responsibility. Hovione shall, promptly upon request by Customer, provide to Customer all information reasonably necessary for the DMF, including without limitation, information relating to the manufacture, controls and release of the Product; [***]. Customer shall own the DMF and shall be responsible for maintaining the DMF on file with the FDA, and amending the DMF, as may be required. During the Term, Customer shall provide copies to Hovione of relevant portions of any regulatory filings that relate to Hovione's Manufacturing of Product, and Hovione shall have [***] to review and comment on the portions of any regulatory filings (including, but not limited to Regulatory Applications) that reference Hovione's Manufacturing of the Product or the Facility. For the avoidance of doubt, [***]. For each regulatory filing proposed by Customer that relates to Hovione's Manufacturing of the Product, Hovione shall [***].

2.6 Communications. Immediately after the Effective Date, each Party will appoint a project representative (each, a "**Representative**") who will have primary responsibility for day-to-day interactions with the other Party's Representative concerning the Manufacturing and Services under this Agreement. Either Party may appoint a substitute or successor Representative by providing notice thereof to the other Party.

2.7 Subcontracting. No Manufacturing or Services will be subcontracted by Hovione without Customer's prior written consent, not to be unreasonably withheld or delayed. If Customer consents to any such subcontracting, Hovione may subcontract the performance of its obligations under this Agreement to its Affiliates or to Third Parties to the extent Customer expressly provided its consent with respect to such obligations. In case of a subcontracting pursuant to this Section, Hovione shall remain responsible for the performance of Affiliates or Third Parties, and such Affiliates or Third Parties will perform the activities in a manner consistent with this Agreement and/or the relevant Work Plan, where applicable, and will be obligated, in writing, to protect the confidentiality of Confidential Information under terms no less stringent than those set forth in Section 12 and to assign to Hovione all intellectual property rights developed in the performance of such activities.

2.8 Quality Agreement. Prior to Hovione conducting any Manufacturing or Services that are subject to cGMP requirements, the Parties will enter into a Quality Agreement to establish Parties' respective quality assurance responsibilities relating to the Services. In the event the Quality Agreement contains provisions which are not inconsistent with, but in addition to, the terms set forth herein, the Quality Agreement shall be supplemental to the terms and conditions set forth in this Agreement. Notwithstanding the foregoing or anything in the Agreement or the Quality Agreement to the contrary, in the event of any conflict or inconsistency between the provisions of this Agreement and the provisions of the Quality Agreement, the provisions of this Agreement shall govern.

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2.9 Records. Hovione will maintain all materials, data, and documentation obtained or generated by Hovione in the course of performing the Manufacturing or Services under this Agreement, including all computerized records and files (the "**Records**") in a secure area reasonably protected from fire, theft, and destruction for the longer of (a) a period of [***] years following expiration or termination of this Agreement or (b) [***] past the last expiration date of the Product supplied under this Agreement, or, in each case, such longer period as is required by the Applicable Laws (the "**Retention Period**"). At the end of the Retention Period, all Records will, at Customer's option and expense, either be delivered to Customer or its designee in such form as they are then currently in the possession of Hovione, or disposed of, at the discretion and written request of Customer. In no event will Hovione dispose of any Records without first giving Customer at least [***] days' prior written notice of its intent to do so and an opportunity to have the Records transferred to Customer. While in the possession and control of Hovione, Records shall be available during audits for inspection, examination and review by Customer or its representatives. Hovione will also ensure that all Records are subject to secure, validated controls in accordance with applicable law, including cGMP.

2.10 Facility. Hovione shall perform all work contemplated under this Agreement at its Facilities.

3. Commercial Manufacture and Supply of Product; Exclusivity.

3.1 Manufacture and Supply. Customer shall, commencing on the Effective Date and continuing until [***] years following the first Approval, purchase [***] of its worldwide requirements for the Product from Hovione, and Hovione shall Manufacture and supply the Product ordered by Customer, in accordance with this Agreement. At Customer's request, in addition to the primary Facility in [***], Hovione shall, at Customer's cost, qualify a second facility at which Hovione shall, following such qualification, be ready and able to Manufacture Customer's demand for the Product under this Agreement.

3.2 Forecasts.

(a) Prior to First Approval. No later than [***] months prior to the anticipated date on which Customer will require its first delivery of Product under this Agreement, Customer shall provide Hovione with a non-binding forecast of its anticipated orders for Product for the first [***] calendar quarters of sales, broken down on a monthly basis. Every [***] months thereafter but only prior to the first Approval date of the Product, Customer shall provide Hovione with an updated non-binding forecast of its anticipated orders of Product for the first [***] calendar quarters of sales, broken down on a monthly basis.

(b) After Approval. Within [***] days after the first Approval date, Customer shall provide Hovione with a rolling [***] month forecast of Customer's anticipated orders of the Product Batches and the forecast shall be updated no less frequently than [***] during the Term. The rolling forecast shall be made no later than [***] after the start of the [***] to assist Hovione in planning its production. The first [***] months of each forecast shall constitute a binding order for the amounts of the Product set forth in such forecast; the balance of the forecast shall be non-binding to Customer. In the event there are [***].

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3.3 Purchase Orders. Customer shall place firm orders for the Product using the form of purchase orders mutually agreeable to Customer and Hovione, setting forth the quantity of the Product required (which shall be in increments of full Batches), as well as its required Delivery Dates, which shall be in no event earlier than [***] days from the date of the purchase order. Hovione will notify Customer of its receipt of each purchase order within [***] thereafter. Such notice will accept the binding portion of the purchase order and include confirmation of the Delivery Date, which shall be not less than [***] days and not more than [***] days from the date of the Customer purchase order issue date. If Hovione fails to notify Customer of its receipt of such order within such [***] Business Day period, and subject to the limits set forth in Section 3.7, the order will be deemed to have been received and accepted; *provided, however*, that if the Parties mutually agree, Hovione may deliver a shipment of the Product prior to the date that is [***] days after the date of the applicable purchase order. The expected time until the Delivery Date of Product made at each Facility shall take into account the total number of Batches that can be made at such Facility and other terms, as applicable; provided however, that such Delivery Date shall be made in accordance with the foregoing terms of this Section 3.3.

(a) Within [***] days after an initial Customer Purchase Order issue date, Customer may request that up to [***] of the Product be Manufactured under such Purchase Order, such additional quantity to be delivered not more than [***] days after the initial Customer Purchase Order issue date; *provided* that only such quantity of the Product may be requested per Purchase Order issued hereunder unless otherwise agreed to in writing by Hovione.

(b) In the event of any conflict between the provisions of this Agreement and any Purchase Order, acknowledgement, invoice, bill of lading, acceptance, or other preprinted form provided by either Party, the provisions of this Agreement shall control. No additional provision in any such other document shall apply unless both Parties explicitly agree in writing signed by both Parties that such additional provision shall apply as an additional provision to the Parties rights and obligations under this Agreement.

3.4 Changes. Hovione agrees that no changes that may reasonably affect quality of the Product or require any Regulatory Authority filing or approval will be made to any materials, outside suppliers, equipment or methods of production or testing for the Product without Customer's prior written approval, which shall not be unreasonably conditioned, delayed or withheld. Upon written approval or reasonable request of Customer, Hovione shall make the approved or requested changes in manufacturing procedures in a manner consistent with cGMP and other Applicable Laws.

3.5 Quantities. Hovione shall be required to Manufacture, supply and deliver to Customer such quantities of the Product as Customer orders and Hovione receives pursuant to Section 3.3, including any additional quantities requested by Customer and agreed to by Hovione in accordance with the terms and conditions of Section 3.3(a). Hovione shall use Commercially Reasonable Efforts to supply any quantities of Product that exceed [***]. Notwithstanding the foregoing, Hovione shall [***]. During the Term, and without limiting the Minimum Annual Commitment obligation set forth in Sections 3.7, beginning the calendar year following the Approval date, the Parties acknowledge and agree that each order will include a minimum of [***].

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3.6 Hovione Delays. The Parties agree that time is of the essence with respect to Manufacturing under this Agreement. Accordingly, and without limiting any other terms or conditions in this Agreement, should any condition arise in the course of this Agreement that is reasonably likely to delay Manufacturing or a Delivery Date, including but not limited to, disruption with suppliers, regulatory issues, or failure of any Batch, Hovione shall notify Customer of such condition as soon as reasonably practicable. Similarly, should any Customer response be delayed in such a way to disrupt Hovione's obligations under this Agreement, Customer shall notify Hovione of such condition as soon as reasonably practicable.

3.7 Minimum Annual Commitment. Beginning January 1 of the Calendar Year [***], in consideration for Hovione's reservation of sufficient Manufacturing capacity to meet Customer's forecasted demand for the Product under this Agreement, Customer commits to purchase from Hovione an amount of Product in such Calendar Year and each Calendar Year thereafter that corresponds to the values set forth in Exhibit 8 attached hereto ("**Minimum Annual Commitment**"). For the avoidance of doubt, Customer may be required to pay additional amounts based on the Minimum Annual Commitment as set forth in Section 10.7(v).

3.8 Annual Commitment True Up. During the Term, on December 31 of each such Calendar Year, if Customer has not met its Minimum Annual Commitment for the applicable Calendar Year, Hovione shall invoice Customer for the difference between the value of the sales of Product in such Calendar Year [***] and the Minimum Annual Commitment. The difference is the "**Annual Shortfall**". The invoice for the Annual Shortfall shall be issued no later than [***] of the following Calendar Year and such invoice shall be paid in full within [***] days by Customer.

4. Materials.

4.1 Supply of Project Specific Raw Materials. The Parties acknowledge and agree that the price for Product set forth on Exhibit 7 is: (a) [***]; and (b) [***]. In addition to the [***], Customer shall [***], which Hovione shall include in the invoice for such Product delivered pursuant to Section 7.8. [***] and based upon the rolling forecast provided under Section 3.2, Hovione shall order and maintain at all times a [***] month supply of such materials necessary to Manufacture the Product from vendors that have been mutually agreed to and approved by the Parties. Hovione shall keep Customer informed of any exposure to import duties and value added tax that are suspended at the time of import in anticipation that the resulting Product will be exported. [***].

4.2 Title to and Risk of Loss of the Project Specific Raw Materials and Starting Materials.

(a) Delivery and Risk of Loss. In addition to any amounts owed by Customer under this Agreement, Customer agrees to reimburse Hovione for [***]. Hovione will at all times take such measures as in accordance with the industry standard to protect the Project Specific Raw Materials, Starting Materials and the Product from risk of loss or damage at all stages of Manufacturing, and, except for normal in process yield losses, [***] of Product manufactured by Hovione at commercial scale according to the validated process (including such batches manufactured by Hovione pursuant to the MSA). Hovione will immediately notify Customer if at

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any time it believes any Customer's Project Specific Raw Materials or Products have been damaged, lost, stolen, or contain a non-conformity whether through the sampling and testing process or a Latent Defect.

(b) Title. Customer shall retain title to the Project Specific Raw Materials and Starting Materials while it is in the Facility. Hovione shall assume responsibility [***]; *provided, however*, Customer at all times retains responsibility for [***].

(c) Project Specific Raw Materials and Starting Materials. Hovione shall be responsible for planning, managing, and procuring all Project Specific Raw Materials from qualified or specified manufacturers based on the forecasts it receives from Customer. For such purchases, Hovione will not be liable or take responsibility to the extent, for any reason other than because of a Hovione failure, the Supplier does not provide timely supplies. Should Customer fail to promptly pay Hovione for amounts owed on the Project Specific Raw Materials or Starting Materials, Hovione shall have good faith basis to cease procuring such materials. Hovione shall obtain a certificate of analysis or equivalent with each lot of Project Specific Raw Materials purchased. Hovione will store all Project Specific Raw Materials in a secure location under appropriate conditions.

(d) Testing. Hovione shall conduct release testing of the Project Specific Raw Materials and Starting Materials in accordance with Hovione's standard operating procedures and policies and the Quality Agreement. Hovione will (a) account for all Project Specific Raw Materials; (b) not provide the Project Specific Raw Materials to any Third Party without the express prior written consent of Customer; (c) not use the Project Specific Raw Materials for any purpose other than conducting the Services; and (d) destroy or return to Customer all unused quantities of Project Specific Raw Materials according to Customer's written instructions at Customer's cost.

4.3 Hovione-Supplied Materials. Unless the Parties agree otherwise, Hovione will supply, at Customer's expense and in accordance with all relevant approved raw material specifications, all Project Specific Raw Materials and all Starting Materials to be used by Hovione in the performance of Services under this Agreement. Hovione shall use Commercially Reasonable Efforts to plan, manage and procure all materials necessary for the Manufacturing of the Product, other than the Project Specific Raw Materials and Starting Materials, [***]. Hovione shall ensure that all such materials are purchased from qualified or specified manufacturers. Hovione shall obtain a certificate of analysis or equivalent with each lot of materials purchased. For the avoidance of doubt, [***].

4.4 Title to and Risk of Loss of the Customer Materials and Customer Technology.

(a) Title. Title to Customer Materials and Customer Technology supplied by Customer pursuant to this Agreement will at all times remain with Customer. Hovione will acquire no right, title or interest in such Customer Materials and Customer Technology, nor will it take or suffer any action inconsistent with Customer's ownership or interest in the Customer Materials or Customer Technology, including but not limited to the imposition of any lien thereon, the

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conveyance of any interest therein, or any use thereof except as authorized by the terms of this Agreement or the relevant Work Plan, where applicable.

(b) Risk of Loss of the Customer Materials. Risk of loss of the Customers Materials will at all times remain with Customer. Notwithstanding the foregoing:

(i) Hovione will [***] keep secure and account for all Customer Materials; and

(ii) Hovione will [***] (1) [***], or (2) [***]. If requested, [***].

(c) Return. Promptly upon completion of the Services or as may be earlier required under Section 10, all unused Customer Materials and Customer Technology will be returned to Customer, or otherwise disposed of or destroyed in accordance with instructions from Customer, in each case at Customer's reasonable expense.

4.5 Specialist or Capital Equipment. As of the Effective Date, the Parties acknowledge that to the best of their knowledge and based on the quantities estimated by Customer at Effective Date, [***] will be needed in order for Hovione to perform the Manufacture of Product at Hovione's Facilities.

5. Time Schedule for Performance; Change Orders; Delays; Records; Personnel and Inspection.

5.1 Time Schedule for Performance. Hovione will use Commercially Reasonable Efforts to perform the Services according to the schedule agreed upon by the Parties in the relevant executed Work Plan, where applicable. The Parties acknowledge that such schedule (and any Gantt charts or other representations of that schedule) is for planning purposes only.

5.2 Change Orders. Any material change in the details of a Work Plan or the assumptions upon which a Work Plan is based may require changes in the fees and/or timelines and will require a written amendment to the relevant Work Plan (a "**Change Order**"). Each Change Order will be generated by Hovione and will detail the requested changes to the applicable task, responsibility, duty, fees, timelines or other matters. When written approval of the Change Order is received from Customer, the change in the Work Plan will be made and the Services will be modified accordingly.

5.3 Delays. If any material delay in performance of the Services under this Agreement is experienced because of Customer's failure to supply Hovione with Customer Materials, Customer Technology or information required to perform such Services in a timely manner, Customer and Hovione will each use Commercially Reasonable efforts to reduce the impact of such delay and, subject to the foregoing, Hovione shall be entitled to extend (by a period of time commensurate with such material delay) the timelines for completion of the Services taking into consideration the availability of the capacity of the Facility. If any such delay lasts for [***] or more, the Parties will meet to discuss how to resolve the situation including, if appropriate, the impact of cost and timeline and revising the applicable Work Plan or Purchase Order.

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5.4 Records. Hovione will keep complete and accurate records of all results obtained by Hovione in the course of its performance of the Services under this Agreement (the "**Records**"). While in the possession or control of Hovione, Records will be made available for inspection, examination and copying by or on behalf of Customer and at Customer's reasonable expense pursuant to Section 2.9; *provided*, *however*, that Hovione may exclude or redact from such Records any confidential or proprietary information of Third Parties or any Hovione Technology that Hovione regards as trade secrets.

5.5 Inspections. Hovione shall inform Customer of any FDA or other Regulatory Authority inspection of the Facility in which the Product is Manufactured within [***] that such inspection is initiated or known by Hovione, and shall allow Customer (or its designee) to attend and act as a consultant to Hovione in such audits if the inspection is reasonably related to the Manufacture of the Product (Customer will have the right to be present on site, but not participate in, any such investigation or inspection). Hovione shall provide updates to Customer during the inspection as required by the Quality Agreement and, within [***] after receipt by Hovione, provide copies to Customer of all inspection observation reports and other regulatory communications that may affect any of the Product or its Manufacture. Hovione shall also provide copies of Hovione's proposed responses to such inspection observation reports and other regulatory communications within [***] of their preparation (the inspection observation reports, Hovione's proposed and actual responses, and other regulatory communications are referred to collectively as "**Regulatory Audit Materials**"). Customer will be allowed to review and comment on those Regulatory Audit Materials which reasonably pertain to the Product or the Manufacture thereof. Hovione shall promptly notify Customer as to what corrective measure Hovione is taking, whether before or following any regulatory inspection or audit, and keep Customer informed on a regular, ongoing, and periodic basis of related developments. For the avoidance of doubt, Hovione shall control and have full authority with regard to communications in connection with its Facilities with any Regulatory Authority.

5.6 Periodic Manufacturing Audit. Up to [***] Customer representatives shall have the right to conduct [***] Manufacturing Audit (as defined below) [***] during the term of this Agreement.(such Manufacturing Audit to be hereinafter referred to as a "**Periodic MA**"). Each Party shall bear its own costs and expenses incurred in connection with the conduct of such Manufacturing Audit.

5.7 Event Manufacturing Audit. In addition to the Periodic MA referred to in Section 5.6 hereof, in the event that: (a) the Regulatory Authorities schedule a regulatory inspection of the Facility in which the Product is Manufactured; (b) Hovione shall receive a "Warning Letter" or Form 483 Observations from the FDA relating to the Manufacture of the Product by Hovione or compliance with cGMP's at any Facility where the Manufacturing or other activities related to the Product occurs; (c) Customer has rejected a shipment of the Product for failure to meet Specifications; or (d) Customer otherwise has reasonable concern regarding the quality or Manufacturing of the Product supplied by Hovione (individually or collectively, an "**Event**"), Customer shall have the right to conduct additional Manufacturing Audits in respect of the Product according to the terms specified in Section 5.9 (such Event Manufacturing Audit to be hereinafter referred to as an "**Event MA**").

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5.8 [***]. [***].

5.9 Audit. For purposes of this Agreement, the term "**Manufacturing Audit**" shall mean an audit of the relevant Manufacturing Facility to be conducted by Customer and its Product Licensees or designees. Each Manufacturing Audit shall be conducted during Hovione's normal business hours and upon reasonable prior written notice to Hovione ("**reasonable**", for purposes of this provision, shall be at least [***] days, except that an Event MA shall occur as soon as reasonably practicable, and each Manufacturing Audit shall last no longer than [***], except that an Event MA may last longer as reasonably necessary. During a Manufacturing Audit, upon Customer's request, Hovione shall make available for review and photocopying such documents as Customer and its auditors may reasonably request provided they relate to the Product and its Manufacture by Hovione.

6. Shipping and Delivery; Certificate of Analysis and Control Sample; Acceptance.

6.1 Shipping. Shipment of Product and Deliverables will be in accordance with the instructions for shipping and packaging specified by Customer in the relevant Purchase Order or Work Plan or as otherwise agreed to in writing by the Parties. Delivery terms are as set forth in Section 7.7. All shipping instructions of Customer will be accompanied by the name and address of the recipient and the shipping date and any costs and insurance associated with shipping will be borne by Customer, unless otherwise expressly agreed in a writing signed by both Parties. Should Customer require special handling, packaging or services, then the cost of such special handling, packaging or services will be borne entirely by Customer at Hovione's prevailing rates.

6.2 Certificate of Analysis and Control Sample. Each Batch of Product shipped to Customer shall be accompanied by a Certificate of Analysis substantially in the form of Exhibit 4, approved by a responsible representative of the quality assurance function at Hovione. If requested by Customer, each Batch shipped shall also include a control sample for analysis in a container provided or otherwise pre-approved by Customer, or its designee to conduct quality control release testing. Such control sample must be from, and representative of, the lot or Batch of the Product actually shipped.

6.3 Inspection and Rejection.

(a) Inspection. Hovione will ship all Products and/or Deliverables in accordance with Section 6.1 upon completion of any Product testing required to be done by Hovione as specified in the applicable Purchase Order. Customer will have [***] days from delivery to Customer's facility (the "**Inspection Period**") to inspect and test the Product in accordance with Customer's standard operating procedures and using the testing methods identified in the applicable Work Plan and Quality Agreement (including the Specifications). Prior to the expiration of the Inspection Period for a shipment of Product, Customer will provide prompt written notice to Hovione if any such Product does not comply with the applicable requirements or cGMP (if applicable). Such notice will specify the nature of the Product's non-compliance. Subject to Section 6.3(b), failure by Customer to provide such notice within the applicable Inspection Period will be deemed an acceptance of such Product by Customer.

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(b) Latent Defect. Customer may, no later than [***], reject Product if it discovers that such Product has a Latent Defect. Customer must notify Hovione of such Latent Defect in writing within [***] after its discovery of such Latent Defect, which will state in a reasonably sufficient detail a description of the Latent Defect.

6.4 Referee Laboratory. In case of any disagreement between the Parties as to whether Product conforms to the applicable Specifications, a representative sample of such Product will be submitted to an independent testing laboratory mutually agreed upon by the Parties ("**Referee Lab**") for tests and final determination of whether such Product conforms to such Specifications. The Referee Lab must meet the requirements of cGMP, be of recognized standing in the industry, and consent to the appointment of such laboratory will not be unreasonably withheld or delayed by either Party. The Referee Lab will use the test methods contained in the applicable Specifications. The determination of conformance by the Referee Lab with respect to all or part of such Product will be final and binding on the Parties. The fees and expenses of the Referee Lab incurred in making such determination will be paid by the Party against whom the determination is made.

6.5 Remedies. If Hovione agrees or the Referee Lab determines that Product does not conform to the applicable Specifications, then Customer will have the right to reject such non-conforming Product. Customer will promptly return any such rejected Product to Hovione, or at Hovione's direction dispose of such Product at Hovione's expense. [***]. [***]. If the Parties, through their Quality Assurance groups, agree, replacement of the non-conforming Product can be done through reprocessing or reworking the non-conforming Product. The remedies set forth in this Sections 6.5 and 6.6 (to the extent applicable) are Customer's sole remedies under this Agreement with respect to returned, non-conforming Product and are subject to the limitations on liability set forth in Section 14.6.

6.6 Recalls and Returned Product. In the event: (a) Customer or any of its Affiliates reasonably determines that Product or a product containing Product should be recalled for any reason; (b) any Regulatory Authority issues a request, directive, or order that Product be recalled or otherwise withdrawn from any country in the Territory; or (c) a court of competent jurisdiction orders such a recall or withdrawal (either (b) or (c) together, an "**Order**"), the Parties shall take all appropriate corrective actions reasonably requested by the other Party or any Regulatory Authority. To the extent such recall or withdrawal results from Hovione's: (i) [***]; (ii) [***]; or (iii) [***], then Hovione shall be responsible for: (x) [***]; (y) [***]; and (z) [***]. If Customer believes that the recall results from any reason defined in (i), (ii), and/or (iii) above, then Customer and its Affiliates may proceed with such recall at their own risk and expense (subject to the following sentence) and will hold a dialogue with Hovione between the respective chief executive officers of the Parties or their designees to ensure the facts that led to such a decision are shared. If Hovione agrees, or a final determination is made in an arbitration, that the recall results from any reason defined in (i), (ii), and/or (iii) above, then Hovione shall be responsible for [***]; *provided that* Hovione's aggregate liability to Customer under this Section 6.6 for any recall shall be limited to [***]. If the recall results from any other reason, Customer shall be responsible for its own and Hovione's actual documented out-of-pocket costs of such recall or withdrawal. For purposes of this Agreement, out-of-pocket costs of such recall or withdrawal shall be [***]. The Parties each have the right to audit such recall costs. Customer shall be responsible for coordinating any and all such recall or withdrawal activities with the Authorities, its customers, or otherwise. [***].

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7. Exclusivity, Price and Payments.

7.1 Exclusivity. Other than to fulfill its obligations hereunder and subject to Section 7.4, Hovione shall not knowingly, during the Term, and for a period expiring upon the later to occur of (i) [***], or (ii) the [***]. Notwithstanding the foregoing, the exclusivity obligations set forth in this Section 7.1 shall expire [***] months after Hovione's termination of this Agreement pursuant to Section 10.3 (Customer's material breach) or Section 10.4 (Customer bankruptcy).

7.2 Insufficient Supply. During the Term, Hovione shall [***] allocate its inventory and Manufacturing output of the Product so that, in the event Hovione has an insufficient Manufacturing capacity to satisfy all of its customers' orders, Hovione's allocation to Customer on its orders [***]. If at any time during the Term, Hovione is, or expects that it will be, unable, in full or in part, to satisfy Customer's orders for the Product for any reason, including *force majeure* (as defined in Section 11), Hovione shall so notify Customer as soon as possible, detailing the extent to which it will not meet such orders. In the event that at any time Hovione is unable to meet Customer's orders or requirements for the Product for more than [***] days, then Customer will have the right, in its sole discretion, to either (i) cancel any and all outstanding Purchase Orders subject to such supply interruption without penalty and/or purchase any and all of its orders or requirements of API from an alternate supplier [***]; or (ii) terminate this Agreement upon [***] days' prior written notice to Hovione.

7.3 Supply Failure. Notwithstanding anything to the contrary, a "**Supply Failure**" means (a) any notification from Hovione of an anticipated Product shortage, or actual inability, to fill [***] percent or more of a Purchase Order in either case for a period of [***] months or more from the agreed upon Delivery Date; (b) *force majeure* or negligent or intentionally reckless act affecting Hovione's ability to supply Product that meets the Specifications in accordance with this Agreement for a period of [***] months or more from the agreed upon delivery date; or (c) the occurrence on [***] or more occasions within a [***] month period of a material breach by Hovione of its obligation to supply Product that meets the Specifications whether or not such breach has been cured. Notwithstanding any rights or obligations in the Agreement, should there be a Supply Failure and such failure is not due to or caused by the actions of Customer, then (i) Customer is permitted to [***] secure supply of Product from other sources even if such supply would otherwise be contrary to the terms of this Agreement, including but not limited to Section 3.1; and (ii) Customer is excused from for any Minimum Annual Commitment [***], and (iii) if Customer elects to have Hovione conduct technology transfer in accordance with Section 13.5 following such Supply Failure, such technology transfer shall be performed at Hovione's reasonable cost and expense.

7.4 Supply to Third Parties. Customer acknowledges that, notwithstanding anything to the contrary in this Agreement, Hovione shall have the right to (a) [***]; and (b) (i) [***]; and (ii) [***]. Customer agrees that, solely in connection therewith, Hovione may use and disclose under an obligation of confidentiality (such obligation being at least as restrictive as the confidentiality provisions of this Agreement) any [***].

7.5 Price. The initial price for commercial Product supplied by Hovione to Customer during the Term is set forth in Exhibit 7.

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7.6 Price Adjustments. As set forth in this Section below, Hovione shall have the right to adjust prices [***] and Hovione and Customer agree to meet at least [***] days prior to the commencement of each Calendar Year during the Term to discuss the adjustment of the prices for Product hereunder, based on [***]. Commencing after the [***] anniversary of the Effective Date, Hovione shall, [***] per Calendar Year, have the right to increase the price as follows: (i) with regard to the cost to Manufacture the Product (that is, all costs other than the cost of raw materials), Hovione may increase prices to an amount that is [***] (a) the percentage change from January 1 of each Calendar Year of the Producer Price Index (PPI) [***] or (b) [***] percent; and (ii) with regard to the cost of raw materials that are not reimbursed by Customer pursuant to Sections 4.1 or 4.3, Hovione may [***] annually increase prices to incorporate all actual, documented increases in Hovione's cost of raw materials if any such increase(s) exceed an aggregate of a [***] change from January 1 of each Calendar Year. Should such PPI resource become obsolete, the Parties will mutually agree in writing to a new source that measures the substantially identical rate. The increase in prices will be applicable on all orders placed [***] or more [***] after such price is set.

7.7 Product Delivery Terms; Storage. Hovione agrees to deliver all Product ordered by Customer [***] (Incoterms 2010) at the Facility designated in writing in any purchase orders. Title and risk of loss to the Product supplied hereunder shall pass to Customer upon delivery to the designated site. All shipping instructions of Customer shall be accompanied by the name and address of the recipient and the shipping date. Customer shall arrange for shipment and take delivery of such Product from the Facility. Hovione shall provide storage on a bill and hold basis for delivered Product at no charge for up to [***] days after the Delivery Date. Any additional storage shall be at Customer's reasonable cost.

7.8 Invoices. The invoices for the fees under this Agreement shall be marked with the following information:

Purchase Order Number _____;

and the following statement:

"Manufacturing/Services performed under this Commercial Manufacturing Agreement."

7.9 Hovione shall invoice Customer for Product upon the earlier to occur of (i) shipment of such Product, (ii) within [***] days after Batch Release/Disposition by Customer, or (iii) within [***] days of Hovione's Batch Release (as evidenced by the date of Hovione's Certificate of Analysis), (iv) upon Customer's request. Hovione will submit its invoices for Manufacturing, Services, Products, and expenses to Customer by regular mail or by email as noted below:

By electronic mail:

[***]

7.10 Method of Payment. All undisputed invoices shall be due and payable [***] days from receipt of the invoice by Customer; *provided, however*, that invoices for up-front fees shall be paid by Customer within [***] days after receipt thereof or as otherwise specified

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herein. In the event any undisputed payment is not made when due, Hovione shall notify Customer of such nonpayment and, regardless of such notification, shall be entitled, in addition to its other rights and remedies, to charge interest on the unpaid undisputed amount at the rate of [***] percent ([***]%) per month. Customer shall make all payments pursuant to this Agreement by wire transfer of immediately available funds to a bank account designated in writing by Hovione.

7.11 Reimbursement of Costs and Expenses. For any provision in this Agreement requiring Customer to reimburse Hovione for its actual costs or expenses, Hovione agrees to (a) provide Customer with reasonable supporting documentation for such costs or expenses, and (b) use Commercially Reasonable Efforts to minimize such amounts and to reasonably consider any proposals by Customer to reduce such amounts.

7.12 Currency: Currency Conversion. All payments to be made under this Agreement shall be made in US Dollars.

7.13 Taxes. Any use, sales, excise or value added tax, duty, custom, inspection or testing fee, or any other tax, fee or charge of any nature whatsoever imposed by any Governmental Authority on or measured by the transaction between Hovione and Customer (other than Hovione's income tax), will be paid by Customer in addition to the prices quoted or invoiced by Hovione. In the event Hovione is required to pay any such tax, fee, or charge, Customer will reimburse Hovione for such payment, or in lieu of such payment, Customer will provide Hovione at the time the order is submitted an exemption certificate or other document acceptable to the Governmental Authority imposing the tax, fee or charge.

7.14 Import and Export. Without limiting the generality of any other provisions of this Agreement, and in addition to any other amounts due to Hovione under this Agreement, Customer will be responsible for all actual, out-of-pocket costs and expenses approved in advance in writing (including, but not limited to, by providing for such costs and expenses in the applicable Purchase Order) and incurred by Hovione in connection with the import or export of Project Specific Raw Materials or Customer Technology, If applicable, Hovione will provide customary export documentation, as specified by Customer in writing or by separate delivery and shipment documentation instructions, together with each shipment of Product (or such other deliverables). Hovione shall also provide Customer with all relevant shipping information (*e.g.*, carrier, shipment details, scheduled arrival date, quantity) prior to or coincident with shipping any Product (or such other deliverables) under this Agreement.

8. Representations and Warranties.

8.1 By Both Parties. Hovione and Customer each represents and warrants to the other that:

(a) Organization. It is duly organized, validly existing and in good standing under the laws of the jurisdiction of incorporation or organization. Such Party has the requisite legal and corporate power and authority to conduct its business as presently being conducted, and as proposed to be conducted by it, and is duly qualified to do business in those jurisdictions where its ownership of property or the conduct of its business requires.

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(b) Authority. It has all requisite legal and corporate power and authority to enter into this Agreement and to perform the services contemplated hereunder. All corporate actions on the part of such Party, the boards of directors or managers, or similar governing body of such Party and the equity holders of such Party necessary for: (i) the authorization, execution, delivery, and performance by such Party of this Agreement; and (ii) the consummation of the transactions contemplated hereby, have been duly taken.

(c) Binding Obligation. This Agreement is a legally valid and binding obligation of such Party, enforceable against such Party in accordance with its terms.

(d) No Conflicts. None of the execution and delivery of this Agreement, the consummation of the transactions provided for herein or contemplated hereby, or the fulfillment by such Party of the terms hereof or thereof, will (with or without notice or passage of time or both): (i) conflict with or result in a breach of any provision of the certificate or articles of incorporation or formation, by-laws, statutes, operating agreement, or other governing documents of such Party; (ii) result in a breach, constitute a breach under, give rise to any right of termination, cancellation or acceleration, or require any consent or approval (other than approvals that have heretofore been obtained) of any Governmental Authority or under any of the terms, conditions, or provisions of any material note, bond, mortgage, indenture, loan, arrangement, license, agreement, lease, or other instrument or obligation to which such Party is a party or by which its assets may be bound; or (iii) violate any law or regulation applicable to such Party or any of its assets.

(e) Consents and Approvals. All material consents, approvals, qualifications, orders or authorizations of, filings with, or notices to any Governmental Authority or any other person required in connection with such Party's execution, delivery, or performance of: (i) this Agreement; and (ii) the consummation of any other transaction contemplated on the part of such Party hereby, have been obtained, made or given.

8.2 By Hovione. Hovione represents, warrants and covenants to Customer that:

(a) To the best of Hovione's knowledge and/or the use of Hovione Technology in the performance of the Manufacturing and/or Services will not infringe the intellectual property rights of any Third Party, and Hovione will promptly notify Customer in writing should it become aware of any claims asserting such infringement.

(b) All Product supplied to Customer hereunder shall be Manufactured in accordance with the Quality Agreement, cGMP and all other Applicable Laws, and the Specifications, and at the time of delivery shall have a shelf life or retest dating no less than the shelf life or retest dating set forth in the Specifications, or such longer period as equals the retest period (as Customer may approve and communicate to Hovione with supporting documentation) [***]; *provided*, *however*, that Customer provides Hovione with no less than [***] days' prior written notice of any such change in the shelf life or retest dating of the Product.

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(c) All Product and Hovione's Manufacture of the Product shall be performed in accordance with and conform in all respects to the Applicable Laws governing the Manufacture and supply of the Product in the place where Manufactured and the Territory.

(d) As of the date of this Agreement and to the best of its knowledge, all Hovione Technology is owned by Hovione or Hovione is otherwise entitled to use it for purposes of providing Manufacturing or the Services under this Agreement. Hovione will promptly notify Customer in writing if it receives or is notified of a formal written claim from a Third Party that Hovione Technology or Hovione Improvements or that the use by Hovione thereof infringes any intellectual property or other rights of any Third Party.

(e) Hovione shall: (i) retain the minimum number of samples of the Product as are required and specified to comply with the retention requirements as set forth in the cGMPs, DMFs, and Regulatory Application; (ii) report to Customer any confirmed out-of-specification test results with respect to the delivered Product within [***]; and (iii) make stability reports and findings available for reasonable inspection by Customer and/or Customer's designees. Hovione shall retain all production records of the Process and Manufacture of the Product in accordance with Applicable Laws, including cGMP's. Hovione shall perform stability testing as described and required to conform with the Product stability protocol to be agreed upon in writing by the Parties.

(f) Hovione shall: (i) promptly report to Customer and investigate all material out of specification events in Manufacturing and/or complaints by Customer regarding non-conformance; (ii) promptly report to Customer and investigate all critical Manufacturing deviations; (iii) keep Customer apprised no less frequently than every [***] days of the status of such investigations; and (iv) share all investigative reports upon the conclusion of the investigation with Customer.

(g) To the best of Hovione's knowledge, neither Hovione nor any of its officers or employees, nor any other person, consultant or contractor used by Hovione to perform Manufacturing or Services under this Agreement is: (i) an individual who has been debarred by the FDA pursuant to Section 306 of the FDCA, 21 U.S.C. § 335a ("**Debarred Individual**"); (ii) a corporation, partnership or association that has been debarred by FDA pursuant to Section 306 of the FDCA, 21 U.S.C. § 335a ("**Debarred Entity**"); or (iii) the subject of an FDA debarment investigation or proceeding (or similar proceeding of another Regulatory Authority); and Hovione will not retain or employ any personnel, and will not knowingly use the services of any contractor or consultant, who is debarred by the FDA or who is the subject of an FDA debarment investigation or proceeding (or similar sanction or investigation by another Regulatory Authority) in connection with performing any Manufacturing or Services. Hovione has no knowledge of any circumstances which may affect the accuracy of the foregoing representation, including, without limitation, any FDA investigations of, or debarment proceedings against, Hovione or any person or entity performing services or rendering assistance which is in any way related to activities taken pursuant to this Agreement. Hovione shall notify

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Customer in writing as soon as possible if Hovione, at any time during the Term, becomes aware of any such circumstances.

(h) At the time of delivery to Customer, the Product will be free from interest, lien, encumbrance and any other kind of security.

8.3 By Customer. Customer represents and warrants to Hovione that:

(a) To the best of Customer's knowledge, the use of Customer Technology as contemplated in the Services will not infringe the intellectual property rights of any Third Party and Customer will promptly notify Hovione in writing should it become aware of any claims asserting such infringement.

(b) Customer will comply with all Applicable Laws in its use of the Product and the Deliverables.

(c) As of the date of this Agreement and to the best of its knowledge, all Customer Technology is owned by Customer or Customer is otherwise entitled to use it for purposes of conducting the activities under this Agreement. Customer will promptly notify Hovione in writing if it receives or is notified of a formal written claim from a Third Party that Customer Technology or that the use by Hovione thereof infringes any intellectual property or other rights of any Third Party.

(d) to the best of its knowledge, neither the Manufacture, supply, nor use of the Product as contemplated hereby will infringe on any patents or any other proprietary rights of Third Parties, except to the extent arising from any technology or process introduced and used by Hovione in the Manufacture of the Product, and neither Customer, nor any of its Affiliates, has received any notice of any claimed infringement (including, without limitation, patent infringement) in connection with the Product and it will promptly notify Hovione in writing should it (or they) become aware of any claims asserting such infringement. For the avoidance of doubt, and without limiting any other provisions of this Agreement, Customer understands and agrees that, if at any time Hovione reasonably determines, based on legal counsel, that the Manufacture and supply of Product as contemplated hereby does infringe on any patents or any other proprietary rights of Third Parties (except to the extent arising from any technology or process introduced and used by Hovione in the Manufacture of the Product), Hovione shall promptly provide Customer with notice of such determination and, thereafter, Hovione may suspend the Manufacture and supply of Product under this Agreement without breaching any of Hovione's obligations hereunder until Customer has either (i) provided Hovione with sufficient justification for Customer's position that such suspected infringement is not the case, or (ii) provides evidence to Hovione that Customer has secured the rights to rightfully practice the patents or any other proprietary rights of such Third Parties and that those rights are rightfully extended to Hovione under this Agreement, or the Parties mutually agree in a signed writing as to Customer's indemnification obligations for amounts Hovione may owe to any Third Parties with respect to such alleged infringement. In no event shall Hovione be in breach of this Agreement for its refusal to perform any Manufacturing action that would amount to a criminal offense or be in contempt of court. If Hovione

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suspends the Manufacture of the Product under this Section, Customer's obligation to purchase Minimum Annual Commitments shall be suspended until restoration of the Manufacturing.

8.4 Specifications and Other Changes. Customer represents and warrants that the Specifications shall be in conformance with the Regulatory Applications. In the event Customer or any of its Affiliates changes the Specifications, Customer shall promptly advise Hovione in writing of such changes, and Hovione shall promptly inform Customer as to any scheduling and/or price adjustments which may reasonably result from such changes. In the event that Hovione wishes to propose any material change to the Manufacturing (including without limitation, components, equipment, Facility, or Process), the DMF, or the Specifications, it shall provide all relevant details related to such proposed change for review by Customer, but shall not implement any such material change prior to Customer's written approval and any necessary approval by the applicable Regulatory Authority. Customer shall promptly provide Hovione with current, up-to-date copies of portions or sections of each applicable DMF or CMC from the NDA filing that relate to Hovione's Manufacturing and Services that Hovione is expected to complete under this Agreement.

8.5 DISCLAIMER. EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATION OR EXTENDS ANY WARRANTY OF ANY KIND, EITHER EXPRESS OR IMPLIED INCLUDING, BUT NOT LIMITED TO, WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR NON-INFRINGEMENT.

9. Government Approvals and Hazardous Materials.

9.1 Approvals. Customer will be responsible for obtaining, at its expense, all regulatory and governmental approvals and permits necessary for Customer to use the Product or the Deliverables provided under this Agreement, including, without limitation, all submissions filed with the FDA or other Authorities. Hovione will be responsible for obtaining, at its expense, all regulatory and governmental approvals and permits necessary for Hovione to operate its Facility in the manner required to perform the Services.

9.2 Hazardous Materials. Prior to Hovione commencing the Services, Customer will inform Hovione of all characteristics, including all health and safety characteristics, of the Customer Materials and when appropriate, provide Hovione with a Material Data Safety Sheet on Customer Materials. Customer will immediately notify Hovione of any new hazards or potential hazards to the health and safety of Hovione personnel relating to the Customer Materials. If any [***].

10. Expiration and Termination.

10.1 Term. The term of this Agreement shall commence on the Effective Date and shall expire on the seventh (7^{th}) annual anniversary of the first Approval, unless terminated earlier pursuant to the terms hereof (the "**Initial Term**"). This Agreement shall be automatically renewed for successive additional two (2) year terms after the end of the Initial Term, unless (a) either Party provides written notice to the other at least twelve (12) months prior to the end of the Initial Term or twelve (12) months prior to the end of the Renewal Term,

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as the case may be, that this Agreement shall expire at the end of the Initial Term or such Renewal Term, (b) [***], or (c) unless this Agreement is terminated earlier pursuant to the terms hereof (each a "**Renewal Term**"). The Initial Term and all Renewal Terms shall be collectively referred to herein as the "**Term**". Notwithstanding the foregoing, as a condition to the commencement of any Renewal Term, at least [***] months prior to the commencement of such Renewal Term the Parties shall [***]. In the event the Parties [***].

10.2 Termination for Convenience. This Agreement may be terminated by Customer, in whole or in part, for any reason upon twelve (12) months prior written notice to Hovione.

10.3 Termination for Material Breach. This Agreement may be terminated by either Party in the event of the material breach by the other Party of the terms and conditions hereof; *provided*, *however*, the other Party shall first give to the defaulting Party written notice of the proposed termination or cancellation of this Agreement, specifying the grounds therefor. Upon receipt of such notice, the breaching Party shall have [***] days to respond by curing such breach or by confirming to the other Party in writing that such breach is not capable of being cured within such [***] day period and that the breaching Party is working diligently to cure such breach, but in no event shall the non-breaching Party be required to accept any cure period totaling greater than [***] days. If the breaching Party does not so respond or fails to work diligently and to cure such breach within the additional time set forth above, then the other Party may terminate the Agreement. Termination of this Agreement pursuant to this Section 10.3 shall not affect any other rights or remedies which may be available to the non-breaching Party.

10.4 Termination for Bankruptcy; Insolvency. Either Party may terminate this Agreement upon: (a) the entry of a decree or order for relief by a court having jurisdiction in the premises in respect of such Party in an involuntary case under the U.S. Federal Bankruptcy Code, as now constituted or hereafter amended, or any other applicable federal or state insolvency or other similar law and the continuance of any such decree or order unstayed and in effect for a period of [***] days; or (b) filing by such Party of a petition for relief under the U.S. Federal Bankruptcy Code, as now constituted or hereafter amended, or any other applicable federal or state insolvency or similar law.

10.5 Termination by Customer. This Agreement may be terminated by Customer in the event: (a) the FDA does not approve a Regulatory Application for Product or issue a letter indicating that such a Regulatory Application is approvable within [***] years after Customer submits its new drug application ("**NDA**") to the FDA for approval; (b) the Regulatory Application for Product is submitted for approval by the FDA is withdrawn; (c) if Customer, in its sole discretion, stops development of the Product; or (d) the Product is withdrawn from Sale throughout the Territory. Termination under this Section 10.5 shall be effective [***].

10.6 Termination for Breach of Section 17.1 or Section 17.12. Either Party may terminate this Agreement immediately upon written notice if the other Party breaches either Section 17.1 or Section 17.12.

10.7 Obligations upon Termination.

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(a) Of Hovione. Upon termination of this Agreement or any Work Plan(s) or Purchase Orders pursuant to this Section 10 or 11, Hovione will suspend work as early as possible and, with respect to each terminated Purchase Order will invoice Customer and Customer shall promptly reimburse Hovione for:

(i) the reasonable, documented costs and expenses related to the termination of this Agreement which are not ordinarily planned as close-out of Manufacture, including, but not limited to: (a) the return or disposal of Products, Customer Materials, samples, and non-refundable, non-useable raw materials directly related to Hovione's obligations hereunder; and (b) reasonable staff time and related costs necessary to transfer any Product relevant know-how or other information to Customer;

(ii) any outstanding, unpaid invoices issued by Hovione for amounts actually owed to Hovione;

(iii) any amount not yet invoiced but owed by Customer under this Agreement for (A) work in process to Manufacture the Product; and (B) completed Product that is in Hovione's Facilities to fulfill Purchase Orders placed by Customer prior to the notice date of termination;

(iv) reimbursement for any materials purchased (that cannot be cancelled) and/or held by Hovione under this Agreement as of the notices date of termination; and

(v) except in the case of [***], in the event of any early termination of this Agreement during the Initial Term, Customer shall pay to Hovione an amount equal to the sum of [***] (the "**Termination Payment**"); *provided however*:

[***]

The Termination Payment shall be paid by Customer within [***] days after the effective date of such early termination of this Agreement. If, within the [***] months immediately following the effective date of any such early termination, Customer and Hovione, working together in a commercially reasonable manner and in good faith, mutually agree upon terms under which Hovione will perform other services for Customer, either under this Agreement or a separate agreement (the "**Follow-On Services**"), Hovione shall, upon executing the writing memorializing such Follow-On Services, [***]. [***].

(b) Further, Hovione will:

(i) perform only those Services and other activities mutually agreed upon by Customer and Hovione as being necessary or advisable in connection with the close-out of the relevant Work Plan or Purchase Order;

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(ii) use Commercially Reasonable Efforts to cancel any Third Party obligations;

(iii) promptly deliver to Customer all materials ordered by Hovione for Customer and all Deliverables (including any work in process) after receipt of payment in full for such materials and Deliverables by Customer;

(iv) promptly return to Customer all unused and unopened Customer Materials; and

(v) promptly return all Confidential Information of Customer that it has received pursuant to this Agreement.

(c) Of Customer. Upon termination of this Agreement or any Work Plan(s) pursuant to this Section 10 or 11, Customer will, with respect to each terminated Work Plan or Purchase Order:

(i) promptly pay Hovione any monies due and owing Hovione, up to the time of termination, for Services actually performed, all authorized expenses actually incurred and any uncancellable commitments made by Hovione in connection with the Services; and

(ii) promptly return all Confidential Information of Hovione that it has received pursuant to this Agreement.

10.8 Surviving Terms. Expiration or termination of this Agreement for any reason will not affect any rights or obligation of either Party that accrued prior to such expiration or termination. Further, the rights and obligations of the Parties under the following provisions of this Agreement will survive in accordance with their terms: Sections 1, 2.9, 4.4, 5.4, 6, 7.1, 8.5, 10.7, 10.8, 12 through 14, 16 and 17.

11. Force majeure.

Except as otherwise expressly set forth in this Agreement, and except for the obligation to pay any amounts due under this Agreement, neither Party will have breached this Agreement for failure or delay in fulfilling or performing any provision of this Agreement to the extent such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party, including, without limitation, fire, floods, embargoes, epidemics, quarantines, war, acts of war (whether war be declared or not), insurrections, riots, acts of terrorism, civil commotion, strikes, acts of God or acts, omissions, or delays in acting, by any Governmental Authority ("***force majeure***"). The Party affected by any event of *force majeure* will promptly notify the other Party in writing, explaining the nature, details and expected duration of such *force majeure*. The Party experiencing any such *force majeure* further agrees (a) to use Commercially Reasonable Efforts to promptly correct the *force majeure*; (b) to give the other Party periodic updates including notice when it expects to be fully able to perform such obligations; and (c) to continue to perform its obligations to the extent feasible given the *force majeure*. In the event a *force majeure* continues for more than [***] days, the non-affected Party may terminate this Agreement upon [***] days' written notice. The Parties acknowledge and agree that in the event of a *force majeure*, if Customer determines, based upon a convincing demonstration by Hovione, that Hovione can fulfill its obligations hereunder through the use of

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an alternate Facility owned by Hovione at no additional cost to Customer or delay relative to Customer's or its Affiliates' market inventory needs, then Hovione may use such Facility until such *force majeure* has been resolved.

12. Confidentiality; No Insider Trading.

12.1 Definition. "**Confidential Information**" means any and all non-public scientific, technical, financial or business information in whatever form (written, oral or visual) that is furnished or made available to by or on behalf of one Party ("**Disclosing Party**") to the other ("**Receiving Party**"). The Disclosing Party will, to the extent practical, use reasonable efforts to label or identify as confidential, at the time of disclosure all such Confidential Information that is disclosed in writing or other tangible form. Confidential Information of Hovione includes, but is not limited to, Hovione Technology and Hovione Improvements, whether or not labeled confidential. Confidential Information of Customer includes, but is not limited to, Customer Technology, Customer Improvements and the Records, whether or not labeled confidential. The terms of this Agreement are Confidential Information of both Parties.

12.2 Obligations. The Receiving Party agrees (a) to keep confidential the Confidential Information of the Disclosing Party and the terms of this Agreement, (b) not to disclose the Disclosing Party's Confidential Information to any Third Party without the prior written consent of the Disclosing Party, and (c) to use such Confidential Information only as necessary to fulfill its obligations or in the reasonable exercise of rights granted to it hereunder. A Receiving Party, however, may disclose (i) Confidential Information of the Disclosing Party to its employees, consultants, and Product Licensees, and to those of its Affiliates, in each case who have a specific need to know such Confidential Information and who are bound by a like obligation of confidentiality and restriction on use, and (ii) Improvements to the extent required to exploit its rights under Section 13.

12.3 Exceptions.

(a) The Receiving Party's obligations of non-disclosure and non-use under this Agreement will not apply to any portion of the Disclosing Party's Confidential Information that the Receiving Party can demonstrate, by competent proof:

(i) is generally known to the public at the time of disclosure or becomes generally known through no wrongful act on the part of the Receiving Party;

(ii) is in the Receiving Party's possession at the time of disclosure other than as a result of the Receiving Party's breach of any legal obligation;

(iii) becomes known to the Receiving Party on a non-confidential basis through disclosure by sources other than the Disclosing Party having the legal right to disclose such Confidential Information; or

(iv) is independently developed by the Receiving Party without reference to or reliance upon the Disclosing Party's Confidential Information.

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(b) In addition, if the Receiving Party is required by a Governmental Authority or by order of a court of competent jurisdiction to disclose any of the Disclosing Party's Confidential Information, the Receiving Party will give the Disclosing Party prompt written notice thereof and the Receiving Party will take all reasonable and lawful actions to avoid or minimize the degree of such disclosure. The Receiving Party will cooperate reasonably with the Disclosing Party in any efforts to seek a protective order.

12.4 Term of Restriction. The obligations of the Receiving Party under this Agreement with respect to each item of Confidential Information that is subject to the nondisclosure and non-use provisions set forth above shall extend for a period of [***] years from the date of initial disclosure to the Disclosing Party of such item; *provided*, *however*, that with respect to information provided (a) which constitutes chemical structures; or (b) which is in written form under this Agreement and specifically identified by the Disclosing Party as trade secret information, the Receiving Party's obligations shall extend thereafter until such information no longer constitutes a trade secret under Applicable Laws.

12.5 Publicity. Except to the extent required by Applicable Law and as otherwise provided in this Section 12.5 or in Section 12.3, neither Party will make any public statements or releases concerning this Agreement or the transactions contemplated by this Agreement without obtaining the prior written consent of the other Party, which consent will not be unreasonably withheld or delayed. Notwithstanding anything herein to the contrary, Customer shall be free to use Hovione's name and make mention of the existence of this Agreement as necessary or appropriate in connection with any regulatory filings, approvals, or other regulatory matters, and Customer shall be free to disclose information concerning this Agreement as reasonably necessary to ensure and/or exercise its intellectual property rights under this Agreement, and in discussions relating to the Product with potential or actual collaborators/investors and counsel.

12.6 No Insider Trading. The Receiving Party acknowledges that during the performance of this Agreement it may come into possession of certain material information about the Disclosing Party or its Affiliates that has not yet been disclosed to the public. The Receiving Party agrees to comply with the rules and regulations of the United States Securities and Exchange Commission, including those relating to insider trading, for as long as the Receiving Party is in the possession of such material, non-public information about the Disclosing Party or its Affiliates. The Receiving Party is hereby notified that it should not trade in securities of the Disclosing Party that might be issued in the future, either on its own behalf or on the behalf of others while in possession of any such material, non-public information.

13. Ownership of Improvements, Technology Transfer and CMC Documentation.

13.1 Background Technology. All rights to and interest in Customer Technology will remain the exclusive property of Customer, and all rights to and interest in Hovione Technology will remain the exclusive property of Hovione. During the Term, Customer grants Hovione a non-exclusive, non-sublicenseable, non-transferable license to use Customer Technology and Customer Improvements solely at the Facility(ies) for the limited purpose of fulfilling Hovione's obligations under this Agreement.

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13.2 Customer Improvements. Hovione agrees that all Customer Improvements will be the sole and exclusive property of Customer. Hovione hereby transfers and assigns all rights, title and interest in any and all Customer Improvements to Customer or its designee without additional compensation to Hovione. Hovione will take such steps as Customer may reasonably requested by Customer without compensation to Hovione to assign to Customer or Customer's designee, ownership of the Customer Improvements.

13.3 Hovione Improvements. Customer agrees that all Hovione Improvements will be the sole and exclusive property of Hovione, and, if and as necessary, Customer shall take all action reasonably requested by Hovione without compensation to Customer to assign such Hovione Improvements to Hovione or its designee without additional compensation to Customer. Customer will take such steps as Hovione may reasonably request and at Hovione's expense to vest in Hovione or Hovione's designee ownership of the Hovione Improvements. Hovione hereby grants Customer a non-exclusive, worldwide, royalty-free, paid-up license, including the right to grant sublicenses subject to the terms of Section 13.6, to use those Hovione Improvements that are necessary for the Manufacture or processing of the specific Product(s) Manufactured or processed under this Agreement solely for the purpose of Manufacturing or processing those Products.

13.4 Ownership of Tangible Materials. Customer shall retain ownership of all information, documents, and materials which Customer has provided or provides to Hovione, or otherwise [***] Hovione for as agreed to by the Parties, in connection with the performance of the Manufacturing and Services performed under this Agreement. Further, Customer shall solely own all reports, results, records (including Batch Records), documents, and other tangible materials which Hovione has provided or provides to Customer in connection with the activities performed by Hovione pursuant to this Agreement and such materials, and such reports, records (including Batch Records), documents and other tangible materials shall be deemed Customer's Confidential Information. Hovione shall take all Commercially Reasonable steps to transfer all right, title, and interest in such tangible materials to Customer; *provided*, *however*, that Hovione shall be entitled to retain one (1) copy of any such reports, records (including Batch Records), documents, and other tangible materials solely for archival purposes. For the avoidance of doubt, and notwithstanding anything to the contrary in this Agreement, the format of any tangible materials provided by Hovione hereunder shall, together with any other Confidential Information of Hovione, are and will remain Confidential Information of Hovione in accordance with the terms and condition of this Agreement; *provided*, *however*, that Customer and its designees will have the right to use and disclose such materials and information in connection with the development, technology transfer in accordance with Section 13.5, regulatory approval, or Sale of any Product. If and for so long as required under Applicable Law, all such reports, records (including Batch Records), documents, and other tangible materials shall be physically located by Hovione at the applicable Facility.

13.5 Technology Transfer. If Customer elects to have any Product manufactured by an entity other than Hovione pursuant to the terms of this Agreement, or upon termination of this Agreement, the Parties shall undertake those reasonable actions necessary and useful to enable Customer and the Third Party of Customer's choosing to manufacture and supply such Product [***]. Hovione [***] and, in such case, subject to the provisions of Section 13.3. Such actions, at Customer's reasonable expense unless such technology transfer is

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initiated by Customer as a result of material breach of this Agreement (including without limitation for Supply Failure in accordance with Section 6.5), shall include:

(a) Agreement. The technology transfer will be conducted in accordance with a separate agreement setting forth the terms and conditions for the transfer by Customer of the Process for Manufacturing the API (the "**Technology Transfer Agreement**").

(b) Books and Records; Know-How. Pursuant to the Technology Transfer Agreement, Hovione shall make available or transfer, as applicable, to Customer copies of all books and records (other than financial books and records) and Customer Improvements relating directly to the Process and/or Manufacture and supply of the Product, including documentation constituting development reports, and process validation reports, performance reports, Batch Records, analytical method development reports, analytical method operating procedures, shot practice, material specifications for Hovione-supplied materials and their quality control methods, applicable correspondence with Governmental Authorities, and any other material that is necessary or useful to enable Customer or a Third Party of Customer's choosing to manufacture and supply the Product; *provided* that all such information is directly relevant to the process knowledge that is to be transferred. All such information was developed for Customer and paid for by Customer and shall be provided without additional cost to Customer.

(c) Assistance. Pursuant to the Technology Transfer Agreement, Hovione shall provide/allow Hovione designated employees knowledgeable of Customer's manufacturing process and controls to meet with or be made reasonably available to employees or representatives of Customer at the manufacturing facility of Customer or the facility of the Third Party of Customer's choosing, to assist for a period as long as reasonably necessary, with the manufacture and supply of the Product and with the training of Customer's personnel (or the personnel of a Third Party of Customer's choosing) to the extent reasonably necessary to enable Customer or a Third Party of Customer's choosing to manufacture and supply the Product. This support shall be provided during regular business hours for Hovione and Customer shall reimburse Hovione for any actual, documented, out-of-pocket expenses reasonably incurred by Hovione.

(d) Other Assistance. Pursuant to the Technology Transfer Agreement, Hovione shall provide such other assistance as Customer may reasonably request to enable Customer or its designated Third Party to manufacture and supply the API; *provided always that* Hovione shall not be required to transfer information that (i) is not directly related to the Product; (ii) is Hovione Technology or Hovione Improvements except as set forth in Section 13.5; and/or (iii) includes Hovione Confidential Information except as set forth in Section 13.5, and that this other assistance is provided at a time that would not inconvenience Hovione and for a price based on daily rates of required employees plus out-of-pocket expenses.

(e) Nothing contained in Section 13.5 shall be construed as Hovione providing any assurance of success of the technology transfer to a Third Party. Hovione only

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assures that it shall provide all Product and Product process information necessary for Manufacturing and/or resulting from the development.

13.6 Requirements for Sublicenses. Customer will be solely responsible for the actions of any Third Party to which Customer sublicenses its rights to Hovione Improvements under Section 13.3, including indemnifying Hovione for such actions by such Third Parties in accordance with Section 14.2. Customer will cause any such sublicensee to be bound by, and to comply with, (a) the limitations on Customer's use of the Hovione Improvements under the license granted in Section 13.3, and (b) confidentiality requirements relating to the Hovione Improvements and other Hovione Confidential Information that are no less strict than those contained in this Agreement.

13.7 Patents. Customer will have the exclusive right to prepare, file, prosecute, maintain and defend, at its sole expense, any patent applications and/or patents that claim Customer Improvements. Hovione will have the exclusive right to prepare, file, prosecute, maintain and defend, at its sole expense, any patent applications and/or patents that claim Hovione Improvements.

13.8 CMC Documentation. Within [***] days of Hovione's receipt of Customer's written request, Hovione shall supply, at Customer's sole expense, all information required by Customer in support of the Chemistry, Manufacturing & Control ("**CMC**") section of any NDA or other filings to be submitted by Customer or its Affiliates in the Territory with the Regulatory Authorities for any product containing Product Manufactured by Hovione under this Agreement. Hovione shall co-operate with, and provide support and assistance to, at Customer's expense, any consultant that Customer or its Affiliates selects to write the documentation in the CMC section.

14. Indemnification; Liabilities; and Insurance.

14.1 Indemnification by Hovione. Hovione will indemnify, defend and hold harmless Customer and its Affiliates, and its and their directors, officers, employees, successors, assigns and agents ("**Customer Indemnitees**") from and against any and all damages, liabilities, claims, costs, charges, judgments and expenses, including reasonable attorneys' fees (collectively "**Losses**") that may be sustained, suffered or incurred by a Customer Indemnitee in connection with any and all actions, claims or demands that may be brought or instituted against a Customer Indemnitee by any Third Party, in each case only to the extent such Losses arise directly from or by reason of (a) the material breach by Hovione of any warranty, representation or covenant of Hovione in this Agreement, (b) any failure by Hovione to perform any covenant, agreement, or undertaking on the part of Hovione contained in this Agreement; (c) the gross negligence or willful misconduct of Hovione or its Affiliates (or their respective directors, officers, employees, agents, and contractors); or (d) any infringement of any intellectual property or other rights of any Third Party based on the use of Hovione Technology and/or Hovione Improvements. Notwithstanding the foregoing, Hovione shall have no such indemnity obligation to the extent that such Third Party claims are based on, arise out of, or are caused by: (x) the gross negligence or willful misconduct of Customer or its Affiliates (or their respective directors, officers, employees, agents, successors, and assigns); (y) any breach of any representation or warranty made by Customer in this Agreement; or (z) any failure to perform any covenant, agreement, or undertaking on the part of Customer contained in this Agreement.

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14.2 Indemnification by Customer. Customer will indemnify, defend and hold harmless Hovione and its Affiliates, and its and their directors, officers, employees and agents ("**Hovione Indemnitees**") from and against any and all Losses that may be sustained, suffered or incurred by a Hovione Indemnitee in connection with any and all actions, claims or demands that may be brought or instituted against a Hovione Indemnitee by any Third Party, in each case only to the extent such Losses arise directly from or by reason of (a) the manufacturing (other than Manufacturing hereunder), packaging, marketing, distribution, import, use or sale of the Product by Customer or its Affiliates or Product Licensees (including any claim of infringement of any patent or trademark or the unauthorized use of a trade secret and any product liability claims), (b) the material breach by Customer of any warranty, representation or covenant of Customer in this Agreement, (c) any failure by Customer to perform any covenant, agreement, or undertaking on the part of Customer contained in this Agreement, (d) any infringement of any intellectual property rights owned or controlled by a Third Party by the Product or Customer Technology and/or Customer Improvements, or (e) Customer's gross negligence or willful misconduct, except, in each case, to the extent that such claim or suit results from or arises out of any act or omission for which Hovione is obligated to indemnify Customer pursuant to Section 14.1.

14.3 Indemnification Procedure. Each indemnified Party agrees to give the indemnifying Party prompt written notice of any matter upon which such indemnified Party intends to base a claim for indemnification under this Section 14.1 or 14.2, as applicable. The indemnifying Party will have the right, but not the obligation, to defend, negotiate, and settle such claims; *provided*, *however*, that the indemnified Party will be entitled to participate in the defense of such matter and to employ counsel at its expense to assist therein. The Party seeking indemnification will provide the indemnifying Party with such information and assistance as the indemnifying Party may reasonably request, at the expense of the indemnifying Party.

14.4 Customer's Insurance. Customer will, throughout the Term of this Agreement and for [***] years after the latest expiration date of any Product Manufactured pursuant to this Agreement, obtain and maintain at its own cost and expense, commercial general liability insurance and product liability insurance. Such policies will provide protection against any and all types of claims, demands, and causes of action set forth below that could arise under this Agreement. The minimum amount of coverage required by this Agreement will be:

(a) Products liability with a combined single limit in an amount of not less than U.S. $[***] per occurrence and U.S. $[***] in the aggregate during the clinical and development phase of the Product; and not less than U.S. $[***] per occurrence and U.S. $[***] in the aggregate upon the Product receiving its first Regulatory Approval but prior to any commercial sale;

(b) workers' compensation insurance in accordance with Applicable Laws;

(c) commercial general liability including premises operations, blanket contractual liability, personal injury, and advertising injury including fire, legal liability for bodily injury, and property damage in an amount not less than $[***] per occurrence and $[***] in the aggregate; and

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(d) employer's liability with a limit of liability in an amount of not less than the statutory limits.

Customer agrees to furnish within [***] days after execution of this Agreement, and upon each policy renewal thereafter, and upon written request of Customer, a certificate of insurance or self-insurance evidencing that such insurance is in effect. Customer will provide Hovione [***] days' prior written notice of cancellation, non-renewal, or material change in the insurance required by this Agreement.

14.5 Hovione's Insurance. Hovione agrees to maintain, during the Term and for [***] years thereafter, at its own expense (a) commercial liability insurance, which includes product liability coverage, with a maximum limitation of U.S. $[***] per occurrence and U.S. $[***] annual aggregate; and (b) worker's compensation insurance in full compliance with Applicable Laws. Hovione shall submit to Customer, from an insurer with an A.M. Best rating of A- or better or, if less than A-, otherwise acceptable to Customer, a certificate of insurance evidencing that the required insurance is in force and effect. Hovione will provide Customer [***] days' prior written notice of cancellation, non-renewal, or material change in the insurance required by this Agreement.

14.6 Limitations of Liability. NOTWITHSTANDING ANYTHING IN THIS AGREEMENT TO THE CONTRARY, IN NO EVENT WILL EITHER PARTY BE LIABLE FOR ANY SPECIAL, INCIDENTAL, CONSEQUENTIAL OR INDIRECT DAMAGES ARISING OUT OF THIS AGREEMENT, HOWEVER CAUSED AND ON ANY THEORY OF LIABILITY. THIS LIMITATION WILL APPLY EVEN IF THE OTHER PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGE; *PROVIDED, HOWEVER*, THAT THIS LIMITATION WILL NOT APPLY TO [***]. Except for [***], and notwithstanding anything to the contrary in this Section 14.6, the total liability of Hovione for losses or damages under this Agreement will be limited to [***] (i) the [***], and (ii) [***] Dollars ($[***]).

15. No Violation of Law.

15.1 No Violation of Law; Permits. Each Party hereby represents, warrants, and covenants that it is not, and will not be during the Term, in violation of any law or regulation (nor is such Party aware of any violation of any law or regulation by any other person), which violation could reasonably be expected to adversely affect such Party's performance of its obligations hereunder or the ability of the other Party to realize the intended benefits to such other Party under this Agreement, and, except as otherwise contemplated hereby, such Party holds each of the licenses, permits, approvals, or authorizations necessary with respect to its current business and operations (and its rights and obligations contemplated hereby) in compliance with all laws and regulations.

16. Dispute Resolution.

16.1 Dispute Resolution. The Parties recognize that bona fide disputes may arise which relate to the Parties' rights and obligations under this Agreement. Except as otherwise expressly set forth in this Agreement including, prior to proceeding under Section 16.2, try to settle such dispute amicably among themselves by referring such dispute, controversy or claim (a "**Dispute**") to the Parties' respective chief executive officers, or any other executive

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officer designated by such chief executive officer (the "**Executive Officers**"). A dispute shall be referred to such Executive Officers upon one Party providing the other Party with written notice of referral of such Dispute to the Executive Officers. The Parties agree to attempt to resolve such Dispute through good faith discussions. If the Executive Officers fail to come to consensus on such Dispute within [***] days of receipt of such written notice then either Party is free to initiate the dispute resolution procedures set forth in this Article 16.

16.2 Arbitration. Except as otherwise expressly set forth in this Agreement, all controversies, disputes, or claims arising out of or relating to this Agreement or any alleged breach hereof, will be settled by binding arbitration administered by the American Arbitration Association ("**AAA**") in accordance with the then current Commercial Arbitration Rules of the American Arbitration Association except that, to the extent such rules are inconsistent with this ARTICLE 16, this ARTICLE 16 will control. The following rules will apply to any such arbitration:

(a) Any demand for arbitration must be made in writing to the other Party.

(b) There will be one (1) arbitrator to be mutually agreed upon and appointed by the Parties. If the Parties cannot agree on the appointment of the arbitrator within thirty (30) days, then the AAA shall select the arbitrator. The arbiter will have at least (i) five (5) years of dispute resolution experience (including judicial experience); or (ii) ten (10) years legal or business experience in the biotech or pharmaceutical industry. Any arbitration involving patent rights, other intellectual property rights, or intellectual property will be heard by arbitrators who are experienced in such areas.

(c) The arbitration will be held in New York City, New York, or such other place as the Parties agree. The arbitrators will apply the substantive law specified in Section 17.7 except that the interpretation and enforcement of this arbitration provision will be governed by the United States Federal Arbitration Act, 9 U.S.C. Section 1 *et. seq*.

(d) Electronic documents shall normally be furnished on the basis of generally available technology in a searchable format that is usable by the Party receiving it and convenient and economical for the producing Party. When the cost and burden of e-discovery are disproportionate to the likely importance of the requested materials, the arbitrator may deny the requests or require that the requesting Party advance the reasonable cost of production to the other side.

(e) The arbitrator shall not have the authority to modify any provision of this Agreement or to award punitive damages. In no event shall either party be liable for special, consequential, or incidental damages, or lost profits. The arbitrator shall have the power to issue mandatory orders and restraint orders in connection with the arbitration.

(f) There shall be a stenographic record of the proceedings. The decision of the arbitrator will be final and binding upon both Parties. The arbitrator will render a written opinion setting forth findings of fact and conclusions of law on each issue.

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Each Party agrees that, notwithstanding any provision of applicable law, it will not request, and the arbitrator shall have no authority to award damages against any Party that exceed the limits set forth in Section 14.5, to the extent applicable.

(g) A final award shall be issued no later than [***] months from the date the claimant Party files its demand for arbitration.

(h) [***]. Each Party will bear the expenses of its counsel and other experts.

(i) The award shall be final and binding on the Parties, and judgment upon the award rendered by the arbitrators may be entered in any court of competent jurisdiction. The proceedings and the final award shall be confidential.

(j) During the continuance of any arbitration proceeding, the Parties shall continue to perform their respective obligations under this Agreement to the greatest extent practicable.

16.3 Arbitrability. The question of arbitrability and whether a claim, dispute, or other matter in question would be barred by the applicable statute of limitations, which statute of limitations also shall apply to any claim or disputes subject to arbitration under this Agreement, shall be determined by binding arbitration pursuant to this Article 16.

16.4 Injunctive Relief. Notwithstanding anything to the contrary in this Article 16, a Party may seek immediate injunctive or other interim relief from any court of competent jurisdiction, without resort to dispute resolution under this Article as necessary to enforce and prevent infringement of intellectual property Rights owned or Controlled by a Party or its Affiliates, or to prevent breach of Article 12 (Confidentiality).

17. Miscellaneous.

17.1 Assignment. This Agreement may not be assigned or otherwise transferred by either Party without the prior written consent of the other Party; *provided*, *however*, that either Party may, without such consent, but with notice to the other Party, assign this Agreement, in whole or in part, (a) in connection with the transfer or sale of all or substantially all of the assets of the assigning Party or the line of business to which this Agreement relates, (b) to the successor entity or acquirer in the event of the merger, consolidation or change of control of the assigning Party, or (c) to an Affiliate of the assigning Party. Any purported assignment in violation of the preceding sentence shall be void. Any permitted assignee shall assume all obligations of its assignor under this Agreement.

17.2 For the avoidance of doubt, in the event Customer, or if Customer sells, exclusively licenses or assigns all of its business or assets to which this Agreement relates (whether by merger, consolidation, stock sale, asset sale, or otherwise), Customer shall not do anything to change the rights and obligations of Hovione under this Agreement or to impair Hovione's interests in connection with such assignment. If Customer assigns this Agreement to any Third Party as of the Effective Date and Hovione believes, in its reasonable judgment, that any such assignment materially impairs Hovione's interests, then Hovione shall have the right to terminate this Agreement by providing [***] months' written notice to Customer (or its assignee or successor).

*** Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

17.3 Performance by Affiliates. The Parties agree that either Party's rights or obligations hereunder may be exercised or performed by one or more of that Party's Affiliates; *provided* that the Party shall remain liable for the performance of any such obligations by any of its Affiliates.

17.4 Independent Contractors. The relationship between Customer and Hovione is that of independent contractors and nothing herein shall be deemed to constitute the relationship of partners, joint ventures, nor of principal and agent between Customer and Hovione. Neither Party shall have an express or implied right or authority to assume or create any obligations on behalf of or in the name of the other Party or to bind the other Party to any contract, agreement or undertaking with any Third Party. All Services will be rendered by Hovione as an independent contractor for federal, state and local income tax purposes and for all other purposes. Hovione will not in any way represent itself to be a partner or joint venturer of or with Customer. This Agreement does not create an employer-employee relationship between Customer on the one hand and Hovione or any employee, subcontractors, Affiliate of Hovione, or any Hovione personnel on the other. Hovione is acting under this Agreement as an independent contractor with full power and authority to determine the means, manner and method of performance of Hovione's duties. Each Party will be responsible for and will withhold and/or pay any and all applicable federal, state or local taxes, payroll taxes, workers' compensation contributions, unemployment insurance contributions, or other payroll deductions from the compensation of such Party's employees and other personnel. Each Party understands and agrees that it is solely responsible for such matters and that it will indemnify the other Party and hold the other Party harmless from all claims and demands in connection with such matters.

17.5 Cooperation with Collaboration Partner. Hovione acknowledges that Customer may have a collaboration partner in conjunction with certain sales of Product. Hovione agrees to cooperate with such partner as required in matters relating to supply for and regulatory compliance, including in jurisdictions outside the United States. Customer shall reimburse Hovione for any actual, out-of-pocket expenses and overhead reasonably incurred by Hovione in connection with such cooperation.

17.6 Severability. If any provision of this Agreement becomes or is declared by a court of competent jurisdiction to be illegal, unenforceable or void, this Agreement will continue in full force and effect without said provision. If any provision of this Agreement is held to be excessively broad, it will be reformed and construed by limiting and reducing it so as to be enforceable to the maximum extent permitted by law. The Parties will use their Commercially Reasonable Efforts to replace the invalid, illegal or unenforceable provision(s) with valid, legal and enforceable provision(s), which, insofar as practical, implement the intent of the Parties.

17.7 Notices. All notices which are required or permitted hereunder will be made in writing and delivered personally, sent by nationally recognized overnight courier or sent by registered or certified mail, postage prepaid, return receipt requested, addressed as follows:

If to Hovione, to:

Hovione, LLC
Attn: [***]
40 Lake Drive
East Windsor, NJ 08520

*** Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

With a copy to:

Hovione, LLC
Attn: [***]
Estrada do Paco do Lumiar, Campus do Lumiar, Edificio R,
1649-038, Lisbon, Portugal

If to Customer, to:

ChemoCentryx, Inc.
Attn: [***]
850 Maude Avenue
Mountain View, CA 94043

With a copy to:

ChemoCentryx, Inc.
Attn: [***]
850 Maude Avenue
Mountain View, CA 94043

or to such other address as the Party to whom notice is to be given may have furnished to the other Party in writing. Any such notice will be deemed to have been given (a) when delivered, if personally delivered on a Business Day, (b) on the Business Day after dispatch, if sent by nationally-recognized overnight courier, or (c) on the third Business Day following the date of mailing, if sent by first class mail.

17.8 Choice of Law. This Agreement will in all events and for all purposes be governed by, and construed in accordance with, the laws of the State of New York, USA without regard to any law, rule, or principle that would result in the application of the law of another jurisdiction. The Parties agree that the provisions of the United Nations Convention on Contracts for the International Sale of Goods will not apply to this Agreement and are hereby expressly excluded.

17.9 Entire Agreement; Amendment. This Agreement constitutes the entire agreement of the Parties with regard to its subject matter, and supersedes all previous or contemporaneous written or oral representations, agreements and understandings between Customer and Hovione; *provided however*, this Agreement shall not supersede the MSA which shall continue according to its terms (and the terms of any work orders entered into thereunder) and shall not be amended or affected in any way by this Agreement. This Agreement, including any Work Plan or any Purchase Orders issued hereunder, may only be changed in writing signed by authorized representatives of both Parties.

17.10 Conflicts. If there is any conflict, discrepancy, or inconsistency between the terms of this Agreement and the Work Plan, or the Quality Agreement, or any Purchase Order or other form used by the Parties, the terms of this Agreement will control.

17.11 Continuing Obligations. Termination, assignment or expiration of this Agreement shall not relieve either Party from full performance of any obligations incurred prior thereto.

*** Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

17.12 Compliance with Anti-Corruption Practices. Each Party represents and warrants that it and its subsidiaries, officers, directors, agents, and subcontractors (collectively "**Affiliates**") are aware of the provisions of the United States Foreign Corrupt Practices Act of 1977, as amended (15 U.S.C. § 78 *et seq.*) ("**FCPA**"). The Parties have not and will not commit any violation of the FCPA and/or any other anti-corruption or anti-bribery laws applicable to Customer or Hovione in any other jurisdiction (the FCPA and such other similar laws, collectively, "**Anti-Corruption Laws**") or any act or omission which could cause the Parties to be in violation of any Anti-Corruption Laws with respect to any activities related to the Agreement. Each Party further represents and warrants that it and its Affiliates will not, directly or indirectly, pay, promise to pay, or authorize the payment or giving of anything of value to any official or employee of any government except in exchange for legitimate services provided. If either Party breaches this Section 17.11, the other Party shall have the right to terminate this Agreement as set forth in Section 10.6.

17.13 Headings; Construction; Interpretation. The Section headings are intended for convenience of reference only and are not intended to be a part of or to affect the meaning or interpretation of this Agreement. Both Parties have participated equally in the formation of this Agreement and the language of this Agreement will not be presumptively construed against either Party.

17.14 Waiver. Any delay in enforcing a Party's rights under this Agreement, or any waiver as to a particular default or other matter, will not constitute a waiver of such Party's rights to the future enforcement of its rights under this Agreement, except with respect to an express written waiver relating to a particular matter for a particular period of time signed by an authorized representative of the waiving Party, as applicable.

17.15 Counterparts; Electronic Delivery. This Agreement may be executed in two (2) or more counterparts, each of which will be deemed an original, but all of which together will constitute one and the same instrument. Signatures to this Agreement transmitted by facsimile, by email in "portable document format" (".pdf"), or by any other electronic means intended to preserve the original graphic and pictorial appearance of this Agreement shall have the same effect as physical delivery of the paper document bearing original signature.

17.16 Further Action. Each Party shall take, or cause to be taken, all actions, and do, or cause to be done, all things reasonably necessary, proper or advisable under Applicable Laws and regulations, and execute and deliver such further documents as may be reasonably requested by the other Party in connection with the operation of this Agreement.

18. Solicitation of Employees.

Except with the other Party's written approval, during the Term, neither Party will actively solicit for employment the other Party's employees who are involved in providing or receiving Services or Deliverables under this Agreement and further, any employees possessing intrinsic technical, analytical or manufacturing know-how. This Section does not preclude: (a) solicitations made by a recruiting firm on behalf of a Party, *provided that* the firm was not instructed to specifically hire employees of the other Party and (b) a Party's employees pro-actively enquiring for (or responding to publicized) job opportunities.

[Signature Page Follows**]**

*** Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their duly authorized representatives, effective as of the Effective Date.

CHEMOCENTRYX, INC.

By: /s/ Thomas Schall

Name: Thomas Schall

Title: President, CEO

Date: 2020-08-26

HOVIONE LLC

By: /s/ Jean-Luc Herbeaux

Name: Jean-Luc Herbeaux

Title: Chief Operations Officer

Date: August 17, 2020

By: /s/ Marco Gil

Name: Marco Gil

Title: Sr. Director Commercial Services

Date: August 17, 2020

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EXHIBIT 1

TO BE REVIEWED/FINALIZED UPON RECEIPT OF DRAFT FOR FIRST WORK PLAN

WORK PLAN [#]

THIS WORK PLAN NO. [#], dated [_____], (the "**Work Plan Date**") is by and between Hovione, having a place of business at [Loures, Portugal] which is an Affiliate of Hovione LLC, ("**Hovione**") and ChemoCentryx, Inc., having a principle place of business 850 Maude Avenue, Mountain View, CA 94043, and its Affiliates ("**COMPANY**"), and upon execution by both Parties, will be incorporated into the Commercial Manufacturing Agreement between COMPANY and Hovione effective as of [DATE] (the "**Agreement**"). Capitalized terms used in this Work Plan will have the meanings ascribed to them in the Agreement.

Hovione will render to COMPANY the following Services: [Work Plans will contain the following as applicable:]

1. Background

2. Scope of Work

3. Description of Services

4. Responsibilities (for commercial, that would include forecasts, firm POs, ordering and maintaining raw materials and qualified vendors, validation of equipment and processes, PAI readiness, replacement of non-conforming batches, etc.)

5. Regulatory Requirements

6. Quality Agreement Level/Requirements

7. Specifications or Other Requirements (also included as Exhibits to Work Plan)

8. Materials (including authorized vendors, who is responsible to buy)

9. Timeline

10. Deliverables (including minimum yield requirements)

11. Shipping/Storage Requirements

12. Pricing Terms (including price increase frequency and caps)

13. Any other terms and conditions not covered in MSA

14. Exhibits to the Work Plan (*e.g.* specifications, synthesis pathways, Quality Agreement)

WORK PLAN AGREED TO AND ACCEPTED BY:

CHEMOCENTRYX, INC.		**HOVIONE LLC**	
By:	_____	By:	_____
Name:	_____	Name:	_____
Title:	_____	Title:	_____
Date:	_____	Date:	_____

EXHIBIT 2

SPECIFICATIONS

[***]

EXHIBIT 3

QUALITY AGREEMENT

EXHIBIT 4

FORM OF CERTIFICATE OF ANALYSIS

See attached.

EXHIBIT 5

PROJECT SPECIFIC RAW MATERIALS

[***]

EXHIBIT 6

STARTING MATERIALS

[***]

EXHIBIT 7

PRICE

[***]

*Price is exclusive of (1) [***], (2) Customer Materials ([***]), and (3) amounts to be reimbursed by Customer pursuant to Sec. 4.2(a).

EXHIBIT 8

MINIMUM ANNUAL COMMITMENT

During the Initial Term:

Years [***] following the first Approval: $[***]

Years [***] following the first Approval: $[***]

COMMERCIALREALESTATESERVICES

Sandy Izumi
General Manager

CBRE, Inc.
Property Management

225 W. Santa Clara Street
Suite 1200
San Jose, CA 95113

408 453 7483 Tel
408 437 3170 Fax
408 472 5104 Cell

sandy.izumi@cbre.com
www.cbre.com

July 1, 2020

ChemoCentryx, Inc.
840-850 Maude Avenue
Mountain View, CA 94043

Re: 840-850 Maude Avenue – Two (2) Month Extension

Dear Tenant:

As per the Third Amendment dated April 5, 2019 by and between CHEMOCENTRYX, INC., a Delaware corporation ("Tenant") and Google LLC, a limited liability company ("Landlord"), Landlord and Tenant are parties to that certain Lease to which Tenant is currently leasing from Landlord, certain space containing approximately 35,755 rental square feet located at 840-850 Maude Avenue, Mountain View, CA which is scheduled to expire on April 30, 2021 provide either party does not trigger their termination option.

Given the current COVID 19 pandemic and existing governmental shelter-in-place mandates, the Landlord acknowledges that a delay in the tenant's relocation plans may have occurred.

In light of these unprecedented circumstances, the parties hereto agree to extend the Lease term for an additional (2) months based on the following terms and conditions:

1. Extension of Lease Term. The Lease Term, which is currently scheduled to expire on April 30, 2021, is hereby extended for a period of two (2) months (the "**Extended Term Commencement Date**") and expiring on June 30, 2021, unless sooner terminated pursuant to the terms of the Lease.

2. Rent; Operating Expense Payments. Prior to and during the Extended Term, Tenant shall continue to pay (i) monthly installments of monthly Base Rent to Landlord for the Premises at the amount applicable during the last rental period of the Lease Term, and (ii) Tenant's Share of Common Area Operating Expenses for the Project, as set forth in, and in accordance with, the Lease. In addition, any and all amounts payable by Tenant to Landlord pursuant to the terms of the Lease, as amended hereby (including Tenant's Share of Common Area Operating Expenses, but excluding monthly Base Rent), are hereinafter collectively referred to as "**Additional Rent**", and monthly Base Rent and Additional Rent are herein collectively referred to as "**Rent**." Without limitation on other obligations of Tenant which survive the expiration of the Lease Term, as extended, the obligations of Tenant to pay Rent for the Extended Term shall survive the expiration of the Lease Term, as extended.

3. Condition of Premises. Tenant is currently in possession of the Premises and shall continue to accept and occupy the Premises and the Building in their current "AS IS" condition as of the Effective Date and the Extended Term Commencement Date without any agreements, representations, understandings or obligations on the part of Landlord to perform or pay for any alterations, repairs or improvements to the Premises, except as otherwise expressly set forth in the Lease, as hereby amended.

4. No Further Modifications. Except as set forth in this Letter, all of the terms and provisions of the Lease are hereby ratified and confirmed and shall remain unmodified and in full force and effect.

Please sign below with your acknowledgement and agreement.
Regards,
CBRE, Inc.

Property Manager for Landlord

Hereby Signed and Acknowledged

TENANT:
ChemoCentryx, Inc.,
a Delaware corporation

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

Authorized Signatory
Thomas Schall President, CEO

July 1, 2020
Date

LANDLORD:
Google LLC
a Delaware limited liability company

/s/ Emilie Snow

Authorized Signatory
Emilie Snow

July 1, 2020
Date

Exhibit 31.1

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, 2020

Exhibit 31.2

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, 2020

Exhibit 32.1

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, 2020, 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, 2020

/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.

Exhibit 32.2

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, 2020, 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, 2020

/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.