

CHEMOCENTRYX, INC.

FORM 8-K (Current report filing)

Filed 05/10/17 for the Period Ending 05/10/17

Address	850 MAUDE AVENUE MOUNTAIN VIEW, CA 94043
Telephone	650-210-2900
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Industry	Pharmaceuticals
Sector	Healthcare
Fiscal Year	12/31

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

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 OR 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): May 10, 2017

CHEMOCENTRYX, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-35420
(Commission
File Number)

94-3254365
(IRS Employer
Identification No.)

850 Maude Avenue,
Mountain View, CA
(Address of Principal Executive Offices)

94043
(Zip Code)

Registrant's telephone number, including area code: (650) 210-2900

(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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.

Item 2.02 Results of Operations and Financial Condition.

On May 10, 2017, ChemoCentryx, Inc. issued a press release announcing its financial results for the first quarter ended March 31, 2017. A copy of this press release is attached hereto as Exhibit 99.1.

In accordance with General Instruction B.2 of Form 8-K, the information in this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, except as expressly set forth by specific reference in such filing to this Current Report on Form 8-K.

Item 9.01 Financial Statements and Exhibits.

(d) *Exhibits* .

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release, dated May 10, 2017

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 hereunto duly authorized.

CHEMOCENTRYX, INC.

Date: May 10, 2017

By: /s/ Susan M. Kanaya

Name: Susan M. Kanaya

Title: Executive Vice President

Chief Financial and Administrative Officer and
Secretary

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release, dated May 10, 2017



ChemoCentryx Reports First Quarter 2017 Financial Results

— Phase III clinical trial of avacopan for the treatment of ANCA Vasculitis underway as *Journal of American Society of Nephrology (JASN)* publishes results of successful Phase II CLEAR clinical trial —

— Received FDA Orphan Drug Designation for avacopan in the treatment of C3 Glomerulopathy (C3G) —

— Conference call today at 5:00 p.m. Eastern Time —

MOUNTAIN VIEW, Calif., May 10, 2017 — ChemoCentryx, Inc., (Nasdaq: CCXI), a biopharmaceutical company developing new medications targeted at inflammatory and autoimmune diseases and cancer, today announced financial results for the first quarter ended March 31, 2017.

“We end the first quarter of 2017 with a strengthened balance sheet thanks to our expanded kidney health alliance with Vifor Pharma and also with our Phase III trial for avacopan in ANCA Vasculitis (AAV) underway,” said Thomas J. Schall, Ph.D., President and Chief Executive Officer of ChemoCentryx. “We are pleased to have received a third orphan drug designation for avacopan from the FDA, adding C3 glomerulopathy to the previous orphan designations for AAV and atypical hemolytic uremic syndrome (aHUS). By the end of this year, we plan to have four late stage clinical trials in rare renal indications in progress, each of which, if successful, may support registration; one for each of avacopan’s three orphan indications, and one for CCX140 in the treatment of focal segmental glomerulosclerosis.”

Recent Highlights

- In April 2017, the *Journal of the American Society of Nephrology (JASN)* published the clinical results from the Company’s Phase II CLEAR trial, which demonstrated that avacopan provides rapid and effective control of AAV while eliminating the need for chronic high doses of steroids, which are associated with significant safety issues. AAV is an autoimmune disease that destroys blood vessels and can lead to renal failure. The ADVOCATE Phase III trial of avacopan in AAV is now underway, a randomized, double-blind two arm multi-center study enrolling 300 patients.
- In March 2017, ChemoCentryx announced that the U.S. Food and Drug Administration (FDA) granted orphan drug designation for avacopan for the treatment of patients with C3 glomerulopathy (C3G), a disease in which deposits of proteins from the body’s complement system disrupt kidney function and trigger a destructive inflammation of the kidney. There is currently no approved treatment for C3G and relapse is common even after kidney transplant. This is the third disease area for which avacopan has been granted U.S. orphan-drug designation, highlighting its potential to help patients with rare renal diseases. The Company is in discussion with the FDA and the European Medicines Agency (EMA) on the design of a clinical trial, which could lead to submission for regulatory approvals.

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- In February 2017, ChemoCentryx announced an expanded agreement with Vifor Pharma that provides Vifor the rights to commercialize avacopan for orphan and rare renal diseases in all international markets except China, while ChemoCentryx retains the rights to commercialize avacopan in the United States. This agreement harmonizes the international rights for avacopan with those in the agreement signed with Vifor in December 2016 for the Company's late stage drug candidate CCX140 in the treatment of focal segmental glomerulosclerosis (FSGS). FSGS is a disease for which no FDA-approved treatment exists, and which if left untreated leads to end stage renal disease. The \$20 million upfront commitment to ChemoCentryx under the latest agreement brings the total of upfront cash payments and commitments from Vifor Pharma to \$155 million, as well as milestone payments and tiered double-digit royalties on potential net sales.

First Quarter 2017 Financial Results

Pro forma cash, cash equivalents, investments and remaining upfront commitments totaled \$179.7 million at March 31, 2017.

Revenue was \$8.2 million for the first quarter, compared to zero for the same period in 2016.

Research and development (R&D) expenses were \$10.0 million for the first quarter, compared to \$11.2 million for the same period in 2016.

General and administrative (G&A) expenses were \$4.6 million for the first quarter, compared to \$4.1 million for the same period in 2016.

Net losses for the first quarter were \$6.0 million, compared to \$15.2 million for the same period in 2016.

Total shares outstanding at March 31, 2017 were approximately 48.2 million shares.

The Company expects to utilize cash and cash equivalents between \$50 million and \$55 million in 2017.

Conference Call and Webcast

The Company will host a conference call and webcast today, May 10, 2017 at 5:00 p.m. Eastern Time / 2:00 p.m. Pacific Time. To participate by telephone, please dial 877-303-8028 (Domestic) or 760-536-5167 (International). The conference ID number is 13584608. A live and archived audio webcast can be accessed through the Investors section of the Company's website at www.ChemoCentryx.com. The archived webcast will remain available on the Company's website for fourteen (14) days following the conference call.

About ChemoCentryx

ChemoCentryx is a biopharmaceutical company developing new medications targeted at inflammatory and autoimmune diseases and cancer. ChemoCentryx targets the chemokine and chemoattractant systems to discover, develop and commercialize orally-administered therapies. ChemoCentryx is currently focusing on its late stage drug candidates for patients with rare kidney diseases, avacopan (CCX168) and CCX140.

Avacopan is an orally-administered small molecule that is a selective inhibitor of the complement C5a receptor, or C5aR. Avacopan is in Phase III development for the treatment of anti-neutrophil cytoplasmic

auto-antibody-associated vasculitis (AAV). In clinical studies to date, avacopan was shown to be safe, well tolerated and provided effective control of the disease while allowing elimination of high-dose steroids, part of the current standard of care. Avacopan is also being developed in patients with C3 glomerulopathy (C3G) and atypical hemolytic uremic syndrome (aHUS). The U.S. Food and Drug Administration has granted avacopan orphan-drug designation for AAV, C3G and aHUS. The European Commission has granted orphan medicinal product designation for avacopan for the treatment of two forms of AAV: microscopic polyangiitis and granulomatosis with polyangiitis (formerly known as Wegener's granulomatosis). Avacopan was also granted access to the European Medicines Agency's (EMA) PRiority MEdicines (PRIME) initiative, which supports accelerated assessment of investigational therapies addressing unmet medical need.

The Company's other late stage drug candidate is CCX140, an inhibitor of the chemokine receptor known as CCR2, which is currently being developed for patients with focal segmental glomerulosclerosis (FSGS), a debilitating kidney disease.

ChemoCentryx's Kidney Health Alliance with Vifor Pharma provides Vifor Pharma with exclusive rights to commercialize avacopan and CCX140 in markets outside of the U.S. and China.

ChemoCentryx also has early stage drug candidates that target chemoattractant receptors in other Inflammatory and autoimmune diseases and in cancer.

Forward-Looking Statements

ChemoCentryx cautions that statements included in this press release that are not a description of historical facts are forward-looking statements. Words such as "may," "could," "will," "would," "should," "expect," "plan," "anticipate," "believe," "estimate," "intend," "predict," "seek," "contemplate," "potential," "continue" or "project" or the negative of these terms or other comparable terminology are intended to identify forward-looking statements. These statements include the Company's statements regarding the achievement of anticipated goals and milestones, the timing of potential clinical trials and regulatory submissions, whether the Company's alliance with Vifor Pharma will provide milestone payments and royalties on international sales, the company's expectations regarding its utilization of cash and cash equivalents and whether the Company's drug candidates will be shown to be effective in ongoing or future clinical trials. The inclusion of forward-looking statements should not be regarded as a representation by ChemoCentryx that any of its plans will be achieved. Actual results may differ from those set forth in this release due to the risks and uncertainties inherent in the ChemoCentryx business and other risks described in the Company's filings with the Securities and Exchange Commission ("SEC"). Investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof, and ChemoCentryx undertakes no obligation to revise or update this news release to reflect events or circumstances after the date hereof. Further information regarding these and other risks is included under the heading "Risk Factors" in ChemoCentryx's periodic reports filed with the SEC, including ChemoCentryx's Annual Report on Form 10-K filed with the SEC on March 14, 2017 and its other reports which are available from the SEC's website (www.sec.gov) and on ChemoCentryx's website (www.chemocentryx.com) under the heading "Investors." All forward-looking statements are qualified in their entirety by this cautionary statement. This caution is made under the safe harbor provisions of Section 21E of the Private Securities Litigation Reform Act of 1995.

Source: ChemoCentryx, Inc.

CCXI-G

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ChemoCentryx, Inc.
Consolidated Statement of Operations Data
(in thousands, except per share data)

	Three Months Ended	
	March 31,	
	2017	2016
Consolidated Statement of Operations Data:		
Revenue:		
Collaboration and license revenue	\$ 8,230	\$ —
Total revenue	8,230	—
Operating expenses:		
Research and development	9,970	11,245
General and administrative	4,573	4,084
Total operating expenses	14,543	15,329
Loss from operations	(6,313)	(15,329)
Interest income	317	86
Net loss	<u>\$ (5,996)</u>	<u>\$ (15,243)</u>
Basic and diluted net loss per share	<u>\$ (0.12)</u>	<u>\$ (0.34)</u>
Shares used to compute basic and diluted net loss per share	<u>48,115</u>	<u>44,277</u>

	March 31,	December 31,
	2017	2016
(in thousands)		
Consolidated Balance Sheet Data		
Cash, cash equivalents and investments (1)	\$ 149,650	\$ 123,761
Accounts receivable (1)	—	30,205
Working capital	77,354	110,356
Total assets	152,371	155,872
Accumulated deficit	(313,055)	(307,059)
Total stockholders' equity	46,322	49,889

(1) Cash, cash equivalents and investments and accounts receivable exclude the remaining \$30 million cash commitments due from Vifor Pharma, \$20 million of which is due in December 2017 and \$10 million due in February 2018, in connection with the CCX140 Agreement and Avacopan Amendment, respectively.