

CHEMOCENTRYX, INC.

FORM 8-K (Current report filing)

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Address	850 MAUDE AVENUE MOUNTAIN VIEW, CA 94043
Telephone	650-210-2900
CIK	0001340652
Symbol	CCXI
SIC Code	2834 - Pharmaceutical Preparations
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): March 14, 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))
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Item 2.02 Results of Operations and Financial Condition.

On March 14, 2017, ChemoCentryx, Inc. issued a press release announcing its financial results for the fourth quarter and year ended December 31, 2016. 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 March 14, 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: March 14, 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 March 14, 2017



ChemoCentryx Reports Fourth Quarter and Full Year 2016 Financial Results

— Expanded Vifor Pharma partnership now totals \$155 million in upfront cash commitments, \$1.2 billion in potential milestone payments, plus substantial royalties on potential net sales —

— Initiated Phase III clinical trial of Avacopan for the treatment of ANCA Vasculitis —

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

MOUNTAIN VIEW, Calif., March 14, 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 fourth quarter and full year ended December 31, 2016.

“2016 was a transformative year for ChemoCentryx,” said Thomas J. Schall, Ph.D., President and Chief Executive Officer of ChemoCentryx. “We are now entering the next step in our evolution, driving the registration trials of our novel drug candidates and preparing for their commercialization. We have established a strong financial position through our partnership with Vifor Pharma and are now well positioned to execute on our plan to create value for patients and shareholders, starting with kidney disease.”

Recent Highlights

- In December 2016, ChemoCentryx launched the Phase III ADVOCATE trial with avacopan for the treatment of ANCA-associated Vasculitis (AAV), a devastating autoimmune disease that destroys blood vessels and can lead to kidney failure. The design of the trial was agreed upon with the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA). ADVOCATE is a randomized, double-blind two arm study enrolling 300 patients across 200 sites in the United States and Europe.
- In December 2016, ChemoCentryx and Vifor Pharma announced an expansion of their global kidney health alliance to include CCX140. Together with the avacopan deal announced in May 2016, the partnership with Vifor Pharma brought a total of \$135 million in upfront cash commitments to ChemoCentryx in 2016, with the prospect of a further \$1.2 billion in potential milestone payments.
- In February 2017, ChemoCentryx and Vifor Pharma announced that they had harmonized the geographic commercialization rights for both drug candidates, with a further \$20 million upfront commitment to ChemoCentryx.
 - ChemoCentryx retains the rights to commercialize avacopan and CCX140 for orphan and rare renal diseases in the United States and China, and will receive tiered double digit royalties on Vifor Pharma’s net sales in other markets.

Fourth Quarter and Full Year 2016 Financial Results

Pro forma cash, cash equivalents and investments totaled \$194 million at December 31, 2016, which included the \$50.0 million upfront commitment in connection with the December 2016 CCX140 agreement and the \$20.0 million upfront commitment related to the February 2017 amendment to the avacopan agreement.

Revenue was \$4.9 million for the fourth quarter, compared to zero for the same period in 2015. For the full year ended December 31, 2016, revenue was \$11.9 million, compared to zero for 2015. The increase in revenue from 2015 to 2016 was due to: (i) amortization of the upfront payment from Vifor Pharma pursuant to the avacopan agreement and (ii) grant revenue from the FDA to support the clinical development of avacopan for the treatment of patients with AAV.

Research and development (R&D) expenses were \$9.3 million for the fourth quarter, compared to \$8.2 million for the same period in 2015. Full year 2016 R&D expenses were \$38.0 million compared to \$33.2 million in 2015. The increase in R&D expenses from 2015 to 2016 was primarily attributable to higher expenses associated with avacopan for start-up activities and ancillary studies related to the Phase III development program in patients with AAV. This increase was partially offset by lower expenses associated with Phase II development of avacopan, due to the completion of the CLEAR and CLASSIC Phase II clinical trials in 2016.

General and administrative (G&A) expenses were \$3.6 million for the fourth quarter, compared to \$3.4 million for the same period in 2015. Full year 2016 G&A expenses were \$14.7 million, compared to \$14.5 million in 2015. The increase from 2015 to 2016 was primarily due to higher professional service fees relating to the Company's business development efforts.

Net losses for the fourth quarter were \$7.7 million, compared to \$11.6 million for the same period in 2015. Full year 2016 net losses, at \$40.0 million, were also lower than the \$47.3 million net losses in 2015.

Total shares outstanding at December 31, 2016 were approximately 48.1 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, March 14, 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 80376833. 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 now granted avacopan orphan-drug designation for AAV 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, whether the Company's alliance with Vifor Pharma will provide milestone payments and royalties on international sales 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)

	<u>Three Months Ended</u>		<u>Twelve Months Ended</u>	
	<u>December 31,</u>		<u>December 31,</u>	
	<u>2016</u>	<u>2015</u>	<u>2016</u>	<u>2015</u>
Consolidated Statement of Operations Data:				
Revenue:				
Collaboration and license revenue	\$ 4,684	\$ —	\$ 11,435	\$ —
Grant revenue	205	—	500	—
Total revenue	4,889	—	11,935	—
Operating expenses:				
Research and development	9,249	8,230	37,945	33,183
General and administrative	3,556	3,430	14,710	14,506
Total operating expenses	12,805	11,660	52,655	47,689
Loss from operations	(7,916)	(11,660)	(40,720)	(47,689)
Interest income	251	86	757	384
Net loss	<u>\$ (7,665)</u>	<u>\$ (11,574)</u>	<u>\$ (39,963)</u>	<u>\$ (47,305)</u>
Basic and diluted net loss per share	<u>\$ (0.16)</u>	<u>\$ (0.26)</u>	<u>\$ (0.86)</u>	<u>\$ (1.08)</u>
Shares used to compute basic and diluted net loss per share	<u>47,900</u>	<u>44,145</u>	<u>46,432</u>	<u>43,890</u>

	<u>December 31,</u>	
	<u>2016</u>	<u>2015</u>
	<u>(in thousands)</u>	
Consolidated Balance Sheet Data		
Cash, cash equivalents and investments	\$ 123,761	\$ 76,289
Accounts receivable (1)	30,205	—
Working capital	110,356	66,541
Total assets	155,872	78,155
Accumulated deficit	(307,059)	(267,096)
Total stockholders' equity	49,889	72,507

- (1) Accounts receivable excludes the additional \$20 million cash commitment due from Vifor in December 2017 in connection with the CCX140 Agreement as well as the \$20 million cash commitment from Vifor in connection with the February 2017 Avacopan territory expansion agreement.