CHEMOCENTRYX, INC.

FORM 8-K
(Current report filing)

Filed 11/07/17 for the Period Ending 11/07/17

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): November 7, 2017

CHEMOCENTRYX, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-35420**	**94-3254365**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

850 Maude Avenue, Mountain View, CA	**94043**
(Address of Principal Executive Offices)	**(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))

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 November 7, 2017, ChemoCentryx, Inc. issued a press release announcing its financial results for the third quarter ended September 30, 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* .

Exhibit No.	Description
99.1	Press Release, dated November 7, 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: November 7, 2017

By: /s/ Susan M. Kanaya
Name: Susan M. Kanaya
Title: Executive Vice President
Chief Financial and Administrative Officer and Secretary

Exhibit 99.1

ChemoCentryx Reports Third Quarter 2017 Financial Results and Recent Highlights

— Phase III ADVOCATE trial of avacopan remains on track to complete enrollment in mid-2018 —

— Patient enrollment ongoing in registration-supporting trial for avacopan in the treatment C3 Glomerulopathy (C3G) —

— Plan to launch registration-supporting trial for CCX140 in the treatment of Focal Segmental Glomerulosclerosis (FSGS) in the fourth quarter 2017 —

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

MOUNTAIN VIEW, Calif., November 7, 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 third quarter ended September 30, 2017.

"Our pursuit of new and better medicines for people with orphan diseases has been relentless," said Thomas J. Schall, Ph.D., President and Chief Executive Officer of ChemoCentryx. "Dedicated to creating value for patients and shareholder alike, we at CCXI started with basic science in the discovery of novel molecules that selectively inhibit chemoattractant receptors, which are the molecular guidance systems of destructive inflammatory cells involved in a wide range of diseases and conditions. Now we have advanced two of those novel molecules, avacopan and CCX140, well into late stage clinical trials. In doing so, we move closer to the next phase of value creation – the potential commercialization of our targeted medicines to help those suffering from serious renal diseases."

Recent Highlights

- ChemoCentryx's Phase III ADVOCATE trial of avacopan for the treatment of ANCA-associated vasculitis has surpassed 30 percent of its target patient enrollment with more than 185 sites activated. The trial will test the safety and efficacy of avacopan following 12 months of treatment and will include approximately 300 patients. In addition to testing the effect of avacopan on improving active vasculitis, the ADVOCATE trial will also test the effect of avacopan on preventing a recurrence of vasculitis.
- ChemoCentryx recently received orphan designation in Switzerland from SwissMedic for avacopan for the treatment of two forms of ANCA-vasculitis: microscopic polyangiitis and granulomatosis with polyangiitis (formerly known as Wegener's granulomatosis). This designation is in addition to the previously received orphan designations from the U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA) for avacopan to treat ANCA-vasculitis.

- ChemoCentryx recently launched a registration-supporting clinical trial to study avacopan in a second indication, C3 Glomerulopathy (C3G), a rare disorder that often affects the young, requiring dialysis and often kidney transplant. Sites have been activated for the trial and patient enrollment has begun. Earlier this year ChemoCentryx announced that it had received both EMA orphan medicinal product designation and FDA orphan drug designation for avacopan in the treatment of C3G.
- ChemoCentryx is launching a third registration-supporting trial, involving its CCR2 inhibitor, CCX140, to treat the debilitating kidney disorder known as Focal Segmental Glomerulosclerosis (FSGS), for which there is no approved treatment option. The Company plans to launch a trial in the fourth quarter of 2017.

Third Quarter 2017 Financial Results

Pro forma cash, cash equivalents, investments and remaining upfront commitments totaled $154.8 million at September 30, 2017.

Revenue was $9.0 million for the third quarter, compared to $4.1 million for the same period in 2016. The increase in revenue from 2016 to 2017 were due to: (i) amortization of the upfront license fee commitments from Vifor pursuant to the avacopan and CCX140 agreements; as well as (ii) collaboration revenue for development services under the CCX140 Agreement in 2017. These increases were partially offset by lower grant revenue from the FDA to support the clinical development of avacopan for the treatment of patients with ANCA vasculitis.

Research and development expenses were $12.3 million for the third quarter, compared to $8.4 million for the same period in 2016. The increase in research and development expenses from 2016 to 2017 was primarily attributable to the initiation and patient enrollment of the avacopan Phase III ADVOCATE trial in patients with ANCA vasculitis and start-up expenses for the Phase II clinical trial of avacopan for the treatment of C3G. These increases were partially offset by lower costs associated with the completion of the avacopan CLEAR and CLASSIC Phase II clinical trials for the treatment of ANCA vasculitis and enrollment completion of the CCX872 Phase I trial in patients with advanced pancreatic cancer in 2016.

General and administrative expenses were $3.6 million for the third quarter, compared to $3.2 million for the same period in 2016. The increase from 2016 to 2017 was primarily due to accounting related fees associated with preparing to meet the requirements pursuant to the Sarbanes-Oxley Act of 2002.

Net losses for the third quarter were $6.6 million, compared to $7.1 million for the same period in 2016.

Total shares outstanding at September 30, 2017 were approximately 48.8 million shares.

The Company expects to utilize cash and cash equivalents in the range of $50 million and $55 million in 2017, of which $39.0 million has been used for the nine months ended September 30, 2017.

Conference Call and Webcast

The Company will host a conference call and webcast today, November 7, 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 7796287. 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), as well as for C3G. 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 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

Contacts:

Susan M. Kanaya
Executive Vice President,
Chief Financial and Administrative Officer
investor@chemocentryx.com

Media:
Stephanie Tomei
408.234.1279
media@chemocentryx.com

Investors:
Steve Klass, Burns McClellan
212.213.0006
sklass@burnsmc.com

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Consolidated Statement of Operations Data:				
Revenue:				
Collaboration and license revenue	$ 9,029	$ 4,131	$ 26,196	$ 6,751
Grant revenue	—	120	—	295
Total revenue	9,029	4,251	26,196	7,046
Operating expenses:				
Research and development	12,315	8,389	36,614	28,696
General and administrative	3,624	3,193	12,381	11,154
Total operating expenses	15,939	11,582	48,995	39,850
Loss from operations	(6,910)	(7,331)	(22,799)	(32,804)
Interest income	350	259	1,003	506
Net loss	$ (6,560)	$ (7,072)	$ (21,796)	$ (32,298)
Basic and diluted net loss per share	$ (0.13)	$ (0.15)	$ (0.45)	$ (0.70)
Shares used to compute basic and diluted net loss per share	48,602	47,763	48,314	45,942

	September 30, 2017	December 31, 2016
	(in thousands)	
Consolidated Balance Sheet Data		
Cash, cash equivalents and investments (1)	$ 124,768	$ 123,761
Accounts receivable (1)	530	30,205
Working capital	77,983	110,356
Total assets	127,948	155,872
Accumulated deficit	(328,855)	(307,059)
Total stockholders' equity	37,297	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.