CHEMOCENTRYX, INC.

FORM 8-K
(Current report filing)

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Address	850 MAUDE AVENUE MOUNTAIN VIEW, CA 94043
Telephone	650-210-2900
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Industry	Pharmaceuticals
Sector	Healthcare
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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): August 8, 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))

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 August 8, 2017, ChemoCentryx, Inc. issued a press release announcing its financial results for the second quarter ended June 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 August 8, 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: August 8, 2017

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

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release, dated August 8, 2017

Exhibit 99.1

ChemoCentryx Reports Second Quarter 2017 Financial Results and Recent Highlights

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

— Launching second trial of avacopan in patients with C3 Glomerulopathy (C3G) —

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

MOUNTAIN VIEW, Calif., August 8, 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 second quarter ended June 30, 2017.

"We've had a highly productive second quarter, activating many new sites in our avacopan Phase III ADVOCATE trial, which is producing a multiplier effect on patient enrollment," said Thomas J. Schall, Ph.D., President and Chief Executive Officer of ChemoCentryx. "Now we are launching a clinical trial for avacopan in a second indication, C3G, executing on our 'pipeline in a drug' strategy. We are also working with regulatory authorities on the design of a third trial, involving our CCR2 inhibitor, CCX140, intended to support registration in patients with Focal Segmental Glomerulosclerosis (FSGS)."

Recent Highlights

- ChemoCentryx's Phase III ADVOCATE trial of avacopan (formerly CCX168) for the treatment of ANCA-associated vasculitis is gaining momentum, with 143 sites activated in 18 countries across the world. The trial will test the safety and efficacy of avacopan following 12 months of treatment and will include approximately 300 patients. Enrollment rates per activated sites are exceeding projections, and the trial is on track to complete enrollment by mid 2018. 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, one of the major limitations of the current standard of care for this disease.
- In May 2017, ChemoCentryx announced that the European Medicines Agency granted orphan medicinal product designation for avacopan in the treatment of patients with C3G, which followed shortly after orphan drug designation was granted for avacopan in the treatment of C3G by the U.S. Food and Drug Administration. The Company is launching a registration-supporting trial of avacopan in C3G patients. There is currently no approved therapy for C3G.
- In June 2017, ChemoCentryx announced program advances in two oral presentations that were given during the 54th European Renal Association—European Dialysis and Transplant Association (ERA-EDTA) Congress in Madrid, which highlighted an additional potential clinical indication for avacopan and the potential for CCR2 inhibition in FSGS. The Company plans to launch a registration-supporting trial of CCR2 inhibitor CCX140 in patients with FSGS later this year.

Second Quarter 2017 Financial Results

Pro forma cash, cash equivalents, investments and remaining upfront commitments totaled $166.7 million at June 30, 2017.

Revenue was $8.9 million for the second quarter, compared to $2.8 million for the same period in 2016. The increase in revenues from 2016 to 2017 was 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.

Research and development expenses were $14.3 million for the second quarter, compared to $9.1 million for the same period in 2016. The increase in research and development expenses from 2016 to 2017 was primarily attributable to higher Phase III development expenses due to the initiation of the avacopan Phase III ADVOCATE trial in patients with AAV in the fourth quarter of 2016 and start-up expenses related to the Phase II clinical trial of avacopan for the treatment of C3G. These increases were partially offset by decreases in (i) Phase I clinical development expense due to the completion of enrollment in the Phase I clinical trial for CCX872 in patients with advanced pancreatic cancer in 2016 and (ii) Phase II development expense due to the completion of the avacopan CLEAR and CLASSIC Phase II clinical trials for the treatment of AAV in 2016.

General and administrative expenses were $4.2 million for the second quarter, compared to $3.9 million for the same period in 2016. The increase from 2016 to 2017 was primarily due to higher intellectual property related expenses and accounting related fees associated with preparing to meet the requirements pursuant to the Sarbanes-Oxley Act of 2002.

Net losses for the second quarter were $9.2 million, compared to $10.0 million for the same period in 2016.

Total shares outstanding at June 30, 2017 were approximately 48.6 million shares.

The Company expects to utilize cash and cash equivalents in the range of $50 million and $55 million in 2017.

Conference Call and Webcast

The Company will host a conference call and webcast today, August 8, 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 58685442. 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 Medicines Agency (EMA) 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 EMA's 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 timing of potential clinical trials, anticipated enrollment in clinical trials, whether the next clinical studies with avacopan in C3G and with CCX140 in FSGS will serve as registration-supporting trials, 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 June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Consolidated Statement of Operations Data:				
Revenue:				
Collaboration and license revenue	$ 8,937	$ 2,620	$ 17,167	$ 2,620
Grant revenue	—	175	—	175
Total revenue	8,937	2,795	17,167	2,795
Operating expenses:				
Research and development	14,329	9,062	24,299	20,307
General and administrative	4,184	3,877	8,757	7,961
Total operating expenses	18,513	12,939	33,056	28,268
Loss from operations	(9,576)	(10,144)	(15,889)	(25,473)
Interest income	336	161	653	247
Net loss	$ (9,240)	$ (9,983)	$ (15,236)	$ (25,226)
Basic and diluted net loss per share	$ (0.19)	$ (0.22)	$ (0.32)	$ (0.56)
Shares used to compute basic and diluted net loss per share	48,224	45,785	48,169	45,031

	June 30, 2017	December 31, 2016
	(in thousands)	
Consolidated Balance Sheet Data		
Cash, cash equivalents and investments (1)	$ 136,644	$ 123,761
Accounts receivable (1)	218	30,205
Working capital	79,476	110,356
Total assets	140,527	155,872
Accumulated deficit	(322,295)	(307,059)
Total stockholders' equity	40,915	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.