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): July 6, 2021

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.)**

835 Industrial Road, San Carlos, CA	**94070**
(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))

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 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 1034 (§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 7.01 Regulation FD Disclosure

On July 6, 2021, ChemoCentryx, Inc. (the "Company") announced the filing of an amendment to the New Drug Application ("NDA") for avacopan for the treatment of Antineutrophil Cytoplasmic Autoantibody (ANCA)-associated vasculitis (or AAV). The U.S. Food and Drug Administration (FDA) has indicated that such filing constitutes a major amendment to the NDA which will result in the extension of the PDUFA goal date to October 7, 2021. The press release, dated July 6, 2021, is attached hereto as Exhibit 99.1.

The information contained in this Item 7.01 and in Exhibit 99.1 of this Current Report on Form 8-K shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or incorporated by reference in any filing under the Securities Act of 1933, as amended (the "Securities Act"), or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 8.01 Other Events

On July 6, 2021, ChemoCentryx, Inc. (the "Company") announced the filing of an amendment to the New Drug Application ("NDA") for avacopan for the treatment of Antineutrophil Cytoplasmic Autoantibody (ANCA)-associated vasculitis (or AAV). The U.S. Food and Drug Administration (FDA) has indicated that such filing constitutes a major amendment to the NDA which will result in the extension of the PDUFA goal date to October 7, 2021. The press release, dated July 6, 2021, is attached hereto as Exhibit 99.1.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

99.1	Press release, dated July 6, 2021.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

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: July 6, 2021

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

ChemoCentryx Announces Filing of Amendment to NDA Submission and Extension of the PDUFA Review Period for Avacopan in the Treatment of ANCA-Associated Vasculitis

SAN CARLOS, Calif., July 6, 2021 — ChemoCentryx, Inc., (Nasdaq: CCXI), today announced that, following consultations with the U.S. Food and Drug Administration (FDA), it filed an amendment to its New Drug Application (NDA) for avacopan for the treatment of Anti-neutrophil Cytoplasmic Autoantibody (ANCA)-associated vasculitis, addressing points raised during the FDA Advisory Committee meeting on May 6, 2021. The FDA has indicated that the filing constitutes a major amendment to the NDA and will result in the setting of a new PDUFA goal date of October 7, 2021. The NDA is primarily based on data from the Phase III ADVOCATE trial of avacopan for the treatment of ANCA-associated vasculitis. On May 6, the FDA's Arthritis Advisory Committee voted 9-9 on whether the efficacy data support approval of avacopan, 10-8 that the safety profile of avacopan is adequate to support approval, and 10-8 that the benefit-risk profile is adequate to support approval of avacopan at the proposed dose of 30 mg twice daily.

"We appreciate the opportunity to put additional data and information before the Agency, information which we believe addresses many of the issues raised at the Advisory Committee meeting," said Thomas J. Schall, Ph.D., President and Chief Executive Officer of ChemoCentryx. "We look forward to continuing discussions with the Agency."

The Marketing Authorization Application (MAA) for avacopan in the treatment of ANCA-associated vasculitis was validated by the European Medicines Agency (EMA) in November 2020, and the Japanese New Drug Application was accepted for review by the Japanese Pharmaceuticals and Medical Device Agency in February 2021.

About ADVOCATE and ANCA-Associated Vasculitis

The ADVOCATE trial of avacopan was a global, randomized, double-blind, active-controlled, double-dummy Phase III trial of 331 patients with ANCA-associated vasculitis in 20 countries. Eligible study subjects were randomized to receive avacopan plus either rituximab or cyclophosphamide (followed by azathioprine/mycophenolate) or study-supplied oral prednisone plus either rituximab or cyclophosphamide (followed by azathioprine/mycophenolate). Subjects in both treatment groups could also receive non-protocol glucocorticoids if needed.

ANCA-associated vasculitis is a systemic disease in which over-activation of the complement pathway further activates neutrophils, leading to inflammation and destruction of small blood vessels. This results in organ damage and failure, with the kidney as the major target, and is fatal if not treated. Currently, treatment for ANCA-associated vasculitis consists of courses of non-specific immuno-suppressants (cyclophosphamide or rituximab), combined with the administration of daily glucocorticoids (steroids) for prolonged periods of time, which can be associated with significant clinical risk including death from infection.

About Avacopan

Avacopan is a first-in-class, orally-administered small molecule that employs a novel, highly targeted mode of action in the treatment of ANCA-associated vasculitis and other complement-driven autoimmune and inflammatory diseases. By precisely blocking the receptor (the C5aR) for the pro-inflammatory complement system fragment known as C5a on destructive inflammatory cells such as blood neutrophils, avacopan arrests the ability of those cells to do damage in response to C5a activation, which is known to be the driver of ANCA-associated vasculitis. Current therapies for ANCA-associated vasculitis and other related illnesses typically include broad immunosuppression with daily doses of glucocorticoids (steroids) such as prednisone or methylprednisone, which can cause significant illness and even death. Avacopan's selective inhibition of only the C5aR leaves the beneficial C5a pathway through the C5L2 receptor functioning normally.

ChemoCentryx is also developing avacopan for the treatment of patients with C3 glomerulopathy (C3G) and hidradenitis suppurativa (HS). The U.S. Food and Drug Administration has granted avacopan orphan drug designation for ANCA-associated vasculitis and C3G. The European Commission has granted orphan medicinal product designation for avacopan for the treatment of two forms of ANCA-associated vasculitis: microscopic polyangiitis and granulomatosis with polyangiitis (formerly known as Wegener's granulomatosis), as well as for C3G.

ChemoCentryx is responsible for the discovery and development of avacopan and owns and retains the commercial rights to the drug in the United States. ChemoCentryx's Kidney Health Alliance with Vifor Pharma provides Vifor Pharma with exclusive rights to commercialize avacopan in markets outside of the U.S.

About ChemoCentryx

ChemoCentryx is a biopharmaceutical company developing new medications for inflammatory and autoimmune diseases and cancer. ChemoCentryx targets the chemokine and chemoattractant systems to discover, develop and commercialize orally-administered therapies. ChemoCentryx's lead drug candidate, avacopan (CCX168), successfully completed a pivotal Phase III trial in ANCA-associated vasculitis and is in late stage clinical development for the treatment of severe Hidradenitis Suppurativa and C3 glomerulopathy (C3G).

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 anticipated PDUFA date for the avacopan NDA for the treatment of ANCA-associated vasculitis, the achievement of anticipated goals and milestones, whether avacopan will be approved by the FDA for the treatment of ANCA-associated vasculitis, 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 1, 2021 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.

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