# 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)

October 20, 2022

## Amgen Inc.

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation) 001-37702 (Commission File Number) 95-3540776 (IRS Employer Identification No.)

One Amgen Center Drive Thousand Oaks California 91320

(Address of principal executive offices, including zip code)

(805) 447-1000

(Registrant's telephone number, including area code)

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:

□ 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:

	Trading	Name of each exchange
Title of each class	Symbol(s)	on which registered
Common stock, \$0.0001 par value	AMGN	The Nasdaq Stock Market LLC
2.000% Senior Notes due 2026	AMGN26	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 1934 (§240.12b-2 of this chapter). Emerging growth company  $\Box$ 

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.  $\Box$ 

#### Item 7.01. Regulation FD Disclosure.

On October 20, 2022, Amgen Inc. issued a press release announcing the completion of its previously announced acquisition of ChemoCentryx, Inc. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated into this Item 7.01 by reference.

The information contained in this Item 7.01 and Exhibit 99.1 shall not be deemed to be "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act"), or otherwise subject to the liabilities of such section, nor will such information be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as may be expressly set forth by specific reference in such filing.

#### Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.

**Description of Exhibit** 

99.1 Press Release, dated as of October 20, 2022

104 Cover Page Interactive Data File (embedded within the Inline XBRL document)

#### SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

AMGEN INC.

By: <u>/s/ Jonathan P. Graham</u>

Name: Jonathan P. Graham Title: Executive Vice President, General Counsel and Secretary

Date: October 20, 2022



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## AMGEN SUCCESSFULLY COMPLETES ACQUISITION OF CHEMOCENTRYX

### TAVNEOS<sup>®</sup> (avacopan), a First-in-Class Medicine for Patients With Severe Active ANCA-Associated Vasculitis, Added to Inflammation Portfolio

THOUSAND OAKS, Calif., (Oct. 20, 2022) - Amgen (NASDAQ: AMGN) today announced that it has successfully completed its previously announced acquisition of ChemoCentryx, Inc. (NASDAQ: CCXI), a biopharmaceutical company focused on orally administered therapeutics to treat autoimmune diseases, inflammatory disorders and cancer, for \$52 per share in cash, representing aggregate merger consideration of approximately \$3.7 billion.

"ChemoCentryx enhances Amgen's leading inflammation and nephrology portfolio and includes TAVNEOS® (avacopan), a first-in-class treatment for severe active anti-neutrophil cytoplasmic autoantibody-associated vasculitis (ANCA-associated vasculitis), an autoimmune disease for which there remains significant unmet medical need," said Robert A. Bradway, chairman and chief executive officer at Amgen. "We look forward to welcoming the dedicated professionals from ChemoCentryx who share our passion for advancing innovation that makes a difference for patients. Together, we aim to serve more patients affected by serious diseases."

The acquisition includes TAVNEOS<sup>®</sup>, an orally administered selective complement 5a receptor inhibitor that was approved by the U.S. Food and Drug Administration (FDA) in October 2021 as an adjunctive therapy for adults with severe active ANCAassociated vasculitis in addition to standard of care, which generally consists of glucocorticoids and either rituximab or cyclophosphamide immunosuppressant therapy. Beyond its approved ANCA-associated vasculitis indication, TAVNEOS® is also being studied in additional inflammatory diseases, including hidradenitis suppurativa (HS), a severe and deforming chronic dermatological condition, and complement 3 glomerulopathy (C3G), a rare genetic kidney disease.

In addition to TAVNEOS®, the acquisition adds three early-stage drug candidates that target chemoattractant receptors and other inflammatory diseases and an oral checkpoint for cancer.

#### About Amgen

Amgen is committed to unlocking the potential of biology for patients suffering from serious illnesses by discovering, developing, manufacturing and delivering innovative human therapeutics. This approach begins by using tools like advanced human genetics to unravel the complexities of disease and understand the fundamentals of human biology.

Amgen focuses on areas of high unmet medical need and leverages its expertise to strive for solutions that improve health outcomes and dramatically improve people's lives. A biotechnology pioneer since 1980, Amgen has grown to be one of the world's leading independent biotechnology companies, has reached millions of patients around the world and is developing a pipeline of medicines with breakaway potential.

Amgen is one of the 30 companies that comprise the Dow Jones Industrial Average and is also part of the Nasdaq-100 index. In 2021, Amgen was named one of the 25 World's Best Workplaces<sup>™</sup> by Fortune and Great Place to Work<sup>™</sup> and one of the 100 most sustainable companies in the world by Barron's.

For more information, visit www.amgen.com and follow us on www.twitter.com/amgen.

#### About ChemoCentryx

ChemoCentryx is a biopharmaceutical company commercializing and 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. In the United States, ChemoCentryx markets TAVNEOS® (avacopan), the first approved orally administered inhibitor of the complement 5a receptor as an adjunctive treatment for adult patients with severe active ANCA-associated vasculitis. TAVNEOS is also in late-stage clinical development for the treatment of severe hidradenitis suppurativa and C3 glomerulopathy (C3G). Additionally, ChemoCentryx has early-stage drug candidates that target chemoattractant receptors in other inflammatory and autoimmune diseases and in cancer. For more information about ChemoCentryx visit www.chemocentryx.com.

#### About TAVNEOS® (avacopan)

TAVNEOS (avacopan), approved by the FDA as an adjunctive treatment of ANCA-associated vasculitis, is a first-in-class, orally administered small molecule that employs a novel, highly targeted mode of action in complement-driven autoimmune and inflammatory diseases. While the precise mechanism in ANCA vasculitis has not been definitively established, TAVNEOS, by blocking the complement 5a receptor (C5aR) for the pro-inflammatory complement system fragment known as C5a on destructive inflammatory cells such as blood neutrophils, is presumed to arrest the ability of those cells to do damage in response to C5a activation, which is known to be the driver of ANCA vasculitis. TAVNEOS's selective inhibition of only the C5aR leaves the beneficial C5a pathway through the C5L2 receptor functioning normally.

ChemoCentryx is also developing TAVNEOS for the treatment of patients with C3 glomerulopathy (C3G), severe hidradenitis suppurativa (HS) and lupus nephritis (LN). The U.S. Food and Drug Administration granted TAVNEOS orphan drug designation for ANCA-associated vasculitis and C3G. The European Commission has granted orphan medicinal product designation for TAVNEOS 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.

### About ANCA-Associated Vasculitis

ANCA-associated vasculitis is an umbrella term for a group of multi-system autoimmune diseases with small vessel inflammation. Inflamed vessels may rupture or become occluded giving rise to a broad array of clinical symptoms and signs related to a systemic inflammatory response which may result in profound injury and dysfunction in the kidneys, lungs and other organs. Prior to the approval of TAVNEOS, treatment for ANCA-associated vasculitis was limited to 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.

#### **U.S. PRESCRIBING INFORMATION**

TAVNEOS (avacopan) is indicated as an adjunctive treatment of adult patients with severe active anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis (granulomatosis with polyangiitis [GPA] and microscopic polyangiitis [MPA]) in combination with standard therapy including glucocorticoids. TAVNEOS does not eliminate glucocorticoid use.

#### IMPORTANT SAFETY INFORMATION

Contraindications

Serious hypersensitivity to avacopan or to any of the excipients

#### Warning and Precautions

Hepatotoxicity: Serious cases of hepatic injury have been observed in patients taking TAVNEOS, including life-threatening events. Obtain liver test panel before initiating TAVNEOS, every 4 weeks after start of therapy for six months and as clinically indicated thereafter. Monitor patients closely for hepatic adverse reactions, and consider pausing or discontinuing treatment as clinically indicated (refer to section 5.1 of the Prescribing Information). TAVNEOS is not recommended for patients with active, untreated and/or uncontrolled chronic liver disease (e.g., chronic active hepatitis B, untreated hepatitis C, uncontrolled autoimmune hepatitis) and cirrhosis. Consider the risk and benefit before administering this drug to a patient with liver disease.

Serious Hypersensitivity Reactions: Cases of angioedema occurred in a clinical trial, including one serious event requiring hospitalization. Discontinue immediately if angioedema occurs and manage accordingly. TAVNEOS must not be re-administered unless another cause has been established.

Hepatitis B Virus (HBV) Reactivation: Hepatitis B reactivation, including life threatening hepatitis B, was observed in the clinical program. Screen patients for HBV. For patients with evidence of prior infection, consult with physicians with expertise in HBV and monitor during TAVNEOS therapy and for six months following. If patients develop HBV reactivation, immediately discontinue TAVNEOS and concomitant therapies associated with HBV reactivation, and consult with experts before resuming.

Serious Infections: Serious infections, including fatal infections, have been reported in patients receiving TAVNEOS. The most common serious infections reported in TAVNEOS group were pneumonia and urinary tract infections. Avoid use of TAVNEOS in patients with active, serious infection, including localized infections. Consider the risks and benefits before initiating TAVNEOS in patients with chronic infection, at increased risk of infection or who have been to places where certain infections are common.

#### Adverse Reactions

The most common adverse reactions ( $\geq$ 5% of patients and higher in the TAVNEOS group vs. prednisone group) were: nausea, headache, hypertension, diarrhea, vomiting, rash, fatigue, upper abdominal pain, dizziness, blood creatinine increased, and paresthesia.

#### **Drug Interactions**

Avoid coadministration of TAVNEOS with strong and moderate CYP3A4 enzyme inducers. Reduce TAVNEOS dose when co-administered with strong CYP3A4 enzyme inhibitors to 30 mg once daily. Monitor for adverse reactions and consider dose reduction of certain sensitive CYP3A4 substrates.

Please see Full Prescribing Information and Medication Guide.

#### Amgen Forward-Looking Statements

This news release contains forward-looking statements that are based on the current expectations and beliefs of Amgen. All statements, other than statements of historical fact, are statements that could be deemed forward-looking statements, including any statements on the outcome, benefits and synergies of collaborations, or potential collaborations, with any other company (including BeiGene, Ltd., Kyowa-Kirin Co., Ltd., or any collaboration to manufacture therapeutic antibodies against COVID-19), the performance of Otezla<sup>®</sup> (apremilast) (including anticipated Otezla sales growth and the timing of non-GAAP EPS accretion), the Five Prime Therapeutics, Inc. acquisition, the Teneobio, Inc. acquisition, or the ChemoCentryx, Inc. acquisition (including the prospective performance and outlook of ChemoCentryx's business, performance and opportunities and any potential strategic benefits, synergies or opportunities expected as a result of such acquisition), as well as estimates of revenues, operating margins, capital expenditures, cash, other financial metrics, expected legal, arbitration, political, regulatory or clinical results or practices, customer and prescriber patterns or practices, reimbursement activities and outcomes, effects of pandemics or other widespread health problems such as the ongoing COVID-19 pandemic on our business, and other such estimates and results. Forward-looking statements involve significant risks and uncertainties, including those discussed below and more fully described in the Securities and Exchange Commission reports filed by Amgen, including our most recent annual report on Form 10-K and any subsequent periodic reports on Form 10-Q and current reports on Form 8-K. Unless otherwise noted, Amgen is providing this information as of the date of this news release and does not undertake any obligation to update any forward-looking statements contained in this document as a result of new information, future events or otherwise.

No forward-looking statement can be guaranteed and actual results may differ materially from those we project. Our results may be affected by our ability to successfully market both new and existing products domestically and internationally, clinical and regulatory developments involving current and future products, sales growth of recently launched products, competition from other products including biosimilars, difficulties or delays in manufacturing our products and global economic conditions. In addition, sales of our products are affected by pricing pressure, political and public scrutiny and reimbursement policies imposed by third-party payers, including governments, private insurance plans and managed care providers and may be affected by regulatory, clinical and guideline developments and domestic and international trends toward managed care and healthcare cost containment. Furthermore, our research, testing, pricing, marketing and other operations are subject to extensive regulation by domestic and foreign government regulatory authorities. We or others could identify safety, side effects or manufacturing problems with our products, including our devices, after they are on the market. Our business may be impacted by government investigations, litigation and product liability claims. In addition, our business may be impacted by the adoption of new tax legislation or exposure to additional tax liabilities. If we fail to meet the compliance obligations in the corporate integrity agreement between us and the U.S. government, we could become subject to significant sanctions. Further, while we routinely obtain patents for our products and technology, the protection offered by our patents and patent applications may be challenged, invalidated or circumvented by our competitors, or we may fail to prevail in present and future intellectual property litigation. We perform a substantial amount of our commercial manufacturing activities at a few key facilities, including in Puerto Rico, and also depend on third parties for a portion of our manufacturing activities, and limits on supply may constrain sales of certain of our current products and product candidate development. An outbreak of disease or similar public health threat, such as COVID-19, and the public and governmental effort to mitigate against the spread of such disease, could have a significant adverse effect on the supply of materials for our manufacturing activities, the distribution of our products, the commercialization of our product candidates, and our clinical trial operations, and any such events may have a material adverse effect on our product development, product sales, business and results of operations. We rely on collaborations with third parties for the development of some of our product candidates and for the commercialization and sales of some of our commercial products. In addition, we compete with other companies with respect to many of our marketed products as well as for the discovery and development of new products. Discovery or identification of new product candidates or development of new indications for existing products cannot be guaranteed and movement from concept to product is uncertain; consequently, there can be no guarantee that any particular product candidate or development of a new indication for an existing product will be successful and become a commercial product. Further, some raw materials, medical devices and component parts for our products are supplied by sole third-party suppliers. Certain of our distributors, customers and payers have substantial purchasing leverage in their dealings with us. The discovery of significant problems with a product similar to one of our products that implicate an entire class of products could have a material adverse effect on sales of the affected products and on our business and results of operations. Our efforts to collaborate with or acquire other companies, products or technology, and to integrate the operations of companies or to support the products or technology we have acquired, may not be successful. There can be no guarantee that we will be able to realize any of the strategic benefits, synergies or opportunities arising from the ChemoCentryx acquisition, and such benefits, synergies or opportunities may take longer to realize than expected. We may not be able to successfully integrate ChemoCentryx, and such integration may take longer, be more difficult or cost more than expected. A breakdown, cyberattack or information security breach could compromise the confidentiality, integrity and availability of our systems and our data. Our stock price is volatile and may be affected by a number of events. Our business and operations may be negatively affected by the failure, or perceived failure, of achieving our environmental, social and governance objectives. The effects of global climate change and related natural disasters could negatively affect our business and operations. Global economic conditions may magnify certain risks that affect our business. Our business performance could affect or limit the ability of our Board of Directors to declare a dividend or our ability to pay a dividend or repurchase our common stock. We may not be able to access the capital and credit markets on terms that are favorable to us, or at all.

CONTACT: Amgen, Thousand Oaks Jessica Akopyan, 805-440-5721 (media) Megan Fox, 805-447-1423 (media) Arvind Sood, 805-447-1060 (investors)