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): June 1, 2021

Amgen Inc.
(Exact name of registrant as specified in its charter)

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

One Amgen Center Drive **Thousand Oaks** **California**	**91320-1799**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code:
(805) 447-1000

Not Applicable
(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:

☐ 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 under Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock $0.0001 par value	**AMGN**	**The Nasdaq Stock Market LLC**
1.250% Senior Notes Due 2022	**AMGN22**	**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 ☐

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 1.01. Entry Into a Material Definitive Agreement.

On June 1, 2021 (the "Effective Date"), Amgen Inc. ("Amgen") entered into a License and Collaboration Agreement (the "Collaboration Agreement") with Kyowa Kirin Co., Ltd. ("KKC"), pursuant to which Amgen and KKC will collaborate on the development and commercialization of KHK4083 (the "Product"), an anti-OX40 fully human monoclonal antibody, worldwide, except Japan (the "Territory").

The Collaboration Agreement and transactions contemplated thereunder have been approved by the boards of directors of both Amgen and KKC. The consummation of the Agreement is subject to obtaining any necessary consents and approvals, including those that may be required by regulators.

Under the terms of the Collaboration Agreement, Amgen will lead the development, manufacturing and commercialization for the Product in the Territory, under the oversight of joint governing bodies. Additionally, KKC will co-promote the Product with Amgen in the U.S. and co-market the Product in South Korea, and KKC will also have opt-in rights to co-promote the Product in certain other markets outside the U.S. Amgen and KKC will share global development costs and U.S. commercialization costs. Amgen will book all revenue from sales in the Territory. KKC will provide to Amgen certain drug supplies necessary for the development of the Product, with the understanding that Amgen will assume responsibility for manufacturing commercial product.

Amgen will make a $400 million one-time upfront payment, as well as future contingent milestone payments potentially worth up to an additional $850 million, and pay significant royalties on any net sales in the U.S. and significant, tiered royalties on any net sales in the Ex-U.S Territory, until the latest of (i) the expiration of the last valid patent claim owned or exclusively controlled by KKC, (ii) the expiration of regulatory exclusivity, or (iii) the earlier of (x) ten years after the first commercial sale of such product in the country of sale or (y) 20 years after the first commercial sale of such product anywhere in the world.

The Collaboration Agreement contains customary representations, warranties and covenants by the parties, and will continue in effect unless terminated by either party pursuant to its terms. Either Amgen or KKC may terminate the Collaboration Agreement in its entirety for the other side's insolvency, uncured material breach or failure to comply with specified compliance provisions. Amgen may terminate the Collaboration Agreement for convenience upon prior written notice.

During the term of the Collaboration Agreement, Amgen and KKC are subject to certain restrictions in the Territory and worldwide related to the clinical development, commercial manufacture, distribution and commercialization of certain products that, as a therapeutic mechanism of action, are directed to the same target as the Product and are expected to treat the same inflammation-related diseases and conditions as treated by the Product.

The foregoing description of the terms of the Collaboration Agreement is not complete and is qualified in its entirety by reference to the Collaboration Agreement, a copy of which Amgen intends to file as an exhibit to a subsequent periodic report.

Item 7.01 Regulation FD Disclosure.

Amgen has issued a press release which is attached hereto as Exhibit 99.1 and 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, as amended (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	Description
99.1	Press Release, dated June 1, 2021.
104	Cover Page Interactive Data File (the cover page XBRL tags are embedded within the Inline XBRL document).

SIGNATURE

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.

AMGEN INC.

Date: June 1, 2021

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

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News Release

AMGEN AND KYOWA KIRIN TO JOINTLY DEVELOP AND COMMERCIALIZE KHK4083, A PHASE 3-READY, POTENTIAL FIRST-IN-CLASS TREATMENT FOR ATOPIC DERMATITIS

Agreement Renews Successful Global Collaboration That led to Several Groundbreaking Therapies in Multiple Disease Areas

KHK4083 Depletes OX40-Expressing T cells Associated with Atopic Dermatitis and Several Other Inflammatory Diseases

Moderate-to-Severe Atopic Dermatitis Affects Nearly 30 Million People in Major Global Markets[1]

Amgen to Host Investor Call at 8:00 a.m. ET

THOUSAND OAKS, Calif. and TOKYO, Japan, (June 1, 2021) -- Amgen (NASDAQ: AMGN) and Kyowa Kirin Co., Ltd. (TSE: 4151) today announced an agreement to jointly develop and commercialize KHK4083, which is Kyowa Kirin's potential first-in-class, Phase 3-ready anti-OX40 fully human monoclonal antibody in development for the treatment of atopic dermatitis, with potential in other autoimmune diseases. In February, Kyowa Kirin announced positive results from a Phase 2 study of KHK4083 in patients with moderate-to-severe atopic dermatitis, which affects nearly 30 million people in major global markets[1].

Under terms of the agreement, Amgen will lead the development, manufacturing, and commercialization for KHK4083 for all markets globally, except Japan, where Kyowa Kirin will retain all rights. Additionally, Kyowa Kirin will co-promote KHK4083 with Amgen in the U.S. and have opt-in rights to co-promote KHK4083 in certain other markets outside the U.S., including in Europe and Asia. Amgen will make a $400 million up-front payment to Kyowa Kirin and future contingent milestone payments potentially worth up to an additional $850 million, as well as significant royalty payments on future global sales. Kyowa Kirin and Amgen will share global development costs, except in Japan, and U.S. commercialization costs. Amgen will consolidate sales for KHK4083 in all markets globally, except for Japan. Amgen also will leverage unique data from its deCODE Genetics subsidiary to inform the potential use of KHK4083 in indications beyond atopic dermatitis. The closing of the transaction is conditioned on obtaining any necessary consents and approvals.

“Kyowa Kirin has a long legacy of partnering with other companies to deliver the full value of our scientific discoveries and novel medicines for patients,” says Masashi Miyamoto, Ph.D., President and CEO of Kyowa Kirin. “KHK4083 is an important asset in our global pipeline. We know Amgen well, and this alliance will build on the past success and trust we have, bringing additional resources and therapeutic expertise to KHK4083’s development and commercialization, to meet the needs of patients living with atopic dermatitis who seek alternative treatment options.”

KHK4083 is an anti-OX40 fully human monoclonal antibody discovered by Kyowa Kirin and engineered with Kyowa Kirin’s patented POTELLIGENT® defucosylation technology to enhance its antibody dependent cellular cytotoxicity (ADCC) activity. KHK4083 has been shown to selectively deplete activated T cells that are critical in the development of atopic dermatitis. Kyowa Kirin antibodies powered by POTELLIGENT technology with ADCC activity are currently marketed in therapeutic areas including Oncology and Asthma. This potent antibody-enhancement platform is also licensed to numerous third parties throughout the biopharmaceutical industry.

“Kyowa Kirin was one of Amgen’s very first collaborators and we are delighted to be joining forces with them once again to advance this promising late-stage asset to treat atopic dermatitis,” said Robert A. Bradway, chairman and chief executive officer at Amgen. “We will take advantage of our two decades of experience in inflammatory disease, as well as our industry-leading human genetics capabilities, to help realize the full potential of KHK4083 as quickly as possible.”

Amgen is a global leader in treating inflammatory diseases, with a portfolio of marketed medicines that includes Otezla®, Enbrel®, AMGEVITA® (a biosimilar to Humira®), and AVSOLA® (a biosimilar to Remicade®). Amgen’s pipeline of investigational therapies includes tezepelumab (filed for U.S. FDA approval in May 2021 as a potential first-in-class treatment for severe asthma), ABP 654 (a biosimilar to STELARA®), and several innovative molecules in Phase 2b development for systemic lupus erythematosus and celiac disease.

“KHK4083 is another example of our world-leading expertise in antibody engineering, applied target selection and optimization. We are proud to be a science-led organization whose research capabilities continue to produce meaningful discoveries, while also taking advantage of open innovation, that offers potential for improving treatment paradigms,” said Yoshifumi Torii, Ph.D., Executive Officer, Vice President, Head of Global R&D Division of Kyowa Kirin. “Results from clinical trials for KHK4083, including Phase 2 data, show great promise and we look forward to initiating a late-stage global program with Amgen to deepen our understanding of this asset.”

In 1984, Amgen and Kirin Holdings Co., Ltd (former Kirin Brewery Co., Ltd), the parent company of Kyowa Kirin, established a 50-50 joint venture to develop and commercialize EPOGEN® (Japanese brand name: ESPO®), which, in 1989, became the first Amgen medicine approved in the U.S., and, in 1990, became the first Kirin medicine approved in Japan. Over time, the joint venture expanded to include the development and commercialization of several other medicines, including NEUPOGEN® (GRAN® in Japan), Neulasta® (G-Lasta® in Japan), Aranesp® (NESP® in Japan), and Nplate® (Romiplate® in Japan). In 2017, the companies announced that the joint venture would become a wholly owned subsidiary of Amgen, with Kyowa Kirin in-licensing certain Amgen medicines in the Asia-Pacific region.

Amgen Webcast Investor Call

Amgen will host a webcast call for the investment community on June 1, 2021, at 8:00 a.m. ET. Peter H. Griffith, executive vice president and chief financial officer, David M. Reese, M.D., executive vice president of Research and Development, and Murdo Gordon, executive vice president of Global Commercial Operations at Amgen will participate.

Live audio of the conference call will be broadcast over the internet simultaneously and will be available to members of the news media, investors and the general public. The webcast, as with other selected presentations regarding developments in Amgen's business given at certain investor and medical conferences, can be accessed on Amgen's website, www.amgen.com, under Investors. Information regarding presentation times, webcast availability and webcast links are noted on Amgen's Investor Relations Events Calendar. The webcast will be archived and available for replay for at least 90 days after the event.

About the KHK4083 Phase 2 Study

In February 2021, Kyowa Kirin reported that KHK4083 met the primary endpoint in a Phase 2 randomized, double-blind and placebo-controlled clinical study conducted in the U.S., Japan, Canada, and Germany. The study included 274 patients with moderate-to-severe atopic dermatitis, who were not adequately controlled with topical agents. All KHK4083 cohorts achieved superiority to the placebo cohort for the primary endpoint of percent change from baseline in Eczema Area and Severity Index (EASI) at 16 weeks with statistical significance. In addition, there was significant difference in the percentage of patients achieving an EASI-75 (EASI score of 75% or greater improvement from baseline) at 16 weeks and the percentage of patients achieving the Investigator's Global Assessment (IGA) of 0 or 1 with an improvement of 2 points or more at 16 weeks in all KHK4083 cohorts compared to the placebo cohort. Further improvements in the efficacy of KHK4083 were observed beyond week 16.

Common treatment-emergent adverse events for KHK4083 cohorts were pyrexia, nasopharyngitis, worsening of atopic dermatitis and chills during the first 16 weeks. Pyrexia and chills events were mild to moderate in intensity, most of them were due to injection reaction and observed only after the first administration of the investigational product. There were no events of severe hypersensitivity reactions and no deaths observed in the study.

About Atopic Dermatitis

Atopic dermatitis is a chronic disease in which the immune system becomes disordered and overactive, triggering inflammation that damages the skin barrier. People with atopic dermatitis can get rashes anywhere on the body that can ooze, weep fluid and bleed when scratched, making skin vulnerable to infection. Skin can become dry and discolored, and repeated scratching can cause thickening and hardening of the skin. Atopic dermatitis typically begins in childhood, affecting 15% to 20% of children and 1% to 3% of adults worldwide. The incidence of the disease has increased two- to three-fold since the 1970s. People who have asthma and/or hay fever or who have family members who do, are more likely to develop atopic dermatitis.

About OX40

OX40 is a co-stimulatory molecule that is one of the tumor necrosis factor receptor (TNFR) family members. It plays an important role in maintaining T cell proliferation and survival and in the formation of memory T cells. OX40 is expressed on the surface of effector T cells (CD4 positive) activated by antigens. It has been reported that effector T cells expressing OX40 are present in the lesions of atopic dermatitis.

About Kyowa Kirin

Kyowa Kirin strives to create and deliver novel medicines with life-changing value. As a Japan-based Global Specialty Pharmaceutical Company with a more than 70-year heritage, the company applies cutting-edge science including an expertise in antibody research and engineering, to address the needs of patients and society across multiple therapeutic areas including Nephrology, Oncology, Immunology/Allergy and Neurology. Across our four regions – Japan, Asia Pacific, North America and EMEA/International – we focus on our purpose, to make people smile, and are united by our shared values of commitment to life, teamwork/Wa, innovation, and integrity. You can learn more about the business of Kyowa Kirin at: https://www.kyowakirin.com.

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.

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

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. or any collaboration to manufacture therapeutic antibodies against COVID-19), the performance of Otezla® (apremilast) (including anticipated Otezla sales growth and the timing of non-GAAP EPS accretion), the Five Prime Therapeutics, Inc. acquisition, or the collaboration with Kyowa Kirin Co., Ltd. to jointly develop and commercialize KHK4083, 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 Amgen's business, outcomes, progress, or effects relating to studies of Otezla as a potential treatment for COVID-19, 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 its 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 Amgen projects. 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, preclinical results do not guarantee safe and effective performance of product candidates in humans. The complexity of the human body cannot be perfectly, or sometimes, even adequately modeled by computer or cell culture systems or animal models. The length of time that it takes for Amgen to complete clinical trials and obtain regulatory approval for product marketing has in the past varied and Amgen expects similar variability in the future. Even when clinical trials are successful, regulatory authorities may question the sufficiency for approval of the trial endpoints Amgen has selected. Amgen develops product candidates internally and through licensing collaborations, partnerships and joint ventures. Product candidates that are derived from relationships may be subject to disputes between the parties or may prove to be not as effective or as safe as Amgen may have believed at the time of entering into such relationship. Also, Amgen or others could identify safety, side effects or manufacturing problems with its products, including its devices, after they are on the market.

Amgen's results may be affected by its 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 its products and global economic conditions. In addition, sales of Amgen's 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, Amgen's research, testing, pricing, marketing and other operations are subject to extensive regulation by domestic and foreign government regulatory authorities. Amgen's business may be impacted by government investigations, litigation and product liability claims. In addition, Amgen's business may be impacted by the adoption of new tax legislation or exposure to additional tax liabilities. If Amgen fails to meet the compliance obligations in the corporate integrity agreement between Amgen and the U.S. government, Amgen could become subject to significant sanctions. Further, while Amgen routinely obtains patents for its products and technology, the protection offered by its patents and patent applications may be challenged, invalidated or circumvented by its competitors, or Amgen may fail to prevail in present and future intellectual property litigation. Amgen performs a substantial amount of its commercial manufacturing activities at a few key facilities, including in Puerto Rico, and also depends on third parties for a portion of its manufacturing activities, and limits on supply may constrain sales of certain of its 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 Amgen's manufacturing activities, the distribution of Amgen's products, the commercialization of Amgen's product candidates, and Amgen's clinical trial operations, and any such events may have a material adverse effect on Amgen's product development, product sales, business and results of operations. Amgen relies on collaborations with third parties for the development of some of its product candidates and for the commercialization and sales of some of its commercial products. In addition, Amgen competes with other companies with respect to many of its marketed products as well as for the discovery and development of new products. Further, some raw materials, medical devices and component parts for Amgen's products are supplied by sole third-party suppliers. Certain of Amgen's distributors, customers and payers have substantial purchasing leverage in their dealings with Amgen. The discovery of significant problems with a product similar to one of Amgen's products that implicate an entire class of products could have a material adverse effect on sales of the affected products and on its business and results of operations. Amgen's 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 Amgen has acquired, may not be successful. A breakdown, cyberattack or information security breach could compromise the confidentiality, integrity and availability of Amgen's systems and Amgen's data. Amgen's stock price may be volatile and may be affected by a number of events. Global economic conditions may magnify certain risks that affect Amgen's business. Amgen's business performance could affect or limit the ability of the Amgen Board of Directors to declare a dividend or its ability to pay a dividend or repurchase its common stock. Amgen may not be able to access the capital and credit markets on terms that are favorable to it, or at all.

The scientific information discussed in this news release related to Amgen's product candidates is preliminary and investigative. Such product candidates are not approved by the U.S. Food and Drug Administration, and no conclusions can or should be drawn regarding the safety or effectiveness of the product candidates. Further, any scientific information discussed in this news release relating to new indications for Amgen's products is preliminary and investigative and is not part of the labeling approved by the U.S. Food and Drug Administration for the products. The products are not approved for the investigational use(s) discussed in this news release, and no conclusions can or should be drawn regarding the safety or effectiveness of the products for these uses.

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Joice Toh (Asia/Pacific), +65 8725 2790

References

1. Decision Resources Group, Atopic Dermatitis/Atopic Eczema Disease Landscape & Forecast, April 2021. © [2021] DR/Decision Resources, LLC. All rights reserved. Reproduction, distribution, transmission or publication is prohibited. Reprinted with permission. Major global markets are the U.S., France, Germany, Italy, Spain, the U.K. and Japan.