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): September 10, 2021

REGENXBIO Inc.
(Exact Name of Registrant as Specified in its Charter)

Delaware	**001-37553**	**47-1851754**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

9804 Medical Center Drive **Rockville, Maryland**	**20850**
(Address of principal executive offices)	**(Zip Code)**

(240) 552-8181
(Registrant's telephone number, including area code)

N/A
(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, $0.0001 par value per share	**RGNX**	**The Nasdaq Global Select Market**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 under the Securities Act of 1933 (17 CFR 230.405) or Rule 12b-2 under the Securities Exchange Act of 1934 (17 CFR 240.12b-2).

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 September 10, 2021, REGENXBIO Inc. (the "Company") entered into a Collaboration and License Agreement with AbbVie Global Enterprises Ltd. (the "Partner"), a subsidiary of AbbVie Inc., to develop and commercialize RGX-314, a potential one-time gene therapy for the treatment of wet age-related macular degeneration ("wet AMD"), diabetic retinopathy ("DR") and other chronic retinal diseases (the "Collaboration and License Agreement"). The Collaboration and License Agreement will become effective upon the satisfaction of customary closing conditions, including the expiration or termination of the applicable waiting or suspension period under the Hart-Scott Rodino Antitrust Improvements Act of 1976, as amended, and any other applicable competition laws.

Pursuant to the Collaboration and License Agreement, the parties will conduct certain activities for the development of products containing RGX-314 ("Licensed Products") under a development plan determined in accordance with the Collaboration and License Agreement. In the United States, the parties are required to use commercially reasonable efforts to develop one Licensed Product for the treatment of each of (a) wet AMD utilizing suprachoroidal delivery, (b) wet AMD utilizing subretinal delivery and (c) DR and, (d) following the achievement of specified milestone events, one Licensed Product for the treatment of an additional indication. In specified markets outside the United States, the Partner is required to use commercially reasonable efforts to develop one Licensed Product for each such indication. Through December 31, 2022, the Company will be responsible for development expenses for certain ongoing trials of RGX-314 and the parties will share additional development expenses related to RGX-314. Beginning on January 1, 2023, the Partner will be responsible for the majority of all development expenses.

The Company will lead the manufacturing of RGX-314 for clinical development and U.S. commercial supply, and the Partner will lead manufacturing of RGX-314 for commercial supply outside the United States. Manufacturing expenses will be allocated between the parties in accordance with the terms of the Collaboration and License Agreement and mutually agreed supply agreements. In the United States, the Company shall participate in commercialization of Licensed Products to the extent set forth in a commercialization plan to be determined in accordance with the Collaboration and License Agreement, and the parties will equally share net profits and net losses associated with commercialization of the Licensed Products in the United States. Outside the United States, the Partner will be responsible, at its sole cost, for the commercialization of Licensed Products.

The Company will receive an upfront payment of $370.0 million from the Partner. Additionally, the Company will be eligible to receive up to $1.38 billion in development, regulatory and commercial milestone payments, in the aggregate, for the achievement of specified milestones for Licensed Products, of which $782.5 million are based on development and regulatory milestones, with the remainder based on commercial milestones. The Company will also be eligible to receive tiered royalties on net sales by the Partner of Licensed Products outside the United States at percentages in the mid-teens to low twenties, subject to specified offsets and reductions. Royalties will be payable on a product-by-product and country-by-country basis outside the United States commencing on the date of first commercial sale of each Licensed Product, and ending on the later of (a) expiration of all valid claims of specified licensed patents in such country, (b) expiration of regulatory exclusivity in such country and (c)(x) if such country is in the European Union, 12 years following first commercial sale of such product in such country, or (y) if such country is outside the European Union, 10 years following the first commercial sale of such product in such country (the "Royalty Term").

The Collaboration and License Agreement will remain in effect, unless earlier terminated, on a country-by-country basis until (a) in the case of the United States, the later of (i) the 120th day after any quarter in which no Licensed Product is being developed or commercialized under such agreement, and (ii) the date that specified licensed patents for a Licensed Product expire in the United States, and (b) in the case of any country outside the United States, the date the Royalty Term for a Licensed Product expires in such country.

The Collaboration and License Agreement contains provisions for termination by (a) the Company upon a challenge of certain licensed patents specified in the Collaboration and License Agreement by the Partner, (b) either party for an uncured material breach of such agreement, (c) the Partner for convenience, (d) the Partner for safety reasons, and (e) either party upon the insolvency of the other party. Additionally, the Collaboration and License Agreement contains, among other provisions, customary representation and warranties, indemnification obligations and confidentiality and intellectual property provisions.

The foregoing description of the terms of the Collaboration and License Agreement does not purport to be complete and is qualified in its entirety by the full text of such agreement. The Company intends to file a copy of the Collaboration and License Agreement with its Quarterly Report on Form 10-Q for the quarter ending September 30, 2021.

Item 7.01. Regulation FD Disclosure.

The Company and AbbVie Inc. issued a joint press release on September 13, 2021, announcing the entry into the Collaboration and License Agreement, which is attached hereto as Exhibit 99.1 and incorporated herein by reference.

The information in Item 7.01 of this Current Report on Form 8-K and Exhibit 99.1 attached hereto 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 liability under that section, nor shall it be deemed 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.

Forward-Looking Statements.

This Current Report on Form 8-K includes "forward-looking statements," within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act. These statements express a belief, expectation or intention and are generally accompanied by words that convey projected future events or outcomes such as "believe," "may," "will," "estimate," "continue," "anticipate," "assume," "design," "intend," "expect," "could," "plan," "potential," "predict," "seek," "should," "would" or by variations of such words or by similar expressions. The forward-looking statements include statements relating to, among other things, the Company's proposed collaboration with the Partner and the Company's future operations and clinical trials. The Company has based these forward-looking statements on its current expectations and assumptions and analyses made by the Company in light of its experience and its perception of historical trends, current conditions and expected future developments, as well as other factors the Company believes are appropriate under the circumstances. However, whether actual results and developments will conform with the Company's expectations and predictions is subject to a number of risks and uncertainties, including the anticipated completion of the Company's proposed transaction with the Partner, the outcome of the Company's proposed collaboration with the Partner and other factors, many of which are beyond the control of the Company. Refer to the "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of the Company's Annual Report on Form 10-K for the year ended December 31, 2020 and comparable "risk factors" sections of the Company's Quarterly Reports on Form 10-Q and other filings, which have been filed with the U.S. Securities and Exchange Commission (the "SEC") and are available on the SEC's website at www.sec.gov. All of the forward-looking statements made in this Current Report on Form 8-K are expressly qualified by the cautionary statements contained or referred to herein. The actual results or developments anticipated may not be realized or, even if substantially realized, they may not have the expected consequences to or effects on the Company or its businesses or operations. Such statements are not guarantees of future performance and actual results or developments may differ materially from those projected in the forward-looking statements. Readers are cautioned not to rely too heavily on the forward-looking statements contained in this Current Report on Form 8-K. These forward-looking statements speak only as of the date of this Current Report on Form 8-K. Except as required by law, the Company does not undertake any obligation, and specifically declines any obligation, to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release dated September 13, 2021.
104	The cover page from this Current Report on Form 8-K, formatted in Inline XBRL.

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.

REGENXBIO INC.

Date: September 13, 2021

By: /s/ Patrick J. Christmas II
Patrick J. Christmas II
Senior Vice President and Chief Legal Officer

PRESS RELEASE

AbbVie and REGENXBIO Announce Eye Care Collaboration

- *AbbVie and REGENXBIO form a strategic partnership combining eye care and gene therapy expertise*
- *Companies will develop and commercialize RGX-314, an investigational gene therapy for wet age-related macular degeneration, diabetic retinopathy and other chronic retinal diseases*
- *REGENXBIO to receive $370 million upfront payment*

NORTH CHICAGO, Ill. and ROCKVILLE, Md., September 13, 2021 – AbbVie (NYSE: ABBV) and REGENXBIO Inc. (Nasdaq: RGNX) today announced a partnership to develop and commercialize RGX-314, a potential one-time gene therapy for the treatment of wet age-related macular degeneration (wet AMD), diabetic retinopathy (DR) and other chronic retinal diseases. RGX-314 is currently being evaluated in patients with wet AMD in a pivotal trial utilizing subretinal delivery, and in patients with wet AMD and DR in two separate Phase II clinical trials utilizing in-office suprachoroidal delivery.

Under the collaboration, REGENXBIO will be responsible for completion of the ongoing trials of RGX-314. AbbVie and REGENXBIO will collaborate and share costs on additional trials of RGX-314, including the planned second pivotal trial evaluating subretinal delivery for the treatment of wet AMD and future trials. AbbVie will lead the clinical development and commercialization of RGX-314 globally. REGENXBIO shall participate in U.S. commercialization efforts as provided under a mutually agreed upon commercialization plan.

“We are committed to finding solutions for patients living with difficult-to-treat retinal diseases and to helping preserve and protect our patients from visual impairment and devastating vision loss,” said Tom Hudson, MD, senior vice president, R&D, chief scientific officer, AbbVie. “In collaboration with REGENXBIO, we aim to make a remarkable impact for the millions of patients suffering from vision loss associated with retinal diseases.”

“AbbVie is a strong, complementary partner for REGENXBIO. We expect to leverage AbbVie’s global developmental and commercial infrastructure within eye care with our expertise in AAV gene therapy clinical development and deep in-house knowledge of manufacturing and production to continue the development of RGX-314,” said Kenneth T. Mills, president and chief executive officer of REGENXBIO.

Under the terms of the agreement, AbbVie will pay REGENXBIO a $370 million upfront payment with the potential for REGENXBIO to receive up to $1.38 billion in additional development, regulatory and commercial milestones. REGENXBIO and AbbVie will share equally in profits

from net sales of RGX-314 in the U.S. AbbVie will pay REGENXBIO tiered royalties on net sales of RGX-314 outside the U.S. In addition, REGENXBIO will lead the manufacturing of RGX-314 for clinical development and U.S. commercial supply, and AbbVie will lead manufacturing of RGX-314 for commercial supply outside the U.S.

The transaction is expected to close by the end of 2021, subject to the satisfaction of customary closing conditions, including applicable regulatory approvals.

REGENXBIO Conference Call

In connection with this announcement, REGENXBIO will host a webcast and conference call today at 8:00 a.m. ET. To access a live or recorded webcast of the call, please visit the “Investors” section of the REGENXBIO website at www.regenxbio.com. To access the live call by phone, dial (855) 422-8964 (domestic) or (210) 229-8819 (international) and enter the passcode 6379638. The recorded webcast will be available for approximately 30 days following the call.

About RGX-314

RGX-314 is being investigated as a potential one-time treatment for wet AMD, diabetic retinopathy, and other chronic retinal conditions. RGX-314 consists of the NAV AAV8 vector, which encodes an antibody fragment designed to inhibit vascular endothelial growth factor (VEGF). RGX-314 is believed to inhibit the VEGF pathway by which new, leaky blood vessels grow and contribute to the accumulation of fluid in the retina[1].

REGENXBIO is advancing research in two separate routes of administration of RGX-314 to the eye, through a standardized subretinal delivery procedure as well as delivery to the suprachoroidal space. REGENXBIO has licensed certain exclusive rights to the SCS Microinjector® from Clearside Biomedical, Inc. to deliver gene therapy treatments to the suprachoroidal space of the eye.

About Wet AMD

Wet AMD is characterized by loss of vision due to new, leaky blood vessel formation in the retina[2]. Wet AMD is a significant cause of vision loss in the United States, Europe and Japan, with up to 2 million people living with wet AMD in these geographies alone[3]. Current anti-VEGF therapies have significantly changed the landscape for treatment of wet AMD, becoming the standard of care due to their ability to prevent progression of vision loss in the majority of patients[4]. These therapies, however, require life-long repeated intraocular injections, to maintain efficacy[5,6]. Due to the burden of treatment, patients often experience a decline in vision with reduced frequency of treatment over time[7].

About Diabetic Retinopathy

Diabetic retinopathy (DR) is the leading cause of vision loss in adults between 24 and 75 years of age worldwide[8]. DR affects approximately eight million people in the United States alone[9]. The spectrum of DR severity ranges from non-proliferative diabetic retinopathy (NPDR) to proliferative diabetic retinopathy (PDR) and as DR progresses, a large proportion of patients develop vision threatening complications, including diabetic macular edema (DME) and neovascularization that can lead to blindness[10]. Current treatment options for patients with DR include "watchful waiting", anti-VEGF treatment, retinal laser or surgical treatment[8].

About AbbVie

AbbVie's mission is to discover and deliver innovative medicines that solve serious health issues today and address the medical challenges of tomorrow. We strive to have a remarkable impact on people's lives across several key therapeutic areas: immunology, oncology, neuroscience, eye care, virology, women's health and gastroenterology, in addition to products and services across its Allergan Aesthetics portfolio. For more information about AbbVie, please visit us at www.abbvie.com. Follow @abbvie on Twitter, Facebook, Instagram, YouTube and LinkedIn.

About REGENXBIO Inc.

REGENXBIO is a leading clinical-stage biotechnology company seeking to improve lives through the curative potential of gene therapy. REGENXBIO's NAV Technology Platform, a proprietary adeno-associated virus (AAV) gene delivery platform, consists of exclusive rights to more than 100 novel AAV vectors, including AAV7, AAV8, AAV9 and AAVrh10. REGENXBIO and its third-party NAV Technology Platform Licensees are applying the NAV Technology Platform in the development of a broad pipeline of candidates in multiple therapeutic areas.

AbbVie Forward-Looking Statements

Some statements in this news release are, or may be considered, forward-looking statements for purposes of the Private Securities Litigation Reform Act of 1995. The words "believe," "expect," "anticipate," "project" and similar expressions, among others, generally identify forward-looking statements. AbbVie cautions that these forward-looking statements are subject to risks and uncertainties that may cause actual results to differ materially from those indicated in the forward-looking statements. Such risks and uncertainties include, but are not limited to, failure to realize the expected benefits from AbbVie's acquisition of Allergan plc ("Allergan"), failure to promptly and effectively integrate Allergan's businesses, competition from other products, challenges to intellectual property, difficulties inherent in the research and development process, adverse litigation or government action, changes to laws and regulations applicable to our industry and the impact of public health outbreaks, epidemics or pandemics, such as COVID-19. Additional information about the economic, competitive, governmental, technological and other factors that may affect AbbVie's operations is set forth in Item 1A, "Risk Factors," of AbbVie's 2020 Annual Report on Form 10-K, which has been filed with the Securities and Exchange Commission, as updated by its subsequent Quarterly Reports on Form 10-Q. AbbVie undertakes no obligation to release publicly any revisions to forward-looking statements as a result of subsequent events or developments, except as required by law.

REGENXBIO Forward-Looking Statements

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