

**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): November 8, 2021**

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

**Delaware**  
(State or other jurisdiction  
of incorporation)

**001-37553**  
(Commission  
File Number)

**47-1851754**  
(I.R.S. Employer  
Identification No.)

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

**20850**  
(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
<b>Common Stock, \$0.0001 par value per share</b>	<b>RGNX</b>	<b>The Nasdaq Global Select Market</b>

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 8.01. Other Events.**

On November 8, 2021, the waiting period under the Hart-Scott Rodino Antitrust Improvements Act of 1976, as amended, expired with respect to the previously reported Collaboration and License Agreement (the “Collaboration and License Agreement”) between REGENXBIO Inc. (the “Company”) and AbbVie Global Enterprises Ltd. (the “Partner”), a subsidiary of AbbVie Inc. On November 9, 2021, the Collaboration and License Agreement closed.

**Item 7.01. Regulation FD Disclosure.**

On November 9, 2021, the Company issued a press release announcing the closing of the Collaboration and License Agreement. The press release 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, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	<a href="#">Press release dated November 9, 2021.</a>
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: November 9, 2021

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



### **REGENXBIO Announces Closing of Eye Care Collaboration Agreement with AbbVie**

ROCKVILLE, Md., November 9, 2021 — REGENXBIO Inc. (Nasdaq: RGNX) today announced the closing of its Collaboration and License Agreement with AbbVie 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. As previously announced on September 13, 2021, under the terms of the agreement, REGENXBIO will receive an upfront payment from AbbVie of \$370 million with the potential for REGENXBIO to receive up to \$1.38 billion in additional development, regulatory and commercial milestones.

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 will participate in U.S. commercialization efforts as provided under a mutually agreed upon commercialization plan.

REGENXBIO and AbbVie will share equally in profits from net sales of RGX-314 in the U.S. and 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.

#### **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.

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<sup>®</sup> from Clearside Biomedical, Inc. to deliver gene therapy treatments to the suprachoroidal space of the eye.

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**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.

SCS Microinjector® is a trademark of Clearside Biomedical, Inc. All other trademarks referenced herein are registered trademarks of REGENXBIO.

**Forward-Looking Statements**

This press release includes "forward-looking statements," within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. 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, REGENXBIO's collaboration with AbbVie and REGENXBIO's future operations and clinical trials. REGENXBIO has based these forward-looking statements on its current expectations and assumptions and analyses made by REGENXBIO in light of its experience and its perception of historical trends, current conditions and expected future developments, as well as other factors REGENXBIO believes are appropriate under the circumstances. However, whether actual results and developments will conform with REGENXBIO's expectations and predictions is subject to a number of risks and uncertainties, including the outcome of REGENXBIO's collaboration with AbbVie and other factors, many of which are beyond the control of REGENXBIO. Refer to the "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of REGENXBIO's Annual Report on Form 10-K for the year ended December 31, 2020 and comparable "risk factors" sections of REGENXBIO's Quarterly Reports on Form 10-Q and other filings, which have been filed with the U.S. Securities and Exchange Commission (SEC) and are available on the SEC's website at [www.sec.gov](http://www.sec.gov). All of the forward-looking statements made in this press release 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 REGENXBIO 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

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statements contained in this press release. These forward-looking statements speak only as of the date of this press release. Except as required by law, REGENXBIO 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.

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