
**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 23, 2026

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
(IRS Employer
Identification No.)

9804 Medical Center Drive
Rockville, Maryland
(Address of Principal Executive Offices)

20850
(Zip Code)

Registrant's Telephone Number, Including Area Code: (240) 552-8181

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:

- 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 \$0.0001 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 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 8.01. Other Events.

On June 29, 2026, REGENXBIO Inc. (the “Company”) announced that it has earned a milestone payment of \$100.0 million from AbbVie Global Enterprises Ltd. (“AbbVie”), a subsidiary of AbbVie Inc., pursuant to the Collaboration and License Agreement, dated as of September 10, 2021 between the Company and AbbVie, as amended on August 5, 2025. The milestone payment relates to the dosing of the first patient in the Phase IIb/III trial of investigational surabgene lomparvovec (sura-vec, ABBV-RGX-314) in diabetic retinopathy using suprachoroidal delivery and is expected to be received in July 2026.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	REGENXBIO Inc. Press Release dated June 29, 2026.
104	The cover page from this Current Report on Form 8-K, formatted in Inline XBRL.

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.

REGENXBIO Inc.

Date: June 29, 2026

By: /s/ Patrick J. Christmas II
Patrick J. Christmas II
Executive Vice President, Chief Strategy & Legal Officer



REGENXBIO Announces First Patient Dosed in Phase IIb/III NAAVIGATE Trial of Surabgene Lomparovec in Diabetic Retinopathy; Company to Receive \$100 Million Milestone

- *New long-term data from diabetic retinopathy and wet AMD programs to be presented at American Society of Retina Specialists (ASRS) 2026*

ROCKVILLE, Md., June 29, 2026 – REGENXBIO Inc. (Nasdaq: RGNX) today announced the first patient has been dosed in the Phase IIb/III NAAVIGATE clinical trial of investigational surabgene lomparovec (sura-vec, ABBV-RGX-314) in diabetic retinopathy (DR) using suprachoroidal delivery. REGENXBIO will receive \$100 million from AbbVie for this milestone.

“Dosing the first patient in the Phase IIb/III study is a significant milestone in our commitment with AbbVie to bring a one-time gene therapy to patients who continue to face progressive and vision-threatening complications across multiple chronic retinal diseases,” said Steve Pakola, M.D., Chief Medical Officer, REGENXBIO. “We are excited to advance sura-vec for DR, following the two-year data that reinforced the durable and disease-modifying impact that sura-vec has the potential to deliver with a single administration. The opportunity to prevent disease progression before vision damage occurs is critical for this population, and we are collaborating closely with the investigators and AbbVie to progress this innovative treatment option.”

“Diabetic retinopathy is a leading cause of vision loss among working adults, and the goal as a physician is always to prevent the disease from progressing and treat patients before they lose their vision. Current treatment options often require ongoing, repeated interventions, which can lead to undertreatment and progressive vision-threatening complications,” said Arshad Khanani, M.D., M.A., FASRS, Director of Clinical Research at Sierra Eye Associates, Reno, NV. “A one-time, in-office treatment has the potential to transform DR management by improving long-term outcomes while making earlier intervention both practical and scalable for patients worldwide.”

NAAVIGATE is a Phase IIb/III multicenter, randomized, masked, sham-controlled study to evaluate the safety and efficacy of sura-vec in subjects with non-proliferative DR (NPDR) without center-involved diabetic macular edema (CI-DME). Subjects will receive sura-vec at 1.0×10^{12} genome copies (GC)/eye, which was evaluated as dose level 3 in the Phase II ALTITUDE[®] trial of sura-vec, and short-course topical prophylactic steroids. The primary endpoint is ≥ 2 -step improvement on the diabetic retinopathy severity scale (DRSS) at one year. The Phase IIb portion, operationalized by REGENXBIO, is expected to enroll approximately 135 participants in the United States.

REGENXBIO plans to present two and a half-year data from the long term follow up study of the ALTITUDE trial at the ASRS 44th Annual Meeting in July 2026. In two-year dose level 3 data from the ALTITUDE trial, sura-vec demonstrated a durable efficacy profile and was well tolerated with no intraocular inflammation observed (n=15), supporting the potential of an in-office gene therapy approach.

Five-year long-term follow-up data from the Phase I/IIa study of subretinal sura-vec for wet AMD will also be presented at ASRS. REGENXBIO expects to announce topline data with AbbVie from the ATMOSPHERE[®] and ASCENT[®] pivotal trials of sura-vec using subretinal delivery in Q4 2026.

About Surabgene Lomparvovec (sura-vec, ABBV-RGX-314)

Sura-vec is a one-time investigational gene therapy designed to deliver sustained treatment effect in wet AMD, diabetic retinopathy and other chronic retinal conditions. Sura-vec uses the NAV[®] AAV8 vector to encode an antibody fragment designed to inhibit vascular endothelial growth factor (VEGF). Sura-vec 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

About Diabetic Retinopathy

Diabetic retinopathy (DR) is the leading cause of vision loss in adults between 24 and 75 years of age worldwide.² DR affects nearly 10 million people in the United States alone.³ The spectrum of DR severity ranges from non-proliferative diabetic retinopathy (NPDR) to proliferative diabetic retinopathy (PDR).⁴ As DR progresses, a large proportion of patients develop vision threatening complications, including diabetic macular edema (DME) and neovascularization that can lead to blindness.⁴ Current treatment options for patients with NPDR typically include "watchful waiting" or anti-VEGF treatment. For patients with PDR, current treatment options include anti-VEGF treatment or retinal laser; surgical treatment may be required for advanced PDR.²

ABOUT REGENXBIO Inc.

REGENXBIO is a biotechnology company on a mission to improve lives through the curative potential of gene therapy. Since its founding in 2009, REGENXBIO has pioneered the field of AAV gene therapy. REGENXBIO is advancing a late-stage pipeline of one-time treatments for rare and retinal diseases, including RGX-202 for the treatment of Duchenne; surabgene lomparvovec (ABBV-RGX-314) for the treatment of wet AMD and diabetic retinopathy, in collaboration with AbbVie, and NAVSUNLI[™] (clemidsogene lanparvovec-sngl, RGX-121) for the treatment of MPS II and RGX-111 for the treatment of MPS I, both in partnership with Nippon Shinyaku. Thousands of patients have been treated with REGENXBIO's AAV platform, including those receiving Novartis' ZOLGENSMA[®]. REGENXBIO's investigational gene therapies have the potential to change the way healthcare is delivered for millions of people. For more information, please visit www.REGENXBIO.com.

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,

*These are interim results from analyses performed by REGENXBIO for an ongoing trial.

¹ Penn JS, Madan A, Caldwell RB, et al. Vascular endothelial growth factor in eye disease. *Prog Retin Eye Res.* 2008;27(4):331-71.

² Cheung N, Mitchell P, Wong TY. Diabetic retinopathy. *Lancet.* 2010;376(9735):124-36.

³ Lundeen EA, Burke-Conte Z, Rein DB, Wittenborn JS, Saaddine J, Lee AY, Flaxman AD. Prevalence of Diabetic Retinopathy in the US in 2021. *JAMA Ophthalmology.* 2023;141(8):747-754.

⁴ Berrocal MD, Alexandra Acabá. *Current Management of Diabetic Retinopathy*, 2018

among other things, REGENXBIO's future operations and clinical trials, the timing, availability and interpretation of clinical data. 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 risks related to the FDA's review process, the timing of enrollment, commencement, completion and the success of clinical trials conducted by REGENXBIO, its licensees and its partners, the timing of any milestone payments, the timely development and launch of new products, the ability to obtain and maintain regulatory approval of product candidates, trends and challenges in the business and markets in which REGENXBIO operates, the size and growth of potential markets for product candidates and the ability to serve those markets, the rate and degree of acceptance of product candidates, 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, 2025, and comparable "risk factors" sections of REGENXBIO's Quarterly Reports on Form 10-Q and other filings, which have been filed with the 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 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.

Zolgensma® is a registered trademark of Novartis AG. All other trademarks referenced herein are registered trademarks of REGENXBIO.

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