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): August 06, 2026

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)**	**(IRS Employer Identification No.)**
9804 Medical Center Drive Rockville, Maryland		**20850**
(Address of Principal Executive Offices)		**(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 2.02. Results of Operations and Financial Condition.

On August 6, 2026, REGENXBIO Inc. (the "Company") issued a press release regarding its results of operations and financial condition for the quarter ended June 30, 2026. The press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference herein.

The information in Item 2.02 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

Exhibit No.	Description
99.1	Press release dated August 6, 2026 relating to REGENXBIO Inc.'s financial results.
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: August 6, 2026

By: /s/ Patrick J. Christmas II
Patrick J. Christmas II

Executive Vice President, Chief Strategy & Legal Officer

EXHIBIT 99.1

REGENXBIO Reports Second Quarter 2026 Financial Results and Operational Highlights

- *RGX-202 BLA submission for Duchenne muscular dystrophy on track for Q3 2026 initiation, with potential accelerated approval in 2H 2027*
- *Long-term surabgene lomparvovec (sura-vec, ABBV-RGX-314) data highlight durable safety and efficacy profile ahead of key catalyst*
  - *Topline data from pivotal subretinal wet AMD studies, ATMOSPHERE® and ASCENT®, expected in Q4 2026*
  - *Phase IIb/III NAAVIGATE trial for diabetic retinopathy ongoing*
- *Reaffirmed path forward for RGX-121 for Hunter syndrome with FDA during productive July Type A meeting; resubmission on track for Q3 2026*
- *Over $200 million new capital in July 2026 extends cash runway into Q4 2027*
  - *Pro forma ending Q2 2026 cash, cash equivalents and marketable securities in excess of $310 million*
- *Webcast today at 8:00 a.m. ET*

ROCKVILLE, Md., August 6, 2026 (PR Newswire) -- REGENXBIO Inc. (Nasdaq: RGNX) today reported financial results and operational highlights for the second quarter ended June 30, 2026.

“Our second quarter was defined by strong clinical execution across our pipeline: the Phase III AFFINITY DUCHENNE® trial met its primary endpoint, we dosed the first participant in the NAAVIGATE study in diabetic retinopathy, and the FDA reaffirmed the path forward for RGX-121,” said Curran Simpson, President and Chief Executive Officer of REGENXBIO. “With this progress and our strong cash runway, we are well positioned to deliver against multiple near-term, high-value catalysts, including the initiation of the RGX-202 BLA this quarter and wet AMD pivotal data in the coming months, as we advance potentially transformative gene therapies to patients.”

Corporate Updates

- REGENXBIO received over $200 million in July 2026, including a $100 million milestone payment from AbbVie for the dosing of the first patient in the Phase IIb/III NAAVIGATE study for diabetic retinopathy and approximately $108 million in net proceeds from an underwritten public offering.
- In addition to extending the company’s expected cash runway into Q4 2027, proceeds will support the initiation of the planned AFFINITY® RISE ex-U.S. randomized-controlled trial in 1H 2027 to support global regulatory submissions for RGX-202.

PROGRAM HIGHLIGHTS AND MILESTONES

Neuromuscular Disease: RGX-202 is a potential best-in-class gene therapy for Duchenne muscular dystrophy (Duchenne). RGX-202 is designed to address the underlying cause of Duchenne by enabling targeted expression of a novel microdystrophin that is closest to naturally occurring dystrophin. The differentiated therapeutic approach behind RGX-202 includes a novel construct, with the C-Terminal domain, a proactive immune suppression regimen, and a suspension-based manufacturing process that delivers industry-leading product purity levels.

RGX-202 is designed for improved muscle function, durability and positive safety outcomes and is being evaluated in the Phase I/II/III AFFINITY DUCHENNE® trial and confirmatory trial in ambulatory patients aged 1+.

- The confirmatory study of RGX-202 completed enrollment in June 2026 ahead of schedule due to strong patient demand and robust investigator interest.
- In topline pivotal data, the Phase III AFFINITY DUCHENNE® trial met its primary endpoint with high statistical significance ($p<0.0001$).
    - RGX-202 was well-tolerated and continued to demonstrate a favorable interim safety profile and demonstrated statistically significant correlation between RGX-202 microdystrophin expression level and functional improvement at one year (NSAA, n=9).
- REGENXBIO continues to manufacture intended commercial supply of RGX-202 at its in-house Manufacturing Innovation Center.
- REGENXBIO expects to initiate AFFINITY® RISE, a new, ex-U.S. randomized, placebo-controlled study to support RGX-202 global regulatory submissions, in 1H 2027.
- The Company is on track to initiate a BLA submission in Q3 2026 under the accelerated approval pathway, supporting potential approval in 2H 2027.

Retinal Disease: Surabgene lomparvovec (sura-vec, ABBV-RGX-314), developed in collaboration with AbbVie, is potentially the first-in-class gene therapy treatment for wet age-related macular degeneration (wet AMD) and diabetic retinopathy (DR).

Sura-vec for the Treatment of Wet AMD (Subretinal Delivery)

- REGENXBIO expects to announce topline data with AbbVie from the ATMOSPHERE® and ASCENT® pivotal trials of sura-vec using subretinal delivery in Q4 2026.
- Global regulatory submissions are expected in 2027.
- Long-term follow-up data from the Phase I/IIa trial of sura-vec, presented at the ASRS 44th Annual Meeting in July 2026, showed stable to improved visual acuity and meaningful reductions in anti-VEGF treatment burden through five years at doses similar to those used in the pivotal trials, with the exception of one participant in Cohort 4 with polypoidal choroidal vasculopathy refractory to anti-VEGF therapy.

Sura-vec for the Treatment of DR (Suprachoroidal Delivery)

- In June 2026, REGENXBIO announced the first patient had been dosed in the Phase IIb/III NAAVIGATE study. The associated $100 million milestone payment from AbbVie was received in July 2026.
- NAAVIGATE is a Phase IIb/III multicenter, randomized, masked, sham-controlled study enrolling subjects with non-proliferative DR (NPDR) without center-involved diabetic macular edema (CI-DME) to evaluate the safety and efficacy of a one-time, in-office administration of sura-vec.
- Long-term follow-up data from the ALTITUDE® trial, also presented at ASRS in July 2026, showed a durable safety and efficacy profile through 2.5 years at the dose being evaluated in NAAVIGATE with short-course prophylactic topical steroids.

Neurodegenerative Disease: NAVSUNLI™ (clemidsogene lanparvovec, RGX-121) is a potential first-in-class treatment for MPS II, also known as Hunter syndrome, being developed and potentially commercialized in partnership with Nippon Shinyaku.

- REGENXBIO and the FDA held a positive Type A meeting in July 2026. In the meeting, the FDA reaffirmed that no additional studies of RGX-121 are required for the BLA resubmission.
- REGENXBIO plans to resubmit the BLA in Q3 2026. The resubmission will include longer-term efficacy and safety data, including participant imaging that has been submitted to FDA and continues to be collected and analyzed as part of ongoing RGX-121 safety monitoring.
- A post-approval confirmatory study will be discussed as part of BLA review.

FINANCIAL RESULTS

Cash Position: Cash, cash equivalents and marketable securities were $105.5 million as of June 30, 2026, compared to $240.9 million as of December 31, 2025. The decrease was primarily driven by cash used to fund operating activities during the first half of 2026. In July 2026, REGENXBIO received a $100 million milestone payment from AbbVie for the dosing of the first patient in the Phase IIb/III NAAVIGATE study and approximately $108 million estimated net proceeds from an underwritten public offering of common stock and pre-funded warrants. Pro forma cash, cash equivalents and marketable securities as of June 30, 2026 was approximately $313 million, including the impact of the milestone payment and offering proceeds received in July 2026.

Revenues: Revenues were $108.0 million for the three months ended June 30, 2026, compared to $21.4 million for the three months ended June 30, 2025. The increase was primarily attributable to the $100.0 million development milestone achieved in the second quarter of 2026 upon dosing the first patient in the NAAVIGATE study. The increase was partially offset by a $16.7 million decrease in ZOLGENSMA® royalty revenues due to the expiration of licensed patents in the U.S. in January 2026. Novartis launched U.S. sales of ITVISMA® in the first quarter of 2026. ITVISMA is now also approved in the UAE, Japan, Qatar and the EU. REGENXBIO is entitled to royalties on certain net sales of ITVISMA in the U.S. and other jurisdictions with patents extending until 2037.

Research and Development (R&D) Expenses: R&D expenses were $56.1 million for the three months ended June 30, 2026, compared to $59.5 million for the three months ended June 30, 2025. The decrease was primarily attributable to manufacturing-related expenses and clinical trial expenses for sura-vec and NAVSUNLI pivotal trials.

General and Administrative Expenses: General and administrative expenses were $21.6 million for the three months ended June 30, 2026, compared to $19.9 million for the three months ended June 30, 2025. The increase was largely driven by personnel-related costs, commercialization expenses, consulting and other corporate advisory services.

Net Income: Net income was $22.7 million, or $0.43 basic and diluted net income per share, for the three months ended June 30, 2026, compared to net loss of $70.9 million, or $1.38 basic and diluted net loss per share, for the three months ended June 30, 2025.

FINANCIAL GUIDANCE

REGENXBIO expects its balance in cash, cash equivalents and marketable securities of $105.5 million as of June 30, 2026, along with the $100.0 million milestone payment and $107.8 million estimated net offering proceeds received in July 2026, are sufficient to fund operations into Q4 2027. This cash runway guidance is based on the Company's current operational plans and excludes the impact of any material payments that may potentially be received from partners or

licensees upon the achievement of development or regulatory milestones, or upon the approval or commercialization of product candidates, and excludes any additional potential dilutive or non-dilutive funding opportunities.

CONFERENCE CALL
In connection with this announcement, REGENXBIO will host a conference call and webcast at 8:00 a.m. ET today. Listeners can register for the webcast via this link. Analysts wishing to participate in the question and answer session should use this link. A replay of the webcast will be available via the company's investor website approximately two hours after the call's conclusion. Those who plan on participating are advised to join 15 minutes prior to the start time.

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, among other things, REGENXBIO's future operations, clinical trials, costs and cash flow. 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 timing of enrollment, commencement and completion and the success of clinical trials conducted by REGENXBIO, its licensees and its partners, the timing of commencement and completion and the success of preclinical studies conducted by REGENXBIO and its development partners, the timing or likelihood of payments from AbbVie or Nippon Shinyaku, the monetization of any priority review voucher, the timely development and launch of new products, the ability to obtain and maintain regulatory approval of product candidates, the ability to obtain and maintain intellectual property protection for product candidates and technology, 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, filed with the U.S. Securities and Exchange Commission (SEC) 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**. 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.

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REGENXBIO INC.
CONSOLIDATED BALANCE SHEETS
(unaudited)
(in thousands)

	June 30, 2026	December 31, 2025
Assets		
Current assets		
Cash and cash equivalents	$ 36,487	$ 34,466
Marketable securities	69,030	195,604
Accounts receivable	106,754	26,379
Prepaid expenses	11,904	11,927
Restricted cash	225	—
Other current assets	11,757	12,905
Total current assets	236,157	281,281
Marketable securities	—	10,785
Accounts receivable	435	2,312
Property and equipment, net	98,452	104,855
Operating lease right-of-use assets	43,867	47,156
Restricted cash	1,805	2,030
Other assets	5,902	4,613
Total assets	$ 386,618	$ 453,032
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 15,546	$ 21,358
Accrued expenses and other current liabilities	23,073	38,390
Deferred revenue	9,882	10,452
Operating lease liabilities	7,355	8,286
Royalty monetization liabilities	26,765	39,609
Total current liabilities	82,621	118,095
Deferred revenue	15,404	18,943
Operating lease liabilities	61,596	65,215
Royalty monetization liabilities	154,746	147,408
Other liabilities	486	638
Total liabilities	314,853	350,299
Stockholders' equity		
Preferred stock; no shares issued and outstanding at June 30, 2026 and December 31, 2025	—	—
Common stock; 54,164 and 50,892 shares issued and outstanding at June 30, 2026 and December 31, 2025, respectively	5	5
Additional paid-in capital	1,266,004	1,229,442
Accumulated other comprehensive loss	(875)	(687)
Accumulated deficit	(1,193,369)	(1,126,027)
Total stockholders' equity	71,765	102,733
Total liabilities and stockholders' equity	$ 386,618	$ 453,032

REGENXBIO INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME (LOSS)
(unaudited)
(in thousands, except per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2026	2025	2026	2025
Revenues				
License and royalty revenue	$ 103,841	$ 18,465	$ 108,931	$ 105,514
Service revenue	4,178	2,894	5,481	4,857
Total revenues	108,019	21,359	114,412	110,371
Operating Expenses				
Cost of license and royalty revenues	1,042	5,209	12,116	8,645
Research and development	56,086	59,500	113,425	112,587
General and administrative	21,616	19,883	42,922	40,230
Other operating expenses	12	45	48	60
Total operating expenses	78,756	84,637	168,511	161,522
Income (loss) from operations	29,263	(63,278)	(54,099)	(51,151)
Other Income (Expense)				
Interest income from licensing	17	21	33	46
Investment income	1,222	3,379	3,225	5,880
Interest expense	(7,793)	(10,993)	(16,501)	(19,563)
Total other income (expense)	(6,554)	(7,593)	(13,243)	(13,637)
Net income (loss)	$ 22,709	$ (70,871)	$ (67,342)	$ (64,788)
Other Comprehensive Income (Loss)				
Unrealized gain (loss) on available-for-sale securities, net	(5)	12	(188)	(9)
Total other comprehensive income (loss)	(5)	12	(188)	(9)
Comprehensive income (loss)	$ 22,704	$ (70,859)	$ (67,530)	$ (64,797)
Net income (loss) per share:				
Basic	$ 0.43	$ (1.38)	$ (1.28)	$ (1.26)
Diluted	$ 0.43	$ (1.38)	$ (1.28)	$ (1.26)
Weighted-average common shares outstanding:				
Basic	52,820	51,483	52,625	51,423
Diluted	53,016	51,483	52,625	51,423