

**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 12, 2024

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

(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 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

On June 12, 2024, REGENXBIO Inc. (the “Company”) announced that its Board of Directors (the “Board”) accepted the resignation of Kenneth T. Mills from his position as President and Chief Executive Officer of the Company, effective July 1, 2024. Mr. Mills will continue to serve as a director and has been named Chairman of the Board. Mr. Mills will serve as an advisor to the Company to assist the new Chief Executive Officer until June 30, 2025.

The Company also announced that the Board appointed Curran M. Simpson as President and Chief Executive Officer, effective as of July 1, 2024. In connection with his appointment, the Board appointed Mr. Simpson as a Class I director, effective July 1, 2024, with a term expiring at the Company’s 2025 annual meeting of stockholders or until such time as his successor is duly elected and qualified. Additionally, Daniel Tassé was appointed as the Company’s Lead Independent Director, succeeding Jerry Karabelas.

Mr. Simpson, 62, has been a member of the Company’s senior management team since 2015 and has served as Chief Operating Officer since January 2023. In that role, he has been directly responsible for key business functions including Research & Clinical Development, Corporate Strategy, Manufacturing, Quality, Regulatory, and Commercial Operations. Mr. Simpson previously served as the Company’s Chief Operations and Technology Officer. Prior to joining the Company, Mr. Simpson held a series of senior executive operations positions within the life sciences industry, including as Regional Supply Chain Head for North America and Interim Chief Operating Officer at GlaxoSmithKline and the Human Genome Sciences division of GlaxoSmithKline. Mr. Simpson previously served as Director of Manufacturing Sciences at Biogen. He previously held roles of increasing responsibility with Novo-Nordisk Biochem Inc., and in various senior development and engineer roles at Genentech, among other roles. Mr. Simpson has an M.S. in surface and colloid science from Clarkson University and a B.S. in chemical engineering and chemistry from the Clarkson College of Technology.

On June 12, 2024, the Company and Mr. Simpson entered into an employment agreement (the “Employment Agreement”) in connection with Mr. Simpson’s promotion to President and Chief Executive Officer. Under the terms of the Employment Agreement, Mr. Simpson initially will be entitled to a base salary of \$610,000 and his annual bonus target will be established at a minimum level of 60% of his base salary, which for the 2024 fiscal year will be prorated from July 1, 2024. In addition, on July 1, 2024 Mr. Simpson will be granted stock options and restricted stock units with an aggregate grant date fair value of \$2,500,000, of which approximately 75% will consist of stock options and approximately 25% will consist of restricted stock units. The Employment Agreement also provides for certain severance benefits in the event Mr. Simpson is terminated without cause or by reason of death or disability, or if he is terminated or resigns for good reason following a change of control.

Mr. Simpson and his immediate family members are not party to any related party transactions for which disclosure would be required pursuant to Item 404(a) of Regulation S-K. There is no family relationship between Mr. Simpson and any of the Company’s directors or executive officers and no arrangements or understandings with other persons pursuant to which Mr. Simpson was selected as an officer.

On June 12, 2024, the Company and Mr. Mills entered into a Consulting and Separation Agreement (the “Agreement”) for services that he will provide as an advisor to the Company. The Agreement will be effective from July 1, 2024 through June 30, 2025. Under the terms of the Agreement, Mr. Mills will be eligible to receive up to 100% of his targeted bonus payment for the fiscal year ending December 31, 2024. In addition, the Company and Mr. Mills agreed that his outstanding stock options and restricted stock units will continue to vest during his service as an advisor, after which any unvested stock options and restricted stock units will be forfeited. Following the conclusion of his service as an advisor to the Company, Mr. Mills’ stock options will remain exercisable for three months. The Company also will reimburse Mr. Mills’ reasonable legal fees in connection with entering into the Agreement and provide the COBRA coverage for Mr. Mills and his family members through January 30, 2025. Mr. Mills will not receive an initial equity award grant in connection with the commencement of his role as Chairman of the Board and as a non-employee director on the Board, but will be eligible for cash compensation and future annual equity award grants in accordance with the Company’s Compensation Program for Non-Employee Directors.

Item 7.01 Regulation FD Disclosure.

On June 12, 2024, the Company issued a press release announcing the transition of the Company's President and Chief Executive Officer and reiterating its financial and operational guidance. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is 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 the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise be 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	Press release issued by REGENXBIO Inc. on June 12, 2024.
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 12, 2024

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



REGENXBIO Announces Leadership Transition

- *Curran Simpson, Chief Operating Officer, Appointed as President and CEO*
- *Co-Founder Kenneth T. Mills to Step Down as President and CEO; Named Chairman of the Board*

ROCKVILLE, Md. — June 12, 2024 — REGENXBIO Inc. (Nasdaq: RGNX) today announced that Curran Simpson, Chief Operating Officer, has been appointed as President, Chief Executive Officer and a member of the Board of Directors, effective July 1, 2024. Co-Founder Kenneth T. Mills will step down as President and Chief Executive Officer following 15 years of leadership at the Company, and he is taking on an expanded role on the Board as Chairman. In connection with these changes, Board member Daniel Tassé has been appointed as REGENXBIO's Lead Independent Director, a role previously held by Jerry Karabelas, Ph.D. Dr. Karabelas and Co-Founder Allan Fox, who has served as Chairman since 2020, will remain on the Board.

Mr. Simpson is a seasoned biopharmaceuticals leader with over 35 years of industry experience. As the Chief Operating Officer (COO) at REGENXBIO since January 2023, he has been directly responsible for key business functions including Research & Clinical Development, Corporate Strategy, Manufacturing & Quality, Regulatory, and Commercial Operations. Mr. Simpson joined REGENXBIO in 2015 and served as the Company's Chief Technology and Operations Officer before becoming COO. Prior to joining REGENXBIO, he was the Regional Supply Chain Head for North America and Interim Chief Operating Officer at GlaxoSmithKline (GSK). Mr. Simpson earlier served as interim CEO at Human Genome Sciences (HGS), where he led the integration of HGS into GSK.

"I am honored to serve as REGENXBIO's next President and CEO," said Mr. Simpson. "I have been a part of shaping and leading our programs from preclinical to pivotal stages with Ken, and today, our AAV Therapeutics platform is well-positioned to make a meaningful impact. I look forward to our exciting next chapter as I continue to work with Ken and the rest of REGENXBIO's seasoned management team and Board to further advance our pipeline, drive the commercialization and scale of our business and deliver value for patients, shareholders and our other stakeholders."

"Leading REGENXBIO since our founding in 2009 has been a privilege," said Mr. Mills. "We have built the Company into a leader in gene therapy medicines with exciting products progressing through late-stage developments. As we advance our pivotal stage clinical trials, approach commercialization and prepare for our next chapter, now is the right time to transition leadership. Curran and I have worked closely together over the last nine years, and I am confident he brings the R&D, operational, and industry expertise to build on our momentum. I am enthusiastic about the future of REGENXBIO and excited to continue partnering with Curran and working alongside the Board in my role as Chairman."

"Curran has held various leadership roles since joining the Company in 2015 and consistently demonstrated strategic, commercial and operational expertise and acumen," said Mr. Fox. "The Board is confident he is the right leader to advance our strategy and oversee our next phase of meaningful value creation as we capitalize on our significant commercial opportunities. The Board and the entire Company would like to thank Ken for his tremendous contributions to REGENXBIO over the past 15 years. Ken pioneered the development of our leading AAV Therapeutics platform, enhancing the landscape of gene therapies, with programs that remain on track to meet our goals. We look forward to continuing to benefit from his deep knowledge of this field, REGENXBIO and our therapeutics pipeline."

REGENXBIO MAINTAINS FINANCIAL & OPERATIONAL GUIDANCE

The Company today also reiterated its financial guidance previously provided on May 8, 2024: REGENXBIO expects its balance in cash, cash equivalents and marketable securities of \$380.5 million as of March 31, 2024 to fund its operations into 2026. This cash runway guidance is based on the Company's current operational plans and excludes the impact of any payments that may be received from AbbVie upon the achievement of development or commercial milestones under our ABBV-RGX-314 collaboration (including a potential, one-time \$200.0 million milestone for achievement of first patient dosed in the first pivotal trial for suprachoroidal delivery for treatment of DR) and the potential monetization of a priority review voucher that may be received for RGX-121.

ABOUT CURRAN SIMPSON

Mr. Simpson has served as the Chief Operating Officer at REGENXBIO since January 2023. In that role, he has been leading key business functions including Research & Clinical Development, Corporate Strategy, Manufacturing & Quality, Regulatory, and Commercial Operations. Mr. Simpson joined REGENXBIO in 2015 with extensive leadership experience across biopharmaceutical operations and served as the Company's Chief Technology and Operations Officer before becoming COO. Prior to joining REGENXBIO, he was the Regional Supply Chain Head for North America and Interim Chief Operating Officer at GlaxoSmithKline (GSK). Mr. Simpson earlier served as interim CEO of Human Genome Sciences (HGS), where he led the integration of HGS into GSK, and as Senior Vice President of Operations and Vice President of Manufacturing Operations at HGS. Prior to HGS, Mr. Simpson was Director of Manufacturing Sciences at Biogen. Earlier in his career, Mr. Simpson served in an overseas assignment at Novo-Nordisk Biochem in Denmark and in various senior development and engineer roles at Genentech, working on Herceptin® and Avastin®, among other roles. Mr. Simpson has an M.S. in surface and colloid science from Clarkson University and a B.S. in chemical engineering and chemistry from the Clarkson College of Technology.

ABOUT REGENXBIO Inc.

REGENXBIO is a leading clinical-stage biotechnology company seeking to improve lives through the curative potential of gene therapy. Since its founding in 2009, REGENXBIO has pioneered the development of AAV Therapeutics, an innovative class of gene therapy medicines. REGENXBIO is advancing a pipeline of AAV Therapeutics for retinal and rare diseases, including ABBV-RGX-314 for the treatment of wet AMD and diabetic retinopathy, being developed in collaboration with AbbVie, RGX-202 for the treatment of Duchenne and RGX-121 for the treatment of MPS II. Thousands of patients have been treated with REGENXBIO's AAV Therapeutic platform, including Novartis' ZOLGENSMA for children with spinal muscular atrophy. Designed to be one-time treatments, AAV Therapeutics 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 expectations and evaluations of its leadership and management team, 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, 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, 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, 2023, 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. 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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