

**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): October 1, 2026

REGENERON PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

**New York
(State or other jurisdiction of incorporation)**

**000-19034
(Commission
File Number)**

**13-3444607
(I.R.S. Employer
Identification No.)**

**777 Old Saw Mill River Road
Tarrytown, New York
(Address of principal executive offices)**

**10591-6707
(Zip Code)**

Registrant's telephone number, including area code: (914) 847-7000

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 – par value \$0.001 per share	REGN	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 1.01. Entry into a Material Definitive Agreement.

On October 1, 2026, Regeneron Pharmaceuticals, Inc., a New York corporation (“Regeneron” or the “Company”), Sanofi Biotechnology SAS, a *société par actions simplifiée* organized under the laws of France (“Sanofi Biotechnology”), and Sanofi, a *société anonyme* organized under the laws of France (“Sanofi Parent” and, with Sanofi Biotechnology, “Sanofi”), entered into the Sixth Amendment to the Amended and Restated License and Collaboration Agreement (the “Sixth Amendment”), which amends the Amended and Restated License and Collaboration Agreement, dated as of November 10, 2009 (as amended), by and between the Company, Sanofi Biotechnology (as successor in interest to Aventis Pharmaceuticals Inc.), and Sanofi Parent (the “Antibody LCA”). Pursuant to the Sixth Amendment, the parties have agreed to co-develop and co-commercialize four new long-acting, Regeneron-invented antibodies: (i) an antibody targeting interleukin-13 (“IL-13”), (ii) an antibody targeting interleukin-4 (“IL-4”), (iii) an antibody targeting IL-4 receptor alpha (IL-4R α), and (iv) a bispecific antibody targeting IL-4xIL-13 (each, a “New Licensed Product” and, collectively, the “New Licensed Products”). Regeneron will also have the option, on an asset-by-asset basis after completion of certain ongoing clinical trials, to include in the collaboration Sanofi’s Phase 2/3 asset lunsekimig, an investigational bispecific Nanobody[®] VHH therapy targeting thymic stromal lymphopoietin (TSLP) and IL-13, and another Sanofi early development product. In the event Regeneron exercises this option for any such product, it will reimburse Sanofi for certain development costs related to such product.

Pursuant to the Sixth Amendment, Sanofi will make an upfront payment to Regeneron of \$1.0 billion. In addition, the Sixth Amendment provides that Regeneron will be entitled to receive up to an additional \$7.0 billion of payments in the aggregate upon the achievement of certain development, regulatory, and commercial milestones with respect to the New Licensed Products. Global profits realized on the sale of New Licensed Products will be shared equally between Regeneron and Sanofi, as calculated under the Antibody LCA.

Pursuant to the Sixth Amendment, the parties have agreed on an initial global development plan for the IL-13 asset and are to agree on an initial global development plan for each of the other New Licensed Products. All development costs incurred with respect to all licensed products under the Antibody LCA, including the New Licensed Products, will be shared equally by the parties. In addition, development costs in excess of a budget cap for all New Licensed Products will be the responsibility of Regeneron, subject to certain rights to recoup such excess costs in future years. Regeneron will be the lead development party and the lead regulatory party prior to the filing of an application for marketing approval for each New Licensed Product. Regeneron will remain the lead regulatory party for applications for marketing approval and further commercialization in the United States, and Sanofi will be the lead regulatory party for applications for marketing approval and further commercialization outside the United States. Sanofi will be the lead party with respect to the commercialization of the New Licensed Products.

The foregoing description of the Sixth Amendment is qualified in its entirety by reference to the full text of the Sixth Amendment, a copy of which will be filed with the U.S. Securities and Exchange Commission as an exhibit to the Quarterly Report on Form 10-Q to be filed by the Company for the quarterly period ended September 30, 2026.

Item 2.02. Results of Operations and Financial Condition.

Regeneron currently expects that its financial results calculated in accordance with U.S. generally accepted accounting principles (“GAAP”) and its non-GAAP financial results for the third quarter 2026 will include an acquired in-process research and development (“IPR&D”) charge of approximately \$22 million on a pre-tax basis. The acquired IPR&D charge is expected to negatively impact each of GAAP and non-GAAP net income per diluted share for the third quarter 2026 by approximately \$0.18.

Acquired IPR&D charges may include IPR&D acquired in connection with asset acquisitions as well as up-front, opt-in, and development milestone payments and premiums paid on equity securities related to collaboration and licensing agreements. Regeneron does not forecast such acquired IPR&D charges due to the uncertainty of the future occurrence, magnitude, and timing of these transactions in any given period.

Regeneron’s results for the third quarter 2026 have not been finalized and are subject to Regeneron’s financial statement closing procedures. There can be no assurance that actual results will not differ from the preliminary (unaudited) estimates described herein.

The information included in this Item 2.02 shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, nor shall such information be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such a filing.

Item 8.01. Other Events.

In connection with the execution of the Sixth Amendment, Regeneron and Sanofi entered into a settlement agreement pursuant to which Regeneron agreed to dismiss its lawsuit concerning Sanofi's obligation to provide Regeneron with full access to material information relating to the commercialization of Dupixent[®] (dupilumab) and other products commercialized pursuant to the Antibody LCA, and Regeneron's audit rights under the Antibody LCA.

Note Regarding Forward-Looking Statements

This Current Report on Form 8-K (this "Report") includes forward-looking statements that involve risks and uncertainties relating to future events and the future performance of Regeneron, and actual events or results may differ materially from these forward-looking statements. Words such as "anticipate," "expect," "intend," "plan," "believe," "seek," "estimate," variations of such words, and similar expressions are intended to identify such forward-looking statements, although not all forward-looking statements contain these identifying words. These statements concern, and these risks and uncertainties include, among others, the Company's expectations with regard to the development and commercialization of the New Licensed Products and the amounts to be received pursuant to the Sixth Amendment, as well as the Company's expected acquired in-process research and development charge for the quarterly period ended September 30, 2026 and its expected impact on GAAP and non-GAAP net income per diluted share for this period, as discussed in this Report. A more complete description of these and other material risks can be found in Regeneron's filings with the U.S. Securities and Exchange Commission. Any forward-looking statements are made based on management's current beliefs and judgment, and the reader is cautioned not to rely on any forward-looking statements made by Regeneron. The Company does not undertake any obligation to update (publicly or otherwise) any forward-looking statement, including, without limitation, any financial projection or guidance, whether as a result of new information, future events, or otherwise.

Note Regarding Non-GAAP Financial Measures

This Report references non-GAAP net income per diluted share, which is a financial measure that is not calculated in accordance with U.S. Generally Accepted Accounting Principles ("GAAP"). This non-GAAP financial measure is computed by excluding certain non-cash and/or other items from the related GAAP financial measure. The Company also includes a non-GAAP adjustment for the estimated income tax effect of reconciling items. The Company makes such adjustments for items the Company does not view as useful in evaluating its operating performance. Management uses this and other non-GAAP measures for planning, budgeting, forecasting, assessing historical performance, and making financial and operational decisions, and also provides forecasts to investors on this basis. Additionally, such non-GAAP measures provide investors with an enhanced understanding of the financial performance of the Company's core business operations. However, there are limitations in the use of such non-GAAP financial measures as they exclude certain expenses that are recurring in nature. Furthermore, the Company's non-GAAP financial measures may not be comparable with non-GAAP information provided by other companies. Any non-GAAP financial measure presented by Regeneron should be considered supplemental to, and not a substitute for, measures of financial performance prepared in accordance with GAAP.

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.

Date: October 6, 2026

REGENERON PHARMACEUTICALS, INC.

By: /s/ Joseph J. LaRosa

Name: Joseph J. LaRosa

Title: Executive Vice President, General Counsel and Secretary
