

**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): January 9, 2023 (January 9, 2023)

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 Instructions 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	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 January 9, 2023, at the 41st Annual J.P. Morgan Healthcare Conference, Leonard S. Schleifer, M.D., Ph.D., President and Chief Executive Officer of Regeneron Pharmaceuticals, Inc. (“Regeneron” or the “Company”), and George D. Yancopoulos, M.D., Ph.D., President and Chief Scientific Officer of Regeneron, are providing a corporate update.

The presentation includes information regarding the Company’s preliminary (unaudited) U.S. net product sales of EYLEA® (afibercept) Injection of approximately \$6.26 billion for the full year 2022 (based on preliminary (unaudited) fourth quarter 2022 U.S. net product sales of EYLEA of approximately \$1.50 billion). With respect to the preliminary (unaudited) fourth quarter 2022 U.S. net product sales of EYLEA, the presentation further notes the following:

- Negatively impacted by a short-term shift to off-label use of compounded Avastin® (bevacizumab)
- Temporary closing in Q4 2022 of fund that provides patient co-pay assistance
- Most recent Q4 2022 market data suggests that shift to off-label Avastin is already beginning to reverse

The presentation also includes information regarding the Company’s current expectation that its financial results calculated in accordance with U.S. generally accepted accounting principles (“GAAP”) and its non-GAAP financial results for the fourth quarter 2022 and full year 2022 will include an acquired in-process research and development (“IPR&D”) charge of approximately \$30 million relating to an up-front payment in connection with the Company’s previously announced collaboration and licensing agreement with CytomX Therapeutics, Inc. This acquired IPR&D charge is expected to negatively impact each of GAAP and non-GAAP net income per diluted share for the fourth quarter 2022 by approximately \$0.21.

Regeneron's results for the fourth quarter and full year 2022 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.

Item 7.01. Regulation FD Disclosure.

The information set forth under Item 2.02 of this Current Report on Form 8-K is incorporated by reference herein. A copy of the presentation referenced in Item 2.02 is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference in this Item 7.01.

The information included in Item 2.02 and the information included or incorporated in Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, nor shall such information and exhibit 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 9.01. Financial Statements and Exhibits.

(d) Exhibits.

99.1	<u>Presentation by Leonard S. Schleifer, M.D., Ph.D., President and Chief Executive Officer of Regeneron Pharmaceuticals, Inc., and George D. Yancopoulos, M.D., Ph.D., President and Chief Scientific Officer of Regeneron Pharmaceuticals, Inc., at the 41st Annual J.P. Morgan Healthcare Conference.</u>
104	Cover Page Interactive Data File - the cover page XBRL tags are embedded within the Inline XBRL document.

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 Pharmaceuticals, Inc. ("Regeneron" or the "Company"), 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, Regeneron's expectations with respect to commercialization of its marketed products (including EYLEA® (aflibercept) Injection), competitive and other relevant developments affecting the market share of Regeneron's marketed products, and other relevant factors (whether within or without Regeneron's control) impacting the degree to which commercialization of Regeneron's marketed products is successful, as well as the impact of any of the foregoing on Regeneron's results of operations; Regeneron's expected acquired in-process research and development charge in the quarterly period ended December 31, 2022 and its expected impact on GAAP and non-GAAP net income per diluted share for the quarterly period then ended as discussed in this Report; and the potential for any license, collaboration, or supply agreement, including Regeneron's agreement with CytomX Therapeutics, Inc. referenced in this Report, to be cancelled or terminated. 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. Regeneron 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 includes 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 thereunto duly authorized.

REGENERON PHARMACEUTICALS, INC.

/s/ Joseph J. LaRosa
Joseph J. LaRosa
Executive Vice President, General Counsel and Secretary

Date: January 9, 2023
