

REGENERON PHARMACEUTICALS INC
Form 8-K
October 28, 2016

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 28, 2016**

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)

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

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

10591-6707
(Zip Code)

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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))
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Item 8.01. Other Events.

Regeneron Pharmaceuticals, Inc. (Regeneron or the Company) has been advised by its collaborator Sanofi that manufacturing deficiencies have been raised by the U.S. Food and Drug Administration (the FDA) during a routine Current Good Manufacturing Practice (CGMP) inspection of a Sanofi manufacturing facility that conducts fill and finish activities for certain products, including sarilumab, an antibody to the interleukin-6 receptor (IL-6R) being developed by Regeneron in collaboration with Sanofi. Sanofi has provided comprehensive responses to the FDA for the cited deficiencies and has been in discussions with the FDA. Given that the CGMP status of this facility is under review by the FDA, it is unclear whether or how this situation may impact the timing of the potential approval of sarilumab by the FDA. The sarilumab active pharmaceutical ingredient is manufactured by the Company at its Rensselaer, New York facility. The FDA has completed a pre-approval inspection of Regeneron's sarilumab manufacturing facility. No Form 483 was issued in connection with the inspection, which is the form used if the FDA investigators have observed any conditions that in their judgement may constitute a violation of the Food, Drug, and Cosmetic Act and related acts. The sarilumab Biologics License Application continues to be under active review by the FDA, with an expected action date of October 30, 2016.

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, the impact of the manufacturing deficiencies raised by the U.S. Food and Drug Administration (the FDA) and discussed in this Report on the potential FDA approval of sarilumab; the likelihood and timing of possible regulatory approval and commercial launch of sarilumab, including possible regulatory approval of sarilumab by the FDA; determinations by regulatory and administrative governmental authorities (such as the FDA) which may delay or restrict Regeneron's ability to continue to develop or commercialize sarilumab; unforeseen safety issues resulting from the administration of sarilumab in patients, including serious complications or side effects in connection with the use of sarilumab in clinical trials; ongoing regulatory obligations and oversight impacting Regeneron's research and clinical programs, including those relating to sarilumab; the potential for any license or collaboration agreement, including Regeneron's antibody license and collaboration agreement with Sanofi, to be cancelled or terminated without any further product success; and risks associated with intellectual property of other parties and pending or future litigation relating thereto. A more complete description of these and other material risks can be found in Regeneron's filings with the United States Securities and Exchange Commission, including its Form 10-K for the year ended December 31, 2015 and its Form 10-Q for the quarterly period ended June 30, 2016. 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 any forward-looking statement, whether as a result of new information, future events, or otherwise.

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.

By:	/s/ Joseph J. LaRosa
Name:	Joseph J. LaRosa
Title:	Senior Vice President, General Counsel and Secretary

Date: October 28, 2016