

# OPHTHOTECH CORP.

## **FORM 8-K** (Current report filing)

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Address	ONE PENN PLAZA 19TH FLOOR NEW YORK, NY 10119
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**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): **July 3, 2017**

**OPHTHOTECH CORPORATION**

(Exact Name of Registrant as Specified in Charter)

**Delaware**  
(State or Other Jurisdiction  
of Incorporation)

**001-36080**  
(Commission  
File Number)

**20-8185347**  
(I.R.S. Employer  
Identification No.)

**One Penn Plaza, 19th Floor**  
**New York, New York 10119**  
(Address of Principal Executive Offices) (Zip Code)

Registrant's telephone number, including area code: **(212) 845-8200**

(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))

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**Item 1.01 Entry into a Material Definitive Agreement**

On July 3, 2017, Ophthotech Corporation ("Ophthotech") and Novartis Pharma AG ("Novartis" and, collectively with Ophthotech, the "Parties") entered into a letter agreement with respect to the Licensing and Commercialization Agreement by and between the Parties dated May 19, 2014 (the "LCA"). Under the LCA, Ophthotech granted Novartis exclusive rights under specified patent rights, know-how and trademarks controlled by Ophthotech to develop and commercialize Fovista® (pegpleranib) products in all countries outside of the United States (the "Novartis Territory"). Pursuant to the letter agreement, the Parties have agreed to a process and timeline for evaluating data, once it becomes available, from Ophthotech's Phase 3 OPH1004 trial, and, depending on the results from the OPH1004 trial, determining a regulatory strategy in the European Union and continuing efforts under the LCA to develop and commercialize Fovista. The OPH1004 trial is evaluating the safety and efficacy of 1.5mg Fovista administered in combination with 2.0mg Eylea® (aflibercept) or 1.25mg Avastin® (bevacizumab) anti-VEGF therapy compared to Eylea or Avastin monotherapy for the treatment of wet age-related macular degeneration ("AMD"). Data from the OPH1004 trial are expected during the second half of 2017. The failure of two previously completed Phase 3 clinical trials conducted by Ophthotech, OPH1002 and OPH1003, to show any clinically meaningful visual benefit in adding 1.5mg of Fovista to a monthly regimen of 0.5mg of the anti-VEGF therapy Lucentis® (ranibizumab) and the recent failure of a competitor's Phase 2 trial investigating the combination of a PDGF inhibitor and a VEGF inhibitor, may be indicative of a low likelihood of success for OPH1004.

Pursuant to the letter agreement, the Parties have agreed to suspend their affirmative obligations under the LCA regarding development, manufacture and commercialization of Fovista products pending receipt of the OPH1004 data and the determination of a regulatory strategy. The letter agreement also provides

Novartis with a shorter notice period in the event Novartis determines to terminate the LCA in certain circumstances and provides for a process for the parties to determine the scope and funding for additional clinical trial(s), if any, required for regulatory approval of Fovista. If the Parties do not otherwise agree as to the funding for any additional clinical trial(s), each Party shall be required to fund fifty percent (50%) of the cost and expense of such clinical trial(s). Under the letter agreement, Ophthotech permanently waived its right to terminate the LCA under Section 11.06 thereof in the event that the Parties are prevented from materially progressing the development or commercialization of Fovista products for a specified period as a result of specified governmental actions. Ophthotech would have been liable to pay Novartis a substantial termination fee in the event that it had exercised its rights under Section 11.06. In addition, the letter agreement provides Novartis with a fully paid-up, royalty-free license to use data from the Lucentis monotherapy arms of Ophthotech's Phase 2b OPH1001 trial and Phase 3 OPH1002 and OPH1003 trials in the Novartis Territory in connection with the development, manufacturing and commercialization of Novartis-controlled anti-VEGF products. The Lucentis study data license shall continue until the fifth anniversary of the letter agreement or the date the LCA expires or terminates, whichever is later.

Ophthotech expects to file the letter agreement as an exhibit to its Quarterly Report on Form 10-Q for the quarter ending September 30, 2017. The foregoing description is qualified in its entirety by reference to the complete text of the letter agreement when filed.

## CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

Any statements in this Current Report on Form 8-K about Ophthotech's future expectations, plans and prospects constitute forward-looking statements for purposes of the safe harbor provisions under the Private Securities Litigation Reform Act of 1995. Forward-looking statements include any statements about Ophthotech's strategy, future operations and future expectations and plans and prospects for Ophthotech, and any other statements containing the words "anticipate," "believe," "estimate," "expect," "intend," "goal," "may," "might," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue," and similar expressions. In this Current Report, Ophthotech's forward looking statements include statements about the timing, progress and results of the Fovista® Phase 3 clinical trial in combination with Avastin or Eylea and the potential future development of Fovista. Such forward-looking statements involve substantial risks and uncertainties that could cause Ophthotech's clinical development programs, future results, performance or achievements to differ significantly from those expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, those related to the availability of data from clinical trials and other factors discussed in the "Risk Factors" section contained in the quarterly and annual reports that Ophthotech files with the Securities and Exchange Commission. Any forward-looking statements represent Ophthotech's views only as of the date of this Current Report. Ophthotech anticipates that subsequent events and developments will cause its views to change. While Ophthotech may elect to update these forward-looking statements at some point in the future, Ophthotech specifically disclaims any obligation to do so except as required by law.

SIGNATURE

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.

OPHTHOTECH CORPORATION

Date: July 10, 2017

By: /s/ Barbara A. Wood

Barbara A. Wood

Senior Vice President, General Counsel and Secretary