OPHTHOTECH CORP.

FORM 8-K
(Current report filing)

Filed 08/14/17 for the Period Ending 08/14/17

Address	ONE PENN PLAZA 19TH FLOOR NEW YORK, NY 10119
Telephone	212-845-8200
CIK	0001410939
Symbol	OPHT
SIC Code	2834 - Pharmaceutical Preparations
Industry	Biotechnology & Medical Research
Sector	Healthcare
Fiscal Year	12/31

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): **August 14, 2017**

OPHTHOTECH CORPORATION

(Exact Name of Company as Specified in Charter)

Delaware	**001-36080**	**20-8185347**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

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

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

Not Applicable
(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 (*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))

Item 8.01. Other Events.

On August 14, 2017, Ophthotech Corporation issued a press release announcing the results from its third Phase 3 clinical trial of Fovista® in wet age related macular degeneration. A copy of this press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits:

99.1 Press Release dated August 14, 2017.

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.

OPHTHOTECH CORPORATION

Date: August 14, 2017

By: /s/ Barbara A. Wood

Barbara A. Wood
Senior Vice President, General Counsel and Secretary

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release dated August 14, 2017

Ophthotech Announces Results from Third Phase 3 Trial of Fovista ® in Wet Age-Related Macular Degeneration

NEW YORK, August 14, 2017- - Ophthotech Corporation (Nasdaq: OPHT) today announced that the pre-specified primary endpoint of mean change in visual acuity at 12 months was not achieved in its Phase 3 clinical trial investigating the superiority of Fovista ® (pegpleranib) anti-PDGF therapy in combination with Eylea ® (aflibercept) or Avastin ® (bevacizumab) anti-VEGF therapy compared to Eylea ® or Avastin ® monotherapy for the treatment of wet age-related macular degeneration (AMD). The addition of 1.5mg of Fovista ® to an Eylea ® or Avastin ® regimen did not result in benefit as measured by the mean change in visual acuity at the 12-month time point .

“We express our sincere appreciation to the patients and clinical investigators and their staffs for their dedication to completing this third Phase 3 clinical trial of Fovista ® in combination with anti-VEGF therapy,” said Glenn P. Sblendorio, Chief Executive Officer and President of Ophthotech. “This outcome does not affect our strategy as the Company moves forward with multiple ongoing or planned clinical programs in orphan retinal diseases coupled with multiple ongoing or planned clinical trials in back of the eye indications.”

This clinical trial (also known as OPH1004) was an international, multicenter, randomized, double-masked, controlled Phase 3 study. In the OPH1004 trial, subjects receiving Fovista ® in combination with Eylea ® or Avastin ® therapy gained a mean of 9.42 letters of vision on the ETDRS standardized chart at 12 months, compared to a mean gain of 9.04 ETDRS letters in patients receiving Eylea ® or Avastin ® monotherapy, a resulting difference of 0.38 ETDRS letters (p=0.74). The results for the pre-specified primary efficacy analysis were not statistically significant. In addition, the Company did not observe any clinically meaningful visual benefit in the pre-specified secondary endpoints when Fovista ® was added to Eylea ® or Avastin ® regimen. Based on these data, the Company has decided to stop treating patients who are in the second year of the OPH1004 study. The Phase 3 trial enrolled approximately 640 patients with wet AMD.

Based on a preliminary analysis of the safety data from the trial, Fovista ® combination therapy and Eylea ® or Avastin ® monotherapy were generally well tolerated after one year of treatment. The ocular adverse events more frequently reported in the Fovista ® combination therapy group compared to the Eylea ® or Avastin ® monotherapy group were mainly related to the injection procedure. The safety profile of Fovista ® combination therapy remains unchanged from prior trials.

In December 2016, Ophthotech announced that the pre-specified primary endpoint of mean change in visual acuity at 12 months was not achieved in its two pivotal Phase 3 clinical trials (also known as OPH1002 and OPH1003) investigating the superiority of Fovista ® therapy in combination with Lucentis ® (ranibizumab) anti-VEGF therapy compared to Lucentis ® monotherapy for the treatment of wet AMD. The addition of Fovista ® to a monthly Lucentis ® regimen did not result in benefit as measured by the mean change in visual acuity at the 12-month time point .

About Ophthotech Corporation

Ophthotech is a biopharmaceutical company specializing in the development of novel therapeutics for diseases of the eye. For more information, please visit www.ophthotech.com .

Forward-looking Statements

Any statements in this press release 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 press release, Ophthotech's forward looking statements include statements about the implementation of its strategic plan, Ophthotech's projected use of cash and cash balances, the timing, progress and results of clinical trials and other development activities, and the potential utility or commercialization of any of Ophthotech's product candidates. 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 initiation and conduct of clinical trials, availability of data from clinical trials, expectations for regulatory matters 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 press release. 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.

OPHT-G

Investors
Ophthotech Corporation
Kathy Galante , 212-845-8231
Vice President, Investor Relations and Corporate Communications
kathy.galante@ophthotech.com
or
Media
Alex Van Rees , 973-442-1555 ext. 111
SmithSolve LLC on behalf of Ophthotech Corporation
alex.vanrees@smithsolve.com