Ophthotech Corp.
Form 8-K
April 11, 2019

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): April 11, 2019

OPHTHOTECH CORPORATION
(Exact Name of Registrant as Specified in its Charter)

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

One Penn Plaza, 35th Floor
New York, NY 10119
(Address of Principal Executive Offices) (Zip Code)

Registrant'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):

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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 o
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. o

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Item 1.01. Entry into a Material Definitive Agreement.

Exclusive License Agreement with Know-How

On April 11, 2019, Ophthotech Corporation ("Ophthotech") entered into an Exclusive License Agreement with Know-How (the "License Agreement") with the Trustees of the University of Pennsylvania ("Penn") and the University of Florida Research Foundation, Incorporated ("UFRF", and together with Penn, the "Licensors"). Ophthotech entered into the License Agreement by exercising its exclusive option rights under an option agreement that Ophthotech previously entered into with the Licensors in October 2018 (the "Option Agreement"). Under the License Agreement, the Licensors granted Ophthotech a worldwide, exclusive license under specified patent rights and specified know-how and a worldwide, non-exclusive license under other specified know-how to research, develop, manufacture and commercialize certain adeno-associated virus gene therapy products for the treatment of Best vitelliform macular dystrophy and other diseases associated with mutations in the Best1 gene ("bestrophinopathies").

Ophthotech has agreed to use commercially reasonable efforts to pursue an agreed-upon development plan with the intent to develop a licensed product for sale within at least the United States and two major European countries and, subject to obtaining marketing approval, to commercialize such product in at least the United States and two major European countries. In addition, Ophthotech has agreed to meet specified development and regulatory milestones with respect to a licensed product by specified dates, as the same may be extended under the terms of the agreement.

Ophthotech may grant sublicenses of the licensed patent rights and know-how without the consent of the Licensors to certain affiliates and to biopharmaceutical companies that have a minimum market capitalization at the time such sublicense is granted, and may otherwise grant sublicenses to the licensed patent rights and know-how with the consent of the Licensors, not to be unreasonably withheld.

Financial Terms

Ophthotech agreed to pay Penn, on behalf of the Licensors, a $200,000 upfront license issuance fee within 30 days of execution of the License Agreement, and to pay UFRF accrued patent prosecution expenses of approximately $18,000. Ophthotech has also agreed to pay Penn, on behalf of the Licensors, an annual license maintenance fee in the low double-digit thousands of dollars, which fee will be payable on an annual basis until the first commercial sale of a licensed product. In addition, Ophthotech has agreed to pay Penn, on behalf of the Licensors, a one-time patent grant fee in the low triple-digit thousands of dollars, upon the issuance of a U.S. patent that claims inventions disclosed in the licensed patent rights or know-how or inventions generated under certain related sponsored research agreements with Penn or UFRF, and that is exclusively licensed to Ophthotech. Furthermore, Ophthotech has agreed to reimburse Penn and UFRF for the costs and expenses of patent prosecution and maintenance related to the licensed patent rights.

Ophthotech has further agreed to pay Penn, on behalf of the Licensors, up to an aggregate of $15.7 million if Ophthotech achieves specified clinical, marketing approval and reimbursement approval milestones with respect to one licensed product, and up to an aggregate of an additional $3.1 million if Ophthotech achieves these same milestones with respect to a different licensed product. In addition, Ophthotech has agreed to pay Penn, on behalf of the Licensors, up to an aggregate of $48.0 million if Ophthotech achieves specified commercial sales milestones with respect to one licensed product, and up to an aggregate of an additional $9.6 million if Ophthotech achieves these same milestones with respect to a different licensed product.

Ophthotech is also obligated to pay Penn, on behalf of the Licensors, royalties at a low single-digit percentage of net sales of licensed products. Such royalties are subject to customary deductions, credits, and reductions for lack of

patent coverage and loss of regulatory exclusivity. In addition, such royalties with respect to any licensed product in any country may be offset by a specified portion of any royalty payments actually paid by Ophthotech with respect to such licensed product in such country under third-party licenses to patent rights or other intellectual property rights that are necessary to research, develop, manufacture and commercialize the licensed product in such country. Ophthotech's obligation to pay royalties under the License Agreement will continue on a licensed product-by-licensed product and country-by-country basis until the latest of: (a) the expiration of the last-to-expire licensed patent rights covering the sale of the applicable licensed product in the country of sale, (b) the expiration of regulatory exclusivity covering the applicable licensed product in the country of sale and (c) 10 years from the first commercial sale of the applicable licensed product in the country of sale. Beginning on the earlier of (i) the calendar year following the first commercial sale of a licensed product and (ii) calendar year 2032, Ophthotech is also obligated to pay certain minimum royalties, not to exceed an amount in the mid tens of thousands of dollars on an annual basis, which minimum royalties are creditable against Ophthotech's royalty obligation with respect to net sales of licensed products due in

the year the minimum royalty is paid.

If Ophthotech or any of its affiliates sublicenses any of the licensed patent rights to a third party, Ophthotech will be obligated to pay Penn, on behalf of the Licensors, a high single-digit to a mid teen percentage of the consideration received in exchange for such sublicense, with the applicable percentage based upon the stage of development of the sublicensed product at the time Ophthotech or the applicable affiliate enters into the sublicense.

If Ophthotech receives a rare pediatric disease priority review voucher (a “priority review voucher”) from the U.S. Food and Drug Administration in connection with obtaining marketing approval for a licensed product and Ophthotech subsequently uses such priority review voucher in connection with a different product candidate outside the scope of the License Agreement, Ophthotech will be obligated to pay Penn, on behalf of the Licensors, aggregate payments in the low double-digit millions of dollars based on certain approval and commercial sales milestones with respect to such other product candidate. In addition, if Ophthotech sells such a priority review voucher to a third party, Ophthotech will be obligated to pay Penn, on behalf of the Licensors, a high single-digit percentage of any consideration received from such third party in connection with such sale.

Term and Termination

The License Agreement, unless earlier terminated by Ophthotech or the Licensors, will expire upon the expiration of Ophthotech’s obligation to pay royalties to Penn, on behalf of the Licensors, on net sales of licensed products. Before the effectiveness of an Investigational New Drug Application ("IND") for a licensed product, Ophthotech may terminate the License Agreement with respect to such licensed product or in its entirety, at any time for any reason upon prior written notice to the Licensors. Following the effectiveness of an IND for a licensed product, Ophthotech may terminate the License Agreement with respect to such licensed product by providing Penn prior written notice and a certification that it is ceasing all use, research and development and commercialization of such licensed product, subject to certain limited exceptions. Ophthotech may also terminate the License Agreement if Penn or UFRF materially breaches the License Agreement and does not cure such breach within a specified cure period.

The Licensors may terminate the License Agreement if Ophthotech materially breaches the License Agreement and does not cure such breach within a specified cure period, if Ophthotech experiences a specified insolvency event, if Ophthotech ceases to carry on the entirety of its business related to the licensed patent rights, if Ophthotech ceases for more than four consecutive quarters to make any payment of earned royalties on net sales of licensed products following the commencement of commercialization thereof, unless such cessation is based on safety concerns that Ophthotech is actively attempting to address, or if Ophthotech, any of its affiliates or any of its sublicensees challenges or assists a third party in challenging the validity, scope, patentability, and/or enforceability of the licensed patent rights. If Ophthotech materially breaches certain diligence obligations under the License Agreement with respect to only one licensed product, then the Licensors may only terminate Ophthotech’s rights and licenses under the License Agreement for such licensed product, but not for other licensed products.

Following any termination of the License Agreement prior to expiration of the term of the License Agreement, all rights to the licensed patent rights and know-how that the Licensors granted to Ophthotech will revert to the Licensors.

Other Provisions

The License Agreement contains patent prosecution and maintenance, indemnification and dispute resolution provisions that are customary for agreements of this kind.

Master Sponsored Research Agreement

On October 30, 2018, in connection with the Option Agreement, Ophthotech entered into a Master Sponsored Research Agreement (the "Master SRA") with Penn, which is separate from another sponsored research agreement Ophthotech entered into with Penn in June 2018 for a different gene therapy program. Under the Master SRA, Penn agreed to perform, on a project basis, certain sponsored research pertaining to the subject matter of the Option Agreement and License Agreement, and to provide the results of such research to Ophthotech. The scope of each project and certain associated terms, including financial terms, are specified in a statement of work for each project.

Under the Master SRA, Penn has granted Ophthotech an exclusive first option to obtain, for no additional consideration and pursuant to the terms of the License Agreement, an exclusive license to any patents or patent applications resulting from the sponsored research that is fully funded by Ophthotech. In addition, under the Master SRA, Penn has granted

Ophthotech an exclusive first option to negotiate to acquire an exclusive license, on commercially reasonable terms, to any patents or patent applications resulting from the sponsored research that is not fully funded by Ophthotech.

The initial term of the Master SRA expires on October 30, 2021, provided that in the event of a termination of the Master SRA, any statements of work in effect at the time of such termination shall continue in effect, subject to the terms of the Master SRA, until expiration or termination of the applicable statement of work. Either party may terminate the Master SRA or a statement of work if the other party breaches any of the terms or conditions of the Master SRA or statement of work, as applicable, and does not cure such breach within a specified cure period. In addition, either party may terminate an applicable statement of work if the services of the applicable principal investigator are no longer available to Penn and an acceptable substitute is not appointed within an agreed-upon period.

The Master SRA contains indemnification and dispute resolution provisions that are customary for agreements of this kind.

Ophthotech and Penn have entered into a series of statements of work under the Master SRA pursuant to which Penn is conducting additional preclinical studies of a licensed product under the License Agreement, as well as natural history studies of patients with bestrophinopathies. Ophthotech expects to enter into additional statements of work under the Master SRA for additional preclinical studies. The total amount of funding for the sponsored research covered by these statements of work that Ophthotech has committed to date and expects to commit to is in the low single-digit millions of dollars.

Incorporation by Reference

Ophthotech expects to file the License Agreement and the Master SRA as exhibits to its Quarterly Report on Form 10-Q for the quarter ending June 30, 2019, and intends to seek confidential treatment for certain terms and provisions of the License Agreement and Master SRA. The foregoing descriptions of the License Agreement and Master SRA are qualified in their entirety by reference to the complete text of the License Agreement and Master SRA when filed.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Form 8-K contains forward-looking statements of Ophthotech that involve substantial risks and uncertainties. Any statements in this 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,” “w
“continue,” and similar expressions. In this Form 8-K, Ophthotech’s forward looking statements include statements about the potential future performance under the License Agreement and the Master SRA and potential payments thereunder, the implementation of its strategic plan, Ophthotech’s projected use of cash and cash balances, and the timing, progress and results of preclinical studies and other research and development activities. Such forward-looking statements involve substantial risks and uncertainties that could cause Ophthotech’s preclinical and 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 the conduct and design of research and development programs and preclinical studies, availability of data from these programs, reliance on university collaborators and other third parties, expectations for regulatory matters, need for additional financing and negotiation and consummation of in-license and/or acquisition transactions 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 Form 8-K. 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.

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: April 11, 2019 By: /s/ David F. Carroll
David F. Carroll
Senior Vice President, Chief Financial Officer and Treasurer