

Ophthotech Corp.
Form 8-K
June 07, 2018

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): June 6, 2018

OPHTHOTECH CORPORATION

(Exact Name of Registrant as Specified in its Charter)

Delaware 001-36080 20-8185347
(State or Other Jurisdiction (Commission (IRS Employer
of Incorporation) File Number) 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):

- 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))

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 1.01. Entry into a Material Definitive Agreement.

Exclusive License Agreement with Know-How

On June 6, 2018, Ophthotech Corporation (“Ophthotech”) entered into an Exclusive License Agreement with Know-How (the “License Agreement”) with the University of Florida Research Foundation, Incorporated (“UFRF”) and the Trustees of the University of Pennsylvania (“Penn”, and together with UFRF, the “Licensors”). Under the License Agreement, the Licensors granted Ophthotech a worldwide, exclusive license under specified patent rights and a worldwide, non-exclusive license under specified know-how, including specified pre-clinical data, to manufacture, develop and commercialize certain adeno-associated virus (or “AAV”) gene therapy products for the treatment of rhodopsin-mediated diseases. Included in the License Agreement are patent rights covering a novel AAV gene therapy product candidate intended to treat rhodopsin-mediated autosomal dominant retinitis pigmentosa (the “RHO-adRP Licensed Product”).

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 a licensed product in at least the United States and two major European countries. In addition, Ophthotech has agreed to meet specified development and commercial 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 UFRF, on behalf of the Licensors, a \$500,000 upfront license issuance fee within thirty (30) days of execution of the License Agreement, as well as accrued patent prosecution expenses of approximately \$30,000. Ophthotech has also agreed to pay UFRF, 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 reimburse UFRF, on behalf of the Licensors, for the costs and expenses of patent prosecution and maintenance related to the licensed patent rights.

Ophthotech has further agreed to pay UFRF, on behalf of the Licensors, up to an aggregate of \$23.5 million if Ophthotech achieves specified clinical, marketing approval and reimbursement approval milestones with respect to a licensed product. In addition, Ophthotech has agreed to pay UFRF, on behalf of the Licensors, up to an aggregate of an additional \$70 million if Ophthotech achieves specified commercial sales milestones with respect to a licensed product.

Ophthotech is also obligated to pay UFRF, 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 other 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 manufacture, develop and commercialize the licensed product in such country. Ophthotech’s obligation to pay such royalties 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 a licensed product in the country of sale, (b) the expiration of regulatory exclusivity covering a licensed product in the

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country of sale and (c) ten (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) the first business day of 2031, Ophthotech is also obligated to pay certain minimum royalties, not to exceed an amount in the low hundreds of thousands of dollars on an annual basis, which minimum

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m 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 its affiliate sublicenses any of the licensed patent rights to a third party, Ophthotech will be obligated to pay UFRF, on behalf of the Licensors, a low double-digit 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, Ophthotech will be obligated to pay UFRF, 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. In addition, if Ophthotech sells such a priority review voucher to a third party, Ophthotech will be obligated to pay UFRF, on behalf of the Licensors, a low double-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 UFRF, on behalf of the Licensors, on net sales of licensed products. Ophthotech may terminate the License Agreement at any time for any reason upon prior written notice to the Licensors. 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 or its affiliate challenges or assists a third party in challenging the validity, scope, patentability, and/or enforceability of the licensed patent rights.

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.

Indemnification and Dispute Resolution

The License Agreement contains indemnification and dispute resolution provisions that are customary for agreements of its kind.

Master Sponsored Research Agreement

On June 6, 2018, Ophthotech entered into a Master Sponsored Research Agreement (the "Master SRA") with Penn. Under the Master SRA, Penn has agreed to perform, on a project basis, certain sponsored research and to provide the results of such research to Ophthotech. The scope of each project and certain associated terms, including financial terms, will be 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 and that relate to the patent rights licensed under the License Agreement. 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 do not relate to the patent rights licensed under the License Agreement.

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The initial term of the Master SRA is three (3) years from June 6, 2018, 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 its kind.

In connection with entry into the Master SRA, Ophthotech and Penn plan to enter into a series of statements of work pursuant to which Penn will conduct additional preclinical studies for the RHO-adRP Licensed Product, as well as a natural history study for autosomal dominant retinitis pigmentosa. The total amount of funding for the sponsored research covered by these statements of work that Ophthotech 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, 2018, and intends to seek confidential treatment for certain terms and provisions of the License Agreement and the Master SRA. The foregoing descriptions of the License Agreement and the Master SRA are qualified in their entirety by reference to the complete text of the License Agreement and the Master SRA 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," "p", "would," "could," "should," "continue," and similar expressions. In this Current Report on Form 8-K, Ophthotech's forward-looking statements include statements about the timing, progress and results of clinical trials and other research and development activities, and the potential for its business development strategy, including any potential in-license or acquisition opportunities. 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 the conduct and design of research programs and clinical trials, availability of data from these programs, expectations for manufacturing activities and 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 Current Report on 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.

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: June 7, 2018 By: /s/ David F. Carroll

David F. Carroll

Senior Vice President, Chief Financial Officer and Treasurer