

REXAHN PHARMACEUTICALS, INC.

Form 8-K

August 21, 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): August 16, 2018

Rexahn Pharmaceuticals, Inc.

(Exact Name of Registrant as Specified in its Charter)

DELAWARE

001-34079

11-3516358

(State or other jurisdiction of Incorporation) (Commission File Number) (I.R.S. Employer Identification No.)

15245 Shady Grove Road, Suite 455

20850

Rockville, MD

(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: (240) 268-5300

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))

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.

Section 1 – Registrant’s Business and Operations

Item 1.01 Entry into a Material Definitive Agreement.

On August 16, 2018, Rexahn Pharmaceuticals, Inc. (“Rexahn”) entered into a clinical trial collaboration and supply agreement (the “Collaboration Agreement”) with Merck Sharp & Dohme B.V. (“Merck”) to conduct a Phase 2 clinical trial to evaluate the safety and efficacy of the combination of RX-5902 with Merck’s anti-PD 1 therapy, KEYTRUDA® (pembrolizumab), in patients with metastatic triple negative breast cancer (TNBC). Under the terms of the Collaboration Agreement, Rexahn will sponsor the clinical trial and Merck will supply Rexahn with KEYTRUDA for use in the trial at no cost to Rexahn. The Collaboration Agreement provides that Rexahn and Merck will jointly own clinical data generated from the clinical trial.

The Collaboration Agreement expires on delivery of the final study report by Rexahn to Merck concerning the results of the clinical trial, unless earlier terminated by either party in the event of the other party’s uncured material breach or if there are certain safety concerns, regulatory action prevents conduct of the clinical trial or supply of one or both of RX-5902 or KEYTRUDA, or if either Party withdraws regulatory approval for or discontinues development of its compound.

The foregoing description of the Collaboration Agreement is a summary, is not complete and is qualified in its entirety by reference to the full text of the actual agreement, which will be filed as an exhibit to Rexahn’s Quarterly Report on Form 10-Q for the quarter ending September 30, 2018.

Section 7 – Regulation FD

Item 7.01 Regulation FD Disclosure.

Rexahn issued a press release in connection with the announcement of the Collaboration Agreement providing additional information about the clinical trial, and a copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K. Rexahn anticipates enrolling the first patient in the trial in early 2019, with the trial expected to take approximately two years at a cost to Rexahn of approximately \$8.5 million.

Safe Harbor

To the extent any statements made in this current report deal with information that is not historical, these are forward-looking statements under the Private Securities Litigation Reform Act of 1995. Such statements include, but are not limited to, statements about Rexahn’s plans, objectives, expectations and intentions with respect to the Collaboration Agreement, the collaboration and related study, the combination of RX-5902 and Keytruda, the path of clinical trials and development activities, and other statements identified by words such as “will,” “potential,” “could,” “can,” “believe,” “intends,” “continue,” “plans,” “expects,” “anticipates,” “estimates,” “may,” other words of similar meaning or the use of future dates. Forward-looking statements by their nature address matters that are, to different degrees, uncertain. Uncertainties and risks may cause Rexahn’s actual results to be materially different than those expressed in or implied by Rexahn’s forward-looking statements. For Rexahn, particular uncertainties and risks include, among others, understandings and beliefs regarding the role of certain biological mechanisms and processes in cancer; drug candidates being in early stages of development, including clinical development; the costs and timelines associated with clinical development; the ability to transition from our initial focus on developing drug candidates for orphan indications to candidates for more highly prevalent indications; and the expecting timing of results from our clinical trials. More detailed information on these and additional factors that could affect Rexahn’s actual results are described in other Rexahn filings with the Securities and Exchange Commission, including its most recent annual report on Form 10-K and subsequent quarterly reports on Form 10-Q. All forward-looking statements in this current report speak only as of the date of this current report. Rexahn undertakes no obligation to update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

Section 9 – Financial Statements and Exhibits

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
<u>99.1</u>	Rexahn Pharmaceuticals, Inc. press release dated 21, 2018, announcing collaboration with Merck Sharp & Dohme B.V.

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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.

REXAHN PHARMACEUTICALS, INC.

Date: August 21, 2018 /s/ Douglas J. Swirsky
Douglas J. Swirsky
President and Chief Financial Officer