

REXAHN PHARMACEUTICALS, INC.

Form 8-K

February 08, 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): February 5, 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 1.02 Termination of a Material Definitive Agreement.

On February 5, 2018, Rexahn Pharmaceuticals, Inc., a Delaware corporation (the “Company”), and NEXT BT Co. Ltd., a Korean company (“NEXT BT”), the successor in interest to Rexgene Biotech Co., Ltd., a Korean company (“Rexgene”), terminated that certain Research Collaboration Agreement on RX-0201 Clinical Development, dated as of February 6, 2003, by and between the Company and Rexgene (the “Terminated Agreement”).

Pursuant to the Terminated Agreement, Rexgene had agreed to assist the Company with the research, development and clinical trials necessary for the registration in Asia of RX-0201 (Archexin), the Company’s inhibitor of the protein kinase Akt-1 in development for the treatment of cancer. Under the Terminated Agreement, the Company had granted Rexgene an exclusive license, with the right to sublicense, to make, have made, use, sell and import RX-0201 in Asia.

In connection with the termination of the Terminated Agreement, the Company agreed to pay to NEXT BT (i) a royalty in the low single digits based on sales of RX-0201 in Asia and (ii) a percentage of certain other payments received by the Company in the event the Company licenses its rights to research, develop or commercialize RX-0201 in Asia or sells or otherwise disposes of substantially all of its rights to RX-0201 or its nano-liposomal formulation, up to an aggregate cap on payments to NEXT BT of \$5,000,000.

The Terminated Agreement was terminated in order to allow the Company to transition to a new development strategy for RX-0201 and its other drug candidates and to enter into the agreement described in Item 8.01 below.

Section 7 – Regulation FD

Item 7.01 Regulation FD Disclosure.

Furnished as Exhibit 99.1 to this Current Report on Form 8-K is a press release issued by the Company on February 8, 2018, including information described in Item 8.01 below.

Section 8 – Other Events

Item 8.01 Other Events.

On February 8, 2018, the Company entered into a Research Collaboration and License Agreement (the “Haichang Agreement”) with Zhejiang Haichang Biotechnology Co., Ltd., a Chinese company (“Haichang”), to develop RX-0201 for the treatment of hepatic cell carcinoma (“HCC”).

Under the terms of the Haichang Agreement, Haichang will develop a nano-liposomal formulation of RX-0201 using its proprietary QTzome™ technology (the “Product”) and will conduct certain pre-clinical and clinical activities through completion of a Phase IIa proof-of-concept clinical trial for the treatment of HCC in China. Any clinical trials conducted by Haichang will be designed to meet both U.S. and Chinese regulatory requirements. Haichang has agreed to fund all research and development activities through completion of the Phase IIa clinical trial up to an aggregate amount of \$10,000,000.

As between the parties, the Company will own all rights in any inventions arising as a result of the parties’ activities under the agreement that relate to RX-0201 or the Product. Haichang has granted to the Company an exclusive, perpetual, worldwide license under Haichang’s intellectual property to research, develop, commercialize and manufacture the Product. During the term of the Haichang Agreement, the Company may not develop RX-0201 for the treatment of HCC or in a manner that would otherwise compete with the Product except as provided under the Haichang Agreement.

Upon completion of the Phase IIa proof-of-concept clinical trial, Haichang will have a right of first negotiation to obtain an exclusive license to further develop and commercialize the Product in China for the treatment of HCC. If Haichang exercises its right of first negotiation, the parties will negotiate a license agreement pursuant to which Haichang will pay customary license fees, milestone payments and royalties to the Company. If Haichang does not exercise its right of first negotiation, then Haichang will use commercially reasonable efforts to seek one or more sublicensees for the further development, commercialization and manufacture of the Product in China for the treatment of HCC. The Company has agreed to use commercially reasonable efforts to seek one or more sublicensees for the development, commercialization and manufacture of the Product outside of China for the treatment of HCC. The parties have agreed to split downstream licensing fees and royalties that are paid by third party licensees in connection with the further development and commercialization of the Product for the treatment of HCC, with the Company receiving 30% of revenues from downstream licensees in mainland China, Hong Kong, Macau and Taiwan and 70% of revenues from licensees in the rest of the world. The ratios are subject to adjustment in the future in certain circumstances, including where Haichang's expenditures on certain qualified expenses exceed \$10 million, where Rexahn takes over development obligations from Haichang, or if Haichang exercises its right of first negotiation and the parties successfully negotiate an exclusive license agreement.

In connection with the execution of the agreement with Haichang, the Company plans to cease internal development of RX-0201 for the treatment of metastatic renal cell carcinoma and to wind down internally funded programs related to RX-0201 in order to focus its own resources on progressing RX-3117 and RX-5902 (Supinixin) through Phase II clinical development.

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 February 8, 2018, announcing collaboration with Zhejiang Haichang Biotechnology Co., Ltd. for the development of RX-0201. |

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: February 8, 2018 /s/ Peter D. Suzdak
Peter D. Suzdak
Chief Executive Officer