

REXAHN PHARMACEUTICALS, INC.

FORM 8-K (Current report filing)

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**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

(State or other jurisdiction of Incorporation)

001-34079

(Commission File Number)

11-3516358

(I.R.S. Employer Identification No.)

**15245 Shady Grove Road, Suite 455
Rockville, MD**

(Address of principal executive offices)

20850

(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>
99.1	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

Rexahn Pharmaceuticals Announces Collaboration with Zhejiang Haichang Biotechnology Co., Ltd. for the Development of RX-0201 (Archexin®) for the treatment of Hepatocellular Carcinoma

Haichang to fund development through completion of Phase IIa Proof-of-Concept Clinical Trial

Clinical trials will be designed to meet both the US and China FDA requirements

Rockville, MD, February 8, 2018 – Rexahn Pharmaceuticals, Inc. (NYSE American: RNN), a clinical stage biopharmaceutical company developing innovative, targeted therapeutics for the treatment of cancer, today announced that it has entered into a collaboration and license agreement with Zhejiang Haichang Biotechnology Co., Ltd. (Haichang), to develop RX-0201 (Archexin®) for the treatment of hepatocellular carcinoma (HCC), the most common form of liver cancer.

Under the terms of the agreement, Haichang will develop a nano-liposomal formulation of RX-0201 using its proprietary QTsome™ technology and conduct certain pre-clinical and clinical activities through completion of a Phase IIa proof-of-concept clinical trial for the treatment of HCC. Any clinical trials conducted by Haichang will be designed to meet both U.S. and Chinese regulatory requirements. Haichang will fund all research and development activities through completion of the Phase IIa clinical trial.

The parties will share in an agreed ratio downstream licensing fees and royalties paid by third parties in connection with the further development and commercialization of the nano-liposomal formulation of RX-0201 for the treatment of HCC.

“We are delighted to enter into this collaboration to take RX-0201 forward in hepatocellular carcinoma,” said Peter D. Suzdak, Ph.D., Chief Executive Officer of Rexahn. “We are impressed with Haichang’s QTsome™ technology. It has the potential to target RX-0201 to the liver and to promote uptake into cancer cells to enhance efficacy. We are also very pleased to have non-dilutive funding to take the program through Phase IIa proof-of-concept studies.”

“The incidence of liver cancer is growing worldwide, and especially in Asia,” said Dr. Ben Zhao, Chief Executive Officer of Haichang. “There are very few treatment options for patients and unfortunately, the prognosis for patients with advanced disease is very poor. Akt-1 is an important signaling protein in liver cancer and we are excited about the potential for RX-0201. It is an ideal candidate for our liposomal technology and we look forward to advancing the development of RX-0201 in collaboration with Rexahn.”

”While we continue to be encouraged by the safety and efficacy of RX-0201, the treatment landscape for metastatic renal cell carcinoma (mRCC) has significantly changed over the past two years with the approval of three new therapies by the FDA. This will limit the commercial viability of RX-0201 in mRCC. For this reason, Rexahn has decided to stop the development of RX-0201 for mRCC,” said Lisa Nolan, Ph.D., Chief Business Officer for Rexahn. “The Haichang collaboration allows Rexahn to capitalize on the clinical data already generated in Phase I and Phase II clinical studies and change the focus of the RX-0201 program to hepatocellular carcinoma using non-dilutive funding to take the program through Phase IIa proof-of-concept studies while retaining the potential for future milestones/royalties for the product. This will also allow Rexahn to focus its own resources on progressing RX-3117 and Supinixin™ (RX-5902) through Phase II clinical development.”

In connection with the agreement with Haichang, Rexahn plans to discontinue the internally funded programs of Archexin and will cease enrollment in the current Phase IIa clinical study of Archexin in metastatic renal cell carcinoma (mRCC). Patients currently enrolled in the trial will continue to be followed

About Hepatocellular Carcinoma

Hepatocellular carcinoma (liver cancer) is the sixth most common type of cancer worldwide and the second-leading cause of cancer-related deaths. Each year approximately 780,000 new cases of liver cancer are diagnosed worldwide and over 740,000 people will die of the disease. ¹ The incidence of liver cancer in the U.S. has more than tripled since 1980. ² It is estimated that there will be approximately 41,000 new cases of liver and intrahepatic bile duct cancer and 29,000 deaths from these diseases in the U.S. in 2017. ³ The majority of these cases are caused by Hepatitis B virus (HBV) or Hepatitis C virus (HCV) infections. The increasing prevalence of metabolic syndrome and nonalcoholic steatohepatitis (NASH) is expected to contribute to increased rates of liver cancer in the U.S. in the foreseeable future. ⁴ Outside the U.S., the incidence of liver cancer is approximately 40,000 in Europe and 36,000 Japan. Incidence is particularly high in China due to the prevalence of HBV and HCV infections and the incidence is estimated at 260,000 in 2017 .

Treatment options are limited for patients with advanced liver cancer , which account for approximately 30% of newly diagnosed patients. Nexavar® (sorafenib) is approved for first line treatment. Supportive care is the standard of care for second line treatment. Opdivo® (nivolumab) has recently been approved for patients who have disease progression after treatment with Nexavar, but only 14% of patients respond to treatment. Overall, the prognosis for patients with advanced liver cancer is typically very poor.

About Zhejiang Haichang Biotechnology Co. Ltd

Zhejiang Haichang Biotechnology Co. , Ltd . is a privately owned specialized biotechnology company headquartered in Hangzhou, China. The company is focused on the development and manufacture of complex intravenous pharmaceutical products including liposome and microsphere products, primarily for cancer treatment. The company has strategic collaborations with Sinopharm and and its liposomal doxorubicin product (Libaoduo®) is marketed by Shanghai Fudan-Zhangjiang Bio-pharm Co., Ltd in China.

Haichang's QTsome™ technology is a patented gene delivery technology that was co-developed with Professor Robert Lee at the Ohio State University. The technology is designed to enhance cellular uptake of large molecules such as oligonucleotides (antisense, siRNA and miRNA) and to target certain organs such as the liver where nanoparticles accumulate.

About RX-0201 (Archexin®)

RX-0201 is an antisense oligonucleotide compound that is complementary to Akt-1 mRNA and highly selective for inhibiting its mRNA expression, which leads to reduced production of Akt-1. Akt-1 is a protein that is associated with cancer cell growth and proliferation and the development of resistance to certain anticancer agents. Akt-1 is over-expressed in multiple forms of cancer including hepatic, renal, breast, colorectal, gastric, pancreatic, prostate and melanoma. In a Phase I clinical trial in patients with advanced cancers, RX-0201 appears to be safe and well tolerated with minimal side effects. The dose-limiting adverse event in such clinical trial was Grade 3 fatigue with no significant hematological abnormalities observed.

About Rexahn Pharmaceuticals, Inc.

Rexahn Pharmaceuticals, Inc. (NYSE American: RNN) is a clinical stage biopharmaceutical company dedicated to developing novel, targeted therapeutics for the treatment of cancer. The company's mission is to improve the lives of cancer patients by developing next generation cancer therapies that are designed to maximize efficacy while minimizing the toxicity and side effects traditionally associated with cancer treatment. Rexahn's product candidates work by targeting and neutralizing specific proteins believed to be involved in the complex biological cascade that leads to cancer cell growth. Pre-clinical studies show that certain of Rexahn's product candidates may be effective against multiple types of cancer, including drug resistant cancers and difficult-to-treat cancers, and others may augment the effectiveness of current FDA-approved cancer treatments. The company has a broad oncology pipeline that includes three anti-cancer compounds currently in clinical development: RX-3117, RX-5902 (Supinoxin™) and RX-0201 (Archexin®), and a novel nanopolymer-based drug delivery platform technology that may increase the bio-availability of FDA-approved chemotherapies. For more information about the company and its oncology programs, please visit www.rexahn.com.

Safe Harbor

To the extent any statements made in this press release 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 cash flow requirements, future operations and products, relationships with collaborators, the path of preclinical and 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 ability to initially develop drug candidates for orphan indications to reduce the time-to-market and take advantage of certain incentives provided by the U.S. Food and Drug Administration; the ability to transition from our initial focus on developing drug candidates for orphan indications to candidates for more highly prevalent indications; the ability to maintain relationships and enter new markets with our collaborators; 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 Rexahn's 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 news release speak only as of the date of this news release. Rexahn undertakes no obligation to update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

Investor contact:

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 5. Decision Resources, 2017.
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