
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 16, 2019

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. ☐

Item 7.01 Regulation FD Disclosure.

On April 16, 2019, Rexahn Pharmaceuticals, Inc. (“Rexahn”) issued a press release in connection with the announcement of the Collaboration and License Agreement described below. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and incorporated by reference herein.

Item 8.01 Other Events.

On April 16, 2019, Rexahn announced a collaboration and license agreement (the “Collaboration and License Agreement”) with BioSense Global LLC (“BioSense”) to advance the development and commercialization of RX-3117 for pancreatic and other cancers in the Republic of Singapore, China, Hong Kong, Macau and Taiwan (the “Territory”). Under the terms of the Collaboration and License Agreement, Rexahn will grant BioSense an exclusive license to develop and commercialize pharmaceutical products containing RX-3117 as a single agent (“Licensed Products”) for the prevention or treatment of metastatic pancreatic cancer (the “Lead Indication”) in the Territory that is effective upon payment in full of an upfront payment. The upfront payment consists of an aggregate of \$3.0 million, \$1.5 million of which has been paid and the remaining \$1.5 million of which is due August 24, 2019. Under the Collaboration and License Agreement, Rexahn is also eligible to receive milestone payments in an aggregate of up to \$226 million upon the achievement of development, regulatory and commercial goals. Rexahn will also be eligible to receive tiered royalties in the low double digits to mid-teens on annual net sales in the Territory.

Under the terms of the Collaboration and License Agreement, BioSense will conduct a Phase 2 clinical trial of RX-3117 in China in up to three indications other than the Lead Indication based on an agreed upon development plan, and any additional development will take place under an amended development plan. The Phase 2 clinical trial will be conducted at BioSense’s sole expense except that Rexahn will provide a certain supply of RX-3117 for such trial at Rexahn’s sole expense. If Rexahn conducts a global registration-enabling clinical trial for RX-3117 for the Lead Indication, BioSense has the right to include clinical trial sites in China in that trial.

During the term of the Collaboration and License Agreement, Rexahn may not develop or commercialize, either by itself or through a third party, a Licensed Product in the field of oncology (the “Option Field”) in the Territory other than under the terms of the Collaboration and License Agreement. BioSense has the exclusive option to obtain an exclusive license to develop and commercialize Licensed Products in the Territory for additional indications in the Option Field on the financial terms set forth in the Collaboration and License Agreement, subject to the parties agreeing on an amendment to the Collaboration and License Agreement, which may provide for co-development activities relating to such indications if mutually agreed.

The Collaboration and License Agreement will expire on a Licensed Product-by-Licensed Product and country-by-country or region-by-region basis upon the expiration of the last valid intellectual property claim covering a Licensed Product, unless earlier terminated by either party due to material breach, the other party’s insolvency, or certain drug safety issues, by Rexahn in the event of a patent challenge by BioSense or BioSense’s failure to pay the remaining portion of the upfront payment when due, or by BioSense with respect to any indication in the event of the failure of a clinical trial in that indication.

The foregoing description of the Collaboration and License 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 June 30, 2019.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
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<u>99.1</u>	Rexahn Pharmaceuticals, Inc. press release dated April 16, 2019, announcing collaboration and license agreement with BioSense Global LLC.
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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: April 16, 2019

/s/ Douglas J. Swirsky

Douglas J. Swirsky
President and Chief Executive Officer



Rexahn and BioSense Global Announce Collaboration and License Agreement for RX-3117 in Greater China

ROCKVILLE, MD and SUZHOU, CHINA – April 16, 2019 - Rexahn Pharmaceuticals, Inc. (NYSE American: RNN), a clinical stage, biopharmaceutical company focused on oncology, and BioSense Global LLC, a New Jersey- and Suzhou, China-based biopharmaceutical company, today announced a collaboration and license agreement to advance the development and commercialization of RX-3117 for pancreatic cancer and other cancers in Greater China.

Under the agreement, Rexahn will grant BioSense an exclusive license to develop and commercialize RX-3117 in Greater China. Rexahn will receive an upfront payment and will be eligible to receive additional development, regulatory and commercial milestones up to a total of \$226 million contingent on achieving regulatory and commercial goals related to pancreatic cancer and additional indications. Rexahn will also be eligible to receive tiered royalties in the low double digits to mid teens on annual net sales in the territory. The companies will collaborate to develop RX-3117 for pancreatic cancer and other indications. BioSense will fund all activities related to the development and commercialization of RX-3117 in Greater China and will initiate a Phase 2 study to evaluate the drug candidate in up to three additional indications not previously studied by Rexahn.

"Rexahn is focused on developing novel therapies for people with difficult-to-treat cancers. This partnership will enable us to extend the development of RX-3117 to patients in Greater China and also to evaluate RX-3117 in additional indications in collaboration with BioSense," said Douglas Swirsky, President and CEO of Rexahn. "We are excited to work with the experienced regulatory and development team at BioSense to advance the development of RX-3117 towards regulatory approval in Greater China."

Andy Li, PhD, President and CEO of BioSense Global, added, "We are delighted to partner with Rexahn to develop RX-3117 for the Greater China markets. Cancer is the leading cause of death in China with over four million new diagnoses and almost three million deaths per year. Prognosis is poor for certain cancers and treatment options are limited. Despite the significant success of immunotherapy, chemotherapy will remain a critical component of treatment regimens for many cancers. With its unique tumor-targeting mechanism, we believe RX-3117 could become a safer, more efficacious yet affordable treatment option to patients and doctors. We are excited to advance the development of RX-3117 for cancers that are especially prevalent among Chinese patients."

Additional information on the collaboration and license agreement can be found in the Current Report on Form 8-K being filed by Rexahn today with the Securities and Exchange Commission.

About RX-3117

RX-3117 is a novel, investigational, oral, small molecule nucleoside compound. Once intracellularly activated (phosphorylated) by UCK2, it is incorporated into the DNA or RNA of cells and inhibits both DNA and RNA synthesis, which induces apoptotic death of tumor cells. Due to the high level of over expression of UCK2 in cancer cells, RX-3117 offers the potential for a targeted anti-cancer therapy with an improved efficacy and safety profile. RX-3117 is currently being studied in a Phase 2a clinical trial in combination with Abraxane® (paclitaxel protein-bound particles for injectable suspension) in first line metastatic pancreatic cancer patients and a Phase 2a clinical trial in patients with advanced or metastatic bladder cancer. It has received Orphan Drug designation for the treatment of pancreatic cancer. Additional information on RX-3117 can be found at: <https://rexahn.com/cms/portfolio/rx-3117/>.

Abraxane is a registered trademark of Abraxis Bioscience, LLC, a wholly owned subsidiary of Celgene Corporation.

About Rexahn Pharmaceuticals, Inc.

Rexahn Pharmaceuticals, Inc. (NYSE American: RNN) is a clinical stage biopharmaceutical company developing innovative therapies to improve patient outcomes in cancers that are difficult to treat. 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. Preclinical studies show that several of Rexahn's product candidates may be effective against multiple types of cancer, including drug resistant cancers, difficult-to-treat cancers and others, may augment the effectiveness of current FDA-approved cancer treatments. The Company has two oncology product candidates, RX-3117 and RX-5902, in Phase 2 clinical development and additional compounds in preclinical development, including RX-0301. For more information about the Company and its oncology programs, please visit www.rexahn.com.

About Biosense Global LLC

BioSense is an emerging biotech company established to address the business needs of the global biopharmaceutical market with a focus on China, Europe, and the U.S. The company is based in New Jersey (US) and Suzhou (China). The organization's mission is to bridge the gap between undercapitalized biopharmaceutical projects, resources and markets to add value to its stakeholders and address significant unmet medical needs and bring affordable treatment options to patients. BioSense's expert team of international biopharma executives and seasoned investors has extensive experience in developing, registering and commercializing some of the most successful products in key markets, including, US, Europe and China, plus the business management and cross-cultural knowledge. www.biosensegloballlc.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 regarding expectations and intentions with respect to Rexahn's relationship with Biosense, the potential effectiveness and safety of Rexahn's product candidates, including RX-3117, Rexahn's plans, objectives, expectations and intentions with respect to future operations and products, 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," and 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 availability and access to capital; and the expected 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. 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:

ir@rexahn.com
