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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): November 5, 2015**

**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))
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## **Section 8 – Other Events**

### **Item 8.01 Other Events.**

On November 5, 2015, Rexahn Pharmaceuticals, Inc., a Delaware corporation (the “Company”), issued a press release announcing interim clinical data from an ongoing Phase IIa study of Archexin<sup>®</sup>, the Company’s novel inhibitor of the protein kinase phosphorylated Akt-1 in development for the treatment of cancer. The results will be presented on Friday, November 6, 2015 at the 14<sup>th</sup> International Kidney Cancer Symposium in Miami, Florida. A copy of the press release is attached to this Current Report on Form 8-K as Exhibit 99.1 and incorporated herein by reference.

## **Section 9 – Financial Statements and Exhibits**

### **Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
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<a href="#"><u>99.1</u></a>	Rexahn Pharmaceuticals, Inc. press release dated November 5, 2015, announcing the presentation of interim clinical data.
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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: November 5, 2015

/s/ Tae Heum Jeong

Tae Heum Jeong

Senior Vice President of Finance and Chief Financial Officer

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**REXAHN PHARMACEUTICALS REPORTS INTERIM CLINICAL DATA FOR ARCHEXIN® AT THE 14<sup>TH</sup> INTERNATIONAL KIDNEY CANCER SYMPOSIUM**

***Interim Data Show Archexin is Well Tolerated at the Doses Tested to Date with Early Evidence of Anti-Tumor Activity Observed in a Phase IIa Clinical Study in Metastatic Renal Cell Carcinoma***

**ROCKVILLE, MD – November 5, 2015** -- Rexahn Pharmaceuticals, Inc. (NYSE MKT: RNN), a clinical stage biopharmaceutical company developing next generation therapeutics for the treatment of cancer, announced today that interim clinical data from an ongoing Phase IIa study of its novel anti-cancer drug candidate, Archexin®, will be presented on Friday, November 6, 2015 at the 14<sup>th</sup> International Kidney Cancer Symposium in Miami, Florida.

“We are excited to present interim data from the ongoing Phase IIa clinical trial showing that Archexin, in combination with everolimus (Afinitor®), appears to be safe and well tolerated at the doses tested to date. We have also noted early evidence of clinical activity at low doses in patients with metastatic kidney cancer,” commented Peter D. Suzdak, Chief Executive Officer. “We look forward to completing the randomized, open-label, 2-arm dose expansion study of Archexin in combination with everolimus versus everolimus alone in order to further evaluate Archexin in metastatic renal cell carcinoma.”

**Archexin Clinical Data**

Interim data from the Phase IIa Archexin clinical trial will be presented on Friday, November 6, 2015 by study investigators, Drs. S. Tagawa, G. Chatta and N. Agarwal in a poster presentation entitled “*RX-0201, An Anti-Sense Targeting AKT-1 to Treat Metastatic Renal Cancer – Preliminary Phase IIa Data.*”

The interim results show that at the dose levels tested to date, Archexin appeared to be safe and well tolerated. The most commonly reported adverse events in the patients taking both Archexin and everolimus included: thrombocytopenia, mouth ulcerations, decreased weight, facial edema, and hyponatremia. To date, none of these adverse events has been dose limiting.

Early evidence of the potential clinical activity of Archexin in combination with everolimus has been observed. Among the patients enrolled in the study, two patients experienced stable disease, which has persisted for 170 and 334 days (as of October 28, 2015). In addition, at the lowest dose tested one patient experienced a 15% reduction in tumor size, as compared to a baseline CT scan taken prior to treatment with Archexin and everolimus.

Scott Tagawa, MD, MS, Medical Director, Genitourinary Oncology Research Program, Associate Professor of Clinical Medicine and Urology, Division of Hematology & Medical Oncology, Weill Cornell Medical College, commented, “The treatment of patients with metastatic RCC remains a significant unmet medical need and the early evidence supporting the potential clinical benefit of Archexin is therefore very promising. With a unique mechanism of action targeting a well validated cancer pathway (Akt-1 suppression), it is possible that Archexin in combination with everolimus could have a two-fold effect in the treatment of RCC, both by inhibiting the growth and proliferation of RCC, but also potentially by overcoming resistance to mTOR inhibitors. I look forward to further evaluation of this promising approach.”

The ongoing Phase IIa clinical study is designed to evaluate the efficacy of Archexin in combination with everolimus (Afinitor®) to treat metastatic RCC patients and is being conducted in two stages. Stage 1 is an open-label, dose-escalation study designed to identify a safe and tolerable dose of Archexin when given in combination with everolimus. Stage 2 is a randomized, open-label, 2-arm dose expansion study of Archexin in combination with everolimus versus everolimus alone to determine safety and efficacy of the combination.

In Stage 1, escalating doses of Archexin of 125, 200 and 250 mg/m<sup>2</sup>/day are administered by continuous IV infusion for 14 days followed by 1 week of rest. Based on previous clinical data, the target dose of Archexin is anticipated to be no more than 250 mg/m<sup>2</sup> per day. Patient assessments include safety, pharmacokinetics, laboratory and physical exams. Once the maximum tolerated dose of Archexin in combination with everolimus has been determined, thirty RCC patients will be randomized to receive either Archexin in combination with everolimus, or everolimus alone, in a ratio of 2:1.

The primary endpoint of Stage 2 is the percentage of progression free patients following eight cycles of therapy. Patients are scanned (CT or MRI) for the assessment of tumor progression after every 2 cycles of therapy. Secondary endpoints include pharmacokinetic profile, incidence of adverse events, changes in clinical laboratory tests and vital signs over time, tumor response, duration of response, time to response, and response rate. Exploratory endpoints include blood levels of AKT pathway biomarkers, tumor apoptosis biomarkers, or other relevant biomarkers.

In preclinical studies, Archexin has been shown to inhibit the growth of human renal cell carcinoma (RCC) cells in tissue culture. Archexin has also been shown to exhibit an additive anti-tumor effect when combined with other cancer drugs in inhibiting the growth of human RCC cells in tissue culture.

#### **About Archexin®**

Archexin is a unique anti-sense drug candidate that specifically inhibits the cancer cell signaling protein Akt-1. Archexin is the only specific inhibitor of Akt-1 in clinical development. The activated form of Akt-1, which is involved in cancer cell growth, survival, angiogenesis, and drug resistance, has been shown to be present or elevated in more than 12 different human cancer cell lines, including pancreatic and renal cell carcinoma. By inhibiting Akt-1, Archexin has been shown to both inhibit the growth of renal cell carcinoma cell lines and exhibit a longer survival benefit in the human renal cell carcinoma animal xenograft model. Thus, while Akt-1 is a very specific anti-cancer target, it may have broad therapeutic potential across multiple types of cancer.

Archexin has completed a Phase I clinical trial in cancer patients with solid tumors and was shown to be safe and well tolerated. The dose-limiting toxicity was Grade 3 fatigue. In a small Phase IIa trial in advanced pancreatic cancer patients, Archexin in combination with gemcitabine was shown to be safe and well tolerated and showed a preliminary efficacy signal with a median survival of 9.1 months in evaluable patients.

Metastatic RCC represents an attractive market opportunity with an estimated annual incidence of 90,000 patients worldwide. Metastatic RCC patients receiving standard of care treatment have a poor prognosis with an overall survival of less than 2 years. Rexahn has received U.S. Food and Drug Administration (FDA) Orphan Drug Designation for Archexin for metastatic RCC as well as four other cancers.

#### **About Rexahn Pharmaceuticals, Inc.**

Rexahn Pharmaceuticals Inc. (NYSE MKT: RNN) is a clinical stage biopharmaceutical company dedicated to developing novel, best-in-class 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, 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: Supinoxin; RX-3117; and 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](http://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, future operations and products, enrollments in clinical trials, the path of clinical trials and development activities, anticipated market sizes, 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, the difficulty of developing pharmaceutical products, obtaining regulatory and other approvals and achieving market acceptance; that the early or potential evidence in a clinical trial will not reflect the complete results of the trial; that results of preclinical studies and earlier stage clinical trials may not be predictive of the results of later-stage clinical trials; the success and design of clinical testing; and Rexahn's need for and ability to obtain additional financing. 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.

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