
**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): September 28, 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 7 – Regulation FD

Item 7.01 Regulation FD Disclosure.

On September 28, 2015, Rexahn Pharmaceuticals, Inc., a Delaware corporation (the “Company”), issued a press release announcing preliminary clinical data from ongoing Phase I studies of its anti-cancer compounds Supinoxin™ and RX-3117 were presented in two poster presentations at the joint 18th ECCO-40th ESMO European Cancer Congress 2015.

A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

Section 9 – Financial Statements and Exhibits

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No. Description

[99.1](#) Rexahn Pharmaceuticals, Inc. press release dated September 28, 2015, announcing the presentation of preliminary clinical data.

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: September 28, 2015

/s/ Tae Heum Jeong

Tae Heum Jeong

Senior Vice President of Finance and Chief Financial Officer



**REXAHN PHARMACEUTICALS PRESENTS PRELIMINARY CLINICAL DATA
FOR SUPINOXIN™ AND RX-3117 ONCOLOGY PROGRAMS
AT THE EUROPEAN CANCER CONGRESS 2015**

*Supinoxin™ and RX-3117 Are Safe and Well Tolerated in Cancer Patients with Advanced and Metastatic Solid Tumors and
Demonstrate Preliminary Evidence of Clinical Activity*

ROCKVILLE, MD – September 28, 2015 -- Rexahn Pharmaceuticals, Inc. (NYSE MKT: RNN), a clinical stage biopharmaceutical company developing next generation therapeutics for the treatment of cancer, announced today that preliminary clinical data from ongoing Phase I studies of its anti-cancer compounds, Supinoxin™ and RX-3117, were presented on Sunday, September 27, 2015 in two poster presentations at the joint 18th ECCO – 40th ESMO European Cancer Congress 2015 – a biennial congress focused on improving the prevention, diagnosis, treatment and care of cancer patients, taking place in Vienna, Austria, September 25-29, 2015.

“We were pleased to have the opportunity to showcase promising preliminary data from both the Supinoxin and RX-3117 clinical programs at this prestigious cancer meeting,” commented Dr. Peter D. Suzdak, Chief Executive Officer of Rexahn Pharmaceuticals. “The initial clinical results demonstrate that both Supinoxin and RX-3117 appear to be safe and well tolerated and also show encouraging preliminary evidence of clinical activity. We believe these results underscore the unique mechanism of action of both compounds and their ability to selectively target key molecular pathways involved in cancer biology.”

Supinoxin Clinical Program

Preliminary results from the Phase I Supinoxin clinical trial were presented on September 27, 2015 by study investigator, Dr. Gail Eckhardt, Professor of Medicine/Oncology at the University of Colorado Cancer Center, in a poster presentation entitled “*Single Agent Supinoxin Targeting Phosphorylated p-68 Preliminary Phase I Data.*”

The results demonstrated that, at the dose levels tested to date, Supinoxin administered orally appeared to be safe and well tolerated with no Grade 3 or Grade 4 adverse events and only one unrelated Grade 2 adverse event. The most frequently reported drug related adverse events were mild nausea, vomiting and fatigue. Pharmacokinetic analyses of the current data demonstrate both a predictable and desirable pharmacokinetic profile for an orally-administered route of therapy.

Clinical evidence of single-agent activity of Supinoxin was also observed in 4 patients who showed stable disease persisting from between 255 and 497 days as of September 14, 2015. Currently, 3 of the 4 patients exhibiting stable disease remain on active treatment and continue to be followed in the study.

“Supinoxin’s novel mechanism of action targets a new biological pathway that is involved in the proliferation and metastasis of numerous types of cancers,” said Dr. Eckhardt. “We are very excited about the novelty of this approach and the potential for Supinoxin to treat historically difficult-to-treat cancers, such as triple negative breast cancer, for which there is a tremendous unmet medical need.”

Dr. Ely Benaim, Chief Medical Officer of Rexahn Pharmaceuticals, remarked “We are very encouraged by the emerging data from the Phase I study, which demonstrate that Supinoxin can be administered safely to cancer patients with advanced disease and appears to have a pharmacokinetic profile suggesting its utility as an orally administered, novel targeted therapy to treat cancer patients. Moreover, the observation of stable disease for relatively prolonged periods of time in certain patients is particularly encouraging and certainly warrants further clinical investigation. We look forward to determining the maximum tolerated dose in the current study and then using that dose to treat selected patient populations in Phase Ib/IIa clinical proof-of-concept studies with Supinoxin next year.”

Supinoxin is a first-in-class, orally bioavailable, small molecule inhibitor of a cancer protein (phosphorylated p-68) believed to play a prominent role in cancer cell development and proliferation. Supinoxin is currently being evaluated in an ongoing Phase I multi-center, dose-finding, open-label, single agent clinical study in patients with advanced or metastatic solid tumors. Patients in the study were treated once weekly for 3 weeks, with 1 week off treatment, comprising a 28-day treatment cycle.

The Phase I clinical study is designed to evaluate the safety, tolerability, dose-limiting toxicities, and maximum tolerated dose (MTD) of Supinoxin and identify a recommended phase Ib/IIa dose and dosing schedule for continued clinical development. Secondary endpoints in the study include pharmacokinetics and anti-tumor activity.

Based on the favorable safety and pharmacokinetic profile seen at the highest dose levels (575 mg and 775 mg), Rexahn has initiated a dosing schedule modification to increase patients’ daily exposure of Supinoxin. All newly enrolled patients are now receiving Supinoxin either three or five times weekly as opposed to once weekly. The new dosing paradigm will increase drug exposure, maximizing potential therapeutic activity and enable more rapid determination of the MTD for further clinical study.

RX-3117 Clinical Program

In a second poster presentation entitled, “*Preliminary Phase I Data of Single Agent RX-3117, an Oral Antimetabolite Nucleoside*,” Dr. Drew W. Rasco, Clinical Investigator at South Texas Accelerated Research Therapeutics, presented preliminary clinical findings from an ongoing Phase Ib clinical trial of RX-3117.

In the Phase Ib multi-center, dose escalation, open-label clinical trial of RX-3117, patients with advanced and metastatic solid tumors were treated 3 times per week for 3 weeks, with 1 week off of treatment, comprising a 28-day treatment cycle. The primary objectives of the study were to characterize the safety, tolerability, pharmacokinetics and preliminary anti-tumor activity of RX-3117, and to determine a maximum tolerated dose and dosing schedule for further clinical development in Phase Ib/IIa clinical studies.

Preliminary results from the ongoing Phase Ib clinical trial presented at the conference demonstrate that – at the doses tested to date, RX-3117, administered orally, appeared to be safe and well tolerated with a predictable pharmacokinetic profile. The most frequently reported treatment emergent adverse events were mild to moderate fatigue, gastrointestinal disturbances, anemia, pyrexia, decreased appetite and dehydration.

In addition, preliminary anti-tumor activity was seen in the Phase Ib clinical trial, with evidence of tumor reduction observed in 1 patient and stable disease observed in 5 patients persisting from between 112 and 276 days before disease progression occurred.

“It is certainly encouraging that at this early stage there is some preliminary evidence of anti-tumor activity in patients with relapsed, refractory tumors. Based on the accumulating preclinical and clinical data, RX-3117 could hold promise in the treatment of gemcitabine-resistant cancers. This type of targeted, next generation chemotherapy, that can potentially be given orally with less systemic toxicity, could advance the treatment paradigm for cancer, improving outcomes and quality of life for patients,” remarked Dr. Rasco.

“While these are early-stage trials, which should be interpreted with caution, we are very encouraged by the excellent tolerability profile and preliminary evidence of clinical activity and disease control observed in the ongoing clinical studies. We are excited about the interest in our programs within the oncology community and look forward to continuing the clinical development of Supinixin and RX-3117 in Phase Ib/IIa clinical proof-of-concept studies,” said Dr. Benaim.

RX-3117 is a novel, orally bioavailable small molecule, investigational anti-cancer therapy that targets a unique biological pathway implicated in the development and metastasis of numerous cancers. Preclinical studies of RX-3117 in patient-derived, cancer cell xenograft models have demonstrated broad anti-tumor activity of RX-3117 and, most importantly, an ability to treat cancer cells that have become resistant to gemcitabine – a widely-used chemotherapy. Unfortunately, resistance to gemcitabine occurs in a significant number of patients over time, reducing overall treatment efficacy and further limiting options for patients.

Based on the favorable safety and pharmacokinetic profile seen at the highest dose levels (1,500 mg and 2,000 mg) Rexahn has initiated a dosing schedule modification to increase patients’ daily exposure of RX-3117. All newly enrolled patients are now receiving RX-3117 either five or seven times weekly as opposed to three times weekly. The new dosing paradigm will increase drug exposure, maximizing potential therapeutic activity and enable more rapid determination of the MTD for further clinical study.

About Supinoxin™ (RX-5902)

Supinoxin™ (RX-5902) is an orally administered, potential first-in-class, small molecule inhibitor of phosphorylated-p68 (P-p68). P-p68, which is selectively overexpressed in cancer cells and is absent in normal tissue, increases the activity of multiple cancer related genes including cyclin D1, c-jun and c-myc, and plays a role in tumor progression and metastasis. Over-expression of phosphorylated-p68 has been observed in solid tumors, such as melanoma, colon, ovarian and lung tumors. In preclinical studies, Supinoxin has been shown to inhibit proliferation of cells in over 100 different human cancer cell lines, including breast, colon, pancreas, ovarian, and stomach cancers, and showed potent activity in drug-resistant cancer cells. In preclinical animal models, where human cancer cells from melanoma, pancreas, renal or ovarian tumors were grafted into animals, treatment with Supinoxin resulted in a significant reduction in tumor growth.

Supinoxin is currently being evaluated in a Phase I dose-escalation clinical trial in cancer patients with solid tumors designed to evaluate the safety, tolerability, dose-limiting toxicities and maximum tolerated dose (MTD). Secondary endpoints include pharmacokinetic analysis and an evaluation of the preliminary anti-tumor effects of Supinoxin. This trial is being conducted at three clinical oncology centers in the United States. Each patient has the ability to continue on the drug for up to six cycles of treatment (a dosing cycle is defined as three weeks of drug treatment followed by one week off) if no disease progression is seen. Patients are assessed by CT or MRI prior to the start of therapy and after every two cycles of therapy to assess tumor progression. The decision to escalate dose is made after completion of one cycle of treatment based on safety and tolerability. Patients may receive up to six cycles of treatment if their disease does not progress. Tumor biopsy samples are taken to assess the biomarker phosphorylated-p68. Patients in nine dose groups (25, 50, 100, 150, 225, 300, 425, 575, and 775 mg) have been enrolled to date, and at this time, the MTD has not yet been reached. Given the robust preliminary safety profile observed in the Phase I clinical trial to date, it is difficult to predict when the MTD will be achieved and the trial will be completed.

About RX-3117

RX-3117 is a novel, investigational 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 cell death of tumor cells. UCK2 is overexpressed in various human cancer cells. Preclinical studies have shown that RX-3117 inhibits the growth of various human cancer xenograft models, including pancreatic, lung, bladder, cervical and colon, as well as gemcitabine resistant cancer cells.

RX-3117 has demonstrated broad spectrum anti-tumor activity against over 100 different human cancer cell lines and efficacy in 17 different mouse xenograft models. Notably, the efficacy of RX-3117 in the mouse xenograft models was superior to that of gemcitabine. Further, RX-3117 still retains its full anti-tumor activity in human cancer cell lines made resistant to the anti-tumor effects of gemcitabine. In August 2012, Rexahn reported the completion of an exploratory Phase I clinical trial of RX-3117 in cancer patients conducted in Europe, to investigate the oral bioavailability, safety and tolerability of the compound. In this study, oral administration of a 50 mg dose of RX-3117 demonstrated an oral bioavailability of 56% and a plasma half-life ($T_{1/2}$) of 14 hours. In addition, RX-3117 appeared to be safe and well tolerated in all subjects throughout the dose range tested.

RX-3117 is currently being evaluated in a Phase Ib clinical trial in cancer patients with solid tumors. The Phase Ib clinical trial is a multi-center, dose-escalation study that will evaluate the safety, tolerability, dose-limiting toxicities, and maximum tolerated dose (MTD) of RX-3117 in patients with solid tumors. Secondary endpoints include pharmacokinetic analysis, and an evaluation of the preliminary anti-tumor effects of RX-3117. Patient enrollment has been completed in nine dose groups (30, 60, 100, 150, 200, 500, 1000, 1500 and 2000 mg). The MTD of RX-3117 has not yet been achieved. Given the robust preliminary safety profile observed in the Phase Ib clinical trial to date, it is difficult to predict when the MTD will be achieved and the trial will be completed.

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.

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, enrollments in clinical trials, 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, the difficulty of developing pharmaceutical products, obtaining regulatory and other approvals and achieving market acceptance; that results of preclinical studies and early 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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