

August 10, 2015



# Rexahn Pharmaceuticals Reports Second Quarter 2015 Financial Results and Provides Corporate Update

## Presentations at Recent Scientific Conferences Showcase Novel Anti-Tumor Properties of Rexahn Compounds

ROCKVILLE, Md., Aug. 10, 2015 (GLOBE NEWSWIRE) -- Rexahn Pharmaceuticals, Inc. (NYSE MKT:RNN), a clinical stage biopharmaceutical company developing best-in-class therapeutics for the treatment of cancer, today announced financial results for the second quarter ended June 30, 2015 and provided a corporate and pipeline update.

“Our momentum in 2015 continued as we made important advances in our clinical development and pipeline programs,” said Peter Suzdak, Chief Executive Officer. “Each of these programs shares a unique feature – the ability to selectively target cancerous cells at the molecular level with the goal of improving efficacy and minimizing the toxicity associated with traditional, non-selective cancer therapy. We are very encouraged by the progress we continue to make and remain committed to advancing novel, next generation treatments that may bring meaningful quality of life improvements for cancer patients and their families.”

### Second Quarter 2015 Corporate Highlights:

- **Trials in Progress Posters Presented at the American Society of Clinical Oncology Annual Meeting:** During the quarter, Rexahn scientists and their scientific collaborators presented ‘Trials in Progress’ poster presentations for the Company’s Supinoxin™, RX-3117, and Archexin® clinical development programs at the 2015 American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago.
- **Promising New Findings for RX-3117 Presented at Two Additional Scientific Meetings:** Rexahn scientists, in collaboration with Dr. Godefridus J. Peters of the VU University Medical Center in Amsterdam, presented new preclinical data for RX-3117 at the 16<sup>th</sup> International Symposium of the Purine and Pyrimidine Society demonstrating its ability to potentially induce apoptotic cell death in a human non-small cell lung cancer (NSCLC) cell line. In addition, Dr. Peters presented data on RX-3117 at the 2015 American Association for Cancer Research (AACR) Annual Meeting showing a correlation between the enzymatic activity of UCK2, which is responsible for the activation of RX-3117, and RX-3117’s subsequent ability to inhibit the growth of various cancer cells in preclinical models. Both findings add to the growing body of promising preclinical data for this compound. RX-3117 possesses a

unique mechanism of action that we believe exclusively targets cancer cells. Preclinical studies have demonstrated its anti-tumor activity against a broad spectrum of human cancer cell lines, including: pancreatic, lung, bladder, cervical and colon cancers, among other solid tumor types. Preclinical research has also shown that RX-3117 can block the growth of human cancer cells that are resistant to gemcitabine (Gemzar), which is the current standard of care treatment for certain cancers. Resistance to gemcitabine is a limitation in cancer therapy and represents an unmet need for novel, targeted cancer treatments such as RX-3117.

- **New Preclinical Data Shows Supinoxin Decreases Migration of Human Triple Negative Breast Cancer Cells in a Metastatic Cancer Model:** Frances Fuller-Pace Ph.D. from the Division of Cancer Research, University of Dundee, United Kingdom and Rexahn scientists presented preclinical data on Supinoxin at the 2015 AACR Annual Meeting. The data showed that Supinoxin dose-dependently decreased the migration of human triple negative breast cancer cells (MDA-MB-231) in a preclinical model of cancer cell metastasis. These encouraging preliminary findings suggest Supinoxin's potential utility in treating difficult cancers, such as triple negative breast cancer, where metastatic disease is a common occurrence and is one of the main factors that impact prognosis.
- **National Cancer Institute Selects Rexahn's Novel Polymer Technology Platform for Preclinical Advancement:** Following a rigorous internal scientific review, the National Cancer Institute's (NCI) Nanotechnology Characterization Laboratory (NCL) selected Rexahn's polymer-drug conjugate candidate, RX-21101, for inclusion in its preclinical characterization program. Under this program, the NCL will be responsible for conducting various IND-enabling studies with the goal of advancing RX-21101 towards human clinical trials. RX-21101 is a novel, polymer-conjugated form of the widely-used chemotherapeutic, docetaxel, and is designed to deliver docetaxel directly into tumor cells potentially increasing efficacy and minimizing the toxic effects of chemotherapy.
- **Expanded Patent Portfolio for Novel CPMA Drug Delivery Program:** In July, the Japanese Patent Office awarded a patent for Rexahn's novel CPMA drug delivery platform technology, supplementing patent coverage already obtained in the United States for this program. CPMA is a promising new drug delivery technology which is designed to transport anti-cancer drugs directly into cancerous cells to enhance their cytotoxic activity.
- **New Chairman Appointed:** Rexahn Director and former Pfizer executive Peter Brandt was appointed Chairman of the Board of Directors, succeeding Dr. Chang Ahn, the Company's scientific founder, who will remain on the Board as Chairman Emeritus. In addition, biotechnology executive Dr. Reza Mazhari joined the leadership team as Vice President of Translational Medicine.

## **Second Quarter 2015 Financial Results:**

**Cash Position** - Rexahn's cash and investments totaled approximately \$26.0 million as of

June 30, 2015, compared to approximately \$32.7 million as of December 31, 2014. The decrease in cash and investments during the first six months of 2015 was primarily due to \$8.4 million of cash used in operating activities, offset by approximately \$1.7 million in proceeds received from the exercise of stock options and the sale of common stock. Rexahn expects that its cash and investments as of June 30, 2015 will be sufficient to fund the Company's cash flow requirements for its current activities into the second half of 2016.

**R&D Expenses** - Research and development expenses were \$3.2 million for the three months ended June 30, 2015, compared to \$1.7 million for the three months ended June 30, 2014. Research and development expenses for the six month period ended June 30, 2015 were \$6.1 million compared to \$3.0 million for the same period in 2014. The increase in research and development expenses during both the three and six month periods of 2015 is primarily attributable to additional clinical trial and drug manufacturing costs related to ongoing Archexin<sup>®</sup>, Supinoxin<sup>™</sup> and RX-3117 clinical studies, and partially attributable to an increase in personnel expenses.

**G&A Expenses** - General and administrative expenses for the three months ended June 30, 2015 were approximately \$1.6 million, compared to \$1.8 million for the three months ended June 30, 2014. General and administrative expenses for the six month period ended June 30, 2015 were \$3.1 million compared to \$3.3 million for the same period in 2014. The year over year decrease is primarily attributable to a decrease in professional fees, offset by an increase in personnel expenses. General and administrative expenses consist primarily of salaries and related expenses for executive, finance and other administrative personnel, recruitment expenses, professional fees, and other corporate expenses, including business development, investor relations, and general legal activities.

**Net (Loss) Income** - Rexahn's loss from operations was \$4.8 million and \$3.5 million for the three months ended June 30, 2015 and 2014, respectively. Rexahn's net loss was \$3.2 million, or \$0.02 per share, for the three months ended June 30, 2015, compared to a net income of \$0.2 million, or \$0.00 per share, for the three months ended June 30, 2014. For the six month period ending June 30, 2015, Rexahn's net loss was \$7.5 million, or \$0.04 per share compared to \$14.4 million or \$0.08 per share for the same period in 2014. Included in the net (loss) income for the three months ended June 30, 2015 and 2014 is an unrealized gain on the fair value of warrants of \$1.6 million and \$3.7 million, respectively. For the six month period ended June 30, 2015 and 2014, Rexahn recorded an unrealized gain (loss) on the fair value of warrants of \$1.7 million and \$(8.0) million, respectively. The fair value adjustments are primarily a result of the changes in the stock price between reporting periods.

### **About Supinoxin<sup>™</sup> (RX-5902)**

Supinoxin<sup>™</sup> (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 (PK) 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 Ib clinical trial to date, it is difficult to predict when we will achieve the MTD and complete the clinical trial. Rexahn intends to present preliminary clinical findings from the ongoing Phase Ib clinical study in the third quarter of 2015.

### **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 12 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 PK analysis,

and an evaluation of the preliminary anti-tumor effects of RX-3117. Patient enrollment has been completed in eight dose groups (30, 60, 100, 150, 200, 500, 1000 and 1500 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 we will achieve the MTD and complete the clinical trial. Rexahn intends to present preliminary clinical findings from the ongoing Phase Ib clinical study in the third quarter of 2015.

### **About Archexin®**

Archexin® is a specific inhibitor of the cancer cell signaling protein Akt-1. The activated form of Akt-1 (phospho-Akt-1) has been shown to be involved in cancer cell growth, survival, angiogenesis, and drug resistance. Phospho-Akt-1 has been shown to be significantly increased in more than 12 different human cancer cell lines including human renal cell carcinoma (RCC) cells. Archexin has been shown to inhibit the growth of human RCC cells in tissue culture and produce a substantial survival benefit in animal xenograft models of RCC. Archexin also exhibits additive anti-tumor effect when combined with other cancer drugs in inhibiting the growth of human RCC cells in tissue culture. In addition, resistance to the anti-cancer effects of clinically used mTOR inhibitors such as everolimus (Afinitor®), which is used as second line therapy in RCC patients, has been attributed to an increase in Akt-1 activity. Thus, treatment with Archexin may both inhibit the growth/proliferation of RCC and overcome the resistance to mTOR inhibitors such as everolimus, resulting in an increase in efficacy. Rexahn has initiated a Phase IIa proof-of-concept clinical trial, designed to evaluate the efficacy of Archexin in combination with everolimus (Afinitor®) to treat metastatic RCC patients, that is being conducted in two stages. Stage 1 is a dose ranging study with up to 3 cohorts of 3 RCC patients to determine the maximum tolerated dose of Archexin in combination with everolimus.

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. The decision to enroll the next group of patients and escalate the dose will be made after completion of the first 21 day cycle of treatment. Patient assessments will include safety, pharmacokinetics, laboratory and physical exams. Once the maximum tolerated dose of Archexin in combination with everolimus has been determined, stage 2 will be initiated with 30 RCC patients being randomized to either Archexin in combination with everolimus, or everolimus alone, in a ratio of 2:1.

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

Rexahn Pharmaceuticals is a clinical stage biopharmaceutical company dedicated to developing best-in-class therapeutics for the treatment of cancer. Rexahn currently has three clinical stage oncology candidates, Supinoxin™ (RX-5902), RX-3117 and Archexin® and a robust pipeline of preclinical compounds to treat multiple types of cancer. Rexahn has also developed proprietary drug discovery platform technologies in the areas of Nano-Polymer-Drug Conjugate Systems (NPDCS), nano-medicines, 3D-GOLD, and TIMES. For more information, 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, 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.

CONTACT:

Stacey Jurchison  
Rexahn Investor Relations  
(240) 268-5300 x324  
jurchisons@rexahn.com



Source: Rexahn Pharmaceuticals