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# Rexahn Pharmaceuticals Reports Second Quarter 2014 Financial Results and Pipeline Update

## *Continued Progress in the RX-3117, Supinoxin and Archexin Clinical Development Programs*

ROCKVILLE, Md.--(BUSINESS WIRE)-- Rexahn Pharmaceuticals, Inc. (NYSE MKT: RNN), a clinical stage biopharmaceutical company developing best-in-class therapeutics for the treatment of cancer, is providing an overview of its three clinical development programs and financial results for the quarter ended June 30, 2014.

“We are pleased with the continued progress of the RX-3117, Supinoxin™ and Archexin® clinical development programs,” stated Rexahn’s Chief Executive Officer Peter D. Suzdak, PhD. “Positive data from these studies would be major milestones and will help direct the next steps for the Company.”

### **Pipeline Update:**

#### ***Supinoxin™ (RX-5902)***

In August 2013, Rexahn initiated a Phase I dose-escalation study of Supinoxin designed to evaluate the safety, tolerability, dose-limiting toxicities and maximal tolerated dose (MTD) in cancer patients with solid tumors that have previously failed treatment with approved therapies. Secondary endpoints include pharmacokinetic analysis and evaluating the preliminary anti-tumor effects of Supinoxin. In July, Rexahn announced that four dose groups (25, 50, 100 and 150 mg) had been enrolled. The Company is currently enrolling patients for its fifth dose group (225 mg), and the MTD has not yet been achieved. Depending upon the number of dose groups needed to determine the MTD, Rexahn expects to complete this trial in the fourth quarter of 2014.

#### ***RX-3117***

Rexahn initiated a Phase Ib clinical trial of RX-3117 in cancer patients with solid tumors in January 2014. The Phase Ib clinical trial is a multi-center dose-escalation study that will evaluate the safety, tolerability, dose-limiting toxicities and MTD of RX-3117 in patients with solid tumors. Secondary endpoints will include characterizing the pharmacokinetic profile of RX-3117 and evaluating the preliminary anti-tumor effects of RX-3117. Patient enrollment has been completed in three dose groups (30, 60 and 100 mg) and is in the middle of recruitment for the fourth dose group (150 mg). The MTD of RX-3117 has not yet been achieved. The Company expects to complete patient enrollment of the RX-3117

Phase Ib clinical trial late in the fourth quarter of 2014 or early 2015. Based on the progress of the RX-3117 clinical development program and the level of interest expressed from a number of oncology-focused pharmaceutical companies, Rexahn is continuing its discussions with multiple companies to explore collaborative business structures in an effort to maximize the potential upside value of the program.

### **Archexin<sup>®</sup>**

The Phase IIa proof-of-concept clinical trial of Archexin in metastatic renal cell carcinoma (RCC) patients is ongoing. The first stage of this study is dose ranging, with up to three dose groups with three RCC patients each, to determine its MTD of Archexin in combination with everolimus, an FDA approved drug for the treatment of RCC. Once the MTD has been determined, thirty RCC patients will be randomized to either Archexin in combination with everolimus or everolimus alone, in a ratio of 2:1. Rexahn expects to complete the initial safety component of this study late in the fourth quarter of 2014 or early 2015.

### **Additional Highlights from Second Quarter 2014:**

- Presented preclinical results for RX-21101, the Company's first development candidate derived from its Nano-Polymer-Drug Conjugate System (NPDCS) platform at the American Association for Cancer Research (AACR) Annual Meeting 2014.
- Announced additional data from preclinical studies on the anti-tumor effects of RX-3117, demonstrating that oral administration of RX-3117 inhibited tumor growth in 12 different human cancer xenograft models.

### **Financial Update:**

**Cash Position** - Rexahn's cash and investments totaled \$38.3 million as of June 30, 2014, compared to \$40.3 million as of March 31, 2014. The decrease of \$2.0 million was primarily due to \$2.9 million of net cash used in operating activities, which amount was offset by \$0.9 million from the exercise of stock warrants and options to purchase common stock. Rexahn expects that its cash and cash equivalents as of June 30, 2014 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 approximately \$1.7 million for the second quarter of 2014, compared to approximately \$1.3 million for the first quarter of 2014. The increase is primarily attributable to the clinical trials that were started in the first quarter, but continued into the second quarter. Research and development expenses were \$3.0 million for the six months ended June 30, 2014, compared to \$1.5 million for the six months ended June 30, 2013. The increase was primarily attributable to expenses related to additional clinical studies in 2014.

**G&A Expenses** - General and administrative expenses were approximately \$1.7 million for the second quarter of 2014, compared to approximately \$1.4 million for the first quarter of 2014. The increase is primarily related to expenses related to the shareholder meeting held in the second quarter, and an increase in legal and professional fees related to

corporate organizational matters. General and administrative expenses for the six months ended June 30, 2014 were approximately \$3.1 million compared to \$2.1 million in the six months ended June 30, 2013. The increase was primarily attributable to an increase in investor relations and financial advisory services relating to the Company's financing activities and additional legal and professional fees.

**Net Income (Loss)** - Rexahn's net income was \$0.2 million, or \$0.00 per share, for the three months ended June 30, 2014, compared to a net loss of \$14.6 million, or \$0.09 per share, for the three months ended March 31, 2014. Included in net income (loss) for the three months ended June 30 and March 31, 2014 is an unrealized gain (loss) on the fair value of warrants of \$3.7 million and (\$11.7 million), respectively. The fair value adjustments are primarily a result of the changes in the stock price between reporting periods. Rexahn's loss from operations was \$3.5 million and \$2.8 million for the three months ended June 30 and March 31, 2014, respectively.

### **About Supinoxin™ (RX-5902)**

Supinoxin is an orally administered, first-in-class, small molecule inhibitor of phosphorylated-p68 RNA helicase (P-p68). P-p68, which is selectively expressed 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 P-p68 has been observed in solid tumors such as melanoma, colon, ovarian and lung.

### **About RX-3117**

RX-3117 is a novel small molecule anti-metabolite that is incorporated into DNA or RNA of cells and inhibits both DNA and RNA synthesis which induces apoptotic cell death of tumor cells. RX-3117 also mediates the downregulation of DNA methyltransferase 1 (DNMT1), an enzyme responsible for the methylation of cytosine residues on newly synthesized DNA and also a target for anticancer therapies. Preclinical studies have shown RX-3117 to be effective in both inhibiting the growth of various human cancer xenograft models, including colon, lung, renal and pancreas, as well as overcoming chemotherapeutic drug resistance.

RX-3117 has demonstrated a broad spectrum anti-tumor activity against 50 different human cancer cell lines and efficacy in 12 different mouse xenograft models. The efficacy in the mouse xenograft models was superior to that of gemcitabine. In addition, RX-3117 still retains its full anti-tumor activity in human cancer cell lines made resistant to the anti-tumor effects of gemcitabine. These findings have either been previously presented at the American Association of Cancer Research Meeting in 2012 or will be the subject of a peer reviewed publication to be published in early 2014. 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 RX-3117 demonstrated an oral bioavailability of 56% and a plasma half-life ( $T_{1/2}$ ) of 14 hours. In addition, RX-3117 was safe and well tolerated in all subjects throughout the dose range tested.

### **About Archexin®**

Archexin® is a unique anti-cancer drug candidate that inhibits the cancer cell signaling protein Akt-1, which is involved in cancer cell growth, survival, angiogenesis, and drug resistance. 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 a 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 demonstrated a preliminary efficacy signal with a median survival of 9.1 months in evaluable patients.

### **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, Archexin®, RX-3117 and Supinoxin™ (RX-5902) 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; 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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