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Rexahn Reports Third Quarter 2018 Financial Results

ROCKVILLE, Md., Nov. 05, 2018 (GLOBE NEWSWIRE) -- Rexahn Pharmaceuticals, Inc. (NYSE American: RNN), a clinical stage biopharmaceutical company developing innovative, targeted therapeutics for the treatment of cancer, announced financial results for the three and nine months ended September 30, 2018.

“This quarter, Rexahn achieved important milestones in our RX-3117 and RX-5902 clinical development programs. First, we presented clinical data from our ongoing Phase 2a trial of RX-3117 in combination with ABRAXANE® (nab-paclitaxel) in newly diagnosed metastatic pancreatic cancer patients. We are encouraged by the preliminary data reflecting a disease control rate of 86% and an overall response rate of 29%. In addition, one patient achieved a complete response (CR) that has been maintained for almost five months, demonstrating the durability of the treatment effect. We look forward to completing the study enrollment and plan to report the final data in 2019,” said Peter D. Suzdak, Ph.D., chief executive officer of Rexahn.

“Second, we announced a clinical trial collaboration agreement with Merck to evaluate the combination of RX-5902 and its anti-PD-1 therapy, KEYTRUDA® (pembrolizumab), in a Phase 2 trial of patients with metastatic triple negative breast cancer (mTNBC). Based on the mechanism of action of RX-5902 and our observations in preclinical studies, we are optimistic that this combination may provide meaningful clinical benefit in patients with mTNBC,” continued Dr. Suzdak.

Recent Highlights:

- Presented preliminary safety and efficacy data from an ongoing Phase 2a clinical trial of RX-3117 in combination with ABRAXANE in patients newly diagnosed with metastatic pancreatic cancer at the 5th NCI Pancreatic Cancer Symposium. The combination appears to be safe and well tolerated (no dose limiting toxicities) and exhibited evidence of clinical activity. Of the 14 subjects that had at least one on-study scan (after 2 cycles of therapy): one complete response (CR: 100% reduction in tumor volume), three partial responses (PR: greater than 30% reduction in tumor volume) and eight patients with stable disease (SD) who had tumor reductions of up to 16%. These patients are still being dosed in the study. Pancreatic tumor marker (CA19-9) reductions were seen ranging between 43%-69%. The disease control rate (CR+PR+SD) for evaluable patients was 86% and the overall response rate (CR+PR) was 29%.

- Entered into a clinical trial collaboration agreement with Merck (known as MSD outside the United States and Canada) to evaluate the combination of Rexahn’s RX-5902 and Merck’s anti-PD-1 therapy, KEYTRUDA (pembrolizumab), in a Phase 2 trial in patients with mTNBC. mTNBC is difficult to treat and anti-PD-1 monotherapies have shown limited benefit due to the limited immunogenic nature of this tumor. RX-5902 has been shown to increase tumor infiltrating lymphocyte migration into the tumor, transforming a “cold” tumor into a “hot” tumor, which can then be recognized by the immune system and make the tumor more susceptible to the anti-tumor effects of anti-PD-1 therapy.

- In the ongoing Phase 2 monotherapy trial in mTNBC, RX-5902 has been preliminarily shown to be safe and well-tolerated with six patients showing clinical responses (stable disease for two or more months), including one patient who has had stable disease for 320 days.

- Completed a registered direct offering with institutional investors to purchase approximately 5.8 million shares of its common stock and warrants exercisable for up to 5.8 million shares of its common stock for gross proceeds of $7.5 million. The net proceeds of the offering will be used to advance Rexahn's clinical development programs and for working capital and general corporate purposes.

- As of November 2, 2018, had $18.0 million in cash, cash equivalents and investments (unaudited). Rexahn expects that its cash, cash equivalents and investments will be sufficient to fund the company’s currently expected cash flow requirements for its activities through the third quarter of 2019.

Q3 2018 Financial Results:

R&D Expenses: Research and development expenses were $2.9 million for the three months ended September 30, 2018, compared to $2.6 million for the three months ended September 30, 2017. Research and development expenses were $10.4 million for the nine months ended September 30, 2018, compared to $7.5 million for the nine months ended September 30, 2017. The increase in research and development expenses is primarily attributable to increases in clinical trial costs and patient enrollment costs from the advancement of our RX-3117 and RX-5902 clinical trials, as well as drug manufacturing costs for new campaigns.

G&A Expenses: General and administrative expenses were $1.8 million for the three months ended September 30, 2018, compared to $1.6 million for the three months ended September 30, 2017. General and administrative expenses were $5.2 million for the nine months ended September 30, 2018, compared to $5.0 million for the nine months ended September 30, 2017.

Net Loss: Rexahn’s loss from operations was $4.7 million and $4.2 million for the three months ended September 30, 2018 and 2017, respectively. Rexahn's net loss was $5.3 million, or $0.17 per share, for the three months ended September 30, 2018, compared to a net loss of $1.0 million, or $0.04 per share, for the three months ended September 30, 2017. The net loss for the three-month periods ended September 30, 2018 and 2017 includes an unrealized (loss) gain on the fair value of warrants of ($0.7 million) and $3.1 million, respectively. For the nine-month period ended September 30, 2018, Rexahn’s net loss was $11.3 million, or $0.35 per share, compared to a net loss of $21.7 million, or $0.83 per share, for the nine months ended September 30, 2017. Included in the net loss for the nine months ended September 30, 2018 and 2017 is an unrealized gain (loss) on the fair value of warrants of $3.8 million and ($9.0 million), respectively. The fair value adjustments are non-cash charges and are primarily a result of changes in stock price between reporting periods.

About Rexahn Pharmaceuticals, Inc.

Rexahn Pharmaceuticals Inc. (NYSE American: RNN) is a clinical stage biopharmaceutical company dedicated to developing novel, targeted 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. Preclinical studies show that several of Rexahn's product candidates may be effective against multiple types of cancer, including drug resistant cancers, and 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-0201. 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," 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 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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(Tables to follow)

Rexahn Pharmaceuticals, Inc.
Condensed Statement of Operations
(unaudited)

	For the Three Months Ended September 30,		For the N Se
	2018	2017	2018
Revenues:	$ -	$ -	$ -
Expenses:			
General and administrative	1,795,952	1,574,323	5,192,122
Research and development	2,887,955	2,644,999	10,379,081
Total Expenses	4,683,907	4,219,322	15,571,203
Loss from Operations	(4,683,907)	(4,219,322)	(15,571,203)
Other Income (Expense)			
Interest income	55,153	60,750	198,362
Other income	-	-	368,750
Unrealized (loss) gain on fair value of warrants	(710,065)	3,120,500	3,752,131
Financing expense	-	-	-
Total Other Income (Expense)	(654,912)	3,181,250	4,319,243
Net Loss Before Provision for Income Taxes	(5,338,819)	(1,038,072)	(11,251,960)
Provision for income taxes	-	-	-
Net Loss	$ (5,338,819)	$ (1,038,072)	$ (11,251,960)
Net loss per share, basic and diluted	$ (0.17)	$ (0.04)	$ (0.35)
Weighted average number of shares outstanding, basic and diluted	31,751,450	28,459,316	31,742,531

Selected Balance Sheet Information
(unaudited)

		Septembe 2018
Cash, Cash Equivalents and Marketable Securities	$	12
Working Capital[(1)]	$	10
Total Assets	$	13
Total Liabilities	$	7
Stockholders' Equity	$	6

(1) Working Capital defined as current assets less current liabilities

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Source: Rexahn Pharmaceuticals