

**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): January 14, 2014**

**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 Disclosure**

### **Item 7.01 Regulation FD Disclosure.**

Attached as Exhibit 99.1 are slides being presented by Rexahn Pharmaceuticals, Inc. in investor and other meetings.

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

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

(d) Exhibits.

<b><u>Exhibit No.</u></b>	<b><u>Description</u></b>
99.1	Rexahn Pharmaceuticals, Inc. slides for investor and other meetings, dated January 14, 2014.

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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: January 14, 2014

/s/ Tae Heum Jeong

Tae Heum Jeong  
Senior Vice President of Finance & Chief Financial  
Officer

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A grayscale photograph of several white, oval-shaped pills. Some of the pills have the word "Health" embossed on them. The pills are scattered on a light-colored surface.

**Revolutionizing the Treatment of Cancer**

January 2014

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# Safe Harbor Statement

The statements that follow (including projections and business trends) are forward-looking statements. Rexahn's actual results may differ materially from anticipated results, and expectations expressed in these forward-looking statements, as a result of certain risks and uncertainties, including Rexahn's lack of profitability, the need for additional capital to operate its business to develop its product candidates; the risk that Rexahn's development efforts relating to its product candidates may not be successful; the possibility of being unable to obtain regulatory approval of Rexahn's product candidates; the risk that the results of clinical trials may not be completed on time or support Rexahn's claims; demand for and market acceptance of Rexahn's drug candidates; Rexahn's reliance on third party researchers and manufacturers to develop its product candidates; Rexahn's ability to develop and obtain protection of its intellectual property; and other risk factors set forth from time to time in our filings with the Securities and Exchange Commission. Rexahn assumes no obligation to update these forward-looking statements.



# Rexahn: Revolutionizing the Treatment of Cancer

Identify novel drug targets which are specific to cancer cells:

- Increased efficacy, reduced toxicity
- Efficacy against multiple drug resistant cancer cells
- Synergism with existing cytotoxic compounds

Develop in-licensed targeted drug delivery platforms:

- Nano-Polymer-Drug Conjugate System (NPDCS) combines existing anticancer agents with a polymer/signaling moiety which directs the drug directly to the tumor
- Lipid-Coated Albumin Nanoparticle (LCAN) to enhance delivery of oligonucleotides

# Rexahn Investment Highlights

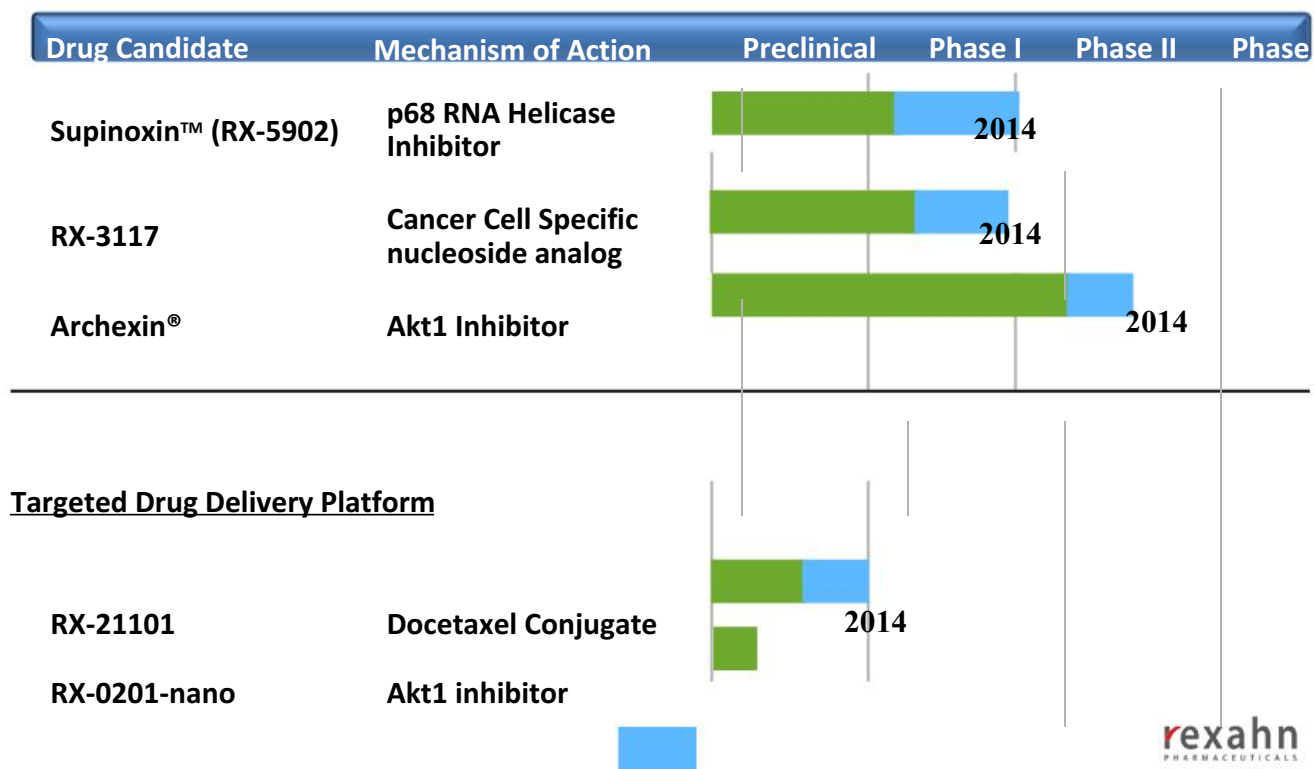
## Rapidly advancing pipeline: Initiated three clinical trials in 2013 with data in 2014

### Pipeline

- Supinoxin (RX-5902): Phosphorylated p68 RNA Helicase inhibitor. **Phase I** clinical trial in cancer patients with solid tumors; initiated August 2013
- RX-3117: Next generation cancer cell specific nucleoside analog. Completed European exploratory **Phase I** trial in cancer patients with solid tumors. IND filed and **Phase Ib** clinical trial in cancer patients initiated in December 2013
- Archexin: Akt1 inhibitor completed an exploratory **Phase IIa** clinical trial in pancreatic cancer. A **Phase IIa** clinical trial in cancer patients with metastatic renal cell carcinoma initiated in December 2013
- Nano-Polymer-Drug Conjugate System (NPDCS)
  - RX-21101: polymer conjugated form of docetaxel containing a signaling moiety which directs the drug into the tumor maximizing efficacy and minimizing toxicity
- Lipid-Coated Albumin Nanoparticle (LCAN)
  - RX-0201-nano: nanoliposomal Akt1 inhibitor, similar to Archexin®

## Strong Intellectual Property position

# Deep Oncology Pipeline



- Anticipated progress during 2014





**Supinoxin™ (RX-5902)**

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# Supinoxin: Best-in-Class p68 Helicase Inhibitor

## Mechanism

- Inhibition of phosphorylated p68 RNA helicase
- Blocks upregulation of cancer related genes

## Current and Future Indications

- Solid tumors: pancreas, NSCLC, colon, renal and other solid tumors

## Advantages

- Anti-proliferative effects
- Synergistic with cytotoxic agents
- Efficacy against drug resistant cancer cells
- Orally bioavailable

## Patent

- New chemical entity with a strong patent position

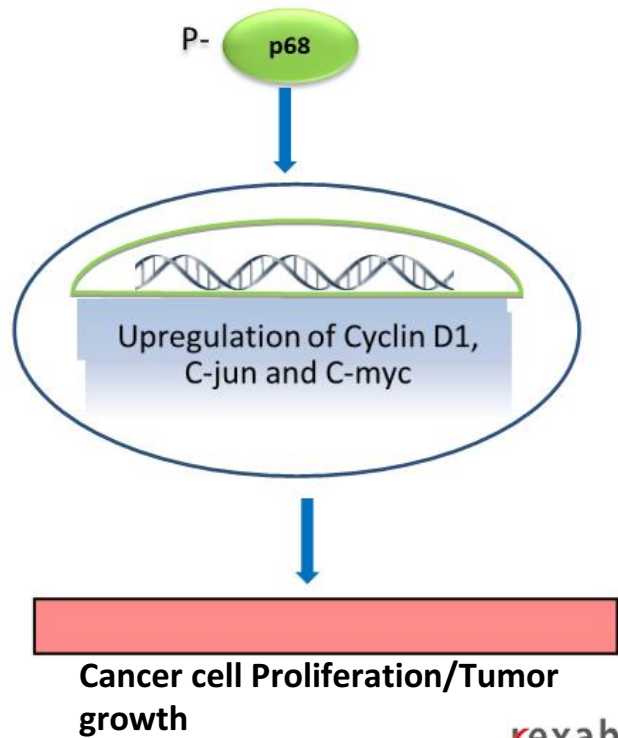
## Clinical Development

- **Phase I** clinical trial in cancer patients initiated August 2013
- Initial data expected in **Q1 2014**

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# Supinoxin: Mechanism of action

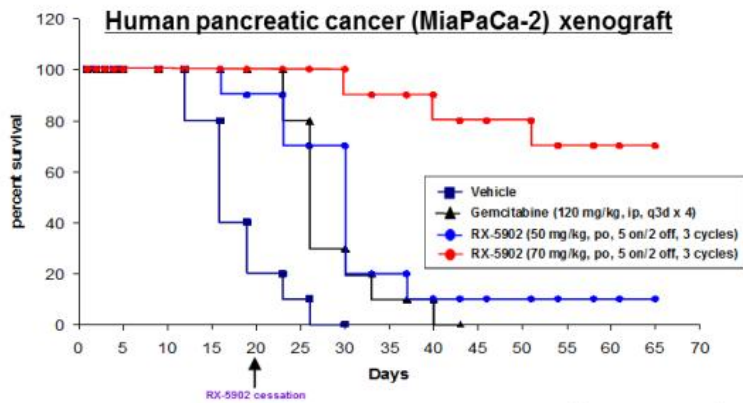
- Phosphorylated p68 is highly expressed in cancer cells but not in normal cells, and upregulates cancer-related genes
- Supinoxin selectively inhibits phosphorylated p68 RNA Helicase
  - Decreased proliferation/growth of cancer cells
  - Synergism with cytotoxic agents
  - Activity against drug resistant cancer cells



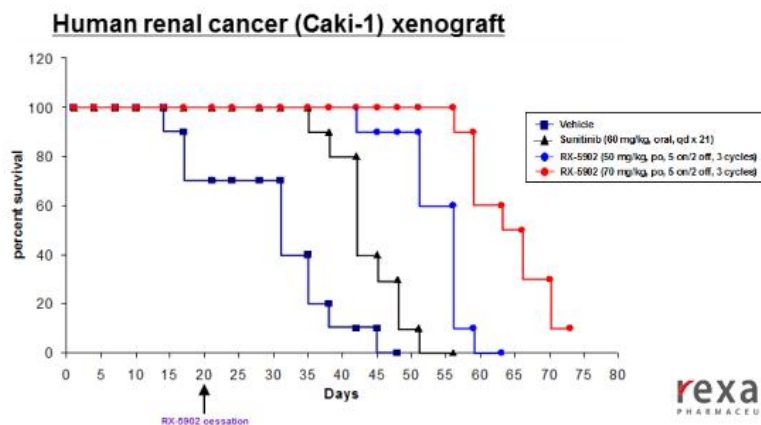
## Supinoxin: Phase I Clinical Trial (ongoing)

- Initiated August 2013
- Conducted at three clinical oncology centers in the United States
- Up to 20 cancer patients with solid tumors
- Dose escalation design; currently enrolling 4<sup>th</sup> dosing group
  - Escalation decisions based on safety, dosing, PK, laboratory, etc
  - Patients may receive up to 6 cycles of treatment
  - Primary endpoint: incidence of dose limiting toxicities; Secondary endpoint: changes in tumor size, plasma concentrations
  - Patients will be scanned (CT or MRI) prior to initiating treatment and after every 2 cycles
- Rexahn anticipates updating investors with data in early 2014

# Supinoxin: Increased Survival in Human Renal Cell Carcinoma and Pancreatic Cancer Xenograft Models



Treatment with Supinoxin on days 1 to 20 produced a survival benefit beyond 65 days



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**RX-3117**

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# RX-3117: Novel DNA synthesis inhibitor

## Mechanism of Action

- Cancer cell specific nucleoside compound that inhibits DNA synthesis
- Activated by UCK1 & UCK2

## Current and Future Indications

- Solid tumors: pancreas, NSCLC, colon, renal and other solid tumors

## Advantages

- Effective against gemcitabine-resistant human cancer cell lines
- Orally administered
- Specifically targeted against cancer cells; reduced adverse events

## Patent

- New chemical entity with a strong patent position

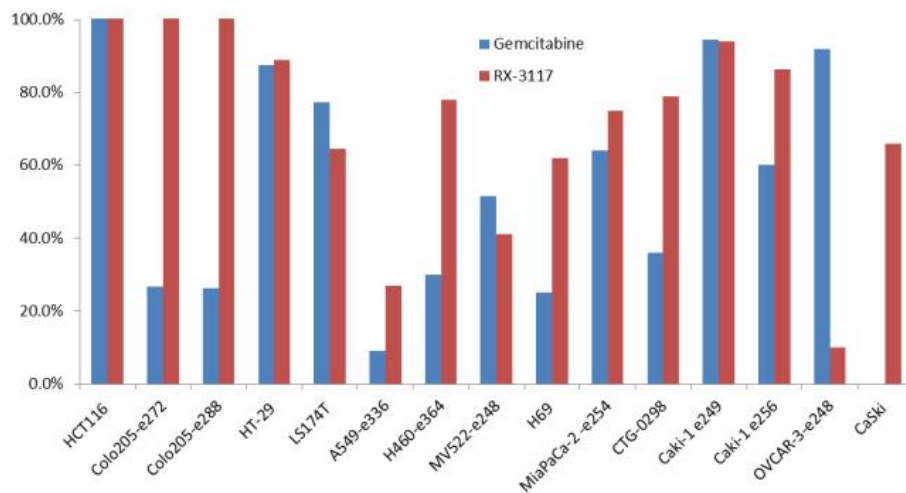
## Clinical Development

- Completed exploratory **Phase I** clinical trial in cancer patients
  - Confirmed oral bioavailability and safety
- **Phase Ib** clinical trial in cancer patients initiated Dec 2013

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## RX-3117: Compelling Efficacy in Animal Models

RX-3117 has shown robust anti-tumor effects across a broad variety of tumor types in animal models (Colon, Non-Small Cell Lung, Small Cell Lung, Pancreatic, Renal, Ovarian and Cervical)

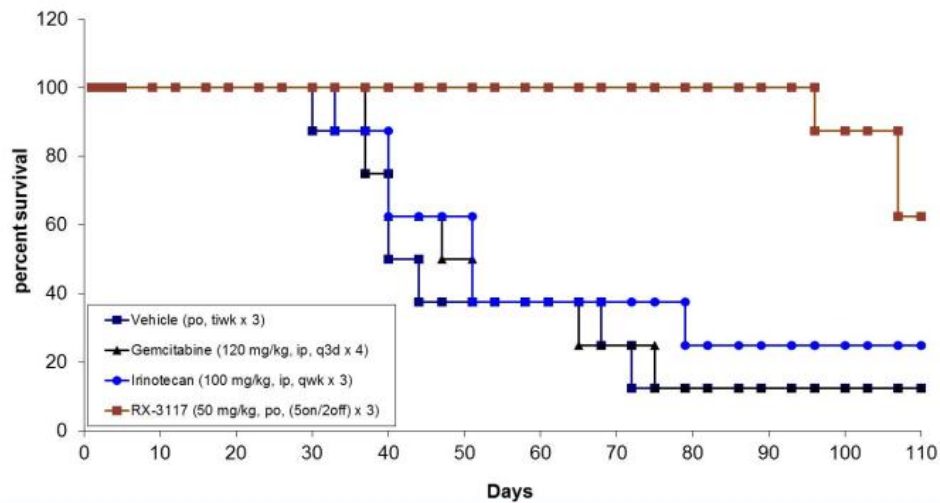


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## RX-3117: Compelling Efficacy in Animal Models

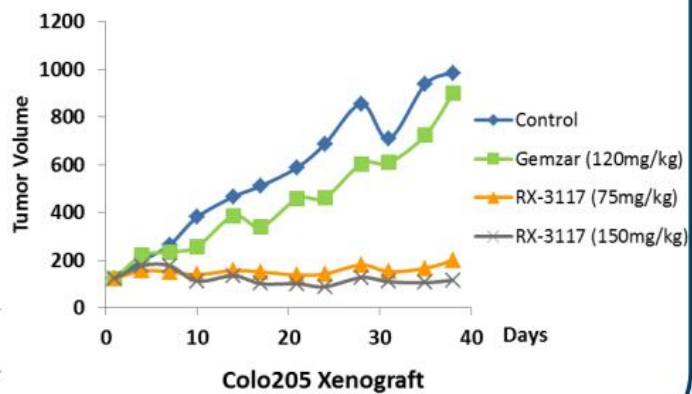
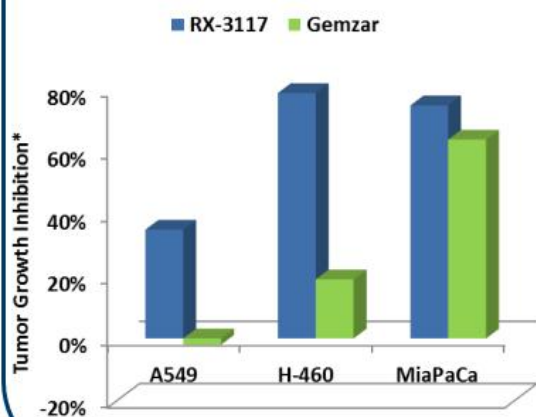
RX-3117 offers significant benefits based on overall-survival via oral administration in nude mice



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## RX-3117: Efficacy in Gemcitabine-Resistant Cell Lines

The efficacy of RX-3117 was examined in 12 different human tumor (Colon, Non-Small Cell Lung, Small Cell Lung, Pancreatic, Renal, Ovarian and Cervical)



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## RX-3117: Exploratory Phase I clinical Trial (Completed)

- Exploratory Phase I clinical trial in cancer patients was conducted in Europe in 2012
- Objectives:
  - Evaluate oral bioavailability and pharmacokinetics
  - Assess safety and tolerability
- Drug administration cohorts:
  - 20 mg IV (n=3)
  - 50 mg oral (n=3)
  - 100 mg oral (n=3)
- Results:
  - Nine subjects, ages 47 to 67 years, were enrolled
  - RX-3117 was orally bioavailable with T<sub>max</sub> of 2-3 hours, T<sub>1/2</sub> of 14-21 hours, and oral bioavailability of 33 to 56%
  - RX-3117 was well tolerated with no post-dose adverse events, laboratory abnormalities, or ECG changes emerging through 7 days of follow-up

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## RX-3117: Phase Ib Study Design (ongoing)

- Initiated December 2013
- Cancer patients with solid tumors
- Up to 30 patients and three clinical sites
- Treatment cycle is 28 days
  - Dosing 3 times a week for 3 weeks followed by 1 week off
- Dose Finding Study Design
  - Escalation decisions based on safety, dosing, PK, laboratory, etc
  - Patients may receive up to 8 cycles of treatment
  - Anti-tumor activity secondary endpoint
  - Patients will be scanned (CT or MRI) prior to initiating treatment and after every 2 cycles



# Archexin: Best-in-Class Akt1 Inhibitor

## Mechanism of Action

- Novel inhibitor of the protein kinase Akt1 – Major cancer cell signaling protein
- Activated Akt-1 only present in cancer cells
- Increases apoptosis by inhibiting Akt1 expression and activation
- Inhibition of Akt1-mediated drug resistance

## Current Indications

- Metastatic renal cell carcinoma

## Advantages

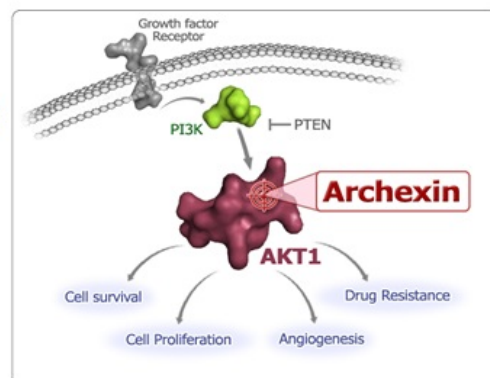
- Only compound in clinical development to selectively inhibit Akt1
- Excellent safety profile in humans

## Patent

- Strong patent position

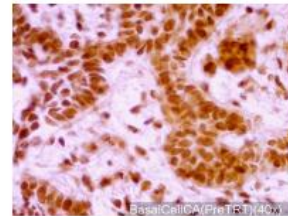
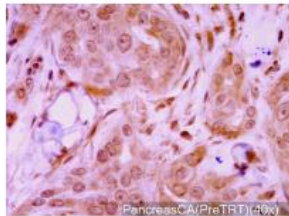
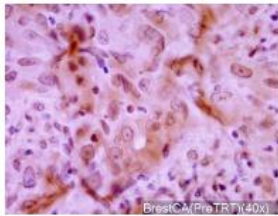
## Clinical Development

- **Phase I** trial in cancer patients completed
- Pancreatic cancer- **Phase IIa** completed
- **Phase IIa** trial in metastatic renal cell carcinoma (RCC) - ongoing



# Archexin: Phase I Clinical trial (completed)

- Phase I objective
  - To determine maximum tolerated dose, safety and pharmacokinetic profiles
- Phase I results:
  - MTD was 250 mg/m<sup>2</sup>/d in Patients with an advanced cancer after up to two cycles of treatment.
  - The dose limiting toxicity was Grade 3 fatigue; no significant hematological abnormalities
- Phospho-Akt1 being developed as a clinical biomarker



## Archexin: Phase IIa Study in Metastatic Pancreatic Cancer (completed)

- Open label 2-stage study to assess the safety and efficacy of Archexin in combination with gemcitabine
- 31 subjects enrolled (10 for safety, 21 for efficacy) with ages ranging 18-65 years with metastatic pancreatic cancer
- Archexin in combination with gemcitabine provided a median survival of 9.1 months compared to the historical survival data of 5.65 months (Burris et al., 1997, J. Clin Oncol 15:2403) for standard single agent gemcitabine therapy



## Archexin® Phase IIa Renal Carcinoma Clinical Trial Design

- Initiated December 2013
- Administered in combination with everolimus (Afinitor®) as a second line therapy to treat subjects with metastatic renal cell carcinoma
  - Resistance to mTOR inhibitors (everolimus) mediated by upregulation of Akt-1
- Part A – Identify maximum tolerated dose up to a target dose of 250 mg/m<sup>2</sup>/day in combination with everolimus
  - Dosing escalation decisions will be made following 1 cycle of therapy in 3 subjects
  - Assessment will include safety, dosing, PK, laboratory and physical exam
- Part B – Determine safety and efficacy of Archexin in 30 additional subjects with metastatic renal cell carcinoma
  - Randomized, 2:1 ratio of everolimus plus Archexin vs everolimus alone
  - Primary endpoint progression free survival following up to 8 cycles of therapy
  - Subjects are scanned (CT or MRI) for assessment of solid tumors at the end of every 2 treatment cycles



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## Major Milestones for 2014

- Initial data from Supinoxin Phase I Clinical trial (1Q14)
- Complete RX-3117 corporate partnership (mid year)
- Complete Supinoxin Phase I clinical trial (4Q14)
- Complete safety component of Archexin Phase IIa clinical trial (4Q14)
- Complete patient enrollment in RX-3117 Phase I clinical trial (4Q14/1Q15)

## Financial Highlights

Rexahn Financial Highlights	
Ticker	RNN
Exchange	NYSE MKT
Market Price (1/10/14)	\$1.14
Market Capitalization (1/10/14)	\$167 MM
Shares Outstanding (12/31/13)	147 MM
Insider Ownership	10%
Cash Balance (12/31/13)	\$19 MM
Monthly Est. Cash Burn	\$0.9 MM



# Rexahn Investment Highlights

**Rapidly advancing pipeline: Initiated three clinical trials in 2013 with data in 2014**

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**Strong Intellectual Property position**





## Revolutionizing the Treatment of Cancer

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