#### **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 10, 2015

# Rexahn Pharmaceuticals, Inc. (Exact Name of Registrant as Specified in its Charter)

<b>DELAWARE</b> (State or other jurisdiction of Incorporation)	<b>001-34079</b> (Commission File Number)	11-3516358 (I.R.S. Employer Identification No.)			
15245 Shady Grove Roa Rockville, MI	,	20850			
(Address of principal exec	utive offices)	(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 underly of the following provisions:				
<ul> <li>□ Written communications pursuant to Rule 425 u</li> <li>□ Soliciting material pursuant to Rule 14a-12 und</li> <li>□ Pre-commencement communications pursuant to Rule 425 u</li> </ul>	er the Exchange Act (17 CFR 240.14a-1 o Rule 14d-2(b) under the Exchange Act	2) t (17 CFR 240.14d-2(b))			

#### Section 7 — Regulation FD Disclosure

#### Item 7.01 Regulation FD Disclosure.

Furnished as Exhibit 99.1 to this Current Report on Form 8-K are slides for a presentation by Rexahn Pharmaceuticals, Inc. at the Rodman & Renshaw 17th Annual Global Investment Conference on September 10, 2015.

#### Section 9 - Financial Statements and Exhibits

#### Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

#### **Exhibit No.** Description

99.1 Rexahn Pharmaceuticals, Inc. investor presentation for the Rodman & Renshaw 17th Annual Global Investment Conference, dated September 10, 2015.

#### **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 10, 2015

/s/ Tae Heum Jeong

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





### **Investor Presentation**

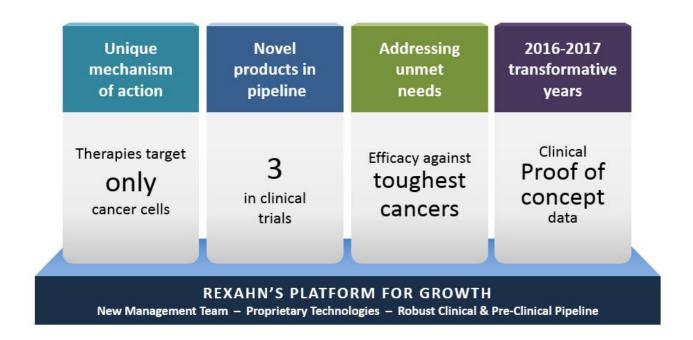
September 2015

### **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, including as a result of certain risks and uncertainties, such as 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.

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### Rexahn: Developing the Next Generation of Cancer Therapies\*



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\*Based on pre-clinical animal model data

# **Next Generation of Cancer Therapies**

# **The Company**

The Pipeline

**The Future** 



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### Rexahn: At a Glance

- Clinical stage biopharmaceutical company developing novel targeted cancer therapeutics
  - selectively destroy cancer cells
  - spare normal, healthy cells
- · Headquartered in Rockville, Maryland
- NYSE MKT: RNN
- Market cap: \$105M
  - 7% owned by management/insiders
- Cash and investments at June 30, 2015: \$26.0M
  - Estimated quarterly burn rate: ~4.0M
  - GAAP net loss for the three months ended June 30, 2015: \$(0.02)







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### New, Experienced Leadership Team - Built in Last 2 Years

#### Peter Suzdak Ph.D., Chief Executive Officer

- 25+ years experience in the biopharmaceutical industry
- Broad experience spanning pre-clinical, development and commercialization; 18 IND filings, 3 NDA submissions



#### Ely Benaim M.D., Chief Medical Officer

- 25+ years experience in healthcare including 15 years of clinical research experience in academia, government and pharmaceutical industry
- · Extensive experience in global regulatory affairs



#### Ted Jeong D.Mgt., Sr. Vice President and Chief Financial Officer

- · Extensive experience in venture capital and investment banking
- Oversees all aspects of capital raising, accounting, operations, and corporate development



#### Reza Mazhari, Vice President, Translational Medicine

- Experienced pharmaceutical executive; success taking multiple compounds from concept to clinic
- Co-Founder of Cardioxyl Pharmaceuticals, VP, Drug Discovery and Development at Cerecor





# **A Diversified Portfolio of Targeted Cancer Therapeutics**

Drug Candidate	Mechanism of Action	Preclinical	Phase I	Phase Ib/Ila	Preliminary Data	Clinical Proof of Concept
Supinoxin™ (RX-5902)	Phosphorylated p68 inhibitor				Phase I Q3 2015	Initiate 2016
RX-3117	Cancer cell specific nucleoside analog				Phase I Q3 2015	Initiate 2016
Archexin®	Akt-1 inhibitor				Phase IIa Part 1 H2 2015	Complete 2016
Targeted Nano Technology Drug Delivery Platform						
RX-21101	Docetaxel conjugate					

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## What Differentiates Rexahn's Programs:

### **Potential Advantages Over Existing and Emerging Therapies**

	Traditional Chemotherapy	PD1 / CAR T-Cell Therapies	Rexahn Therapies
Selectively targets cancer cells			V
Reduced adverse events			V
Convenient oral dosing (Supinoxin™ and RX 3117)			V
Active against toughest cancers		V	V
Synergistic with existing therapies		V	V
Broad spectrum of anti-cancer activity	V		V

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# **Next Generation of Cancer Therapies**

## **The Company**

# **The Pipeline**

### **The Future**



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# **Advancing Our Clinical-Stage Products**\*

DRUG CANDIDATE	POTENTIAL INDICATION	STATUS	MARKET OPPORTUNITY
Supinoxin™	Relapsed & Refractory Solid Tumors	Phase I	>\$3B
RX-3117	Gemcitabine Resistant Solid Tumors	Phase Ib	>\$4B
Archexin®	Metastatic Renal Cell Carcinoma	Phase IIa	>\$700M









\*Company estimates based on information from Datamonitor, Global Data and MedTrack reports as of August 2015

#### SUPINOXIN™ OVERVIEW

### Potential First-in-Class Inhibitor of a Unique Cancer Protein

#### The Candidate

Orally active, highly potent small molecule inhibitor of phosphorylated p68 (p-p68)

#### Significant Unmet Medical Need

• Demonstrated activity in >100 human cancer cell lines including: triple-negative breast, colon, ovarian, pancreas, non small cell lung cancer, and renal

#### Clinical Development – Status

- Phase I clinical trial with Supinoxin<sup>™</sup> in cancer patients is ongoing
  - Preliminary data expected Q3 2015
- Initiate Clinical Proof-of-Concept study in 2016

#### **Commercial Potential**

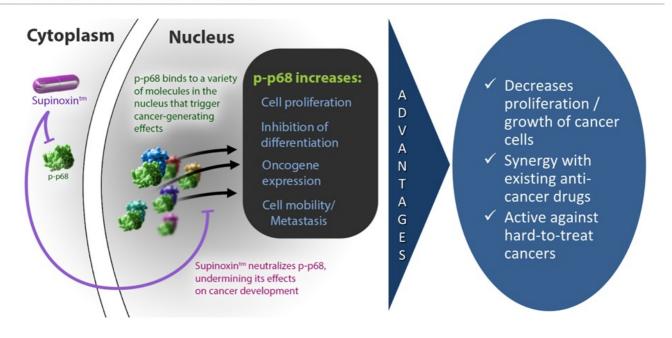
- Potential market opportunity: >\$3B
- · Strong intellectual property protection
- · Ongoing corporate partnership discussions





#### SUPINOXIN™ UNIQUE MECHANISM OF ACTION

# Potent, Well-Tolerated with Activity Against Difficult-to-Treat Cancers\*



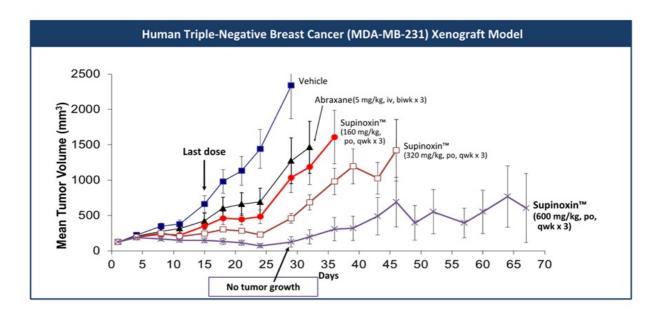
Supinoxin™ MOA supports a biomarker strategy for patient selection



\*Based on available clinical and pre-clinical data as of August 2015

SUPINOXIN™ EVIDENCE OF SUCCESS

# Blocks the Growth of Human Triple-Negative Breast Cancer Cells

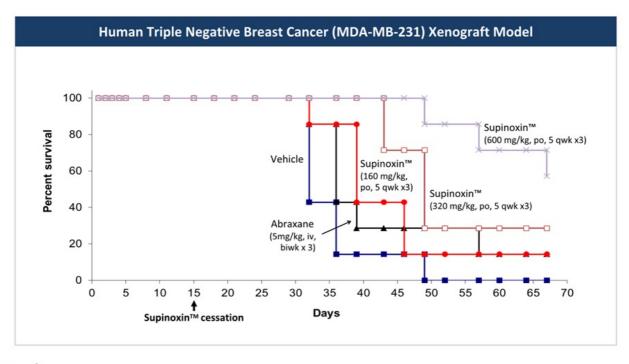


Large opportunity: Triple Negative Breast Cancer represents 20% of breast cancer diagnoses with limited treatment options; potential rapid path to market

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SUPINOXIN™ EVIDENCE OF SUCCESS

# **Survival Benefit in Human Triple Negative Breast Cancer Animal Models**



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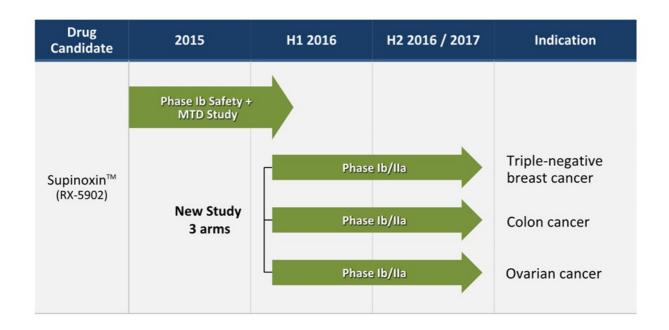
# **Ongoing Phase I Dose-Escalation Trial**

Primary Endpoints				
Maximum Tolerated Dose (MTD)	<ul> <li>✓ 25, 50, 100, 150, 225, 300, 425, 575, and 775 mg dose cycles complete</li> <li>✓ Patient enrollment and dosing ongoing</li> <li>□ Maximum tolerated dose (MTD) not yet achieved</li> </ul>			
Dose Limiting Toxicities	□ Not yet determined			
Safety Profile*	<ul> <li>Preliminary - Safe and well tolerated requiring testing of additional higher doses to define MTD</li> <li>Preliminary data expected Q3 2015</li> </ul>			
	Secondary Endpoints			
Pharmacokinetics	<ul> <li>✓ Dose-proportional exposure – Estimated oral bioavailability of 51%</li> <li>✓ Pharmacokinetics similar to what was seen in preclinical models</li> <li>□ Preliminary data expected Q3 2015</li> </ul>			
Tumor Response	□ Preliminary data expected Q3 2015			



\*Based on available clinical data as of August 2015

# Clinical Plan – Determine Clinical Activity Prior to Initiating Pivotal Phase Ib/IIa Clinical Trial





# **Advancing Our Clinical-Stage Products**\*

DRUG CANDIDATE	POTENTIAL INDICATION	STATUS	MARKET OPPORTUNITY
Supinoxin™	Relapsed & Refractory Solid Tumors	Phase I	>\$3B
RX-3117	Gemcitabine Resistant Solid Tumors	Phase Ib	>\$4B
Archexin®	Metastatic Renal Cell Carcinoma	Phase IIa	>\$700M









\*Company estimates based on information from Datamonitor, Global Data and MedTrack reports as of August 2015

### **Novel Next Generation Nucleoside Compound**

#### The Candidate

- Cancer cell specific small molecule nucleoside analogue that inhibits DNA and RNA synthesis causing cell death
- Prodrug activated by UCK2 which is only present in cancer cells
- · Active following oral administration

#### **Significant Unmet Medical Need**

 Gemcitabine-resistant cancers: bladder, colon, pancreatic, non-small cell lung cancer, renal and other solid tumors

#### Clinical Development - Status

- · Completed Phase I trial confirming oral bioavailability and initial safety
- · Phase Ib clinical trial in cancer patients is ongoing
  - Preliminary data expected Q3 2015
- · Initiate Clinical Proof-of-Concept study in 2016

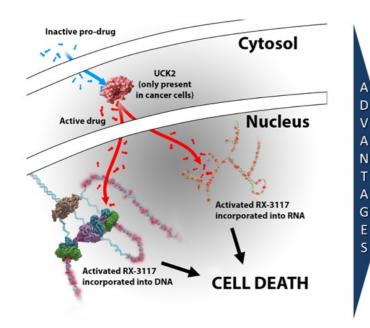
#### **Commercial Potential**

- Potential market opportunity: >\$4B
- · Strong intellectual property portfolio
- · Ongoing partnership discussions



#### RX-3117 UNIQUE MECHANISM OF ACTION

### Well Tolerated with Tumor-Specific Activity in Drug-Resistant Cancers\*



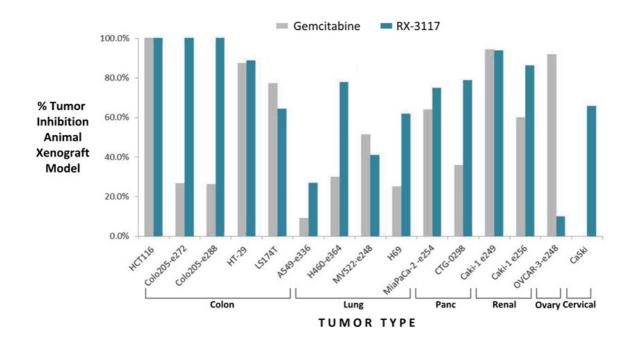
- ✓ Anti-tumor activities against a broad spectrum of cancers
- ✓ Anti-cancer effect on gemcitabine resistant cancers

RX-3117 MOA supports a biomarker strategy for patient selection



\*Based on available clinical and pre-clinical data as of August 2015

### **Efficacy Against Broad Range of Human Cancer Cell Types**

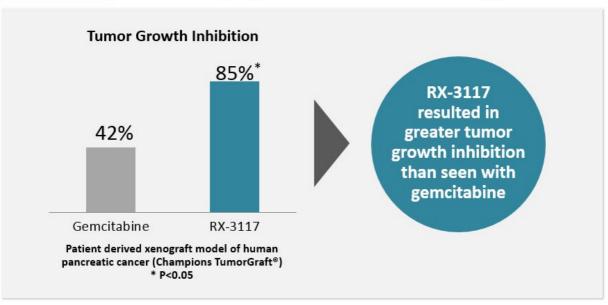


More effective than Gemcitabine across broad range of human tumor types



# Effective Against Gemcitabine Resistant Cancers - Key Advantage

### 25%-40% of cancer patients receiving gemcitabine The Need rapidly become resistant to chemotherapy



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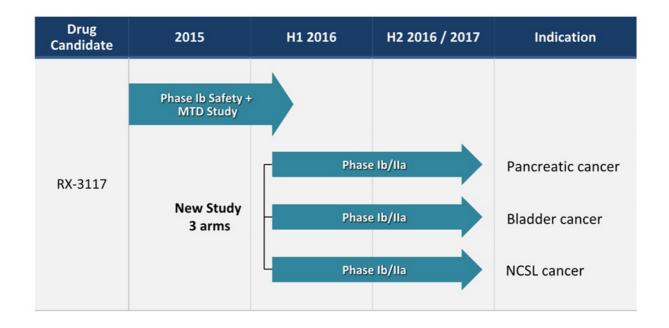
# **Ongoing Phase Ib Dose-Escalation Trial**

Primary Endpoints				
Maximum Tolerated Dose (MTD)	<ul> <li>✓ 30, 60, 100, 150, 200, 500, 1000, and 1500 mg dose cycles complete</li> <li>✓ Patient enrollment and dosing ongoing</li> <li>Maximum tolerated dose (MTD) not yet achieved</li> </ul>			
Dose Limiting Toxicities	□ Not yet determined			
Safety Profile*	<ul> <li>Preliminary - Safe and well tolerated requiring testing of additional higher doses to define MTD</li> <li>Preliminary data expected Q3 2015</li> </ul>			
Secondary Endpoints				
Pharmacokinetics	□ Preliminary data expected Q3 2015			
Tumor Response	□ Preliminary data expected Q3 2015			



\*Based on available clinical data as of August 2015

# Clinical Plan – Determine Clinical Activity Prior to Initiating a Pivotal Phase Ib/IIa Clinical Trial



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# **Advancing Our Clinical-Stage Products**\*

DRUG CANDIDATE	POTENTIAL INDICATION	STATUS	MARKET OPPORTUNITY
Supinoxin™	Relapsed & Refractory Solid Tumors	Phase I	>\$3B
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Archexin®	Metastatic Renal Cell Carcinoma	Phase IIa	>\$700M









\*Company estimates based on information from Datamonitor, Global Data and MedTrack reports as of August 2015

#### ARCHEXIN® OVERVIEW

### **Potential Best-in-Class AKT-1 Inhibitor**

#### The Candidate

- Novel inhibitor of cancer cell signaling protein, Akt-1, increasing cancer cell death
- Targets clinically validated cancer pathway
- · Also inhibits drug resistance; synergistic with approved drugs

#### **Significant Unmet Medical Need**

· Currently targeting metastatic renal cell carcinoma (mRCC)

#### Clinical Development - Status

- · Completed Phase I trial in cancer patients
- · Pancreatic cancer- Phase IIa completed
- · Phase IIa trial in metastatic RCC ongoing
  - Initial combination safety data mid 2015

#### **Commercial Potential**

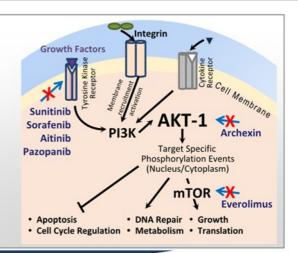
- FDA orphan drug designation for 5 cancers (renal, glioblastoma, ovarian, stomach, pancreas)
- Potential market opportunity: >\$700M
- Strong intellectual property portfolio
- · Ongoing partnership discussions

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### **Archexin® Targets A Clinically Validated Cancer Pathway**\*

#### Mechanism of Action

- PI3K/AKT-1/mTOR pathway involved in cancer cell growth and proliferation
- · AKT-1 inhibition
  - Blocks the development of resistance to mTOR and TKI inhibitors
  - Blocks the growth/proliferation of cancer cells



#### **ADVANTAGES**

- ✓ Decreases proliferation / growth of cancer cells
- ✓ Decreases new blood vessel growth
- ✓ Decreases drug resistance

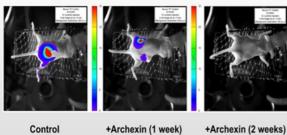
AKT-1 may be used as a biomarker to aid in patient selection



\*Based on available pre-clinical data as of August 2015

### **Archexin®: A Selective Inhibitor of AKT-1**

#### Xenograft model using luciferase-expressing human pancreatic cancer cells



Control +Archexin (1 week)

Archexin®: AKT-1 Inhibitor

- · Anti-cancer activity against multiple solid cancer tumors
- Synergistic with mTOR and tyrosine kinase inhibitors
- Prevents the development of resistance to mTOR inhibitors

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### **Completed Phase I and Phase IIa Trials**

#### Phase I (Cancer Patients with Solid Tumors)

#### **Primary Endpoints**

#### Maximum Tolerated Dose (MTD)

 250 mg/m2/d in patients with an advanced cancer after up to two cycles of treatment

#### Dose Limiting Toxicities

Grade 3 fatigue; no significant hematological abnormalities

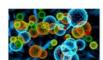
#### Phase IIa (Metastatic Pancreatic Cancer Patients)

#### **Primary Endpoint**

#### Tumor Response

 Archexin in combination with gemcitabine provided a median survival of 9.1 months compared to 5.65 months for gemcitabine alone









### Only Selective AKT-1 Inhibitor in Clinical Development - Status

#### Phase IIa

### Study Design

- Metastatic renal cell carcinoma (mRCC)
- Second line therapy
- Administered in combination with everolimus (Affinitor®)
- Part A: Identify maximum tolerated dose in combination with everolimus
- Part B: Determine safety and efficacy in 30 additional mRCC patients







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# **Next Generation of Cancer Therapies**

## **The Company**

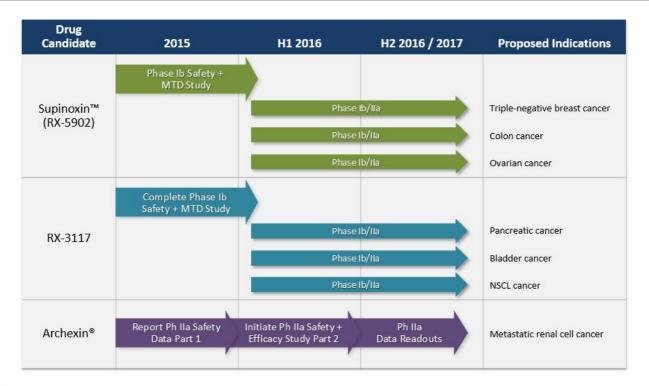
# The Pipeline

### **The Future**



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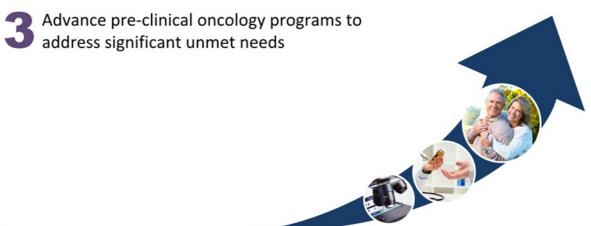
# **Robust Pipeline Targeting Multiple Cancer Indications**





### **Developing the Next Generation of Cancer Therapies**

- Advance cancer therapies through proof-of-concept clinical development
- **2** Establish partnerships with pharmaceutical companies; focus on maximizing shareholder value



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### **Investor Presentation**

September 2015