

**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 12, 2015**

**RESTORGENEX CORPORATION**

(Exact name of registrant as specified in its charter)

**Nevada**  
(State or other jurisdiction of  
incorporation)

**000-24477**  
(Commission File  
Number)

**30-0645032**  
(I.R.S. Employer  
Identification No.)

**2150 E. Lake Cook Road, Suite 750**  
**Buffalo Grove, Illinois**  
(Address of principal executive offices)

**60089**  
(Zip Code)

**(847) 777-8092**  
(Registrant's telephone number, including area code)

**Not applicable**  
(Former name or former address, if changed since last report)

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))

**Item 7.01 Regulation FD Disclosure.**

Beginning on or about January 12, 2015, representatives of RestorGenex Corporation intend to make presentations at investor conferences and in other forums and these presentations may include the information contained in Exhibit 99.1 attached to this current report on Form 8-K. A copy of the presentation slides containing such information that may be disclosed by RestorGenex is attached as Exhibit 99.1 to this report and the information set forth therein is incorporated herein by reference and constitutes a part of this report. RestorGenex expects to disclose the information contained in Exhibit 99.1, in whole or in part, and possibly with modifications, in connection with presentations to investors, analysts and others during the remainder of 2015.

RestorGenex is furnishing the information contained in Exhibit 99.1 pursuant to Regulation FD and Item 7.01 of Form 8-K. The information in Exhibit 99.1 shall not be deemed to be "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section, nor shall it be deemed to be incorporated by reference in any filing under the Securities Act of 1933, as amended, except as expressly set forth by specific reference in such filing.

The information contained in Exhibit 99.1 is summary information that is intended to be considered in the context of RestorGenex's Securities and Exchange Commission ("SEC") filings and other public announcements that RestorGenex may make, by press release or otherwise, from time to time. RestorGenex undertakes no duty or obligation to publicly update or revise the information contained in Exhibit 99.1, although it may do so from time to time as its management believes is warranted. Any such updating may be made through the filing of other reports or documents with the SEC, through press releases or through other public disclosure. By filing this current report on Form 8-K and furnishing this information, RestorGenex makes no admission as to the materiality of any information contained in this report, including Exhibit 99.1.

**Item 9.01. Financial Statements and Exhibits**

<u>Exhibit No.</u>	<u>Description</u>
99.1	Investor Presentation Slides to be used by RestorGenex Corporation (furnished herewith)

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: January 12, 2015

**RESTORGENEX CORPORAITON**

By: /s/ Phillip B. Donenberg  
Name: Phillip B. Donenberg  
Title: Chief Financial Officer

**RESTORGENEX CORPORATION  
CURRENT REPORT ON FORM 8-K**

**EXHIBIT INDEX**

<u>Exhibit No.</u>	<u>Description</u>	<u>Method of Filing</u>
99.1	Investor Presentation Slides to be used by RestorGenex Corporation	Furnished herewith



This presentation includes "forward-looking statements" under the Private Securities Litigation Reform Act of 1995. All statements other than statements of historical facts contained in this presentation, including statements regarding our anticipated future clinical and regulatory events, future financial/position, business strategy and plans and objectives of management for future operations, are forward-looking statements. Forward-looking statements can be identified by words such as "potential," "may," "will," "should," "forecast," "project," "could," "expect," "believe," "estimate," "anticipate," "intend," "plan," "continue", other words of similar meaning, derivations of such words and the use of future dates. Forward-looking statements in this presentation include, without limitation, statements regarding our current business strategies, the potential future commercialization of our product candidates, potential estimated market sizes for our product candidates, anticipated start dates, durations and completion dates, as well as potential future results, of our future clinical trials, anticipated designs of our future clinical trials, and anticipated future regulatory submissions and events. Uncertainties and risks may cause actual results to be materially different than those expressed in or implied by our forward-looking statements. Particular uncertainties and risks include, among others, uncertainties regarding our ability to license out our existing and license in additional products and technologies and the terms of such licenses; uncertainties involved in clinical testing, the difficulty of developing pharmaceutical products, obtaining regulatory and other approvals and achieving market acceptance, and other risks and uncertainties described in our filings with the Securities and Exchange Commission, including our most recent annual report on Form 10-K/A, subsequent quarterly reports on Form 10-Q and final prospectus dated July 31, 2014. All forward-looking statements in this presentation speak only as of the date of this presentation and we undertake no obligation to update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

- **Two core technologies**
  - PI3K/Akt/mTOR Pathway Inhibitor
  - “Soft” Anti-Androgen
- **Three clinical trials to be initiated in 2016**
  - Age related macular degeneration
  - Glioblastoma
  - Acne
- **Strong preclinical in-vitro and in-vivo data**
- **Lead product completed two Phase I clinical trials**
- **Experienced board of directors and management**

## Overview



- **Specialty pharmaceutical company initially focused on developing products for ophthalmology, oncology and dermatology**
  - Headquartered in Chicago
  - Eight employees
    - One MD
    - Three PhDs
- **Indications in development**
  - Age related macular degeneration
  - Glioblastoma
  - Acne

- **Stephen M. Simes - Chief Executive Officer**
  - BioSante, Unimed, Bio-Technology General, Gynex, Searle
- **Phillip B. Donenberg – Chief Financial Officer**
  - BioSante, Unimed, Gynex
- **Mark Weinberg, MD, MBA – Senior VP, Clinical Development**
  - Astellas, Lundbeck, Ovation, Takeda, Abbott
- **David Sherris, Ph.D. - Chief Scientific Officer**
  - Paloma/Vasculomedics, OXiGENE, Serono, Unilever, Centocor
  - Ph.D. in Biochemistry and Molecular Genetics
- **Yael Schwartz, Ph.D. – Executive VP, Preclinical Development**
  - Hygeia/Canterbury Labs, Sepracor, Parexel International, Dana-Farber Cancer Institute
  - Ph.D. in Endocrine Physiology

# Board of Directors

- **Sol Barer, PhD - Chairman**
  - Former CEO & Executive Chairman, and Chairman, Celgene Corporation
- **Isaac Blech - Vice-Chairman**
  - Leading biotechnology entrepreneur and investor
  - Genetic Systems, Nova, Celgene, ICOS, Texas BioTechnology, Pathogenesis
- **Stephen M. Simes – CEO**
  - BioSante, Unimed, Bio-Technology General, Gynex, Searle
- **Rex Bright**
  - SkinMedica, J&J, GlaxoSmithKline, Allergan
- **Nelson Stacks**
  - Waveguide Corporation
- **Yael Schwartz, PhD – Executive VP, Preclinical Development**
  - Hygeia/Canterbury Labs, Sepracor, Parexel International, Dana-Farber Cancer Institute
- **David Sherris, PhD – Chief Scientific Officer**
  - Paloma/Vasculomedics, OXiGENE, Serono, Unilever, Centocor



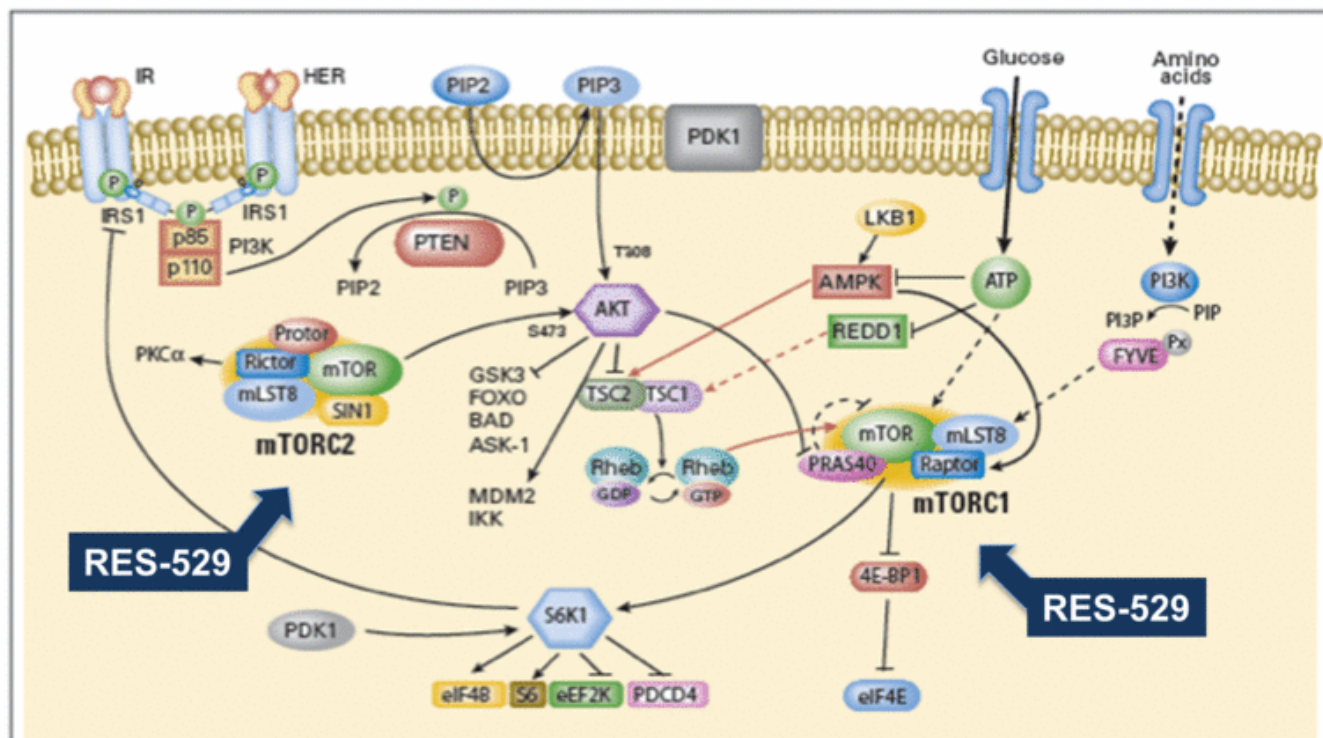
# Summary Product Portfolio

Program / Therapeutic Area		2014	2015	2016
RES-529	<b>OPHTHALMOLOGY</b>			
	Age-Related Macular Degeneration (AMD)	Phase I IVR Phase I SubConj (NEI)	Formulation / Nonclinical	Phase I/II SubConj
	<b>ONCOLOGY</b>			
	Glioblastoma Multiforme (GBM)		Formulation / Nonclinical	Phase I/II
RES-440	<b>DERMATOLOGY</b>			
	Acne		Formulation / Nonclinical	Phase I/II
RES-214	<b>COSMECEUTICAL</b>			
	Hormonally Aging Skin / Wrinkling		Development by Ferndale	Launch

## RES-529 & the PI3K Pathway

- **First-in-class PI3K/Akt/mTOR pathway inhibitor**
- The PI3K/Akt/mTOR pathway is an important signaling pathway for many cellular functions such as **cell proliferation, angiogenesis and vascular permeability**
  - Many opportunities for drugs to interfere with its signaling
  - Agents in development affect different targets
    - PI3K inhibitors
    - Akt inhibitors
    - mTOR inhibitors
  - These agents are believed to be limited by feedback loops within the pathway
- ***RES-529 is a novel approach to inhibition of the PI3K pathway.*** Rather than interfering with signaling via specific receptors (e.g. PI3K, Akt, mTOR) it interferes with the molecular components which make up TORC1 and TORC2 preventing these complexes from generating and potentiating signaling within the pathway.

# RES-529 Mechanism of Action



**RES-529** interferes with the molecular components of TORC1 and TORC2 preventing these complexes from generating and potentiating signaling and thereby interferes with the activities of the PI3K/Akt/mTOR pathway: translation, cell growth, ribosome biogenesis, metabolism, proliferation, and autophagy



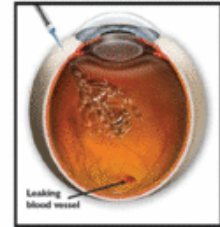
# Ophthalmology

- **Back of the eye diseases have large market size and financial potential**
  - **Age-related macular degeneration**
    - 20 million cases of age-related macular degeneration in the US/EU
    - Approximately 10% of patients 66 to 74 years of age will have findings of macular degeneration
      - The prevalence increases to 30% in patients 75 to 85 years of age
    - Two drugs approved, **Lucentis** (Genentech/Novartis) and **Eylea** (Regeneron/Bayer/Sanofi)
      - Cost of single injection approximately \$2,000.00
      - Treatments required every four to six weeks (Lucentis), eight to twelve weeks (Eylea) for life
      - Estimated 2013 Eylea sales \$1.4 billion, Lucentis US sales \$1.7 billion

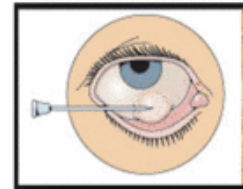
- RES-529 is being developed as a subconjunctival injection for maintenance treatment
- Clinical trials for RES-529 will be designed to demonstrate that patients may transition from acute therapy (Lucentis, Avastin, Eylea) to RES-529
  - Enabling patients to be maintained with subconjunctival (vs. intravitreal) administration
  - Once every three month therapy (vs. monthly or on demand requiring frequent follow up)

Drug	Acute period (3 months)	Chronic administration (estimates for next nine months)
Lucentis (current label)	Monthly intravitreal injections	Intravitreal injections every 4 wks "although not as effective"* patients can be treated with intravitreal injections every 3 months OR intravitreal injections as needed (average of 4-5 over 9 months)
Eylea (current label)	Monthly intravitreal injections	Intravitreal injection every 8 weeks
RES-529 (To be evaluated in clinical trials)	Acute treatment with Lucentis / Eylea	Subconjunctival administration every 3 months

\*Lucentis prescribing information.



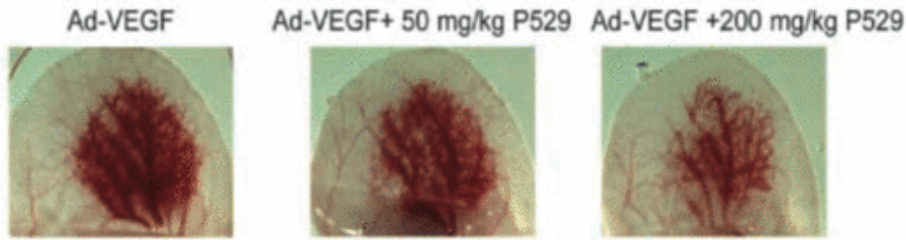
**Intravitreal** – needle penetrates into the globe of the eye



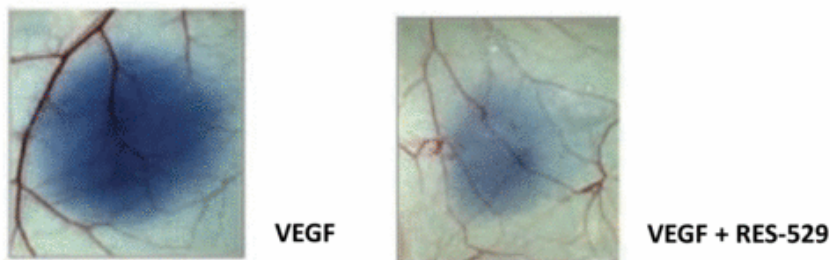
**Subconjunctival** – fluid is injected beneath the conjunctiva

# RES-529 Inhibits VEGF Induced Angiogenesis (top) and Permeability (bottom)

- Mice pretreated with RES-529 IP 24 hrs prior to intradermal injection of adenovirus expressing mouse VEGF-A164 to mouse ear



- Mice pretreated with RES-529 IP 24 hrs prior to intradermal injection of 100 ng VEGF to ear; 0.1 ml of 0.5% Evans Blue given IV 30 minutes after VEGF treatment

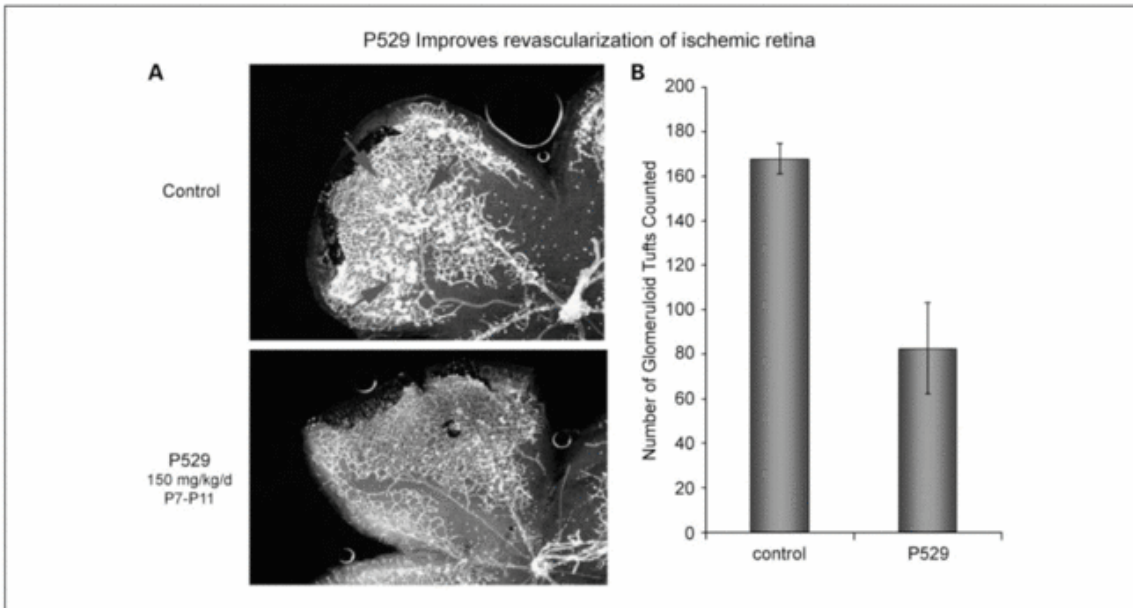


Xue Q. et al. Palomid 529, a Novel Small-Molecule Drug, Is a TORC1/TORC2 Inhibitor That Reduces Tumor Growth, Tumor Angiogenesis, and Vascular Permeability. *Cancer Res* 2006;68(22):9551-7.

RES-529 = P529 = Palomid 529

# RES-529 Inhibits Pathogenic Angiogenesis

- RES-529 was evaluated in an in vivo model of oxygen-induced retinopathy in the neonatal mouse.
- Treatment reduced the number of incompletely formed and aberrant vascular structures.



**Figure 2.** P529 inhibition of retinal neovascularization. *A*, the blood vessel proliferation in control retinas and retinas treated for 5 d with 1 mg/d P529 are shown after staining for lectin and flat mounting. The abnormal angiogenesis associated with vitreal invasion can be seen as glomeruloid-like tufts of cells (*arrow*). *B*, counting the glomeruloid tufts was used to provide a quantitative measure of P529 angiogenesis inhibition. *Bars*, SD.

Xue Q. et al. Palomid 529, a Novel Small-Molecule Drug, Is a TORC1/TORC2 Inhibitor That Reduces Tumor Growth, Tumor Angiogenesis, and Vascular Permeability. *Cancer Res* 2008;68(22):9551-7.

RES-529 = P529 = Palomid 529



## RES-529: Completed Phase I Trials in AMD

- **Protocol P52901 sponsored Company and conducted by Dr. Jeffrey Heier (Eye Boston) and Dr. David Brown (Retinal Consultants Houston)**
  - A Phase I Open-Label Study to Investigate the Safety, Tolerability and Pharmacokinetic Profile of Single Intravitreal and Subconjunctival Doses of RES-529 in Patients with Advanced Neovascular Age-Related Macular Degeneration (AMD)
  - 15 patients treated via intravitreal injection
  - Doses between 0.004mg and 0.5mg
- **Protocol 11-EI-0066 sponsored by National Eye Institute (NEI) and conducted by Dr. Catherine Meyerle**
  - A Phase I Unmasked Study to Investigate the Safety and Tolerability of Subconjunctival Injections of RES-529 in Patients with Neovascular Age-Related Macular Degeneration\*
  - 5 patients treated with subconjunctival injections of 2mg qmo x 3

\*Dalal M. et al. Subconjunctival Palomid 529 in the treatment of neovascular age-related macular degeneration. *Graefes Arch Clin Exp Ophthalmol* (2013) 251:2705–2709.  
RES-529 = P529 = Palomid 529

## RES-529: Clinical Data

- **Patients enrolled:**
  - End stage patients, refractory to VEGF therapy
  - Most had significant visual deficits and retinal fluid on OCT
- **Safety/Tolerability:**
  - **Intravitreal administration (Company sponsored study)**
    - 0.5 mg (highest dose studied) associated with temporary visual disturbance from haze in vitreous attributed to drug particles in the vitreous. This effect resolved.
  - **Subconjunctival administration (NEI study)**
    - 2mg monthly x 3 administered
    - Depot formed at injection site
- **Efficacy:**
  - **Preliminary evidence of biologic activity based on:**
    - fluid pocket reduction
    - retinal thinning
    - cyst reduction

## RES-529: Status in AMD

- **2015:**
  - **Synthesis of additional API**
  - **Formulation of subconjunctival drug product**
  - **Toxicology studies to support future trials with subconjunctival formulation**
- **2016:**
  - **Phase I/II clinical trial**
    - **Additional assessment of safety and tolerability**
    - **Determine MTD for subconjunctival administration**
    - **Clinical efficacy**



# Oncology

## RES-529 in Glioblastoma

- **Glioblastoma is lead oncology indication**
- **Why glioblastoma:**
  - Tremendous unmet medical need
  - Proving efficacy is challenging but upside is significant
  - PI3K/Akt/mTOR pathway significantly up-regulated in glioblastoma
  - Plan to conduct phase 2a studies in other tumors once MTD is determined
  - Orally available
  - Potential orphan indication
- **Market size:**
  - WW market about \$1 billion in 2013 to \$4.5 billion by 2020 at a Compound Annual Growth Rate of approximately 28%.\* Growth will be driven primarily by new agents.

\* EvaluatePharma, Adis R&D Insight

\*\* Treatment options and outcomes for glioblastoma in the elderly patient, N.D. Arvold and D. A. Reardon, *Interv Aging*. 2014; 9: 357–367

## RES-529 in Glioblastoma

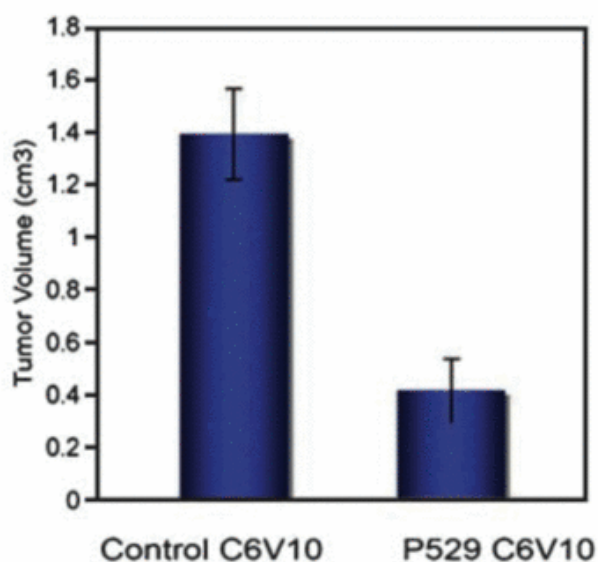
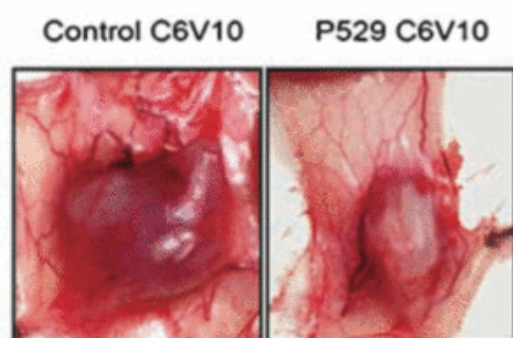
- **Current products:**
  - Current standard of care products Temodar, Avastin, Gliadel Wafer
  - Median survival with only supportive care, less than 6 months\*\*
  - Median survival with aggressive chemotherapy in combination with radiotherapy, 12 to 15 months\*\*
- **RES-529 benefits:**
  - Activity shown in multiple in vitro and in vivo animal models for GBM with evidence that it can pass the blood brain barrier
  - First-in-class mechanism of action exerting PI3K/Akt/mTOR pathway control above other drugs targeting this pathway (PI3K pathway significantly up-regulated in GBM)

\* EvaluatePharma, Adis R&D Insight

\*\* Treatment options and outcomes for glioblastoma in the elderly patient, N.D. Arvold and D. A. Reardon, *Interv Aging*. 2014; 9: 357–367

## RES-529 inhibits C6V10 Glioma Tumor Growth in Orthotopic Xenograft Model

- Four- to 6-wk-old female nude mice were pretreated with P529 (200 mg/kg/2 d, i.p.) for 1 wk, and then  $1 \times 10^5$  C6V10 rat glioma cells were injected s.c. Treatment continued while tumors were allowed to grow for 21 d.



Xue Q. et al. Palomid 529, a Novel Small-Molecule Drug, Is a TORC1/TORC2 Inhibitor That Reduces Tumor Growth, Tumor Angiogenesis, and Vascular Permeability. *Cancer Res* 2008;68(22):9551-7.

## RES-529 has been extensively studied by academia in preclinical oncology models

- Similar efficacy in glioma orthotopic xenograft model regardless of route of administration (iv, po, or ip)<sup>1</sup>
- Potent effects in NCI60 cell line panel<sup>2</sup>
- Penetration of the blood brain barrier with pharmacologically active levels reached in murine brain<sup>3</sup>
- Efficacy in breast cancer xenografts<sup>4</sup>
- Synergy with XRT and chemotherapy in prostate cancer xenografts<sup>5,6</sup>

<sup>1</sup>Xue Q. et al. Palomid 529, a Novel Small-Molecule Drug, Is a TORC1/TORC2 Inhibitor That Reduces Tumor Growth, Tumor Angiogenesis, and Vascular Permeability. *Cancer Res* 2008;68(22):9551-7 and Xue Q. unpublished data.

<sup>2</sup>Díaz R. et al. The novel Akt inhibitor Palomid 529 (P529) enhances the effect of radiotherapy in prostate cancer. *Br J Cancer* 2009Mar24;100(6):932-40.

<sup>3</sup>Lin F. et al. Dual mTORC1 and mTORC2 inhibitor Palomid 529 penetrates the Blood-Brain Barrier without restriction by ABCB1 and ABCG2. *Int J Cancer* 2013Sep1;133(5):1222-33.

<sup>4</sup>Xiang T. et al. Targeting the Akt/mTOR pathway in Brca1-deficient cancers. *Oncogene* 20011May26;30(21):2443-50.

<sup>5</sup>Gravinia GL. et al. Torc1/Torc2 Inhibitor, Palomid 529, Enhances Radiation Response Modulating CRM1-Mediated Survivin Function and Delaying DNA Repair in Prostate Cancer Models. *Prostate* 2014JanJun74(8):852-68.

<sup>6</sup>Gravinia GL. et al. The TORC1/TORC2 inhibitor, Palomid 529, reduces tumor growth and sensitizes to docetaxel and cisplatin in aggressive and hormone-refractory prostate cancer cells. *Endocrine Related Cancer* (2011);18:385-400

RES-529 = P529 = Palomid 529



## RES-529: Status in Glioblastoma

- **2015:**
  - Synthesis of additional API
  - Development of oral formulation
  - Toxicology studies to support systemic administration in oncology
- **2016:**
  - Phase I/II clinical trial
    - Determine MTD in glioblastoma
    - Efficacy assessment in recurrent glioblastoma
    - Launch Phase 2a studies in other oncology indications utilizing MTD dose
      - Including prostate cancer and breast cancer



# **Dermatology**

## **RES-440: Our Lead Anti-androgen**

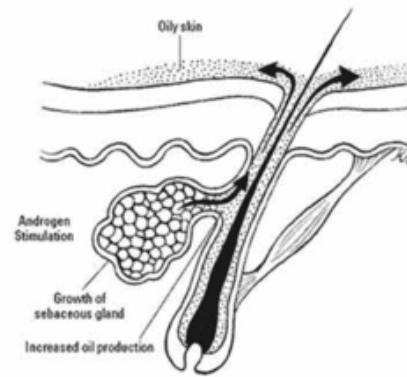
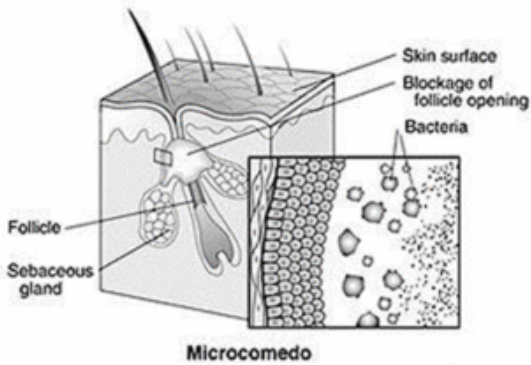
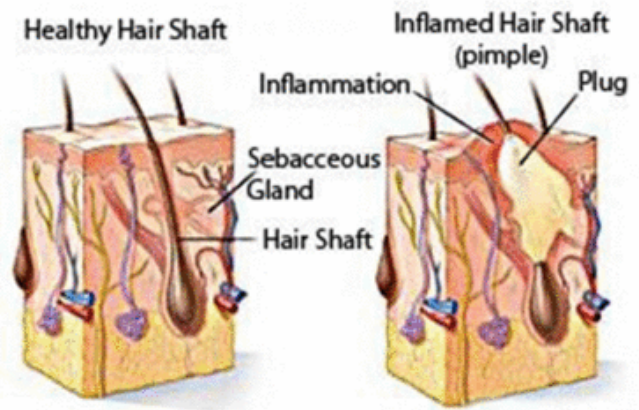
**An Easily Deactivated, Topically Active “Soft” Anti-Androgen  
for Local Disorders Resulting from Excess Androgen**

**Acne Vulgaris is the Primary Initial Market Opportunity**

## RES-440: Directly Targets the Pilosebaceous Unit of the Skin

Skin disorders that could be treated topically with an anti-androgen include:

- Acne
- Hirsutism
- Androgenic Alopecia
- Seborrhea



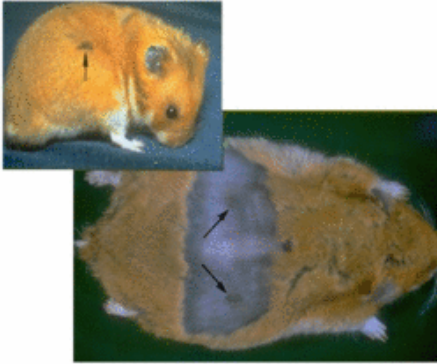
## RES-440 (“soft” anti-androgen)



- **Proposed indication:**
  - Acne
- **Market size:**
  - \$1B-\$2B\*\* (Acne affects 40 million to 50 million Americans)
- **Current products:**
  - Retinoids: skin irritation, sunlight sensitivity;
  - Accutane: systemic effects, birth defects;
  - Antibiotics: tooth discoloration and resistance
- **RES-440 benefits:**
  - A first-in-class topical that directly targets the androgen receptor;
  - no systemic exposure;
  - non-irritating, no sunlight sensitivity
- **Status: Phase I/II Q1 2016 (12 week trial)**

\*\*IBIS World, 2012; GlobalData, 2010: Acne Drug Pipeline Analysis and Market Forecasts to 2016

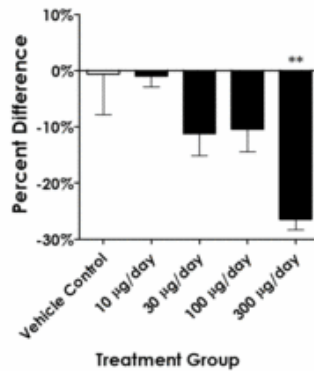
# RES-440: Adult Male Syrian Golden Hamsters as a Model for Antiandrogen Activity *In Vivo* and ability to assess local vs. systemic activity



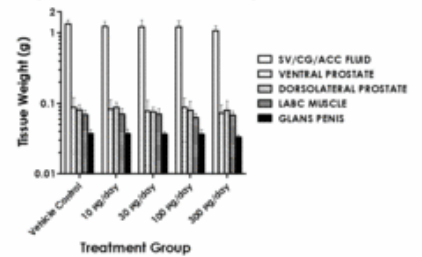
- The arrows in this image show the location of the flank glands, one of the unique anatomic characteristics of Syrian hamsters.
- The flank glands are composed of sebaceous glands, terminal hairs (indicated by the arrow), and pigment cells.
- Male secretions are produced in response to androgens and are used to mark territory.
- Topically, Flutamide significantly reduced both treated and untreated flank organs as well as reducing the size of androgen-sensitive internal organs.

- Once-daily RES-440 treatment applied to the right flank organ for 21 days (n =6).
- Peak effect observed between Days 7-10 and remained through Day 21
- Unlike Flutamide at these doses, no decreases of the untreated flank organ were observed.
- At necropsy, no evidence of antiandrogenic effects on internal androgen-sensitive tissues

Mean (SE) Flank Organ Area Differences (Days 10, 14, 18 and 21 Combined)



Androgen-sensitive Hamster Tissue Weights



## RES-440: Status in Acne

- **2015:**
  - Synthesis of API
  - Development of topical formulation for clinical trials in acne
  - Toxicology work to support IND
- **2016:**
  - Phase I/II clinical trial
    - Assess safety and tolerability
    - Efficacy in treatment of acne

## **RestorGenex Summary Financial Information**

as of December 31, 2014

- **Cash: \$22,000,000**
- **Accounts payable: \$94,000**
- **Debt: \$0**
- **Burn rate into 2015: Approximately \$600,000/month**
  
- **Shares outstanding: 18,621,153**
- **Options outstanding: 3,658,701**
- **Warrants outstanding: 4,571,799**
- **Fully diluted: 26,851,653**



# Overview

- **Specialty pharmaceutical company initially focused on developing products for ophthalmology, oncology and dermatology**
- **Indications in development**
  - **Ophthalmology**
    - Age-related macular degeneration (AMD);
    - Two Phase I trials completed
    - Current market: over \$3 billion
  - **Oncology**
    - Initially targeting glioblastoma, follow-on to other oncology indications
    - Current market: over \$1 billion in glioblastoma; multi-billion in several oncology indications
  - **Dermatology:**
    - Acne is lead indication
    - Current market: over \$1 billion

# Investment Opportunity



- **Board and management have built major value in public and private biotechnology companies**
- **Multiple products in development**
  - Relatively short/inexpensive trials leading to rapid and numerous valuation inflection points
- **Multi-billion dollar indications**
- **Proposed products based on proprietary platforms**
- **Financial security**
- **Near-term goal: increased stockholder value through development programs and licensing**

