
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 9, 2012

Ohr Pharmaceutical, Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other Jurisdiction of Incorporation)

333-88480

(Commission File Number)

#90-0577933

(IRS Employer Identification No.)

489 5th Ave, 28th Floor, New York, NY

(Address of Principal Executive Offices)

10017

(Zip Code)

Registrant's telephone number, including area code: (212)-682-8452

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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ITEM 7.01. Regulation FD Disclosure.

Ohr Pharmaceutical Inc. (the "Company") will be making a presentation to potential investors and executives at the Biotech Showcase conference on January 9, 2012 at 4:30pm PST. The slide address is attached to this Current Report on Form 8-K as exhibit 99.1. The slide address will provide those in attendance with, among other things, an update on our active clinical development programs, the Company's business outlook, select financial and operational metrics, and expected milestones for 2012. The slide address will be available at www.ohrpharmaceutical.com

The information contained herein is being furnished pursuant to Item 7.01 of Form 8-K, "Regulation FD Disclosure." This information shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Exhibit	No.	Description
99.1		Slide address for presentation on January 9, 2012 at the Biotech Showcase conference

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.

OHR PHARMACEUTICAL, INC.

Dated: January 9, 2012

By: /s/ Irach Taraporewala

Dr. Irach Taraporewala, President and CEO



Biotech Showcase™
San Francisco, CA

January 9, 2012





Safe Harbor Statement

This presentation contains forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. These forward looking statements are made only as the date thereof, and Ohr undertakes no obligation to update or revise the forward looking statement whether as a result of new information, future events or otherwise. Our actual results may differ materially and adversely from those expressed in any forward-looking statements as a result of various factors and uncertainties, including the future success of our scientific studies, our ability to successfully develop products, rapid technological change in our markets, changes in demand for our future products, legislative, regulatory and competitive developments, the financial resources available to us, and general economic conditions. For example, there can be no assurance that Ohr will be able to sustain operations for expected periods. Shareholders and prospective investors are cautioned that no assurance of the efficacy of pharmaceutical products can be claimed or assured until final testing; and no assurance or warranty can be made that the FDA will approve final testing or marketing of any pharmaceutical product. Ohr's most recent Annual Report and subsequent Quarterly Reports discuss some of the important risk factors that may affect our business, results of operations and financial condition. We disclaim any intent to revise or update publicly any forward-looking statements for any reason.



Corporate History

- Founded in late 2008
- Execute on strategy to acquire late stage clinical programs
 - Wealth of preclinical and clinical data
 - Clear competitive path forward
 - Risk mitigation
- Acquisitions
 - OHR/AVR118- March 2009
 - Advanced Viral Research Corp.
 - Squalamine & Trodusquemine- August 2009
 - Genaera Corp.

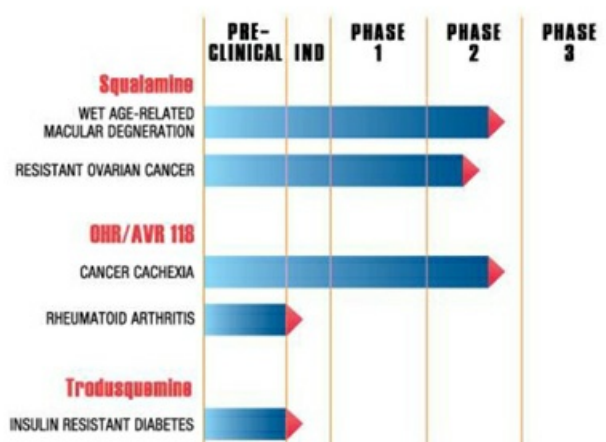


Company Overview

- 2 compounds in active development
- 3 major clinical Phase II applications
- Extensive clinical data showing safety and activity of compounds
- Multiple indications with billion dollar market potential
- Lead indications address unmet medical needs including an orphan drug indication
- Good management team with tight expense controls
- Unknown story with several upcoming catalysts



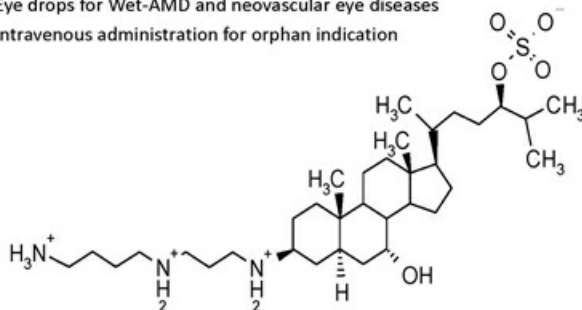
Drug Pipeline





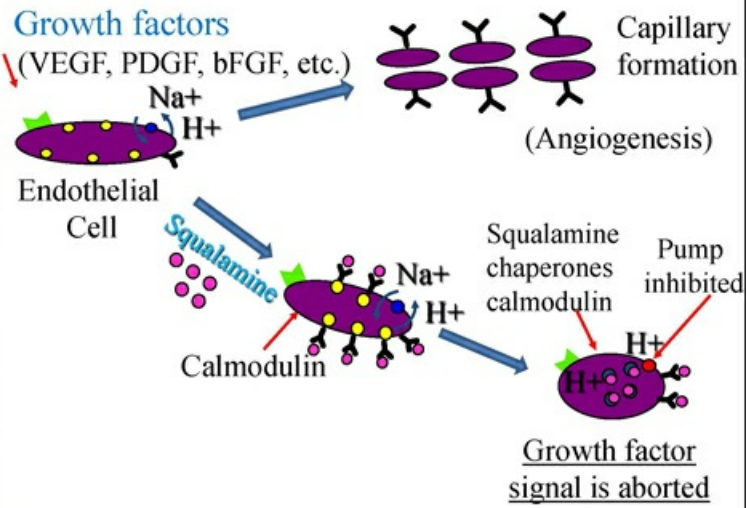
Squalamine

- Small molecule aminosterol
- Novel intracellular anti-angiogenic mechanism
- Inhibitor of multiple angiogenic growth factors
 - VEGF, PDGF, and bFGF
- Development pathway
 - Eye drops for Wet-AMD and neovascular eye diseases
 - Intravenous administration for orphan indication





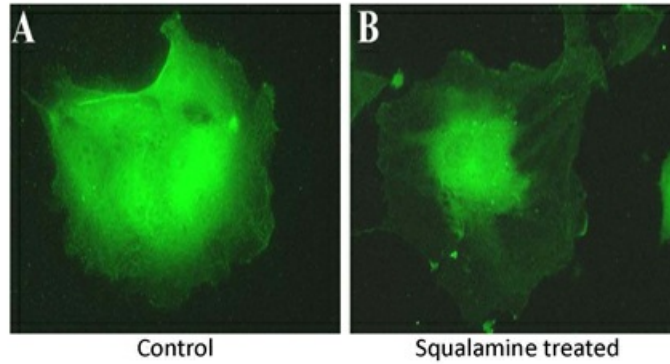
Anti-Angiogenic Mechanism





Squalamine Chaperones Calmodulin

After Entry into Activated Endothelial Cells, Squalamine and Calmodulin Bind, and the Complex is Transported to a Perinuclear Membrane Compartment



FITC (green fluorescence) labeled anti-calmodulin antibody



Squalamine Ophthalmic Snapshot

- Lead clinical indication for treatment of Wet-AMD using an eye drop formulation
- Previously studied in over 450 patients using an intravenous formulation by Genaera Corp.
 - ~250 patients with Wet-AMD
 - ~200 oncology patients (solid tumors, ovarian, lung, and prostate cancers)
- Intravenous clinical data in Wet-AMD
 - Demonstrated biologic effect
 - Gains in visual acuity
 - Strong maintenance of vision
 - Effect in advanced, low vision wet-AMD ("fellow eye")
- IV formulation entered phase III trials for wet-AMD under fast track status and a Special Protocol Assessment (US FDA)
 - Discontinued due to enrollment difficulty of chronic IV infusion and suboptimal dosing/pharmacokinetics of systemic administration



IV Drawbacks & Topical Solutions

- IV drawbacks
 - **Suboptimal dosing**- Pharmacokinetic analysis confirms that prior IV dosing was suboptimal especially when entering the monthly "maintenance" dosing period
 - **Patient compliance**- 40 minute weekly infusion very burdensome on elderly patient population
 - **Commercial challenges**- ophthalmologist offices not equipped to give large scale prolonged infusions
 - **Infusion site reactions**
- Topical solutions
 - *In vivo* studies confirm tissue concentrations well in excess of what is necessary to provide therapeutic effect in wet-AMD and consistently stay above threshold levels
 - Eye drop is easy to use for self administration
 - Topical treatment does not require ophthalmologist infrastructure build up to accommodate large scale infusions
 - *In vivo* studies indicate no systemic uptake and topical dosing is orders of magnitude less than previous IV MTD

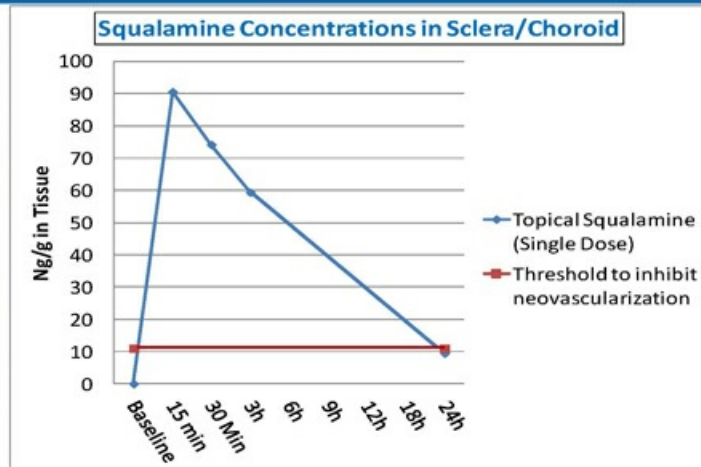


Squalamine Eye Drop Formulation

- Proprietary reformulation using FDA approved excipients
- *In-vivo* studies in Dutch belted rabbits
 - 28 day ocular tolerance and toxicity
 - Demonstrated safety and tolerability to ocular tissues
 - No macroscopic or histopathology changes
 - Biodistribution study- single dose
 - Peak concentrations 8x the threshold level to inhibit choroidal neovascularization
 - Biodistribution study- QD & BID up to 14 days
 - Results to be disclosed at scientific meetings 2012



Topical- *Single Administration*



Threshold level refers to tissue concentrations above which Squalamine is known to inhibit neovascularization



The Next Frontier in Wet-AMD

Intravitreal Injections (Lucentis®, Eylea®)



Eye Drops



VS.

The choice is obvious...



Competitive Advantages

Potential advantages over intravitreal injections ("IVT") for Wet-AMD

- **Superior delivery method**
 - Proprietary reformulation of Squalamine into a topical eye drop for increased patient ease of use and a consistent delivery of therapeutic concentrations.
 - Current approved therapies are delivered via intravitreal injection directly into the eye every month or two.
- **Efficacy in the "fellow eye"; Potential orphan or fast track indication**
 - Many Wet-AMD patients have a more advanced, low vision wet AMD eye ("fellow eye"). Squalamine clinical data has shown significant VA improvement in these fellow eyes using the IV formulation.
- **Cost effective manufacture**
 - IVT's are large molecules which cost ~\$11,000-\$24,000 per year of treatment. Squalamine is a small molecule which is inexpensive to produce.
- **Safety profile**
 - Squalamine had minimal systemic or ocular drug-related adverse events when tested using the IV formulation at higher doses.
 - IVT's cause increased IOP as well as incidence of adverse ocular events including cataracts and potential complications associated with injections of the eye.
- **Broad spectrum inhibition**
 - Novel intracellular mechanism inhibits the effects of VEGF and PDGF angiogenesis, as opposed to Lucentis & Eylea which targets VEGF.
 - Recent clinical evidence has shown that inhibiting VEGF and PDGF almost doubles historical Lucentis VA gain response rates.



Topical Path Forward

- CMC and regulatory preparations underway
- Clinical site selection ongoing
- Trial design crafted with input from KOL's in the wet-AMD space
- Trial will focus on newly diagnosed wet-AMD patients
 - Randomized, placebo controlled study (n=120)
- Adjunct therapy to anti-VEGF treatment (Lucentis)
 - Initial focus on lengthening interval and limiting number of intravitreal injections
- Potential parallel path and indication: Fellow eye (low vision, advanced wet-AMD)
 - Potential Orphan Drug or Fast Track indication
 - Discuss sponsored pilot Phase II with the National Eye Institute
 - Shorter path to approval; currently no efficacious options for this population
 - Revenue generation to fund future wet-AMD trials and additional ophthalmic indications
- **Initiate clinical Phase II trial mid 2012 for wet-AMD**



Resistant Ovarian Cancer Indication

•Primary mechanism

- Interaction with endothelial cells indicate that it binds with cell membranes and inhibits the membrane Na^+/H^+ antiporter, thus creating entry points in the cell membrane for chemotherapeutic agents to enter
- Secondary anti-angiogenic activity, blocking the tumor's ability to obtain additional nutrients

Comparison to standard of care

	Doxil	Hycamtin	Squalamine + Carboplatin
Objective Response Rate	12.3%	6.5%	34%*
Complete Response Rate	0.8%	0.8%	15%*
Median PFS (Weeks)	9.1	13.6	To be presented at scientific meeting 2012
Median Overall Survival (weeks)	35.6	41.3	
N=	130	124	26

- Awarded **Orphan Drug Status** for resistant ovarian cancer

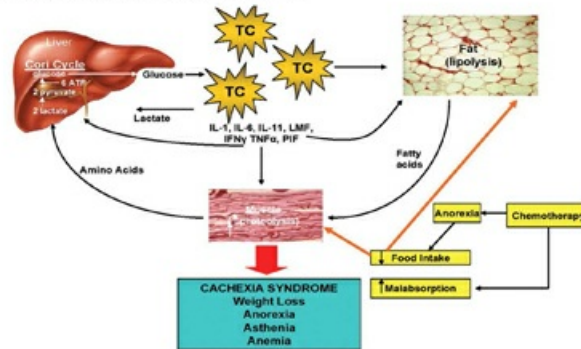
Development Plan

- Planning to conduct a sponsored Phase IIb study at a cancer research center or enter into a strategic partnership to further this indication



OHR/AVR118 in Cancer Cachexia

- Broad spectrum, peptide based immuno-modulator
- Modulates immune response by regulating multiple cytokines and chemokines including IL-6 and TNF-Alpha



From Loberg, R. D. et al.
CA Cancer J Clin 2007;57:225-241.



Cancer Cachexia Indication

- Wasting disorder often seen in late stage cancer patients characterized by anorexia, loss of muscle mass, fatigue, weakness, and poor quality of life
- Cachexia is triggered by the cellular stress of chemotherapy, radiation and the cancer itself
- Research has shown that the etiology of cancer cachexia is likely attributable to a cascade of pro-inflammatory cytokine release (cytokine storm)
- OHR/AVR 118 modulates immune response to temper the release of multiple cytokines implicated in the disease process
- 20-30% of cancer patients will succumb to cachexia
- Currently in a Phase II trial at the Ottawa Cancer Centre
- Presented positive Phase II interim data at the Society of Cachexia and Wasting Disorders Conference in Barcelona
- **No FDA approved therapy for cancer cachexia**
- **Phase II trial fully funded to completion from QTDP grant**



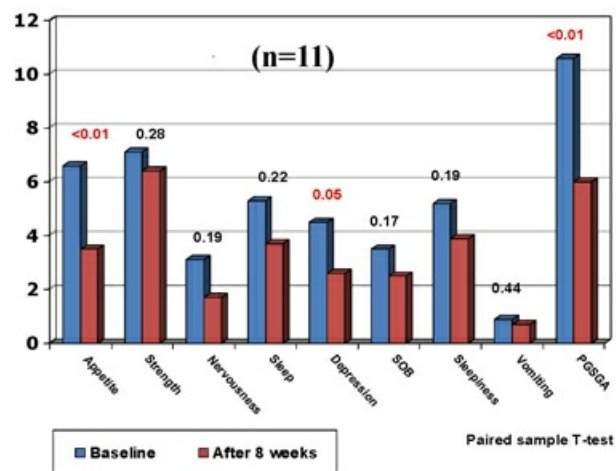
Interim Phase II Data

- Interim Phase II data selected for oral presentation at the 5th annual meeting of the Society of Cachexia and Wasting Disorders
- Weight stabilization or gain was observed in 7 of 11 patients.
- Total PG-SGA scores improved significantly ($p \leq 0.01$)
- Appetite ($p \leq 0.01$) and depression ($p = 0.05$) scores improved on ESAS
- Frequent burping / belching ($p = 0.02$), feeling full ($p = 0.04$) and stomach distention ($p = 0.03$) improved on the DSSI
- OHR/AVR118 was well tolerated with no serious side effects reported

Chasen, *et al*, J Am Med Dir Assoc 2011; 12: 62–67



Interim Data-ESAS & PGSGA Means



*Lower score denotes improvement in criteria (0 is best, 11 is worst)



Competitive Advantages- OHR/AVR 118

- **Addresses underlying etiology**
 - Broad spectrum modulation of pro-inflammatory cytokine response cascade that is the root cause of cancer cachexia, as opposed to therapies that target a single cytokine or just one of the cachexia symptoms
- **Mitigates multiple symptoms**
 - By modulating the underlying immune response to the cancer/chemotherapy, OHR/AVR 118 addresses many of the cachexia symptoms
- **Allows concomitant chemotherapy**
 - OHR's trial allows concomitant chemotherapy as opposed to the other investigational drugs which do not. Chemotherapy has been shown to exacerbate the cytokine response in cachectic patients, thereby accelerating the wasting syndrome
- **Safety profile**
 - Good safety profile demonstrated in all clinical trials to date
- **First mover advantage**
 - OHR/AVR 118 is at the forefront of clinical development for cancer cachexia



Financial Highlights

Ticker	OTCBB: OHRP
Recent Share Price (1-5-12)	\$0.70
Market Capitalization (1-5-12)	~\$29mm
Average Daily Volume (90 day)	11,124
Cash on Hand (12-31-11)	~\$1.3mm
Debt (12-31-11)	\$0
Shares outstanding (12-31-11)	41,535,922
Preferred Shares* (12-31-11)	5,583,333
Fully Diluted** (12-31-11)	76,241,702

*Convertible 1:1 into common stock at the holders option, no coupon

**Preferred + Warrants & options at strike prices ranging from \$0.50 to \$1.19. ~12mm warrant tranche exercisable at \$1.19 expiring 10/31/12

Potential proceeds from warrant exercises are ~\$18.4mm



Investment Summary

- 2 compounds in late stage development
- **Significant milestone events expected in 2012**
 - Initiation of Phase II wet-AMD trial
 - Presentation of additional longer term *in-vivo* Squalamine eye drop data at scientific meetings
 - Results of phase II cancer cachexia trial
 - Publication of final trial results on resistant ovarian cancer orphan indication (median PFS, overall survival)
- Lead indications address large unmet medical needs
- Extensive safety and efficacy data from drugs under development
- Unknown story with several upcoming catalysts
- Good management team with tight expense controls



Thank You!

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