
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): February 11, 2014

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.)

800 3rd Ave, 11th Floor, New York, NY

(Address of Principal Executive Offices)

10022

(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 Bio-CEO Conference on February 11, 2014 at 9:00 am EST. 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 2014. 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.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Ohr Pharmaceutical Slide Deck for the BIO CEO Conference Presentation, February 11, 2014

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: February 11, 2014

By: /s/ Irach Taraporewala
Dr. Irach Taraporewala
President and CEO



Bio-CEO Conference

New York, NY

February 11, 2014





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.



Company Overview

- Founded in late 2008, NasdaqCM: OHRP
- Executed on strategy to acquire two late stage clinical programs in 2009 that address large unmet medical needs: *wet-AMD & cancer cachexia*
 - *Wealth of preclinical and clinical data*
 - *Clear competitive path forward*
 - *Risk mitigation*
- Experienced management team headquartered in New York, NY
- Strong intellectual property protection
- Tight expense controls
- Several upcoming catalysts



Drug Pipeline

	Preclinical	Phase 1	Phase 2	Phase 3
SQUALAMINE				
<i>Eye-drop formulation</i> WET AGE RELATED MACULAR DEGENERATION		FDA Fast Track		
<i>IV formulation</i> RESISTANT OVARIAN CANCER		Orphan Drug Designation		
OHR / AVR 118				
CANCER CACHEXIA				
TRODUSQUEMINE				
UNDISCLOSED INDICATION				

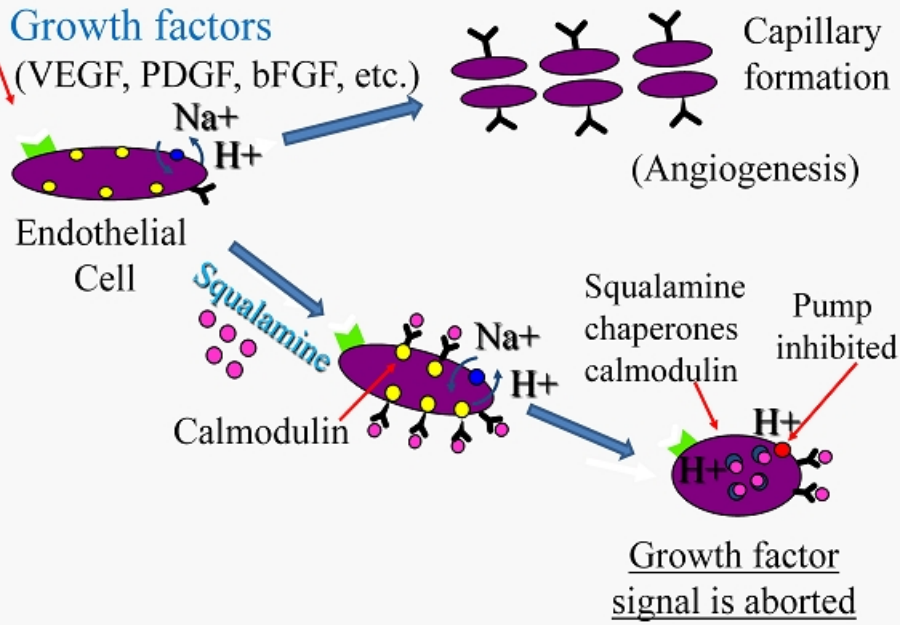


Squalamine

- First-in-class small molecule anti-angiogenic drug with a novel intracellular mechanism of action
- Inhibitor of multiple angiogenic growth factors
 - VEGF, PDGF, and bFGF
- Ohr Pharmaceutical has developed a non-invasive **proprietary eye drop formulation**
 - Biodistribution studies show ability of the drug to reach the back of the eye at concentrations that can inhibit neovascularization.
 - Practical delivery method that is superior to IV administration. More convenient and less painful than intravitreal injections.
 - Favorable safety profile
- Development pathway
 - Eye drops for Wet-AMD and neovascular eye diseases
 - Granted Fast Track Designation by US FDA for Wet-AMD
 - Phase 2 in Wet-AMD ongoing (n= 120), interim data expected 2Q-2014



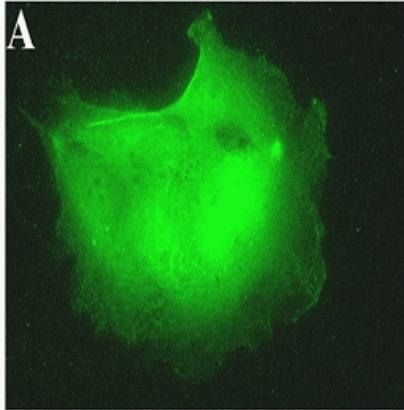
Anti-Angiogenic Mechanism



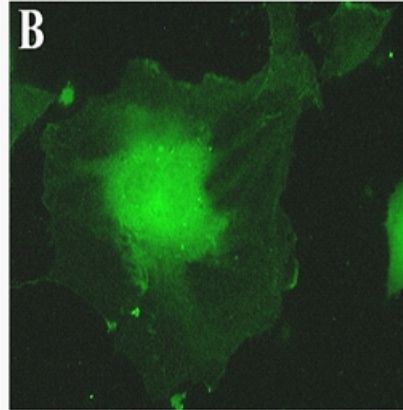


Squalamine Chaperones Calmodulin

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



Control



Squalamine treated

FITC (green fluorescence) labeled anti-calmodulin antibody



Squalamine Ophthalmic Snapshot

- Phase II development proceeding with eye drop administration
- Previously studied in over 450 patients using an intravenous formulation
 - ~250 patients with Wet-AMD
 - ~200 oncology patients (solid tumors, ovarian, lung, and prostate cancers)
- Intravenous clinical data in Wet-AMD
 - Demonstrated biological 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



Squalamine has promising properties as a topical agent to treat CNV

- ✓ High potency at nanomolar levels
- ✓ Ability to inhibit multiple angiogenic growth factors including VEGF, PDGF
- ✓ Diffusion from the front of the eye into the choroid, where the choroidal neovascularization (CNV) process actually occurs
- ✓ Long retention time in the choroid

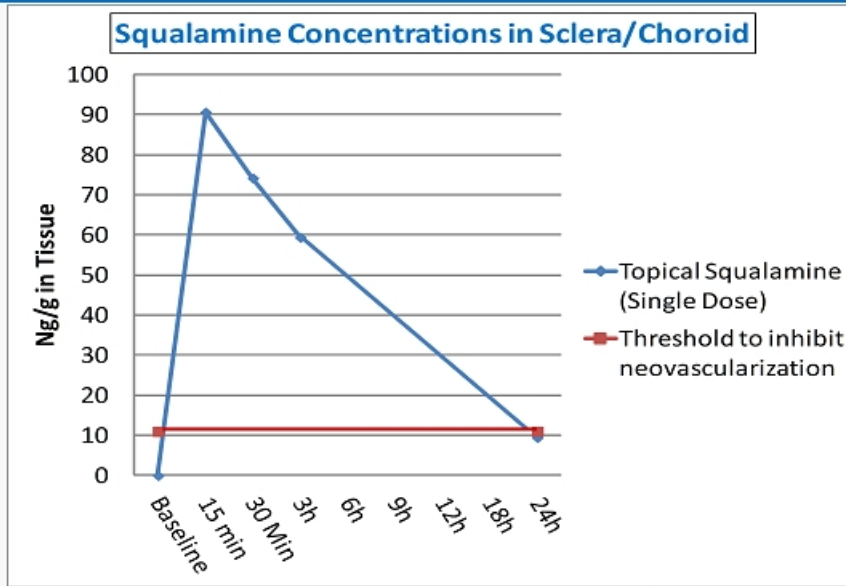


Squalamine Eye Drop Formulation

- 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 presented at ARVO & Macula Society- 2012
 - 6 month BID ocular tolerance and toxicity
 - No adverse findings



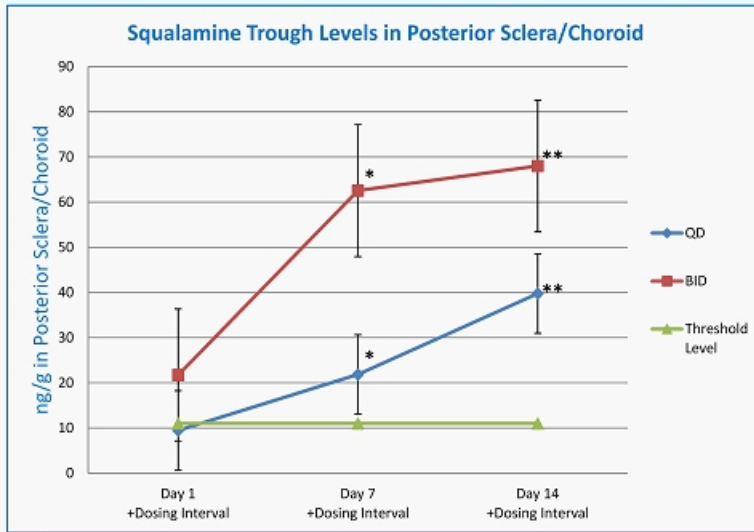
Eye Drop Single Administration



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



Eye Drop Multi Dose Trough Levels



Dosing Interval= QD 24 Hours, BID 12 Hours
*p-value < .01 **p-value < .001 (values vs day 1 +Dosing Interval)

Trough levels represent lowest tissue concentrations prior to next dosing (QD 24h, BID 12h)

Presented at ARVO and Macula Society 2012. Full poster can be found at
<http://ohrpharmaceutical.com/ARVO%20poster%20FINAL.pdf>



Eye Drop Solves IV Drawbacks

IV Drawbacks

- **Suboptimal dosing-** Pharmacokinetic analysis confirms that prior IV dosing was suboptimal especially when going from a weekly to 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-** Due to rapid infusion rates

Eye Drop Advantages

- **Sustained Therapeutic Levels-** *In vivo* studies confirm tissue concentrations well in excess of the antiangiogenic level and can consistently stay above threshold levels
- **Self administered eye drop**
- **No Ophthalmologist infrastructure build out** to accommodate large scale IV infusions
- **Negligible systemic uptake** and topical dosing is orders of magnitude lower than previous IV MTD



Risk Mitigation

IV Clinical Data Demonstrated Activity

Visual Acuity Gains

Maintenance of VA

Biological Effect



....Even while being dosed suboptimally....

Rapid systemic clearance

Lack of sustained concentrations



Data demonstrates the eye drop achieves

Sustained inhibitory concentrations

Efficient delivery to back of the eye tissues



Competitive Advantages

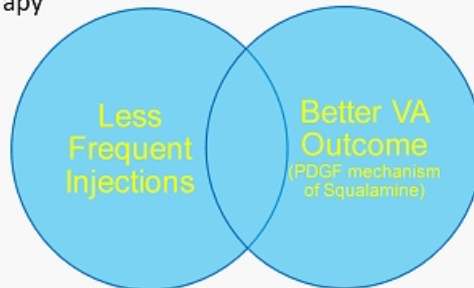
Potential advantages over intravitreal injections (“IVT”) for Wet-AMD

- ***Superior delivery method***
 - Current approved therapies are delivered via intravitreal injection directly into the eye every four to eight weeks
- ***Inhibition of Multiple Angiogenic Growth Factors***
 - Clinical evidence has shown that inhibiting VEGF ***and*** PDGF provides improvement over Lucentis VA gain response rates
- ***Activity in advanced AMD cases***
 - Previous intravenous data suggests activity in more advanced AMD lesions
- ***Safety profile***
 - Squalamine had minimal systemic or ocular drug-related adverse events when tested using the IV formulation at much higher doses
- ***Cost effective manufacture***



Topical Path Forward

- Phase II trial designed by KOL's in the wet-AMD space
- Trial focuses on newly diagnosed wet-AMD patients
 - Randomized, double masked, placebo controlled study (n=120) at 20+ US Sites
- Trial design includes anti-VEGF treatment (Lucentis) as needed
 - Helps facilitate enrollment while providing clear indication of efficacy
- Design provides for multiple outcome scenarios to guide the path forward in future registration studies
 - Monotherapy
 - Adjunct therapy

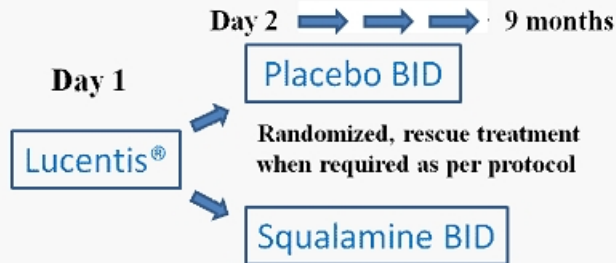


16 Clinical Phase II trial began enrolling in late 2012 for wet-AMD



Phase II Trial Design

- Newly diagnosed wet-AMD patients
- Duration: 9 month treatment period with interim analysis (50% completed)



- Rescue criteria based on objective parameters
- Efficacy Endpoints (10 endpoint hierarchical analysis)
 - 1°: Mean number of Lucentis injections
 - 2°: Mean time to Lucentis retreatment
 - 2°: VA gains, maintenance, and safety
- Primary endpoint is powered (90%) to detect a 1.5 injection difference between the arms
- 60 patients per arm (120 total)
- Interim Data anticipated in Q2 2014



Ophthalmic Advisory Board

Key Opinion Leaders (KOL) in retinal disorders

- David Boyer MD
Retina-Vitreous Associates Medical Group (Los Angeles, CA)
- Thomas Ciulla MD
Midwest Eye Institute (Indianapolis, IN)
- Michael Elman MD
Elman Retina Group (Baltimore, MD)
- Jeffrey Heier MD
Ophthalmic Consultants of Boston (Boston, MA)
- Daniel Roth MD
Retina Vitreous Center (New Brunswick, NJ)
- Lawrence Singerman MD
Retina Associates of Cleveland (Cleveland, OH)
- Jason Slakter MD
Vitreous Retina Macula Consultants of NY (New York, NY)
- John Wroblewski MD
Cumberland Valley Retina Consultants (Hagerstown, MD)



Ongoing Investigator Sponsored Trials (ISTs)

- Proliferative Diabetic Retinopathy (PDR) (OHR-003)
 - Monotherapy
 - 5 patients
 - PI: Dr. Michael Elman
- Case Study data to be presented at the Macula Society Annual Meeting on February 19, 2014
 - Presentation entitled “Regression of Retinal Neovascularization in Proliferative Diabetic Retinopathy using Squalamine Lactate Eye Drops”
- Branch and Central Retinal Vein Occlusion (BRVO/CRVO) (OHR-004)
 - 20 Patients
 - PI: Dr. John Wroblewski



Planned New ISTs in Q1 2014

- Squalamine Eye Drops in Diabetic Macula Edema
 - 30 Patients
 - Randomized, masked, placebo controlled
 - Investigators: Drs. David Boyer, Daniel Roth, Lawrence Singerman
- Squalamine Eye Drops in DME Patients Sub-responsive to Monthly Lucentis
 - 20 Patients
 - Randomized, masked, placebo controlled
 - Combination therapy with Monthly Lucentis
 - PI: Dr. Glenn Stoller



Competitive Landscape

	Squalamine	Lucentis®	Eylea®	Fovista®	Pazopanib	DARPin's
Developer	Ohr Pharmaceutical	Genentech/ Roche	Regeneron	Ophthotech	Glaxo	Molecular Partners
Mechanism	Intracellular	Extracellular	Extracellular	Extracellular	Intracellular	Extracellular
Target	VEGF, PDGF, bFGF	VEGF	VEGF	PDGF	Tyrosine Kinases	VEGF, VEGF & PDGF
Delivery	Eye Drops	Intravitreal	Intravitreal	Intravitreal	Eye Drops	Intravitreal
Dev. Stage	Phase II	FDA Approved	FDA Approved	Entering Phase III	Phase II	Phase II & Preclinical
Molecule size	Small Molecule	Large molecule	Large molecule	Large molecule	Small molecule	Large Molecule
Cost/Dose	–	\$2,000	\$1,850	–	–	–
Revenue/ Partnership	–	\$4b (‘12 global)	\$838mm (‘12 U.S.)	–	–	\$1.4b deal with Allergan



Squalamine Markets

Initial Indication

Wet Macular Degeneration



1,750,000 Patients (U.S.)



200,000 New Cases
(Annual, U.S.)



Current Market Leader:
Intravitreal Lucentis®
(~\$4b Annual Revenue(WW))

Future Indications

Retinopathy & Macular Edema



1,200,000 Patients
(U.S.)



130,000 New Cases
(Annual, U.S.)



Dry AMD
Prophylaxis



13,000,000
Patients (U.S.)

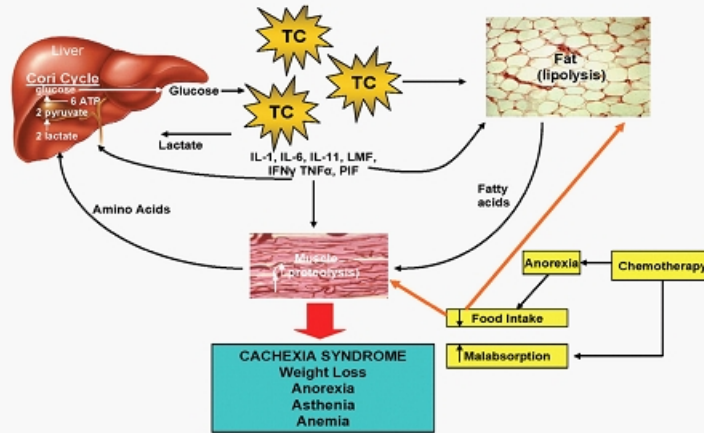


300-700K New
Cases (Annual,
U.S.)



OHR/AVR118 in Cancer Cachexia

- Broad spectrum, peptide immuno-modulator
- Modulates immune response by regulating multiple cytokines and chemokines involved in the disease process



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



Phase IIa Clinical Data

- 18 Patients, various tumor types, primarily stage IV (84%)
- Results Demonstrated
 - Stabilization of weight, lean body mass, and body fat
 - Appetite increased ($p=.001$)
 - Total PG-SGA scores improved significantly ($p=.025$)
 - Enhanced quality of life
- Results seen even though 8/18 patients took concomitant chemotherapy or radiation
- 11/18 patients continued therapy after completion of the protocol for up to 153 days
- OHR/AVR118 was well tolerated with no serious side effects reported
- Detailed data were presented at the annual Cachexia and Wasting Disorders in Kobe, Japan in December 2013 .



Corporate Strategy

Transition to core ophthalmology focus:

- Novel drug delivery for back of the eye diseases including combination products
- Front of the eye diseases

In-license promising compounds to build pipeline

Out license or monetize non ophthalmology assets:

- OHR/AVR118 in cancer cachexia
- Trodusquemine and several analogs



Financial Highlights

Ticker	NasdaqCM: OHRP
Recent Share Price (2-7-14)	\$13.33
Market Capitalization (2-7-14)	\$266mm
Average Daily Volume (30 day)	149k shares
Cash on Hand (9-30-13)	\$5.1mm
Cash Burn Per Quarter	~\$500k-1mm
Shares outstanding (12-27-13)	~20mm
Fully Diluted (12-27-13)	~27mm

Cash on hand to fund operations into 2015

Analyst Coverage

- Jonathan Aschoff, Brean Capital



2014 Milestones

- **Anticipated milestone events in 2014**
 - *Data on Eye Drop ISTs (1Q & 2H 2014)*
 - *Completion of enrollment in wet-AMD trial (Q1 2014)*
 - *Initiation of additional eye drop ISTs (Q1 2014)*
 - *Interim data from wet-AMD eye drop trial (Q2 2014)*
 - *Moving Trodusquemine pipeline product forward in a new clinical indication (1H 2014)*
 - *Publication of final trial results on resistant ovarian cancer orphan indication (median PFS, overall survival) (mid 2014)*
 - *Final data from wet AMD eye drop trial (Q4 2014)*