
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): December 10, 2013

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))

ITEM 7.01. Regulation FD Disclosure.

Ohr Pharmaceutical Inc. (the "Company") will be making a presentation to potential investors and executives at the Oppenheimer 24th Annual Healthcare Conference on December 10, 2013 at 11:30am 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.

Exhibit No.Description

| | |
|------|---|
| 99.1 | Ohr Pharmaceutical Slide Deck for Oppenheimer Healthcare Conference Presentation, December 10, 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: December 10, 2013

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



Oppenheimer 24th Annual Healthcare Conference

December 10, 2013





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.





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 | | | | |

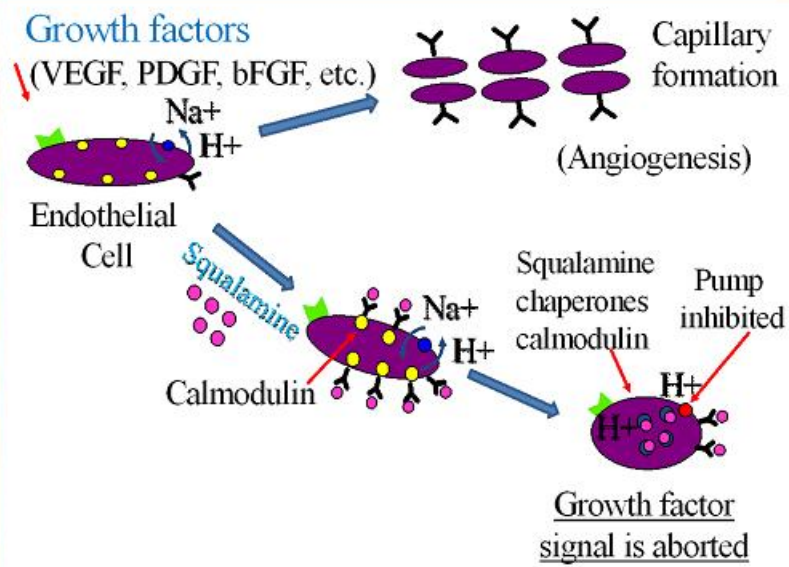


Squalamine

- 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 **proprietary eye drop formulation** using FDA approved excipients
 - 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

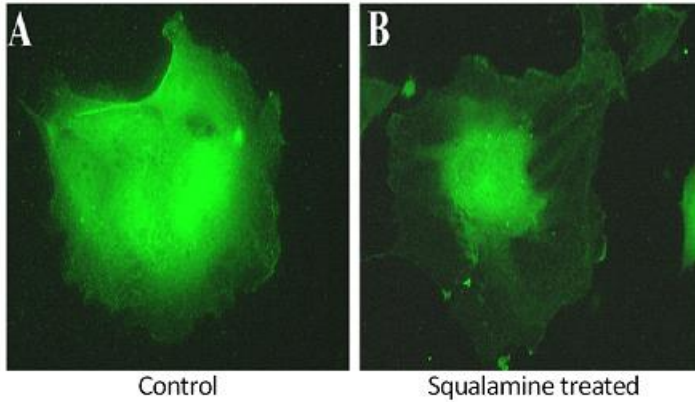


Anti-Angiogenic Mechanism



Squalamine Chaperones Calmodulin

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



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



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

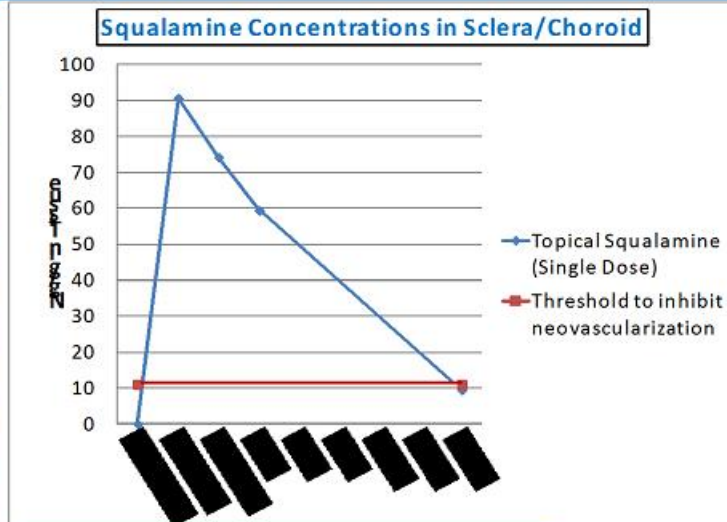


Squalamine Eye Drop Formulation

- 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

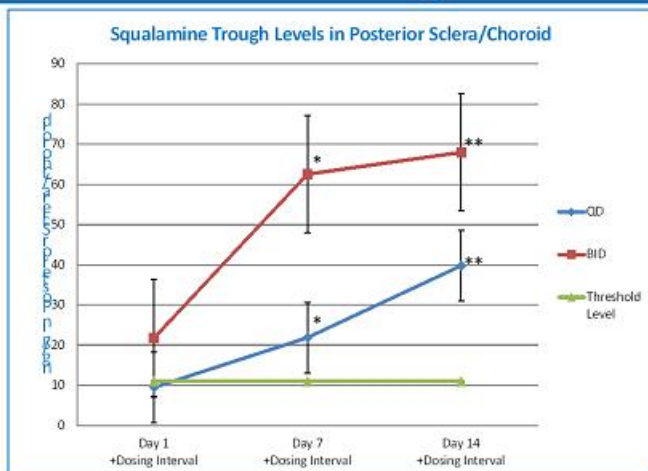


Threshold level refers to tissue concentrations above which Squalamine is known to inhibit neovascularization



Eye Drop

Multi Dose Trough Levels



Dosing Interval: QD 24 Hours, BID 12 Hours
*p-value < 0.05 **p-value < 0.01 (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

12 <http://ohpharmaceutical.com/ARVO%20poster%20FINAL.pdf>



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

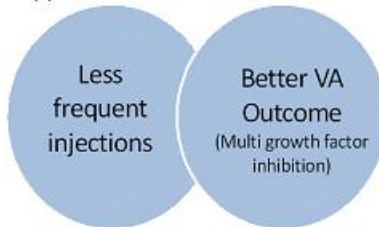
Potential advantages over intravitreal injections ("IVT") for Wet-AMD

- ***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***
 - 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.
- ***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

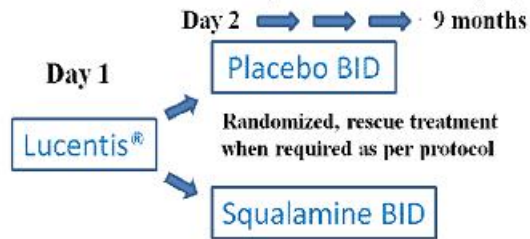


- 15 Clinical Phase II trial began enrolling in late 2012 for wet-AMD



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



Investigator Sponsored Trials

- Branch and Central Retinal Vein Occlusion (BRVO/CRVO)
 - 20 Patients
 - PI: Dr. John Wroblewski
- Proliferative Diabetic Retinopathy (PDR)
 - 5 patients
 - PI: Dr. Michael Elman



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)



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 | 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.)



Corporate Strategy

Transition to core ophthalmology focus:

- Non-invasive 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 (12-9-13) | \$8.02 |
| Market Capitalization (12-9-13) | \$158mm |
| Average Daily Volume (30 day) | 55k shares |
| Cash on Hand (6-30-13) | \$6.05mm |
| Cash Burn Per Quarter | ~\$500-750K |
| Shares outstanding (8-13-13) | 19.7mm |
| Fully Diluted (6-30-13) | 26.9mm |

Cash on hand to fund operations through Q1 2015

Analyst Coverage

- Jonathan Aschoff, Brean Capital



Investment Highlights

- 2 compounds in late stage development to address large unmet medical needs: *wet-AMD* & *cancer Cachexia*
- Strong intellectual property protection
- Experienced Management Team
- **Significant milestone events through 2014**
 - Presentation of OHR/AVR118 phase II results at society for cachexia and wasting disorders conference (Dec. 2013)
 - Completion of enrollment in wet-AMD trial (Q1 2014)
 - Interim data from wet-AMD eye drop trial (Q2 2014)
 - Publication of final trial results on resistant ovarian cancer orphan indication (median PFS, overall survival) (1H 2014)
 - Data from Squalamine eye drop Investigator sponsored trials (2014)
 - Final data from Wet-AMD eye drop clinical trial (Q4 2013)

