
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): May 6, 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))

ITEM 7.01. Regulation FD Disclosure.

On May 6, 2012, Ohr Pharmaceutical Inc. (the "Company") presented a poster presentation discussing biodistribution and safety data on the Squalamine eye drop. The poster is attached to this Current Report on Form 8-K as exhibit 99.1 and will be available on the investor page of the company's website.

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.

Item 8.01. Other Items.

On May 7, 2012, the Company issued a press release announcing the safety and biodistribution results of a preclinical study for the Squalamine eye drop program presented at ARVO on May 6, 2012.

A copy of the press release is attached to this Current Report on Form 8-K as exhibit 99.2.

Exhibit No. Description

99.1 [ARVO Poster Presentation dated May 6, 2012](#)

99.2 [Squalamine Study Results Press Release dated May 7, 2012](#)

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.

Dated: May 9, 2012

OHR PHARMACEUTICAL, INC.

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



A Novel Eye Drop Formulation of Squalamine For Exudative AMD: Evaluation Of Ocular Distribution And Ocular Safety In Rabbits

Irach B. Taraporewala¹, Michael J. Elman², Shalom Z. Hirschman¹, Samuel I. Backenroth¹.
¹Ohr Pharmaceutical Inc., New York, NY; ²Elman Retina Group, Baltimore, MD

Program #457

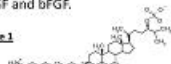
Purpose:

To evaluate the ocular tissue distribution and ocular safety of a novel eye drop formulation of Squalamine, a potent antiangiogenic small molecule inhibitor of multiple growth factors (VEGF, PDGF, bFGF) with previously demonstrated systemic activity *in vivo* in ocular pathologies and in clinical trials for exudative macular degeneration.

Introduction:

Squalamine, a small molecule aminosterol is an anti-angiogenic compound (Figure 1) which inhibits multiple protein angiogenic growth factors through a unique intracellular mechanism of action by binding to the cell membrane-bound regulatory protein calmodulin and chaperoning it into the cytoplasm (Figure 2) where it becomes unavailable to modulate the downstream signaling of VEGF, PDGF and bFGF.

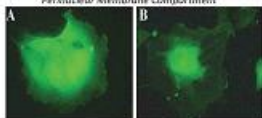
Figure 1



Unlike other VEGF targeting agents, squalamine does not cause the blockade of the action of endothelial nitric oxide synthase (eNOS) which is linked to producing hypertension, while it does target the MAP kinase cellular proliferative pathway, the p38 inflammatory pathway, as well as VEGFR and αvβ3 and their downstream signaling pathways which lead to neovascularization.

Squalamine had previously been evaluated in Phase II and III clinical trials in wet AMD as an intravenous infusion where it had demonstrated anti-angiogenic effects. The molecule has now been formulated into an eye drop formulation that has been demonstrated to be safe pre-clinically in rabbits.

Figure 2
 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) (fluorescein) labeled anti-calmodulin antibody

Methods:

Male Dutch belted rabbits (n=24) were administered Squalamine eye drops (40 µL) in both eyes, either QD (every 24 hours) or BID (every 12 hours) for 1, 7, and 14 days (n=4/group/dosing regimen). Animals were necropsied and ocular tissues were harvested 24 (+2) or 12(+1) hours post last dosing in the QD or BID groups, respectively. Posterior sclera/choroid, aqueous and vitreous humors, and plasma were assayed for Squalamine concentrations using a validated LC-MS/MS method with a lower limit of quantification (LLOQ) of 10ng/g of tissue. Values below the LLOQ are reported as below quantifiable limits, or BQL. The ocular toxicity and irritation of the formulation were also evaluated through clinical observations and tissues were excised and sectioned by a board certified ophthalmologist.

Results:

Squalamine eye drops, given QD or BID were well tolerated with no adverse clinical effects. Given QD, mean trough concentrations of Squalamine in posterior sclera/choroid were 9.5, 21.9, and 39.8ng/g in the 1, 7, and 14 day groups, respectively (Figure 3).

Given BID, mean trough concentrations of Squalamine in posterior sclera/choroid were 21.7, 62.6, and 68ng/g in the 1, 7, and 14 day groups, respectively (Figure 3). Values represent trough levels at one full dosing interval after last administration (QD 24(+2) hours, BID 12(+1) hours). Both QD and BID values demonstrate levels of Squalamine in the posterior sclera/choroid well above the threshold level previously shown to inhibit tissue angiogenesis (11ng/g).

Conclusions:

Squalamine eye drops were well tolerated, consistent with previous longer term preclinical studies in which there were no adverse clinical findings or changes in ocular histopathology. Posterior sclera/choroid tissue concentrations of Squalamine given QD or BID exceeded the threshold at which Squalamine is known to inhibit neovascularization in a cell-based model (11 ng/mL). Importantly, as evidenced by trough concentrations in posterior sclera/choroid above the anti-angiogenic threshold level, sustained therapeutically relevant posterior ocular exposure levels were maintained for the duration of a full dosing interval (QD 24h, BID 12h), indicating the ability to consistently remain above the threshold level with continuous QD or BID administration.

Squalamine had rapid uptake, prolonged residence time, and slow tissue clearance when administered QD or BID in the eye drop formulation up to 14 days. Minimal systemic uptake reduces potential systemic safety concerns. The absence of Squalamine concentrations in aqueous humor suggests a passive diffusion mechanism from anterior to posterior sclera and subsequently into the choroid, while also limiting the potential for corneal opacities and deposits which have not been seen in longer term *in vivo* studies.

These results, consistent with previous preclinical topical data and intravenous clinical studies, warrant the further clinical investigation of Squalamine eye drops to treat neovascular ocular disorders. A Phase II clinical trial of the eye drop formulation in wet AMD patients is planned for the third quarter of 2012.

Figure 3



Squalamine concentrations in aqueous and vitreous humors were <LLOQ (10 ng/g) in all animals and <LLOQ in plasma (10ng/mL) in 23/24 animals (Table 1).

Table 1

	Aqueous Humor		Vitreous Humor		Plasma	
	QD	BID	QD	BID	QD	BID
Day 1	BQL	BQL	BQL	BQL	BQL	BQL
Day 7	BQL	BQL	BQL	BQL	BQL	3/4 BQL
Day 14	BQL	BQL	BQL	BQL	BQL	BQL

BQL: Below Quantification Limit, 10ng/g Tissue, 10ng/mL Plasma
 Squalamine eyedrops proved innocuous and produced no discernible changes in ophthalmological ocular examinations.

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Ohr Pharmaceutical Presents Biodistribution and Safety Data on Squalamine Eye Drops at ARVO 2012 Annual Meeting

Key Study Demonstrates Therapeutic Potential for Treating Wet-AMD

NEW YORK, NY--(Marketwire – 5/7/12) - Ohr Pharmaceutical Inc. (OTCBB:OHRP-News) announced today that it presented a poster presentation titled “A Novel Eye Drop Formulation of Squalamine For Exudative AMD: Evaluation Of Ocular Distribution And Ocular Safety In Rabbits” on Sunday, May 6, 2012 at the Association for Research in Vision and Ophthalmology (ARVO) 2012 Annual Meeting taking place May 6-10, 2012, in Ft. Lauderdale, FL.

Dr. Taraporewala, Ph.D., CEO of Ohr, presented data on the ocular tissue uptake and biodistribution of Squalamine eye drops in Dutch belted rabbits when administered once or twice daily in each eye for up to fourteen days. Squalamine concentrations in the posterior sclera/choroid tissues, where neovascularization in wet-AMD originates, were well above the target therapeutic levels where Squalamine has previously shown clinical benefit and is sustained well above that level for a full dosing interval. Moreover, the eye drop was found to be safe to ocular tissues, consistent with previous longer term studies.

The results indicate:

- Rapid uptake to the posterior sclera/choroid ocular tissues with slow tissue clearance
- Sustained Squalamine concentrations well above threshold anti-angiogenic levels, which persist throughout the period in between doses (“trough level”)
- Safety to ocular tissues with no signs of ocular adverse clinical findings, consistent with previous longer term toxicity studies
- Negligible systemic uptake which minimizes the potential for systemic adverse events

“These results demonstrate the compelling clinical potential of Squalamine eye drops in Wet-AMD and other ophthalmic neovascular disorders,” said Dr. Michael Elman, co-author of the presentation. “I am excited at the opportunity to be involved in this promising drug program.”

Dr. Irach B. Taraporewala, Ph.D., CEO of Ohr, added, “Our eye drop could provide immeasurable benefit to the large wet-AMD patient population. The current standards of care, Roche/Genentech’s Lucentis® and Regeneron’s Eylea®, are injected directly into the eye, and had combined 2011 annual revenues in excess of \$3 billion dollars.”

The poster can be viewed in its entirety by going to the investor page of the Company’s website and clicking on the ARVO poster link.

About Squalamine

Squalamine is an anti-angiogenic small molecule with a novel intracellular mechanism of action, that counteracts not only Vascular Endothelial Growth Factor ("VEGF") but also other angiogenic growth factors such as Platelet Derived Growth Factor ("PDGF") with high potency at nanomolar concentrations. Recent clinical evidence has shown PDGF to be an additional key target for the treatment of wet-AMD. Using the intravenous formulation in over 250 patients in Phase 1 and Phase 2 trials for the treatment of wet-AMD, Squalamine demonstrated favorable biologic effect and maintained and improved visual acuity outcomes, with both early and advanced lesions responding. Ohr Pharmaceutical has developed a novel eye drop formulation of squalamine for the treatment of wet-AMD designed for self-administration which may provide several potential advantages over the FDA approved current standards of care, Roche/Genentech's Lucentis® and Regeneron's Eylea®, which require intravitreal injections directly into the eye. Preclinical testing has demonstrated that the eye drop formulation is both safe to ocular tissues and achieves in excess of target anti-angiogenic concentrations in the tissues of the back of the eye.

About Ohr Pharmaceutical Inc.

Ohr Pharmaceutical Inc. (OTCBB:OHRP-News) (www.ohrpharmaceutical.com) is a pharmaceutical company dedicated to the clinical development of new drugs for underserved therapeutic needs in large and growing markets. The company is focused on two lead compounds: Squalamine eye drops for the treatment of the wet form of age-related macular degeneration, and OHR/AVR118 for the treatment of cancer cachexia, currently being investigated in a Phase II trial.

Safe Harbor Statement under the Private Securities Litigation Reform Act of 1995:

This news release 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 Pharmaceutical 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 or Health Canada 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.

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