
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): October 14, 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)

#46-5622433

(IRS Employer Identification No.)

800 Third Avenue, 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 8.01. Other Items.

On October 14, 2014, the registrant issued a press release announcing guidance from an end of Phase II FDA meeting and plans for Phase III registration studies for OHR-102 (Squalamine eye drops) for the treatment of wet age-related macular degeneration, a copy of which is being furnished as exhibit 99.1 to Form 8-K.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release, dated October 14, 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.

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

Dated: October 14, 2014



Ohr Pharmaceutical Announces Successful End of Phase II Meeting with the FDA on Squalamine Eye Drops (OHR-102) in Wet AMD

Primary Endpoint for Approval to be Based on Visual Acuity Improvements at 9 Months

Phase III Trials to Commence in the First Half of 2015

NEW YORK, New York – October 14, 2014 – Ohr Pharmaceutical, Inc. (NasdaqCM: OHRP), an ophthalmology research and development company, today announced details of the planned pivotal Phase III registration trials for Squalamine Eye Drops (OHR-102) in the treatment of wet age-related macular degeneration (wet AMD). The trials are being designed based on guidance provided by the U.S. Food and Drug Administration (FDA) at a recent “end of Phase II” meeting. The FDA has agreed with Ohr on a 9 month primary efficacy endpoint based on the proportion of patients achieving a ≥ 3 line gain in visual acuity. In the interim analysis of the ongoing Phase II IMPACT study, more than twice the proportion of patients achieved ≥ 3 line gains in visual acuity at 9 months with the combination of OHR-102 eye drops and Lucentis[®] as compared to the Lucentis monotherapy group (overall $p=0.025$, classic lesions $p=0.007$). Two identical Phase III studies will be performed. The Company plans to initiate the Phase III trials in the first half of 2015 with the goal of submitting a New Drug Application (NDA) following collection and analysis of the 9 month primary efficacy data.

“Our recent meeting has provided us with valuable input to formulate a clear regulatory strategy for OHR-102,” said Dr. Irach Taraporewala, President and Chief Executive Officer of Ohr. “Importantly, the Agency has agreed with our plan to use visual acuity, as defined by gains of ≥ 3 lines at 9 months, as the primary endpoint in Phase III trials. Visual acuity is the most clinically relevant endpoint for retinal disease.”

“Data from the IMPACT Phase II study demonstrated improvements in best-corrected visual acuity (BCVA) and ≥ 3 line gains using the combination of OHR-102 and Lucentis as compared to the Lucentis monotherapy group at all timepoints from 4 to 38 weeks. We believe this robust and rapid response to OHR-102 is a result of its potent inhibition of multiple angiogenic targets,” said Dr. Jason Slakter, Chief Medical Officer of Ohr and retina specialist. “Considering that the Phase III primary endpoint will be at the same 9 month timepoint as the Phase II study, we believe we have set a very realistic goal of achieving a similar outcome in the planned Phase III trials.”

The Phase III trials for Squalamine eye drops are being designed to measure the efficacy of combination therapy with OHR-102 eye drops plus Lucentis injections compared with Lucentis monotherapy at 9 months. All patients will be followed for safety for 2 years. The primary endpoint will be a measure of improvement in visual acuity, as defined by the proportion of patients achieving gains of ≥ 3 lines or more on the early treatment diabetic retinopathy study chart. During the first year of the study, patients will be randomized 1:1 to receive monthly Lucentis plus OHR-102 (Squalamine eye drops) twice a day or Lucentis plus placebo. During the second year they will receive Lucentis PRN (as needed) plus OHR-102 or placebo twice a day.

About Squalamine Eye Drops (OHR-102)

Squalamine is an anti-angiogenic small molecule with a novel intracellular mechanism of action, which counteracts multiple growth factors and pathways implicated in the angiogenic process, including vascular endothelial growth factor (VEGF), platelet-derived growth factor (PDGF), and basic fibroblast growth factor (bFGF). Ohr Pharmaceutical has developed a novel eye drop formulation of Squalamine (OHR-102) for the treatment of wet AMD, designed for convenient, patient self-administration, which may provide clinical utility for this patient population and other back-of-the-eye disorders. In May 2012, the Squalamine eye drop program was granted Fast Track Designation by the FDA. Interim Phase II data from the ongoing IMPACT study has demonstrated benefit in visual function versus placebo across multiple standard parameters. Three additional investigator sponsored trials are evaluating Squalamine eye drops for the treatment of proliferative diabetic retinopathy, retinal vein occlusion, and diabetic macular edema, and two Phase III studies in wet AMD are expected to be initiated in the first half of calendar 2015.

About Ohr Pharmaceutical, Inc.

Ohr Pharmaceutical, Inc. (OHRP) is an ophthalmology research and development company. The company's lead product, Squalamine, is currently being studied as an eye drop formulation in several company sponsored and investigator sponsored Phase II clinical trials for various back-of-the-eye diseases, including the wet form of age-related macular degeneration, retinal vein occlusion, diabetic macular edema, and proliferative diabetic retinopathy. In addition, Ohr is developing a sustained release micro fabricated micro-particle ocular drug delivery platform with several preclinical drug product candidates in development for glaucoma, steroid-induced glaucoma, ocular allergies, and protein drug delivery. The lead sustained release program in glaucoma is proceeding under a collaboration with a large global pharmaceutical company. Additional information on the company may be found at www.ohrpharmaceutical.com.

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. Shareholders and prospective investors are cautioned that no assurance of the safety and 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.

Lucentis® is a registered trademark of Genentech, Inc.

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