
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 14, 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 8.01. Other Items.

On May 14, 2012, the Company issued a press release announcing that the U.S. Food and Drug Administration has granted Fast Track designation to the Squalamine eye drop program for the treatment of the wet form of macular degeneration (wet-AMD).

A copy of the press release is attached to this Current Report on Form 8-K as exhibit 99.1.

Exhibit No.	Description
99.1	Press Release Announcing U.S. FDA Fast Track Designation, dated May 14, 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.

OHR PHARMACEUTICAL, INC.

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

Date: May 14, 2012

U.S. FDA Grants Fast Track Designation to Ohr Pharmaceutical's Squalamine Eye Drops for the Treatment of Wet-AMD

Expects to Commence Phase II Clinical Trial in Third Quarter 2012

NEW YORK, NY--(Marketwire – 5/14/12) - Ohr Pharmaceutical Inc. (OTCBB:OHRP-News) announced today that its Squalamine Eye Drops, a potent inhibitor of multiple growth factors implicated in angiogenesis, has been awarded Fast Track designation by the U.S. Food and Drug Administration (FDA) for the potential treatment of the wet form of macular degeneration (wet-AMD).

“We believe the Fast Track designation underscores the importance of developing an eye drop for the treatment of wet-AMD and its potential to address an unmet medical need for this large and growing patient population,” commented Dr. Irach B. Taraporewala, CEO of Ohr. “Our eye drop could provide tremendous benefit to these patients who currently need to take chronic intravitreal injections of Roche/Genentech's Lucentis® or Regeneron's Eylea® directly into the eye. We are thrilled with the continued progress of the program and anticipate commencing a Squalamine Eye Drop phase II clinical trial in the third quarter of 2012.”

The Company recently presented data from a key biodistribution and safety study at the ARVO 2012 Annual Meeting, which highlighted the potential therapeutic value of the Squalamine eye drop program in treating wet-AMD and ophthalmic neovascular disorders. The results indicated the following:

- 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

Fast Track Designation in the United States

Under the FDA Modernization Act of 1997, the Fast Track process was designed to facilitate the development and expedite the review of drug candidates intended to treat serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs. A potential drug that receives Fast Track designation is eligible for Accelerated Approval, which provides for a potential approval by the FDA on the basis of a demonstrated effect on a surrogate endpoint deemed reasonably likely to predict clinical benefit, and Rolling Review, which facilitates the submission of individual sections of a New Drug Application (NDA) as they are completed for review by FDA. In addition, Fast Track designation for a potential drug may allow more frequent meetings between the sponsor and FDA to discuss the proposed development plan and ensure collection of appropriate data needed to support approval, as well as possibly more frequent written correspondence from FDA about such matters as the suitability of designs for proposed clinical trials. Many drugs that are eligible for Fast Track designation are also considered appropriate to receive Priority Review, an additional designation that may reduce the time required for FDA review.

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. In May 2012, the Squalamine eye drop program was granted Fast Track Designation by the U.S. FDA.

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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