

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): November 12, 2015

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
(I.R.S. Employer
Identification No.)

800 Third Avenue, 11th Floor, New York, NY
(Address of Principal Executive Offices)

10022
(Zip Code)

(212) 682-8452
(Registrant's Telephone Number, Including Area Code)

Not Applicable
(Former Name or Former Address, if Changed Since Last Report)

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 communication pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communication pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 7.01 Regulation FD Disclosure

On November 12, 2015, Ohr Pharmaceutical, Inc., a Delaware corporation (the “Company”), issued a press release relating to the submission of a Special Protocol Assessment to the U.S. Food and Drug Administration and the Company’s presentation at the American Academy of Ophthalmology annual meeting. This press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information in this Current Report on Form 8-K, including Exhibit 99.1 and the information therefrom incorporated in Item 7.01 by reference to Exhibit 99.1, are being furnished, and shall not be deemed “filed,” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to liability under that section, nor shall they be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits:

99.1 Press release, dated November 12, 2015.

SIGNATURE

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.
(Registrant)

Date: November 12, 2015

By: /s/ Sam Backenroth
Sam Backenroth
Chief Financial Officer

EXHIBIT INDEX

| <u>Exhibit No.</u> | <u>Description</u> |
|--------------------|---|
| 99.1 | Press release, dated November 12, 2015. |



Ohr Pharmaceutical Announces Submission of a Special Protocol Assessment and Upcoming Presentation on OHR-102 at American Academy of Ophthalmology

Additional Results from Phase II IMPACT Study to be Featured at Podium Presentation at AAO on Friday, November 13

NEW YORK, November 12, 2015 -- Ohr Pharmaceutical, Inc. (Nasdaq: OHRP), an ophthalmology research and development company, today announced the company has submitted a Special Protocol Assessment (SPA) request to the U.S. Food and Drug Administration (FDA or agency), as part of the ongoing interaction with the FDA on the detailed design of the Phase 3 clinical development program of OHR-102 (Squalamine Lactate Ophthalmic Solution, 0.2%) for the treatment of neovascular Age-Related Macular Degeneration (wet AMD).

The SPA request includes a detailed protocol that was designed based on previous guidance the company received from the agency, to address and adequately provide the agency with a Phase 3 program that produces data that would allow assessment of efficacy and safety of OHR-102 for the treatment of patients with wet AMD. The FDA may take up to 45 calendar days to provide comments to Ohr Pharmaceutical.

“We have submitted an SPA request to the FDA with the goal of solidifying the development and regulatory pathway for OHR-102, and specifically, the details of our planned Phase 3 clinical trials,” said Jason Slakter, M.D., Chief Executive Officer of Ohr. “OHR-102 may offer wet AMD patients a convenient, topical approach that produces clinically meaningful improvements in vision beyond that achieved with anti-VEGF injections alone, and we are excited to be moving the program into Phase 3 development.”

The planned Phase 3 clinical trials are designed as well-controlled, double-masked, placebo-controlled, multicenter, international studies of OHR-102 administered twice a day in patients with newly diagnosed wet AMD, in combination with Lucentis[®] injections. The company expects to initiate the Phase 3 program in late 2015 and enroll the first patients by year-end 2015 or in the first calendar quarter of 2016.

Presentation at the Annual American Academy of Ophthalmology Meeting

The company will be presenting additional detailed data from the recently completed Phase II IMPACT study during the retina subspecialty meeting at the American Academy of Ophthalmology annual meeting, taking place from November 13-17, 2015, in Las Vegas, NV. The podium presentation will be given by Dr. David S. Boyer, retina specialist at Retina-Vitreous Associates Medical Group, Beverly Hills, and investigator in the IMPACT study. Details of the presentation are as follows:

Title: Squalamine Eye Drops in Retinal Vascular Diseases
Speaker: Dr. David S. Boyer
Location: Sands Expo/Venetian



Time: Friday, November 13, 2015, 3:43pm PST

About a Special Protocol Assessment (SPA)

A Special Protocol Assessment (SPA) from the FDA is a binding agreement that the design and planned analysis of a study adequately address the objectives necessary to support a regulatory submission. More information about the FDA's Special Protocol Assessment process is available at <http://www.fda.gov/downloads/Drugs/.../Guidances/ucm080571.pdf>.

About Ohr Pharmaceutical, Inc.

Ohr Pharmaceutical, Inc. (NasdaqCM:OHRP) is an ophthalmology research and development company. The company's lead product, OHR-102 (Squalamine Lactate Ophthalmic Solution, 0.2%), is currently being studied as an eye drop formulation in clinical trials for back-of-the-eye diseases, including the wet form of age-related macular degeneration, retinal vein occlusion, and proliferative diabetic retinopathy. In addition, Ohr has 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. 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 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 Report discuss some of the important risk factors that may affect our business, results of operations and financial condition.



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