

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 16, 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, 11<sup>th</sup> 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 16, 2015, Ohr Pharmaceutical, Inc., a Delaware corporation, issued a press release announcing that it has presented additional data from the Phase 2 IMPACT study evaluating OHR-102 (Squalamine lactate ophthalmic solution, 0.2%) combination therapy for the treatment of the wet form of age-related macular degeneration (wet-AMD) at the annual meeting of the American Academy of Ophthalmology. 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 16, 2015.

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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 17, 2015

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

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EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	<a href="#">Press release, dated November 16, 2015</a>

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**Ohr Pharmaceutical Presents New Data from OHR-102 Phase II IMPACT Study in Wet-AMD at American Academy of Ophthalmology Annual Meeting**

Occult CNV Size in Wet-AMD is Predictive of Success of OHR-102 Combination Therapy

Results Drive Patient Selection and Design for Phase 3 Program

**NEW YORK, New York – November 16, 2015** – Ohr Pharmaceutical, Inc. (NasdaqCM: OHRP), an ophthalmology research and development company, presented additional positive data from the Phase 2 IMPACT study evaluating OHR-102 (Squalamine lactate ophthalmic solution, 0.2%) combination therapy for the treatment of the wet form of age-related macular degeneration (wet-AMD). The data were presented by Dr. David S Boyer, retina specialist at Retina-Vitreous Associates Medical Group and investigator in the study, at the annual meeting of the American Academy of Ophthalmology (AAO), in Las Vegas.

New data from the IMPACT study demonstrates that visual acuity outcomes correlate with the size and composition of lesions in the study patients. Previously, a positive benefit in terms of visual acuity outcomes was shown in patients with classic containing lesions. Detailed analyses of lesion characteristics and their predictive effect on visual acuity outcomes demonstrated that the smaller the occult CNV size, the more pronounced the combination treatment effect on visual acuity, whether or not there was a classic component present. This size effect was not observed in those patients treated with Lucentis<sup>®</sup> (anti-VEGF) monotherapy.

The size of occult CNV, irrespective of a classic CNV component, was most important in predicting treatment success with the combination of OHR-102 plus Lucentis. In those patients with occult CNV less than 10mm<sup>2</sup> in area (n=94 of 128 completing the study), 40% of those treated with the combination of OHR-102 plus Lucentis achieved a gain of 3 or more lines of vision, compared with 26% of patients in the Lucentis monotherapy arm, a 54% additional benefit. In addition, mean gains in visual acuity compared to baseline were +11.0 letters for the OHR-102 plus Lucentis combination arm and +5.7 letters with Lucentis monotherapy, a clinically meaningful benefit of +5.3 letters. Importantly, this group of patients represents a larger proportion of the subjects enrolled in the IMPACT study than the classic containing group.

“The latest results from the IMPACT study support the ability of topical OHR-102 given in combination with anti-VEGF injections to improve visual function in patients with wet AMD over anti-VEGF treatment alone. Importantly, this analysis gives us insight into the mechanism of action and optimal patient population for OHR-102 and suggests that patients with occult CNV less than a certain size are the most likely to benefit the most,” stated Dr. David S. Boyer. “I look forward to the further clinical development of this exciting therapy.”

“These robust results allow us to optimize the design for our planned Phase III development program, in particular, the inclusion criteria for enrolling the patient population which has the highest likelihood of significant visual acuity gains,” stated Dr. Jason Slakter, Chief Executive Officer at Ohr. “We look forward to the initiation of the Phase 3 program, which we anticipate will occur in late 2015, and enrolling the first patients by year-end 2015 or in the first calendar quarter of 2016.”

**Phase III Clinical Program Design:**

The comprehensive Phase 3 clinical program will be comprised of 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 primary endpoint will be a measurement of visual acuity gains at nine months, with patients followed to two years for safety. The eligibility criteria will include patients with choroidal neovascularization (CNV) secondary to AMD. The lesions in these patients may contain classic and/or occult CNV. The occult CNV component of these lesions must measure less than 10mm<sup>2</sup> as assessed on fluorescein angiography.

**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](http://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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