

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): January 5, 2018

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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 8.01 Other Events.

On January 5, 2018, Ohr Pharmaceutical, Inc. issued a press release announcing efficacy results from its MAKO study in wet-AMD. This press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits:

99.1 Press release, dated January 5, 2018.

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: January 5, 2018

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

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press release, dated January 5, 2018



Ohr Pharmaceutical Announces Efficacy Results from the MAKO Study in Wet-AMD

NEW YORK, New York – January 5, 2018 – Ohr Pharmaceutical, Inc. (NASDAQ: OHRP), a clinical-stage pharmaceutical company developing novel therapies for ophthalmic diseases, today reported topline data from the MAKO study which did not meet its primary efficacy endpoint. The MAKO study evaluated the efficacy and safety of topically administered squalamine in combination with monthly Lucentis[®] injections for the treatment of wet age-related macular degeneration (“wet-AMD”). The primary efficacy endpoint was the mean visual acuity gain at nine months, using a mixed-effects model for repeated measures (MMRM) analysis. Subjects receiving squalamine combination therapy (n=119) achieved a mean gain of 8.33 letters from baseline versus 10.58 letters from baseline with Lucentis[®] monotherapy (n=118). There were no differences in the safety profile between the two treatment groups.

“We are very disappointed with the outcome of the MAKO study,” commented Dr. Jason Slakter, chief executive officer of Ohr. “We are grateful to the patients and physicians who participated in the clinical trial. Based on these results, we intend to evaluate strategic alternatives to maximize shareholder value.”

About the MAKO Study

The MAKO study was a multi-center, randomized, double-masked, placebo-controlled clinical trial to evaluate the efficacy and safety of squalamine combination therapy for the treatment of wet-AMD. Subjects were randomized 1:1 to receive topical squalamine lactate ophthalmic solution, 0.2%, (“squalamine”) twice daily (“BID”) and monthly Lucentis[®] injections (“squalamine combination”) or topical placebo BID and monthly Lucentis[®] injections (“Lucentis monotherapy”). Eligibility criteria for the study eye included: newly diagnosed with wet-AMD and no previous treatment, occult neovascularization, if present, measured less than 10mm² as assessed by fluorescein angiography, and visual acuity between 20/40 and 20/320. A total of 237 subjects were randomized. Visual acuity was measured monthly using the Early Treatment of Diabetic Retinopathy (ETDRS) eye chart. The primary efficacy endpoint was the mean visual acuity gain at nine months, using a mixed-effects model for repeated measures (MMRM) analysis.

About Ohr Pharmaceutical, Inc.

Ohr Pharmaceutical, Inc. (OHRP) is a clinical-stage pharmaceutical company developing novel therapies for ophthalmic diseases. The company has completed two clinical trials with squalamine lactate ophthalmic solution, 0.2%, for the treatment of the wet form of age-related macular degeneration. In addition, Ohr has a sustained-release micro-fabricated micro-particle ocular drug delivery platform technology.

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 we undertake 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 our ability to raise sufficient funds to perform and conclude clinical trials, the financial resources available to us, the ability to negotiate and conclude a strategic partnership, 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, 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. Our most recent Annual Report on Form 10-K and subsequent Quarterly Reports on Form 10-Q discuss some of the important risk factors that may affect our business, results of operations and financial condition.

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