
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): December 10, 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))
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Item 2.02 Results of Operations and Financial Condition

On December 10, 2015, Ohr Pharmaceutical, Inc., a Delaware corporation, issued a press release announcing its results for the fiscal year ended September 30, 2015. 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 December 10, 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: December 10, 2015

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

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release, dated December 10, 2015



Ohr Pharmaceutical Reports Fiscal Year 2015 Financial and Business Results

OHR-102 Phase 3 Program in Wet-AMD to be Initiated Upon Completion of SPA; Enroll Patients in Q1 2016

Conference Call and Webcast with Slides, Today at 5:00pm Eastern Time

NEW YORK, New York – December 10, 2015 – Ohr Pharmaceutical, Inc. (NasdaqCM: OHRP), an ophthalmology research and development company, today reported results for its fiscal year ended September 30, 2015.

“I am pleased with the continued positive momentum over the past year in the development of our lead candidate OHR-102 for the treatment of the wet form of age-related macular degeneration (wet-AMD) and other back of the eye disorders,” stated Jason S. Slakter, MD, Chief Executive Officer of Ohr Pharmaceutical. “We successfully completed the Phase 2 IMPACT study in patients with wet AMD, demonstrating a positive and clinically meaningful treatment effect with OHR-102 combination therapy. The various analyses we conducted of the IMPACT data, which were featured at major ophthalmology meetings in the U.S. and internationally through the year, gave us insight into the mechanism of action of OHR-102 and identified the patients most likely to benefit from OHR-102 combination therapy.”

“The strong body of clinical evidence we have accumulated supports our conviction that OHR-102 combination therapy has the potential to establish a new standard of care in wet AMD,” continued Dr. Slakter. “Importantly, we now have the data we need to optimize the design for our planned Phase 3 development program, in particular, the inclusion criteria for enrolling the patient population which has the highest likelihood of significant visual acuity gains. Our goal is to initiate the Phase 3 program upon completion of the Special Protocol Assessment (SPA) procedure, and enroll patients in the first calendar quarter of 2016.”

Corporate Highlights for 2015

- Jason S. Slakter, MD, appointed to Board of Directors in January.
- Raised approximately \$29 million in gross proceeds from a public offering of common stock in February.
- Avner Ingerman, MD, appointed Chief Clinical Officer in February.
- Jason S. Slakter, MD appointed Chief Executive Officer in August.
- Submitted a Special Protocol Assessment request to the FDA for a Phase 3 clinical program for OHR-102 for the treatment of wet-AMD in November.

Clinical and Preclinical Highlights for 2015

- In March, announced final topline data from Phase 2 IMPACT Study of OHR-102 in Wet-AMD.
 - Positive visual and clinically meaningful treatment effect achieved in classic containing CNV using OHR-102 combination therapy.
 - In patients with classic CNV (ITT-LOCF), mean gains in visual acuity were +10.5 letters for the OHR-102 combination arm and +5.4 letters with Lucentis® (anti-VEGF) monotherapy, a clinically meaningful benefit of +5.1 letters.
 - Detailed results were presented at the Association for Research in Vision and Ophthalmology (ARVO) conference, in Denver, CO., in May.
- In July, announced positive results from a Phase 2 investigator sponsored clinical trial in retinal vein occlusion (RVO), at the Annual Meeting of the American Society of Retina Specialists (ASRS) in Vienna, Austria.
 - OHR-102 combination therapy enhances visual recovery in macular edema secondary to RVO.
 - This was the second clinical study in a retinal vascular disorder which demonstrated a positive and clinically meaningful benefit in visual acuity using OHR-102 combination therapy versus an intravitreal anti-VEGF injection alone.
 - A clinically meaningful 4.5 letter difference was demonstrated in patients that received OHR-102 combination therapy versus the patients randomized to Lucentis monotherapy from week 10 to 38.

- In July, commenced an exploratory Phase 2 study to evaluate the combination of OHR-102 administered twice daily with monthly Lucentis injections in patients with wet-AMD.
 - Utilizing new and enhanced retinal imaging technologies to further elucidate the effects of OHR-102 combination therapy on neovascular lesions.
- In November, announced additional data from Phase 2 IMPACT study in wet-AMD at the American Academy of Ophthalmology (AAO) Annual Meeting, in Las Vegas, NV.
 - The size of occult CNV at baseline, irrespective of a classic CNV component, was most important in predicting treatment success with the combination of OHR-102 plus Lucentis. For patients with occult CNV less than 10mm² 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.
 - 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 in this occult <10mm² population.
 - Occult <10mm² population represents a larger proportion of the subjects enrolled in the IMPACT study than the classic containing group.
 - Phase 3 program will enroll this optimized patient population.
- Also in November, announced positive preclinical data in proprietary SKS sustained release technology.
 - In an animal model used to evaluate ophthalmic compounds, sustained supratherapeutic levels of active drug were achieved in target ocular tissues at all time points in the study.
 - The results serve as an important validation for the company's SKS sustained release technology which holds the promise of improving the standard of care in a number of ocular conditions.

Financial Results for the Year Ended September 30, 2015

- For the fiscal year ended September 30, 2015, the Company reported a net loss of approximately \$15.2 million, or (\$0.54) per share, compared to a net loss of approximately \$9.1 million, or (\$0.41) per share in the same period of 2014.
- For the fiscal year ended September 30, 2015, total operating expenses were approximately \$17.8 million, consisting of \$7.5 million in general and administrative expenses, \$8.8 million in research and development expenses, \$1.2 million in depreciation and amortization, and \$0.3 million in impairment of intangibles. This compared to approximately \$9.1 million in 2014, consisting of \$4.3 million in general and administrative expenses, \$4.4 million in research and development expenses, \$0.5 million in depreciation and amortization, and no impairment of intangibles.
- Cash and cash equivalents of approximately \$28.7 million at September 30, 2015. This compares to cash and cash equivalents of approximately \$13.2 million at September 30, 2014.

Conference call details

Thursday, December 10, 2015 at 5:00pm Eastern Time

Domestic: 877-407-0789
 International: 201-689-8562
 Conference ID: 13626497
 Webcast with Slides: <http://public.viaavid.com/index.php?id=117510>

Replays – Available through December 17, 2015

Domestic: 877-870-5176
 International: 858-384-5517
 Conference ID: 13626497

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.

Contact:

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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 Reports discuss some of the important risk factors that may affect our business, results of operations and financial condition.

Lucentis® is a registered trademark of Genentech, Inc.

OHR PHARMACEUTICAL, INC.
Consolidated Balance Sheets
(Unaudited)

<u>ASSETS</u>	<u>September 30, 2015</u>	<u>September 30, 2014</u>
CURRENT ASSETS		
Cash	\$ 28,697,323	\$ 13,220,494
Prepaid expenses and other current assets	338,713	133,527
Total Current Assets	29,036,036	13,354,021
EQUIPMENT, net	248,753	104,425
OTHER ASSETS		
Security deposit	12,243	12,243
Investment in joint venture	—	3,143
Intangible assets, net	16,332,863	17,810,400
Goodwill	740,912	740,912
TOTAL ASSETS	\$ 46,370,807	\$ 32,025,144
<u>LIABILITIES AND STOCKHOLDERS' EQUITY</u>		
CURRENT LIABILITIES		
Accounts payable and accrued expenses	\$ 1,592,348	\$ 351,864
Notes payable	48,063	43,899
Contingent consideration	2,239,603	4,877,359
Total Current Liabilities	3,880,014	5,273,122
TOTAL LIABILITIES	3,880,014	5,273,122
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS' EQUITY		
Preferred stock, Series B; 6,000,000 shares authorized, \$0.0001 par value, 0 shares issued and outstanding, respectively	—	—
Common stock; 180,000,000 shares authorized, \$0.0001 par value, 30,331,309 and 25,254,190 shares issued and outstanding, respectively	3,033	2,525
Additional paid-in capital	100,999,173	70,063,045
Accumulated deficit	(58,511,413)	(43,313,548)
Total Stockholders' Equity	42,490,793	26,752,022
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 46,370,807	\$ 32,025,144

The accompanying notes are an integral part of these consolidated financial statements.

OHR PHARMACEUTICAL, INC.
Consolidated Statements of Operations
(Unaudited)

	For the Twelve Months Ended		
	September 30,		
	2015	2014	2013
OPERATING EXPENSES			
General and administrative	\$ 7,509,601	\$ 4,287,205	\$ 1,775,857
Research and development	8,777,519	4,369,413	2,753,914
Depreciation and amortization	1,179,254	466,306	91,145
Impairment of Intangibles	338,906	—	—
OPERATING LOSS	17,805,280	9,122,924	4,620,916
OTHER INCOME (EXPENSE)			
Interest expense	(5,977)	(5,576)	(4,689)
Change in derivative liability	—	—	(1,117,642)
Change in fair value of contingent consideration	2,637,756	—	—
Share in losses on investment in joint venture	(103,143)	(10,643)	—
Royalty income	35,813	—	—
Other income and expense	42,966	8,479	90,759
Total Other Income (Expense)	2,607,415	(7,740)	(1,031,572)
LOSS FROM OPERATIONS BEFORE			
INCOME TAXES	(15,197,865)	(9,130,664)	(5,652,488)
PROVISION FOR INCOME TAXES	—	—	—
NET LOSS	\$ (15,197,865)	\$ (9,130,664)	\$ (5,652,488)
BASIC AND DILUTED LOSS PER SHARE	\$ (0.54)	\$ (0.41)	\$ (0.30)
WEIGHTED AVERAGE NUMBER			
OF SHARES OUTSTANDING:			
BASIC AND DILUTED	28,404,405	22,141,538	18,707,759

The accompanying notes are an integral part of these consolidated financial statements.