
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 10, 2016

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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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 2.02 Results of Operations and Financial Condition

On May 10, 2016, Ohr Pharmaceutical, Inc., a Delaware corporation, issued a press release announcing its results for the second quarter ended March 31, 2016. 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 May 10, 2016.

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: May 10, 2016

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

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	<u>Press release, dated May 10, 2016</u>



Ohr Pharmaceutical Reports Second Quarter 2016 Financial and Business Results

Conference Call Today at 5:00pm Eastern Time

NEW YORK, New York – May 10, 2016– Ohr Pharmaceutical, Inc. (NasdaqCM: OHRP), an ophthalmology research and development company, today reported results for its second quarter ended March 31, 2016.

“We achieved a number of important milestones in advancing our lead drug candidate, Squalamine, during the first few months of 2016,” said Jason S. Slakter, MD, Chief Executive Officer of Ohr. “In commencing the enrollment of patients in our Phase 3 clinical program, we move closer to potentially providing a much-needed, safe and efficacious new treatment for patients with neovascular age-related macular degeneration or wet AMD. Importantly, we are conducting the Phase 3 trials under an agreed upon Special Protocol Assessment (SPA) with the United States Food and Drug Administration. The trials are designed to generate data to support regulatory approval of Squalamine in the United States and other major ophthalmic markets worldwide.”

Second Quarter and Recent 2016 Clinical and Pre-Clinical Highlights

- Enrolled the first patient in the Phase 3 clinical development program to investigate Squalamine lactate ophthalmic solution, 0.2% (“Squalamine,” also known as OHR-102), when administered as part of a combination therapy, as a treatment to improve visual function for patients with wet AMD.
 - The Phase 3 program includes two clinical trials designed as double-masked, placebo-controlled, multicenter, international studies of Squalamine administered twice a day in patients with newly diagnosed wet AMD, in combination with Lucentis[®] injections.
 - The first of the two randomized trials will include approximately 165 centers in the United States and Canada and has a target enrollment of 650 treatment naïve subjects with wet AMD.
 - The primary endpoint in both studies will be a measurement of visual acuity gains at nine months, which is the most clinically meaningful endpoint for wet AMD patients. Subjects will be followed to two years for safety.
- Reached an agreement on a Special Protocol Assessment (SPA) with the United States Food and Drug Administration on the design of the Phase 3 trials for Squalamine.
- Presented two posters at the Association for Research in Vision and Ophthalmology (ARVO) Conference, which took place May 1 through May 5 in Seattle, Washington.
 - *CNV Lesion Characteristics as a Predictor of Visual Outcomes in Wet AMD Patients Receiving Combination Therapy with Ranibuzimab (Lucentis[®]) and topical Squalamine Lactate Ophthalmic Solution (David M. Brown et al)* Included detailed analysis of lesion characteristics as predictors of visual outcome in the previously conducted Phase 2 IMPACT trial, and demonstrated that combination therapy with Squalamine was most effective in those patients whose occult component was less than 10mm². These new data support the choice of the target population in the ongoing Phase 3 registration program.
 - *Sustained Retinal Concentrations of OHR3031 Achieved with Intravitreal Injection of a Biodegradable Microparticle Formulation to Rabbits (Modi et al)*. This poster discussed the use of Ohr’s proprietary sustained release technology to successfully deliver supratherapeutic concentrations of OHR3031, a novel small molecule anti-angiogenic compound, to target tissues in the back of the eye.

Financial Results for Second Quarter ended March 31, 2016

- For the second quarter ended March 31, 2016, the Company reported a net loss of approximately \$5.3 million, or (\$0.17) per share, compared to a net loss of approximately \$3.4 million, or (\$0.12) per share in the same period of 2015.
- For the second quarter ended March 31, 2016, total operating expenses were approximately \$6.6 million, consisting of approximately \$3.0 million in general and administrative expenses, \$4.0 million in research and development expenses, \$0.3 million in depreciation and amortization, and \$0.7 million in gain on settlement of accounts payable. This compares to total operating expenses in the same period of 2015 of approximately \$6.8 million, consisting of \$3.3 million in general and administrative expenses, \$3.2 million in research and development expenses, and \$0.3 million in depreciation and amortization.
- At March 31, 2016, the Company had cash and cash equivalents of approximately \$21.9 million. This compares to cash and equivalents of approximately \$28.7 million at September 30, 2015.

Financial Results for the Six-Months ended March 31, 2016

- For the six months ended March 31, 2016, the Company reported a net loss of approximately \$11.4 million, or (\$0.37) per share, compared to a net loss of approximately \$7.9 million, or (\$0.30) per share in the same period of 2015.
- For the six months ended March 31, 2016, total operating expenses were approximately \$10.2 million, consisting of \$4.2 million in general and administrative expenses, \$6.1 million of research and development expenses, \$0.6 million in depreciation and amortization, and \$0.7 million in gain on settlement of accounts payable. This compares to total operating expenses of \$10.7 million in the same period of 2015, comprised of approximately \$4.2 million in general and administrative expenses, \$5.9 million in research and development expenses, and \$0.6 million in depreciation and amortization.

Conference Call & Webcast***Tuesday, May 10 at 5:00pm Eastern Time***

Domestic: 877-407-0789
International: 201-689-8562
Conference ID: 13636051
Webcast: <http://public.viavid.com/index.php?id=119332>

Replays – Available through May 16, 2016

Domestic: 877-870-5176
International: 858-384-5517
Conference ID: 13636051

About Ohr Pharmaceutical, Inc.

Ohr Pharmaceutical, Inc. (Nasdaq: OHRP) is an ophthalmology research and development company. The company's lead drug candidate, Squalamine lactate ophthalmic solution, 0.2% (also known as OHR-102), is currently being studied using an eye drop formulation in a Phase 3 clinical program 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 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 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 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. 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.

Lucentis[®] is a registered trademark of Genentech Inc.

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OHR PHARMACEUTICAL, INC.
Consolidated Balance Sheets
(Unaudited)

	<u>March 31,</u> <u>2016</u>	<u>September 30,</u> <u>2015</u>
<u>ASSETS</u>		
CURRENT ASSETS		
Cash	\$ 21,881,370	\$ 28,697,323
Prepaid expenses and other current assets	456,514	338,713
Total Current Assets	<u>22,337,884</u>	<u>29,036,036</u>
EQUIPMENT, net	<u>229,363</u>	<u>248,753</u>
OTHER ASSETS		
Security deposit	12,243	12,243
Intangible assets, net	15,770,541	16,332,863
Goodwill	740,912	740,912
TOTAL ASSETS	<u>\$ 39,090,943</u>	<u>\$ 46,370,807</u>
<u>LIABILITIES AND STOCKHOLDERS' EQUITY</u>		
CURRENT LIABILITIES		
Accounts payable and accrued expenses	\$ 1,869,265	\$ 1,592,348
Notes payable	215,810	48,063
Contingent consideration	1,430,393	2,239,603
Total Current Liabilities	<u>3,515,468</u>	<u>3,880,014</u>
TOTAL LIABILITIES	<u>3,515,468</u>	<u>3,880,014</u>
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, 31,496,869 and 30,331,309 shares issued and outstanding, respectively	3,150	3,033
Additional paid-in capital	105,514,059	100,999,173
Accumulated deficit	(69,941,734)	(58,511,413)
Total Stockholders' Equity	<u>35,575,475</u>	<u>42,490,793</u>
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	<u>\$ 39,090,943</u>	<u>\$ 46,370,807</u>

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

	For the Three Months Ended March 31,		For the Six Months Ended March 31,	
	2016	2015	2016	2015
OPERATING EXPENSES				
General and administrative	\$ 2,966,363	\$ 3,334,971	\$ 4,184,492	\$ 4,151,834
Research and development	4,043,859	3,175,855	6,120,139	5,919,977
Depreciation and amortization	296,077	295,262	593,816	600,884
Gain on settlement of accounts payable	(710,264)	—	(710,264)	—
OPERATING LOSS	6,596,035	6,806,088	10,188,183	10,672,695
OTHER INCOME (EXPENSE)				
Change in fair value of contingent consideration	1,305,623	3,786,193	(1,251,926)	3,102,807
Share in losses on investment in joint venture	—	(41,211)	—	(67,861)
Other income	—	—	3,419	35,813
Interest income, net	5,553	(536)	6,369	(663)
Impairment of intangibles	—	(338,906)	—	(338,906)
Total Other Income (Expense)	1,311,176	3,405,540	(1,242,138)	2,731,190
LOSS FROM OPERATIONS BEFORE INCOME TAXES	(5,284,859)	(3,400,548)	(11,430,321)	(7,941,505)
PROVISION FOR INCOME TAXES	—	—	—	—
NET LOSS	\$ (5,284,859)	\$ (3,400,548)	\$ (11,430,321)	\$ (7,941,505)
BASIC AND DILUTED LOSS PER SHARE	\$ (0.17)	\$ (0.12)	\$ (0.37)	\$ (0.30)
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING:				
BASIC AND DILUTED	31,344,424	27,713,410	30,906,114	26,479,538

Consolidated Statements of Cash Flows
(Unaudited)

	For the Six Months Ended	
	March 31,	
	2016	2015
OPERATING ACTIVITIES		
Net loss	\$ (11,430,321)	\$ (7,941,505)
Adjustments to reconcile net loss to net cash used by operating activities:		
Common stock issued for services	715,952	353,876
Warrants issued for services	—	8,559
Stock option expense	1,724,375	2,269,785
Change in fair value of contingent consideration	1,251,926	(3,102,807)
Share in losses on investment in joint venture	—	67,861
Depreciation	31,494	24,866
Amortization of intangible assets	562,322	576,018
Impairment of Intangibles	—	338,906
Gain on settlement of accounts payable	(710,264)	—
Changes in operating assets and liabilities		
Prepaid expenses and deposits	98,009	(419,991)
Accounts payable and accrued expenses	987,180	1,018,156
Net Cash Used in Operating Activities	<u>(6,769,327)</u>	<u>(6,806,276)</u>
INVESTING ACTIVITIES		
Investment in joint venture	—	(100,000)
Purchase of property and equipment	(12,103)	(86,891)
Net Cash Used in Investing Activities	<u>(12,103)</u>	<u>(186,891)</u>
FINANCING ACTIVITIES		
Proceeds for issuance of common stock for cash	—	26,582,998
Proceeds from warrants exercised for cash	13,540	80,005
Repayments of short-term notes payable	(48,063)	(67,068)
Net Cash Provided by Financing Activities	<u>(34,523)</u>	<u>26,595,935</u>
NET CHANGE IN CASH	(6,815,953)	19,602,768
CASH AT BEGINNING OF PERIOD	<u>28,697,323</u>	<u>13,220,494</u>
CASH AT END OF PERIOD	<u>\$ 21,881,370</u>	<u>\$ 32,823,262</u>
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION		
CASH PAID FOR:		
Interest	\$ —	\$ 1,533
Income Taxes	—	—
NON CASH FINANCING ACTIVITIES:		
Settlement of contingent consideration	\$ 2,061,136	\$ —
Financing of insurance premiums through issuance of short term notes	215,810	212,400
Common stock issued to settle accounts payable	—	50,000