
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 22, 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 December 22, 2016, Ohr Pharmaceutical, Inc., a Delaware corporation, issued a press release announcing its results for the fiscal year ended September 30, 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 December 22, 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: December 22, 2016

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

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release, dated December 22, 2016.



Ohr Pharmaceutical Reports Fiscal Year 2016 Financial and Business Results

Conference Call Today at 5:00pm Eastern Time

NEW YORK, New York – December 22, 2016 – Ohr Pharmaceutical, Inc. (NasdaqCM: OHRP), an ophthalmology research and development company, today reported results for its fourth quarter and fiscal year ended September 30, 2016.

“Fiscal year 2016 was another highly productive year for Ohr, as we made significant progress in advancing both our lead candidate Squalamine for the treatment of wet AMD as well as our pipeline of sustained release drug candidates,” said Jason Slakter, MD, Chief Executive Officer of Ohr. “Building off the Squalamine phase 2 results, we negotiated an SPA with the FDA in advance of commencing the pivotal phase 3 program. This comprehensive phase 3 program is now underway which, if successful, will position us to bring an innovative, meaningful treatment to market that has the potential to improve vision outcomes beyond current therapies and set a new standard of care in wet AMD.”

Fiscal 2016 and Recent Corporate Highlights

- Reached an agreement on a Special Protocol Assessment (SPA) with the US FDA on the design of Phase 3 trials for Squalamine lactate ophthalmic solution, 0.2% (“Squalamine”, also known as OHR-102) for patients with wet AMD.
- Appointed David M. Brown, MD to serve as the chair of the Steering Committee for the Phase 3 clinical program of Squalamine in wet-AMD.
- Closed a public offering of shares of common stock and warrants resulting in net proceeds of approximately \$6.9 million.

Fiscal 2016 Clinical and Development Program Highlights

- In September, presented new data from the Phase 2 IMPACT study at the American Society of Retina Specialists (ASRS). Subjects with occult CNV <10mm² achieved final mean visual acuity outcomes of 71.7 letters with Squalamine combination therapy compared to 67.4 letters with Lucentis® monotherapy. The final mean visual acuity outcomes in the combination therapy group translates to approximately 20/40 vision (Snellen equivalent). This underscores the potential of Squalamine combination therapy to allow patients to reach higher levels of visual function and improve their overall quality of life.
- In May, presented two posters on the Squalamine Phase 2 IMPACT study and OHR3031 sustained release in vivo studies at the Association for Research in Vision and Ophthalmology (ARVO) Conference.
- In April, commenced enrollment in the Phase 3 clinical development program investigating Squalamine as a treatment to improve visual acuity for patients with wet AMD.
 - The Phase 3 program includes two double-masked, placebo-controlled, multicenter, international studies of Squalamine administered topically twice a day in patients with newly diagnosed wet AMD, in combination with Lucentis® injections.

- The primary endpoint in both studies is a measurement of visual acuity gain at nine months, which is the most clinically meaningful endpoint for wet AMD patients. Subjects will be followed to two years for safety.
- In November 2015, presented new data from the Phase 2 IMPACT Study in Wet-AMD at American Academy of Ophthalmology (AAO) Annual Meeting.
 - Data showed that the size of occult CNV at baseline, irrespective of a classic CNV component, was the most important factor in predicting treatment success with the combination of Squalamine plus Lucentis®. This correlation was not seen in the Lucentis® monotherapy group.
- Also in November 2015, 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 Fiscal Year ended September 30, 2016

- For the year ended September 30, 2016, the Company reported a net loss of approximately \$25.8 million, or (\$0.82) per share, compared to a net loss of approximately \$15.2 million, or (\$0.54) per share in the same period of 2015.
- For the year ended September 30, 2016, total operating expenses were approximately \$24.6 million, consisting of \$7.7 million in general and administrative expenses, \$16.5 million of research and development expenses, and \$1.2 million in depreciation and amortization. This compares to total operating expenses of \$17.8 million in the same period of 2015, comprised of approximately \$7.5 million in general and administrative expenses, \$8.8 million in research and development expenses, and \$1.2 million in depreciation and amortization.
- At September 30, 2016, the Company had cash and cash equivalents of approximately \$12.5 million. This compares to cash and equivalents of approximately \$28.7 million at September 30, 2015.
- On December 7, 2016, the Company sold in a public offering, an aggregate of approximately 3,885,000 shares of its common stock, together with Series A common stock purchase warrants exercisable for up to an aggregate of approximately 1,942,500 shares of common stock and Series B common stock purchase warrants exercisable for up to an aggregate of approximately 3,885,000 shares of common stock. Net proceeds from the offering were approximately \$6.9 million, after deducting placement agent fees and estimated offering expenses payable but excluding the proceeds, if any, from the exercise of the Series A and Series B Warrants issued in the offering.

Conference Call & Webcast

Thursday, December 22 at 5:00pm Eastern Time

Domestic: 877-407-0789
 International: 201-689-8562
 Conference ID: 13651651
 Webcast: <http://public.viaavid.com/index.php?id=122267>

Replays – Available through December 29, 2016

Domestic: 844-512-2921
International: 412-317-6671
Conference ID: 13651651

About Ohr Pharmaceutical, Inc.

Ohr Pharmaceutical, Inc. (NasdaqCM: 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 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>September, 30th</u> <u>2016</u>	<u>September 30,</u> <u>2015</u>
<u>ASSETS</u>		
CURRENT ASSETS		
Cash	\$ 12,546,890	\$ 28,697,323
Prepaid expenses and other current assets	738,118	338,713
Total Current Assets	<u>13,285,008</u>	<u>29,036,036</u>
EQUIPMENT, net	<u>198,631</u>	<u>248,753</u>
OTHER ASSETS		
Security deposit	12,243	12,243
Intangible assets, net	15,208,219	16,332,863
Goodwill	<u>740,912</u>	<u>740,912</u>
TOTAL ASSETS	<u>\$ 29,445,013</u>	<u>\$ 46,370,807</u>
<u>LIABILITIES AND STOCKHOLDERS' EQUITY</u>		
CURRENT LIABILITIES		
Accounts payable and accrued expenses	\$ 4,394,068	\$ 1,592,348
Notes payable	87,798	48,063
Contingent consideration	<u>—</u>	<u>2,239,603</u>
Total Current Liabilities	<u>4,481,866</u>	<u>3,880,014</u>
TOTAL LIABILITIES	<u>4,481,866</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, 32,076,396 and 30,331,309 shares issued and outstanding, respectively	3,207	3,033
Additional paid-in capital	109,237,551	100,999,173
Accumulated deficit	<u>(84,277,611)</u>	<u>(58,511,413)</u>
Total Stockholders' Equity	<u>24,963,147</u>	<u>42,490,793</u>
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	<u>\$ 29,445,013</u>	<u>\$ 46,370,807</u>

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

For the Year Ended September 30,

	2016	2015	2014
OPERATING EXPENSES			
General and administrative	\$ 7,656,327	\$ 7,509,601	\$ 4,287,205
Research and development	16,460,714	8,777,519	4,369,413
Depreciation and amortization	1,189,276	1,179,254	466,306
Gain on settlement of accounts payable	(710,264)	—	—
Impairment of Intangibles	—	338,906	—
OPERATING LOSS	24,596,053	17,805,280	9,122,924
OTHER INCOME (EXPENSE)			
Change in fair value of contingent consideration	(1,185,667)	2,637,756	—
Share in losses on investment in joint venture	—	(103,143)	(10,643)
Other income and expense	3,419	42,966	8,479
Interest income (expense), net	12,103	(5,977)	(5,576)
Royalty income	—	35,813	—
Total Other Income (Expense)	(1,170,145)	2,607,415	(7,740)
LOSS FROM OPERATIONS BEFORE			
INCOME TAXES	(25,766,198)	(15,197,865)	(9,130,664)
PROVISION FOR INCOME TAXES			
	—	—	—
NET LOSS	\$ (25,766,198)	\$ (15,197,865)	\$ (9,130,664)
BASIC AND DILUTED LOSS PER SHARE	\$ (0.82)	\$ (0.54)	\$ (0.41)
WEIGHTED AVERAGE NUMBER			
OF SHARES OUTSTANDING:			
BASIC AND DILUTED	31,349,223	28,404,405	22,141,538

OHR PHARMACEUTICAL, INC.
Consolidated Statements of Cash Flows
(Unaudited)

For the Twelve Months Ended
September 30,

	2016	2015	2014
OPERATING ACTIVITIES			
Net loss	\$ (25,766,198)	\$ (15,197,865)	\$ (9,130,664)
Adjustments to reconcile net loss to net cash used by operating activities:			
Common stock issued for services	1,754,814	635,288	—
Warrants issued for services	—	8,559	1,177,095
Stock option expense	2,913,626	3,579,788	2,074,487
Change in fair value of contingent consideration	1,185,667	(2,637,756)	—
Share in losses on investment in joint venture	—	103,143	10,643
Depreciation	64,632	40,623	17,850
Amortization of intangible assets	1,124,644	1,138,631	448,456
Impairment of intangibles	—	338,906	—
Gain on settlement of accounts payable	(710,264)	(40,636)	—
Changes in operating assets and liabilities			
Prepaid expenses and deposits	(64,794)	7,214	105,823
Accounts payable and accrued expenses	3,511,984	1,331,120	(63,822)
Net Cash Used in Operating Activities	(15,985,889)	(10,692,985)	(5,360,132)
INVESTING ACTIVITIES			
Acquisition of SKS Ocular's assets	—	—	(3,500,000)
Investment in joint venture	—	(100,000)	(13,786)
Purchase of property and equipment	(14,510)	(184,951)	(1,083)
Net Cash Used in Investing Activities	(14,510)	(284,951)	(3,514,869)
FINANCING ACTIVITIES			
Proceeds for issuance of common stock for cash	—	26,582,998	16,876,000
Proceeds from warrants exercised for cash	26,041	80,003	260,752
Repayments of short-term notes payable	(176,075)	(208,236)	(164,152)
Net Cash Provided by/ (Used in) Financing Activities	(150,034)	26,454,765	16,972,600
NET CHANGE IN CASH	(16,150,433)	15,476,829	8,097,599
CASH AT BEGINNING OF PERIOD	28,697,323	13,220,494	5,122,895
CASH AT END OF PERIOD	\$ 12,546,890	\$ 28,697,323	\$ 13,220,494
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION			
CASH PAID FOR:			
Interest	\$ 6,071	\$ 5,977	\$ 5,576
Income Taxes	—	—	—
NON CASH FINANCING ACTIVITIES:			
Settlement of contingent consideration	\$ 3,425,270	\$ —	\$ —
Financing of insurance premiums through issuance of short term notes	215,810	212,400	194,000
Subscription receivable from exercise of warrants	118,801	—	—
Conversion of preferred for common stock	—	—	50
Noncash exercise of options and warrants	—	—	223
Common stock issued to acquire intangible assets	—	—	10,180,224
Common stock issued to settle accounts payable	—	50,000	50,000