

December 22, 2014



# Ohr Pharmaceutical Reports Fiscal Year 2014 Financial and Business Results

## Company to Host Conference Call at 5:00pm Eastern Time Today

NEW YORK, Dec. 22, 2014 (GLOBE NEWSWIRE) -- Ohr Pharmaceutical, Inc. (Nasdaq:OHRP), an ophthalmology research and development company, today reported results for its fiscal year ended September 30, 2014.

"The past year has been transformational for Ohr Pharmaceutical and has been marked by significant progress across all aspects of our business," stated Dr. Irach Taraporewala, President and Chief Executive Officer of Ohr Pharmaceutical. "On the clinical front, we announced positive interim clinical data from the ongoing Phase II IMPACT trial evaluating our lead candidate OHR-102 (Squalamine Eye Drops) in patients with wet age-related macular degeneration (wet AMD). Treatment with OHR-102 demonstrated an improvement in visual acuity, the most clinically relevant endpoint for back-of-the-eye disorders. The results were supported by additional data showing an improvement in retinal anatomy in patients. We have laid the groundwork for continued advancement in fiscal 2015. The positive IMPACT data and successful outcome of our recent FDA meeting give us a clear path for future registration studies for OHR-102 which we expect to begin in the first half of calendar 2015. We have a number of other upcoming critical milestones including: reporting final data from our OHR-102 trial in wet AMD in the first quarter of 2015, reporting clinical data from our two investigator sponsored trials evaluating OHR-102 in proliferative diabetic retinopathy and retinal vein occlusion, both targeted in the first half of calendar 2015. We look forward to discussing our progress in the coming weeks and months."

"During 2014 we also acquired SKS Ocular and its sustained release technology, which is complementary to our efforts to develop and commercialize OHR-102 for retinal disease," continued Dr. Taraporewala. "Our expanded pipeline now includes both early and late stage clinical assets that address multi-billion dollar market opportunities for retinal disease, glaucoma, and other ocular indications. The SKS acquisition was also important in terms of building out our management team with the appointment of Drs. Jason S. Slakter, Glenn L. Stoller, and Peter K. Kaiser to senior roles at OHR."

## Clinical Highlights for 2014

- In June, announced positive data from the interim analysis of the ongoing IMPACT Phase II study evaluating OHR-102 in combination with Lucentis for the treatment of wet-AMD.

- The data demonstrated a positive benefit in clinically relevant visual function in the OHR-102 arm across multiple key secondary endpoints.
- In the interim analysis group, 48.3 percent of OHR-102 treated patients showed best corrected visual acuity (BCVA) gains of  $\geq 15$  letters ( $\geq 3$  lines) on a standard early treatment diabetic retinopathy study eye-chart, compared with 21.2 percent in the Lucentis monotherapy arm at the end of the study ( $p=0.025$ ).
- Patients receiving OHR-102 drops were more than twice as likely to gain  $\geq 4$  and  $\geq 5$  lines of vision compared with patients in the Lucentis monotherapy arm ( $\geq 4$  lines  $p=0.022$ ,  $\geq 5$  lines  $p=0.059$ ).
- Mean change in visual acuity at the end of study visit was +10.4 letters with OHR-102 eye drops plus Lucentis PRN versus +6.3 letters in the placebo eye drops plus Lucentis PRN arm, a 65 percent additional relative benefit ( $p=0.18$ ).
- There were no significant differences in the frequency of Lucentis injections, which was the primary endpoint of this initial study.
- In October, presented additional positive clinical data from IMPACT at the 2014 American Academy of Ophthalmology (AAO) Annual Scientific Meeting, in Chicago.
  - The data demonstrated that the combination of OHR-102 plus Lucentis® resulted in a marked improvement in retinal anatomy, as measured by a quantitative analysis of sub retinal hyperreflective material (SHRM).
  - The OHR-102 combination arm also had better resolution of SHRM and a greater proportion of patients with total resolution of SHRM compared to the Lucentis monotherapy arm. Importantly, the reduction of SHRM correlated with the improved vision seen in the study.
- Held a successful "end of Phase II" meeting with the U.S. Food and Drug Administration (FDA) in which the FDA agreed on a nine month primary efficacy endpoint for the planned Phase III trials for OHR-102 based on improvement in visual acuity.
  - Two identical Phase III trials confirmatory studies will be required, designed to measure the efficacy of combination therapy with OHR-102 eye drops plus Lucentis injections compared with Lucentis monotherapy. The Company expects to begin these studies in the first half of calendar 2015.
- Announced the initiation of an investigator sponsored, multicenter Phase II clinical trial, to test OHR-102 in patients with diabetic macular edema (DME), which affects more than half a million patients in the U.S. alone.
- Announced data in August at the 2014 Annual Meeting of the American Society of Retina Specialists that supports the use of OHR-102 to treat macular edema secondary to branch or central retinal vein occlusion.
- Announced case report presentation at the 2014 Macula Society meeting demonstrating regression of retinal neovasculation using OHR-102 monotherapy, with regrowth of the abnormal vessels upon cessation of treatment.

#### **Operational and business developments for 2014:**

- In June, completed the acquisition of privately held SKS Ocular LLC, adding a proprietary, patent-protected, sustained-release technology platform as well as a pipeline of pre-clinical sustained release drug product candidates that address ocular indications including glaucoma, ocular allergy, and retinal disease among other

ophthalmic indications. In connection with the SKS Ocular transaction, three of its cofounders were appointed to senior roles at Ohr Pharmaceutical:

- Drs. Jason S. Slakter and Glenn L. Stoller were appointed to the newly created positions of Chief Medical Officer and Chief Scientific Officer at Ohr, respectively.
- Dr. Peter K. Kaiser was appointed as Head of Product Development.
- Formed a joint venture with Cold Spring Harbor Laboratory, called DepYMed, to advance the preclinical and clinical development of Ohr's Trodusquemine and several analogues
  - The initial clinical focus of the JV will be in oncology applications. DepYMed anticipates initiating a Phase I dose escalation study evaluating Trodusquemine in breast cancer patients.

## **Financial Results for the Year Ended September 30, 2014**

- For the fiscal year ended September 30, 2014, the Company reported a net loss of approximately \$9.1 million, or \$0.41 per share, compared with \$5.7 million, or \$0.30 per share, for the 2013 fiscal year. Operating expenses for fiscal 2014 totaled approximately \$9.1 million, compared with \$4.6 million, for the fiscal year ended September 30, 2013.
- For fiscal 2014, operating expenses consisted of approximately \$4.0 in research and development costs, \$1.8 million in professional fees, \$2.8 million in salaries and wages, and approximately \$600,000 in general and administrative expenses. This compared with fiscal 2013 expenses of approximately \$2.6 million in research and development costs, \$600,000 in professional fees, \$1.1 million in salaries and wages, and \$300,000 in general and administrative expenses.
- Cash and equivalents for the fiscal year ended September 30, 2014 totaled \$13.2 million, up from \$5.1 million at September 30, 2013. The Company raised \$16.9 million in net proceeds from a registered direct offering in April 2014.
- Based on the Company's current projections and estimations, management anticipates expenses will increase in fiscal year 2015, particularly related to clinical development activities. Management also believes the Company has sufficient capital to meet its planned operating needs through September 30, 2015.

## **Conference Call Details**

*Monday, December 22, 2014 @ 5:00pm Eastern Time/2:00pm Pacific Time*

Toll Free: 877-407-0789

International: 201-689-8562

Conference ID: 13597765

Webcast: <http://public.viavid.com/player/index.php?id=112342>

Replays through January 5, 2015:

Toll Free: 877-870-5176

International: 858-384-5517

Replay PIN: 13597765

## About Ohr Pharmaceutical, Inc.

Ohr Pharmaceutical, Inc. (OHRP) is an ophthalmology research and development company. The company's lead product, Squalamine, is currently being studied as an eye drop formulation in several company sponsored and investigator sponsored Phase II clinical trials for various back-of-the-eye diseases, including the wet form of age-related macular degeneration, retinal vein occlusion, diabetic macular edema, 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. The company also has a research agreement with Alcon on a sustained release program. Additional information on the company may be found at [www.ohrpharmaceutical.com](http://www.ohrpharmaceutical.com).

### OHR PHARMACEUTICAL, INC.

#### Consolidated Balance Sheets

	<u>September 30, 2014</u>	<u>September 30, 2013</u>
ASSETS		
CURRENT ASSETS		
Cash	\$ 13,220,494	\$ 5,122,895
Prepaid expenses and other current assets	<u>133,527</u>	<u>45,350</u>
Total Current Assets	<u>13,354,021</u>	<u>5,168,245</u>
EQUIPMENT, net	<u>104,425</u>	<u>29,755</u>
OTHER ASSETS		
Security deposit	12,243	--
Investment in joint venture	3,143	--
Intangible assets, net	17,810,400	545,865
Goodwill	<u>740,912</u>	<u>--</u>
TOTAL ASSETS	<u>\$ 32,025,144</u>	<u>\$ 5,743,865</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable and accrued expenses	\$ 351,864	\$ 465,686
Notes payable	43,899	14,051
Contingent consideration	<u>4,877,359</u>	<u>--</u>
Total Current Liabilities	<u>5,273,122</u>	<u>479,737</u>
TOTAL LIABILITIES	<u>5,273,122</u>	<u>479,737</u>

## COMMITMENTS AND CONTINGENCIES

### STOCKHOLDERS' EQUITY

Preferred stock, Series B; 6,000,000 shares authorized, \$0.0001 par value, 0 and 500,000 shares issued and outstanding, respectively	--	50
Common stock; 180,000,000 shares authorized, \$0.0001 par value, 25,254,190 and 19,741,541 shares issued and outstanding, respectively	2,525	1,974
Additional paid-in capital	70,063,045	39,444,988
Accumulated deficit	<u>(43,313,548)</u>	<u>(34,182,884)</u>
 Total Stockholders' Equity	 <u>26,752,022</u>	 <u>5,264,128</u>
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	<u>\$ 32,025,144</u>	<u>\$ 5,743,865</u>

## OHR PHARMACEUTICAL, INC.

### Consolidated Statements of Operations

	For the Year Ended		
	September 30,		
	<u>2014</u>	<u>2013</u>	<u>2012</u>
<b>OPERATING EXPENSES</b>			
General and administrative	\$ 555,735	\$ 312,541	\$ 135,552
Professional fees	1,780,657	608,408	875,868
Research and development	3,990,875	2,610,120	1,625,695
Salaries and wages	<u>2,795,657</u>	<u>1,089,847</u>	<u>649,293</u>
 Total Operating Expenses	 <u>9,122,924</u>	 <u>4,620,916</u>	 <u>3,286,408</u>
 OPERATING LOSS	 (9,122,924)	 (4,620,916)	 (3,286,408)
<b>OTHER INCOME (EXPENSE)</b>			
Interest expense	(5,576)	(4,689)	(1,817)
Change in derivative liability	--	(1,117,642)	1,812,224
Share in losses on investment in joint venture	(10,643)	--	--
Gain on settlement of debt	--	--	21,005
Other income and expense	<u>8,479</u>	<u>90,759</u>	<u>112</u>
 Total Other Income (Expense)	 <u>(7,740)</u>	 <u>(1,031,572)</u>	 <u>1,831,524</u>
 LOSS FROM OPERATIONS BEFORE INCOME TAXES	 (9,130,664)	 (5,652,488)	 (1,454,884)

PROVISION FOR INCOME TAXES	--	--	--
NET LOSS	<u>\$ (9,130,664)</u>	<u>\$ (5,652,488)</u>	<u>\$ (1,454,884)</u>
BASIC AND DILUTED LOSS PER SHARE	\$ -0.41	\$ -0.30	\$ -0.10
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING:			
BASIC AND DILUTED	22,141,538	18,707,759	14,242,792

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Source: Ohr Pharmaceutical, Inc.