
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, 2013

Ohr Pharmaceutical, Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other Jurisdiction of Incorporation)

333-88480

(Commission File Number)

#90-0577933

(IRS Employer Identification No.)

489 5th Ave, 28th Floor, New York, NY

(Address of Principal Executive Offices)

10017

(Zip Code)

Registrant's telephone number, including area code: (212)-682-8452

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 communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 8.01. Other Items.

On December 10, 2013, results from the registrant's OHR/AVR 118 Phase II clinical trial for the treatment of cancer cachexia were presented at the 7th International Cachexia Conference in Kobe, Japan. The registrant issued a press release with additional details from the presentation, a copy of which is being furnished as exhibit 99.1 to Form 8-K.

Exhibit No.

Description

99.1

Press Release Dated December 11, 2013

SIGNATURES

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.

Dated: December 11, 2013

By: /s/ Irach Taraporewala
Name: Dr. Irach Taraporewala
Title: President and CEO



Phase II Data on OHR/AVR118 in Advanced Cancer Patients with Cachexia Presented at International Cachexia Conference in Kobe, Japan

NEW YORK, New York – December 11, 2013 – Ohr Pharmaceutical (NasdaqCM: OHRP), a pharmaceutical company focused on the development of novel therapeutics for large unmet medical needs, announced that full results from a Phase II trial to evaluate the effects of OHR/AVR118 in advanced cancer patients with cachexia were presented yesterday at the 7th International Cachexia Conference in Kobe, Japan. The data were selected for podium presentation of late breaking clinical trials and were presented by principal investigator Dr. Martin Chasen, Medical Director, Palliative Care, Ottawa Hospital Cancer Centre, Canada.

In this Phase 2 trial with OHR/AVR118, 29 patients with advanced cancer and cachexia were enrolled. 18 patients, 3 with stage III and 15 with stage IV cancers completed the treatment protocol. This included 5 patients with pancreatic cancer, 5 with lung cancer, 2 with prostate cancer and one each with colon, stomach, esophageal, liver cancers, head and neck cancer and multiple myeloma. While the primary trial end point of weight gain was not met, at the completion of treatment, patients achieved stabilization of body weight, body fat and muscle mass with a significant increase in appetite ($p < .005$). Moreover, there was an improvement in PG-SGA (Patient Generated Subjective Global Assessment) scores ($p = .025$), indicating an enhanced quality of life (QOL). No statistically significant differences from baseline (as indicated by the paired t test) were observed in body fat content, arm circumference, triceps fold measurement, nausea or vomiting.

After completing the initial 28 day treatment period, patients had the option to continue receiving study drug if they felt it was in their best interest. Eleven of the 18 patients (61%) elected to do so, being treated with the drug for a total of between 42 to 153 days. Sustained body weight stabilization was maintained even on prolonged therapy with the drug in this sub-group of patients. These results were seen despite the fact that 7 of the 18 patients were receiving concomitant chemotherapy, and 1 was receiving concomitant radiotherapy during the trial treatment period with OHR/AVR118. Chemotherapy and radiation frequently exacerbate the symptoms of cachexia. Overall, the drug appeared well tolerated with minimal side effects.

"The results we achieved with OHR/AVR 118 are very promising" commented Dr. Martin Chasen, principal investigator in the study. "Cachexia is a debilitating complication in late stage cancer. It is known to be a factor in the mortality of cancer patients and we believe that it impacts treatment responses and patients' ability to tolerate treatment. We were pleased to see that treatment with OHR/AVR 118 resulted in improved quality of life in the patients as well as stabilization of body weights and functional abilities even when drug was administered over prolonged periods."



"The International Cachexia Conference is a great opportunity to introduce OHR/AVR 118 to an audience of clinicians from around the world" added Dr. Irach Taraporewala, CEO of Ohr Pharmaceutical. "We continue to explore strategic options to provide value from the program to our shareholders and further the clinical development of this important drug candidate."

About the Study

Ohr Pharmaceutical previously announced top line results from this trial in March 2013. The purpose of this open label phase II study was to evaluate OHR/AVR118 in patients with advanced cancer and to determine if daily administration could mitigate symptoms of cachexia and provide improvement in functional status and quality of life. Patients with stage III or IV solid tumors meeting the inclusion and exclusion criteria were enrolled and received daily subcutaneous injections of OHR/AVR118 for the treatment period (28 days). The patients underwent weekly assessment visits to test for improvements in function, ability to complete daily tasks, weight and muscle mass measurements, and overall quality of life parameters. Patients who benefitted from the treatment could elect to continue receiving OHR/AVR118 during the extension period beyond the initial 28 day regimen. The study was conducted at McGill University Cancer Center and Ottawa Hospital Cancer Centre under a HealthCanada IND.

About OHR/AVR118

OHR/AVR118 is a broad-spectrum peptide immunomodulator drug, which regulates cytokine action. The drug has shown a good safety profile in human clinical trials to date. The drug mitigates the deleterious effects of various pro-inflammatory cytokines that are implicated in the etiology of cachexia, whose activation has a direct effect on muscle metabolism and anorexia. OHR/AVR118 had been previously evaluated in clinical trials in over 70 AIDS cachexia patients, where it showed beneficial effects in mitigating multiple symptoms of the disease. Also completed with the drug was a 27 patient open label trial in rheumatoid arthritis.

About Cancer Cachexia

Cancer cachexia is the complex, multi-symptom syndrome in late-stage cancer patients, characterized by anorexia and unintended loss of appetite, progressive and continual weight loss, accompanied by generalized host tissue wasting, skeletal muscle atrophy, immune and metabolic dysfunction, and a greatly diminished quality of life. It is estimated that the market for cancer cachexia exceeds \$1 billion globally. There is currently no FDA approved therapy for cancer cachexia.

About Ohr Pharmaceutical Inc.

Ohr Pharmaceutical Inc. (OHRP) is a pharmaceutical company dedicated to the clinical development of new drugs for underserved therapeutic needs in large and growing markets.



The Company is focused on advancing its pipeline products currently in phase II clinical development: Squalamine Eye Drops for the treatment of the wet form of age-related macular degeneration, and OHR/AVR118 for the treatment of cancer cachexia. Additional information on the company can 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 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 or Health Canada 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. We disclaim any intent to revise or update publicly any forward-looking statements for any reason.

Contact:

Ohr Pharmaceutical Inc.
Investor Relations
(877) 215-4813
ir@ohrpharmaceutical.com

LifeSci Advisors, LLC
Michael Rice
646-597-6987
mrice@lifesciadvisors.com
