

ORE PHARMACEUTICAL HOLDINGS INC. (ORXE)

8-K

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**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): November 13, 2009

ORE PHARMACEUTICAL HOLDINGS INC.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

0-23317
(Commission File Number)

27-1088078
(IRS Employer
Identification No.)

610 Professional Drive, Suite 101
Gaithersburg, Maryland 20879
(Address of principal executive offices and zip code)

Registrant's telephone number, including area code: (240) 361-4400

(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 obligations 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))
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Item 2.02 Results of Operations and Financial Condition.

On November 13, 2009, Ore Pharmaceutical Holdings Inc. (the “Company”) issued a press release (the “Press Release”) announcing the Company’s operating results for the quarter and nine months ended September 30, 2009.

A copy of the Press Release is furnished as Exhibit 99.1.

The information in this Current Report on Form 8–K, including Exhibit 99.1, shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section, nor shall it 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 filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Ore Pharmaceutical Holdings Inc. press release, dated November 13, 2009.

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.

ORE PHARMACEUTICAL HOLDINGS INC.

Date: November 13, 2009

/s/ Benjamin L. Palleiko

Benjamin L. Palleiko

Senior Vice President and Chief Financial Officer

EXHIBIT INDEX

<u>Exhibit Number</u>	<u>Description</u>
99.1	Ore Pharmaceutical Holdings Inc. press release, dated November 13, 2009.

Ore Pharmaceutical Holdings Inc. Reports Results for Third Quarter 2009

GAITHERSBURG, Md.—(BUSINESS WIRE)—November 13, 2009—Ore Pharmaceutical Holdings Inc. (NASDAQ:ORXE) today reported financial results and provided an operational update for the third quarter ended September 30, 2009.

Highlights

During the third quarter of 2009, Ore Pharmaceutical Holdings Inc. (“Ore Holdings” or “Ore”) completed its transition into a pharmaceutical asset management company. The Company’s strategy is focused on acquiring interests in pharmaceutical assets whose value, Ore believes, it can significantly enhance through targeted development, with the goal of then monetizing these assets through sale or out–licensing transactions. Ore anticipates that it will fund these programs through designing, raising and investing alternative financing vehicles as a regular part of its ongoing activities as a company. Progress during the third quarter and since includes:

- Continued tight control of cash and expenses. Due to ongoing cost reductions, the collection of a note receivable and sale of an equity investment in the third quarter, the Company’s cash and marketable securities balance at the end of the third quarter was \$7 million, which is \$2.3 million higher than at the end of the second quarter. As a result of these aggressive cost controls and cash generation efforts, the Company now anticipates that it has sufficient financial resources to be able to fund operations into the first quarter of 2011;
- Received shareholder approval in October for, and completed, a reorganization whereby Ore Pharmaceuticals Inc. became a wholly owned subsidiary of a new company, Ore Holdings, with Ore Holdings becoming the new publicly traded, NASDAQ listed company with the symbol “ORXE”. This reorganization was undertaken primarily in order to better protect for shareholders the value of Ore’s approximately \$324 million in gross net operating loss carryforwards;
- Continued on track to initiate a Phase Ib/IIa trial for ORE1001 in ulcerative colitis in the fourth quarter of 2009; and
- Established a research agreement with the Armed Forces Radiobiology Research Institute and the Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc. to evaluate ORE1001 as a potential countermeasure agent in treating radiation injury.

Portfolio Update

During the third quarter, the Company continued to advance its lead drug candidate, ORE1001. Ore is currently developing ORE1001 under its incubation program, in which the Company may conduct initial development on certain drug assets in order to determine the best investment pathway forward. Pathways may include monetizing the asset through partnership or out–licensing, or funding further development through one of the alternative financing vehicles that are central to Ore’s business strategy.

Ore is in the process of initiating a Phase Ib/IIa clinical trial for ORE1001 in ulcerative colitis – one of the two main disorders comprising Inflammatory Bowel Disease (“IBD”). This trial is designed as a randomized, double blind, placebo controlled trial of 50 patients with ulcerative colitis and is intended to assess the safety, tolerability and therapeutic activity of ORE1001 when administered by mouth as capsules. Ore selected ulcerative colitis as the initial indication for ORE1001 on the basis of multiple preclinical studies, although Ore believes that ORE1001 may also have efficacy in Crohn’s disease, the other major category of IBD. Ore currently anticipates that this trial will be completed in the third quarter of 2010.

In addition, during the third quarter Ore entered into a research agreement with the Armed Forces Radiobiology Research Institute (AFRRI) and the Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc. for ORE1001. Under the terms of this agreement, AFRRI will assess the utility of ORE1001 in preventing or treating adverse effects from exposure to ionizing radiation as part of their screening project funded by a National Institute of Allergy and Infectious Diseases (NIAID)–AFRRI interagency agreement.

The AFRRI agreement provides Ore with a means to evaluate ORE1001 as a potential countermeasure agent in treating radiation injury. ORE1001 has demonstrated beneficial effects in several animal models of gastrointestinal disease, including a model of radiation injury. Severe gastrointestinal injury can occur after exposure to ionizing radiation, such as from a nuclear accident or attack. AFRRI will perform testing in their established program investigating radiation effects and will share the data with Ore.

In traditional drug development progression, a drug candidate undergoes extensive efficacy testing in clinical trials. A drug intended as a radiation countermeasure, however, must rely solely on animal data as evidence for efficacy. Therefore, as long as the safety profile of the drug can be established, the path to approval of the drug can be greatly accelerated relative to the traditional route that requires demonstration of efficacy in humans. Ore believes that ORE1001, a small molecule inhibitor of the ACE2 enzyme, has characteristics that could facilitate rapid development, including an efficient manufacturing route, oral administration via capsules, and good tolerability results in both preclinical toxicology studies and Phase 1 clinical trials.

Under the AFRRI agreement, Ore will retain all commercial rights to ORE1001. Pending results of the collaboration with AFRRI, Ore may choose to examine the utility of ORE1001 as a supportive treatment in connection with radiation therapy for certain cancers in addition to its ongoing incubation for IBD.

AFRRI, a part of the Uniformed Services University of the Health Sciences and located at the National Navy Medical Center, is a leader in studying the short and long–term effects of ionizing radiation injury. AFRRI has been actively involved in developing pharmaceutical agents that can be used to protect or mitigate injury resulting from exposure to different types of radiation.

The Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc. provides innovative services to meet the unique needs of military medicine.

Liquidity

As of September 30, 2009, the Company had \$7.0 million in cash, cash equivalents and marketable securities available–for–sale, compared to \$10.8 million as of December 31, 2008. The Company currently anticipates that its existing cash, cash equivalents and marketable securities available–for–sale, combined with anticipated payments on its remaining note receivable, will be sufficient to fund its operations into the first quarter of 2011.

Results of Operations

The Company recorded no revenue for the third quarter of 2009.

When compared to the prior year, third quarter 2009 Research and Development expenses decreased \$1.8 million primarily as a result of lower employee and facility-related costs due to significant workforce reductions.

Compared to the prior year, Selling, General and Administrative expenses decreased \$1.6 million primarily as a result of lower employee costs due to significant workforce reductions and reduced professional fees relating to strategic planning.

For the third quarter of 2009, the Company's net loss was \$0.6 million, or \$0.11 per share, compared to a net loss of \$7.4 million, or \$1.36 per share, for the third quarter of 2008.

For the first nine months of 2009, the Company's net loss was \$6.3 million, or \$1.15 per share, compared to a net loss of \$19.1 million, or \$3.33 per share, for the first nine months of 2008.

About Ore Pharmaceutical Holdings Inc.

Ore Pharmaceutical Holdings Inc. (the "Company") is a pharmaceutical asset management company. The Company acquires interests in pharmaceutical assets whose value, it believes, it can significantly enhance through targeted development, with the goal of then monetizing these assets through sales or out-licensing transactions. The Company currently is focusing on developing and monetizing its current portfolio, which includes four clinical-stage compounds in-licensed from major pharmaceutical companies. The four compounds in the Company's development portfolio are: ORE1001, its lead compound, ORE10002, ORE5002 (tiapamil) and ORE5007 (romazarit).

Because the reorganization whereby Ore Pharmaceuticals Inc. became a wholly owned subsidiary of Ore Pharmaceutical Holdings Inc. occurred subsequent to the quarterly reporting period ended September 30, 2009, the financial results included herein consist of the accounts of Ore Pharmaceuticals Inc.

Safe Harbor Statement

This press release contains "forward-looking statements," as such term is used in the Securities Exchange Act of 1934, as amended. Such forward-looking statements include our ability to identify strategies for making our business successful and the impact of such strategies on our business and financial performance and on shareholder value. Forward-looking statements typically include the words "expect," "anticipate," "believe," "estimate," "intend," "may," "will," and similar expressions as they relate to Ore Pharmaceutical Holdings Inc. or its management. Forward-looking statements are based on our current expectations and assumptions, which are subject to risks and uncertainties. They are not guarantees of our future performance or results. Our actual performance and results could differ materially from what we project in forward-looking statements for a variety of reasons and circumstances, including particularly risks and uncertainties that may affect the Company's operations, financial condition and financial results and that are discussed in detail in our Annual Report on Form 10-K and our other subsequent filings with the Securities and Exchange Commission. They include, but are not limited to: whether the compounds we develop will be commercially viable; the timing of initiation of, and receipt of results from, our Phase Ib/Ia clinical trial of ORE1001 in ulcerative colitis; the pathway for development of ORE1001 as a potential countermeasure agent in treating radiation injury; whether we will be able to begin to generate sufficient new revenue from licensing or other transactions early enough to support our operations and continuing compound development; whether there will be valid claims for indemnification from the buyers of our Genomics Assets; whether there will be claims from the landlords of the leased properties we have assigned, the buyer of our Preclinical Division or the assignee of our Cambridge facility lease, that we would be required to pay as guarantors of such leases; whether we will be able to collect amounts due under the terms of the promissory note from the buyer of our molecular diagnostic business; whether we will be able to manage our existing cash adequately and whether we will have access to financing on sufficiently favorable terms to maintain our businesses and effect our strategies; whether we will be able to maintain our NASDAQ listing; whether we will be able to attract and retain qualified personnel for our business; and potential negative effects on our operations and financial results from workforce reductions and the transformation of our business. Ore Pharmaceutical Holdings Inc. undertakes no obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

Ore Pharmaceuticals Inc.
Consolidated Condensed Statements of Operations
(in thousands, except per share amounts)
(unaudited)

	<u>Three Months Ended</u>		<u>Nine Months Ended</u>	
	<u>September 30,</u>		<u>September 30,</u>	
	<u>2009</u>	<u>2008</u>	<u>2009</u>	<u>2008</u>
Services revenue	<u>\$ —</u>	<u>\$ 200</u>	<u>\$ 25</u>	<u>\$ 1,950</u>
Expenses:				
Research and development	<u>501</u>	<u>2,342</u>	<u>2,080</u>	<u>8,547</u>
Selling, general and administrative	<u>986</u>	<u>2,632</u>	<u>5,292</u>	<u>10,302</u>
Total expenses	<u>1,487</u>	<u>4,974</u>	<u>7,372</u>	<u>18,849</u>
Loss from operations	<u>(1,487)</u>	<u>(4,774)</u>	<u>(7,347)</u>	<u>(16,899)</u>
Interest (income), net	<u>(335)</u>	<u>(146)</u>	<u>(502)</u>	<u>(648)</u>
(Income)/loss on equity investments	<u>(558)</u>	<u>2,964</u>	<u>(558)</u>	<u>2,964</u>
Gain on sale of DioGenix Inc.	<u>—</u>	<u>(146)</u>	<u>—</u>	<u>(146)</u>
Net loss	<u>\$ (594)</u>	<u>\$ (7,446)</u>	<u>\$ (6,287)</u>	<u>\$ (19,069)</u>
Basic and diluted net loss per share	<u>\$ (0.11)</u>	<u>\$ (1.36)</u>	<u>\$ (1.15)</u>	<u>\$ (3.33)</u>
Shares used in computing basic and diluted net loss per share	<u>5,474</u>	<u>5,477</u>	<u>5,474</u>	<u>5,719</u>

Ore Pharmaceuticals Inc.
Consolidated Condensed Balance Sheets
(in thousands, except share data)

	September 30,	December 31,
	2009	2008
ASSETS		
(unaudited)		
Current assets:		
Cash and cash equivalents	\$ 6,957	\$ 10,784
Marketable securities available-for-sale	68	-
Prepaid expenses	229	200
Notes receivable, net	790	3,252
Other current assets	37	70
Total current assets	8,081	14,306
Property and equipment, net	36	483
Other intangibles, net	694	573
Notes receivable, net	-	338
Other assets	25	-
Total assets	\$ 8,836	\$ 15,700
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 758	\$ 623
Accrued compensation and employee benefits	144	1,185
Other accrued expenses	1,434	1,267
Current portion of long-term debt	450	477
Total current liabilities	2,786	3,552
Deferred rent	24	-
Total liabilities	2,810	3,552
Commitments and contingencies	-	-
Stockholders' equity:		
Preferred stock, \$.01 par value; 10,000,000 shares authorized; and no shares issued and outstanding as of September 30, 2009 and December 31, 2008	-	-
Common stock, \$.01 par value; 60,000,000 shares authorized; 5,473,519 and 5,483,519 shares issued and outstanding as of September 30, 2009 and December 31, 2008, respectively	55	55
Additional paid-in capital	385,019	384,922
Accumulated other comprehensive income	68	-
Accumulated deficit	(379,116)	(372,829)
Total stockholders' equity	6,026	12,148
Total liabilities and stockholders' equity	\$ 8,836	\$ 15,700

CONTACT:

Ore Pharmaceutical Holdings Inc.

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SVP & CFO

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