



Idera Pharmaceuticals Reports Third Quarter 2015 Financial Results and Provides Corporate Update

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CAMBRIDGE, Mass. and EXTON, Pa., Nov. 06, 2015 (GLOBE NEWSWIRE) -- Idera Pharmaceuticals, Inc. (NASDAQ:IDRA), a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of novel nucleic acid-based therapeutics for oncology and rare diseases, today reported its financial and operational results for the third quarter ended September 30, 2015.

"We've made a great deal of progress at Idera through the first three quarters of 2015, which sets up our company for a number of important catalysts in this last quarter of the year," stated Vincent Milano, Idera's Chief Executive Officer. "As we announced yesterday, we will be presenting the clinical and safety data analysis from our Phase 1/2 clinical trial of IMO-8400 in Waldenström's macroglobulinemia at the American Society of Hematology Annual Meeting in December. We also are initiating our clinical studies of our TLR9 agonist, IMO-2125 in combination with ipilimumab in patients with metastatic melanoma and IMO-8400 Phase 2 study in dermatomyositis, this quarter. Finally, as detailed in the following text, we are today announcing the first two gene targets for our third generation antisense technology platform."

Continued Milano, "I'm very pleased with the progress that our team at Idera has made over the past months and quarters as we've integrated the existing Idera team with many new contributors all the while maintaining the rigor and momentum to ensure our company is positioned for both near and long-term success."

Research and Development Program Updates

IMO-8400 and IMO-2125 are our lead clinical development drug candidates. IMO-8400 is an oligonucleotide-based antagonist of Toll-like receptors (TLRs) 7, 8, and 9. IMO-2125 is an oligonucleotide-based agonist of TLR9.

Toll-like Receptor (TLR) Agonism Program

Immuno-Oncology Program

In June 2015, the company announced that it had entered into a strategic clinical research alliance with MD Anderson Cancer Center to advance the clinical development of intra-tumoral TLR9 agonists in combination with checkpoint inhibitors. The company also announced that it expects to initiate the first trial from the alliance, a Phase 1/2 study to assess the safety and efficacy of intra-tumoral IMO-2125 in combination with ipilimumab in approximately 45 patients with metastatic melanoma. The company is on track to initiate this study in the fourth quarter of 2015. Planning of additional studies as part of the clinical research alliance with MD Anderson Cancer Center is in progress. Additionally, the company presented new preclinical data demonstrating the combination of IMO-2125 and PD1 in cancer models at the AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics on November 5th in Boston, MA.

Toll-like Receptor (TLR) Antagonism Programs

Genetically Defined Forms of B-cell Lymphoma

Idera's program in genetically defined forms of B-cell lymphoma is based on pre-clinical studies that have demonstrated, in certain B-cell lymphomas that the presence of the MYD88 L265P oncogenic mutation led to over-activation of TLR7 and TLR9 signaling and that blocking these TLRs with our antagonists promoted tumor cell death.

In the company's Phase 1/2 study in Waldenström's macroglobulinemia, the targeted number of patients at each of the three dose levels completed assessment through the end of their first cycle of treatment; the dose escalation portion of the study has also been completed. The trial is designed to evaluate IMO-8400's safety, tolerability and potential clinical activity in patients who have a history of relapse after or failure to respond to prior therapies. Idera announced yesterday that data from this Phase 1/2 clinical study will be presented as a poster at the American Society of Hematology (ASH) Annual Meeting on Saturday, December 5th from 5:30 PM ET – 7:30 PM ET.

During the third quarter the company also continued to enroll patients into the first of three dose cohorts of our Phase 1/2 clinical trial of IMO-8400 in patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) who are harboring the MYD88 L265P oncogenic mutation. The company currently anticipates that data from this trial will become available in 2016.

Idera previously announced that the U.S. Food and Drug Administration (FDA) granted us orphan drug designation for IMO-8400 for the treatment of Waldenström's macroglobulinemia and DLBCL.

Rare Disease Programs

The company is planning to initiate clinical development of IMO-8400 for the treatment of rare autoimmune and autoinflammatory diseases. The company has selected dermatomyositis and Duchenne muscular dystrophy (DMD) as the first rare diseases for which we plan to develop IMO-8400. The company selected these indications for development based on the reported increase in TLR expression in these disease states, expression of cytokines indicative of key TLR-mediated pathways, the identification of prospective biomarkers for evaluation in early clinical trials and significant unmet needs. The company plans to progress clinical development in these two indications by initiating a Phase 2 clinical trial in dermatomyositis in the fourth quarter of 2015 and a Phase 2 clinical trial in DMD in 2016.

Third Generation Antisense Platform

Throughout 2015, the company undertook an analysis and prioritization of oncology and rare disease indications for potential development of drug candidates derived from our third generation antisense technology platform. The key considerations in identifying disease indications from our third generation antisense program included: strong evidence that the disease is caused by a specific protein; clear criteria to identify a target patient population; biomarkers for early assessment of clinical proof-of-concept; a targeted therapeutic mechanism for action; and unmet medical need to allow for a well-defined development path to approval and commercial opportunity. As a result of this analysis, the company has selected NLRP3 (NOD-like receptor family, pyrin domain containing protein 3) and DUX4 (Double Homeobox 4) as gene targets to advance into IND-enabling activities, which will occur throughout 2016. Potential disease indications include, but are not limited to interstitial cystitis, uveitis and facioscapulohumeral muscular dystrophy (FSHD), respectively. The company intends to describe these programs in more detail during the 2016 JP Morgan Healthcare Conference early next year.

Financial Results

Third Quarter 2015 Results

Net loss applicable to common stockholders for the three months ended September 30, 2015 was \$11.4 million, or \$ (0.10) per diluted share, compared to a net loss applicable to common stockholders of \$9.6 million, or \$ (0.11) per diluted share, for the same period in 2014. For the nine month period ended September 30, 2015, the Company's net loss applicable to common stockholders was \$36.6 million, or \$ (0.32) per diluted share, compared to a net loss applicable to common stockholders of \$27.1 million, or \$ (0.33) per diluted share, for the same period in 2014. The company recognized nominal revenue in the third quarter and nine month periods of 2015 and 2014.

Research and development expenses for the three months ended September 30, 2015 totaled \$7.5 million compared to \$6.7 million for the same period in 2014. For the nine month period ended September 30, 2015, research and development expenses totaled \$25.1 million compared to \$19.2 million for the same period in 2014.

General and administrative expenses for the three months ended September 30, 2015 totaled \$4.0 million compared to \$2.9 million for the same period in 2014. For the nine month period ended September 30, 2015, general and administrative expenses totaled \$11.7 million compared to \$7.6 million for the same period in 2014.

As of September 30, 2015, Idera's cash, cash equivalents and investments totaled \$94.7 million compared to \$48.6 million as of December 31, 2014.

About Idera Pharmaceuticals, Inc.

Idera Pharmaceuticals is a clinical-stage biopharmaceutical company developing novel nucleic acid-based therapies for the treatment of certain cancers and rare diseases. Idera's proprietary technology involves using a TLR-targeting technology, to design synthetic oligonucleotide-based drug candidates to act by modulating the activity of specific TLRs. In addition to its TLR programs, Idera is developing a third generation antisense technology platform that it has created using its proprietary technology to inhibit the production of disease-associated proteins by targeting RNA. To learn more about Idera, visit www.iderapharma.com.

Forward Looking Statements

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. All statements, other than statements of historical fact, included or incorporated in this press release, including statements regarding the Company's strategy, future operations, collaborations, intellectual property, cash resources, financial position, future revenues, projected costs, prospects, clinical trials, plans, and objectives of management, are forward-looking statements. The words "believes," "anticipates," "estimates," "plans," "expects," "intends," "may," "could," "should," "potential," "likely," "projects," "continue," "will," and "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Idera cannot guarantee that it will actually achieve the plans, intentions or expectations disclosed in its forward-looking statements and you should not place undue reliance on the Company's forward-looking statements. There are a number of important factors that could cause Idera's actual results to differ materially from those indicated or implied by its forward-looking statements. Factors that may cause such a difference include: whether results obtained in preclinical studies and clinical trials such as the results described in this release will be indicative of the results that will be generated in future clinical trials; whether products based on Idera's technology will advance into or through the clinical trial process when anticipated or at all or warrant submission for regulatory approval; whether such products will receive approval from the U.S. Food and Drug Administration or equivalent foreign regulatory agencies; whether, if the Company's products receive approval, they will be successfully distributed and marketed; whether the Company's collaborations will be successful; and such other important factors as are set forth under the caption "Risk Factors" in the Company's Quarterly Report on Form 10-Q for the period ended September 30, 2015. Although Idera may elect to do so at some point in the future, the Company does not assume any obligation to update any forward-looking statements and it disclaims any intention or obligation to update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

Idera Pharmaceuticals, Inc.
Condensed Statements of Operations - Unaudited
(In thousands, except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Alliance Revenue	\$ 20	\$ 30	\$ 59	\$ 71
Operating Expenses				
Research & Development	7,454	6,678	25,134	19,248
General & Administrative	4,030	2,873	11,688	7,646
Total Operating Expenses	11,484	9,551	36,822	26,894
Loss from Operations	(11,464)	(9,521)	(36,763)	(26,823)
Other Income (Expense), Net	99	66	198	99
Net Loss	(11,365)	(9,455)	(36,565)	(26,724)

Preferred stock dividends	--	119	--	422
Net loss applicable to common stockholders	<u>\$ (11,365)</u>	<u>\$ (9,574)</u>	<u>\$ (36,565)</u>	<u>\$ (27,146)</u>
Basic and diluted net loss per common share applicable to common stockholders	<u>\$ (0.10)</u>	<u>\$ (0.11)</u>	<u>\$ (0.32)</u>	<u>\$ (0.33)</u>
Shares used in computing basic and diluted net loss per common share applicable to common stockholders	<u>118,248</u>	<u>84,527</u>	<u>113,821</u>	<u>81,200</u>

Idera Pharmaceuticals, Inc.
Condensed Balance Sheet Data
(In thousands)

	At September 30, 2015	At December 31, 2014
	(Unaudited)	
Cash, Cash Equivalents & Investments	\$ 94,694	\$ 48,571
Other Assets	4,390	2,855
Total Assets	<u>\$ 99,084</u>	<u>\$ 51,426</u>
Total Liabilities	\$ 6,426	\$ 8,024
Total Stockholders' Equity	92,658	43,402
Total Liabilities & Stockholders' Equity	<u>\$ 99,084</u>	<u>\$ 51,426</u>

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