

# Idera Pharmaceuticals Reports Second Quarter 2015 Financial Results and Provides Corporate Update

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CAMBRIDGE, Mass. and EXTON, Pa., Aug. 6, 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 second guarter ended June 30, 2015.

"From a program execution perspective, we've continued to make steady progress across the board during the second quarter of 2015," stated Vincent Milano, Idera's Chief Executive Officer. "We recently announced our strategic clinical research alliance with MD Anderson, with the first planned study of this alliance evaluating the combination of IMO-2125 (TLR9 agonist) and ipilimumab (an anti-CTLA4 antibody) in melanoma patients. We are targeting commencing this study in the fourth quarter of this year. Our B-cell lymphoma programs with IMO-8400 (TLR7, 8 and 9 antagonist) are advancing, as we are rapidly approaching the release of data from the Waldenström's macroglobulinemia (WM) trial in the fourth quarter. Also in the second quarter, we began enrolling patients into the first dose cohort in the diffuse large B-cell lymphoma (DLBCL) clinical trial. Our rare disease programs are moving forward nicely, most notably with the initiation of our dermatomyositis Phase 2 study planned for the fourth quarter. Finally, we continue to expect to announce the first two diseases we plan to target with our exciting third generation antisense platform technology, which was previously referred to as our GSO program, by the end of this year."

Continued Milano, "Our team at Idera has made good progress executing against the goals that we established for ourselves at the beginning of the year. Importantly, I am pleased with the progress we've made developing and implementing a corporate culture and value system that aligns all facets of our company towards both near and long term success. While these are not necessary externally-viewed measures, they are paramount elements to any organization that places high expectations upon itself. During the most recent quarter, we've added several extremely skilled individuals to our team who've made immediate impacts on our organization and programs to enhance our ability to achieve our goals. By no means have we completed building out our team at Idera, however, I am pleased with the progress that has been made to date; and with this group's ability to adapt and grow, while continuing to remain focused and execute our programs with the rigor that is necessary."

# **Research and Development Program Updates**

# 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 intratumoral 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 intratumoral IMO-2125 in combination with ipilimumab in approximately 45 patients with metastatic melanoma. The company intends to initiate this study in the fourth quarter of 2015 with data expected in 2016. Planning of additional studies as part of the clinical research alliance with MD Anderson Cancer Center is in progress. Additionally, the company recently has had two abstracts accepted with new pre-clinical data on intratumoral IMO-2125 activity, and its impact on the tumor microenvironment and checkpoints at the CRI-CIMT-EATI-AACR Inaugural International Cancer Immunotherapy Conference taking place in September in New York.

#### 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 independent research conducted at Idera. Pre-clinical studies have demonstrated that, in certain B-cell lymphomas, 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 Waldenstrom's macroglobulinemia, the targeted number of patients at each of the three dose levels have completed assessment through the end of their first cycle of treatment and the dose escalation portion of the study has 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 anticipates data from this trial will be available in the fourth quarter of 2015.

During the second quarter the company also continued to activate clinical sites and 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 DLBCL, who are harboring the MYD88 L265P oncogenic mutation. The company anticipates that data from this trial will be available in 2016. Idera also announced during the second quarter that the U.S. Food and Drug Administration (FDA) had granted us orphan drug designation for IMO-8400 for the treatment of DLBCL.

#### Rare Disease Programs

The company is planning to initiate clinical development of IMO-8400 for the treatment of rare 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 anticipates commencing clinical development in these two indications by initiating a Phase 2 clinical trial in dermatomyositis by the end of 2015 and a Phase 2 clinical trial in DMD in 2016.

# **Third Generation Antisense Platform**

The company is currently undertaking an analysis and prioritization of oncology and rare disease indications for potential development of drug candidates from our third generation antisense technology platform. Idera's key considerations in identifying disease indications in our third generation antisense program include: 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. The company is currently conducting disease model studies and plans to begin IND-enabling development programs in the first two disease indications selected for further development in our third generation antisense program in the second half of 2015.

### **Recent Corporate Highlights**

In June 2015, Idera announced the appointment of Mark J. Casey as General Counsel and Secretary of the Board of Directors.

#### **Financial Results**

#### Second Quarter 2015 Results

Net loss applicable to common stockholders for the three months ended June 30, 2015 was \$12.7 million, or \$0.11 per diluted share, compared to a net loss applicable to common stockholders of \$8.4 million, or \$0.10 per diluted share, for the same period in 2014. For the six month period ended June 30, 2015, the Company's net loss applicable to common stockholders was \$25.2 million, or \$0.23 per diluted share, compared to a net loss applicable to common stockholders of \$17.6 million, or \$0.22 per diluted share, for the same period in 2014. The company recognized nominal revenue in the second quarter and six month periods of 2015 and 2014.

Research and development expenses for the three months ended June 30, 2015 totaled \$9.0 million compared to \$5.6 million for the same period in 2014. For the six month period ended June 30, 2015, research and development expenses totaled \$17.7 million compared to \$12.6 million for the same period in 2014.

General and administrative expenses for the three months ended June 30, 2015 totaled \$3.8 million compared to \$2.7 million for the same period in 2014. For the six month period ended June 30, 2015, general and administrative expenses totaled \$7.7 million compared to \$4.8 million for the same period in 2014.

As of June 30, 2015, Idera's cash, cash equivalents and investments totaled \$106.3 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 <a href="https://www.iderapharma.com">www.iderapharma.com</a>.

# **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 June 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

(In thousands, except per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
Alliance Revenue	\$ 5	\$ 38	\$ 39	\$ 41
Operating Expenses				
Research & Development	8,960	5,637	17,680	12,570

General & Administrative	3,821	2,730	7,658	4,773
Total Operating Expenses	12,781	8,367	25,338	17,343
Loss from Operations	(12,776)	(8,329)	(25,299)	(17,302)
Other Income (Expense), Net	57	21	99	33
Net Loss	(12,719)	(8,308)	(25,200)	(17,269)
Preferred stock dividends		118		303
Net loss applicable to common stockholders	\$ (12,719)	\$ (8,426)	\$ (25,200)	\$ (17,572)
Basic and diluted net loss per common share applicable to common stockholders	\$ (0.11)	\$ (0.10)	\$ (0.23)	\$ (0.22)
Shares used in computing basic and diluted net loss per common share applicable to common stockholders	118,002	82,961	111,570	79,509

Idera Pharmaceuticals, Inc.

Condensed Balance Sheet Data

(In thousands)

	At June 30,	At December 31,	
	2015	2014	
Cash, Cash Equivalents & Investments	\$ 106,304	\$ 48,571	
Other Assets	3,527	2,855	
Total Assets	\$ 109,831	\$ 51,426	
Total Liabilities	\$ 7,322	\$ 8,024	
Total Stockholders' Equity	102,509	43,402	
Total Liabilities & Stockholders' Equity	\$ 109,831	\$ 51,426	

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