



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

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CAMBRIDGE, Mass. and EXTON, Pa., May 11, 2015 (GLOBE NEWSWIRE) -- Idera Pharmaceuticals, Inc. (Nasdaq:IDRA), a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of novel therapeutics for oncology and rare diseases, today reported its financial and operational results for the first quarter ended March 31, 2015.

"During the first quarter of this year, we continued to build momentum as we executed on our numerous clinical development programs focused on oncology and rare diseases," stated Vincent J. Milano, Chief Executive Officer of Idera. "The focus and efforts of our team are leading to important milestones for our company over the next six to twelve months. We recently completed enrollment into the dose escalation portion of our ongoing clinical trial of IMO-8400 in Waldenström's macroglobulinemia (WM) and we continue to anticipate releasing efficacy and safety data from this trial in the fourth quarter of this year."

"We also are pleased to report that we recently enrolled our first patient harboring the MYD88 L265P oncogenic mutation into our Phase 1/2 clinical trial for diffuse large B-cell lymphoma (DLBCL)," continued Milano. "We are closing in on finalizing clinical arrangements for our intratumoral TLR9 agonist development program and look forward to providing details of the first trial which we plan to initiate in the second half of this year. Our rare disease development programs are on track as we plan to initiate clinical studies in dermatomyositis (DM) and Duchenne muscular dystrophy (DMD) in late 2015 and early 2016, respectively. Finally, our team is continuing the momentum with our gene silencing oligonucleotides (GSO) technology platform as we plan to announce our first disease indications in the second half of this year."

Program Updates

Oncology Programs

Genetically Defined Forms of B-cell Lymphoma

Our program in genetically defined forms of B-cell lymphoma is based on independent research and our pre-clinical studies offering evidence 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 promoted tumor cell death.

We have enrolled the targeted number of patients at each of the three dose levels to fulfill the requirements for dose escalation, pending successful completion of treatments through the next scheduled data review by the independent safety data monitoring committee, of our Phase 1/2 clinical trial of IMO-8400 in patients with Waldenström's macroglobulinemia, a form of non-Hodgkin lymphoma.

The trial is designed to evaluate IMO-8400's safety, tolerability and potential clinical activity in patients who have a history of relapse or failure to respond to one or more prior therapies. We anticipate efficacy and safety data from this trial will be available in the fourth quarter of 2015.

In April 2015, we announced that the U.S. Food and Drug Administration (FDA) had granted us orphan drug designation for IMO-8400 for the treatment of DLBCL. We continue to activate clinical sites and are now enrolling patients with relapsed or refractory DLBCL, harboring the MYD88 L265P oncogenic mutation in a Phase 1/2 clinical trial of IMO-8400 in DLBCL. We anticipate that efficacy and safety data from this trial will be available in 2016.

Immuno-Oncology Program

We are currently finalizing our first clinical arrangement for our planned clinical trials to determine the safety and efficacy of intratumorally delivered TLR9 agonist in combination with check-point inhibitors. The company intends to initiate the first of multiple clinical trials in the second half of 2015 with anticipated data availability in 2016.

Rare Disease Programs

We are planning to initiate clinical development of IMO-8400 for the treatment of rare diseases. We have selected dermatomyositis and DMD as the first rare diseases for which we plan to develop IMO-8400. We 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 with respect to dermatomyositis, the presence of auto-antibodies that can induce TLR-mediated immune responses. We anticipate commencing clinical development in these two indications by initiating a Phase 2 clinical trial in dermatomyositis by the end of 2015 and a Phase 1/2 clinical trial in DMD in early 2016.

Gene Silencing Oligonucleotides

We are currently undertaking an analysis of priority oncology and rare disease indications for development of drug candidates from our GSO technology. Our key considerations in identifying disease indications in our GSO 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 rapid development path to approval. We are planning to conduct disease model studies and begin IND-enabling development programs in each of the first two disease indications selected for further development in our GSO program in the second half of 2015.

Recent Corporate Highlights

Financing

In February 2015, we completed an underwritten public offering of common stock which generated net proceeds of approximately \$80.6 million.

Financial Results

First Quarter 2015 Results

Net loss applicable to common stockholders for the three months ended March 31, 2015 was \$12.5 million, or \$0.12 per diluted share, compared to a net loss applicable to common stockholders of \$9.1 million, or \$0.12 per diluted share, for the same period in 2014. We recognized nominal revenue in each of the first quarters of 2015 and 2014. Research and development expenses for the three months ended March 31, 2015 totaled \$8.7 million compared to \$6.9 million for the same period in 2014. General and administrative expenses for the three months ended March 31, 2015 totaled \$3.8 compared to \$2.0 million for the same period in 2014.

As of March 31, 2015, our cash, cash equivalents and investments totaled \$116.9 million compared to \$48.6 million as of December 31, 2014.

About Idera Pharmaceuticals, Inc.

Idera Pharmaceuticals is a clinical-stage biopharmaceutical company developing a novel therapeutic approach for the treatment of genetically defined forms of B-cell lymphoma 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 gene silencing oligonucleotides (GSOs) that it has created using its proprietary technology to inhibit the production of disease-associated proteins by targeting RNA.

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, 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 March 31, 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	
	March 31,	
	2015	2014
Alliance Revenue	\$ 34	\$ 3
Operating Expenses		
Research & Development	8,720	6,933
General & Administrative	3,837	2,043
Total Operating Expenses	12,557	8,976
Loss from Operations	(12,523)	(8,973)
Other Income (Expense), Net	42	12

Net Loss	(12,481)	(8,961)
Preferred stock dividends	<u>--</u>	<u>185</u>
Net loss applicable to common stockholders	<u>\$ (12,481)</u>	<u>\$ (9,146)</u>
Basic and diluted net loss per common share applicable to common stockholders	<u>\$ (0.12)</u>	<u>\$ (0.12)</u>
Shares used in computing basic and diluted net loss per common share applicable to common stockholders	<u>105,067</u>	<u>76,018</u>

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

	At March 31, 2015	At December 31, 2014
Cash, Cash Equivalents & Investments	\$ 116,877	\$ 48,571
Other Assets	<u>3,433</u>	<u>2,855</u>
Total Assets	<u>\$ 120,310</u>	<u>\$ 51,426</u>
Total Liabilities	\$ 7,045	\$ 8,024
Total Stockholders' Equity	<u>113,265</u>	<u>43,402</u>
Total Liabilities & Stockholders' Equity	<u>\$ 120,310</u>	<u>\$ 51,426</u>

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[Idera Pharmaceuticals Logo](#)

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