



Idera Pharmaceuticals Reports Fourth Quarter and Year End 2015 Financial Results and Provides Corporate Update

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CAMBRIDGE, Mass. and EXTON, Pa., March 10, 2016 (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 fourth quarter and year ended December 31, 2015.

During the fourth quarter of 2015 we:

- Presented positive clinical data from the ongoing Phase 1/2 trial of IMO-8400 in patients with Waldenstrom's Macroglobulinemia at the 57th Annual Meeting of the American Society of Hematology (ASH);
- Initiated a Phase 2 clinical trial of IMO-8400 in patients with dermatomyositis;
- Entered into a collaboration and license agreement with GSK to identify, develop and commercialize 3rd Generation Antisense (3GA) molecules for treatment of renal diseases;
- Announced first two gene targets for internal development from 3GA platform;
- Initiated a Phase 1/2 clinical trial of intra-tumoral IMO-2125 in combination with ipilimumab in patients with metastatic melanoma;
- Presented additional pre-clinical IMO-2125 data at AACR-NCI-EORTC International Conference; and
- Announced several key leadership appointments, including new Chief Medical Officer, Dr. Joanna Horobin.

"2015 represented a foundational and momentum-building period for Idera," stated Vincent Milano, Idera's Chief Executive Officer. "As a company we made meaningful progress in 2015, particularly in the fourth quarter as we presented the first positive clinical data from our IMO-8400 study in Waldenstrom's Macroglobulinemia, which strengthens our belief that 8400 has the potential to ultimately become a real-world solution for physicians treating patients suffering from B-cell malignancies. We also further built upon our clinical pipeline by advancing IMO-8400 into clinical development for the treatment of dermatomyositis and initiated the first clinical study of intra-tumoral IMO-2125 in combination with a check point inhibitor, which represents the first step in our immuno-oncology strategy. Finally, our research team continued the advancement of our 3GA platform, and also conducted numerous in-house preclinical studies to guide and support all of our various clinical development programs."

Continued Milano, "Overall, I am pleased with the progress made to date on many levels within the Idera organization, and also cognizant of the fact that we have much more work ahead of us. I am confident that if we continue to focus on the overall goal of delivering solutions to patients suffering severe unmet medical needs, we will achieve success and ultimately deliver the value our shareholders deserve."

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. The company also announced during the fourth quarter, the first two development targets from its proprietary 3GA Technology platform: NLRP3 (NOD-like receptor family, pyrin domain containing protein 3) and DUX4 (Double Homeobox 4).

Toll-like Receptor (TLR) Agonism

Immuno-Oncology Program

Idera's development program in immuno-oncology is based on pre-clinical studies that demonstrated through the mechanism of intra-tumoral injections of the TLR9 agonist, IMO-2125, the tumor microenvironment could be impacted in a manner which positively increases the efficacy of check-point inhibition. These studies have lead Idera into a strategic research alliance with the University of Texas MD Anderson Cancer Center to clinically explore the combination of checkpoint inhibitors.

In December 2015, Idera announced the initiation of a Phase 1/2 clinical trial of intra-tumoral IMO-2125 in combination with Ipilimumab in patients with relapsed or refractory Metastatic Melanoma being conducted at the University of Texas MD Anderson Cancer Center. Additionally, the company will present new preclinical data demonstrating the combination of IMO-2125 and indoleamine-pyrolle 2,3-dioxygenase (IDO) in cancer models at the American Association for Cancer Research (AACR) Annual Meeting on Tuesday, April 19th in New Orleans, LA.

Toll-like Receptor (TLR) Antagonism

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 December 2015, Idera presented positive clinical data from the ongoing Phase 1/2 trial of IMO-8400 in patients with Waldenstrom's Macroglobulinemia at the 57th Annual Meeting of the American Society of Hematology (ASH) in Orlando, FL. Subsequently, the company also announced plans to continue further dose escalation of IMO-8400 in both the ongoing trials in Waldenstrom's Macroglobulinemia and Diffuse Large B-cell Lymphoma to further explore the full potential of IMO-8400 based on the safety profile and efficacy signals seen to date.

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

Rare Diseases

In November 2015, Idera announced the initiation of a Phase 2 clinical trial of IMO-8400 in patients with Dermatomyositis. The company is also announcing that due to the resources required to fully commit to a Duchenne muscular dystrophy (DMD) clinical development endeavor, the company has reached the decision to suspend internal efforts at this time to advance IMO-8400 into clinical development for DMD.

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 3GA 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, in the fourth quarter of 2015 Idera announced the selection of NLRP3 (NOD-like receptor family, pyrin domain containing protein 3) and DUX4 (Double Homeobox 4) as initial 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 is currently conducting clinical and regulatory pathway and commercial analysis activities in advance of conducting full IND-enabling studies throughout the remainder of 2016, with the plan to enter the clinic in 2017 for the first disease indication.

Also during the fourth quarter of 2015, Idera announced the first licensing agreement from the 3GA platform. The company entered into a worldwide collaboration and licensing agreement with GSK to research, develop and commercialize selected molecules from the platform for the treatment of selected undisclosed targets in renal disease. Under the terms of the agreement, Idera is eligible to receive approximately up to \$100 million in development and regulatory milestone payments, including a \$2.5 million upfront payment. Additionally, Idera is eligible to receive royalties on all sales upon commercialization at varying rates up to five percent on annual net sales in excess of \$500 million.

Recent Corporate Highlights

During the fourth quarter of 2015, Idera announced the following additions to company leadership:

- Joanna Horobin, M.B. Ch.B. as Senior Vice President, Chief Medical Officer
- Mark J. Cornfeld, M.D., M.P.H. as Vice President and Medical Lead, Oncology
- Tanya Lewis, as Vice President, Regulatory Affairs and Quality
- John Kirby, as Vice President, Corporate Accounting
- Kirsten Gruis, M.D., M.S. as Senior Medical Director, Rare Diseases

Financial Results

Fourth Quarter Results

Net loss applicable to common stockholders for the three months ended December 31, 2015 was \$12.0 million, or \$0.10 per basic and diluted share, compared to a net loss applicable to common stockholders of \$12.0 million, or \$0.14 per basic and diluted share, for the same period in 2014. There was nominal revenue recognized in each of the fourth quarters of 2015 and 2014. Research and development expenses for the three months ended December 31, 2015 totaled \$8.6 million compared to \$8.2 million for the same period in 2014. General and administrative expense for the three months ended December 31, 2015 and December 31, 2014 totaled \$3.7 million, respectively.

Full Year Results

Net loss applicable to common stockholders for the year ended December 31, 2015 was \$48.6 million or \$0.42 per diluted share, compared to net loss applicable to common stockholders of \$39.2 million, or \$0.47 per diluted share, for the same period in 2014. There was nominal revenue recognized during the years ended December 31, 2015 and 2014. Research and development expenses for the year ended December 31, 2015 totaled \$33.7 million compared to \$27.5 million for the same period in 2014. General and administrative expenses for the year ended December 31, 2015 totaled \$15.4 million compared to \$11.3 million for the same period in 2014.

As of December 31, 2015, our cash, cash equivalents and investments totaled \$87.2 million compared to \$48.6 million as of December 31, 2014. We currently anticipate our cash position is capable of funding our operations into the third quarter of 2017.

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 has created a third generation antisense technology platform 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 Annual Report on Form 10-K for the period ended December 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		Years Ended	
	December 31,		December 31,	
	<u>2015</u>	<u>2014</u>	<u>2015</u>	<u>2014</u>
Alliance Revenue	\$ 190	\$ 2	\$ 249	\$ 73
Operating Expenses				
Research & Development	8,565	8,245	33,699	27,493
General & Administrative	3,708	3,686	15,396	11,332
Total Operating Expenses	<u>12,273</u>	<u>11,931</u>	<u>49,095</u>	<u>38,825</u>
Loss from Operations	(12,083)	(11,929)	(48,846)	(38,752)
Other Income (Expense), Net	93	11	291	110
Net Loss	(11,990)	(11,918)	(48,555)	(38,642)
Preferred stock dividends	-	97	-	519
Net loss applicable to common stockholders	<u>\$ (11,990)</u>	<u>\$ (12,015)</u>	<u>\$ (48,555)</u>	<u>\$ (39,161)</u>
Basic and diluted net loss per common share applicable to common stockholders	<u>\$ (0.10)</u>	<u>\$ (0.14)</u>	<u>\$ (0.42)</u>	<u>\$ (0.47)</u>
Shares used in computing basic and diluted net loss per common share applicable to common stockholders	<u>118,865</u>	<u>87,657</u>	<u>115,092</u>	<u>82,827</u>

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

	At December 31,	
	<u>2015</u>	<u>2014</u>
Cash, Cash Equivalents & Investments	\$ 87,157	\$ 48,571
Other Assets	5,119	2,855
Total Assets	<u>\$ 92,276</u>	<u>\$ 51,426</u>
Total Liabilities	\$ 8,694	\$ 8,024
Total Stockholders' Equity	<u>83,582</u>	<u>43,402</u>
Total Liabilities & Stockholders' Equity	<u>\$ 92,276</u>	<u>\$ 51,426</u>

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