Idera Pharmaceuticals Reports Second Quarter 2016 Financial Results and Provides Corporate Update

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CAMBRIDGE, Mass. and EXTON, Pa., Aug. 02, 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 second quarter ended June 30, 2016.

"The second quarter of this year represented a period of solid execution throughout the organization," stated Vincent Milano, Idera's Chief Executive Officer. "As a result of the efforts of the team to continue driving our programs forward, we are rapidly approaching critical data readouts for Idera. During the second half of this year, we expect to be in position to share important data from our melanoma trial with IMO-2125, as well as the next steps in the program. We also expect to be in a position to select a recommended Phase 2 dose for our B-cell lymphoma program with IMO-8400. Lastly, we plan to begin elucidating the path forward for the 3GA (third generation antisense) platform, which we believe represents a pillar in the foundation of the company we are building."

Continued Milano, "I'm very proud of the team's focus and determination as they continued to advance our research and development programs. We certainly have much more work ahead of us to arrive at our ultimate goal of delivering solutions to patients; however, we are energized knowing that we will soon be in possession of critical information to further understand the potential of these opportunities."

Research and Development Program Updates
IMO-2125 and IMO-8400 are the Company's lead clinical development drug candidates. IMO-2125 is an oligonucleotide-based agonist of Toll-like receptor (TLR) 9. IMO-8400 is an oligonucleotide-based antagonist of TLRs 7, 8, and 9. The Company also announced during the fourth quarter of 2015, 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). The Company continues to evaluate these and other potential targets for clinical proof of concept. The Company plans to take the first 3GA candidate into human proof of concept studies in 2017.

Toll-like Receptor (TLR) Agonism

Immuno-Oncology Program
Idera's development program in immuno-oncology is based on the rationale that intra-tumoral injections of IMO-2125, a TLR9 agonist, will activate dendritic cells and modulate the tumor microenvironment to potentiate the anti-tumor activity of checkpoint inhibitors. This rationale is supported by pre-clinical data in multiple tumor types. These studies have led Idera into a strategic alliance with the University of Texas MD Anderson Cancer Center to evaluate the combination of intra-tumoral IMO-2125 with 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, a CTLA4 antibody being conducted at the University of Texas MD Anderson Cancer Center. This study is in patients with relapsed or refractory Metastatic Melanoma who have failed prior PD-1 therapy. The trial continues to accrue patients according to plan and the Company intends to present the first clinical immune response translational data from this trial, addressing the mechanism of action, during the second half of 2016 at a select immuno-oncology conference, with clinical results expected in 2017.

The study has recently been amended to include the exploration of the combination of IMO-2125 with pembrolizumab, an anti-PD1 antibody.

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 that, in certain B-cell lymphomas driven by the oncogenic MYD88-L265P mutation, blocking TLR7 and 9 signaling can promote 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. The Company is continuing dose escalation of IMO-8400 in the ongoing trials in Waldenstrom's Macroglobulinemia and Diffuse Large B-cell Lymphoma to explore the full potential of IMO-8400 based on the safety profile and efficacy signals seen to date. The Company plans to be in position to select a recommended Phase 2 dose by year end 2016.

Idera previously announced that the U.S. Food and Drug Administration (FDA) granted 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, a rare auto-immune condition, which negatively affects skin and may result in debilitating muscle weakness. TLRs have been reported to play a role in the pathogenesis of the disease. This randomized, double-blind, placebo controlled Phase 2 trial is expected to enroll 36 patients and is being conducted at approximately 20 clinical sites worldwide. The Company plans to complete enrollment of this trial by the end of 2017.

Third Generation Antisense Platform (3GA)
Idera's proprietary third-generation antisense (3GA) platform technology is focused on silencing the mRNA associated with disease causing genes. Idera has designed 3GA oligonucleotides to overcome specific challenges associated with earlier generation antisense technologies and RNAi technologies.

In late 2015, Idera announced the identification 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 related to these targets include, but are not limited to, interstitial cystitis, lupus nephritis, uveitis and facioscapulohumeral muscular dystrophy (FSHD). The Company

is currently conducting clinical, regulatory and commercial analysis activities and conducting IND-enabling studies with the plan to enter the clinic in 2017 for the first clinical development program. In addition to these activities, over the first half of 2016, Idera generated 3GA compounds for a series of additional gene targets. These will enable the Company to continue to expand its future pipeline opportunities for both internal development as well as partnerships in areas outside of Idera's focus. Idera plans to present pre-clinical data at several conferences in the second half of 2016.

In late 2015, Idera entered into a collaboration and license agreement with GSK to research, develop and commercialize compounds from its 3GA technology for the treatment of undisclosed, selected renal targets. As per the terms of the agreement, Idera received an upfront payment of $2.5 million and is eligible to receive up to approximately $100 million in milestone payments in addition to royalties.

Financial Results

Second Quarter 2016 Results

Net loss for the three months ended June 30, 2016 was $13.5 million, or $0.11 per basic and diluted share, compared to a net loss of $12.7 million, or $0.11 per basic and diluted share, for the same period in 2015. Revenue totaled $0.3 million and $0.6 million during the three and six months ended June 30, 2016, respectively. There was nominal revenue recognized during the corresponding 2015 periods. For the six month period ended June 30, 2016, the Company's net loss was $26.3 million, or $0.22 per basic and diluted share, compared to a net loss of $25.2 million, or $0.23 per diluted share, for the same period in 2015.

Research and development expenses for the three months ended June 30, 2016 totaled $10.1 million compared to $9.0 million for the same period in 2015. For the six month period ended June 30, 2016, research and development expenses totaled $19.4 million compared to $17.7 million for the same period in 2015.

General and administrative expense for the three months ended June 30, 2016 and June 30, 2015 totaled $3.8 million, respectively. For the six month period ended June 30, 2016 and June 30, 2015, general and administrative expenses totaled $7.7 million, respectively.

As of June 30, 2016, Idera's cash, cash equivalents and investments totaled $64.1 million compared to $87.2 million as of December 31, 2015. The company expects the current cash position and investments to fund its 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 pre-clinical 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 and Quarterly Report on Form 10-Q for the periods ended December 31, 2015, and June 30, 2016, respectively. 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 June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Alliance Revenue	$ 301	$ 5	$ 595	$ 39
Operating Expenses				
Research & Development	10,128	8,960	19,424	17,680
General & Administrative	3,778	3,821	7,694	7,658
Total Operating Expenses	13,906	12,781	27,118	25,338

Loss from Operations	(13,605)	(12,776)	(26,523)	(25,299)
Other Income (Expense), Net	120	57	215	99
Net Loss	$ (13,485)	$ (12,719)	$ (26,308)	$ (25,200)
Basic and diluted net loss per common share applicable to common stockholders	$ (0.11)	$ (0.11)	$ (0.22)	$ (0.23)
Shares used in computing basic and diluted net loss per common share applicable to common stockholders	121,323	118,002	121,304	111,570

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

	At June 30, 2016	At December 31, 2015
	(Unaudited)	
Cash, Cash Equivalents & Investments	$ 64,096	$ 87,157
Other Assets	5,141	5,119
Total Assets	$ 69,237	$ 92,276
Total Liabilities	$ 8,188	$ 8,694
Total Stockholders' Equity	61,049	83,582
Total Liabilities & Stockholders' Equity	$ 69,237	$ 92,276

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