



Idera Pharmaceuticals Reports Third Quarter 2016 Financial Results

October 28, 2016 11:30 AM EDT

CAMBRIDGE, Mass. and EXTON, Pa., Oct. 28, 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 third quarter ended September 30, 2016.

Since June 30, 2016, the Company:

- Announced positive clinical data from the initial cohorts of the phase 1 dose escalation portion of the Company's ongoing Phase 1/2 clinical trial of intratumoral IMO-2125 in combination with ipilimumab in patients with PD-1 refractory metastatic melanoma;
- Presented pre-clinical data updates on both novel mechanism of action and selective targeting of single point mutations with 3rd Generation Antisense (3GA) at the Cold Springs Harbor Laboratory Conference on Regulatory & Non-Coding RNAs conference and the Annual Meeting of the Oligonucleotide Therapeutic Society, respectively;
- Received acceptance of an abstract entitled "Reactivating the Anti-tumor Immune Response by Targeting Innate and Adaptive Immunity in a Phase I/II Study of intratumoral IMO-2125 in Combination with Systemic Ipilimumab in Patients with Anti-PD-1 Refractory Metastatic Melanoma" for an oral presentation at the upcoming Society for Immunotherapy of Cancer (SITC) Annual Meeting in November 2016;
- Received acceptance of an oral presentation entitled "IMO-2125, An Investigational intratumoral Toll-Like Receptor 9 Agonist, Modulates the Tumor Microenvironment to Enhance Anti-Tumor Immunity" at SITC Annual Meeting;
- Generated estimated net proceeds of \$48.9M, after deducting underwriters' discounts and commissions and estimated offering expenses, from a public offering of common stock, including from the partial exercise by the underwriters of their option to purchase additional shares in the offering, which option exercise is expected to close today. The Company believes that, based on its current operating plan, its existing cash, cash equivalents and investments, including the net proceeds from the offering, will enable it to fund its operations into the first quarter of 2018 and continue acceleration and development of key research and clinical development programs; and
- Announced increased prioritization of IMO-2125 with plans to initiate two additional multi-center clinical trials in 2017 both as monotherapy and in combination with check-point inhibitors in multiple tumor types.

"The third quarter of 2016 was a very productive period for our team at Idera and positions us well to close out the year very strong and carry that momentum into a catalyst rich 2017," stated Vincent Milano, Idera's Chief Executive Officer "As I noted in late September, we are incredibly energized by the IMO-2125 data we announced in such an early phase of the development and are now mobilized to advance this program rapidly, to potentially alter the lives of other patients who have exhausted all other good options."

Continued Milano, "I am also proud of the conduct of our team to complete all the work that was necessary to inform and enable our recent decision to suspend work on the B-cell program, which, while difficult, allows us to redirect additional resources to accelerate the development of IMO-2125. We remain excited for the prospects of dermatomyositis with IMO-8400 and we are looking forward to being in a position to go into greater detail in January on our plans to begin the clinical phases of development with the 3GA platform."

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, in late 2015, the first two potential 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. 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 and other immunotherapies. This rationale is supported by pre-clinical data in multiple tumor types. These pre-clinical studies led Idera into a strategic alliance with the University of Texas MD Anderson Cancer Center to evaluate the combination of intratumoral IMO-2125 with checkpoint inhibitors.

In late 2015, Idera announced the initiation of a Phase 1/2 clinical trial of intratumoral IMO-2125 in combination with ipilimumab, a CTLA4 antibody, which is being conducted at the University of Texas MD Anderson Cancer Center. This trial is being conducted in patients with relapsed or refractory metastatic melanoma who have failed prior PD-1 therapy. In September 2016, the Company announced positive preliminary clinical data from the initial dosing cohorts in the ipilimumab arm of the dose escalation portion of the trial. The trial has recently been amended to also include the evaluation of the combination of intratumoral IMO-2125 with pembrolizumab, an anti-PD1 antibody, with enrollment in this arm now underway. The Company plans to expand the trial to additional clinical trial sites to conduct the phase 2 portion of the trial.

The results announced are summarized as follows:

Safety

- 10 patients in 3 dosing cohorts (4mg, 8mg and 16mg) were dosed and assessable for safety, as of the September 19, 2016 cutoff date;
- IMO-2125 in combination with ipilimumab was being generally well tolerated at all 3 dose levels;
- Immune related adverse events have been observed in 3 subjects: 2 responding patients have experienced hypophysitis and 1 patient has discontinued the study due to a recurrence of immune related hepatitis previously observed on pre-study therapy with ipilimumab;
- No dose limiting toxicities (DLTs) were identified and the study is currently enrolling at the highest (32mg) dosing cohort in combination with ipilimumab.

Clinical activity

- 6 patients treated in the first two dosing cohorts (4mg and 8mg) were assessable for initial clinical activity, as of the September 19, 2016 cutoff date;
- 3 of the 4 patients with cutaneous melanoma were investigator-assessed responders with one Complete Response (CR) and 2 Partial Responses (PR).

Translational observations

- Translational data seen through the first two dosing cohorts (4mg and 8mg) were promising relative to the induction of immune responses and consistent with the underlying hypothesis of the mechanism of action;
- Detailed information on the translational findings from biopsies taken in the first two dosing cohorts and the relationship of these to clinical response is the subject of an accepted oral presentation on November 11, 2016 at the 2016 Society for Immunotherapy of Cancer (SITC) Annual Meeting by Cara Haymaker, Ph.D., University of Texas, MD Anderson Cancer Center.

The Company also announced plans to take another data cut at the end of 2016 and request an End of Phase 1 (EOP) meeting with the U.S. Food and Drug Administration to discuss next steps and the path to a regulatory filing. The Company also anticipates requesting a meeting with the European Medicines Agency (EMA) for scientific advice.

Idera also plans to initiate trials to explore IMO-2125 as a monotherapy in multiple tumor types as well as a Phase 2 basket study of IMO-2125 in combination with check point inhibitors in additional tumor types beyond melanoma. Both of these studies are planned to initiate in 2017.

Toll-like Receptor (TLR) Antagonism

Dermatomyositis Clinical Development Program

In late 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 will be conducted at approximately 22 clinical sites worldwide. The Company plans to complete enrollment of this trial by the end of 2017 and have clinical data available in early 2018.

B-cell Lymphoma Clinical Development Program

In September 2016, Idera announced that the company had suspended the clinical development of IMO-8400 for B-cell lymphomas, including studies in Waldenstroms Macroglobulinemia (WM) and Diffuse Large B-Cell Lymphoma (DLBCL), and planned to explore strategic options in these indications. This decision was based upon the prioritization of the clinical development plans for IMO-2125 and the Company's assessment that the level of clinical activity seen in the WM trial does not support monotherapy, the very slow enrollment rate in DLBCL and the Company's commercial assessment of IMO-8400. IMO-8400 was generally well tolerated at all dose levels evaluated in the studies.

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). Over the first three quarters of 2016, Idera has generated additional 3GA compounds for a series of additional gene targets, which join NLRP3 and DUX4 as potential gene targets for the first clinical development program. The Company is currently conducting clinical, regulatory and commercial analysis activities and conducting IND-enabling studies. The Company plans to enter the clinic in 2017 for the first clinical development program. These additional compounds will enable the Company to continue to expand its potential future pipeline opportunities for both internal development as well as partnerships in areas outside of Idera's focus.

In August 2016, Idera presented new pre-clinical data demonstrating the novel mechanism of action of the 3GA platform at the Cold Springs Harbor Laboratory Conference on Regulatory & Non-Coding RNAs. Subsequently, Idera presented in September 2016, new pre-clinical data demonstrating how the 3GA platform's unique mechanism of action supports selective targeting of single point mutations as well as a pre-clinical data presentation of 3GA targeting of NLRP3 for the treatment of inflammatory disorders. These presentations were made at the 12th Annual Meeting of the Oligonucleotide Therapeutics Society (OTS).

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, including the \$2.5 million payment, in addition to royalties.

Financial Results

Third Quarter 2016 Results

Net loss for the three months ended September 30, 2016 was \$12.9 million, or \$(0.10) per basic and diluted share, compared to a net loss of \$11.4 million, or \$(0.10) per basic and diluted share, for the same period in 2015. Revenue totaled \$0.3 million and \$0.9 million during the three and nine months ended September 30, 2016, respectively. There was nominal revenue recognized during the corresponding 2015 periods. For the nine month period ended September 30, 2016, the Company's net loss was \$39.2 million, or \$(0.32) per basic and diluted share, compared to a net loss of \$36.6 million, or \$(0.32) per diluted share, for the same period in 2015.

Research and development expenses for the three months ended September 30, 2016 totaled \$9.4 million compared to \$7.5 million for the same period in 2015. For the nine month period ended September 30, 2016, research and development expenses totaled \$28.8 million compared to \$25.1 million for the same period in 2015.

General and administrative expense for the three months ended September 30, 2016 totaled \$3.9 million compared to \$4.0 million for the same period in 2015. For the nine month period ended September 30, 2016, general and administrative expenses totaled \$11.6 million compared to \$11.7 million for the same period in 2015.

As of September 30, 2016, Idera's cash, cash equivalents and investments totaled \$53.4 million compared to \$87.2 million as of December 31, 2015.

In October 2016, the Company completed a public offering of its common stock, generating estimated net proceeds of \$48.9M, after deducting underwriters' discounts and commissions and estimated offering expenses, including from the partial exercise by the underwriters of their option to purchase additional shares in the offering, which option exercise is expected to close today. The Company believes that, based on its current operating plan, its existing cash, cash equivalents and investments, including the net proceeds from the offering, will enable it to fund its operations into the first quarter of 2018 and continue acceleration and development of key research and clinical development programs.

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 the Company's cash resources will be sufficient to fund the Company's continuing operations and the further development of the Company's programs for the period anticipated; whether interim results from a clinical trial, such as the preliminary results reported in this release, will be predictive of the final results of the trial; 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, including in clinical trials in different disease indications; 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 prospectus supplement filed on October 7, 2016. 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,	
	<u>2016</u>	<u>2015</u>	<u>2016</u>	<u>2015</u>
Alliance Revenue	\$ 323	\$ 20	\$ 918	\$ 59
Operating Expenses				
Research & Development	9,393	7,454	28,817	25,134
General & Administrative	3,907	4,030	11,601	11,688
Total Operating Expenses	13,300	11,484	40,418	36,822
Loss from Operations	(12,977)	(11,464)	(39,500)	(36,763)
Other Income (Expense), Net	74	99	289	198
Net Loss	<u>\$ (12,903)</u>	<u>\$ (11,365)</u>	<u>\$ (39,211)</u>	<u>\$ (36,565)</u>
Basic and diluted net loss per common share applicable to common stockholders	<u>\$ (0.10)</u>	<u>\$ (0.10)</u>	<u>\$ (0.32)</u>	<u>\$ (0.32)</u>
Shares used in computing basic and diluted net loss per common share applicable to common stockholders	<u>121,389</u>	<u>118,248</u>	<u>121,332</u>	<u>113,821</u>

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

	At September 30, 2016	At December 31, 2015
	(Unaudited)	
Cash, Cash Equivalents & Investments	\$ 53,418	\$ 87,157
Other Assets	5,060	5,119
Total Assets	<u>\$ 58,478</u>	<u>\$ 92,276</u>
Total Liabilities	\$ 8,606	\$ 8,694
Total Stockholders' Equity	49,872	83,582
Total Liabilities & Stockholders' Equity	<u>\$ 58,478</u>	<u>\$ 92,276</u>

IDERA PHARMACEUTICALS Contact:

Robert A. Doody, Jr.
VP, Investor Relations & Communications
Phone (617) 679-5515
RDOODY@IDERAPHARMA.COM



