Idera Pharmaceuticals Reports Third Quarter 2010 Financial Results and Provides Pipeline Update

November 4, 2010 12:33 PM EDT

CAMBRIDGE, Mass., Nov 04, 2010 (BUSINESS WIRE) --

Idera Pharmaceuticals, Inc. (Nasdaq: IDRA), a biotechnology company engaged in the discovery and development of DNA- and RNA-based drug candidates targeted to Toll-like Receptors (TLRs), today reported results for the third quarter ended September 30, 2010.

"During this quarter we demonstrated progress in many key areas across the company. In our clinical programs, we recently presented positive Phase 1 data for our two internal drug candidates - IMO-2125 in null-responder HCV patients and IMO-3100 in healthy subjects. In addition, our collaborator, Merck KGaA, initiated a Phase 1b clinical trial to evaluate our partnered drug candidate, EMD 1201081, in patients with head and neck cancer," said Sudhir Agrawal, D.Phil., Chairman and Chief Executive Officer. "In our preclinical programs, we recently presented data on our novel TLR3 agonist compounds, which show activity as vaccine adjuvants, and we plan to present data on our dual TLR7 and TLR8 agonist in models of hematological malignancies by year-end."

Dr. Agrawal continued, "We continue to work diligently to evaluate additional data that will inform our decisions about the Phase 2 clinical development strategies for IMO-2125 and IMO-3100 and look forward to providing an update on the timing of those programs."

"Idera ended the third quarter of 2010 with $43.0 million in cash, cash equivalents, and investments, which includes net proceeds of $14.1 million from our third quarter financing and a $4.1 million milestone payment under our collaboration with Merck KGaA. Net cash used in operations for the first nine months of 2010 was $11.3 million. We believe that we have the financial resources to fund our operations at least through December 31, 2011 based on our current operating plan," commented Lou Arcudi, Chief Financial Officer.

Research and Development Highlights

IMO-2125, a TLR9 Agonist, in Chronic Hepatitis C Virus (HCV) Infection

- Data were presented at a recent scientific meeting from the Company's Phase 1 clinical trial in the difficult-to-treat null-responder patient population. The data demonstrated that once-weekly dosing with IMO-2125 monotherapy induced a dose-dependent broad immune response and was well tolerated in the trial. The Company is now enrolling additional patients to evaluate twice-weekly dosing of IMO-2125.
- The Company expects to announce data from its ongoing Phase 1 clinical trial in treatment-naïve patients evaluating once-weekly and twice-weekly dosing regimens of IMO-2125 in combination with ribavirin compared to the standard of care for four weeks of treatment in the fourth quarter of 2010.
- The Company plans to provide an update on its IMO-2125 Phase 2 clinical development strategy by the end of 2010 based on the data from the ongoing trials and evaluation of the upcoming changes in the HCV development and treatment landscape.

IMO-3100, a Dual Antagonist of TLR7 and TLR9, in Autoimmune and Inflammatory Diseases

- The Company completed a Phase 1 single-dose, dose escalation clinical trial of IMO-3100. In 30 healthy subjects, IMO-3100 was well tolerated and target engagement of TLR7 and TLR9 was observed.
- In the ongoing Phase 1 four-week multiple-dose clinical trial of IMO-3100 all 24 healthy subjects have completed treatment and follow-up visits. The study remains blinded, however, no treatment-related discontinuations or serious adverse events have been reported. The Company intends to present preliminary data from this clinical trial at a scientific meeting in the first half of 2011.
- Idera plans to conduct additional nonclinical studies of IMO-3100. The Company anticipates providing in the first quarter of 2011 an update on the nonclinical studies and the anticipated

timing for the initiation of a Phase 2 clinical trial of IMO-3100.

EMD 1201081 (IMO-2055), a TLR9 Agonist, in Cancer Treatment (Collaboration with Merck KGaA)

- Merck KGaA initiated a Phase 1b clinical trial of EMD 1201081 in squamous cell carcinoma of the head and neck resulting in a $4.1 million milestone payment from Merck KGaA to Idera.

Preclinical Programs

- Idera recently presented data at a scientific meeting describing a proprietary class of TLR3 agonist compounds that demonstrated activity as vaccine adjuvants in a preclinical model. The Company plans to expand preclinical evaluation of these compounds.
- Idera is evaluating a dual agonist of TLR7 and TLR8 that has demonstrated antitumor activity in preclinical models of hematological malignancies. The Company plans to present preclinical data on its TLR7/8 agonist at an upcoming scientific meeting and anticipates selecting a lead candidate for this program by the end of 2010.

Third Quarter and Nine-Month 2010 Results

The Company reported a net loss of $4.7 million, or $0.18 per diluted share, for the three months ended September 30, 2010, compared to net income of $24,000, or $0.00 per diluted share, for the same period in 2009. For the 2010 nine-month period, the Company's net loss was $12.0 million, or $0.49 per diluted share, compared to net income of $3.6 million, or $0.15 per diluted share, for the same period in 2009.

Total revenues for the three months ended September 30, 2010 were $5.1 million compared to $6.5 million for the same period in 2009. For the 2010 nine-month period, revenues totaled $15.1 million compared to $24.3 million for the same period in 2009.

Research and development expenses for the three months ended September 30, 2010 totaled $7.8 million compared to $4.3 million for the same period in 2009. For the 2010 nine-month period, R&D expenses totaled $19.3 million compared to $14.2 million for the same period in 2009.

General and administrative expenses for the three months ended September 30, 2010 totaled $2.2 million compared to $2.2 million for the same period in 2009. For the 2010 nine-month period, G&A expenses totaled $7.7 million compared to $6.5 million for the same period in 2009.

As of September 30, 2010, cash, cash equivalents and investments totaled approximately $43.0 million compared to $40.2 million at December 31, 2009.

Clinical and Preclinical Programs

IMO-2125, a TLR9 Agonist, in Chronic Hepatitis C Virus (HCV) Infection

- Phase 1 Clinical Trial of IMO-2125 Monotherapy in Null-Responder Patients with Chronic HCV Infection

This Phase 1 clinical trial has evaluated IMO-2125 in null-responder HCV patients with 41 patients receiving IMO-2125 monotherapy at five dose levels and 10 patients receiving placebo once per week for four weeks. Most of these patients were infected with HCV genotype 1 and had the CT or TT IL28B gene alleles. IMO-2125 was well tolerated at all dose levels. IMO-2125 induced a broad immune response with dose-dependent increases in serum concentrations of antiviral proteins and activation of cellular immune responses. Across the three highest dose levels, seventy-five percent of patients receiving IMO-2125 achieved a 1 $\log_{10}$ or greater decrease in viral load at least once during the treatment period. Consistent with the proposed mechanism of IMO-2125, induction of higher serum concentrations of interferon-alpha correlated with greater decreases in HCV viral load.

IL28B genotype data were available for 14 of the 16 patients treated with IMO-2125 at 0.32 or 0.48 mg/kg/week. Thirteen of these patients had CT or TT IL28B genotype, of which 10 had maximum viral load reductions ranging from -1 to -2.6 $\log_{10}$ at least once during the treatment period. The 14^{th} patient had CC IL28B genotype and had a maximum viral load reduction of 3.5 $\log_{10}$ at least once during the treatment period.

Additional patients are being enrolled in this Phase 1 trial to evaluate the safety and the effect on HCV viral load of twice-weekly IMO-2125 administration for four weeks.

- Phase 1 Clinical Trial of IMO-2125 in Combination with Ribavirin in Treatment-naïve Patients with Chronic HCV Infection

This clinical trial in treatment-naïve HCV patients is evaluating IMO-2125 at multiple dose levels using both once-weekly and twice-weekly dosing regimens for four weeks in combination with ribavirin, compared to a control arm of patients receiving pegylated recombinant interferon-alpha and ribavirin. The primary objective of the trial is to assess the safety and tolerability of IMO-2125 in combination with ribavirin. In addition, this trial is designed to monitor the effect of treatment on HCV viral load and on activation of the immune system.

The Company expects to report top-line data from this Phase 1 clinical trial of IMO-2125 in the fourth quarter of 2010.

- Plans for Future Clinical Evaluation of IMO-2125 in Chronic Hepatitis C

Prior to initiating a Phase 2 clinical trial for IMO-2125, the Company plans to analyze the full data sets from the ongoing Phase 1 IMO-2125 trials and evaluate the upcoming changes in the development and treatment landscape for HCV. The Company expects that, after assessing these factors, it will outline its clinical development strategy and plans for a Phase 2 program for IMO-2125 by the end of 2010.

IMO-3100, a Dual Antagonist of TLR7 and TLR9, in Autoimmune and Inflammatory Diseases

- Phase 1 Single-Dose, Dose Escalation Clinical Trial of IMO-3100 in Healthy Subjects: Safety and Mechanism of Action

In January 2010, the Company initiated a single-dose, dose escalation, Phase 1 clinical trial of IMO-3100 in healthy subjects. In this trial, six healthy subjects in each of five dosage cohorts received single doses of IMO-3100 from 0.04 to 0.64 mg/kg. Six additional subjects each received a single dose of placebo. The primary objective was evaluation of safety and tolerability. Secondary objectives were to characterize the blood levels of IMO-3100 and to assess the pharmacodynamic mechanism of action through the response of peripheral blood mononuclear cells to agonists of TLR7 and TLR9.

In October 2010, the Company presented results from the Phase 1 single-dose, dose escalation clinical trial of IMO-3100. IMO-3100 was well tolerated at all dose levels evaluated in the 30 healthy subjects that received IMO-3100, and target engagement of TLR7 and TLR9 was observed through inhibition of TLR7- and TLR9-mediated immune responses.

- Phase 1 Multiple-Dose Clinical Trial of IMO-3100 in Healthy Subjects: Safety and Mechanism of Action

In July 2010, the Company initiated a four-week multiple-dose clinical trial of IMO-3100 in healthy subjects. The purpose of the multiple-dose clinical trial was to evaluate the safety, blood levels of IMO-3100, and pharmacodynamic mechanism of action of IMO-3100 with multiple-dose subcutaneous administration over four weeks. The trial was designed to include 16 subjects treated with IMO-3100 and eight subjects treated with placebo.

The study remains blinded. However, all 24 subjects have completed dosing and scheduled follow-up visits with no treatment-related discontinuations or serious adverse events. The Company intends to present the preliminary data from this clinical trial at a scientific meeting in the first half of 2011.

- Plans for Future Clinical Evaluation of IMO-3100 in Autoimmune Disease

Prior to initiation of a Phase 2 clinical trial, Idera plans to conduct additional nonclinical studies in light of some reversible immune responses observed in 13-week nonclinical toxicology studies conducted by the Company that are inconsistent with other nonclinical studies of IMO-3100. The Company expects to provide in the first quarter of 2011 an update on the nonclinical studies and the anticipated timing for the initiation of a Phase 2 clinical trial of IMO-3100.

EMD 1201081 (IMO-2055), a TLR9 Agonist, in Cancer Treatment (Collaboration with Merck KGaA)

In December 2007, the Company entered into an exclusive, worldwide license agreement with Merck KGaA to research, develop and commercialize products containing its TLR9 agonists for the treatment of cancer, excluding cancer vaccines.

In August 2010, Merck KGaA initiated a Phase 1b clinical trial of EMD 1201081 in patients with squamous cell carcinoma of the head and neck (SCCHN). Idera achieved a milestone related to this trial initiation and received a payment of $4.1 million from Merck KGaA.

Merck KGaA currently is conducting the following clinical trials of EMD 1201081:

- Phase 2 clinical trial of EMD 1201081 in combination with Erbitux(R) in patients with recurrent or metastatic SCCHN
- Phase 1b clinical trial of EMD 1201081 in combination with cisplatin, fluorouracil and cetuximab (Erbitux(R)) in patients with SCCHN
- Phase 1b clinical trial of EMD 1201081 in combination with Tarceva(R) and Avastin(R) in non-small cell lung cancer
- Phase 1b clinical trial of EMD 1201081 in combination with Erbitux(R) and chemotherapy in colorectal cancer

IMO-2134, a TLR9 Agonist, for Respiratory Diseases

IMO-2134 was identified as a lead compound for development in asthma and allergy indications during the Company's collaboration with Novartis, and Novartis initiated a Phase 1 clinical trial of IMO-2134, also known as QAX935. Upon the termination of the research collaboration and option agreement in February 2010, the Company regained the rights to IMO-2134. Idera is in the process of obtaining from Novartis data from the IMO-2134 development program and plans to evaluate the next steps in developing IMO-2134 for respiratory diseases following receipt of such data.

TLR3, 7, 8 and 9 Agonists as Vaccine Adjuvants

- ***Collaboration with Merck & Co., Inc.***

In December 2006, the Company and Merck & Co., Inc. (now Merck Sharp & Dohme Corp. and referred to herein as Merck) entered into an exclusive license and research collaboration agreement to research, develop and commercialize vaccine products containing the Company's TLR7, 8, and 9 agonists in the fields of oncology, infectious diseases and Alzheimer's disease. As part of the agreement, the two companies engaged in a research collaboration to generate novel agonists targeting TLR7 and TLR8, incorporating both Merck and Idera chemistry, for use in the licensed fields. In November 2009, Merck extended the research collaboration with the Company for a fourth year to December 2010. Under the terms of the agreement, Merck is funding the research and development activities under the collaboration.

- ***TLR3 Agonists***

Idera has created proprietary TLR3 agonists that are synthetic double-stranded RNA structures of defined length and composition.

These agonists have been shown to induce Th1-specific immune responses through TLR3 in cell-based assays. Subcutaneous administration of the TLR3 agonists in mice resulted in increased serum levels of certain cytokines and chemokines. In addition, mice vaccinated with hepatitis B surface antigen (HBsAG) and one of the TLR3 agonists showed dose-dependent increases in antibodies in the serum and increased interferon-gamma (IFN-) production in their spleen recalled response compared with mice vaccinated with HBsAG alone. Induction of these antibodies and IFN- generally indicates a protective immune response to the antigen administered.

TLR7 and TLR8 Agonists

The Company has created synthetic **s**tabilized **i**mmune **m**odulatory **R**N**A** (SIMRA) compounds that mimic viral RNA and induce immune responses by functioning as agonists of TLR7 and TLR8.

The Company is continuing to study selected dual TLR7 and TLR8 agonists in preclinical models of hematological cancers and has observed in these models antitumor activity of a dual agonist of TLR7 and TLR8 as monotherapy and in combination with selected targeted drugs currently approved for cancer treatment. The Company is planning to present preclinical data on its dual agonist of TLR7 and TLR8 in models of hematological cancers at a scientific meeting in the fourth quarter of 2010 and intends to select a dual TLR7 and TLR8 agonist as a lead drug candidate by the end of the year.

TLR Antisense

The Company has identified antisense compounds targeted to human TLRs 2, 3, 4, 5, 7, 8 and 9 and to the TLR-associated signaling protein MyD88. The Company is studying these compounds for potential applications in autoimmune and inflammatory diseases.

Scientific Highlights

Data Presentations

- A presentation entitled "Differential patterns of response to Toll-like receptor 9 agonist and exogenous Interferon-a in the mouse liver" was made by Zuzanna Makowska, University Hospital Basel, Basel, Switzerland, at the Joint Meeting of the International Cytokine Society (ICS) and the International Society for Interferon and Cytokine Research on Cytokines in Infectious Diseases, Autoimmune Disorders and Cancer held October 3-7, 2010 in Chicago, IL.
- A presentation entitled "Safety and Pharmacodynamics of IMO-3100, a Novel Toll-like Receptor Antagonist for Autoimmune and Inflammatory Diseases, in a Rising Single-Dose Phase 1 Clinical Trial" was made by Idera scientists at the 6th Annual Meeting of the Oligonucleotide Therapeutic Society held October 20-23, 2010, in Dana Point, CA.
- A presentation entitled "Novel synthetic double-stranded oligoribonucleotides act as agonists of Toll-like receptor 3, induce immune responses, and show potent adjuvant activity with HBsAg in mice" was made by Idera scientists at the Keystone Symposium on Immunological Mechanisms of Vaccination held October 27-November 1, 2010 in Seattle, WA.
- An oral presentation entitled "IMO-2125, a TLR9 Agonist, Induces Immune Responses which Correlate with Reductions in Viral Load in Null Responder HCV Patients" was made by M. Rodriguez-Torres, Medical Director, Internal Medicine, Gastroenterology,Fundacion de Investigacion, Santurce, PR, United States, at the 61st Annual Meeting of the American Association for the Study of Liver Diseases (AASLD) held October 29-November 2, 2010, in Boston, MA.

Intellectual Property

The Company's intellectual property portfolio contains over 500 patents and patent applications worldwide.

Immune Modulatory Oligonucleotide (IMO$^{(R)}$) Technology

This portfolio holds over 290 patents and patent applications worldwide covering the Company's IMO technologies and includes claims covering novel

agonists of TLRs 3, 7, 8, and 9, and antagonists of TLR7 and TLR9. These patents and patent applications also include claims covering IMO-2055, IMO-2125, IMO-2134, and IMO-3100. The Company was granted the following U.S. patents during the third quarter of 2010:

- US 7,749,975, entitled "Modulation of immunostimulatory properties of oligonucleotide-based compounds by optimal presentation of 5' ends"
- US 7,776,834, entitled "Immunostimulatory properties of oligonucleotide-based compounds comprising modified immunostimulatory dinucleotides"
- US 7,786,089, entitled "Immunostimulatory activity of immune modulatory oligonucleotides (IMO$^{(R)}$) containing different lengths of palindromic segments"
- US 7,790,168, entitled "Modulation of immunostimulatory activity of immunostimulatory oligonucleotide analogs by positional chemical changes"

Antisense Technology

The Company's antisense technology portfolio includes more than 210 patents and patent applications worldwide owned or licensed by Idera covering novel antisense compounds and methods of their use. These patents and patent applications include claims covering second-generation antisense chemistry, oral delivery of second-generation antisense compounds, and certain genes, antisense sequences, and therapeutic targets (including various TLRs and signaling molecules).

About Idera Pharmaceuticals, Inc.

Idera Pharmaceuticals is developing drug candidates that act by modulating immune responses through specific Toll-like Receptors (TLRs). TLRs, a family of immune system receptors and the immune system's first line of defense, recognize pathogens and initiate an immune response. Idera's DNA and RNA chemistry expertise has generated a pipeline of compounds designed to interact with specific TLRs for a broad range of diseases. Through its internal pipeline and collaborative alliances, Idera has established a portfolio of TLR-targeted therapeutic candidates for infectious diseases, autoimmune and inflammatory diseases, cancer, and respiratory diseases, and for use as vaccine adjuvants.

Idera Forward-Looking Statements

This press release contains forward-looking statements concerning Idera Pharmaceuticals, Inc. that involve a number of risks and uncertainties. For this purpose, any statements contained herein that are not statements of historical fact may be deemed to be forward-looking statements. Without limiting the foregoing, the words "believes," "anticipates," "plans," "expects," "estimates," "intends," "should," "could," "will," "may," and similar expressions are intended to identify forward-looking statements. There are a number of important factors that could cause Idera's actual results to differ materially from those indicated by such forward-looking statements, including whether results obtained in preclinical studies and early clinical trials such as the trials referred to in this release will be indicative of results obtained in future clinical trials; whether products based on Idera's technology will advance into or through the clinical trial process on a timely basis or at all and receive approval from the United States 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 with Merck KGaA and Merck Sharp & Dohme Corp., will be successful; whether the patents and patent applications owned or licensed by the Company will protect the Company's technology and prevent others from infringing it; whether Idera's cash resources will be sufficient to fund the Company's operations; and such other important factors as are set forth under the caption "Risk Factors" in Idera's Quarterly Report on Form 10-Q for the three months ended September 30, 2010, which important factors are incorporated herein by reference. Idera disclaims any intention or obligation to update any forward-looking statements.

Tarceva is a registered trademark of OSI Pharmaceuticals, Inc. Avastin is a registered trademark of Genentech, Inc. Erbitux is a registered trademark of ImClone LLC. The Patent Board is a trademark of The Patent Board.

Idera Pharmaceuticals, Inc.
Condensed Statements of Operations
(Unaudited)

(in thousands, except per share data)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Revenue	$ 5,089	$ 6,538	$ 15,052	$ 24,338
Operating Expenses:				
Research & Development	7,786	4,288	19,333	14,177
General & Administrative	2,193	2,210	7,709	6,492
Total Operating Expenses	9,979	6,498	27,042	20,669
(Loss) Income from Operations	(4,890)	40	(11,990)	3,669
Other, net	179	14	40	116
(Loss) Income Before Income Taxes	(4,711)	54	(11,950)	3,785
Income Tax Provision	-	(30)	-	(170)
Net (Loss) Income	$ (4,711)	$ 24	$ (11,950)	$ 3, 615
Basic Net (Loss) Income per Share	$ (0.18)	$ -	$ (0.49)	$ 0.15
Diluted Net (Loss) Income per Share	$ (0.18)	$ -	$ (0.49)	$ 0.15
Shares Used in Computing Basic Net (Loss) Income per Share	25,980	23,441	24,314	23,409
Shares Used in Computing Diluted Net (Loss) Income Per Share	25,980	24,341	24,314	24,188

Idera Pharmaceuticals, Inc.
Condensed Balance Sheet Data
(Unaudited)

(in thousands)	September 30, 2010	December 31, 2009
Cash, Cash Equivalents And Investments	$ 42,951	$ 40,207
Receivables	26	4,497
Other Assets	3,101	2,935
Total Assets	$ 46,078	$ 47,639
Accounts Payable and Accrued Liabilities	$ 6,700	$ 2,369
Deferred Revenue	1,050	12,165
Stockholders' Equity	38,328	33,105
Total Liabilities & Stockholders' Equity	$ 46,078	$ 47,639

SOURCE: Idera Pharmaceuticals, Inc.

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