Idera Pharmaceuticals Reports Fourth Quarter and Full Year 2010 Financial Results

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CAMBRIDGE, Mass., Mar 10, 2011 (BUSINESS WIRE) --

Idera Pharmaceuticals, Inc. (Nasdaq: IDRA) today reported financial results for the fourth quarter and year ended December 31, 2010.

"In 2010 we completed Phase 1 clinical trials of IMO-2125 in patients with chronic hepatitis C virus infection, and of IMO-3100, our lead candidate for autoimmune and inflammatory diseases, in healthy subjects. Both drug candidates showed good safety profiles and confirmed the intended mechanism of action in these clinical trials. In addition, we have expanded our pipeline with the selection of IMO-4200 as a lead candidate for the treatment of hematological malignancies," said Sudhir Agrawal, D.Phil., Chairman and Chief Executive Officer. "Our objectives in 2011 are to advance IMO-2125 and IMO-3100 into Phase 2 clinical trials and to continue progression of our preclinical programs. We also look forward to additional progress in our partnered program evaluating IMO-2055 in Phase 2 and Phase 1b clinical trials in multiple cancer indications."

"We ended the year with approximately $34.6 million in cash, cash equivalents, and investments," commented Lou Arcudi, Chief Financial Officer. "Over the course of 2011, we plan to seek additional funding through collaborations, licensing or other means to strengthen our cash resources."

Financial Results

As of December 31, 2010, cash, cash equivalents and investments totaled $34.6 million compared to $40.2 million at December 31, 2009.

Fourth Quarter Results

Net loss for the three months ended December 31, 2010 was $6.0 million, or $0.22 per diluted share, compared to net income of $3.9 million, or $0.17 per diluted share, for the same period in 2009. Total revenues for the three months ended December 31, 2010 were $1.1 million compared to $10.2 million for the same period in 2009. Research and development expenses for the three months ended December 31, 2010 totaled $4.9 million compared to $4.4 million for the same period in 2009. General and administrative expenses for the three months ended December 31, 2010 totaled $2.2 million compared to $2.1 million for the same period in 2009.

Full Year Results

Net loss for the year ended December 31, 2010 was $18.0 million, or $0.71 per diluted share, compared to net income of $7.5 million, or $0.31 per diluted share, for 2009. Total revenues for the year ended December 31, 2010 were $16.1 million compared to $34.5 million for 2009. Research and development expenses for the year ended December 31, 2010 totaled $24.2 million compared to $18.6 million for 2009. General and administrative expenses for the year ended December 31, 2010 totaled $9.9 million compared to $8.6 million for 2009.

2010 Research and Development Highlights

IMO-2125 for Chronic Hepatitis C Virus (HCV) Infection

IMO-2125, a TLR9 agonist, is being developed as a novel immune modulator for the treatment of chronic HCV-infected patients as a potential alternative to recombinant interferon. Idera has completed two Phase 1 clinical trials of IMO-2125 and intends to initiate enrollment in a Phase 2 clinical trial early in the second quarter of 2011.

Phase 1 Clinical Trial in Null-Responder HCV Patients

- Idera has completed a four-week placebo-controlled Phase 1 clinical trial of IMO-2125 monotherapy in 58 null-responder HCV patients involving six treatment regimens. The most common treatment-related adverse events were flu-like symptoms that typically lasted less than one day and injection site reactions. IMO-2125 induced a broad immune response with dose-dependent increases in serum concentrations of antiviral proteins, including interferon-alpha, and activation of cellular immune responses. IMO-2125 treatment produced dose-dependent reductions in viral load during the treatment period.

  During 2010, Idera presented data from this trial at the Annual Meeting of the European Association for the Study of the Liver (EASL) and at the Annual Meeting of the American Association for the Study of Liver Diseases (AASLD).

Phase 1 Clinical Trial in Treatment-Naïve Genotype 1 HCV Patients

- Idera has completed a four-week comparator-controlled Phase 1 clinical trial of IMO-2125 plus ribavirin in 60 treatment-naïve genotype 1 HCV patients involving four dose regimens. Twelve patients received pegylated interferon plus ribavirin. In December 2010, Idera reported

preliminary data from the trial showing that IMO-2125 was well tolerated with no treatment-related serious adverse events and no treatment discontinuations. The most common adverse events observed with IMO-2125 treatment were flu-like symptoms and injection site reactions. Patients receiving IMO-2125 experienced limited to no thrombocytopenia or neutropenia compared to patients receiving pegylated interferon plus ribavirin. In the trial, IMO-2125 induced substantial declines in viral levels when measured two days after the first dose at all dose levels. At the mid-week evaluation in the fourth week of treatment, mean viral load reductions with the three higher-dose IMO-2125 regimens ranged from -2.0 to -3.4 $\log_{10}$. Patients who received pegylated interferon plus ribavirin achieved a mean viral load reduction of -3.8 $\log_{10}$ at the same timepoint.

The Company plans to present detailed results of the Phase 1 clinical trial in treatment-naïve HCV patients at the 2011 EASL meeting in April.

Phase 2 Clinical Trial in Treatment-Naïve Genotype 1 HCV Patients

- Idera plans to initiate enrollment in a 12-week Phase 2 randomized clinical trial in treatment-naïve genotype 1 HCV patients early in the second quarter of 2011. The Company expects that the Phase 2 trial of IMO-2125 will provide longer-term safety and antiviral data and determine optimal dosing. The results of this trial should provide the basis for subsequent clinical development of IMO-2125 as an alternative immune modulator to recombinant interferon in HCV treatment combinations using direct-acting antiviral agents.

IMO-3100 for Autoimmune and Inflammatory Diseases

IMO-3100, a dual antagonist of TLR7 and TLR9, is being developed as a novel approach to treat autoimmune and inflammatory diseases. IMO-3100 has shown activity in preclinical models of lupus, psoriasis, rheumatoid arthritis and hyperlipidemia. Idera has completed two Phase 1 clinical trials of IMO-3100 monotherapy in healthy subjects.

Phase 1 Single-Dose Clinical Trial in Healthy Subjects

- In January 2010, Idera initiated a Phase 1 placebo-controlled, single-dose, dose escalation clinical trial evaluating IMO-3100 in 36 healthy subjects in five dosage cohorts.

  In October 2010, data from this study were presented demonstrating that IMO-3100 was well tolerated at all dose levels evaluated, and target engagement of TLR7 and TLR9 was observed through inhibition of key cytokines, including TNF-a, IL-1B, and IL-6, mediated through TLR7 and TLR9.

Phase 1 Multiple-Dose Clinical Trial in Healthy Subjects

- In July 2010, Idera initiated a Phase 1 four-week, placebo-controlled, multiple-dose clinical trial of IMO-3100 in 24 healthy subjects at two dose levels. There were no treatment-related discontinuations or serious adverse events.

  Idera plans to present data from this clinical trial at a scientific meeting in April 2011.

Next Steps in Clinical Development of IMO-3100

- The next step in the clinical development of IMO-3100 is intended to be a Phase 2 clinical trial in a selected autoimmune disease indication. As announced in October 2010, the Company is conducting nonclinical studies prior to initiation of the Phase 2 clinical trial. Idera expects to complete these ongoing nonclinical studies during the first half of 2011 and to submit a Phase 2 clinical trial protocol during the third quarter of 2011.

IMO-2134 for Respiratory Diseases

IMO-2134, a TLR9 agonist, was identified as a lead compound for development in asthma and allergy indications under Idera's collaboration arrangement with Novartis. During the collaboration, Novartis conducted a Phase 1 clinical trial of IMO-2134, also known as QAX935.

- In February 2010, upon the termination of our research collaboration and option agreement with Novartis, Idera regained development and commercialization rights to IMO-2134. Idera is evaluating the next steps in developing IMO-2134 in asthma and allergy indications.

IMO-4200 for Hematological Malignancies

IMO-4200, a dual agonist of TLR7 and TLR8, is a lead drug candidate Idera has selected for the treatment of hematological malignancies.

- In December 2010, Idera scientists presented data at the 52nd Annual American Society for Hematology Meeting showing that IMO-4200, when administered in combination with approved cancer therapy agents in preclinical lymphoma models, resulted in improved antitumor activity, increased survival compared to single-agent treatments, and immune activation consistent with the TLR7/TLR8 mechanism of action.

  The Company intends to outline a development program strategy and timeline for IMO-4200 in the treatment of hematological malignancies during the first half of 2011.

TLR3 Agonists

In October 2010, Idera introduced a novel class of double-stranded RNA-based compounds that act as specific TLR3 agonists. Idera's proprietary TLR3 agonists showed potent activity when used as a vaccine adjuvant in preclinical studies. Idera plans to expand preclinical evaluation of these compounds.

Partnered Programs

EMD 1201081 (IMO-2055) for Cancer Treatment

IMO-2055, a TLR9 agonist, is being developed by Merck KGaA as a novel immunotherapy for the treatment of cancer under an exclusive, worldwide license agreement established between Idera and Merck KGaA to research, develop and commercialize Idera's TLR9 agonists for the treatment of cancer, excluding cancer vaccines. Merck KGaA refers to IMO-2055 as EMD 1201081.

Merck KGaA is currently conducting four clinical trials of EMD 1201081 in combination with other cancer therapeutic agents:

- *Phase 2 Clinical Trial in Second-Line Patients with Recurrent or Metastatic Squamous Cell Carcinoma of the Head and Neck (SCCHN)evaluating EMD 1201081 in combination with Erbitux(R)*
- *Phase 1b Clinical Trial in First-Line Patients with Recurrent/MetastaticSCCHNevaluating EMD 1201081 in combination with Erbitux(R) and chemotherapy*
- *Phase 1b clinical trial in non-small cell lung cancer evaluating EMD 1201081 in combination with Tarceva(R) and Avastin(R)*
- *Phase 1b clinical trial in colorectal cancer evaluating EMD 1201081 in combination with Erbitux(R) and chemotherapy*

During 2010, Idera received milestone payments of $8.2 million in connection with initiation of the two SCCHN trials.

TLR7, 8 and 9 Agonists as Vaccine Adjuvants

Idera and Merck & Co., Inc. entered into an exclusive license and research collaboration agreement in December 2006 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. The research phase of the collaboration has concluded.

- During 2010, Merck scientists published a paper entitled "Synthesis and immunological activities of novel agonists of Toll-like receptor 9" in *Cellular Immunology*, March 2010 and made a presentation entitled "Novel TLR9 agonists combined with "alum" for use as vaccine

adjuvants" at the Keystone Symposia meeting on Innate Immunity in June 2010.

2010 Business Highlights

- In August 2010, Idera issued 4 million units, each unit consisting of one share of common stock and a warrant to purchase 0.40 of a share of common stock, in a registered direct offering resulting in net proceeds to the Company of $14.1 million.
- In 2010, the Company was issued 20 new U.S. and foreign patents related to its Immune Modulatory Oligonucleotide (IMO(R)) technologies. Presently, the Company's intellectual property portfolio contains over 500 patents and patent applications worldwide, including over 300 patents and patent applications covering the Company's IMO(R) technologies and more than 225 patents and patent applications owned or licensed by Idera covering other nucleic acid-based compounds and methods of their use.
- In 2010, Idera appointed two new members to its Board of Directors: Malcolm MacCoss, Ph.D., former Group Vice President for Chemical Research at the Schering-Plough Research Institute and former Vice President of Basic Chemistry and Drug Discovery Sciences at Merck & Co., and Eve Slater, M.D., F.A.C.C., former Senior Vice President for Worldwide Policy at Pfizer, Inc. and former Assistant Secretary for Health for the U.S. Department of Health and Human Services.

About Idera Pharmaceuticals, Inc.

Idera Pharmaceuticals develops drug candidates to treat infectious diseases, autoimmune and inflammatory diseases, cancer, and respiratory diseases, and for use as vaccine adjuvants. Our proprietary drug candidates are designed to modulate specific Toll-like Receptors, which are a family of immune system receptors that direct immune system responses. Our pioneering DNA and RNA chemistry expertise enables us to create drug candidates for internal development and generates opportunities for multiple collaborative alliances. For more information, visit www.iderapharma.com.

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 studies and 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 & Co, Inc., 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 Annual Report on Form 10-K for the year ended December 31, 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.

Idera Pharmaceuticals, Inc.
Condensed Statements of Operations
(In thousands, except per share data)

	Three Months Ended December 31,		Years Ended December 31,	
	2010	2009	2010	2009
	(Unaudited)			
Revenues	$ 1,058	$ 10,180	$ 16,110	$34,518
Operating Expenses				
Research & Development	4,893	4,391	24,226	18,570
General & Administrative	2,158	2,070	9,867	8,561
Total Operating Expenses	7,051	6,461	34,093	27,131
(Loss) Income from Operations	(5,993)	3,719	(17,983)	7,387
Other, net	(20)	(1)	20	115
(Loss) Income Before Income Taxes	(6,013)	3,718	(17,963)	7,502
Income Tax Benefit	-	214	-	44
Net (Loss) Income	$ (6,013)	$ 3,932	$(17,963)	$ 7,546

Basic Net (Loss) Income Per Common Share	$ (0.22)	$ 0.17	$ (0.71)	$ 0.32
Diluted Net (Loss) Income Per Common Share	$ (0.22)	$ 0.17	$ (0.71)	$ 0.31
Shares Used in Computing Basic Net (Loss) Income Per Common Share	27,587	23,452	25,139	23,420
Shares Used in Computing Diluted Net (Loss) Income Per Common Share	27,587	23,808	25,139	24,079

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

	At December 31,	
	2010	2009
Cash, Cash Equivalents & Investments	$34,643	$40,207
Receivables	2	4,497
Other Assets	2,236	2,935
Total Assets	$36,881	$47,639
Accounts Payable & Accrued Liabilities	$ 3,780	$ 2,369
Deferred Revenue	-	12,165
Stockholders' Equity	33,101	33,105
Total Liabilities & Stockholders' Equity	$36,881	$47,639

SOURCE: Idera Pharmaceuticals, Inc.

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