Idera Pharmaceuticals Reports First Quarter 2011 Financial Results

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CAMBRIDGE, Mass., May 05, 2011 (BUSINESS WIRE) --

Idera Pharmaceuticals, Inc. (Nasdaq: IDRA) today reported financial results for the quarter ended March 31, 2011. Idera is engaged in the discovery and development of DNA-and RNA-based drug candidates targeted to Toll-Like Receptors, or TLRs, to treat infectious diseases, autoimmune and inflammatory diseases, cancer, and respiratory diseases, and for use as vaccine adjuvants.

"In the first quarter of 2011, Idera presented clinical data from our proprietary programs in hepatitis C and autoimmune diseases and took steps to advance these programs toward Phase 2 development. We are finalizing the clinical development plan for IMO-3100 and expect to initiate a Phase 2 clinical trial in a selected autoimmune indication by the end of this year," said Sudhir Agrawal, D.Phil., Chairman and Chief Executive Officer. "We chose to delay the initiation of the Phase 2 clinical trial for IMO-2125 for hepatitis C as recently announced and we plan to determine our path forward following analysis of data from ongoing nonclinical toxicology studies of IMO-2125 which we anticipate will be available in the second half of the year."

Dr. Agrawal continued, "In addition to the progress in our clinical programs targeted to Toll-like Receptors, our research efforts have also continued to be productive. We recently published data from *in vitro* and *in vivo* studies of a novel class of compounds we call gene-silencing oligonucleotides, or GSOs, that demonstrated robust gene-silencing activity and systemic effect without the use of any delivery enhancement technology. We believe that GSOs provide Idera with a new platform for validating targets and for identifying new drug candidates."

Financial Results

As of March 31, 2011, cash, cash equivalents and investments totaled $28.3 million compared to $34.6 million at December 31, 2010.

First Quarter Results

Net loss for the three months ended March 31, 2011 was $6.8 million, or $0.25 per diluted share, compared to net loss of $1.9 million, or $0.08 per diluted share, for the same period in 2010. The Company recognized $8,000 in revenue for the three-month period ended March 31, 2011. Total revenues for the three-month period ended March 31, 2010 were $5.6 million . Research and development expenses totaled $4.6 million for each of the three-month periods ended March 31, 2011 and 2010. General and administrative expenses for the three-month period ended March 31, 2011 totaled $2.3 million compared to $2.7 million for the same period in 2010.

1Q 2011 Research and Development Highlights

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 in healthy subjects evaluating the safety and mechanism of action of IMO-3100. The first Phase 1 study was a single-dose, dose escalation study involving 36 healthy subjects at five IMO-3100 dose levels. The second Phase 1 study was a four-week, placebo-controlled, multiple-dose clinical trial of IMO-3100 in 24 healthy subjects using two IMO-3100 treatment regimens.

Phase 1 Clinical Data Presented

- Idera presented data from the Phase 1 multiple-dose clinical trial of IMO-3100 in a presentation entitled "IMO-3100, a novel toll-like receptor antagonist for autoimmune and inflammatory diseases: safety and pharmacodynamics in a multiple-dose Phase 1 clinical trial" at a Keystone meeting in April 2011. In the trial, IMO-3100 was well tolerated over the four weeks of treatment. There were no treatment-related discontinuations or serious adverse events.

  Suppression of multiple cytokines, including IFN-a, IL-6, MIP-1B, and IL-1Ra, mediated through TLR7 and TLR9 was observed in IMO-3100-treated subjects, when post-dose responses were compared to pre-dose responses in each subject. No consistent suppression of any cytokines was observed in placebo-treated subjects. Suppression of multiple cytokines was maintained in IMO-3100-treated subjects throughout the four-week treatment period, based on responses measured from the third day after the first dose through four or more days after the last dose.

  These results provide evidence that IMO-3100 suppressed TLR7- and TLR9-mediated

immune responses in the trial.

Next Steps in Clinical Development of IMO-3100

- The next step in the clinical development of IMO-3100 is a Phase 2 clinical trial in a selected autoimmune disease indication. The Company expects to complete ongoing nonclinical toxicology studies of IMO-3100 during the second quarter of 2011 and to submit to the FDA a protocol for a Phase 2 clinical trial of IMO-3100 in a selected autoimmune disease indication during the third quarter of 2011 that it anticipates initiating by the end of 2011.

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

IMO-2125, a TLR9 agonist, is a novel immune modulator being developed as a potential alternative to recombinant interferon in the treatment of chronic HCV-infected patients.

Idera has completed two Phase 1 clinical trials of IMO-2125. The first Phase 1 clinical trial evaluated IMO-2125 monotherapy for four weeks in 58 null-responder patients using six IMO-2125 treatment regimens. The second Phase 1 clinical trial evaluated IMO-2125 in combination with ribavirin for four weeks in 63 treatment-naïve patients using four IMO-2125 treatment regimens.

Phase 1 Clinical Data Presented

- The Company presented detailed results of the Phase 1 clinical trial in treatment-naïve genotype 1 HCV patients in a presentation entitled "IMO-2125 plus ribavirin gives substantial first-dose viral load reductions, cumulative antiviral effect, is well tolerated in naïve genotype 1 HCV patients: a Phase 1 trial" at the 2011 EASL meeting in April 2011. In the trial, IMO-2125 was well tolerated with no treatment-related serious adverse events and no treatment discontinuations. Patients receiving IMO-2125 experienced limited to no thrombocytopenia or neutropenia compared to patients receiving pegylated interferon plus ribavirin in the trial. 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 treatment regimens ranged from -2.0 to -3.4 $\log_{10}$. Patients who received pegylated interferon plus ribavirin in the trial achieved a mean viral load reduction of -3.8 $\log_{10}$ at the same timepoint.

Next steps in Clinical Development of IMO-2125

- The planned next step in the clinical development of IMO-2125 was a 12-week Phase 2 clinical trial in treatment-naïve genotype 1 HCV-infected patients. As recently announced, Idera has chosen to delay the initiation of the Phase 2 clinical trial of IMO-2125 plus ribavirin based on preliminary observations in an ongoing chronic nonclinical toxicology study of IMO-2125. The Company plans to determine its path forward after it evaluates all of the data from its chronic nonclinical toxicology studies of IMO-2125, which it expects will become available during the second half of 2011.

Gene-silencing Oligonucleotide (GSO) Technology

Idera's GSOs are single-stranded RNA or DNA constructs, with two exposed 3'-ends, that are complementary to targeted mRNA or miRNA sequences of therapeutic interest. GSOs provide Idera with a new technology platform for validating targets and for identifying new drug candidates.

- In April 2011, Idera announced a publication on GSOs entitled "Novel Oligonucleotides Containing Two 3'-Ends complementary to Target mRNA Show Optimal Gene Silencing Activity" in the Journal of Medicinal Chemistry, 2011, 54, 1327-1336. In these studies, in cell-based assays and in mouse models, GSOs demonstrated length-dependent gene-silencing activity following systemic administration without the need for any delivery enhancement technology. Data from the studies showed that 19-mer GSOs demonstrated greater activity and a longer duration of activity against multiple targets including MyD88, VEGF, and TLR9 mRNAs, as compared to the traditional antisense compounds evaluated.

Idera is conducting preclinical studies of GSOs targeted to mRNA and miRNA and plans to report data from these studies during 2011.

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 is conducting clinical trials of IMO-2055, which Merck KGaA refers to as EMD 1201081, in combination with other cancer therapy agents in cancer indications including a Phase 2 clinical trial in squamous cell carcinoma of the head and neck.

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.

Additional Proprietary Programs

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 selected for the treatment of hematological malignancies. IMO-4200, when administered in combination with approved cancer therapy agents in preclinical lymphoma models, has shown improved antitumor activity and 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 second quarter 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. In April 2011, preclinical data were presented at the Fourth International Conference on Immunopotentiators in Modern Vaccines in a presentation entitled "Novel synthetic dsRNA-based TLR3 agonists enhance antigen-specific antibody and cellular immune responses to influenza vaccine". Idera plans to expand preclinical evaluation of these compounds.

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 the data from the IMO-2125 nonclinical toxicology studies will negatively impact the Company's ability or plans to proceed with development of IMO-2125; 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 Quarterly Report on Form 10-Q for the quarter ended March 31, 2011 which important factors are incorporated herein by reference. Idera disclaims any intention or obligation to update any forward-looking statements.

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

	Three Months Ended March 31,	
	2011	2010
	(Unaudited)	
Revenues	$ 8	$ 5,577

Operating Expenses		
Research & Development	4,553	4,586
General & Administrative	2,286	2,732
Total Operating Expenses	6,839	7,318
Loss from Operations	(6,831)	(1,741)
Other, net	(14)	(202)
Net Loss	$ (6,845)	$ (1,943)
Basic and Diluted Net Loss Per Common Share	$ (0.25)	$ (0.08)
Shares Used in Computing Basic and Diluted Net Loss Per Common Share	27,604	23,462

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

	At March 31, 2011	At December 31, 2010
	(Unaudited)	
Cash, Cash Equivalents & Investments	$ 28,346	$ 34,643
Other Assets	2,307	2,238
Total Assets	$ 30,653	$ 36,881
Accounts Payable & Accrued Liabilities	$ 3,704	$ 3,780
Stockholders' Equity	26,949	33,101
Total Liabilities & Stockholders' Equity	$ 30,653	$ 36,881

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