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

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CAMBRIDGE, Mass., May 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 (TLR), today reported financial results for the first quarter ended March 31, 2010.

"We are very encouraged by the interim clinical data with IMO-2125, a TLR9 agonist, in the difficult-to-treat null responder HCV patients. The data presented at EASL 2010 show that IMO-2125 monotherapy for four weeks was well tolerated and induced dose-dependent increases in natural interferon-alpha and other antiviral proteins. Consistent with the intended mechanism of action, levels of induced interferon-alpha correlated with reductions in HCV viral load. Our next objective is to initiate in the second half of 2010 a Phase 2 clinical trial with IMO-2125 in combination with ribavirin," said Sudhir Agrawal, D.Phil., Chief Executive Officer and Chief Scientific Officer. "We also are progressing the clinical development of IMO-3100, our lead antagonist drug candidate for the treatment of autoimmune diseases. Following evaluation of safety and pharmacodynamic mechanism of action in healthy subjects, we expect to identify an initial autoimmune disease indication by end of the year."

"We ended the first quarter of 2010 with $37.6 million in cash, cash equivalents, and investments. With cash used in operations for the first quarter of $2.5 million, we believe we have the financial resources to meet key objectives for this year," commented Lou Arcudi, Chief Financial Officer.

First Quarter 2010 Results

The Company reported a net loss of $1.9 million, or $0.08 per share, for the three months ended March 31, 2010, compared to a net loss of $0.3 million, or $0.01 per share, for the same period in 2009.

Total revenues for the three months ended March 31, 2010 were $5.6 million compared to $6.3 million for the same period in 2009.

Research and development expenses for the three months ended March 31, 2010 totaled $4.6 million compared to $4.5 million for the same period in 2009.

General and administrative expenses for the three months ended March 31, 2010 totaled $2.7 million compared to $2.1 million for the same period in 2009.

As of March 31, 2010, cash, cash equivalents and investments totaled approximately $37.6 million compared to $40.2 million at December 31, 2009.

Clinical and Preclinical Programs

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

- Phase 2 Clinical Trial of EMD 1201081 in Squamous Cell Carcinoma of the Head and Neck (SCCHN)

In December 2009, Merck KGaA, Darmstadt, Germany, initiated a Phase 2 clinical trial of EMD 1201081 in patients with recurrent or metastatic SCCHN. The study is designed to enroll 104 adult patients who have had disease progression on a first-line cytotoxic chemotherapy regimen. Enrolled patients will be randomized to receive Erbitux(R) alone or Erbitux combined with EMD 1201081. The primary endpoint of the trial is progression-free survival time of patients treated with EMD 1201081 plus Erbitux compared to Erbitux alone.

- Phase 1b Clinical Trial of EMD 1201081 in Combination with Tarceva(R) and Avastin(R) in Non-small Cell Lung Cancer (NSCLC)

In this ongoing Phase 1b clinical trial, EMD 1201081 is being evaluated in combination with Tarceva and Avastin in patients with NSCLC who had progressed during previous therapy.

- Phase 1b Clinical Trial of EMD 1201081 in Combination with Erbitux and Chemotherapy in Colorectal Cancer (CRC)

In this ongoing Phase 1b clinical trial, EMD 1201081 is being evaluated in combination with Erbitux and chemotherapy in patients with CRC who had progressed during previous therapy.

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

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

In April, during the 45th Annual Meeting of the European Association for the Study of the Liver, the Company presented positive interim data through the originally planned four cohorts of this clinical trial. Null responder HCV patients, who had no response to a prior regimen of the current standard of care for chronic HCV infection, received IMO-2125 or placebo treatment once per week for four weeks. IMO-2125 was well tolerated by all patients in the four cohorts, with no discontinuations due to drug-related adverse events. All adverse events were of short duration, mild to moderate grade, and consistent with the intended mechanism of action for IMO-2125, being related to either injection site reactions or "flu-like" symptoms. The presentation included results at four dose levels of IMO-2125, 0.04, 0.08, 0.16, and 0.32 mg/kg. Highlights of the interim data are as follows:

- IMO-2125-treated patients showed dose-dependent increases in natural interferon-alpha and other antiviral proteins, consistent with the intended mechanism of action of IMO-2125. At increasing dose levels, interferon-alpha responses were both more frequent and of greater magnitude.
- At dose levels of 0.08 to 0.32 mg/kg/week, an increasing percentage of patients achieved maximum reduction in viral load of 1 log10 or more at least once during the treatment period as shown in the following table.

Dosage (mg/kg/wk)	N	Pts with greater-than or equal to 1 log10 decrease in HCV RNA	Mean maximum log10 reduction in HCV RNA	Range of decreases greater-than or equal to 1 log10
Placebo	8	0/8	-0.4	NA
0.04	8	0/8	-0.5	NA
0.08	9	4/9	-1.1	-1.1 to -2.3
0.16	8	5/8	-1.2	-1.2 to -2.0
0.32	8	6/8	-1.7*	-1.0 to -3.5

*p<0.001 compared to placebo

- Serum concentrations of natural interferon-alpha induced by IMO-2125 treatment correlated with reductions in HCV RNA viral titers.

At present, recruitment is continuing at the IMO-2125 dosage of 0.48 mg/kg/week. The Company also intends to evaluate twice-weekly administration of IMO-2125 in null responder HCV patients. In addition, during the second half of 2010, the Company plans to initiate a Phase 2 clinical trial of IMO-2125 administered in combination with ribavirin for 12 weeks.

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

In this clinical trial, patients receive IMO-2125 by subcutaneous injection once per week for four weeks at escalating dose levels in combination with daily oral administration of standard doses of ribavirin. The primary objective of the trial is to assess the safety and tolerability of IMO-2125 in combination with standard doses of ribavirin. In addition, this trial is designed to monitor the effect of treatment on HCV viral load. The clinical trial is currently being conducted at sites in France and Russia.

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

- Phase 1 Clinical Trial with IMO-3100 in Healthy Subjects

In January 2010, the Company initiated a single-dose, dose-escalation Phase 1 clinical trial of IMO-3100 in healthy subjects. In this trial, IMO-3100 is being administered by subcutaneous injection, with the primary objective being the evaluation of safety and tolerability. Secondary objectives are to characterize the blood levels of IMO-3100 and to assess the pharmacodynamic mechanism of action through the measurement of response of peripheral blood mononuclear cells to agonists of TLR7 and TLR9. The trial is being conducted at a single U.S. site.

The Company plans to use the results from this rising single-dose clinical trial to select dosages for an anticipated follow-up trial in healthy subjects, the purpose of which would be to characterize safety, blood levels, and pharmacodynamic mechanism of action of IMO-3100 with repeat-dose subcutaneous administration over four weeks. The Company intends to identify an initial autoimmune disease indication for further clinical development of IMO-3100 by the end of 2010.

IMO-2134, a TLR9 Agonist, for Respiratory Diseases

During our collaboration with Novartis International Pharmaceutical, Ltd., IMO-2134 was identified as a lead compound for development in asthma and allergy indications 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. The Company is currently evaluating the next steps in developing IMO-2134 for respiratory diseases.

TLR7, 8 and 9 Agonists as Vaccine Adjuvants (Collaboration with Merck Sharp & Dohme Corp., previously known as Merck & Co., Inc.)

In December 2006, the Company and Merck Sharp & Dohme Corp., which we refer 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.

Scientists from Merck and Idera co-authored two recent publications:

- "A TLR9 agonist enhances therapeutic effects of telomerase genetic vaccine" appeared in *Vaccine*, 2010.
- "Synthesis and immunological activities of novel agonists of Toll-like receptor 9" appeared in *Cell Immunology*, 2010.

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 antitumor activity of a dual agonist of TLR7 and TLR8 as monotherapy and in combination with selected targeted drugs currently approved for cancer treatment.

TLR Antisense

The Company has identified antisense compounds targeted to human TLRs 2, 3, 4, 5, 6, 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

- An oral presentation, entitled "A Phase 1, Multi-Center, Randomized, Placebo-controlled, Dose-escalation Study of IMO-2125, a TLR9 Agonist, in Hepatitis C Non-responders", was made by John McHutchison, M.D., Associate Director, Duke Clinical Research Institute and Director, Gastroenterology and Hepatology Research, Duke University Medical Center, and Principal Investigator for this trial, at the 45th Annual Meeting of the European Association for the Study of the Liver (EASL) held April 14-18, 2010, in Vienna, Austria.
- A presentation, entitled "IMO-2125, an agonist of TLR9 that induces endogenous IFN-alpha, upregulates broader range of gene expression profiles compared to exogenously added IFN-alpha in human PBMCs" was made by Idera scientists at the 45th Annual Meeting of the EASL.
- A presentation, entitled "A novel antagonist of TLR7 and TLR9 exerts anti- atherogenic effects in ApoE-/- mouse model of atherosclerosis" was made by Idera scientists at the American Heart Association conference "Arteriosclerosis, Thrombosis and Vascular Biology 2010 Scientific Sessions" held April 8-10, 2010, in San Francisco, CA.
- A presentation, entitled "IMO-3100, a novel antagonist, suppresses TLR7- and TLR9-mediated immune responses in non-human primates" was made by Idera scientists at the Keystone Symposia conference "Tolerance and Autoimmunity" held February 21-26, 2010, in Taos, New Mexico.
- A presentation, entitled "Control of atherogenic lipids by a novel antagonist of TLR7 and 9 in mouse models of hyperlipidemic disease" was made by Idera scientists at the Keystone Symposia conference "Advances in Molecular Mechanisms of Atherosclerosis" held February 12-17, 2010, in Banff, Alberta, Canada.

Publications

- A paper entitled "Peptide conjugation at the 5'-end of oligodeoxynucleotides abrogates Toll-like receptor 9-mediated immune stimulatory activity" appeared in *Bioconjugate Chemistry*, 2010.
- A paper entitled "Impact of nature and length of linker incorporated in agonists on Toll-like receptor 9-mediated immune responses" appeared in *Journal of Medicinal Chemistry*, 2010.

Intellectual Property

The Company's intellectual property portfolio contains over 500 patents and patent applications worldwide. In February, the Company was again recognized by the Patent Board(TM) as one of the top 35 companies in the biotechnology field based on its technology and intellectual property advances. The Patent Board(TM) is an independent group that tracks and analyzes intellectual property and technology assets across 17 industries globally and publishes its results in the Wall Street Journal.

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

This portfolio holds over 300 patents and patent applications worldwide covering the Company's IMO technologies and includes claims covering novel agonists of TLRs 7, 8, and 9, and antagonists of TLR7 and TLR9. These patents and patent applications include claims covering IMO-2055, IMO-2125, IMO-2134, and IMO-3100. The following U.S. patent was issued during the first quarter:

- US 7,700,570, entitled "Oligonucleotide Mediated Specific Cytokine Induction and Reduction of Tumor Growth in a Mammal"

In addition to the issued U.S. patent, a patent corresponding to two issued US patents (US 6,815,429 and US 7,329,648) was granted to the Company during the first quarter, entitled "Modulation of Oligonucleotide CpG-mediated Immune Stimulation by Positional Modification of Nucleosides" in Japan (JP 4,443,810).

Antisense Technology

The Company's antisense technology portfolio includes 220 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). The following U.S. patent was issued during the first quarter:

- US 7,671,035, entitled "Epidermal Growth Factor Receptor Antisense Oligonucleotides"

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 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 March 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. The Patent Board is a trademark of The Patent Board.

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

	Three Months Ended March 31,	
	2010	2009
Alliance Revenue	$ 5,577	$ 6,303
Operating Expenses		
Research & Development	4,586	4,478
General & Administrative	2,732	2,148
Total Operating Expenses	7,318	6,626
Loss from Operations	(1,741)	(323)
Other, net	(202)	71
Net Loss	$ (1,943)	$ (252)
Basic and Diluted Net Loss Per Common Share	$ (0.08)	$ (0.01)
Shares Used In Computing Basic and Diluted Net Loss Per Common Share	23,462	23,379

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

	March 31, 2010 (unaudited)	December 31, 2009
Cash, Cash Equivalents & Investments	$ 37,646	$ 40,207
Receivables	42	4,497
Other Assets	4,434	2,935
Total Assets	$ 42,122	$ 47,639
Accounts Payable & Accrued Liabilities	$ 3,096	$ 2,369
Deferred Revenue	6,618	12,165
Stockholders' Equity	32,408	33,105
Total Liabilities & Stockholders' Equity	$ 42,122	$ 47,639

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