Idera Pharmaceuticals Reports Fourth Quarter and Full Year 2009 Financial Results

March 10, 2010 12:11 PM EST

CAMBRIDGE, Mass., Mar 10, 2010 (BUSINESS WIRE) -- Idera Pharmaceuticals, Inc. (Nasdaq: IDRA) today reported financial results for the fourth quarter and full year ended December 31, 2009.

"We met our 2009 key objectives of advancing our Toll-like Receptor-targeted drug candidates and expanding our pipeline with the addition of IMO-3100, a TLR antagonist for potential application in autoimmune diseases," said Sudhir Agrawal, D.Phil., Chief Executive Officer and Chief Scientific Officer. "Our objectives this year are to progress clinical studies of our proprietary compounds IMO-3100 and IMO-2125, with a focus on null responder HCV-infected patients, and to support our partnered programs in oncology and vaccine adjuvants."

"We ended the year with approximately $40.2 million in cash, cash equivalents, and investments as compared to $55.6 million at the end of 2008. We have prudently managed our cash, with net cash used in operations totaling$15.6 million in 2009, and are in a strong financial position to continue the advancement of our drug candidate pipeline during 2010," commented Lou Arcudi, Chief Financial Officer.

Financial Results

As of December 31, 2009, cash, cash equivalents and investments totaled $40.2 million compared to $55.6 million at December 31, 2008. Additionally, in December 2009 the Company earned a milestone payment of EUR 3.0 million from Merck KGaA and recognized this milestone payment as revenue in 2009. The Company received $4.1 million in payment of this milestone in the first quarter of 2010 which is not included in December 31, 2009 cash.

Fourth Quarter Results

Net income for the three months ended December 31, 2009 was $3.9 million, or $0.17 per diluted share, compared to net income of $0.4 million, or $0.01 per diluted share, for the same period in 2008.

Total revenues for the three months ended December 31, 2009 were $10.2 million compared to $6.3 million for the same period in 2008.

Research and development expenses for the three months ended December 31, 2009 totaled $4.4 million compared to $4.3 million for the same period in 2008.

General and administrative expenses for the three months ended December 31, 2009 totaled $2.1 million compared to $1.8 million for the same period in 2008.

Full Year Results

Net income for the year ended December 31, 2009, was $7.5 million, or $0.31 per diluted share, compared to net income of $1.5 million, or $0.06 per diluted share, for 2008.

Total revenues for the year ended December 31, 2009 were $34.5 million compared to $26.5 million for 2008.

Research and development expenses for the year ended December 31, 2009 totaled $18.6 million compared to $16.2 million for 2008.

General and administrative expenses for the year ended December 31, 2009 totaled $8.6 million compared to $9.8 million for 2008.

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

In December 2009, Merck KGaA initiated a Phase 2 clinical trial of EMD 1201081, also known as IMO-2055, in patients with recurrent or metastatic squamous cell carcinoma of the head and neck. The Company achieved a milestone under its agreement with Merck KGaA related to this trial initiation and received a milestone payment of EUR 3.0 million (approximately $4.1 million) from Merck KGaA in the first quarter of 2010.

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

In September 2009, the Company presented preliminary data from a Phase 1b clinical trial evaluating EMD 1201081 in combination with Tarceva and Avastin in patients with NSCLC that had progressed during previous therapy. EMD 1201081 was well tolerated at dosages up to 0.48 mg/kg/week in combination with Tarceva plus Avastin. Eight of 16 patients in the dose-escalation portion of the trial remained on treatment at least 18 weeks. Of the 13 patients evaluable for disease status, three had a partial response and eight experienced stable disease.

Subsequent to the preliminary data presented in September 2009, Merck KGaA recruited patients for an expanded cohort at the anticipated recommended phase 2 dose level for EMD 1201081 in combination with Tarceva and Avastin.

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

In January 2009, dosing of patients was initiated in a Phase 1b clinical trial evaluating EMD 1201081 in combination with Erbitux and chemotherapy in patients with CRC that had progressed during previous therapy. EMD 1201081 is being evaluated at three escalating dose levels in combination with standard dose regimens of Erbitux and chemotherapy to evaluate the safety of the combination and to determine the recommended dosage of IMO-2055 for potential use in a subsequent Phase 2 clinical trial.

As of March 2010, Merck KGaA has assumed responsibility for all current and future clinical trials in the development of EMD 1201081 for the treatment of cancer, excluding vaccines.

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 December 2009, the Company announced interim results from a Phase 1 clinical trial of IMO-2125 in null responder HCV patients treated through the first four cohorts of the trial. The Company defines null responder HCV patients as patients who have failed to achieve a 2 log10 reduction in viral load during previous 12 to 24 weeks of treatment with pegylated recombinant interferon-alpha plus ribavirin. IMO-2125 was well tolerated by all patients in the four cohorts at dosages of 0.04, 0.08, 0.16, and 0.32 mg/kg/week. IMO-2125-treated patients showed dose-dependent increases in natural interferon-alpha and other antiviral proteins. In addition, an increasing percentage of patients, ranging from 40% at the 0.08 mg/kg/week dose level to 75% at the 0.32 mg/kg/week dose level, achieved a maximum reduction in viral load of 1 log10 or more at least once during the four-week treatment period. In contrast, none of the patients who received placebo treatment or IMO-2125 at the 0.04-mg/kg/week dose level achieved a maximum reduction in viral load of 1 log10 or greater at any time during the four-week treatment period. The Company plans to present detailed interim results of the trial at a scientific meeting in the second quarter of 2010.

Based on the interim data, the Company extended the trial and is currently recruiting patients in a fifth cohort at 0.48 mg/kg/week.

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

In October 2009, the Company announced initiation of a Phase 1 clinical trial to assess the safety of IMO-2125 in combination with ribavirin in treatment-naïve patients with chronic HCV infection. A total of 15 patients are planned for the first cohort, with 12 randomized to receive IMO-2125 and ribavirin and three randomized to receive placebo and ribavirin. Starting with the second cohort, 12 patients will be randomized to receive IMO-2125 and ribavirin and six patients will be randomized to receive pegylated recombinant alfa-2a interferon and ribavirin as the control. The primary objective of the trial is to assess the safety and tolerability of IMO-2125 in combination with ribavirin. In addition, the Company plans to monitor the effect of treatment on HCV RNA levels.

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

- Phase 1 Clinical Trial with IMO-3100

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 to healthy subjects, with the primary objective being the evaluation of safety and tolerability. Secondary objectives are to characterize the pharmacokinetic profile of IMO-3100 and to assess the pharmacodynamic mechanism of action through measurement of the *ex vivo* response of peripheral blood mononuclear cells to TLR7 and TLR9 agonists. The trial is being conducted at a single U.S. site.

The Company plans to use the results from this rising single-dose trial to select dosages for an anticipated follow-up trial in healthy subjects, the purpose of which would be to characterize safety, pharmacokinetics, and *ex vivo* pharmacodynamic mechanism of action with weekly subcutaneous administration for 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, 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 all 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 & Co., Inc.)

In December 2006, the Company and Merck & Co. Inc. 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 two-year 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, including our research and development activities under the collaboration.

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

During 2009 and to date in 2010, Company scientists and collaborators have published and presented on the following studies:

IMO-2125, TLR9 Agonist

- A presentation entitled "IMO-2125, a TLR9 agonist, induces Th-1 type cytokines and interferons with potent anti-HCV activity in human peripheral blood mononuclear cells (PBMCs) and plasmacytoid dendritic cells (pDCs)" was made at the 60th Annual Meeting of the American Association for the Study of Liver Diseases (AASLD) in November 2009.
- A presentation entitled "Gene expression profiles induced by IMO-2125, an agonist of Toll-like receptor 9, in human peripheral blood mononuclear cells" was made at the 60th Annual Meeting of the AASLD in November 2009.

IMO-2055 (EMD 1201081), TLR9 Agonist

- A paper entitled "A novel Toll-like Receptor 9 (TLR9) agonist cooperates with trastuzumab in trastuzumab-resistant breast tumors via multiple mechanisms of action" was published in *Clin. Cancer Res.*, 2009, 15:6921-6930.
- A presentation entitled "Toll-like receptor 9 (TLR9) interacts with ErbB receptors at membrane level and a TLR9 agonist synergizes with trastuzumab in trastuzumab-resistant breast cancer xenografts via modulation of ErbB signaling" was made at the 2009 Annual Meeting of the American Association for Cancer Research (AACR) in April 2009.
- A presentation entitled "Phase 1 study of the toll-like receptor 9 (TLR9) agonist, IMO-2055, combined with erlotinib (E) and bevacizumab (B) in patients (pts) with advanced or metastatic non-small cell lung cancer (NSCLC)" was made at the joint 15th Congress of the European Cancer Organisation and 34th Congress of the European Society for Medical Oncology in September 2009.
- A presentation entitled "A novel drug Toll-like receptor 9 (TLR9) agonist synergizes with trastuzumab in different trastuzumab-resistant breast tumours via multiple mechanisms of action" was made at the joint 15th Congress of the European Cancer Organisation and 34th Congress of the European Society for Medical Oncology in September 2009.
- A presentation entitled "A phase 2 multicenter, randomized, open-label study of two dose levels of IMO-2055 in patients with metastatic or recurrent renal cell carcinoma" was made at the Eighth International Kidney Cancer Symposium in September 2009.

IMO-3100 and Antagonists of TLR7 and 9

- A paper entitled "Oligodeoxyribonucleotide-based antagonists for Toll-like receptors 7 and 9" was published in *J. Med. Chem.*, 2009, 52:551-558.
- A paper entitled "Modifications incorporated in CpG motifs of oligodeoxynucleotides lead to antagonist activity of Toll-like receptors 7 and 9" was published in *J. Med. Chem.,* 2009, 52:5108-5114.
- A presentation entitled "IMO-3100, an antagonist of Toll-like receptors 7 and 9, modulates

gene expression and regulatory networks induced by ligands" was made at the 2009 Annual Meeting of The American Association of Immunologists in May 2009.

- A presentation entitled "Antagonists of Toll-like receptors 7 and 9 and potential application for treatment of rheumatoid arthritis" was made at the Fall 2009 National Meeting of the American Chemical Society in August 2009.
- A presentation entitled "Studies of combination of IMO-3100, an antagonist of TLR7 and TLR9, and Etanercept, a TNF-alpha inhibitor, in a mouse model of collagen-induced arthritis (CIA)" was made at the 2009 Annual Scientific Meeting of the American College of Rheumatology (ACR) and Association of Rheumatology Health Professionals (ARHP) in October 2009.
- A presentation entitled "Modulation of TLR7 and TLR8 activation in human macrophages" was made at the 2009 Annual Scientific Meeting of the ACR and ARHP in October 2009.
- A presentation entitled "Control of atherogenic lipids by a novel antagonist of TLR7 and 9 in mouse models of hyperlipidemic disease" was made at the Keystone Symposia Conference on Advances in Molecular Mechanisms of Atherosclerosis in February 2010.
- A presentation entitled "IMO-3100, a novel antagonist, suppresses TLR7- and TLR9-mediated immune responses in non-human primates" was made at the Keystone Symposia Conference on Tolerance and Autoimmunity in February 2010.

TLR7, 8, and 9 Agonists as Vaccine Adjuvants

- A paper entitled "Treatment of mammary carcinomas in HER-2 transgenic mice through combination of genetic vaccine and an agonist of Toll-like receptor 9" was published in *Clin. Cancer Res.*, 2009, 15:1575-1584.
- A paper entitled "Co-administration of telomerase genetic vaccine and a novel TLR9 agonist in nonhuman primates" was published in *Mol. Ther.*, 2009, 17:1804-1813.
- A presentation entitled "Strategies and challenges for discovery and development of novel vaccine adjuvants" was made at Modern Vaccine Adjuvants and Delivery Systems in October 2009.
- A presentation entitled "In vitro and in vivo characterization of novel TLR9 agonists for use as vaccine adjuvants" was made at the Cold Spring Harbor Symposium on Harnessing Immunity to Prevent and Treat Disease in November 2009.
- A presentation entitled "In vitro and in vivo characterization of novel TLR9 agonists for use as vaccine adjuvants" was made at Vaccines Europe Conference in November 2009.

TLR7, 8, and 7/8 Agonists

- A paper entitled "Synthetic oligoribonucleotides-containing secondary structures act as agonists of Toll-like receptors 7 and 8" was published in *Biochem. Biophys. Res. Commun.,* 2009, 386:443-448.
- A paper entitled "Synthetic oligoribonucleotides containing arabinonucleotides act as agonists of TLR7 and 8" was published in *Bioorg. Med. Chem. Lett.,* 2009, 19:2044-2047.
- A paper entitled "Toll-like Receptor 7 Selective Synthetic Oligoribonucleotide Agonists: Synthesis and Structure-Activity Relationship Studies" was published in *J. Med. Chem.*, 2009, 52, 6871-6879.

- A presentation entitled "Antitumor activity of a novel dual agonist of TLR7 and TLR8 in a preclinical model of 3LL-C75 lung carcinoma in wild type, TLR7$^{-/-}$, TLR9$^{-/-}$, and MyD88$^{-/-}$ mice" was made at the 2009 Annual Meeting of the AACR in April 2009.
- A presentation entitled "Antitumor activity of a dual agonist of TLR7 and TLR8 in combination with bevacizumab in preclinical models of human non-small cell lung and colon cancers" was made at the 2009 Annual Meeting of the AACR in April 2009.

Antisense - Related

- A presentation entitled "Modulation of Toll-like receptors 7 and 9 expression with antisense for potential applications in autoimmune and inflammatory diseases" was made at the 2009 Annual Meeting of the Federation of Clinical Immunology Societies (FOCIS) in June 2009.
- A presentation entitled "Studies of Toll-like receptors 7 and 9 antisense in a preclinical model of colitis" was made at the 2009 Annual Meeting of FOCIS in June 2009.
- A presentation entitled "Modulation of Toll-like receptor 3 expression with antisense" was made at the 2009 Annual Meeting of FOCIS in June 2009.

Intellectual Property

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

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

In 2009, the Company's U.S. and foreign patents and patent applications covering the Company's TLR-targeted technologies increased by over 30 and now total 271. The following U.S. patents were issued to the Company in 2009:

- US 7,632,822, entitled "Modulation Of Immunostimulatory Properties Of Oligonucleotide-Based Compounds By Utilizing Modified Immunostimulatory Dinucleotides"
- US 7,595,305, entitled "Modulation Of Immunostimulatory Properties Of Oligonucleotide-Based Compounds By Utilizing Modified Immunostimulatory Dinucleotides"
- US 7,569,554, entitled "Synergistic Treatment of Cancer Using Immunomers in Conjunction with Chemotherapeutic Agents"
- US 7,566,702, entitled "Immunostimulatory Oligonucleotide Multimers"
- US 7,517,862, entitled "Modulation of Immunostimulatory Properties of Oligonucleotide-based Compounds by Optimal Presentation of 5' Ends"
- US 7,498,426, entitled "Immunostimulatory Oligonucleotide Multimers"
- US 7,498,425, entitled "Immunostimulatory Oligonucleotide Multimers"
- US 7,470,674, entitled "Immunostimulatory Properties of Oligonucleotide-based Compounds Comprising Modified Immunostimulatory Dinucleotides"

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).

Additionally, in 2009 and early 2010, the Company was recognized three times 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.

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 an affiliate of 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, 2009, 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. Enbrel is a registered trademark of Amgen and Wyeth Pharmaceuticals. The Patent Board is a trademark of The Patent Board.

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

	Three Months Ended December 31,		Years Ended December 31,	
	2009	2008	2009	2008
	(Unaudited)			
Revenues	$ 10,180	$ 6,274	$34,518	$26,450
Operating Expenses				
Research & Development	4,391	4,286	18,570	16,152
General & Administrative	2,070	1,805	8,561	9,798
Total Operating Expenses	6,461	6,091	27,131	25,950
Income from Operations	3,719	183	7,387	500
Other, net	(1)	157	115	985
Income Before Income Taxes	3,718	340	7,502	1,485
Income Tax Benefit	214	24	44	24
Net Income	$ 3,932	$ 364	$ 7,546	$ 1,509
Basic Net Income Per Common Share	$ 0.17	$ 0.02	$ 0.32	$ 0.07
Diluted Net Income Per Common Share	$ 0.17	$ 0.01	$ 0.31	$ 0.06
Shares Used in Computing Basic Income Per Common Share	23,452	23,331	23,420	22,655
Shares Used in Computing Diluted Income Per Common Share	23,808	24,822	24,079	25,331

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

	At December 31,	
	2009	2008
Cash, Cash Equivalents & Investments	$40,207	$55,606
Receivables	4,497	474
Other Assets	2,935	3,320
Total Assets	$47,639	$59,400
Accounts Payable & Accrued Liabilities	$ 2,369	$ 2,773
Deferred Revenue	12,165	34,460
Stockholders' Equity	33,105	22,167
Total Liabilities & Stockholders' Equity	$47,639	$59,400

SOURCE: Idera Pharmaceuticals, Inc.

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