



Idera Pharmaceuticals Reports Third Quarter 2009 Financial Results and Provides Pipeline Update

November 5, 2009 12:06 PM EST

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Nov. 5, 2009-- Idera Pharmaceuticals, Inc. (Nasdaq: IDRA) today reported financial results for the third quarter and nine months ended September 30, 2009.

"We have continued development of our pipeline of drug candidates targeted to Toll-like receptors for potential applications in chronic hepatitis C virus infection and autoimmune diseases, and to support our partnered programs in oncology, respiratory disease, and vaccine adjuvants," said Sudhir Agrawal, D. Phil., President, Chief Executive Officer and Chief Scientific Officer. "We are pleased to have presented clinical data of IMO-2055 in renal cell cancer and in non-small cell lung cancer. We look forward to presenting data from our ongoing clinical trials of IMO-2125 in HCV patients."

"With \$46.1 million in cash, cash equivalents and investments at the end of the third quarter 2009, we are in a strong financial position to continue advancing our clinical and preclinical programs. Due to the receipt of milestone and other payments from our partnered programs, our cash, cash equivalents and investments have decreased by only \$9.5 million for the nine months ended September 30, 2009," added Lou Arcudi, Chief Financial Officer.

Third Quarter and Nine-Month 2009 Results

The Company reported net income of \$24,000 for the three months ended September 30, 2009, compared to a net income of \$2.0 million, or \$0.08 per diluted share, for the same period in 2008. For the nine-month period, the Company's net income was \$3.6 million, or \$0.15 per diluted share, compared to a net income of \$1.1 million, or \$0.04 per diluted share, for the same period in 2008.

Total revenues for the three months ended September 30, 2009 were \$6.5 million compared to \$7.5 million for the same period in 2008. For the nine-month period, revenues totaled \$24.3 million compared to \$20.2 million for the same period in 2008.

Research and development expenses for the three months ended September 30, 2009 totaled \$4.3 million compared to \$3.6 million for the same period in 2008. For the nine-month period, R&D expenses totaled \$14.2 million compared to \$11.9 million for the same period in 2008.

General and administrative expenses for the three months ended September 30, 2009 were \$2.2 million compared to \$2.3 million for the same period in 2008. For the nine-month period, G&A expenses totaled \$6.5 million compared to \$8.0 million for the same period in 2008.

As of September 30, 2009, cash, cash equivalents and investments totaled \$46.1 million compared to \$55.6 million at December 31, 2008.

Clinical and Preclinical Programs

IMO-2055, a TLR9 agonist, in Cancer Treatment (collaboration with Merck KGaA)

- **Phase 2 Clinical Trial of IMO-2055 in Renal Cell Carcinoma (RCC)**

In September 2009, the Company presented final data from a clinical trial evaluating IMO-2055 as monotherapy in an open-label phase 2 clinical trial. Treatment-naïve and second-line patients with RCC were randomly assigned to receive IMO-2055 subcutaneously at 0.16 mg/kg/week or 0.64 mg/kg/week. Eighty-nine patients were evaluable for efficacy (intent-to-treat population).

Based on the final data analysis:

- Progression-free survival (PFS) medians for treatment-naïve patients were 4.5 months at 0.16 mg/kg/week and 1.9 months at 0.64 mg/kg/week.
- PFS medians for second-line patients were 3.4 months at 0.16 mg/kg/week and 4.3 months at 0.64 mg/kg/week.
- Median overall survival was 23.5 months overall, although medians were not estimable in 2 of the 4 treatment groups.
- 7 patients received weekly IMO-2055 treatment for at least 1 year.
- 2 patients (1 second-line and 1 treatment-naïve), each receiving 0.64 mg/kg/week, had confirmed partial responses.
- 52 patients (58%) across all groups had stable disease.
- IMO-2055 treatment was generally well-tolerated: neither dosage was associated with

any dose-limiting toxicity, although the relative dose intensity was higher with the 0.16 mg/kg dosage.

- The most common treatment-related adverse events (any grade across groups) were fatigue (51%), nausea (46%), chills (45%), headache (37%), and pyrexia (33%), consistent with IMO-2055-related immune stimulation.
- Phase 1b Clinical Trial of IMO-2055 in Combination with Tarceva[®] and Avastin[®] in Non-small Cell Lung Cancer (NSCLC)

In September 2009, the Company presented interim data from a phase 1b, single arm clinical trial evaluating IMO-2055 in combination with Tarceva and Avastin in patients with NSCLC. Interim data presented show:

- IMO-2055 was tolerated at dosages up to 0.48 mg/kg/week in combination with Tarceva plus Avastin.
- The most common possibly-related adverse events were injection site reactions, fatigue and fever.
- Six grade 3 adverse events were reported: injection site reactions (2), diarrhea (2), fatigue (1) and low potassium (1).
- 8 of 16 patients remained on treatment at least 18 weeks.
- Of the 13 evaluable patients, 3 had a partial response and 8 experienced stable disease.

Recruitment of additional patients is continuing at the anticipated recommended phase 2 dose level for IMO-2055 in this combination.

- Phase 1b Clinical Trial of IMO-2055 in Combination with Erbitux[®] and Camptosar[®] in Colorectal Cancer

Patient recruitment is ongoing with three escalating dose levels of IMO-2055 being investigated in combination with standard dose regimens of Erbitux and Camptosar to evaluate the safety of the combination.

In September 2009, Merck KGaA assumed sponsorship of the ongoing Phase 1b clinical trials of IMO-2055 in non-small cell lung cancer and in colorectal cancer, and responsibility for conducting all future clinical trials of IMO-2055 for the treatment of cancer, excluding use in vaccines.

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

- Phase 1 Clinical Trial with IMO-2125 Monotherapy in Chronic HCV Infection in Patients Non-responsive to Standard of Care Therapy

The Company expects to complete patient enrollment in the fourth cohort of this trial by the end of 2009 and to announce interim data during the first quarter of 2010.

- 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. The Company plans to enroll approximately 45 patients in three cohorts at escalating IMO-2125 dose levels, with four weeks of treatment. Of the 15 patients per cohort, 12 will be randomized to receive weekly IMO-2125 by subcutaneous administration and daily oral ribavirin, and three will be randomized to receive placebo and daily oral ribavirin. This clinical trial also is designed to evaluate the effects of IMO-2125 and ribavirin combination treatment on HCV RNA levels and on parameters of immune system activation. The Company is currently considering modifications to the trial design based on regulatory discussions. The Company intends to conduct the trial at five or more sites in France and Russia.

QAX935 (IMO-2134), a TLR9 agonist, in Asthma and Allergy (collaboration with Novartis)

- Phase 1 Clinical Trial with QAX935

In September 2008, Novartis initiated a Phase 1 clinical trial of QAX935.

IMO-3100, a dual antagonist of TLR7 and TLR9, in Autoimmune and Inflammatory Diseases

- **Investigational New Drug (IND)-Enabling Preclinical Development Studies of IMO-3100**

The Company is currently conducting IND-enabling preclinical development studies to support the clinical evaluation of IMO-3100 in autoimmune and inflammatory diseases. The Company anticipates submitting an IND application to the U.S. Food and Drug Administration by the end of 2009.

In October 2009, the Company presented preclinical data from studies of IMO-3100 in combination with Enbrel® (etanercept), an inhibitor of TNF-alpha, in a mouse model of arthritis. Mice treated with a combination of IMO-3100 and Enbrel had lower arthritic scores, less inflammation, and less bone pathology as compared to mice treated with either agent alone. The data also showed that the activity of a low Enbrel dosage was markedly enhanced when combined with IMO-3100 in this mouse model.

TLR7, 8 and 9 agonists as vaccine adjuvants (collaboration with Merck & Co., Inc.)

- The Company is collaborating with Merck & Co. under an agreement to research, develop, and commercialize vaccine products containing the Company's TLRs 7, 8, and 9 agonists in the fields of oncology, infectious diseases, and Alzheimer's disease.

TLR7 and TLR8 agonists

- The Company is studying its novel TLR7 and/or TLR8 agonists for potential applications in oncology and infectious diseases.

TLR Antisense

- The Company has identified antisense candidates 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 candidates for potential applications in autoimmune and inflammatory diseases.

Scientific Highlights

The Company and its collaborators recently have presented and published on the following studies:

Data Presentations

- Abstract P-9148 "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)" at the joint 15th Congress of the European CanCer Organisation and 34th Congress of the European Society for Medical Oncology held in September 2009. The presentation was made by David Smith, M.D., of US Oncology in Vancouver, WA.
- Abstract O-1000 "A novel drug Toll-like receptor 9 (TLR9) agonist synergizes with trastuzumab in different trastuzumab-resistant breast tumours via multiple mechanisms of action" at the joint 15th Congress of the European CanCer Organisation and 34th Congress of the European Society for Medical Oncology held in September 2009. The presentation was made by Giampaolo Tortora, M.D., of Università di Napoli Federico II in Naples, Italy.
- Abstract 9.148 "A phase 2 multicenter, randomized, open-label study of two dose levels of IMO-2055 in patients with metastatic or recurrent renal cell carcinoma" at the Eighth International Kidney Cancer Symposium held in Chicago, September 2009. The presentation was made by Timothy Kuzel, M.D., of Northwestern University's Feinberg School of Medicine in Chicago, IL.
- Abstract 659 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)" at the 2009 Annual Scientific Meeting of the American College of Rheumatology and Association of Rheumatology Health Professionals in October, 2009.
- Abstract 1593: "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)” at the 60th Annual Meeting of the American Association for the Study of Liver Diseases in November 2009.

- Abstract 1597: “Gene expression profiles induced by IMO-2125, an agonist of Toll-like receptor 9, in human peripheral blood mononuclear cells” at the 60th Annual Meeting of the American Association for the Study of Liver Diseases in November 2009.

Publications

- A paper entitled “Modifications incorporated in CpG motifs of oligodeoxynucleotides lead to antagonist activity of Toll-like receptors 7 and 9” was published in *Journal of Medicinal Chemistry* 2009, 52, 5108-14.
- A paper entitled “Coadministration of telomerase genetic vaccine and a novel TLR9 agonist in nonhuman primates” was published in *Molecular Therapy* 2009, 17, 1804-13. The paper was co-authored by scientists from Merck & Co. Inc. and Idera.
- A paper entitled “Synthetic oligoribonucleotides-containing secondary structures act as agonists of Toll-like receptors 7 and 8” was published in *Biochemical and Biophysical Research Communications* 2009, 386, 443-8.
- A paper entitled “Synthetic oligoribonucleotides containing arabinonucleotides act as agonists of TLR7 and 8” was published in *Bioorganic & Medicinal Chemistry* 2009, 19, 2044-7.

Intellectual Property

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

Immune Modulatory Oligonucleotides (IMO®)

This portfolio holds over 280 patents and patent applications worldwide covering Idera's IMO technologies and includes claims covering novel agonists of Toll-like Receptors (TLRs) 7, 8 and 9 and antagonists of TLRs 7 and 9. These patents and patent applications include claims covering IMO-2055, IMO-2125, IMO-3100, and QAX935. The following patents were recently issued:

- 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”

In addition to the issued U.S. patents, patents corresponding to the US 7,569,554 patent were granted to the Company in Guatemala, Latvia, Macedonia, Morocco, New Zealand, and Singapore. The Company was also granted patents entitled “Synergistic Stimulation of the Immune System Using Immunostimulatory Oligonucleotides and/ or Immunomer Compounds in Conjunction with Cytokines and/or Chemotherapeutic Agents or Radiation Therapy” in China (ZL200480026430.5) and India (228,424).

Antisense Technology

This portfolio holds over 220 patents and patent applications worldwide 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 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 Novartis, Merck & Co. Inc., and Merck KGaA 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, 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 Systems Incorporated. Camptosar is a registered trademark of Pfizer. Enbrel is a registered trademark of Amgen and Wyeth Pharmaceuticals.

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

(in thousands, except per share data)	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2009	2008	2009	2008
Revenue	\$ 6,538	\$ 7,517	\$ 24,338	\$ 20,196
Operating Expenses:				
Research & Development	4,288	3,580	14,177	11,866
General & Administrative	2,210	2,323	6,492	8,013
Total Operating Expenses	<u>6,498</u>	<u>5,903</u>	<u>20,669</u>	<u>19,879</u>
Income from Operations	40	1,614	3,669	317
Other, net	14	366	116	828
Income before Income Taxes	54	1,980	3,785	1,145
Income Tax Provision	(30)	-	(170)	-
Net Income	<u>\$ 24</u>	<u>\$ 1,980</u>	<u>\$ 3,615</u>	<u>\$ 1,145</u>
Basic Net Income per Share	<u>\$ 0.00</u>	<u>\$ 0.09</u>	<u>\$ 0.15</u>	<u>\$ 0.05</u>
Diluted Net Income per Share	<u>\$ 0.00</u>	<u>\$ 0.08</u>	<u>\$ 0.15</u>	<u>\$ 0.04</u>
Shares Used in Computing Basic Net Income per Share	<u>23,441</u>	<u>23,022</u>	<u>23,409</u>	<u>22,428</u>
Shares Used in Computing Diluted Net Income per Share	<u>24,341</u>	<u>25,779</u>	<u>24,188</u>	<u>25,538</u>

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

(in thousands)	September 30, December 31,	
	2009	2008
Cash, Cash Equivalents and Investments	\$ 46,071	\$ 55,606
Other Assets	3,890	3,794
Total Assets	<u>\$ 49,961</u>	<u>\$ 59,400</u>
Accounts Payable and Accrued Liabilities	\$ 3,796	\$ 2,773
Deferred Revenue	17,711	34,460
Stockholders' Equity	28,454	22,167
Total Liabilities & Stockholders' Equity	<u>\$ 49,961</u>	<u>\$ 59,400</u>

Source: Idera Pharmaceuticals, Inc.

Idera Pharmaceuticals, Inc.
Kelly Luethje, 617-679-5519
kluehje@iderapharma.com
or
MacDougall Biomedical Communications
Chris Erdman, 781-235-3060
cerdman@macbiocom.com