Idera Pharmaceuticals Reports Second Quarter 2011 Financial Results

August 5, 2011 12:02 PM EDT

CAMBRIDGE, Mass., Aug 05, 2011 (BUSINESS WIRE) -- Idera Pharmaceuticals, Inc. (Nasdaq: IDRA) today reported financial results for the second quarter ended June 30, 2011. Idera is a biotechnology company engaged in the discovery and development of DNA- and RNA-based drug candidates targeted to Toll-Like receptors (TLRs).

"Idera's pipeline of drug candidates is derived from a chemistry-based drug discovery approach that has generated candidates for multiple disease indications. In our autoimmune disease program, we are reviewing the FDA comments on a Phase 2 protocol that we recently submitted for evaluating IMO-3100 in patients with psoriasis, and are assessing our next steps for developing IMO-3100 in psoriasis," commented Sudhir Agrawal, D.Phil., Chairman and Chief Executive Officer. "We also look forward to Merck KGaA completing the ongoing Phase 2 trial of IMO-2055 in combination with Erbitux for second-line treatment of head and neck cancer."

Agrawal continued, "We are conducting a thorough strategic review of our diverse pipeline which may result in a re-prioritization of our programs and development efforts. We are undertaking this process to ensure that we allocate our financial resources appropriately in light of recent events."

Financial Results

As of June 30, 2011, cash, cash equivalents and investments totaled $23.5 million compared to $34.6 million at December 31, 2010.

Net loss for the three months ended June 30, 2011, was $6.3 million, or $0.23 per diluted share, compared to a net loss of $5.3 million, or $0.23 per diluted share, for the same period in 2010. For the six-month period, the Company's net loss was $13.1 million, or $0.48 per diluted share, compared to a net loss of $7.2 million, or $0.31 per diluted share, for the same period in 2010.

Total revenues for the three months ended June 30, 2011, were $33,000 compared to $4.4 million for the same period in 2010. For the six-month period, revenues totaled $41,000 compared to $10.0 million for the same period in 2010.

Research and development expenses for the three months ended June 30, 2011, totaled $4.1 million compared to $7.0 million for the same period in 2010. For the six-month period, R&D expenses totaled $8.7 million compared to $11.5 million for the same period in 2010.

General and administrative expenses for the three months ended June 30, 2011, totaled $2.2 million compared to $2.8 million for the same period in 2010. For the six-month period, G&A expenses totaled $4.5 million compared to $5.5 million for the same period in 2010.

Second Quarter 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 of IMO-3100 monotherapy in healthy subjects. In the second quarter of 2011, we continued to conduct nonclinical toxicology studies of IMO-3100 that we had commenced in the fourth quarter of 2010 in light of some reversible immune responses that we had observed in a nonclinical study.

Next Steps in Clinical Development of IMO-3100

- In June 2011, we submitted to the FDA a protocol for a Phase 2 clinical trial to evaluate IMO-3100 in patients with psoriasis. In July 2011, the FDA placed a clinical hold on the proposed clinical trial. We are reviewing the FDA comments on this protocol and assessing our next steps with respect to evaluating IMO-3100 in patients with psoriasis.

Phase 1 Multiple-Dose Clinical Trial in Healthy Subjects

- In April 2011, Idera presented data from a Phase 1 four-week, placebo-controlled, multiple-dose clinical trial of IMO-3100 in 24 healthy subjects at two dose levels at the Keystone Symposium on Immunoregulatory Networks. In the trial, IMO-3100 was well tolerated over the four weeks of treatment. There were no treatment-related discontinuations or serious adverse events. Target engagement of TLR7 and TLR9 was observed, confirming the intended mechanism of action of IMO-3100, and suppression of multiple cytokines was maintained during the treatment period.

Idera continues to evaluate IMO-3100 in additional pre-clinical models of autoimmune diseases. In June 2011, Idera presented "Treatment with IMO-3100, a novel TLR7 and TLR9 dual antagonist, inhibits disease development in a mouse model of collagen anti-body induced arthritis (CAIA)" at the Federation of Clinical Immunology Societies (FOCIS) Annual Meeting.

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.

Next Steps in Clinical Development of IMO-2125

- In April 2011, Idera announced a delay in the initiation of its proposed 12-week Phase 2 clinical trial of IMO-2125 in treatment-naïve genotype 1 HCV-infected patients based on preliminary observations in a chronic nonclinical toxicology study. The Company expects data from its ongoing chronic nonclinical toxicology studies to be available in the second half of 2011. The data will be used to assist the Company in making decisions on the further development of IMO-2125.

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

- In April 2011, Idera presented "IMO-2125 plus ribavirin gives substantial first-dose viral load reductions, cumulative anti-viral effect and good tolerability in naïve genotype 1 HCV patients: A phase 1 trial" at the 2011 European Association for the Study of the Liver (EASL) meeting.

Gene-silencing Oligonucleotide Technology

Gene-silencing oligonucleotides (GSOs) are single-stranded RNA or DNA constructs with two exposed 3'-ends that are complementary to targeted mRNA sequences of therapeutic interest.

- In April 2011, Idera announced the publication in the *Journal of Medicinal Chemistry* of its studies of a new class of compounds, which it refers to as gene-silencing oligonucleotides (GSOs). In studies using cell-based assays and mouse models, GSOs demonstrated length-dependent gene-silencing activity following systemic administration without the use of any delivery technology. In the studies, 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.
- In May 2011, Idera presented "Novel oligonucleotides containing two 3'-ends complementary to target mRNA show optimal gene-silencing activity" at the TIDES: Oligonucleotides and Peptide Research, Technology and Product Development conference.
- In July 2011, Idera presented "Gene Silencing Technology: Oligonucleotides Containing Two 3'-ends Engaging Cellular RNAi Machinery" at the 2nd RNAi Research and Therapeutics Conference.

Idera is conducting preclinical studies of GSOs targeted to messenger RNA and micro RNA and plans to report data from these studies during 2011.

Partnered Programs

IMO-2055 (EMD 1201081) for Cancer Treatment

IMO-2055, a TLR9 agonist, is currently in a Phase 2 clinical trial in second-line patients with recurrent or metastatic squamous cell carcinoma of the head and neck, evaluating IMO-2055 in combination with Erbitux$^{(R)}$. In July 2011, Merck KGaA informed Idera that it has determined that it will not conduct further development of IMO-2055 beyond completion of the ongoing Phase 2 trial. Merck KGaA also informed Idera that it plans to continue to evaluate follow-on TLR9 agonists created by Idera under the collaboration between Idera and Merck KGaA to research, develop and commercialize Idera's TLR9 agonists for the treatment of cancer, excluding cancer vaccines.

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.

- In July 2011, Merck and Idera scientists published a paper entitled "Synthesis and immunological activities of novel Toll-like receptor 7 and 8 agonists" in the journal *Cellular Immunology.*

Additional Proprietary Programs

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. In preclinical lymphoma models, IMO-4200 has shown improved antitumor activity, increased survival compared to single-agent treatments and immune activation consistent with the TLR7/TLR8 mechanism of action, when administered in combination with approved cancer therapy agents.

- In June 2011, Idera's abstract, number e13076, entitled "Supra-additive effect of IMO-4200, a novel TLR7 and TLR8 dual agonist, with rituximab and cytotoxics in preclinical models of hematologic malignancies", was published in the proceedings of the American Society of Clinical Oncology Annual Meeting.

IMO-2134

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

- In May 2011, Idera obtained data from non-clinical and clinical studies of IMO-2134 conducted by Novartis. Idera may use the data to further develop IMO-2134.

TLR3 Agonists

Idera has created a new class of synthetic 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 is continuing to evaluate the adjuvant activity of these compounds in preclinical models.

- 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."

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 http://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 the impact of our strategic review on our plans for the development of our drug candidates and technologies; 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 June 30, 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 (Unaudited)
(In thousands, except per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2011	2010	2011	2010
Revenues	$ 33	$ 4,386	$ 41	$ 9,963
Operating Expenses				
Research & Development	4,142	6,961	8,695	11,547
General & Administrative	2,166	2,784	4,452	5,516
Total Operating Expenses	6,308	9,745	13,147	17,063
Loss Income from Operations	(6,275)	(5,359)	(13,106)	(7,100)
Other, net	(7)	63	(21)	(139)
Net Loss	$ (6,282)	$ (5,296)	$(13,127)	$(7,239)

Basic Net Loss Per Common Share	$ (0.23)	$ (0.23)	$ (0.48)	$ (0.31)
Diluted Net Loss Per Common Share	$ (0.23)	$ (0.23)	$ (0.48)	$ (0.31)
Shares Used in Computing Basic Net Loss Per Common Share	27,619	23,473	27,612	23,467
Shares Used in Computing Diluted Net Loss Per Common Share	27,619	23,473	27,612	24,467

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

	June 30, 2011 (Unaudited)	December 31, 2010
Cash, Cash Equivalents & Investments	$ 23,508	$ 34,643
Other Assets	1,845	2,238
Total Assets	$ 25,353	$ 36,881
Accounts Payable & Accrued Liabilities	$ 3,879	$ 3,780
Stockholders' Equity	21,474	33,101
Total Liabilities & Stockholders' Equity	$ 25,353	$ 36,881

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