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

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CAMBRIDGE, Mass.--(BUSINESS WIRE)--Aug. 4, 2009-- Idera Pharmaceuticals, Inc. (Nasdaq: IDRA) today reported financial results for the second quarter and six months ended June 30, 2009.

“Over the next 12-18 months, we expect that results from ongoing clinical trials in our hepatitis C program and our partnered oncology and respiratory disease programs will enable decisions to be made for subsequent steps in the development for these indications,” said Sudhir Agrawal, D. Phil., President, Chief Executive Officer and Chief Scientific Officer. “In addition, we are advancing IMO-3100, a dual antagonist of TLR7 and TLR9, toward clinical evaluation with potential application to autoimmune and inflammatory diseases such as lupus, arthritis, psoriasis, and others based on a novel mechanism of action.”

“With $50.4 million in cash and investments, we are in a strong financial position to continue advancing our clinical and preclinical programs. During the second quarter, we received a $4.0 million milestone payment from Merck KGaA for the initiation of a clinical trial in colorectal cancer. Our net cash and investments decreased by only $5.2 million for the six months ended June 30, 2009,” added Lou Arcudi, Chief Financial Officer.

Second Quarter and Six Month 2009 Results

The Company reported net income of $3.8 million, or $0.16 per diluted share, for the three months ended June 30, 2009, compared to a net income of $1.3 million, or $0.05 per diluted share, for the same period in 2008. For the six-month period, the Company’s net income was $3.6 million, or $0.15 per diluted share, compared to a net loss of $0.8 million, or $0.04 per diluted share, for the same period in 2008.

Total revenues for the three months ended June 30, 2009 were $11.5 million compared to $7.9 million for the same period in 2008. For the six-month period, revenues totaled $17.8 million compared to $12.7 million for the same period in 2008.

Research and development expenses for the three months ended June 30, 2009 totaled $5.4 million compared to $3.8 million for the same period in 2008. For the six-month period, R&D expenses totaled $9.9 million compared to $8.3 million for the same period in 2008.

General and administrative expenses for the three months ended June 30, 2009 were $2.1 million compared to $3.2 million for the same period in 2008. For the six-month period, G&A expenses totaled $4.3 million compared to $5.7 million for the same period in 2008.

As of June 30, 2009, cash, cash equivalents and investments totaled $50.4 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)

The Company conducted a Phase 2 Stage A clinical trial of IMO-2055 monotherapy in patients with renal cell carcinoma. The trial consisted of four arms, with treatment-naïve and previously treated patients each randomly assigned to two different dose levels of IMO-2055. Preliminary data were announced in October, 2008. Based on the final data analysis, the median progression-free survival for each of the four arms in the trial was 4.5 months, 4.3 months, 3.4 months, and 1.9 months. The Company expects to report detailed data from this trial at a scientific meeting in the third quarter of 2009.

- Phase 1b Clinical Trial of IMO-2055 in Combination with Avastin® and Tarceva® in Non-small Cell Lung Cancer

In this trial, IMO-2055 is being administered at four escalating dose levels with fixed standard dose regimens of Avastin and Tarceva. The Company expects preliminary data from the dose-escalation portion of the trial to be presented at a scientific meeting in the third quarter of 2009. Of the four dose levels of IMO-2055, a dose level has been selected for expanded patient recruitment to evaluate further the safety and pharmacokinetics of the 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.

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

Patient enrollment in the planned fourth and final cohort is ongoing. The Company expects to complete dosing in the trial and to announce interim data by the end of 2009.

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

The Company is preparing to conduct 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 design of this trial provides that three dose levels of IMO-2125 will be administered weekly for four weeks, with daily oral ribavirin. The target enrollment is approximately 45 patients. Of the 15 patients per cohort, 12 will be randomized to receive weekly IMO-2125 and daily oral ribavirin, and three will be randomized to receive placebo and daily oral ribavirin. This clinical trial 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 expects to commence this trial during the second half of 2009.

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

IMO-3100 is a dual antagonist of TLR7 and TLR9 and provides a novel mechanism of action for potential applications in autoimmune and inflammatory diseases. The Company has evaluated IMO-3100 with encouraging results in preclinical mouse models including lupus, rheumatoid arthritis, multiple sclerosis, psoriasis and colitis.

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 expects to submit an IND application to the U.S. Food and Drug Administration by the end of 2009.

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

Preclinical Data Presentations

During the second quarter of 2009, the Company made the following presentations:

- Abstract 48.25 entitled "IMO-3100, an antagonist of Toll-like Receptors 7 and 9, modulates gene expression and regulatory networks induced by ligands" at the 2009 Annual Meeting of The American Association of Immunologists.
- Abstract S.105 entitled "Modulation of Toll-like receptors 7 and 9 expression with antisense for potential applications in autoimmune and inflammatory diseases" at the 2009 Annual Meeting of the Federation of Clinical Immunology Societies (FOCIS).
- Abstract S.106 entitled "Studies of Toll-like receptors 7 and 9 antisense in a preclinical model of colitis" at the 2009 Annual Meeting of FOCIS.

- Abstract S.108 entitled “Modulation of Toll-like receptor 3 expression with antisense” at the 2009 Annual Meeting of FOCIS.

Intellectual Property

Immune Modulatory Oligonucleotides

The Company currently holds over 260 issued patents and pending patent applications world-wide covering the compositions and methods of using the Company’s novel agonists and antagonists of TLR7, 8 and 9. These patents and patent applications include claims covering IMO-2055, IMO-2125, IMO-3100, and QAX935.

Antisense Technology

The Company is currently the owner or licensee of over 200 patents and patent applications world-wide covering novel antisense compositions and methods of using these compositions. These patents and patent applications include claims covering second-generation antisense chemistry (US6,346,614; US5,652,355; US6,143,881; US6,683,167; US6,645,943), oral delivery of second-generation antisense compounds (US5,591,721; US6,608,035; US6,936,593) and certain genes, sequences, and therapeutic targets.

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 June 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.

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

(In thousands, except per share data)	Three Months Ended June 30,		Six Months Ended June 30,	
	2009	2008	2009	2008
Revenue	$ 11,497	$ 7,876	$17,800	$12,660
Operating Expenses				
Research & Development	5,413	3,752	9,890	8,286
General & Administrative	2,133	3,243	4,282	5,671
Total Operating Expenses	7,546	6,995	14,172	13,957
Income (Loss) from Operations	3,951	881	3,628	(1,297)
Other, net	31	405	102	462
Income (Loss) Before Income Taxes	3,982	1,286	3,730	(835)
Income Tax (Provision) Benefit	(140)	50	(140)	-
Net Income (Loss)	$ 3,842	$ 1,336	$ 3,590	$ (835)
Basic Net Income (Loss) per Share	$ 0.16	$ 0.06	$ 0.15	$ (0.04)
Diluted Net Income (Loss) per Share	$ 0.16	$ 0.05	$ 0.15	$ (0.04)
Shares Used in Computing Basic Net Income (Loss) per Share	23,407	22,481	23,393	22,190
Shares Used in Computing Diluted Net Income (Loss) Per Share	23,956	25,507	24,103	22,190

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

(In thousands)	June 30, 2009	December 31, 2008
Cash, Cash Equivalents And Investments	$ 50,441	$ 55,606

Other Assets	4,942	3,794
Total Assets	$ 55,383	$ 59,400
Accounts Payable and Accrued Liabilities	$ 4,472	$ 2,773
Deferred Revenue	23,445	34,460
Stockholders' Equity	27,466	22,167
Total Liabilities & Stockholders' Equity	$ 55,383	$ 59,400

Source: Idera Pharmaceuticals, Inc.

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