Idera Pharmaceuticals Reports 2008 Fourth Quarter and Full Year Financial Results

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CAMBRIDGE, Mass.--(BUSINESS WIRE)--Mar. 11, 2009-- Idera Pharmaceuticals, Inc. (Nasdaq: IDRA) today reported financial results for the fourth quarter and full year ended December 31, 2008.

"Together with our collaborators, we currently have three novel Toll-like Receptor-targeted drug candidates undergoing clinical evaluation in multiple indications, and we expect to submit an IND for a fourth compound, IMO-3100, by the end of 2009," said Sudhir Agrawal, D.Phil., Chief Executive Officer and Chief Scientific Officer. "We continue to deliver on our business strategy in which our partners bring developmental expertise to their respective programs involving our compounds, and we focus on advancing our proprietary programs."

"2008 was a strong year for us financially. We ended the year with approximately $55.6 million in cash and investments, as compared to $23.7 million at the end of 2007, and our revenue increased to $26.4 million in 2008 compared $8.0 million in 2007. With net cash used in operations totaling $18.4 million in 2008, we have prudently managed our cash and are in a sound financial position to continue the advancement of our drug candidate pipeline during these tough economic times," commented Lou Arcudi, Chief Financial Officer.

Financial Results

As of December 31, 2008, cash, cash equivalents and short-term investments totaled approximately $55.6 million compared to $23.7 million at December 31, 2007. Additionally, the Company earned a milestone payment of €3.0 million from Merck KGaA, which the Company expects to receive during the second quarter of 2009.

Fourth Quarter Results

Net income for the three months ended December 31, 2008 was $0.4 million, or $0.01 per diluted share, compared to a net loss of $4.5 million, or $0.21 per diluted share, for the same period in 2007.

Total revenues for the three months ended December 31, 2008 were $6.2 million compared to $2.2 million for the same period in 2007.

Research and development expenses for the three months ended December 31, 2008 totaled $4.3 million compared to $3.9 million for the same period in 2007.

General and administrative expenses for the three months ended December 31, 2008 totaled $1.8 million compared to $3.1 million for the same period in 2007.

Full Year Results

Net income for the year ended December 31, 2008, was $1.5 million, or $0.06 per diluted share, compared to a net loss of $13.2 million, or $0.62 per diluted share, for 2007.

Total revenues for the year ended December 31, 2008 were $26.4 million compared to $8.0 million for 2007. The increase in revenue in 2008 primarily reflects license fee revenue recognized under the Company's collaboration with Merck KGaA.

Research and development expenses for the year ended December 31, 2008 totaled $16.2 million compared to $13.2 million for 2007.

General and administrative expenses for the year ended December 31, 2008 totaled $9.7 million compared to $9.5 million for 2007.

Development Program Highlights

IMO-2055

IMO-2055, a synthetic DNA-based Toll-like Receptor 9 (TLR9) agonist, is a lead drug candidate for the treatment of cancer. In December 2007, the Company entered into a worldwide licensing and collaboration agreement with Merck KGaA for the research, development and commercialization of the Company's TLR9 agonists for the treatment of cancer, excluding cancer vaccines. Under this collaboration, Merck KGaA currently is funding all on-going development activities related to IMO-2055 for cancer. At present, IMO-2055 is being evaluated in two on-going clinical trials:

IMO-2055 in combination with Tarceva® and Avastin®: In December 2007, the Company initiated a Phase 1b trial of IMO-2055 in combination with Avastin and Tarceva in patients with non-small cell lung cancer. The trial is designed to assess the safety of IMO-2055 in combination with standard dosages and schedules of Tarceva and Avastin and to determine the recommended dosage of IMO-2055 for potential use in a subsequent Phase 2 trial. The initial three planned dose levels of IMO-2055 were well tolerated by patients in this trial, and patients currently are being recruited at a fourth dose level for the trial.

IMO-2055 in combination with Erbitux® and Camptosar®: In February 2009, the Company began dosing in a Phase 1b clinical trial of IMO-2055 in combination with Erbitux and Camptosar in patients with colorectal cancer. The trial is designed to assess the safety of the IMO-2055, Erbitux, and Camptosar combination and to determine the recommended dosage of IMO-2055 for potential use in a subsequent Phase 2 clinical trial. Three dose levels of IMO-2055 are being investigated with standard dosages and schedules of Erbitux and Camptosar.

IMO-2055 monotherapy: In October 2008, the Company reported preliminary data from a Phase 2 Stage A clinical trial of IMO-2055 monotherapy in patients with renal cell carcinoma. In this trial, two patient populations each were randomly assigned to two different dose levels of IMO-2055. The primary objective of tumor response was not achieved in the trial. Median progression-free survival for each of the four arms of the trial was 2 months, 3 months, 4 months, and 4 months. IMO-2055 treatment was generally well-tolerated with good dose intensity in all arms of the trial. The Company intends to present data from this clinical trial at a scientific conference in the second half of 2009.

IMO-2125

IMO-2125, a synthetic DNA-based TLR9 agonist, is a lead drug candidate for the treatment of infectious diseases, with an initial focus on chronic hepatitis C virus (HCV) infection. In preclinical models, IMO-2125 was shown to induce high levels of natural interferon and other antiviral proteins.

IMO-2125 monotherapy: The Company is conducting a Phase 1 clinical trial of IMO-2125 in patients with chronic HCV infection who have not responded to current standard of care therapy. Four dose levels of IMO-2125 are being investigated. At present, patients are being recruited into the third dose level of the trial. The Company expects interim results from this trial to be available late in 2009.

IMO-2125 in combination with ribavirin: The Company plans to conduct a clinical trial to assess the safety of IMO-2125 in combination with ribavirin in treatment-naïve patients with chronic HCV infection. This clinical trial also will be designed to evaluate the effects of IMO-2125 and ribavirin combination treatment on HCV RNA levels and on parameters of immune system activation.

QAX935 (IMO-2134)

QAX935 (IMO-2134) is a novel TLR9 agonist exclusively licensed by the Company to Novartis International Pharmaceutical, Ltd. In May 2005, the Company and Novartis entered into research collaboration and license agreements involving the application of TLR9 agonists to treating asthma and allergies. In September 2008, Idera achieved a milestone under this collaboration upon the initiation of a Phase 1 clinical trial of QAX935 by Novartis. Under this collaboration, Novartis is conducting and funding all research activities.

IMO-3100

IMO-3100 is a dual TLR7 and TLR9 antagonist and lead drug candidate for autoimmune and inflammatory diseases. The Company has identified DNA-based compounds that act as antagonists of TLR7 and TLR9 and has evaluated these compounds in preclinical mouse models of lupus, rheumatoid arthritis, multiple sclerosis, psoriasis and colitis. The Company is currently conducting preclinical development studies of IMO-3100 in anticipation of submitting an Investigational New Drug (IND) application to the U.S. Food and Drug Administration by the end of 2009.

TLR7, 8 and 9 agonists as vaccine adjuvants

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 2008, Merck extended the research collaboration with the Company for an additional year to December 2009. 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 designed and created RNA-based compounds that act as agonists of TLR7 and/or TLR8. In preclinical studies, these TLR7 and/or TLR8 agonists induced immune responses that the Company believes may be applicable to the treatment of cancer and infectious diseases.

Scientific Highlights

Academic Collaborations

In addition to on-going discoveries in the Company's laboratories, the Company is collaborating with several leading investigators at academic institutions to advance studies with its TLR-targeted compounds.

Principal investigators of these collaborations are affiliated with Boston University Medical Center, Boston, MA; Children's Hospital Boston, Boston, MA; Duke University Medical Center, Durham, NC; New York University School of Medicine, New York, NY; University of Naples, Naples, Italy; and University of North Carolina School of Medicine, Chapel Hill, NC; and additional institutions.

Selected Publications and Presentations

During 2008 and to date in 2009, Company scientists and collaborators have published and presented on studies of TLR-targeted compounds:

- Two presentations were made on preclinical data of novel TLR7, 8 and 9 agonists at the 2008 Annual Meeting of the American Association for Cancer Research (AACR) held in San Diego, CA.
- A presentation was made on preclinical data on a cancer vaccine using a TLR9 agonist as an adjuvant at the 2008 Annual Meeting of AACR by scientists from Merck & Co. Inc.
- A presentation was made on preclinical data from studies evaluating a TLR antagonist in a mouse model of multiple sclerosis at the 60th Annual Meeting of the American Academy of Neurology held in Chicago, IL.
- A presentation on preclinical data entitled "Effects of a novel synthetic TLR9 agonist on repeated allergen challenge in allergic monkeys" at the TOLL2008 meeting held in Cascais, Portugal, by scientists from Novartis.
- Two presentations were made on preclinical data from studies evaluating novel TLR antagonist candidates in mouse models of lung inflammation and psoriasis at the Federation of Clinical Immunology Societies 2008 Annual Meeting held in Boston, MA.

- A presentation was made on the chemistry of immunomodulatory oligonucleotides at the 4th Annual Meeting of Oligonucleotide Therapeutic Society (OTS) held at the Harvard Medical School Conference Center in Boston, MA.
- Multiple presentations were made on preclinical data from studies on novel TLR agonists and antagonists at the 4th Annual Meeting of OTS.
- A paper entitled “Oligodeoxyribonucleotide-Based Antagonists for Toll-Like Receptors 7 and 9” authored by Company scientists was published in the *Journal of Medicinal Chemistry* (2009, 52, 551–558).
- 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” co-authored by scientists from Merck & Co. Inc. and Idera was published in *Clinical Cancer Research* (2009, 15, 1575-84).

Intellectual Property

In 2008, the Company’s U.S. and foreign patents and patent applications covering novel TLR-targeted compounds increased by over 40 and now total over 250. The following patents were issued to the Company in 2008:

- US 7,354,907, entitled “Short Immunomodulatory Oligonucleotides”
- US 7,329,648, entitled “Modulation of Oligonucleotide CpG-mediated Immune Stimulation by Positional Modification of Nucleosides”
- EP 1322656, entitled “Modulation of Immunostimulatory Activity of Immunostimulatory Oligonucleotide Analogs by Positional Chemical Changes”
- EP 1252307, entitled “Modulation of Oligonucleotide CpG-mediated Immune Stimulation by Positional Modification of Nucleosides”
- AU 2005218065, entitled “Modulation of Oligonucleotide CpG-mediated Immune Stimulation by Positional Modification of Nucleosides”
- US 7,427,405, entitled “Immunostimulatory Oligonucleotide Multimers”
- US 7,407,944, entitled “Modulation of Immunostimulatory Properties of Oligonucleotide-Based Compounds by Optimal Presentation of 5’ Ends”
- US 7,405,285, entitled “Immunostimulatory Oligonucleotide Multimers”
- AU 2006203435, entitled “Modulation of Immunostimulatory Activity of Immunostimulatory Oligonucleotide Analogs by Positional Chemical Changes”
- US 7,470,674, entitled “Immunostimulatory Properties of Oligonucleotide-based Compounds Comprising Modified Immunostimulatory Dinucleotides”

Additionally, in 2008 and early 2009, the Company was recognized three times by the Patent Board™ as one of the top 35 companies in the biotechnology field based on its technology and intellectual property advances. The Patent Board™ 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 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 Annual Report on Form 10-K filed on March 11, 2009, which important factors are incorporated herein by reference. Idera disclaims any intention or obligation to update any forward-looking statements.

Erbitux is a registered trademark of ImClone Systems Incorporated. Camptosar is a registered trademark of Pfizer. Tarceva is a registered trademark of OSI Pharmaceuticals, Inc. Avastin is a registered trademark of Genentech, Inc. 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,	
	2008	2007	2008	2007
	(unaudited)	(unaudited)		
Revenues	$6,241	$2,233	$26,376	$7,981
Operating Expenses				
Research & Development	4,286	3,907	16,152	13,195
General & Administrative	1,772	3,144	9,724	9,513
Total Operating Expenses	6,058	7,051	25,876	22,708
Income (Loss) from Operations	183	(4,818)	500	(14,727)
Other, net	157	312	985	1,519
Income (Loss) Before Income Taxes	340	(4,506)	1,485	(13,208)
Income Tax Benefit	24	—	24	—
Net Income (Loss)	$364	$(4,506)	$1,509	$(13,208)
Basic Net Income (Loss) Per Common Share	$0.02	$(0.21)	$0.07	$(0.62)
Diluted Net Income (Loss) Per Common Share	$0.01	$(0.21)	$0.06	$(0.62)
Shares Used In Computing Basic Income (Loss) Per Common Share	23,331	21,485	22,655	21,221
Shares Used in Computing Diluted Income (Loss) Per Common Share	24,822	21,485	25,331	21,221

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

	At December 31,	
	2008	2007
Cash, Cash Equivalents		
And Short-term Investments	$ 55,606	$ 23,743
Other Assets	3,794	3,971
Total Assets	$ 59,400	$ 27,714
Accounts Payable and Accrued Liabilities	$ 2,773	$ 3,067
Notes Payable	0	1,143
Deferred Revenue	34,460	15,785
Stockholders' Equity	22,167	7,719
Total Liabilities &		
Stockholders' Equity	$ 59,400	$ 27,714

Source: Idera Pharmaceuticals, Inc.

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