Idera Pharmaceuticals Reports First Quarter 2012 Financial Results

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CAMBRIDGE, Mass., May 09, 2012 (BUSINESS WIRE) --Idera Pharmaceuticals, Inc. (NASDAQ: IDRA) today reported financial results for the quarter ended March 31, 2012.

"We are focusing our development effort on our autoimmune disease program and have continued to advance our lead candidates, IMO-3100 and IMO-8400. We initiated a Phase 2 study of IMO-3100 in patients with psoriasis in the second quarter and expect to complete it during the first half of 2013. We are also on target to submit an Investigational New Drug application on IMO-8400 with lupus as the first indication in the fourth quarter of 2012," said Sudhir Agrawal, D.Phil., Chairman and Chief Executive Officer. "We plan to seek to advance our drug candidates in oncology, infectious diseases and respiratory diseases through collaborations. Additionally, we continue to validate our proprietary gene-silencing oligo technology and support our collaboration with Merck in the area of vaccine adjuvants for cancer, infectious diseases and Alzheimer's disease."

Financial Results

As of March 31, 2012, cash and cash equivalents totaled $18.7 million compared to $24.6 million at December 31, 2011.

First Quarter Results

Net loss for the three months ended March 31, 2012, was $7.0 million, or $0.25 per diluted share, compared to net loss of $6.8 million, or $0.25 per diluted share, for the same period in 2011. Research and development expenses for the three-month period ended March 31, 2012, totaled $3.8 million compared to $4.6 million for the same period in 2011. General and administrative expenses for the three-month period ended March 31, 2012, totaled $1.7 million compared to $2.3 million for the same period in 2011.

1Q 2012 Research and Development Highlights

Autoimmune and Inflammatory Disease Program

IMO-3100 - Clinical Candidate for Psoriasis

IMO-3100, a dual antagonist of TLR7 and TLR9, is the lead clinical candidate being developed by the Company for the treatment of psoriasis.

Phase 2 Trial of IMO-3100 in Patients with Psoriasis

- In the second quarter of 2012, the Company initiated a Phase 2 randomized, placebo-controlled clinical trial of IMO-3100 in patients with psoriasis. In the study, 45 patients with moderate to severe plaque psoriasis will receive IMO-3100 at 0.16 or 0.32 mg/kg or placebo by subcutaneous injection once weekly for four weeks. Assessments of safety will be performed throughout the treatment and follow-up periods. Psoriasis intensity will be monitored throughout the study. Skin biopsies of an active psoriasis plaque will be obtained prior to treatment and one week after the last treatment and will be analyzed by immunohistologic staining for changes in epidermal thickness, immune cell infiltrates and cytokine expression. This trial is being conducted at multiple sites in the United States, and skin biopsies will be analyzed at a central laboratory. We expect to complete the Phase 2 study for IMO-3100 in patients with psoriasis during the first half of 2013.

IMO-8400 - Lead Candidate for Lupus

IMO-8400 is an antagonist of TLRs 7, 8 and 9, and is the lead candidate for the treatment of lupus. The Company expects to submit to the FDA an Investigational New Drug application for IMO-8400 during the fourth quarter of 2012.

Presentation of Preclinical Efficacy data at American Association of Immunologists (AAI) in Q2 2012

- In the second quarter of 2012, the Company made a presentation, entitled "IMO-8400, a novel TLR7, TLR8, and TLR9 antagonist, inhibits disease development in lupus-prone NZBW/F1 mice". In the study, treatment with IMO-8400 decreased autoimmune antibodies, multiple pro-inflammatory serum cytokines and indicators of kidney damage compared to untreated mice.
- In addition, the Company made a second presentation entitled "IMO-8400, a novel TLR7,

TLR8, and TLR9 antagonist, inhibits disease development in mouse models of psoriasis".

- The Company and collaborators from the Ragon Institute of MIT, Massachusetts General Hospital and Harvard Medical School also made a presentation entitled "Modification of immune activation in HIV-1 infected humanized mouse models using TLR7/9 antagonists".

Oncology Program

The Company reacquired the rights to IMO-2055, a TLR9 agonist, in oncology from Merck KGaA in the fourth quarter of 2011. Since that time, Merck KGaA has completed three clinical studies of IMO-2055.

Top-line Data Announced from a Phase 1b Trial of IMO-2055 in Combination with Tarceva(R) and Avastin(R) for the Treatment of Non-Small Cell Lung Cancer (NSCLC)

- During the first quarter of 2012, the Company announced top-line data from a Phase 1b trial of IMO-2055 in combination with Tarceva and Avastin for the treatment of advanced NSCLC. The goal of the study was to establish a recommended Phase 2 dose of IMO-2055 for use in either doublet or triplet combinations.

  Top-line efficacy results based on thirty-three evaluable patients show a disease control rate of 79%, a median progression-free survival of 5.6 months and a median overall survival of 16 months. The recommended dose of IMO-2055 for Phase 2 was identified at 0.32 mg/kg. Detailed data is expected to be presented at a medical meeting in the second quarter of 2012.

Top-line Data Announced from a Phase 2 Trial of IMO-2055 in Combination with Erbitux(R) in Second-Line Erbitux-Naïve Subjects with Recurrent or Metastatic Squamous Cell Carcinoma of the Head and Neck (SCCHN)

- In the second quarter of 2012, the Company announced top-line data from a Phase 2 trial of IMO-2055 in combination with Erbitux in second-line Erbitux-naïve subjects with advanced SCCHN. The goal of this study was to compare overall progression-free survival following treatment with IMO-2055 in combination with Erbitux compared to treatment with Erbitux alone. In the study, 106 patients with SCCHN were randomized into two arms of 53 patients each.

  In the study, the combination of IMO-2055 and Erbitux did not meet the primary endpoint. The median progression-free survival based on investigator assessments was 2.9 months in both arms; based on independent radiology review it was 1.9 months in the Erbitux arm and 1.5 months in the combination arm. The hazard ratio in both evaluations was 1.1 with no statistical difference between the treatment arms. The relative dose intensity was 96% for IMO-2055 and 99% for Erbitux in the combination arm and was 96% for Erbitux in the Erbitux-alone arm. We expect to present the detailed data from this trial at a medical conference.

Phase 1b Trial of IMO-2055 in Combination with FOLFIRI and Erbitux in Patients with Colorectal Cancer who have Progressed Following Chemotherapy for Advanced or Metastatic Disease

- During the second quarter of 2012, the Company received data from a Phase 1b trial of IMO-2055 in combination with FOLFIRI and Erbitux in patients with advanced colorectal cancer. The goal of the study was to determine the recommended Phase 2 dose of IMO-2055 when combined with FOLFIRI and Erbitux.

  Fifteen patients were enrolled in the dose escalation portion of the study and received IMO-2055 at 0.16, 0.32 or 0.48 mg/kg/week in combination with weekly Erbitux and FOLFIRI once every two weeks. The combination of IMO-2055 Erbitux, and FOLFIRI was generally well tolerated, and 0.48 mg/kg/week was identified as the recommended Phase 2 dose of IMO-2055 in this setting.

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 the first quarter of 2012, Merck selected several novel agonists targeted to TLR7, TLR8 or TLR9 for evaluation and exclusive use as vaccine adjuvant candidates under the companies' collaboration and license agreement.

Gene-silencing Oligonucleotide Technology

Idera has developed a gene-silencing oligonucleotide (GSO) drug discovery platform with the potential to overcome specific limitations associated with traditional gene silencing technologies. GSOs are proprietary single-stranded RNA or DNA constructs that are complementary to targeted messenger RNA and microRNA sequences of therapeutic interest that do not require conventional delivery techniques.

GSOs targeted to the mRNA of apolipoprotein B (ApoB) or proprotein convertase subtilisin/kexin type 9 (PCSK9), two validated targets associated with cardiovascular diseases, have been studied following systemic administration in mice. In these studies, GSOs showed a dose-dependent reduction in the level of the targeted mRNA and associated protein and resulted in a decrease in serum total cholesterol and LDL-cholesterol concentration. The reduction of cholesterol was sustained for an extended duration following the termination of the dosing. These studies have been conducted to validate the potential of GSO technology.

Additional Proprietary Programs

The Company is seeking to advance other TLR-targeted candidates in infectious diseases, respiratory diseases, oncology and adjuvant applications of TLR3 agonists through licensing and partnering.

About TLRs and Idera's Pipeline

Toll-like Receptors (TLRs) represent a class of proteins that play a key role in both inflammation and immunity. Of the 10 human TLRs identified to date, Idera is focusing on compounds targeted to TLRs 3, 7, 8 and 9, which are expressed in different cells and serve unique functions. For example, activation of TLR7 and TLR9 present in certain dendritic cells and lymphocytes may be useful for the treatment of various types of cancer by stimulating immunity. In contrast, inhibition of specific TLRs may be useful in treating autoimmune disorders, such as psoriasis and lupus, by blocking the production of multiple pro-inflammatory mediators. Using its chemistry-based approach, Idera is advancing novel drug candidates to modulate immune response through activation or inhibition of specific TLRs to treat a broad range of diseases, including autoimmune diseases and cancer, and to enhance the effectiveness of vaccines.

In autoimmune diseases, Idera is developing inhibitors of TLRs 7, 8 and 9 for the potential treatment of psoriasis, lupus and other diseases. Idera's lead clinical candidate is IMO-3100, an antagonist of TLR7 and TLR9, which is in Phase 2 development for psoriasis. IMO-8400 is an antagonist of TLRs 7, 8 and 9. Idera expects to submit an IND application for IMO-8400 during the fourth quarter of 2012. Idera has selected lupus as the initial disease indication for clinical development of IMO-8400.

In oncology, Idera's lead product candidate is IMO-2055, which is designed to activate TLR9. IMO-2055 has been the subject of several clinical trials including the trials that are described above: A randomized, controlled Phase 2 trial in combination with Erbitux(R) as a second-line therapy for patients with recurrent or metastatic squamous cell carcinoma of the head and neck that have not been previously treated with Erbitux; a Phase 1b trial in combination with Tarceva(R) and Avastin(R) for the treatment of non-small cell lung cancer; and a Phase 1b trial in combination with FOLFIRI and Erbitux in patients with advanced colorectal cancer who progressed following chemotherapy.

About Psoriasis

Psoriasis is a systemic immune-mediated disorder, characterized by inflammatory skin and joint manifestations. The most common form, plaque psoriasis, appears as raised, red patches covered with a silvery white buildup of dead skin cells. Psoriasis can occur on any part of the body and is associated with other serious health conditions, such as diabetes, heart disease and depression.

Psoriasis is the most prevalent autoimmune disease in the U.S., according to the National Psoriasis Foundation, affecting as many as 7.5 million Americans.

About Lupus

Lupus is a chronic autoimmune disease where the body's immune system becomes hyperactive and attacks normal healthy tissue. This results in symptoms such as inflammation, swelling and damage to joints and almost every major organ in the body, including the heart, kidneys, skin, lungs and brain. According to The Lupus Foundation of America, an estimated 1.5 million Americans and at least five million people worldwide have a form of lupus.

About Idera Pharmaceuticals, Inc.

Idera Pharmaceuticals applies its proprietary Toll-like receptor (TLR) drug discovery platform to create immunomodulatory drug candidates and has clinical development programs in autoimmune diseases and cancer. Additionally, Idera has a collaboration with Merck & Co. for the use of TLR-targeted candidates as vaccine adjuvants. The Company is also advancing its gene-silencing oligonucleotide technology for the purpose of inhibiting the expression of disease-promoting genes. 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 whether results obtained in preclinical studies and early clinical trials such as the studies 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 will be able to license IMO-2055 for further development for oncology or our other TLR target candidates on a timely basis or at all; whether the Company's collaboration with 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 March 31, 2012 which important factors are incorporated herein by reference. Idera disclaims any intention or obligation to update any forward-looking statements.

ERBITUX(R) is a registered trademark of ImClone LLC, a wholly-owned subsidiary of Eli Lilly and Company. Tarceva(R) is a registered trademark of OSI Pharmaceuticals, LLC, an affiliate of Astellas Pharma US, Inc. Avastin(R) is a registered trademark of Genentech, Inc.

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

	Three Months Ended March 31,	
	2012	2011
	(Unaudited)	
Revenues	$ 9	$ 8
Operating Expenses		
Research & Development	3,813	4,553
General & Administrative	1,689	2,286
Total Operating Expenses	5,502	6,839
Loss from Operations	(5,493)	(6,831)
Increase in Fair Value of Warrant Liability	(1,321)	-
Other, net	(72)	(14)
Net Loss	(6,886)	(6,845)
Preferred Stock Dividends	160	-
Net Loss Applicable to Common Stockholders	$ (7,046)	$ (6,845)
Basic and Diluted Net Loss Per Common Share Applicable to Common Stockholders	$ (0.25)	$ (0.25)
Shares Used in Computing Basic and Diluted Net Loss Per Common Share Applicable to Common Stockholders	27,637	27,604

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

	At March 31, 2012	At December 31, 2011
	(Unaudited)	
Cash & Cash Equivalents	$ 18,689	$ 24,571
Other Assets	943	1,024
Total Assets	$ 19,632	$ 25,595
Total Liabilities	$ 8,140	$ 7,650
Redeemable Preferred Stock	5,921	5,921
Stockholders' Equity	5,571	12,024
Total Liabilities, Redeemable Preferred Stock & Stockholders' Equity	$ 19,632	$ 25,595

SOURCE: Idera Pharmaceuticals, Inc.

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