Idera Pharmaceuticals Reports Fourth Quarter and Full Year 2012 Financial Results and Provides Update on Autoimmune Disease Program

March 11, 2013 1:21 PM EDT

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Mar. 11, 2013-- Idera Pharmaceuticals, Inc. (Nasdaq: IDRA) today reported its financial and operational results for the fourth quarter and year ended December 31, 2012.

“During the past year, Idera has demonstrated promising clinical activity for the use of Toll-like Receptor antagonists as a novel approach for the potential treatment of autoimmune diseases,” said Sudhir Agrawal, D.Phil., Chairman and Chief Executive Officer. “We recently completed dosing in the escalating single-dose portion of our Phase 1 study of IMO-8400, an antagonist of TLRs 7, 8 and 9. In this portion of the trial, IMO-8400 was well-tolerated and showed TLR target engagement at three dose levels in healthy subjects. These results build on the results of our Phase 2 clinical trial of IMO-3100, an antagonist of TLRs 7 and 9, in patients with plaque psoriasis, which we believe provided clinical proof of concept of our approach of targeting specific TLRs for the treatment of psoriasis and other autoimmune and inflammatory diseases.”

Dr. Agrawal continued, “Our next step is to conduct a Phase 2 clinical trial in patients with psoriasis with an extended treatment period of up to 12 weeks. Based on our evaluation of the comparative profiles of IMO-3100 and IMO-8400, including the engagement of TLR8 by IMO-8400, Idera has determined to conduct this Phase 2 trial with IMO-8400. Subject to successful completion of our ongoing multiple dose Phase 1 trial of IMO-8400 and to obtaining the necessary financing to conduct this trial, we expect to initiate this Phase 2 clinical trial in the second quarter of 2013.”

“Our 2012 year-end cash and cash equivalents totaled $10.1 million. We are exploring financial alternatives to obtain the additional capital to continue progress with our autoimmune disease program,” said Mr. Lou Arcudi, Senior Vice President of Operations and Chief Financial Officer.

Financial Results

As of December 31, 2012, cash and cash equivalents totaled $10.1 million compared to $24.6 million at December 31, 2011.

Fourth Quarter Results

Net loss applicable to common stockholders for the three months ended December 31, 2012 was $6.5 million, or $0.24 per diluted share, compared to net loss applicable to common stockholders of $9.7 million, or $0.35 per diluted share, for the same period in 2011. There was no significant revenue recognized in the fourth quarter of 2012 or 2011. Research and development expenses for the three months ended December 31, 2012 totaled $3.1 million compared to $5.7 million for the same period in 2011. General and administrative expenses for the three months ended December 31, 2012, totaled $1.3 million compared to $1.5 million for the same period in 2011.

Full Year Results

Net loss applicable to common stockholders for the year ended December 31, 2012 was $22.5 million, or $0.81 per diluted share, compared to net loss applicable to common stockholders of $28.3 million, or $1.03 per diluted share, for 2011. Total revenues in each of the years ended December 31, 2012 and 2011 were $0.1 million. Research and development expenses for the year ended December 31, 2012 totaled $13.7 million compared to $18.0 million for 2011. General and administrative expenses for the year ended December 31, 2012 totaled $6.3 million compared to $7.9 million for 2011.

2012 Research and Development Highlights

Autoimmune and Inflammatory Diseases Program

Idera’s approach to the potential treatment of autoimmune and inflammatory diseases involves inhibiting the induction of immune responses mediated through TLR7, TLR8 and TLR9. These TLRs are known to be activated in autoimmune and inflammatory diseases by aberrant complexes that contain host RNA or DNA. The Company has two TLR antagonist drug candidates in clinical evaluation.

IMO-8400 is an antagonist of TLR7, TLR8 and TLR9.

Phase 1 Single Ascending Dose Trial in Healthy Subjects Completed

During the first quarter of 2013, the Company completed the escalating single-dose portion of a Phase 1 trial of IMO-8400 in healthy subjects.

The Company initiated the Phase 1 clinical trial of IMO-8400 in the fourth quarter of 2012 to assess the safety and the pharmacodynamic activity of IMO-8400 in healthy subjects. The single-dose portion of this trial involved three escalating dose levels of 0.1, 0.3, and 0.6 mg/kg of IMO-8400, or placebo with six subjects receiving each treatment, and was completed during the first quarter of 2013. IMO-8400 treatment was well tolerated at all dose levels, and the intended target engagement of TLR7, TLR8, and TLR9 was observed in IMO-8400 treated subjects compared to placebo-treated subjects.

The Company commenced the multiple-dose portion of this trial in the first quarter of 2013. The multiple-dose portion of this trial involves two dose levels of IMO-8400, 0.3 and 0.6 mg/kg, and placebo, with six subjects receiving each treatment of four weekly doses. The Company expects data from the multiple-dose portion of this trial to be available in the second quarter of 2013.

Next Steps in Clinical Development

The next step in the Company’s autoimmune and inflammatory diseases program is to initiate a Phase 2 clinical trial of IMO-8400 in patients with plaque psoriasis with a treatment period of up to 12 weeks. In the planned Phase 2 trial, 32 patients will be randomized to receive weekly doses for up to 12 weeks of IMO-8400 at one of three dose levels or placebo. Safety and improvement in Psoriasis Area Severity Index (PASI) score will be monitored throughout the study. The Company anticipates initiation of the study during the second quarter of 2013. In March 2013, a protocol for the

trials was submitted to the regulatory authorities in Europe for review. The Company also expects to initiate a Phase 2 clinical trial of IMO-8400 in patients with lupus during the second half of 2013. Both trials are subject to successful completion of the ongoing multiple dose Phase 1 trial of IMO-8400 and to the Company obtaining the necessary financing to conduct the trials.

Pre-clinical studies and presentations

Dr. James G. Krueger, M.D., Ph.D., of The Rockefeller University, gave an oral presentation entitled “Novel Toll-like Receptor Antagonists Strongly Decrease Expression of IL-23-induced and Psoriasis Profile Genes in a Mouse Model” in the Late-Breaking Research Symposium on March 2nd, 2013, during the American Academy of Dermatology Annual Meeting. Dr. Krueger presented data showing that, in a preclinical model of IL-23-induced skin inflammation, genes related to the production of key mediators of psoriasis including Interleukin (IL) -17, IL-6, IL-12/23, IL-1, IL-21 Receptor, and INF-gamma were restored toward normal levels by treatment with IMO-3100 and IMO-8400. The inclusion of TLR8 activity with IMO-8400 was additive to the effect on gene expression that was observed with IMO-3100.

IMO-3100 is a dual antagonist of TLR7 and TLR9.

Top-line Results of Phase 2 Trial of IMO-3100 in Patients with Psoriasis Announced

In December 2012, the Company announced top-line results from a Phase 2 trial of IMO-3100 in patients with moderate to severe plaque psoriasis. The Company expects that full data from this trial will be presented at the International Investigative Dermatology meeting in May 2013.

In this double-blind, placebo-controlled trial, 44 patients were randomized on a 1:1:1 basis to receive IMO-3100 monotherapy at 0.16 or 0.32 mg/kg or placebo by subcutaneous injection once weekly for four weeks with four weeks of follow-up. Assessments of safety and multiple parameters of clinical activity, including PASI score, were monitored throughout the study. In addition to the clinical assessments, biopsies of psoriasis plaques were evaluated for treatment-related changes in epidermal thickness and immune cell infiltrates consistent with the intended mechanism of action.

Previously announced top-line clinical results from this trial include:

- Treatment at both IMO-3100 dose levels was well tolerated, with no treatment-related discontinuations
- A treatment effect was demonstrated in measures of clinical efficacy in patients in both IMO-3100 dose cohorts and PASI reductions at both dose levels were sustained throughout the four-week follow-up period
- At the end of the four-week follow-up period, 48% of patients treated with either dose of IMO-3100 (12 of 25) demonstrated improvements of 35% to 90% from baseline PASI scores compared with 0 of 12 in the placebo cohort; this difference was statistically significant ($p<0.005$)
- The trial achieved the pre-specified clinical endpoint of reduction in PASI scores at the end of treatment in the 0.16-mg/kg dose cohort with statistical significance ($p<0.02$) compared to the placebo cohort, but not in the 0.32-mg/kg dose cohort
- The 0.16-mg/kg cohort also achieved, with statistical significance ($p<0.02$), the pre-specified clinical endpoint of improvement in plaque induration, a measure of plaque thickness, at the end of treatment and during the follow-up period
- At the end of the four-week follow-up period, 25% (3 of 12) of patients treated with 0.16 mg/kg/dose and 31% (4 of 13) with 0.32 mg/kg/dose achieved PASI 50 or greater, compared to 0 of 12 placebo patients

Skin biopsies were collected at baseline and after completion of treatment to investigate changes in epidermal thickness and immune cell infiltrates. Change in epidermal thickness was the primary endpoint for the trial. Placebo-treated patients had a median change in epidermal thickness of +7.7% compared to a median change of -6.4% among IMO-3100 treated patients; this difference was not statistically significant and the primary endpoint of the trial was not achieved. A known limitation of skin biopsies after four weeks of treatment is that psoriatic plaques do not resolve in a uniform fashion, and therefore, biopsies may not provide a representative sampling of lesions (ref: Ann Rheum Dis 2005;64:65-68).

Partnered Programs

TLR7, TLR 8 and TLR9 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, TLR8 and TLR9 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.

Additional Proprietary Programs

The Company is seeking to enter into collaborations with third parties to advance its clinical programs in oncology and respiratory diseases and research programs in hematologic malignancies, use of TLR3 agonists as vaccine adjuvants, and applications of gene-silencing Oligonucleotide technology.

Intellectual Property

In 2012, the Company was issued 22 new U.S. and foreign patents related to its TLR-targeted compounds. Presently, the Company's intellectual property portfolio contains over 400 patents and patent applications worldwide, including over 200 patents and patent applications covering the Company's TLR-targeted compounds. In addition, the Company's intellectual property portfolio includes more than 150 patents and patent applications for antisense technology and 10 patents and patent applications for GSO technology.

Financing

In November 2012, Idera raised $7.0 million in gross proceeds in a convertible preferred stock and warrant offering. In the offering, the Company issued and sold 424,242 shares of its Series E convertible preferred stock (convertible into 8,484,840 shares of common stock) and warrants to purchase 8,484,840 shares of common stock.

About Idera Pharmaceuticals, Inc.

Idera Pharmaceuticals is developing a novel approach to the treatment of autoimmune and inflammatory diseases by targeting specific Toll-like Receptors (TLRs) to inhibit the induction of immune responses. The Company has two drug candidates in clinical development: IMO-8400, an antagonist of TLRs 7, 8 and 9, and IMO-3100, an antagonist of TLR7 and 9. Additionally, Idera has a collaboration with Merck & Co. for the use of TLR agonists as vaccine adjuvants for cancer, infectious diseases and Alzheimer's disease. 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 Idera will be able to obtain cash resources sufficient to fund the Company's operations; 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 Idera's clinical trials will commence and will be completed when expected by Idera; 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 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; and such other important factors as are set forth under the caption "Risk Factors" in Idera's Annual Report on Form 10-K for the year ended December 31, 2012 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
(In thousands, except per share data)

	Three Months Ended December 31,		Year Ended December 31,	
	2012	2011	2012	2011
	(Unaudited)			
Revenues	$ 11	$ 8	$ 51	$ 53
Operating Expenses				
Research & Development	3,078	5,700	13,673	17,969
General & Administrative	1,265	1,539	6,279	7,939
Total Operating Expenses	4,343	7,239	19,952	25,908
Loss from Operations	(4,332)	(7,231)	(19,901)	(25,855)
Decrease in Fair Value of Warrant Liability	569	1,974	675	1,974
Other, net	(35)	97	(14)	105
Net Loss	(3,798)	(5,160)	(19,240)	(23,776)
Preferred Stock Accretion and Dividends	2,730	4,548	3,210	4,548
Net Loss Applicable to Common Stockholders	$ (6,528)	$ (9,708)	$(22,450)	$(28,324)
Basic and Diluted Net Loss Per Common Share Applicable to Common Stockholders	$ (0.24)	$ (0.35)	$ (0.81)	$ (1.03)
Shares Used in Computing Basic and Diluted Net Loss Per Common Share Applicable to Common Stockholders	27,642	27,635	27,639	27,623

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

	At December 31,	
	2012	2011

Cash & Cash Equivalents	$10,096	$24,571
Other Assets	727	1,024
Total Assets	$10,823	$25,595
Total Liabilities	$ 4,196	$ 7,650
Redeemable Preferred Stock	5,921	5,921
Stockholders' Equity	706	12,024
Total Liabilities, Redeemable Preferred Stock & Stockholders' Equity	$10,823	$25,595

Source: Idera Pharmaceuticals, Inc.

Idera Pharmaceuticals, Inc.
Lou Arcudi, 617-679-5517
larcudi@iderapharma.com