Idera Pharmaceuticals Reports Fourth Quarter and Full Year 2011 Financial Results and Provides Pipeline Update

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CAMBRIDGE, Mass.--(BUSINESS WIRE)--Mar. 14, 2012-- Idera Pharmaceuticals, Inc. (Nasdaq: IDRA) today reported financial and operational results for the fourth quarter and year ended December 31, 2011.

"Idera's proprietary drug candidates targeting Toll-like Receptors, or TLRs, have advanced to Phase 2 clinical trials in both of our key therapeutic areas of focus: oncology and autoimmune diseases," said Sudhir Agrawal, D.Phil., Chairman and Chief Executive Officer. "During the second quarter of this year, we anticipate data from a randomized Phase 2 trial of IMO-2055 in combination with Erbitux in patients with second-line squamous cell carcinoma of the head and neck. We also expect to initiate a Phase 2 study of IMO-3100 in patients with psoriasis in the second quarter."

Dr. Agrawal continued, "We have expanded our pipeline in autoimmune diseases with the addition of IMO-8400, a first-in-class antagonist of TLRs 7, 8 and 9. We have selected lupus as the first disease indication for IMO-8400. However, based on the roles of TLR7, 8 and 9 in multiple autoimmune diseases, IMO-8400 has potential applications in additional disease indications."

Financial Results

As of December 31, 2011, cash, cash equivalents and investments totaled $24.6 million compared to $34.6 million at December 31, 2010.

Fourth Quarter Results

Net loss applicable to common stockholders for the three months ended December 31, 2011, was $9.7 million, or $0.35 per diluted share, compared to net loss applicable to common stockholders of $6.0 million, or $0.22 per diluted share, for the same period in 2010. Total revenues were $1.1 million for the three months ended December 31, 2010. There was no significant revenue recognized in the fourth quarter of 2011 since we completed the research portions of our collaborations in 2010. Research and development expenses for the three months ended December 31, 2011, totaled $5.7 million compared to $4.9 million for the same period in 2010. General and administrative expenses for the three months ended December 31, 2011, totaled $1.5 million compared to $2.2 million for the same period in 2010.

Full Year Results

Net loss applicable to common stockholders for the year ended December 31, 2011, was $28.3 million, or $1.03 per diluted share, compared to net loss applicable to common stockholders of $18.0 million, or $0.71 per diluted share, for 2010. Total revenues for the year ended December 31, 2011, were $0.1 million compared to $16.1 million for 2010. Research and development expenses for the year ended December 31, 2011, totaled $18.0 million compared to $24.2 million for 2010. General and administrative expenses for the year ended December 31, 2011, totaled $7.9 million compared to $9.9 million for 2010.

2011 Research and Development Highlights

Autoimmune and Inflammatory Disease Program

IMO-3100, a dual antagonist of TLR7 and TLR9, is the lead candidate in this program. We are developing it as a novel approach to treat autoimmune and inflammatory diseases. IMO-3100 has shown activity in preclinical models of psoriasis, lupus, rheumatoid arthritis and hyperlipidemia. We have selected psoriasis as the initial disease indication for clinical development of IMO-3100.

Idera has completed Phase 1 clinical trials of IMO-3100 monotherapy in healthy subjects. In these studies, IMO-3100 was well-tolerated at the doses studied and showed target engagement of TLR7 and TLR9. Data from these studies have been presented at scientific meetings.

Phase 2 Trial of IMO-3100 in Patients with Psoriasis

- The Company anticipates the initiation of a Phase 2 study during the second quarter of 2012. In this study, IMO-3100 will be evaluated in adult patients with moderate to severe plaque psoriasis, randomized into three arms. Two dose levels of IMO-3100 will be evaluated with a concurrent placebo arm.

IMO-8400 is an antagonist of TLRs 7, 8 and 9 that the Company has selected as its second drug candidate for the treatment of autoimmune diseases. The Company created IMO-8400 using Idera's chemistry-based approach to target TLRs.

- IMO-8400 has shown activity in mouse models of lupus as evidenced by increased survival, suppression of anti-DNA and anti-RNA antibodies and inflammatory cytokines, decreased tissue pathology and improved renal function.
- The Company expects to submit to the FDA an Investigational New Drug application for IMO-8400 during the fourth quarter of 2012, and has selected lupus as the initial disease indication for clinical development.

Oncology Program

IMO-2055, a TLR9 agonist, is the lead candidate in the Company's oncology program. The Company is developing IMO-2055 as a novel immune modifier for the treatment for cancer. The Company's clinical development strategy involves the use of IMO-2055 in combination with targeted anti-cancer agents, including biologics and small molecules. The Company reacquired the rights to IMO-2055 in oncology from Merck KGaA in the fourth quarter of 2011.

The Company is evaluating IMO-2055 in clinical trials in multiple cancer indications in combination with targeted agents, including Tarceva®, Avastin® and Erbitux®.

Phase 1b Trial of IMO-2055 in Combination with Tarceva and Avastin for the Treatment of Non-Small Cell Lung Cancer (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. Top-line results were announced in January 2012. Detailed data will be presented at a medical meeting.

  In this study, IMO-2055 was evaluated at four dose levels in combination with standard doses of Tarceva and Avastin in 36 patients with advanced NSCLC. The recruited patient population was second- to fifth-line. Patients received oral Tarceva at 150 mg once per day and Avastin at 15 mg/kg once every three weeks by intravenous infusion in addition to subcutaneous doses of IMO-2055 once per week until disease progression or other discontinuation criteria was met. The trial was conducted at 10 centers in the United States.

  Nineteen patients were recruited to the dose-escalation portion of the trial, in which 0.32 mg/kg was identified as the recommended Phase 2 dosage of IMO-2055. An additional 17 patients were recruited and treated at 0.32 mg/kg/week to further document safety and efficacy. No new or unexpected toxicities were observed in the study, and rates of well-known side effects of the three agents were consistent with results from previously presented clinical trials of IMO-2055 and of the combination of Tarceva and Avastin. In this trial, the combination of IMO-2055 with Tarceva and Avastin was well tolerated, and the most common adverse events were diarrhea, nausea, fatigue and rash.

Phase 2, 1:1 Randomized, Controlled Trial of IMO-2055 in Combination with Erbitux in Second-Line Erbitux-Naïve Subjects with Recurrent or Metastatic Squamous Cell Carcinoma of the Head and Neck (SCCHN)

- The study is fully enrolled. Patient treatment and follow-up are ongoing. The Company anticipates top-line data during the second quarter of 2012.

  In this study, 104 patients with SCCHN who had progressed on a cytotoxic therapy were randomized into two arms. In one arm, patients were treated with IMO-2055 at a dose of 0.32 mg/kg given once weekly subcutaneously in combination with weekly Erbitux. In the other arm of the study, patients were treated with Erbitux alone. The trial is being conducted at multiple centers in Europe and the United States.

  The primary endpoint of the study is progression-free survival. Secondary outcome measures include overall response rate (by RECIST), disease control rate, overall survival, safety and tolerability in subjects treated with IMO-2055 + Erbitux compared to Erbitux alone.

  In this study, crossover of the patients who progress on Erbitux alone is permitted to the combination arm of IMO-2055 and Erbitux. Evaluation of response rate and progression-free

survival in the crossover patients presents a second setting to evaluate the efficacy of adding IMO-2055 to Erbitux in patients whose disease is refractory to that agent.

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

- The goal of the study was to establish a recommended Phase 2 dose.

  16 patients have been enrolled at three dose levels. We anticipate the data from this study to be available during the second quarter of 2012.

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. Further studies are ongoing for undisclosed gene targets.

Partnered Programs

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 January 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 advance its other TLR-targeted programs in infectious diseases, respiratory diseases, hematologic oncology and adjuvant applications of TLR3 agonists through licensing and partnering.

Intellectual Property

In 2011, the Company was issued 19 new U.S. and foreign patents related to its TLR-targeted compounds. Presently, the Company's intellectual property portfolio contains over 500 patents and patent applications worldwide, including over 300 patents and patent applications covering the Company's TLR-targeted compounds. In addition, the Company's intellectual property portfolio includes more than 200 patents and patent applications for antisense technology and 5 patent applications for GSO technology.

Financing

In November 2011, Idera raised $9.5 million in gross proceeds in a convertible preferred stock and warrant offering. In the offering, the Company issued and sold 1,124,260 shares of its convertible preferred stock convertible into 5,621,300 shares of common stock and warrants to purchase 2,810,650 shares of common stock. Each share of convertible preferred stock is convertible into five shares of common stock at a conversion price of $1.6275 per share and warrants are exercisable at $1.6275 per share.

About Idera Pharmaceuticals, Inc.

Idera Pharmaceuticals applies its proprietary Toll-like Receptor (TLR) drug discovery platform to create immunomodulatory drug candidates. The Company's TLR-targeted candidates are being developed to treat autoimmune and inflammatory diseases and cancer, and for use as vaccine adjuvants. Additionally, the Company is advancing its gene-silencing oligonucleotide (GSO) 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 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 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 Annual Report on Form 10-K for the year ended December 31, 2011 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 LLC, a wholly-owned subsidiary of Eli Lilly and Company. Tarceva® is a registered trademark of OSI Pharmaceuticals, LLC, an affiliate of Astellas Pharma US, Inc. Avastin® is a registered trademark of Genentech, Inc.

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

	Three Months Ended December 31,		Years Ended December 31,	
	2011	2010 (Unaudited)	2011	2010
Revenues	$ 8	$ 1,058	$ 53	$ 16,110
Operating Expenses				
Research & Development	5,700	4,893	17,969	24,226
General & Administrative	1,539	2,158	7,939	9,867
Total Operating Expenses	7,239	7,051	25,908	34,093
Loss from Operations	(7,231)	(5,993)	(25,855)	(17,983)
Decrease in Fair Value of Warrant Liability	1,974	-	1,974	-
Other, net	97	(20)	105	20
Net Loss	(5,160)	(6,013)	(23,776)	(17,963)
Preferred Stock Accretion and Dividends	4,548	-	4,548	-
Net Loss Applicable to Common Stockholders	$ (9,708)	$ (6,013)	$(28,324)	$(17,963)
Basic and Diluted Net Loss Per Common Share Applicable to Common Stockholders	$ (0.35)	$ (0.22)	$ (1.03)	$ (0.71)
Shares Used in Computing Basic and Diluted Net Loss Per Common Share Applicable to Common Stockholders	27,635	27,587	27,623	25,139

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

	At December 31,	
	2011	2010
Cash, Cash Equivalents & Investments	$24,571	$34,643
Other Assets	1,024	2,238
Total Assets	$25,595	$36,881
Total Liabilities	$ 7,650	$ 3,780
Redeemable Preferred Stock	5,921	-
Stockholders' Equity	12,024	33,101
Total Liabilities, Redeemable Preferred Stock & Stockholders' Equity	$25,595	$36,881

Source: Idera Pharmaceuticals, Inc.

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