Idera Pharmaceuticals Reports Third Quarter 2011 Financial Results

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CAMBRIDGE, Mass., Nov 09, 2011 (BUSINESS WIRE) -- Idera Pharmaceuticals, Inc. (Nasdaq: IDRA) today reported financial results for the third quarter ended September 30, 2011. Idera is a biotechnology company engaged in the discovery and development of DNA- and RNA-based drug candidates targeted to Toll-like receptors (TLRs).

"Based on a recently completed strategic assessment and prioritization of our discovery and development pipeline, we are focusing our internal development efforts on our proprietary TLR-targeted autoimmune and inflammatory disease development program and on our gene silencing oligonucleotide technology platform," commented Sudhir Agrawal, D.Phil., Chairman and Chief Executive Officer of Idera. "Our near-term goal is to evaluate IMO-3100, a lead development candidate for autoimmune and inflammatory diseases, in a clinical proof-of-concept study in patients with psoriasis. Concurrently, we are continuing to work to validate the applications of our GSO technology platform, which we believe holds the potential to overcome significant challenges associated with earlier gene silencing technologies."

Agrawal continued, "In addition, Merck KGaA is completing a Phase 2 trial of IMO-2055 in combination with Erbitux(R) for second-line treatment of head and neck cancer and we expect the results of this study, as well as two Phase 1b studies in colon and non-small cell lung cancer conducted by Merck KGaA, to be available in 2012."

"Idera ended the third quarter with $19.1 million in cash and cash equivalents, and after the quarter end, completed a $9.5 million financing. With the prioritization of internal programs, along with the alignment of our financial and human resources, we believe our current cash position will be sufficient to meet key near-term objectives," said Lou Arcudi, Chief Financial Officer.

Financial Results

As of September 30, 2011, cash, cash equivalents and investments totaled $19.1 million compared to $34.6 million at December 31, 2010.

In November 2011, we raised $9.5 million in gross proceeds through the issuance and sale of preferred stock and warrants not included in the end of third quarter accounts.

Net loss for the three months ended September 30, 2011, was $5.5 million, or $0.20 per diluted share, compared to a net loss of $4.7 million, or $0.18 per diluted share, for the same period in 2010. For the nine-month period, the Company's net loss was $18.6 million, or $0.67 per diluted share, compared to a net loss of $12 million, or $0.49 per diluted share, for the same period in 2010.

Research and development expenses for the three months ended September 30, 2011, totaled $3.6 million compared to $7.8 million for the same period in 2010. For the nine-month period, R&D expenses totaled $12.3 million compared to $19.3 million for the same period in 2010.

General and administrative expenses for the three months ended September 30, 2011, totaled $1.9 million compared to $2.2 million for the same period in 2010. For the nine-month period, G&A expenses totaled $6.4 million compared to $7.7 million for the same period in 2010.

Third Quarter 2011 Research and Development Highlights

IMO-3100 for Autoimmune and Inflammatory Diseases

IMO-3100, a dual antagonist of TLR7 and TLR9, is being developed as a novel approach to treat autoimmune and inflammatory diseases. IMO-3100 has shown activity in preclinical models of lupus, psoriasis, rheumatoid arthritis and hyperlipidemia.

Idera has completed two Phase 1 clinical trials of IMO-3100 monotherapy in healthy subjects. Data from the Phase 1 clinical trials have been presented at scientific meetings.

Next Steps in Clinical Development of IMO-3100

- The next step in the clinical development of IMO-3100 is to conduct a clinical proof-of-concept study in a selected autoimmune disease indication. With input from our Autoimmune Disease Scientific Advisory Board and key opinion leaders, we have selected psoriasis as the initial disease indication in which to assess IMO-3100 clinical activity.
- In June 2011, we submitted to the FDA a protocol for a Phase 2 clinical trial to evaluate IMO-3100 in patients with psoriasis. In July 2011, the FDA placed a clinical hold on the proposed protocol. We are continuing to communicate with the FDA regarding the evaluation of IMO-3100 in patients with psoriasis. Our goal is to initiate a clinical trial of IMO-3100 in 2012 to establish proof of concept.

Gene-silencing Oligonucleotide Technology

Gene-silencing oligonucleotides (GSOs) are single-stranded RNA or DNA constructs with two exposed 3'-ends that are complementary to targeted messenger RNA and microRNA sequences of therapeutic interest.

Recent Developments in the GSO Program

- In October 2011, Idera presented preclinical data on its GSOs at the Cell Symposium on Regulatory RNAs. In the preclinical studies presented, systemic delivery of GSOs targeted to the mRNA of ApoB or PCSK9, two validated targets associated with cardiovascular diseases, caused a reduction in the level of the targeted mRNA and associated protein and resulted in a decrease in serum total cholesterol and LDL-cholesterol concentration.

Partnered Programs

IMO-2055 (EMD 1201081) for Cancer Treatment

IMO-2055, a TLR9 agonist, is being developed by Merck KGaA as a novel immunotherapy for the treatment for cancer under an exclusive, worldwide license agreement established between Idera and Merck KGaA in December 2007. In July 2011, Merck KGaA informed Idera that it had determined that it would not conduct further development of IMO-2055, but that it planned to complete of the ongoing Phase 2 trial. Merck KGaA has the right to evaluate follow-on compounds provided by Idera under the collaboration.

IMO-2055 Clinical Studies

Merck KGaA has conducted clinical trials of IMO-2055 in combination with other cancer therapy agents including:

- Phase 2 clinical trial for the second-line treatment of squamous cell carcinoma of the head and neck (SCCHN) in combination with Erbitux(R). This trial is ongoing.
- Phase 1b trial of IMO-2055 in combination with Tarceva(R) and Avastin(R) for the treatment of non-small cell lung cancer.
- Phase 1b trial of IMO-2055 in combination with Erbitux and FOLFIRI for the treatment of colorectal cancer.
- Phase 1 trial of IMO-2055 in combination with Erbitux, cisplatin, and 5-fluorouracil for the first-line treatment of SCCHN. This trial has been discontinued.

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 July 2011, Merck and Idera scientists published a paper entitled "Synthesis and immunological activities of novel Toll-like receptor 7 and 8 agonists" in the journal Cellular Immunology.

Additional Proprietary Programs

Based on its strategic assessment and prioritization, the Company has discontinued further development of IMO-2125 in hepatitis C virus infection and decided to advance its TLR-targeted programs in infectious diseases, respiratory diseases, hematologic oncology, and additional vaccine adjuvant applications only through licensing and partnering.

ERBITUX(R) is a registered trademark of ImClone LLC, a wholly-owned subsidiary of Eli Lilly and Company. Tarceva(R) is a trademark of OSI Pharmaceuticals, LLC, Farmingdale, NY 11735, USA, an affiliate of Astellas Pharma US, Inc. Avastin(R) is a registered trademark of Genentech, Inc

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, 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 such as the results referenced in this release will be indicative of results obtained in later preclinical studies and future clinical trials, if any; 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 the clinical hold on IMO-3100 will be lifted and the FDA will agree on additional clinical evaluation of IMO-3100; whether clinical trials will be completed and results announced on a timely basis; whether, if the Company's

products receive approval, they will be successfully distributed and marketed; whether the Company's collaborations 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 September 30, 2011, 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 (Unaudited)
(In thousands, except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Revenues	$ 4	$ 5,089	$ 45	$ 15,052
Operating Expenses				
Research & Development	3,574	7,786	12,269	19,333
General & Administrative	1,948	2,193	6,400	7,709
Total Operating Expenses	5,522	9,979	18,669	27,042
Loss from Operations	(5,518)	(4,890)	(18,624)	(11,990)
Other, net	29	179	8	40
Net Loss	$ (5,489)	$ (4,711)	$(18,616)	$(11,950)
Basic Net Loss Per Common Share	$ (0.20)	$ (0.18)	$ (0.67)	$ (0.49)
Diluted Net Loss Per Common Share	$ (0.20)	$ (0.18)	$ (0.67)	$ (0.49)
Shares Used in Computing Basic Net Loss Per Common Share	27,632	25,980	27,618	24,314
Shares Used in Computing Diluted Net Loss Per Common Share	27,632	25,980	27,618	24,314

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

	September 30, 2011	December 31, 2010
	(Unaudited)	
Cash, Cash Equivalents & Investments	$ 19,081	$ 34,643
Other Assets	1,359	2,238
Total Assets	$ 20,440	$ 36,881
Accounts Payable & Accrued Liabilities	$ 3,787	$ 3,780
Stockholders' Equity	16,653	33,101
Total Liabilities & Stockholders' Equity	$ 20,440	$ 36,881

SOURCE: Idera Pharmaceuticals, Inc.

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