ZIOPHARM Oncology, Inc.

ZIOPHARM Reports Fourth Quarter and Full Year 2011 Financial Results

Significant Progress for Lead Programs

NEW YORK, Feb. 29, 2012 (GLOBE NEWSWIRE) -- ZIOPHARM Oncology, Inc. (Nasdaq:ZIOP) announced today its financial results for the fourth quarter and full year ending December 31, 2011, and the filing of its Annual Report on Form 10-K with the Securities and Exchange Commission.

Fourth Quarter Results

The Company's cash used in operations during the fourth quarter was $13.8 million, an increase of $8.0 million from $5.8 million for the same period of 2010. The increase in spending is attributable primarily to research and development activities for the palifosfamide pivotal Phase 3 trial (PICASSO 3), additional activities supporting palifosfamide development, and expenditures supporting the Company's synthetic biology therapeutics development program established early in 2011. The Company reported a net loss of $13.2 million for the fourth quarter, or $(0.19) per share, compared to a net loss of $11.9 million, or $(0.25) per share, in the fourth quarter of 2010. Excluding recognition of a non-cash gain of $3.2 million attributable to the change in liability-classified warrants, there was a net loss of $16.4 million, or $(0.24) per share, for the fourth quarter ended December 31, 2011.

Full Year Results

Net loss for the year was $63.8 million, or $(0.97) per share, compared to a net loss of $32.7 million, or $(0.71) per share, for 2010. The increase in net loss of $31.1 million included a one-time, non-cash charge of $17.5 million for in process research and development expense related to the Company's issuance of stock in conjunction with entering into the Company's Exclusive Channel Partnership with Intrexon Corporation. The remaining increase is primarily attributable to the ongoing pivotal Phase 3 palifosfamide trial as well as related support activity and the Company's synthetic biology program. Total operating expenses for 2011 were $72.1 million, compared to $24.5 million for 2010, or an increase of $47.6 million. The difference between 2011 full year operating expenses and net loss is primarily attributable to a non-cash gain of $7.6 million related to the change in fair value of liability-classified warrants.

The Company ended the year with $104.7 million in cash and cash equivalents which, along with net proceeds of approximately $49.1 million from a financing transaction completed in January of 2012, is currently expected to support operations into the second half of 2013.

Progress and Milestones within Lead Programs

Palifosfamide (Zymafos® or ZIO-201):

ZIOPHARM recently announced positive preliminary overall survival (OS) data from the multicenter, randomized, Phase 2 trial of palifosfamide plus doxorubicin vs. doxorubicin alone (PICASSO) in patients with unresectable or metastatic soft tissue sarcoma. The hazard ratio for OS was 0.78 favoring the palifosfamide arm (with 2-year survival of 40% compared to 30%). These OS data correlate with the previously announced progression-free survival (PFS) results from the study, which demonstrated a hazard ratio of 0.43. The control arm included cross-over, in that subjects in this arm — who were measured for OS in the most recent analysis — could receive palifosfamide once they progressed on control therapy. Before and after cross-over, safety outcomes were similar between both arms, and the study was well balanced for the stratification criteria -- the same criteria used in the Phase 3 trial, the PICASSO 3 study, which has no cross-over. These OS data, together with PFS and safety data from the randomized Phase 2 study, demonstrate that the ongoing, randomized Phase 3 trial of palifosfamide in front-line metastatic soft tissue sarcoma is optimally modeled and powered for PFS and OS.

The PICASSO 3 study recently underwent a third review by the Independent Data Monitoring Committee (IDMC), which recommended continuation of the study with no change. Targeted completion of enrollment for PICASSO 3 is expected by the end of the first quarter of 2012. The outcome in PFS, the study's primary endpoint for accelerated approval, is anticipated in the second half of 2012.

ZIOPHARM also announced, in the fourth quarter, encouraging clinical results from an ongoing multicenter Phase

1b, open-label, dose escalation study of palifosfamide in combination with etoposide and carboplatin in patients with small cell lung cancer (SCLC) and other selected cancers. These data, presented at the AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics, demonstrated good tolerability and clinical activity in subjects with SCLC, germ cell tumor and ovarian cancer.

Synthetic Biology, IL-12 DNA Therapeutics:

In January of 2011, the Company announced a global, exclusive channel partnership in oncology with Intrexon Corporation, a next-generation synthetic biology company. Under the partnership, ZIOPHARM acquired rights to Intrexon's entire human in vivo effector platform within the field of oncology, which the Company will use to develop and commercialize DNA-based therapeutics.

The partnership includes two lead clinical-stage product candidates targeting the tightly controlled, intra-tumoral expression of a potent anti-cancer cytokine, Interleukin-12 (IL-12). In June, ZIOPHARM announced initial positive clinical results from the first-ever treatment demonstrating *in vivo* control over transgene encoding of a therapeutic anticancer protein in humans using a small molecule activator ligand at the 2011 Annual Meeting of the American Society of Clinical Oncology (ASCO). Data showed a correlation between T-cell immune responses and clinical outcome, a desired outcome with the highly focused use of IL-12, with limited adverse events and one significant adverse event that completely resolved.

The Company also announced the submission and acceptance of an Investigation New Drug application with the FDA, and subsequent dosing of patients with advanced melanoma in a Phase 1 clinical study of Ad-RTS-IL-12, a DNA therapy employing an adenoviral vector to deliver, directly into the patient's own cells, a gene which expresses Interleukin-12 (IL-12). The multi-center, single-arm, open-label, dose-escalation study, treating patients with unresectable Stage III or IV melanoma, will assess the safety and tolerability of intratumoral injections of Ad-RTS-IL-12. Secondary endpoints include a determination of the recommended Phase 2 dose, an evaluation of T cell immunity markers, and preliminary anti-tumor activity. The Company expects additional Phase 1 results from its IL-12 DNA program in 2012, with a pivotal Phase 2 study to commence in the second half of 2012. In addition to clinical-stage synthetic biology candidates, extensive ongoing preclinical and discovery development is continuing.

2011 and Recent Financing Highlights:

- In January, in conjunction with ZIOPHARM's entry into the Intrexon exclusive channel partnership, Intrexon purchased $11.6 million worth of ZIOPHARM common stock in a private placement. Subject to certain conditions and limitations, Intrexon further committed to purchase up to $50.0 million in conjunction with future qualifying Company securities offerings. Intrexon's $11.0 million participation in the Company's February 2011 public offering was applied against this aggregate purchase commitment.
- In February, the Company announced that it had raised approximately $59.8 million, after deducting underwriting discounts and commissions and estimated offering expenses, in a public offering of its common stock.
- In January 2012, the Company announced that it had raised approximately $49.1 million, after deducting underwriting discounts and commissions and estimated offering expenses, in a public offering of its common stock. The underwritten public offering included 9,650,000 shares of common stock, with a 30-day option granted to the underwriters to purchase up to an additional 1,447,500 shares to cover any over-allotments. The underwriters partially exercised their option to purchase an additional 464,401 shares, resulting in the Company's issuing total of 10,114,401 shares.

About ZIOPHARM Oncology, Inc.:

ZIOPHARM Oncology is a biopharmaceutical company engaged in the development and commercialization of small molecule and synthetic biology approaches to new cancer therapies. The Company's clinical programs include:

Palifosfamide (Zymafos® or ZIO-201) is a novel DNA cross-linker that in preclinical study has been shown to bypass resistance mediated by aldehyde dehydrogenase (ALDH), in addition to conferring a favorable toxicity profile compared to other in-class agents. Palifosfamide, administered intravenously, is currently in a randomized, double-blinded, placebo-controlled Phase 3 trial for the treatment of metastatic soft tissue sarcoma in the front-line setting. A Phase 1 trial is also nearing completion with palifosfamide in combination with etoposide and carboplatin to determine appropriate safety for initiating a potentially pivotal, adaptive Phase 3 trial in front-line, extensive SCLC expected to initiate in the second half of 2012. Additionally, an investigational new drug application has been accepted for the oral form of palifosfamide.

DNA-based therapeutics (synthetic biology), in partnership with Intrexon Corporation, include two clinical-stage product candidates, both of which are DNA IL-12 using the RheoSwitch Therapeutic System® to be turned *on/off* by an oral activator ligand and are currently in Phase 1. Additionally, multiple INDs are expected in the next 12-24 months resulting from preclinical

and discovery work underway to advance multiple antibody, immunotoxin, and protein decoy candidates, systemic delivery and a next generation RheoSwitch Therapeutic System®.

Indibulin (Zybulin™ or ZIO-301) is a novel, oral tubulin binding agent that is expected to have several potential benefits including oral dosing, application in multi-drug resistant tumors, no neuropathy and a quite tolerable toxicity profile. It is currently being studied in Phase 1/2 in metastatic breast cancer.

Darinaparsin (Zinapar® or ZIO-101) is a novel mitochondrial- and hedgehog-targeted agent (organic arsenic) currently in a solid tumor Phase 1 study with oral administration and has been developed intravenously for the treatment of relapsed peripheral T-cell lymphoma.

ZIOPHARM's operations are located in Boston, MA, Germantown, MD and New York City. Further information about ZIOPHARM may be found at www.ziopharm.com.

Forward-Looking Safe Harbor Statement:

This press release contains certain forward-looking information about ZIOPHARM Oncology that is intended to be covered by the safe harbor for "forward-looking statements" provided by the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements are statements that are not historical facts. Words such as "expect(s)," "feel(s)," "believe(s)," "will," "may," "anticipate(s)" and similar expressions are intended to identify forward-looking statements. These statements include, but are not limited to, statements regarding our ability to successfully develop and commercialize our therapeutic products; our ability to expand our long-term business opportunities; financial projections and estimates and their underlying assumptions; and future performance. All of such statements are subject to certain risks and uncertainties, many of which are difficult to predict and generally beyond the control of the Company, that could cause actual results to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements. These risks and uncertainties include, but are not limited to: whether Palifosfamide, Darinaparsin, Indibulin, or any of our other therapeutic products will advance further in the clinical trials process and whether and when, if at all, they will receive final approval from the U.S. Food and Drug Administration or equivalent foreign regulatory agencies and for which indications; whether Palifosfamide, Darinaparsin, Indibulin, and our other therapeutic products will be successfully marketed if approved; whether our DNA-based biotherapeutics discovery and development efforts will be successful; our ability to achieve the results contemplated by our collaboration agreements; the strength and enforceability of our intellectual property rights; competition from pharmaceutical and biotechnology companies; the development of and our ability to take advantage of the market for DNA-based biotherapeutics; our ability to raise additional capital to fund our operations on terms acceptable to us; general economic conditions; and the other risk factors contained in our periodic and interim SEC reports filed from time to time with the Securities and Exchange Commission, including but not limited to our Annual Report on Form 10-K for the fiscal year ended December 31, 2011. Readers are cautioned not to place undue reliance on these forward-looking statements that speak only as of the date hereof, and we do not undertake any obligation to revise and disseminate forward-looking statements to reflect events or circumstances after the date hereof, or to reflect the occurrence of or non-occurrence of any events.

Zymafos and Zinapar are registered trademarks of ZIOPHARM Oncology, Inc.

ZIOPHARM Oncology, Inc.
Condensed Statements of Operations
(in thousands except share and per share data)

	Three Months Ended December 31,		Year Ended December 31,	
	2011	2010	2011	2010
Revenue	$ 200	$ --	$ 667	$ --
Operating expenses:				
Research and development	12,650	3,038	57,083	12,910
General and administrative	3,967	3,323	14,984	11,636
Total operating expenses	16,617	6,361	72,067	24,546
Loss from operations	(16,417)	(6,361)	(71,400)	(24,546)

Other income, net	13	736	39	765
Change in fair value of warrants	3,160	(6,226)	7,583	(8,889)
Net loss	$ (13,244)	$ (11,851)	$ (63,778)	$ (32,670)
Basic and diluted net loss per share	$ (0.19)	$ (0.25)	$ (0.97)	$ (0.71)
Weighted average common shares outstanding used to compute basic and diluted net loss per share	68,160,207	48,040,198	66,003,789	46,003,996

ZIOPHARM Oncology, Inc.
Balance Sheet Data
(in thousands)

	December 31, 2011 (unaudited)	December 31, 2010 (unaudited)
Cash and cash equivalents	104,713	60,392
Working capital	92,742	57,204
Total assets	108,108	61,520
Total stockholders' equity	71,607	30,553

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