



## NeoPharm, Inc. Announces Fourth Quarter And Full Year 2009 Financial Results

LAKE BLUFF, Ill., Mar 18, 2010 (BUSINESS WIRE) -- NeoPharm, Inc. (Other OTC: NEOL.PK), a publicly traded biopharmaceutical company dedicated to the research, development and commercialization of new and innovative therapeutic applications of drugs for cancer and other diseases, today announced its fourth quarter and full year 2009 financial results.

"During the past year we have continued to make solid progress with the development of our drug candidate portfolio and are extremely pleased to announce the results of our Phase II trials of LEP in recurrent breast cancer patients. The Phase II trial of LEP with 35 patients at a dose of 275 mg/m<sup>2</sup> showed a response rate of 46% compared to 11% with free Taxol<sup>(R)</sup> and 22% with Abraxane<sup>(R)</sup>. While preparations are underway to start a Phase III trial of LEP, we are pleased to announce that we have started a second Phase II trial of LEP to enroll 35 additional patients to significantly increase the sample size to 70 patients."

"We also are expecting to enroll patients in our Phase II clinical trial for the study of Liposome Entrapped Docetaxel (LE-DT), a novel, proprietary liposomal delivery system of docetaxel, the active ingredient of Taxotere<sup>(R)</sup>, for locally advanced or metastatic pancreatic cancer patients. The Phase II trial of LE-DT will soon start enrolling patients for advanced prostate cancer patients," commented Dr. Aquilur Rahman, President and Chief Executive Officer of NeoPharm. "We also recently announced the filing of an IND with the FDA for IL13-PE38QQR (IL13-PE) for the treatment of Idiopathic Pulmonary Fibrosis (IPF) which is the most deadly disease of the lungs in humans and for which there is currently no proven effective treatment. We expect to start a Phase I clinical trial for IPF in the second half of 2010."

### **Drug Candidate Pipeline Update**

#### ***LEP-ETU, Liposomal Encapsulated Paclitaxel***

In January 2010, the Company announced the results of a Phase II clinical trial of Liposome-Entrapped Paclitaxel (LEP), an active component of Taxol<sup>(R)</sup> that was conducted at 5 clinical sites in India. Thirty-five patients were enrolled and received LEP doses of 275 mg/m<sup>2</sup> administered over 90 minutes every 21 days without routine prophylactic pre-medication for infusion-related reactions. Patients received a median of 6 cycles (range 2 to 10) with 22 patients receiving greater-than or equal to 6 cycles. Fully audited overall tumor responses included: 16 patients (46%) with tumor response including 15 partial responses and one complete response; 10 patients (29%) with stable disease (mean duration, 6 cycles; range, 2-10 cycles); and 9 patients (25%) with progressive disease. LEP was well tolerated with sensory polyneuropathy greater-than or equal to grade 3 in only one subject (3%) and neutropenia greater-than or equal to grade 3 in 2 subjects (6%), two common toxicities of Taxol<sup>(R)</sup> and Abraxane<sup>(R)</sup>. No significant infusion-related reactions were observed as indicated by adverse events or prophylactic pre-medication use. The Company has started another Phase II trial for recurrent breast cancer to enroll 35 more patients while rapidly working to embark on a Phase III randomized trial of LEP with free Taxol<sup>(R)</sup> as a comparator arm in metastatic breast cancer patients with the goal being to achieve regulatory approval of LEP as an effective modality for the treatment of cancer patients as early as possible.

#### ***LE-DT, Liposomal Encapsulated Docetaxel***

In March 2010, NeoPharm expects to enroll patients in a Phase II clinical trial for the study of Liposome Entrapped Docetaxel (LE-DT), a novel, proprietary liposomal delivery system of docetaxel, the active ingredient of Taxotere<sup>(R)</sup>, for locally advanced or metastatic pancreatic cancer patients. This open-label, Phase II study is designed to determine the antitumor effect of LE-DT in locally advanced pancreatic cancer patients as evidenced radiologically and CA 19-9 as the surrogate biologic marker.

In addition, NeoPharm is going to embark on another Phase II trial of LE-DT for prostate cancer. This open label Phase II trial will define the clinical activity of LE-DT as antitumor response in soft tissues as well as defined by the serum Prostate Specific Antigen (PSA) levels as biological surrogate marker, disease response, progression free survival, and quality of life in patients with metastatic prostate cancer. The Company anticipates a total of 63 patients to be enrolled in this Phase II trial at up to six locations in the United States and overseas. Previously, the Company completed a Phase I study of LE-DT, which was designed to define the maximum tolerated dose (MTD) of the drug. The data from this trial was presented at the EORTC/AACR/NCI joint meeting held in Boston on November 16, 2009 which demonstrated that LE-DT has minimal toxicities compared to Taxotere<sup>(R)</sup>, in particular, peripheral neurotoxicity and water retention (edema).

#### ***Cintredekin Besudotox, IL-13, for Idiopathic Pulmonary Fibrosis (IPF)***

In December 2009, NeoPharm filed an investigational new drug application (IND) with the U.S. Food and Drug Administration (FDA) for IL13-PE38QQR (IL13-PE) for the treatment of Idiopathic Pulmonary Fibrosis (IPF). IPF is the most deadly disease of the lungs in humans with very high morbidity, and there is currently no proven effective treatment for the cure of this disease. In the fourth quarter of 2009, the Company signed a letter of intent to enter into a clinical research agreement with Duke University, a non-profit educational and health care institution acting for and on behalf of its Duke Clinical Research Institute ("Duke"), regarding potential clinical trials with IL13-PE38 in patients with IPF. Upon submission of this IND, the FDA raised a few scientific and technical questions to which the Company is in the process of responding. The Company expects to begin enrolling patients in a Phase I clinical trial in the second half of 2010.

#### ***LE-rafAON for Pancreatic Cancer with Gemcitabine***

All preclinical studies related to the IND submission have been completed, and the preclinical data is positive. NeoPharm is developing clinical protocols in collaboration with Georgetown University for Phase I and II studies of pancreatic cancer with LE-rafAON in combination with Cyber Knife radiation and in combination with Gemcitabine. The Company anticipates filing an IND for LE-rafAON in mid 2010.

#### ***Cintredekin Besudotox, IL-13, for Pediatric Brain Cancer***

Patient enrollment started in January 2010 for a Phase I clinical trial conducted by the National Institutes of Health ("NIH") in connection with the Company's Cooperative Research and Development Agreement ("CRADA") with the National Institute of Neurological Diseases and Stroke ("NINDS"), a part of the NIH, for research on a therapeutic agent for untreatable brain diseases, primarily in children. Under the terms of the CRADA, NINDS will deliver IL-13, in conjunction with a surrogate marker via NINDS' patented methodology of Convection Enhanced Delivery ("CED"), which is licensed to NeoPharm. The Company is providing its proprietary drug and technical resources to study its effects in various brain cancers in humans. NeoPharm has granted NINDS authorization to cross-reference its prior IL-13 IND for the treatment of GBM. NINDS plans to expedite the enrollment of patients in this Phase I study of brain stem cancers.

#### **Fourth Quarter and Full Year 2009 Financial Results**

For the fourth quarter ended December 31, 2009, NeoPharm reported a net loss of \$1.5 million, or (\$0.05) per diluted share, as compared to a net loss of \$2.2 million, or (\$0.08) per diluted share, for the same period last year. The decrease in the Company's 2009 fourth quarter net loss is primarily due to a decrease in clinical trial and preclinical development activities related to the completion of various clinical trials prior to the fourth quarter of 2009, as the Company prepares to initiate new clinical trials in 2010. The net loss for the fourth quarter of 2009 also includes a credit to research and development expenses of \$0.8 million related to the settlements reached on legacy trial and drug manufacturing obligations, an unrealized loss on the Company's auction rate securities ("ARS") put option of \$0.7 million and employee severance costs of \$0.3 million.

During the fourth quarter, the Company held its cash consumption to a level consistent with the prior quarter, allocating \$1.7 million in cash to its operations, versus \$1.8 million in the third quarter of 2009. NeoPharm anticipates future cash consumption levels to increase consistent with the advancement and progression of its clinical trials and other preclinical development activities. With \$5.0 million in cash and cash equivalents at December 31 2009, the Company estimates that it has adequate resources to fund its operations into the third quarter of 2010. The Company also is reviewing alternatives to raise additional capital to fund operations for the rest of 2010 and beyond.

For the year ended December 31, 2009, NeoPharm reported a net loss of \$7.5 million, or (\$0.26) per diluted share, as compared to a net loss of \$8.2 million, or (\$0.29) per diluted share, for the same period last year. The decrease in the Company's net loss for 2009 is primarily attributed to the decrease in general and administrative expenses in connection with the Company's voluntary decision to delist and deregister its common stock and opt-out of SEC reporting requirements in January 2009, along with the credit to research and development expenses in the fourth quarter of 2009 as described above. The decrease in general and administrative expenses was partially offset by a decrease in the Company's net interest income, a decrease in gains on sales of equipment and furniture, the unrealized loss on the ARS put option and employee severance costs.

#### **About NeoPharm, Inc.**

*NeoPharm, Inc., based in Lake Bluff, Illinois, is a publicly traded biopharmaceutical company dedicated to the research, development and commercialization of new and innovative cancer and other drugs for therapeutic applications. Additional information can be obtained by visiting NeoPharm's web site at [www.neopharm.com](http://www.neopharm.com).*

*Forward Looking Statements - This press release contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. The Company has tried to identify such forward-looking statements by use of such words as "expects," "intends," "hopes," "anticipates," "believes," "could," "may," "evidences" and "estimates," and other similar expressions, but these words are not the exclusive means of identifying such statements. Such statements include, but are not limited to, any statements relating to the Company's strategic review of*

projects and operations, the Company's drug development programs, the initiation, progress and outcomes of clinical trials of the Company's drug product candidates, projections regarding cash used in operations, financial projections, and any other statements that are not historical facts. Such statements involve risks and uncertainties, including, but not limited to, those risks and uncertainties relating to difficulties or delays in financing, development, testing, regulatory approval, production, and marketing of the Company's drug compounds including, but not limited to, the Company's ability to fund and pursue additional testing of Cintredekin Besudotox and its NeoLipid drug product candidates, uncertainty regarding the outcomes of ongoing or potential clinical studies, the Company's financial guidance and projection, including but not limited to, the fact that the Company's financial statements have not been subjected to a review by the Company's independent registered accounting firm in accordance with Statement of Auditing Standards No. 100, the Company's ability to evaluate the strategic alternatives available to the Company and to cut back on its funding of certain of its development projects in order to conserve its cash resources, the ability of the Company to procure additional future sources of financing, unexpected adverse side effects or inadequate therapeutic efficacy of the Company's drug compounds, including, but not limited to, Cintredekin Besudotox and its NeoLipid drug product candidates, that could slow or prevent products coming to market, uncertainty regarding the Company's ability to market its drug products, including, but not limited to Cintredekin Besudotox and its NeoLipid drug product candidates, the uncertainty of patent protection for the Company's intellectual property or trade secrets, and other risks of the type previously detailed in filings the Company formerly made with the Securities and Exchange Commission ("SEC"). Such statements are based on management's current expectations, but actual results may differ materially due to various factors, including those risks and uncertainties mentioned or referred to in this press release. At the Company's request, the Company's obligation to file reports with the SEC was suspended effective February 12, 2009. For the foregoing reasons, you should not rely on these forward-looking statements or on previously filed SEC reports as a prediction of actual future results.

NEOPHARM, INC.

Consolidated Statements of Operations

Three Months and Year Ended December 31, 2009 and December 31, 2008

	Three Months Ended		Year Ended	
	(unaudited)			
	December 31, 2009	December 31, 2008	December 31, 2009	December 31, 2008
Total revenue	\$ -	\$ -	\$ -	\$ -
Expenses:				
Research and development	158,000	1,536,000	3,598,000	4,827,000
Selling, general, and administrative	305,000	743,000	2,911,000	4,315,000
Employee termination costs	303,000	-	303,000	-
Facility consolidation costs	-	-	-	(63,000)
Gain on sale of equipment and furniture	-	-	(21,000)	(350,000)
Total Expenses	<u>766,000</u>	<u>2,279,000</u>	<u>6,791,000</u>	<u>8,729,000</u>
Loss from operations	(766,000)	(2,279,000)	(6,791,000)	(8,729,000)
Unrealized loss on auction rate securities put option	(735,000)	-	(735,000)	-
Interest income	46,000	97,000	217,000	596,000
Interest expense	(46,000)	(39,000)	(152,000)	(85,000)
Net loss	<u>\$ (1,501,000)</u>	<u>\$ (2,221,000)</u>	<u>\$ (7,461,000)</u>	<u>\$ (8,218,000)</u>
Net loss per share - basic and diluted	<u>\$ (0.05)</u>	<u>\$ (0.08)</u>	<u>\$ (0.26)</u>	<u>\$ (0.29)</u>
Weighted average shares outstanding - basic and diluted	<u>28,498,814</u>	<u>28,497,049</u>	<u>28,498,814</u>	<u>28,492,453</u>
	Selected Balance Sheet data			
			December 31, 2009	December 31, 2008
Cash and cash equivalents			5,042,000	7,298,000
Auction rate securities (current)			12,393,000	-
Put option on auction rate securities (current)			1,557,000	-
Total current assets			19,302,000	7,636,000
Auction rate securities (non-current)			-	12,321,000
Put option on auction rate securities (non-current)			-	2,379,000
Total assets			20,202,000	23,353,000
Short-term debt			13,950,000	-
Interest expense payable (current)			61,000	-
Total current liabilities			16,079,000	3,542,000
Long-term liabilities			39,000	9,259,000

Accumulated deficit	(287,913,000)	(280,452,000)
Total stockholders' equity	4,084,000	10,552,000

The interim financial information presented above has not been subjected to a review by the Company's independent registered public accounting firm.

SOURCE: NeoPharm, Inc.

NeoPharm, Inc.  
Martin K. McCarthy  
847-887-0800  
[mmccarthy@neopharm.com](mailto:mmccarthy@neopharm.com)

Copyright Business Wire 2010