



Chelsea Therapeutics Reports Fourth Quarter and Full Year 2011 Results

Company to Host Conference Call at 4:30 PM ET

CHARLOTTE, N.C., March 6, 2012 (GLOBE NEWSWIRE) -- Chelsea Therapeutics International, Ltd. (Nasdaq:CHTP) today reported financial results for the fourth quarter and full year 2011 and will host a conference call this afternoon at 4:30 PM ET to discuss these results and provide an update on the Company's development progress.

2011 Highlights

- Reported data from NORTHERA™ (droxidopa) open-label Study 303 supporting sustained symptomatic benefit over 12-month treatment period in Neurogenic Orthostatic Hypotension (Neurogenic OH or NOH)
- Completed dedicated, thorough QTc Study of Northera showing no cardiac safety concerns including no prolongation of QTc interval
- New Drug Application (NDA) for Northera for the treatment of symptomatic Neurogenic OH accepted for filing and granted priority review
- Unblinded interim results from Northera Study 306 demonstrating a dramatic reduction in falls associated with Northera treatment in patients with symptomatic Neurogenic OH associated with Parkinson's Disease and announced plans to seek supplemental NDA to potentially expand future Northera label to include the reduction of falls associated with symptomatic Neurogenic OH in Parkinson's Disease
- Presented new data from Northera Phase III program in symptomatic Neurogenic OH at the Movement Disorder Society's 15th International Congress
- Awarded two new patents for droxidopa covering both a novel, controlled release formulation and methods of reducing pain associated with fibromyalgia by administering droxidopa alone, or in combination with other specified medications
- Reported positive topline results from Phase II trials of droxidopa in both fibromyalgia and adult attention deficit disorder
- Conducted unblinded interim analysis of the two lower doses in the Phase II trial of CH-4051 in rheumatoid arthritis suggesting a dose response, comparable efficacy with methotrexate and the opportunity for the 3 mg dose groups to demonstrate superior efficacy

"This past year was characterized by remarkable achievement across each of our strategic goals as we successfully submitted and were granted Priority Review of our first NDA, reported promising data from studies in two new potential indications for droxidopa, significantly augmented our intellectual property portfolio for droxidopa and saw positive data during an interim analysis of our Phase II trial of CH-4051 in rheumatoid arthritis," commented Dr. Simon Pedder, president and CEO of Chelsea.

"These achievements set the stage for an exciting 2012 as we near our March 28th PDUFA date for Northera for the treatment of symptomatic Neurogenic OH, anticipate the full results of our Phase II study in rheumatoid arthritis and work toward the completion of our ongoing Phase III Northera falls study in patients with symptomatic Neurogenic OH associated with Parkinson's disease."

Financial Results for the Fourth Quarter

Chelsea reported a net loss for the quarter ended December 31, 2011 of \$12.5 million or (\$0.20) per share versus a net loss of \$12.4 million or (\$0.25) per share for the comparable period in 2010.

Research and development expenses for the three months ended December 31, 2011 were \$7.7 million, compared to \$10.2 million for the same period in 2010. The decrease in research and development expense was primarily the result of the completion of clinical trials and the associated decrease in drug development costs.

Selling, general and administrative (SG&A) expenses were \$4.8 million for the three months ended December 31, 2011 compared to \$2.3 million for the same period in 2010. The increase in SG&A expense during the quarter is primarily the result of costs associated with pre-launch sales and marketing initiatives including market research, promotional preparations and the addition of key personnel working on launch preparations.

Financial Results for the Year Ended December 31, 2011

Chelsea reported a net loss for the year ended December 31, 2011 of \$50.5 million or (\$0.84) compared to a net loss of \$37.3 million or (\$0.91) per share for the year ended December 31, 2010.

Research and development expenses for the year ended December 31, 2011 were \$37.3 million, compared to \$30.9 million for the same period in 2010. This increase of approximately \$6.4 million was driven by costs related to the anticipated registration of Northera including the completion of the Northera QTc study, preparation of the Northera NDA, the implementation of a Medical Science Liaison Team and the manufacturing of commercial drug product.

Selling, general and administrative expenses for the 12 months ended December 31, 2011 were \$13.3 million compared to \$6.6 million for the same period in 2010. Consistent with expense during the fourth quarter 2011, the overall increase in SG&A for the year reflects increases in compensation and related expenses associated with the anticipated commercialization of Northera and increased expense related to the implementation of certain pre-launch sales and marketing initiatives including market research, sales force preparations, advertising and promotional campaign planning, public relations and conference sponsorships.

Chelsea ended the year with \$45.6 million in cash and cash equivalents and short-term investments. This compares to \$47.6 million in cash and cash equivalents at December 31, 2010. Chelsea anticipates that the cash and cash equivalents at year-end combined with net proceeds of \$22.1 million from the public offering completed in January 2012, anticipated revenue and a planned working line of credit will fund the company's current development programs and launch initiatives through commercialization and into the first quarter of 2013.

Conference Call Today at 4:30 PM ET

Chelsea will discuss its fourth quarter and full year financial results and provide an update on its clinical development programs in a conference call today at 4:30 PM Eastern Time. Interested investors may participate in the conference call by dialing 877-638-9567 (domestic) or 720-545-0009 (international). A replay will be available for one week following the call by dialing 855-859-2056 for domestic participants or 404-537-3406 for international participants and entering passcode 58177398 when prompted. Participants may also access both the live and archived webcast of the conference call on Chelsea's web site at www.chelseatherapeutics.com.

CHELSEA THERAPEUTICS INTERNATIONAL, LTD. AND SUBSIDIARY

(A Development Stage Company)

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(unaudited)

	<u>For the three months ended December 31,</u>		<u>For the years ended December 31,</u>	
	<u>2011</u>	<u>2010</u>	<u>2011</u>	<u>2010</u>
Operating expenses:				
Research and development	\$ 7,712,687	\$ 10,171,696	\$ 37,270,138	\$ 30,871,125
Sales and marketing	3,428,463	1,133,073	8,067,709	2,476,494
General and administrative	1,347,891	1,136,645	5,276,146	4,154,944
Total operating expenses	<u>12,489,041</u>	<u>12,441,414</u>	<u>50,613,993</u>	<u>37,502,563</u>
Operating loss	(12,489,041)	(12,441,414)	(50,613,993)	(37,502,563)
Interest income	30,708	54,405	161,828	242,883
Interest expense	--	--	--	(70,389)
Net loss	<u>\$ (12,458,333)</u>	<u>\$ (12,387,009)</u>	<u>\$ (50,452,165)</u>	<u>\$ (37,330,069)</u>
Net loss per basic and diluted share of common stock	<u>\$ (0.20)</u>	<u>\$ (0.25)</u>	<u>\$ (0.84)</u>	<u>\$ (0.91)</u>
Weighted average number of basic and diluted common shares outstanding	<u>61,893,905</u>	<u>48,649,758</u>	<u>60,136,326</u>	<u>41,184,623</u>

See accompanying notes to condensed consolidated financial statements.

CHELSEA THERAPEUTICS INTERNATIONAL, LTD. AND SUBSIDIARY
(A Development Stage Company)
Condensed Consolidated Balance Sheet Data
(unaudited)

	<u>As of December 31,</u>	
	<u>2011</u>	<u>2010</u>
	(in thousands)	
Cash and cash equivalents	\$ 41,106	\$ 47,593
Short-term investments	4,500	--
Total assets	46,903	48,374
Total liabilities	13,238	13,186
Deficit accumulated during the development stage	(183,326)	(132,873)
Stockholders' equity	33,665	35,188

About Chelsea Therapeutics

Chelsea Therapeutics (Nasdaq:CHTP) is a biopharmaceutical development company that acquires and develops innovative products for the treatment of a variety of human diseases, including central nervous system, rheumatoid arthritis, psoriasis and other inflammatory diseases. Founded in 2004 around its library of unique anti-inflammatory and autoimmune technology, Chelsea has further expanded its product development portfolio with early- and late-stage candidates that leverage the company's development expertise and accelerate the company's drug commercialization efforts. For more information about the company, visit www.chelseatherapeutics.com.

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