



## Chelsea Therapeutics Reports Fourth Quarter and Full Year 2008 Results

### Company to Host Conference Call At 11:00 AM ET

CHARLOTTE, N.C., March 4, 2009 -- Chelsea Therapeutics International, Ltd. (Nasdaq:CHTP) today reported financial results for the fourth quarter and full year 2008 and will host a conference call this morning at 11:00 AM ET to discuss these results and provide a quarterly update on the Company's development progress.

#### 2008 Highlights

##### Droxidopa:

- \* Initiated two pivotal Phase III trials of Droxidopa in neurogenic orthostatic hypotension
- \* Received Special Protocol Assessment of Phase III trial of Droxidopa in neurogenic orthostatic hypotension
- \* Awarded Fast Track status by FDA for Droxidopa in neurogenic orthostatic hypotension
- \* Granted MHRA approval to initiate Phase II study of Droxidopa in fibromyalgia
- \* Reported significant reduction in severity of symptoms during titration phase of pivotal Droxidopa study in neurogenic orthostatic hypotension
- \* Completed enrollment in Phase II trial of Droxidopa in intradialytic hypotension

##### Non-metabolized Antifolates:

- \* Initiated Phase II trial of CH-1504 in rheumatoid arthritis
- \* Reported positive interim data safety monitoring board recommendation for Phase II study of CH-1504 in rheumatoid arthritis
- \* Completed patient enrollment in Phase II trial of CH-1504 in rheumatoid arthritis
- \* Initiated Phase I study of CH-4051 in healthy volunteers

"2008 marked a year of unprecedented development activity and clinical accomplishment for Chelsea," commented Dr. Simon Pedder, President and CEO of Chelsea. "Over the course of the past year, we not only successfully initiated five clinical trials, but completed enrollment in two of them by year end. As a direct result of the traction made in each of our programs last year, we have already begun delivering the first in a series of much anticipated reporting events beginning with the positive efficacy data reported from our Phase II IDH study earlier this week, followed by our CH-1504 proof-of-concept data before the end of this quarter and culminating in data from two pivotal trials in our lead Droxidopa indication of neurogenic orthostatic hypotension."

#### Key 2009 Milestones

- \* Report results of Phase II study of CH-1504 in rheumatoid arthritis
- \* Report results of Phase I study of CH-4051
- \* Report results of pivotal Phase II trials of Droxidopa in neurogenic orthostatic hypotension
- \* File new drug application for Droxidopa in neurogenic orthostatic hypotension

#### Financial Results for the Fourth Quarter

In October, Chelsea accepted an offer of settlement with UBS AG relating to its \$11.575 million in auction rate securities

("ARS") maintained at UBS. Pursuant to the settlement, UBS AG has issued to Chelsea certain Auction Rate Securities Rights, which provide Chelsea the right to sell the underlying ARS to UBS at par value at any time between June 30, 2010 and July 2, 2012. In connection with the settlement, Chelsea entered into a no net cost loan agreement with UBS Bank USA and UBS Financial Services Inc., and during the fourth quarter drew down approximately \$7.3 million under the loan agreement, with the Company's ARS held in accounts with UBS and its affiliates as collateral. In March of 2009, Chelsea amended its settlement and loan agreements with UBS to allow Chelsea to borrow up to \$11,575,000.

The Company reported a net loss for the quarter ended December 31, 2008 of \$9.0 million or (\$0.30) per share versus a net loss of \$4.8 million or (\$0.18) per share for the comparable period in 2007. Net loss for the quarter includes the recognition of an impairment charge of approximately \$2.7 million on its ARS, offset by recognition of an asset related to the ARS Rights with UBS of approximately \$2.0 million, resulting in a net charge of \$0.7 million or \$0.02 cents per share related to our holdings of auction rate securities.

Research and development expenses for the three months ended December 31, 2008 were \$7.2 million, compared to \$4.4 million for the same period in 2007. Total research and development expense increased \$2.8 million during the quarter compared to the same period a year ago due primarily to an increase in research and development expenses related to expansion of Chelsea's clinical activity.

Selling, general and administrative expenses were \$1.3 million for the three months ended December 31, 2008 compared to \$1.1 million for the same period in 2007. The increase resulted primarily from costs associated with increased headcount and with the initiation of pre-launch activities for Droxidopa.

#### Financial Results for the Year Ended December 31, 2008

Chelsea reported a net loss for the year ended December 31, 2008 of \$35.1 million or (\$1.17) compared to a net loss of \$15.1 million or (\$0.66) per share for the year ended December 31, 2007. The net loss for 2008 includes the recognition of impairment charges totaling approximately \$6.4 million on its ARS. This charge is offset by the recognition of an asset associated with Rights related to our agreement with UBS of \$2.0 million for a net expense of \$4.4 million. Excluding this expense, Chelsea's net loss on a non-GAAP basis for the year ended December 31, 2008 was \$30.7 million, or (\$1.02) per share. The increase in net loss was primarily attributable to increased activity related to our clinical programs.

Research and development expenses for the year ended December 31, 2008 were \$27.1 million, compared to \$12.3 million for the same period in 2007. This increase of approximately \$14.8 million was due primarily to increased clinical trial costs and manufacturing costs associated with Chelsea's expanded clinical programs.

Selling, general and administrative expenses for the 12 months ended December 31, 2008 were \$5.3 million compared to \$4.2 million for the same period in 2007. The \$1.1 million increase was mainly due to salaries and other expenses associated with increased headcount, including stock based compensation expense, as well as increased sales and marketing expenses related to our pre-launch activities for Droxidopa.

Chelsea ended the year with \$21.5 million in cash and cash equivalents, which includes \$7.3 million in proceeds under the UBS line of credit, and \$21.6 million in investments, which includes the value of UBS ARS serving as collateral for the line of credit. Total cash and investments at year-end totaled \$43.2 million. This compares to \$62.7 million in cash and investments consisting of \$34.1 million in cash and cash equivalents and \$28.6 million in short-term investments at December 31, 2007.

#### Conference Call Today at 11:00 AM 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 11:00 AM Eastern Time. Interested investors may participate in the conference call by dialing 877-795-3649 (domestic) or 719-325-4801 (international). A replay will be available for one week following the call by dialing 888-203-1112 for domestic participants or 719-457-0820 for international participants and entering passcode 5698477 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](http://www.chelseatherapeutics.com).

#### About Chelsea Therapeutics

Chelsea Therapeutics is a biopharmaceutical development company that acquires and develops innovative products for the treatment of a variety of human diseases. Chelsea's most advanced drug candidate, Droxidopa, is an orally active synthetic precursor of norepinephrine initially being developed for the treatment of neurogenic orthostatic hypotension. Currently approved and marketed in Japan for the treatment of symptomatic orthostatic hypotension, freezing gait in Parkinson's disease and intradialytic hypotension, Droxidopa has accumulated over 15 years of proven safety and efficacy, historically generating annual revenues of approximately \$50 million in Japan. In addition to Droxidopa, Chelsea is also developing a portfolio of metabolically inert oral antifolate molecules engineered to have potent anti-inflammatory and anti-tumor activity to treat a range

of immunological disorders, including two clinical stage product candidates: CH-1504 and CH-4051. Preclinical and clinical data suggests superior safety and tolerability, as well as increased potency versus methotrexate (MTX), currently the leading antifolate treatment and standard of care for a broad range of abnormal cell proliferation diseases including RA.

CHELSEA THERAPEUTICS INTERNATIONAL, LTD. AND SUBSIDIARY  
(A Development Stage Company)  
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	For the three months ended December 31,		For the years ended December 31,	
	2008	2007	2008	2007
	----- (unaudited)	----- (unaudited)	-----	-----
Operating expenses:				
Research and development	\$ 7,193,969	\$ 4,361,224	\$ 27,109,174	\$ 12,336,266
Sales and marketing	384,325	239,164	1,561,223	1,294,359
General and administrative	929,008	840,330	3,726,915	2,874,762
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Total operating expenses	8,507,302	5,440,718	32,397,312	16,505,387
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Operating loss	(8,507,302)	(5,440,718)	(32,397,312)	(16,505,387)
Interest income	213,309	601,296	1,706,568	1,423,842
Interest expense	(4,920)	--	(4,920)	--
Other expense	(714,314)	--	(4,390,487)	--
	-----	-----	-----	-----
Net loss	\$(9,013,227)	\$(4,839,422)	\$(35,086,151)	\$(15,081,545)
	=====	=====	=====	=====
Net loss per basic and diluted share of common stock	\$ (0.30)	\$ (0.18)	\$ (1.17)	\$ (0.66)
	=====	=====	=====	=====
Weighted average number of basic and diluted common shares outstanding	30,111,479	26,785,120	30,027,031	22,936,780
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Chelsea Pharmaceuticals International, Ltd.  
Condensed Consolidated Balance Sheet Data  
(unaudited)

	As of December 31,	
	2008	2007
	-----	-----
Cash and cash equivalents	\$ 21,532	\$ 34,076
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	(in thousands)	

Short-term investments	10,306	28,638
Long-term investments	11,329	--
Total assets	44,130	63,163
Line of credit payable	7,277	--
Total liabilities	19,583	5,197
Deficit accumulated during the development stage	(69,771)	(34,685)
Stockholders' equity	24,548	57,967

A reconciliation of GAAP to non-GAAP loss per share is as follows:

	For the three months ended December 31,		For the year ended December 31,	
	2008	2007	2008	2007
GAAP loss per share	\$(0.30)	\$(0.18)	\$(1.17)	\$(0.66)
Net other expense related to investments in auction rate securities	0.02	--	0.15	--
Non-GAAP loss per share	\$(0.28)	\$(0.18)	\$(1.02)	\$(0.66)

To view the Notes to the Company's Financial Statements and Management's Discussion and Analysis, please see the Company's Annual Report on Form 10-K for the year ended December 31, 2008 available on Chelsea's website at [www.chelseatherapeutics.com](http://www.chelseatherapeutics.com)

This press release contains forward-looking statements regarding future events. These statements are just predictions and are subject to risks and uncertainties that could cause the actual events or results to differ materially. These risks and uncertainties include our need to raise operating capital, our history of losses, risks and costs of drug development, risk of regulatory approvals, our reliance on our lead drug candidates Droxidopa and CH-1504, reliance on collaborations and licenses, intellectual property risks, competition, market acceptance for our products if any are approved for marketing, reliance on key personnel including specifically Dr. Pedder.

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