



**Source:** *Chelsea Therapeutics*  
May 08, 2014 07:54 ET

## Lundbeck to Acquire Chelsea Therapeutics

- *By acquiring Chelsea Therapeutics, Lundbeck gains the rights to Chelsea Therapeutics' recently FDA-approved product, NORTHERA™ (droxidopa), which is expected to be launched later in 2014*
- *NORTHERA is an orphan neurology opportunity with strong commercial and strategic fit with Lundbeck's existing U.S. neurology franchise*
- *Chelsea stockholders are entitled to USD 6.44 per share in cash and CVRs that may pay up to USD 1.50, for a total potential consideration of up to USD 7.94 per share, or USD 658 million on a fully diluted basis*
- *The offer provides Chelsea stockholders with immediate and certain upfront value as well as participation in potential commercial upside of NORTHERA*
- *The transaction is expected to be cash accretive to Lundbeck in 2015 and earnings accretive in 2016*

VALBY, Denmark and CHARLOTTE, N.C., May 8, 2014 (GLOBE NEWSWIRE) -- H. Lundbeck A/S (Lundbeck) and Chelsea Therapeutics International, Ltd. (Chelsea) (Nasdaq:[CHTP](#)) today announced that the companies have entered into a definitive agreement under which Lundbeck will acquire Chelsea.

Under the terms of the agreement, Lundbeck will commence a tender offer for all outstanding shares of Chelsea, whereby Chelsea stockholders will be offered an upfront payment and contingent value rights (CVRs), representing a total potential consideration of up to USD 7.94 per share, or USD 658 million (approximately DKK 3.54 billion) on a fully diluted basis. The total potential consideration represents an attractive premium of 59% over the closing price of Chelsea shares on 7 May 2014.

Consideration includes USD 6.44 per share in cash, or approximately USD 530 million (approximately DKK 2.8 billion) on a fully diluted basis, as well as CVRs that may pay up to a total of an additional USD 1.50 upon achievement of certain commercial milestones related to NORTHERA's commercial performance in the period 2015-2017. The proposed upfront per-share price represents a premium of approximately 29% over Chelsea's closing price of USD \$5.00 on 7 May 2014.

The terms of the CVR payments reflect the parties' agreement over the sharing of potential economic upside benefits from certain future net sales of NORTHERA as described in the CVR agreement and do not necessarily reflect anticipated sales of the product. There can be no assurance such levels of net sales will occur or that any or all of the contingent payments will be made.

Lundbeck intends to acquire any shares of Chelsea not tendered into the tender offer through a merger for the same per share consideration as will be payable in the tender offer. The merger will be effected as soon as possible after the closing of the tender offer.

The transaction will allow Lundbeck to leverage its expertise in rare neurologic disorders in the U.S. through the upcoming launch of NORTHERA, which was approved by the FDA on 18 February 2014 for the treatment of symptomatic neurogenic orthostatic hypotension (NOH). NORTHERA is the first and only therapy approved by the FDA that demonstrates symptomatic benefit in adult patients with NOH caused by primary autonomic failure (Parkinson's disease, multiple system atrophy and pure autonomic failure), dopamine beta hydroxylase deficiency and non-diabetic autonomic neuropathy. NORTHERA is expected to be launched in the second half of 2014 and will strengthen Lundbeck's existing neurology franchise in the U.S., which currently includes Onfi, Sabril and Xenazine, and ahead of potential future products like desmotepase and Lu AE58054 currently in clinical phase III.

*"I believe this offer represents an attractive offer to the stockholders of Chelsea and is consistent with Lundbeck's strategic and disciplined approach to acquisitions,"* said Ulf Wiinberg, President & Chief Executive Officer of Lundbeck. He continued, *"The proposed strategic acquisition of Chelsea – and the launch of its lead therapy, NORTHERA – aligns with Lundbeck's core strengths in addressing rare and challenging neurological disorders. As a company committed to people living with brain disorders, we are uniquely positioned to make NORTHERA available to those who need it most."*

Joseph G. Oliveto, President & Chief Executive Officer of Chelsea Therapeutics, stated, *"This transaction provides attractive and certain upfront value to our stockholders, and enables them to participate in the potential commercial upside of NORTHERA. Lundbeck's expertise in commercializing rare disorder CNS products will enable a rapid and successful launch of NORTHERA into the U.S. market and ultimately will provide added benefit to patients suffering from NOH."*

The transaction is expected to be financed by Lundbeck's existing cash reserves.

The board of directors of Chelsea has unanimously approved the transaction. The transaction is expected to close in the third quarter of 2014, subject to the tender of a majority of Chelsea's outstanding shares in the tender offer, and the receipt of customary regulatory approvals, including a Hart-Scott-Rodino review in the U.S. The terms and conditions of the tender offer will be described in the tender offer documents, which will be filed with the U.S. Securities and Exchange Commission (SEC).

Moelis & Company acted as financial advisor and Cravath, Swaine & Moore LLP provided legal advice to Lundbeck. Deutsche Bank Securities Inc. and Torrey Capital acted as financial advisors, and Morgan, Lewis & Bockius LLP provided legal advice to Chelsea.

### Financial guidance

If closed, this acquisition of Chelsea will impact Lundbeck's financial guidance for 2014.

While the transaction is not expected to have a material positive impact on revenue in 2014, it is expected to be dilutive to both cash flow and EBIT for the year, and cash flow accretive in 2015. The expected impact on Lundbeck's profitability in 2014 will depend on the timing of the closing of the transaction. However, on a pro forma basis assuming the transaction is closed on 1 July 2014, Lundbeck expects to incur costs of approximately DKK 500 million in incremental costs related to the acquisition of Chelsea. Approximately half of the costs are related to amortization expenses.

### Financial forecast 2014

<b>DKK billion</b>	2013 actual	"Old" 2014 forecast	Potential revision of 2014 forecast
Revenue	15.3	~13.5	~13.5
EBIT	1.6	0.5-1.0	0-0.5
<i>Core EBIT</i>	2.3	1.2-1.7	0.9-1.4

### Important information

The tender offer described in this press release has not yet commenced. This press release is for informational purposes only, and it is neither an offer to purchase nor a solicitation of an offer to sell shares of Chelsea's common stock. At the time any such tender offer is commenced, Lundbeck will cause a new wholly-owned subsidiary, Charlie Acquisition Corp., to file a Tender Offer Statement, containing an offer to purchase, a form of letter of transmittal and other related tender offer documents with the SEC, and Chelsea will file a Solicitation/Recommendation Statement relating to such tender offer with the SEC. Chelsea's stockholders are strongly advised to read these tender offer materials carefully and in their entirety when they become available, as they may be amended from time to time, because they will contain important information about such tender offer that Chelsea's stockholders should consider prior to making any decisions with respect to such tender offer. Once filed, stockholders of Chelsea will be able to obtain a free copy of these documents at the website maintained by the SEC at [www.sec.gov](http://www.sec.gov), or by directing a request to H. Lundbeck A/S, Attention: Investor Relations, Ottiliavej 9, DK-2500 Valby, Copenhagen, Denmark or to the Information Agent for the tender offer which will be named in the Tender Offer Statement. Copies of Chelsea's filings with the SEC may also be obtained free of charge at the "Investors" section of Chelsea's website at [www.chelseatherapeutics.com](http://www.chelseatherapeutics.com).

### Conference call

Today at 2.00 pm (CET), Lundbeck will be hosting a conference call for the financial community, find dial-in numbers below. You can listen to the call online at [www.lundbeck.com](http://www.lundbeck.com) under the investor section.

DK: +45 354 455 83

UK: +44 203 194 05 44

US: +1 855 269 2604

### About symptomatic neurogenic orthostatic hypotension (NOH)

It is estimated that 80,000 to 150,000 patients suffer from symptomatic NOH in the U.S. Symptomatic NOH is a chronic disorder that is caused by an underlying neurogenic disorder, such as Parkinson's disease, multiple system atrophy or pure autonomic failure. Symptoms of NOH may include dizziness, lightheadedness, blurred vision, fatigue, poor concentration, and fainting episodes when a person assumes a standing position. These symptoms can severely limit a person's ability to perform routine daily activities that require standing or walking for both short and long periods of time<sup>i, ii</sup>.

## About NORTHERA (droxidopa)

NORTHERA is indicated for the treatment of orthostatic dizziness, lightheadedness, or the "feeling that you are about to black out" in adult patients with symptomatic NOH caused by primary autonomic failure (Parkinson's disease, multiple system atrophy and pure autonomic failure), dopamine beta hydroxylase deficiency and non-diabetic autonomic neuropathy.

The NORTHERA approval was granted under the FDA's accelerated approval program, which allows for conditional approval of a medicine that fills a serious unmet medical need, provided additional confirmatory studies are conducted. The package insert indicates that effectiveness beyond two weeks of treatment has not yet been demonstrated; therefore the continued effectiveness of NORTHERA in patients should be assessed periodically. A multi-center, placebo-controlled, randomized study, which is designed with the goal of definitively establishing the durability of the clinical benefits of NORTHERA, has been preliminarily agreed to with the FDA.

NORTHERA carries a boxed warning for supine hypertension. The most common (> 5%) adverse events experienced in controlled studies are headache, dizziness, nausea, hypertension and fatigue. Please see NORTHERA full Prescribing Information for additional Important Safety Information at <http://www.chelseatherapeutics.com>.

## IMPORTANT SAFETY INFORMATION

---

### WARNING: SUPINE HYPERTENSION

See full prescribing information for complete boxed warning. Monitor supine blood pressure prior to and during treatment and more frequently when increasing doses. Elevating the head of the bed lessens the risk of supine hypertension, and blood pressure should be measured in this position. If supine hypertension cannot be managed by elevation of the head of the bed, reduce or discontinue NORTHERA.

---

## CONTRAINDICATIONS

- None

## WARNINGS AND PRECAUTIONS

- **Supine Hypertension:** NORTHERA therapy may cause or exacerbate supine hypertension in patients with NOH, which may increase cardiovascular risk if not well-managed.
- **Ischemic Heart Disease, Arrhythmias, and Congestive Heart Failure:** NORTHERA therapy may exacerbate symptoms in patients with existing ischemic heart disease, arrhythmias, and congestive heart failure.
- **Hyperpyrexia and Confusion:** Postmarketing cases of a symptom complex resembling neuroleptic malignant syndrome (NMS) have been reported in Japan with NORTHERA use. Observe patients carefully when the dosage of NORTHERA is changed or when concomitant levodopa is reduced abruptly or discontinued, especially if the patient is receiving neuroleptics. NMS is an uncommon but life-threatening syndrome characterized by fever or hyperthermia, muscle rigidity, involuntary movements, altered consciousness, and mental status changes. The early diagnosis of this condition is important for the appropriate management of these patients.
- **Allergic Reactions:** This product contains FD+C Yellow No. 5 (tartrazine) which may cause allergic-type reactions (including bronchial asthma) in certain susceptible persons. Although the overall incidence of FD+C Yellow No. 5 (tartrazine) sensitivity in the general population is low, it is frequently seen in patients who also have aspirin hypersensitivity.

## ADVERSE REACTIONS

- The most common adverse reactions (greater than 5%) were headache, dizziness, nausea, hypertension, and fatigue.

## DRUG INTERACTIONS

- Administering NORTHERA in combination with other agents that increase blood pressure (e.g., norepinephrine, ephedrine, midodrine, and triptans) would be expected to increase the risk for supine hypertension; Dopa-decarboxylase inhibitors may require dose adjustments for NORTHERA.

## USE IN SPECIAL POPULATIONS

- Clinical experience with NORTHERA in patients with severe renal function impairment (GFR less than 30 mL/min) is limited; There are no adequate and well controlled trials of NORTHERA in pregnant women; Women

who are nursing should choose nursing or NORTHERA; The safety and effectiveness of NORTHERA in pediatric patients have not been established; No overall differences in safety or effectiveness were observed between subjects aged 75 years and older, and younger subjects in clinical trials, but greater sensitivity of some older individuals cannot be ruled out.

## 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 disorders. Chelsea acquired global development and commercialization rights to droxidopa (L-DOPS), or NORTHERA, from Dainippon Sumitomo Pharma Co., Ltd. in 2006, excluding Japan, Korea, China and Taiwan. For more information about the Company, visit [www.chelseatherapeutics.com](http://www.chelseatherapeutics.com).

For the twelve months ended 31 December 2013, Chelsea reported an EPS loss of (USD 0.24). Total operating expenses were USD 16.4 million. R&D expenses were USD 10.4 million. SG&A expenses were USD 6.1 million. As of 31 December 2013, cash and cash equivalents totaled USD 45.3 million.

### Lundbeck contacts

Investors:

Media:

Palle Holm Olesen

Mads Kronborg

Vice President, Investor Relations

Director, Media Relations

[PALO@lundbeck.com](mailto:PALO@lundbeck.com)

[MAVK@lundbeck.com](mailto:MAVK@lundbeck.com)

+45 36 43 24 26

+45 36 43 30 00

Jens Høyer

Specialist, Investor Relations

[JSHR@lundbeck.com](mailto:JSHR@lundbeck.com)

+45 36 43 33 86

### Chelsea contacts

Investors:

Media:

David Pitts

Chuck Burgess

Argot Partners

Abernathy MacGregor

[david@argotpartners.com](mailto:david@argotpartners.com)

[CLB@abmac.com](mailto:CLB@abmac.com)

+1 212-600-1902

+1 212 371 5999

Liz Micci

Abernathy MacGregor

[EDM@abmac.com](mailto:EDM@abmac.com)

+1 212 371 5999

## About Lundbeck

H. Lundbeck A/S (LUN.CO) (LUN DC) (HLUYY) is a global pharmaceutical company specialized in brain diseases. For more than 50 years, we have been at the forefront of research within neuroscience. Our development and distribution of pioneering treatments continues to make a difference to people living with brain diseases. Our key areas of focus are alcohol dependence, Alzheimer's disease, depression/ anxiety, epilepsy, Huntington's disease, Parkinson's disease, schizophrenia and stroke.

Our approximately 6,000 employees in 57 countries are engaged in the entire value chain throughout research, development, production, marketing and sales, and are committed to improving the quality of life of people living with brain diseases. Our pipeline consists of several late-stage development programs and our products are available in more 100 countries. We have research centers in China, Denmark and the United States, and production facilities in China, Denmark, France, Italy and Mexico. Lundbeck generated revenue of DKK 15.3 billion in 2013 (EUR 2.0 billion; USD 2.7 billion).

Lundbeck's shares are listed on the stock exchange in Copenhagen under the symbol "LUN". Lundbeck has a sponsored Level 1 ADR program listed in the US (OTC) under the symbol "HLUYY". For additional information, we encourage you to visit our corporate site [www.lundbeck.com](http://www.lundbeck.com).

## Safe Harbor/Forward-Looking Statements

The above information contains forward-looking statements that provide our expectations or forecasts of future events such as the tender offer and transactions contemplated by the merger agreement, new product introductions, product approvals and financial performance.

Such forward-looking statements are subject to risks, uncertainties and inaccurate assumptions. This may cause actual results to differ materially from expectations and it may cause any or all of our forward-looking statements here or in other publications to be wrong. Factors that may affect future results include interest rate and currency exchange rate fluctuations, delay or failure of development projects, production problems, unexpected contract breaches or terminations, government-mandated or market-driven price decreases for our products, introduction of competing products, our ability to successfully market both new and existing products, exposure to product liability and other lawsuits, changes in reimbursement rules and governmental laws and related interpretation thereof, unexpected growth in costs and expenses, the possibility that the transaction may not be consummated or that the expected benefits of the transaction may not materialize as expected, Lundbeck's and Chelsea's ability to timely complete the transaction, if at all, or to, prior to the completion of the transaction, if at all, satisfy all closing conditions, the possibility that the merger agreement may be terminated, and the impact of the current economic environment, fluctuations in operating results, market acceptance of NORTHERA, and other risks that are described in Chelsea's Annual Report on Form 10-K for the year ended December 31, 2013 and in its subsequently filed SEC reports. Neither Lundbeck nor Chelsea undertakes any obligation to update these forward-looking statements except to the extent otherwise required by law.

Certain assumptions made by Lundbeck are required by Danish Securities Law for full disclosure of material corporate information. Some assumptions, including assumptions relating to sales associated with product that is prescribed for unapproved uses, are made taking into account past performances of other similar drugs for similar disease states or past performance of the same drug in other regions where the product is currently marketed. It is important to note that although physicians may, as part of their freedom to practice medicine in the United States, prescribe approved drugs for any use they deem appropriate, including unapproved uses, at Lundbeck, promotion of unapproved uses is strictly prohibited.

<sup>i</sup> Freeman R, Wieling W, Axelrod FB, et al. Consensus statement on the definition of orthostatic hypotension, neurally mediated syncope and the postural tachycardia syndrome. *Clin Auton Res* 2011;21:69-72

<sup>ii</sup> Freeman R. Clinical practice. Neurogenic orthostatic hypotension. *N Engl J Med* 2008;358:615-624. 3. Goldstein DS, Holmes C, Kaufmann H, Freeman R. Clinical pharmacokinetics of the norepinephrine precursor L-threo-DOPS in primary chronic autonomic failure. *Clin Auton Res* 2004;14:363-368.