

## **Interim Report, First Quarter 2014**

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### **CORTENDO REPORTS RESULTS AND ACTIVITIES FOR THE FIRST QUARTER 2014**

#### **FIRST AND POST QUARTER HIGHLIGHTS**

- Continued progress on the start-up of NormoCort™ Phase 3 trial
- While start-up phase has experienced delays, company plans to meet recruitment goals by increasing the number of sites from 38 to 45
- BioPancreate received notice of allowance of patent for potential breakthrough treatment concept for Diabetes type 1 and 2
- Net loss for the Group was SEK 11.2 million for the first quarter, compared with a net loss of SEK 4.1 million in the first quarter 2013, reflecting increased overall activities
- Cash and cash equivalents amounted to SEK 85.2 million compared to SEK 19.4 million at 31 March 2013, and SEK 97.1 million at the end of December 2013
- Strategic review to further strengthen focus on orphan drugs and metabolic disease
- Board has asked Dr H. Joseph Reiser to become Chairman to bring strengthened pharmaceutical experience to this position – new CEO to be recruited

#### **OPERATIONAL REVIEW**

##### *Pipeline development*

Cortendo's main operational focus has been to advance its pipeline, in particular NormoCort for Cushing's Syndrome. Continued progress has been made on the start-up of the trial, although the enrolment of the first patient into the NormoCort Phase 3 trial has been delayed due to protocol refinements and logistics related to the activation of clinical sites. The company plans to meet recruitment goals by increasing the number sites from 38 to 45 worldwide, and is in the process of opening the sites. A majority of the sites are expected to be activated by the third quarter this year.

BioPancreate has contracted a manufacturer for the novel biopharmaceutical substance, has scaled up the first batch, and is conducting an initial toxicity study with the produced biological material. It is also in the process of confirming with the FDA the development plan to an investigational new drug application. BioPancreate Inc.'s next major milestone is to complete the pre-clinical development phase and file a US IND. If accepted, this would allow the company to start Phase 1 clinical development for its novel diabetes project.

The next generation cortisol inhibitor project has been focused on the selection of the most promising lead compounds from the group of compounds identified through the chemical synthesis and screening program performed 2011-13. The primary goal of the project is to find a lead candidate and backup that can enter preclinical development in 2015.

##### *Pipeline development - strategic review*

In the second quarter, the board made the decision that the company is to further strengthen its focus on orphan drugs and metabolic disease. Cortendo will prioritize investments in its lead Phase 3 orphan drug NormoCort, next generation cortisol inhibitors for Cushing's Syndrome, and the innovative diabetes projects acquired through BioPancreate, a wholly

owned subsidiary of Cortendo. As a result, Cortendo will discontinue investments in the therapeutic area of osteoarthritis, and the license for the commercial rights of Crespine and Crespine Plus will be returned to its licensor.

### *Preparing for potential public listing*

Cortendo has invested significant resources into improving its internal operations in preparation for a potential official public exchange listing, including adoption of IFRS accounting standards for its financial reporting. This report is the first quarterly report prepared in accordance with IFRS. Also, Cortendo has added new management capacity. Cortendo is planning for a listing on the Oslo Stock Exchange during H2'2014.

### **Key news in the first and post quarter period**

#### *BioPancreate received notice of allowance for core patent for oral diabetes treatment*

In March Cortendo announced that the US Patent Office has granted a Notice of Allowance for the first key patent covering its core technology relating to the use of commensal bacteria that are modified to secrete GLP-1 for the treatment of diabetes. This technology is exclusively licensed to BioPancreate.

#### *More information about the BioPancreate technology*

BioPancreate is developing a novel, orally administered biological therapeutic utilizing modified probiotic human bacteria. These modified human bacteria express an active agent and deliver such agents to the gastrointestinal tract, triggering the transformation of intestinal entero-endocrine cells into glucose-responsive insulin secreting cells, i.e. pancreas-like beta cells. The lead compound is currently in preclinical development.

BioPancreate's biopharmaceutical products under development for diabetes are modifications of naturally occurring commensal bacteria that exist in the human gastrointestinal tract. Natural probiotics have been shown to be both safe and beneficial when taken orally. The BioPancreate technology advances this approach into a distinct therapeutic application for diabetes by utilizing these bacteria to both produce and deliver an active agent into the small intestine that triggers insulin production and subsequent secretion into the systemic vascular system of the body. These effects have been demonstrated in various preclinical diabetes models to date.

#### *Changes and planned changes to the Board of Directors*

Cortendo announced in the first quarter that Dr. Hilde H. Steineger and Espen T. Jørgensen had accepted to stand for election as new members of the Cortendo Board of Directors, and both were elected to the Board of Directors on the shareholder meeting on January 17, 2014. In May, with the support of the Board and the Nomination Committee, CEO Dr. H Joseph Reiser has been asked to become Chairman of the Board. Since Swedish law prohibits a person to hold both the Chairman and CEO position, this change cannot be implemented until a new CEO has been hired. Thus, the Board has initiated a search for a new CEO, and Dr. Reiser will continue in his current position for as long as required to assure flexibility in finding the best candidate and allow for optimal management transition. The changes to the Board of Directors and management are part of a process to prepare the company for a listing on an official public stock exchange, increase Cortendo's competitive position and assure corporate growth.

### **FINANCIAL REVIEW**

Cortendo's products are in the research and development phase, and Cortendo does not currently have any product-based revenues. The following text references the financial statements of the Group in the reporting currency SEK beginning on page 6. In addition, a convenience translation of the Group statement of comprehensive income and balance sheet into US dollars has been provided on page 13.

### **Results for the first quarter 2014**

Adjusted for some delays to the phasing of costs in the pipeline projects, the development of actual costs was broadly in line with planning assumptions. Operating expenses for the first quarter 2014 amounted to SEK 12.0m, compared with SEK 3.8m in the first quarter 2013.

Costs for R&D (which include patent costs) and G&A constitute the key cost drivers. For the first quarter of 2014 R&D costs constituted SEK 7.8m (65%) of operating expenses. G&A costs constituted SEK 4.2m (35%) of operating expenses. For the first quarter of 2013 R&D costs and G&A costs constituted SEK 2.6m (69%) and SEK 1.2m (31%) of operating expenses, respectively. The increase in operating costs reflects increased overall activities including R&D. The key drivers were the start-up of the phase 3 trial for NormoCort as well as increased preclinical activities for BioPancreate.

Net financial items were SEK 0.8m, compared to SEK -0.3m in the prior year. Interest on liquid assets and positive effects from strength in the NOK vs. SEK contributed positively while USD based forward contracts had a negative effect. The current company policy with regards to cash management is to primarily hold its cash with major Nordic banks, but to hedge a significant portion of its future predicted USD based expenses, which represent the vast majority of expected outflows. By the end of the quarter Cortendo had outstanding USD based hedging contracts covering NOK 66.5 million.

The Net Loss was SEK 11.2m for the first quarter 2014, compared to SEK 4.1m for the same period in 2013. Earnings per share were SEK -0.13 for the first quarter 2014, compared to SEK -0.07 for the same period in 2013.

### **Cash flow**

Cash flow from operations was SEK -11.9 million for the first quarter 2014, compared to SEK -4.9m for the same period in 2013.

### **Cash Position and Balance sheet**

At 31 March 2014, cash and cash equivalents amounted to SEK 85.2 million compared to SEK 19.4 million at 31 March 2013, and SEK 97.1 million at the end of December 2013. Equity stood at SEK 121.4 million at 31 March 2014, up from SEK 39.1 million at the end of the first quarter 2013. The increased equity and improved liquidity position mainly reflects share capital increases and the acquisition of BioPancreate Inc. during 2013.

Total liabilities amounted to SEK 5.1 million at 31 March 2014, compared to SEK 2.0 million at the same time last year, and SEK 6.6 million the end of 2013.

### **Shareholder information**

Cortendo AB is currently listed on the NOTC-A-list (OTC) in Norway, and has approximately 500 shareholders mainly from Norway, Sweden and the U.S.

The total number of outstanding shares per 31 March 2014 was 87,335,863, with a total number of outstanding share options of 5,651,000. Strike prices vary from SEK 1.00-6.00 per share, with an average of SEK 2.96 per share.

### **Financial calendar 2014**

Cortendo plans to present its financial results according the following schedule:

Q2 2014: 19 August 2014

Q3 2014: 18 November 2014

Q4 2014: 24 February 2015

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## **Risk and uncertainty**

The development of pharmaceuticals carries significant risk. Failure may occur at any stage during development and commercialization due to safety or clinical efficacy issues. Delays may occur due to requirements from regulatory authorities not anticipated by the company.

## **About Cortendo**

Cortendo AB is a biopharmaceutical company headquartered in Göteborg, Sweden. Its stock is publicly traded on the NOTC-A-list (OTC) in Norway. Cortendo is a pioneer in the field of cortisol inhibition and has completed early clinical trials in patients with Type 2 diabetes. The lead drug candidate NormoCort, the 2S, 4R-enantiomer of ketoconazole, has been re-focused to Cushing's Syndrome, and has entered Phase 3 development. The company's strategy is to primarily focus its resources within orphan drugs and metabolic diseases and to seek opportunities where the path to commercialization or partnership is clear and relatively near-term. Strategically, Cortendo's business model is to commercialize relevant opportunities in the United States while partnering its assets ex-US. Backed by a highly experienced leadership team Cortendo has plans to continue to implement its pipeline expansion efforts, as well as other near term revenue opportunities.

## **Cortendo Forward-looking Statements**

*This press release contains forward-looking statements concerning Cortendo that involve a number of risks and uncertainties. All statements other than statements of historical facts included in this press release, including, without limitation, statements regarding the Company's future financial position, strategy, anticipated investments, costs and results, plans, projects to enhance efficiency, outcomes of products development, future capital expenditures, liquidity requirements and objectives of management for future operations, may be deemed to be forward looking statements. These forward looking statements involve known and unknown risks, uncertainties and other factors that may cause the Company's actual results, performance or achievements or industry results to be materially different from those contemplated, projected, forecasted, estimated or budgeted, whether expressed or implied, by these forward looking statements. Given these risks and uncertainties, investors should not place any undue reliance on forward looking statements as a prediction of actual results. None of these forward looking statements constitutes a guarantee of the future occurrence of such facts and data or of actual results. These statements are based on data, assumptions and estimates that the Company believes are reasonable. The forward looking statements contained in this document are made only as of the date hereof. The Company expressly disclaims any obligation or undertaking to release publicly any updates of any forward-looking statements contained in this press release to reflect any change in its actual results, assumptions, expectations or any change in events, factors, conditions or circumstances on which any forward looking statement contained in this press release is based.*

For the full report including financial results tables, please refer to the pdf icon.

[wrk0006.pdf](#)