

Cortendo Provides 2015 Half-Year Update on Corporate Progress

July 2, 2015 12:11 PM ET

Cortendo Expands Board of Directors and Management Team

Cortendo Provides Update on COR-003 Phase 3 Clinical Development Program

Cortendo Builds Rare Endocrine Disease Franchise with Completion of Transactions for Two-Late Stage Assets

Cortendo Closes Aggregate \$59.6 Million in Two Private Placement Financings and Provides Update on Cash Position

July 2, 2015 – Göteborg, Sweden and Trevose, Pa., USA – Cortendo AB (publ) [ticker: CORT on NOTC-A], a biopharmaceutical company focused on rare endocrine disorders and other rare diseases, today announced an update on 2015 half-year corporate progress.

“The significant leadership experience and industry expertise of our Board of Directors and Management Team are tremendous assets as we continue to build a leading biopharmaceutical company focused on addressing unmet needs in rare diseases, including rare endocrine disorders such as Cushing’s Syndrome and acromegaly,” said Matthew Pauls, president and chief executive officer of Cortendo. “We look forward to simultaneously advancing development and pre-commercialization activities for COR-003, COR-004 and COR-005, as we continue to explore additional late-stage and commercialized opportunities in endocrinology and other therapeutic areas,” Pauls added.

Cortendo Expands Board of Directors and Management Team

Cortendo has expanded its Board of Directors and Management Team to help execute against its strategic plans be a leader in commercializing innovative medicines for rare endocrine disorders and other rare diseases. Earlier this year, the Company welcomed two new members to its Board of Directors with the appointments of John H. Johnson as Chairman and Richard Kollender as Director. In addition, Cortendo’s Management Team has grown this year with the additions of A. Brian Davis as Chief Financial Officer and Stephen Long as Chief Legal Officer.

Cortendo Provides Update on COR-003 Phase 3 Clinical Development Program

Cortendo’s lead product candidate, COR-003 (levoketoconazole), is currently being studied in a pivotal Phase 3 clinical trial for the treatment of endogenous Cushing’s Syndrome. The Phase 3 trial continues to progress on trial implementation and recruitment. We expect to report top-line data during the first half of 2017 and, subject to a completed trial with supporting data, to file applications for regulatory approval in the United States and the European Union in the second half of 2017. For more information about the trial, visit <http://www.cushingssyndromestudy.com/>.

Cortendo Expands Rare Endocrine Disease Franchise with Completion of Transactions for Two-Late Stage Assets

Cortendo has completed its previously announced transactions to in-license commercialization rights to Antisense Therapeutics’ ATL1103 for endocrinology applications and to acquire Aspireo Pharmaceuticals’ Somatoprim (DG3173), an investigational compound being studied for the treatment of acromegaly.

ATL1103, now known as Cortendo’s COR-004, is a novel second-generation antisense compound designed to block the synthesis of growth hormone receptor (GHR) thereby reducing levels of insulin-like growth factor-1 (IGF-1) in the blood. It is in clinical development for the treatment for acromegaly. Under the terms of the license agreement, Cortendo provided Antisense Therapeutics with an initial upfront payment of \$5 million, consisting of \$3 million in cash and a \$2 million investment in Antisense Therapeutics equity.

DG3173, now known as Cortendo’s COR-005, is a next-generation somatostatin analog (SSA) with a unique receptor

affinity profile, being investigated for the treatment of acromegaly, with potential additional applications in Cushing's Syndrome and neuroendocrine tumors. Under the terms of the agreement, Cortendo provided Aspireo Pharmaceuticals approximately \$30 million in Cortendo equity, calculated using a subscription price of \$1.3222 per share. In addition, as part of Cortendo's related round of financing, TVM Capital, Aspireo Pharmaceuticals' primary shareholder, purchased \$4.25 million of Cortendo shares in the private placement described below. The issuance of shares for use in the acquisition of COR-005 was approved by Cortendo shareholders at an Annual General Meeting (AGM) on June 25, 2015.

Cortendo Closes Aggregate \$59.6 Million in Two Private Placement Financings and Provides Update on Cash Position

Cortendo also announced today that the Company has closed its previously announced second private placement financing of the year totaling approximately \$33.2 million with leading U.S. and EU institutional investors, including Longwood Capital, TVM Capital and Granite Point Capital. Several existing investors, including RA Capital Management, New Enterprise Associates, Broadfin Capital and HealthCap, have also extended their investments in Cortendo through this round of financing. In addition, Management and key advisors invested \$0.5 million in the private placement.

The subscription price was \$1.3222 per share and 25,128,559 new shares were issued to the investors. The issuance of these additional shares was approved by Cortendo shareholders at an AGM on June 25, 2015.

As announced on February 11, 2015, Cortendo previously closed a private placement totaling approximately \$26.4 million. That round of financing included leading U.S. institutional specialist healthcare investors RA Capital Management, New Enterprise Associates and Broadfin Capital. HealthCap also participated, increasing its existing investment in Cortendo. The investments in 2015 built off an \$11 million investment in late 2014, bringing Cortendo's total raises from private placements to more than \$70 million in approximately seven months.

"We want to thank all of our investors for their confidence in Cortendo, its leadership team and mission to become a leader in commercializing innovative medicines for rare endocrine disorders and other rare diseases," said Matthew Pauls, president and chief executive officer of Cortendo. "This latest round of financing strengthens Cortendo's ability to further develop and prepare to commercialize the Company's rare endocrine disease franchise," Pauls added.

As of June 30, 2015, Cortendo had cash and cash equivalents of \$54.4 million, which includes the cash impact of the private placement as well as the Aspireo and Antisense transactions. Following the issuances of common stock for the private placement and the Aspireo transaction, the Company has approximately 207 million shares outstanding.

About Cortendo AB

Cortendo AB is a biopharmaceutical company incorporated in Sweden and based in the United States. Cortendo's strategic focus is to be a leader in commercializing innovative medicines for rare endocrine disorders and other rare diseases. Cortendo's lead product candidate, COR-003 (levoketoconazole), is a cortisol inhibitor that is currently being studied in the global Phase 3 trial for the treatment of endogenous Cushing's syndrome. COR-003 (levoketoconazole) has received orphan designation from both the European Medicines Agency and the U.S. Food and Drug Administration. Cortendo's intent is to independently commercialize its orphan/endocrine assets in key global markets.

About COR-004

COR-004 is a second-generation antisense drug designed to block growth hormone receptor (GHR) expression thereby reducing levels of the hormone insulin-like growth factor-1 (IGF-1) in the blood and is a potential treatment for diseases associated with excessive growth hormone and IGF-1 action, such as acromegaly. Acromegaly patients have significantly higher blood IGF-1 levels than healthy individuals. Reduction of these levels to normal is the treatment goal and accepted by regulatory authorities as the primary marker of an effective drug treatment for the disease. GHR is a clinically validated target in the treatment of acromegaly. In a Phase 2 trial in acromegalic patients, COR-004 met its primary efficacy endpoint by showing a statistically significant average reduction in serum IGF-1 levels from baseline ($P < 0.0001$) at week 14 (one week past the last dose) at the twice weekly 200 mg dose tested. Antisense is currently undertaking a higher dose

study (2 x 300 mg/week) in acromegaly patients.

About COR-005

COR-005 is a somatostatin analog (SSA) that is based on a novel amino acid composition and a differentiated backbone cyclization technology used for metabolic stabilization of the peptide. During extensive preclinical testing, COR-005 demonstrated a novel pattern for somatostatin receptor binding and a pharmacological profile that is significantly differentiated from SSAs that are currently marketed or in clinical development. In particular, COR-005 has demonstrated in preclinical models potent inhibition of growth hormone secretion with less effect on insulin, a key hormone for metabolic control. Furthermore, more adenomas, derived from patients with acromegaly, showed suppression of growth hormone secretion when cultured and treated in vitro with COR-005 as compared to a currently approved SSA, suggesting that COR-005 has the potential to increase the response rate of acromegaly patients to SSA therapy.

In three Phase 1 clinical trials and in two Phase 2, single ascending dose clinical trials in patients with acromegaly, inhibition of growth hormone secretion and reduced inhibition of insulin secretion or induction of hyperglycemia was observed confirming the preclinical differentiated profile of COR-005.

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 Cortendo's strategy, anticipated investments, financial position, outcomes of product development efforts 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 Cortendo'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 Cortendo believes are reasonable. The forward-looking statements contained in this document are made only as of the date hereof. Cortendo 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.

Contacts:

Cortendo AB:

Elixir Health Public Relations

Lindsay Rocco

+1 862-596-1304

lrocco@elixirhealthpr.com

Sweden

Box 47

SE-433 21 Partille

Tel. / Fax. +46 (0) 31-263010

USA

900 Northbrook Drive

Suite 200

Treose, PA 19053

Tel. +1 610-254-9200
Fax. +1 215-355-7389

[wkr0006.pdf](#)