



Corcept Therapeutics Announces Fourth Quarter And Full-Year 2018 Audited Financial Results And Provides Update

February 25, 2019

MENLO PARK, Calif., Feb. 25, 2019 (GLOBE NEWSWIRE) -- Corcept Therapeutics Incorporated (NASDAQ: CORT), a commercial-stage company engaged in the discovery and development of drugs to treat severe metabolic, oncologic and psychiatric disorders by modulating the effects of the stress hormone cortisol, today reported its financial results for the quarter- and year-ended December 31, 2018.

Financial Highlights

- 2018 revenue of \$251.2 million, an increase of 58 percent from 2017
- Fourth quarter revenue of \$66.8 million, an increase of 25 percent from fourth quarter 2017
- 2018 GAAP net income of \$0.60 per share, compared to \$1.04 per share in 2017 (2017 includes one-time, non-cash tax benefit of \$0.61 per share)
- Fourth quarter GAAP net income of \$0.18 per share, compared to \$0.77 per share in fourth quarter 2017 (including \$0.60 per share tax benefit)
- Fourth quarter repurchases of 1.1 million shares of common stock; 2018 repurchases totalling 1.8 million shares
- Cash and investments at December 31, 2018 of \$206.8 million, compared to \$104.0 million at December 31, 2017
- Reiterated 2019 revenue guidance of \$285 – 315 million

Relacorilant Phase 2 Trial Positive Top-Line Results

Relacorilant's Phase 2 trial enrolled 35 patients, each of whom received a daily dose of relacorilant that was increased in 50 mg increments, as tolerable, every four weeks. The first 17 patients to enroll (the "low-dose cohort") started at 100 mg per day. The next 18 patients (the "high dose cohort") started at 250 mg per day.

Applying the endpoints for clinical benefit from relacorilant's Phase 3 trial ("GRACE") to the high-dose cohort produces the following results:

- Fifty percent of patients with hyperglycemia achieved improved glucose control, as shown by (i) a 0.5 percent or greater reduction in HbA1c or (ii) normalization of 2-hour oGTT glucose or decreased by at least 50 mg/dL or (iii) a 25 percent or greater decrease in antidiabetic medications
- Sixty-four percent of patients with uncontrolled hypertension achieved a five millimeter or greater drop in either systolic or diastolic blood pressure, as measured by 24-hour ambulatory monitoring
- No evidence of progesterone receptor affinity or hypokalemia
- Plan to present data at the American Association of Clinical Endocrinologist ("AACE") Annual Scientific and Clinical Conference in Los Angeles, California, April 24-28th

Oncologic & Metabolic Disorders

- Placebo-controlled, Phase 2 trial of relacorilant plus Abraxane[®] in metastatic ovarian cancer underway, with planned enrollment of 180 patients in the United States and Europe
- Data from dose-finding trial of relacorilant plus Abraxane to treat patients with metastatic, pancreatic cancer expected in second quarter
- Dosing continues in Phase 1/2 trial of CORT125281 plus Xtand[®] to treat patients with metastatic castration-resistant prostate cancer
- Placebo-controlled trial of CORT118335 for prevention of antipsychotic-induced weight gain to start second quarter; two trials in the reversal of antipsychotic-induced weight gain to start in second half of the year
- Placebo-controlled, Phase 2 trial of CORT118335 to treat non-alcoholic steatohepatitis ("NASH") to start in second half of the year

Financial Results

Corcept's 2018 revenue was \$251.2 million, compared to \$159.2 million in 2017. Fourth quarter revenue was \$66.8 million, compared to \$53.3 million in the fourth quarter of 2017. The company reiterated its 2019 revenue guidance of \$285 – 315 million.

GAAP net income was \$75.4 million for the year and \$22.0 million in the fourth quarter of 2018, compared to \$129.1 million for the year and \$98.3 million in the fourth quarter of 2017. Fourth quarter 2017 net income included a one-time, non-cash gain of \$76.4 million from the recognition of deferred tax assets.

Excluding non-cash tax benefits, non-cash expenses related to stock-based compensation, accreted interest on the company's now-retired royalty financing obligation and related tax effects, non-GAAP net income was \$30.4 in the fourth quarter, compared to \$24.7 million in the fourth quarter of 2017. For the full-year, non-GAAP net income was \$108.2 million, compared to \$63.3 million in 2017. A reconciliation of GAAP to non-GAAP net income is included below.

Cash and investments increased by \$10.1 million in the fourth quarter, to \$206.8 million. This increase was after the expenditure of \$14.8 million to acquire 1.1 million shares of the company's common stock pursuant to its stock repurchase program. Under the program's current terms, \$76.3 million remains available for the repurchase of shares.

"2018 saw increased use of Korlym[®] by patients with Cushing's syndrome in every region of the country," said Joseph K. Belanoff, MD, Corcept's Chief Executive Officer. "In the fourth quarter, 583 physicians were treating patients with the medication – a number that we expect to grow. Increased Korlym uptake fueled our strong financial results: revenue increased by \$92.0 million, non-GAAP net income increased by \$45.0 million. Cash and investments nearly doubled to \$206.8 million. In addition, we repurchased 1.8 million shares of our common stock.

"We continue to protect and extend our Cushing's syndrome franchise. On February 5th, for example, we were issued a patent (U.S. Pat. No. 10,195,214) covering the co-administration of Korlym and strong CYP3A4 inhibitors – a class of drugs that includes powerful antiviral, antibiotic, antifungal and antidepressant medications. The scientific discoveries that gave rise to this patent constituted an important advance in the safe treatment of patients taking Korlym, which is why corresponding instructions to prescribers are included in Korlym's label.

"In 2018, we also made important clinical advances in our Cushing's syndrome program. Data from the Phase 2 trial of our candidate to succeed Korlym – the proprietary, selective cortisol modulator, relacorilant – were strongly positive, with many patients exhibiting meaningful clinical benefit. Just as important, there were no instances of the two off-target effects – progesterone receptor affinity and increased cortisol levels – that cause Korlym's most common and serious adverse events – termination of pregnancy, endometrial thickening, vaginal bleeding and low potassium (hypokalemia). We immediately began relacorilant's Phase 3 trial."

Relacorilant Phase 2 Data

Applying the endpoints for clinical benefit from relacorilant's Phase 3 trial, 50 percent of patients with hyperglycemia in the high-dose cohort achieved improved glucose control (see Figure 1). The response rate in patients with hypertension was 64 percent (see Figure 2). These response rates are comparable to those exhibited by patients at 16 weeks and a dose of 1200 mg in Korlym's pivotal trial ("SEISMIC").

Patients in the high-dose group also met a wide range of secondary endpoints, including statistically significant improvements in hypercoagulopathy, liver function, insulin resistance, cognition and mood.

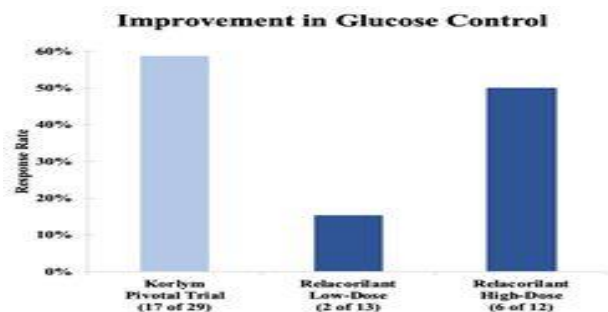


Figure 1. Patients achieving clinically meaningful reductions in HbA1c, 2-hour oGTT or use of antidiabetic medications.



Figure 2. Patients achieving clinically meaningful improvements in hypertension.

Relacorilant was well-tolerated. The most commonly reported adverse events were backpain, peripheral edema, headache and nausea – adverse events that are frequently seen when excess cortisol activity is reduced and that tend to be transitory.

Relacorilant's Phase 3 GRACE trial is underway. It is expected to enroll 130 patients at 60 sites in the United States, Canada, Europe and Israel.

Oncology & Metabolic Disease

"We expect our oncology and metabolic disease programs to take important steps forward in 2019," said Dr. Belanoff. "Following encouraging data from our Phase 1/2 dose-finding study, we have begun a 180 patient, controlled Phase 2 trial of relacorilant plus Abraxane to treat patients with metastatic ovarian cancer, a disease with few good treatment options. We continue to gather data in metastatic pancreatic cancer and plan to release our results and clinical development plan at the time of the ASCO meeting this June. We expect to select the optimal dose of CORT125281 plus Xtandi to treat patients with metastatic castration-resistant prostate cancer this year."

"We are excited to advance CORT118335 as a potential treatment for antipsychotic-induced weight gain and NASH," added Dr. Belanoff. "We plan three placebo-controlled trials in antipsychotic-induced weight gain: the first will investigate CORT118335's ability to prevent weight gain in healthy subjects given olanzapine (Eli Lilly's Zyprexa®). We plan to start this trial in the second quarter. The second two trials will be in patients taking antipsychotic medications – one to study the reversal of recently-established weight gain and the other to study the reversal of long-standing weight gain. They are planned to start in the second half of the year. Our placebo-controlled, Phase 2 trial of CORT118335 as a treatment for NASH is also planned for the second half of 2019."

Conference Call

We will hold a conference call on February 25, 2019, at 5:00 p.m. Eastern Time (2:00 p.m. Pacific Time). To participate, dial 1-888-220-8451 from the United States or 1-323-794-2588 internationally approximately 10 minutes before the start of the call. The passcode is 6598298. A replay will be available through March 11, 2019 at 1-888-203-1112 from the United States and 1-719-457-0820 internationally. The passcode will be 6598298.

Hypercortisolism

Hypercortisolism, often referred to as Cushing's syndrome, is caused by excessive activity of the stress hormone cortisol. Endogenous Cushing's syndrome is an orphan disease that most often affects adults aged 20-50. In the United States, an estimated 20,000 patients have Cushing's syndrome, with about 3,000 new patients being diagnosed each year. Symptoms vary, but most people experience one or more of the following manifestations: high blood sugar, diabetes, high blood pressure, upper-body obesity, rounded face, increased fat around the neck, thinning arms and legs, severe fatigue and weak muscles. Irritability, anxiety, cognitive disturbances and depression are also common. Cushing's syndrome can affect every organ system in the body and can be lethal if not treated effectively.

About Concept Therapeutics Incorporated

Concept is a commercial-stage company engaged in the discovery and development of drugs that treat severe metabolic, oncologic and psychiatric disorders by modulating the effects of the stress hormone cortisol. Korlym® was the first FDA-approved treatment for patients with Cushing's syndrome. Korlym inhibits the effects of excess cortisol by modulating activity at the glucocorticoid receptor, one of the two receptors to which cortisol binds. We have discovered a large portfolio of proprietary compounds that selectively modulate the effects of cortisol but not progesterone. We own extensive United States and foreign intellectual property covering the composition of these selective cortisol modulators and in the use of cortisol modulators, including Korlym, to treat a wide variety of serious disorders.

Non-GAAP Measures of Net Income

To supplement our financial results presented on a GAAP basis, we use a non-GAAP measures of net income, non-GAAP basic net income per share and non-GAAP diluted net income per share including the following non-cash items – stock-based compensation, accreted interest on our royalty financing obligation, use of deferred tax assets and related income tax effects. We believe these non-GAAP measures help investors better evaluate our past financial performance and potential future results. Our non-GAAP measures should not be considered in isolation or as a substitute for comparable GAAP accounting. Investors should read our non-GAAP presentation in conjunction with our financial statements prepared in accordance with GAAP. The non-GAAP measures we use may be different from, and not directly comparable to, similarly titled measures used by other companies.

Forward-Looking Statements

Statements in this press release, other than statements of historical fact, are forward-looking statements, which are based on our current plans and expectations and are subject to risks and uncertainties that might cause actual results to differ materially from those such statements express or imply. These risks and uncertainties include, but are not limited to, our ability to generate sufficient revenue to fund our commercial operations and development programs; the availability of competing treatments, including generic versions of Korlym; our ability to obtain acceptable prices or adequate insurance coverage and reimbursement for Korlym; and risks related to the development of our product candidates, including regulatory approvals, mandates, oversight and other requirements. These and other risks are set forth in our SEC filings, which are available at our website and the SEC's website. In this press release, forward-looking statements include those concerning our 2019 revenue guidance and statements concerning our anticipated increase in Korlym uptake, the progress, timing, design and results of our development programs, including the GRACE trial and our other clinical trials and the therapeutic and commercial attributes of relacorilant, CORT125281 and CORT118335; and scope and protective power of our intellectual property. We disclaim any intention or duty to update forward-looking statements made in this press release.

Abraxane® is a registered trademark of Celgene Corporation.

Xtandi® is a registered trademark of Astellas Pharma Inc.

Zyprexa® is a registered trademark of Eli Lilly and Company.

CORCEPT THERAPEUTICS INCORPORATED CONDENSED CONSOLIDATED BALANCE SHEETS (in thousands)

	December 31, 2018 ⁽¹⁾	December 31, 2017 ⁽¹⁾
ASSETS		
Cash and investments	\$ 206,760	\$ 104,025
Trade receivables, net of allowances	17,588	15,300
Inventory	16,242	8,376
Other receivable	—	12,896
Deferred tax assets	62,659	76,703
Other assets	8,445	3,237
Total assets	\$ 311,694	\$ 220,537
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable	\$ 8,266	\$ 8,579
Other liabilities	27,546	20,990
Stockholders' equity	275,882	190,968

Total liabilities and stockholders' equity

\$ 311,694

\$ 220,537

(¹) Derived from audited financial statements at that date.

CORCEPT THERAPEUTICS INCORPORATED
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except per share amounts)

	Three Months Ended December 31,		Year Ended December 31,	
	2018	2017	2018	2017
Revenues:				
Product revenue, net	\$ 66,831	53,280	\$ 251,247	159,201
Operating expenses:				
Cost of sales	1,579	1,156	5,215	3,554
Research and development	18,794	13,632	75,247	40,376
Selling, general and administrative	21,560	16,795	81,289	62,416
Total operating expenses	\$ 41,933	\$ 31,583	\$ 161,751	\$ 106,346
Income from operations	24,898	21,697	89,496	52,855
Interest and other income (expense)	1,042	188	2,657	(49)
Income before income taxes	25,940	21,885	92,153	52,806
Income tax expense (benefit)	3,932	(76,445)	16,743	(76,316)
Net income	\$ 22,008	\$ 98,330	\$ 75,410	\$ 129,122
Other comprehensive income:				
Net unrealized gain/(loss) on available-for-sale securities, net of tax impact of \$(3), \$0, \$(22) and \$0, respectively	7	(61)	5	(75)
Total comprehensive income	\$ 22,015	\$ 98,269	\$ 75,415	\$ 129,047
Basic net income per common share	\$ 0.19	\$ 0.86	\$ 0.65	\$ 1.14
Diluted net income per common share	\$ 0.18	\$ 0.77	\$ 0.60	\$ 1.04
Shares used to compute basic net income per share	115,191	114,370	115,343	113,527
Shares used to compute diluted net income per share	125,152	127,361	126,688	124,515

CORCEPT THERAPEUTICS INCORPORATED
RECONCILIATION OF GAAP TO NON-GAAP NET INCOME
(in thousands, except per share amounts)

	Three Months Ended December 31,		Year Ended December 31,	
	2018	2017	2018	2017
GAAP net income	\$ 22,008	\$ 98,330	\$ 75,410	\$ 129,122
Non-cash expenses/(benefits):				
Stock-based compensation				
Cost of Sales	259	—	259	—
Research and development	1,624	1,191	7,012	3,743
Selling, general and administrative	4,383	2,640	16,476	9,618
Total stock-based compensation	6,266	3,831	23,747	13,361
Accretion of interest expense related to debt obligation	—	—	—	456
Deferred tax assets	3,464	(76,703)	14,067	(76,703)
Income tax effect of non-GAAP adjustments(¹)	(1,316)	(805)	(4,987)	(2,902)
Non-GAAP net income, as adjusted for non-cash expenses	\$ 30,422	\$ 24,653	\$ 108,237	\$ 63,334
GAAP basic net income per share	\$ 0.19	\$ 0.86	\$ 0.65	\$ 1.14
GAAP diluted net income per share	\$ 0.18	\$ 0.77	\$ 0.60	\$ 1.04
Non-GAAP basic net income per share, as adjusted for non-cash expenses	\$ 0.26	\$ 0.22	\$ 0.94	\$ 0.56
Non-GAAP diluted net income per share, as adjusted for non-cash expenses	\$ 0.24	\$ 0.19	\$ 0.85	\$ 0.51
Shares used to compute basic net income per share	115,191	114,370	115,343	113,527
Shares used to compute diluted net income per share	125,152	127,361	126,688	124,515

(¹) Calculated by applying the statutory tax rate to the pre-tax, non-discrete, non-GAAP adjustments.

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A photo accompanying this announcement is available at <http://www.globenewswire.com/NewsRoom/AttachmentNg/29441968-b5d2-482a-87c2-12f6ff2b6f5a>

A photo accompanying this announcement is available at <http://www.globenewswire.com/NewsRoom/AttachmentNg/4af5c27d-80b1-4996-9f95-19f4e2a25e56>

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