



Corcept Therapeutics Announces First Quarter 2019 Financial Results and Provides Corporate Update

May 9, 2019

MENLO PARK, Calif., May 09, 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 ended March 31, 2019.

Financial Highlights

- Revenue of \$64.8 million, a 12 percent increase from first quarter 2018
- Fully-diluted GAAP net income of \$0.15 per share, compared to \$0.14 per share in first quarter 2018
- Fully-diluted non-GAAP net income of \$0.20 per share, compared to \$0.19 per share in first quarter 2018
- Cash and investments of \$215.7 million, a \$9.0 million increase from year-end 2018
- Reaffirmed 2019 revenue guidance of \$285 – \$315 million

Corcept reported quarterly revenue of \$64.8 million, compared to \$57.7 million in the first quarter of 2018. First quarter GAAP net income was \$18.3 million, compared to \$17.5 million in the same period last year. Excluding non-cash expenses related to stock-based compensation, utilization of deferred tax assets and related income tax effects, non-GAAP net income in the first quarter was \$24.3 million, compared to \$24.5 million in the first quarter of 2018. A reconciliation of GAAP to non-GAAP net income is included below.

First quarter operating expenses were \$45.9 million, compared to \$36.7 million in the first quarter of 2018, primarily due to an increase in research and development personnel and increased spending to advance new compounds towards the clinic and to formulate and manufacture relacorilant, CORT118335 and CORT125281.

Cash and investments were \$215.7 million at March 31, 2019, an increase of \$9.0 million from year-end. This increase was after the expenditure of \$13.6 million in the first quarter to repurchase 1.2 million shares of common stock. At March 31, 2019, \$62.8 million remained available under Corcept's stock repurchase program.

The company reaffirmed 2019 revenue guidance of \$285 – \$315 million.

"As in prior years, our first quarter revenue was reduced as payors forced patients to secure reauthorization of their insurance," said Joseph K. Belanoff, MD, Corcept's Chief Executive Officer. "Our first quarter revenue was also reduced by the requirement that we cover a portion of the 'donut hole' in Medicare Part D insurance plans – a portion that, by statute, increased significantly this year. No patient's care was interrupted, because we provide Korlym® at no cost until coverage is restored. The number of patients receiving Korlym continues to grow.

"Awareness of Cushing's syndrome and the importance of screening more widely for the disorder is increasing," Dr. Belanoff added. "Our goal is to educate physicians about the benefits of cortisol modulation with Korlym and, should it continue to generate positive clinical data and we secure FDA approval, relacorilant, Korlym's planned successor. We believe relacorilant has the potential to offer significant benefits – even beyond what we see with Korlym."

Clinical Highlights

- Dosing continues in Phase 3 trial of relacorilant in patients with Cushing's syndrome ("GRACE")
- European Medicines Agency ("EMA") recommends orphan designation for relacorilant to treat patients with Cushing's syndrome
- Dosing initiated in double-blind, placebo-controlled, Phase 1b trial of CORT118335 for prevention of antipsychotic-induced weight gain; Phase 2 trials in reversal of antipsychotic-induced weight gain planned in second half of 2019
- Placebo-controlled, Phase 2 trial of CORT118335 to treat non-alcoholic steatohepatitis ("NASH") planned in second half of 2019
- Data from Phase 1/2 trial of relacorilant plus Abraxane in solid tumors to be presented at 2019 ASCO Meeting, May 31 – June 4
- Dosing continues in controlled, Phase 2 trial of relacorilant plus Abraxane® in metastatic ovarian cancer
- Dosing continues in Phase 1/2 trial of CORT125281 plus Xtandi® in castration-resistant prostate cancer

"It is an exciting time to join Corcept," said Andreas Grauer, MD, who became Corcept's Chief Medical Officer in March 2019. "Three of our proprietary, selective cortisol modulators have entered the clinic and we are conducting five clinical trials – in Cushing's syndrome, solid tumors and antipsychotic-induced weight gain. Additional trials – in antipsychotic-induced weight gain and NASH – are planned for later in the year."

"Relacorilant's GRACE trial continues to dose patients with Cushing's syndrome and has begun opening sites in Europe, where many of our Phase 2 patients were enrolled. The EMA's recommendation that relacorilant receive orphan drug designation is especially gratifying. Unlike in the United States, orphan designation in Europe requires the authorities to find plausible evidence of a drug's efficacy and potential to confer significant clinical benefit compared to already-approved treatments – findings we hope GRACE will confirm for relacorilant." (For more about GRACE, go to cushingresearch.com.)

Corcept presented data from relacorilant's Phase 2 trial at the 2019 annual meeting of the American Association of Clinical Endocrinologists ("AACE") in April. Subjects in the trial exhibited clinically meaningful improvements in the trial's key endpoints – hypertension and glucose control – and in a variety of secondary endpoints, including weight loss, liver function, coagulopathy, insulin resistance, cognitive function, mood and quality of life. Relacorilant was well-tolerated, with the most common adverse events being those associated with a reduction in excess cortisol activity. These side effects usually resolve with continued treatment. There were no instances of abnormal vaginal bleeding, even in women who had previously experienced abnormal vaginal bleeding with Korlym. Importantly, there were no instances of hypokalemia, an adverse event experienced by 44 percent of patients in Korlym's pivotal trial and a leading cause of Korlym discontinuation. (Corcept's AACE presentation is available at ir.corcept.com/events.)

"Our oncology program is also progressing," said Dr. Grauer. "Enrollment has begun in our 180-patient, controlled, Phase 2 trial of relacorilant plus Abraxane® in patients with metastatic ovarian cancer. At the ASCO congress this June, we will present data from our Phase 1/2 trial of relacorilant plus Abraxane in a variety of solid tumors and discuss our plans in metastatic pancreatic cancer."

"Finally, our most promising compound for metabolic disorders, CORT118335, has entered the clinic. We are dosing healthy subjects in a placebo-controlled Phase 1b trial in the prevention of antipsychotic-induced weight gain and plan to start two placebo-controlled, Phase 2 trials in patients later this year, as well as a placebo-controlled, Phase 2 trial in patients with NASH – a precursor of cirrhosis. These disorders afflict millions of patients and there are no good treatment options."

Conference Call

We will hold a conference call on May 9, 2019, at 5:00 p.m. Eastern Time (2:00 p.m. Pacific Time). To participate, dial 1-800-347-6311 from the United States or 1-323-994-2132 internationally approximately ten minutes before the start of the call. The passcode will be 4773625. A replay will be available through May 23, 2019 at 888-203-1112 in the United States and 719-457-0820 internationally. The passcode will be 4773625.

Hypercortisolism

Hypercortisolism, often referred to as Cushing's syndrome, is caused by excessive activity of the 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. Hypercortisolism can affect every organ system in the body and can be lethal if not treated effectively.

About Corcept Therapeutics Incorporated

Corcept 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. Corcept's approved product, Korlym®, was the first FDA-approved treatment for patients with Cushing's syndrome. Korlym modulates the activity of cortisol at the glucocorticoid receptor, one of the two receptors to which cortisol binds. Corcept has discovered a large portfolio of proprietary compounds that selectively modulate the effects of cortisol but lack Korlym's affinity for the progesterone receptor. Corcept owns extensive intellectual property covering the composition of its 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 non-GAAP measures of net income, non-GAAP basic net income per share and non-GAAP diluted net income per share that exclude the following non-cash expenses – stock-based compensation, our use of deferred tax assets to offset current tax expense 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 measures. 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, increasing awareness of Cushing's syndrome and the importance of screening more widely for the disorder, 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; the clinical and commercial attributes of relacorilant, CORT125281 and CORT118335; and the 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.

CORCEPT THERAPEUTICS INCORPORATED
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands)

	March 31, 2019	December 31, 2018⁽¹⁾
ASSETS		
Cash and investments	\$ 215,747	\$ 206,760
Trade receivables, net of allowances	19,218	17,588
Inventory	15,360	16,242
Operating right-of-use asset	1,465	—
Deferred tax assets	61,681	62,659
Other assets	6,741	8,445
Total assets	\$ 320,212	\$ 311,694
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable	\$ 9,330	\$ 8,266
Operating lease liability	1,521	—
Other liabilities	23,606	27,546
Stockholders' equity	285,755	275,882
Total liabilities and stockholders' equity	\$ 320,212	\$ 311,694

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

	Three Months Ended March 31, 2019	2018
Revenues:		
Product revenue, net	\$ 64,829	\$ 57,659
Operating expenses:		
Cost of sales	1,240	1,174
Research and development	20,244	17,050
Selling, general and administrative	24,389	18,440
Total operating expenses	\$ 45,873	\$ 36,664
Income from operations	18,956	20,995
Interest and other income	1,097	294
Income before income taxes	20,053	21,289
Income tax expense	(1,779)	(3,830)
Net income	\$ 18,274	\$ 17,459
Other comprehensive income:		
Net unrealized income (loss) on available-for-sale investments, net of tax impact of \$(52) and \$48, respectively	164	(152)
Total comprehensive income	\$ 18,438	\$ 17,307
Basic net income per common share	\$ 0.16	\$ 0.15
Diluted net income per common share	\$ 0.15	\$ 0.14
Shares used to compute basic net income per share	114,844	114,882
Shares used to compute diluted net income per share	123,895	127,733

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

	Three Months Ended	
	March 31,	2018
	2019	
GAAP net income	\$ 18,274	\$ 17,459
Non-cash expenses/(benefits):		
Stock-based compensation		
Cost of Sales	28	—
Research and development	1,979	1,464
Selling, general and administrative	4,689	3,490
Total stock-based compensation	6,696	4,954
Deferred tax assets	926	3,169
Income tax effect of non-GAAP adjustments ⁽¹⁾	(1,607) (1,040
Non-GAAP net income, as adjusted for non-cash expenses	\$ 24,289	\$ 24,542
GAAP basic net income per share	\$ 0.16	\$ 0.15
GAAP diluted net income per share	\$ 0.15	\$ 0.14
Non-GAAP basic net income per share, as adjusted for non-cash expenses	\$ 0.21	\$ 0.21
Non-GAAP diluted net income per share, as adjusted for non-cash expenses	\$ 0.20	\$ 0.19
Shares used to compute basic net income per share	114,844	114,882
Shares used to compute diluted net income per share	123,895	127,733

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

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