



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

August 1, 2019

MENLO PARK, Calif., Aug. 01, 2019 (GLOBE NEWSWIRE) -- Corcept Therapeutics Incorporated (NASDAQ: COURT), 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 results for the quarter ended June 30, 2019.

Financial Highlights

- Revenue of \$72.3 million, a 16 percent increase from second quarter 2018
- GAAP net income of \$0.17 per share, compared to \$0.14 per share in second quarter 2018
- Non-GAAP net income of \$0.25 per share, compared to \$0.20 per share in second quarter 2018
- Cash and investments of \$225.7 million, compared to \$215.7 million at March 31, 2019
- Reaffirmed 2019 revenue guidance of \$285 – \$315 million

Corcept reported quarterly revenue of \$72.3 million, compared to \$62.3 million in the second quarter of 2018. Second quarter GAAP net income was \$20.2 million, compared to \$18.2 million in the same period last year. Excluding non-cash expenses related to stock-based compensation and the utilization of deferred tax assets, together with related income tax effects, non-GAAP net income in the second quarter was \$31.0 million, compared to \$25.4 million in the second quarter of 2018. A reconciliation of GAAP to non-GAAP net income is included below.

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

Second quarter operating expenses were \$47.6 million, compared to \$41.7 million in the second quarter of 2018, primarily due to growth in the number of research and development personnel, increased spending to advance new compounds, and increased spending to formulate and manufacture the selective cortisol modulators relacorilant, exicorilant and miricorilant.

Cash and investments were \$225.7 million at June 30, 2019, an increase of \$10.0 million from March 31, 2019. This increase was after the expenditure of \$17.4 million in the second quarter to repurchase 1.6 million shares of common stock pursuant to Corcept's stock repurchase program.

"Our Cushing's franchise had a strong quarter," said Joseph K. Belanoff, MD, Corcept's Chief Executive Officer. "As they have every year, patients taking Korlym® successfully overcame the insurance reauthorization hurdles many of them face in the first quarter. These obstacles do not interrupt their care, because we provide them with free Korlym. They do, however, temporarily reduce our revenue. Meanwhile, our business grew as the number of patients receiving Korlym and the number of physicians prescribing the medication continued to increase."

Clinical Highlights

"It is gratifying to work on development programs that may benefit so many patients," said Andreas Grauer, MD, Corcept's Chief Medical Officer. "We are advancing our proprietary, selective cortisol modulators in Cushing's syndrome, solid tumors and metabolic diseases. Our clinical trials in these areas are progressing and we plan to start important new trials later this year and in 2020."

Cushing's Syndrome

- Dosing continues in Phase 3 trial ("GRACE") of relacorilant in patients with Cushing's syndrome
- Placebo-controlled trial of relacorilant to treat patients with less severe Cushing's syndrome to begin late this year

GRACE seeks to confirm relacorilant's positive Phase 2 results and to provide the basis for its approval in the United States and Europe as a treatment for Cushing's syndrome.¹ Patients in relacorilant's Phase 2 trial exhibited meaningful improvements in glucose control and hypertension – two of Cushing's syndrome's most common and pernicious manifestations. The trial also met a wide range of secondary endpoints, including weight loss, liver function, coagulopathy, insulin resistance, cognitive function, mood and quality of life. These results were achieved without instances of Korlym's significant off-target effects – vaginal bleeding, endometrial thickening and low potassium.²

In the fourth quarter, Corcept plans to start a double-blind, placebo-controlled trial of relacorilant in patients whose Cushing's syndrome is caused by an adrenal adenoma – an etiology where the effect of medical treatment has not been extensively studied. A controlled study is possible in these patients because their symptoms, while serious, are usually less severe than those experienced by patients with other etiologies of the disorder. The trial will enroll approximately the same number of patients as the GRACE trial at sites in the United States and Europe. Most of these sites are also

participating in GRACE.

Metabolic Disease

- *Phase 1b trial underway in reduction of antipsychotic-induced weight gain; results expected late this year*
- *Phase 2 trial in reversal of recent antipsychotic-induced weight gain planned to start late this year*

Corcept's Phase 1b trial in the reduction of weight-gain caused by antipsychotic medication is on track to produce results late this year. Approximately 60 healthy subjects will receive olanzapine (Eli Lilly's Zyprexa[®]) and either miricorilant or placebo for two weeks, with the primary endpoint being change in weight. "We modeled this trial on the successful placebo-controlled studies³ we conducted with Korlym," said Dr. Grauer. "Unfortunately, Korlym's off-target effects preclude its development for such a common disorder. Miricorilant is a better potential medication because it does not bind to the progesterone receptor. Activity at the progesterone receptor is what causes Korlym's off-target effects. We look forward to completing this trial and starting one double-blind, placebo-controlled Phase 2 trial in patients later this year and another in 2020."

Corcept is also advancing miricorilant as a treatment for NASH, a serious and widespread liver disorder, and plans to start a double-blind, placebo-controlled Phase 2 trial in 2020.

Solid Tumors

- *Phase 3 trial of relacorilant plus nab-paclitaxel in patients with metastatic pancreatic cancer planned to start late this year*
- *European Medicines Agency Committee for Orphan Medicinal Products (COMP) recommends orphan drug designation for relacorilant to treat metastatic pancreatic cancer*

"At the American Society of Clinical Oncologists (ASCO) meeting this June, we presented data from our Phase 1/2 study of relacorilant plus the taxane nab-paclitaxel (Celgene's Abraxane[®])," said Dr. Grauer. "Seven of 25 patients with metastatic, pancreatic cancer and five of 11 patients with advanced ovarian cancer achieved "durable disease control," meaning their tumors either shrank or ceased growing for a period of 16 weeks or longer. Tumor response in two patients with pancreatic disease persisted for more than 50 weeks. One patient's ovarian tumor disappeared completely; another's responded for 65 weeks.⁴ Any response to treatment in patients with such advanced disease is surprising. That is especially true in these patients, whose tumors had progressed during multiple lines of prior therapy, including treatments with nab-paclitaxel or another taxane."

"We hope to confirm these findings in larger, more definitive studies. Our 180-patient, placebo-controlled Phase 2 trial in ovarian cancer is enrolling patients. We plan to start a Phase 3 trial in metastatic pancreatic cancer later this year and are seeking FDA guidance regarding the fastest path to approval in that indication. Relacorilant's designation as an orphan drug for pancreatic cancer in the United States and the European Union will be helpful as our program advances."

On July 18, 2019, the COMP recommended orphan designation of relacorilant for the treatment of pancreatic cancer. The COMP's letter stated that "relacorilant has the potential to restore tumour sensitivity to taxane therapy. This was demonstrated by non-clinical and clinical results, i.e. the achievement of durable partial responses or disease control in some patients, despite previously failed treatment regimens. The COMP considered that the preliminary clinical data submitted by the sponsor supported the claim [of] significant benefit for the purpose of an initial orphan designation."

The European Commission is expected to adopt the COMP's recommendation later this year. The FDA designated relacorilant an orphan drug for the treatment of pancreatic cancer in September 2018.

Conference Call

We will hold a conference call on August 1, 2019, at 5:00 p.m. Eastern Time (2:00 p.m. Pacific Time). To participate, dial 1-888-394-8218 from the United States or 1-323-794-2590 internationally approximately ten minutes before the start of the call (passcode 9712194). A replay will be available through August 15, 2019 at 1-888-203-1112 in the United States and 1-719-457-0820 internationally (passcode 9712194).

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 diagnosed each year. Symptoms vary, but most people with Cushing's syndrome 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 treatment approved by the U.S. Food and Drug Administration for patients with Cushing's syndrome. Corcept has discovered a large portfolio of proprietary compounds, including relacorilant, exicorilant and miricorilant, that selectively modulate the effects of cortisol but not progesterone. Corcept owns extensive United States and foreign intellectual property covering the composition of its selective cortisol modulators and the use of cortisol modulators to treat a variety of serious disorders.

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, 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, exicorilant and miricorilant; the benefits of orphan drug designation; 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.

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

Abraxane® is a registered trademark of Celgene Corporation.

¹ For more about GRACE, go to cushingresearch.com.

² For more data, see our [poster](#) from the 2019 American Association of Clinical Endocrinologists' 28th Annual Congress, available at the Investors/Events tab of our website.

³ Gross et al, *Advances in Therapy* (2009); Gross et al, *Obesity* (2010).

⁴ For more data, see our ASCO [poster](#) at the Investors/Past Events tab of our website.

CORCEPT THERAPEUTICS INCORPORATED CONDENSED CONSOLIDATED BALANCE SHEETS (in thousands)

	June 30, 2019 (Unaudited)	December 31, 2018 ⁽¹⁾
ASSETS		
Cash and investments	\$ 225,702	\$ 206,760
Trade receivables, net of allowances	19,774	17,588
Inventory	17,868	16,242
Operating right-of-use asset	1,106	—
Deferred tax assets	56,700	62,659
Other assets	7,529	8,445
Total assets	\$ 328,679	\$ 311,694
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable	\$ 7,026	\$ 8,266
Operating lease liability	1,148	—
Other liabilities	22,452	27,546
Stockholders' equity	298,053	275,882
Total liabilities and stockholders' equity	\$ 328,679	\$ 311,694

⁽¹⁾ Derived from audited financial statements at that date

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

(Unaudited)

Three Months Ended June 30,	Six Months Ended June 30,
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	2019	2018	2019	2018
Revenues:				
Product sales, net	\$ 72,257	\$ 62,312	\$ 137,086	\$ 119,971
Operating expenses:				
Cost of sales	1,377	1,154	2,617	2,328
Research and development	21,656	20,543	41,900	37,593
Selling, general and administrative	24,591	19,981	48,980	38,421
Total operating expenses	\$ 47,624	\$ 41,678	\$ 93,497	\$ 78,342
Income from operations	24,633	20,634	43,589	41,629
Interest and other income	1,178	562	2,275	856
Income before income taxes	25,811	21,196	45,864	42,485
Income tax expense	(5,625)	(3,000)	(7,404)	(6,830)
Net income	\$ 20,186	\$ 18,196	\$ 38,460	\$ 35,655
Other comprehensive income:				
Net unrealized gain (loss) on available-for-sale securities, net of tax impact of \$(73), \$(7), \$(124) and \$41, respectively	227	25	391	(127)
Total comprehensive income	\$ 20,413	\$ 18,221	\$ 38,851	\$ 35,528
Basic net income per common share	\$ 0.18	\$ 0.16	\$ 0.34	\$ 0.31
Diluted net income per common share	\$ 0.17	\$ 0.14	\$ 0.31	\$ 0.28
Shares used to compute basic net income per share	114,340	115,492	114,590	115,189
Shares used to compute diluted net income per share	121,783	127,515	122,831	127,610

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

(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
GAAP net income	\$ 20,186	\$ 18,196	\$ 38,460	\$ 35,655
Non-cash expenses (benefits):				
Stock-based compensation				
Cost of Sales	55	—	83	—
Research and development	2,505	1,963	4,484	3,427
Selling, general and administrative	5,176	4,054	9,865	7,544
Total stock-based compensation	7,736	6,017	14,432	10,971
Deferred tax assets	4,908	2,474	5,834	5,643
Income tax effect of non-GAAP adjustments ⁽¹⁾	(1,857)	(1,264)	(3,464)	(2,304)
Non-GAAP net income, as adjusted for non-cash expenses	\$ 30,973	\$ 25,423	\$ 55,262	\$ 49,965
GAAP basic net income per share	\$ 0.18	\$ 0.16	\$ 0.34	\$ 0.31
GAAP diluted net income per share	\$ 0.17	\$ 0.14	\$ 0.31	\$ 0.28
Non-GAAP basic net income per share, as adjusted for non-cash expenses	\$ 0.27	\$ 0.22	\$ 0.48	\$ 0.43
Non-GAAP diluted net income per share, as adjusted for non-cash expenses	\$ 0.25	\$ 0.20	\$ 0.45	\$ 0.39

Shares used to compute basic net income per share	114,340	115,492	114,590	115,189
Shares used to compute diluted net income per share	121,783	127,515	122,831	127,610

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

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