



Corcept Therapeutics Announces Third Quarter Financial Results and Provides Corporate Update

November 3, 2022

MENLO PARK, Calif., Nov. 03, 2022 (GLOBE NEWSWIRE) -- Corcept Therapeutics Incorporated (NASDAQ: CORT), a commercial-stage company engaged in the discovery and development of medications to treat severe endocrine, oncologic, metabolic and neurological disorders by modulating the effects of the hormone cortisol, today reported its results for the quarter ended September 30, 2022.

Financial Results

- Revenue of \$101.7 million, compared to \$96.1 million in third quarter 2021
- Tightened 2022 revenue guidance of \$400 – \$410 million
- Diluted net income per common share of \$0.30, compared to \$0.24 in third quarter 2021
- Cash and investments of \$401.2 million, compared to \$382.0 million at June 30, 2022

Corcept's third quarter 2022 revenue was \$101.7 million, compared to \$96.1 million in the third quarter of 2021. Third quarter operating expenses were \$69.8 million, compared to \$59.9 million in the third quarter of 2021, due to increased clinical trial and sales and marketing activities and expenses to support the expansion of our clinical development and commercial teams. Net income was \$34.6 million in the third quarter of 2022, compared to \$30.5 million in the third quarter of 2021.

Cash and investments of \$401.2 million at September 30, 2022 reflects the acquisition in the third quarter of \$15.5 million of Corcept common stock in connection with the exercise of employee stock options and vesting of restricted stock grants.

"Diagnosing and treating patients with a complex disease such as Cushing's syndrome requires frequent in-person contact with physicians. Our revenue in the third quarter was affected by fewer than expected in-person interactions as many physician practices have not returned to pre-pandemic patterns of activity. To reflect this near-term challenge, we are tightening our 2022 revenue guidance to \$400 to \$410 million," said Joseph K. Belanoff, MD, Corcept's Chief Executive Officer. "We remain extremely optimistic about the present and the future of our Cushing's syndrome business. Korlym is an excellent treatment for patients with Cushing's syndrome and there are many eligible patients who have yet to receive it. We are making substantial investments to improve the screening and treatment of these patients and we are confident that these initiatives will contribute to our results in the coming quarters."

Clinical Development

"Our clinical trials continue to advance and generate data supporting cortisol modulation's broad therapeutic potential," added Dr. Belanoff. "We are very excited about our most recently initiated studies: ROSELLA, our confirmatory Phase 3 trial in platinum-resistant ovarian cancer; and DAZALS, our Phase 2 trial in ALS. We are also looking forward to important readouts from our two Phase 2 trials in antipsychotic-induced weight gain by the end of this year."

Oncology

- Enrollment continues in ROSELLA – 360-patient pivotal Phase 3 trial of relacorilant plus nab-paclitaxel in patients with recurrent, platinum-resistant ovarian cancer
- Enrollment continues in open-label, Phase 1b trial of relacorilant plus pembrolizumab in patients with adrenal cancer with cortisol excess
- Randomized, placebo-controlled Phase 2 trial of relacorilant plus enzalutamide in patients with prostate cancer to begin next year in collaboration with the University of Chicago

"We and our investigators are excited that ROSELLA is active and enrolling patients," said Bill Guyer, PharmD, Corcept's Chief Development Officer. "Our goal in this trial is to replicate the positive results of our successful Phase 2 study, which demonstrated improvements in progression-free survival, duration of response and overall survival, all without increasing side effect burden. Women with platinum-resistant ovarian cancer do not have good treatment options and relacorilant plus nab-paclitaxel has the potential to become a new standard of care."

Amyotrophic Lateral Sclerosis (ALS)

- Enrollment continues in DAZALS – 198-patient, randomized, double-blind, placebo-controlled Phase 2 trial of dazucorilant in patients with ALS

"ALS, also known as Lou Gehrig's disease, is a devastating neuromuscular illness with an urgent need for better treatment," said Dr. Guyer. "Dazucorilant showed great promise in animal models of ALS – improving motor performance and reducing neuroinflammation and muscular atrophy. We are excited to initiate this important study in collaboration with TRICALS, the leading ALS academic consortium in Europe, to investigate dazucorilant's potential to significantly improve the lives of patients with ALS."

Metabolic Diseases

- *Enrollment completed in GRATITUDE and GRATITUDE II – two double-blind, placebo-controlled Phase 2 trials of miricorilant to reverse recent and long-standing antipsychotic-induced weight gain (AIWG) – data from both trials expected this quarter*
- *Enrollment continues in Phase 1b dose-finding trial of miricorilant in patients with presumed non-alcoholic steatohepatitis (NASH) – data expected in the first half of 2023*

"We expect our double-blind, placebo-controlled GRATITUDE and GRATITUDE II trials in patients with AIWG to build on the positive data from our Phase 1 studies," said Dr. Guyer. "There is a substantial opportunity to improve the medical care of these patients as weight gain and other adverse metabolic effects caused by antipsychotic medications dissuade many patients from adhering to their treatment regimen, pose serious health risks and reduce the life expectancy of millions of patients."

"The goal of our Phase 1b dose-finding study in patients with NASH is to identify a dosing regimen that captures the unprecedented rapidity and magnitude of liver fat reduction observed in our prior study without causing excessive liver irritation," added Dr. Guyer.

Cushing's Syndrome

- *Enrollment continues in Phase 3 GRACE trial of relacorilant as a treatment for patients with all etiologies of Cushing's syndrome – new drug application (NDA) submission expected in second half 2023*
- *Enrollment continues in Phase 3 GRADIENT trial of relacorilant as a treatment for patients with Cushing's syndrome caused by adrenal adenomas*

"We advanced relacorilant to Phase 3 in Cushing's syndrome based on its extremely promising Phase 2 efficacy and safety data. We expect our GRACE trial to serve as the basis for relacorilant's NDA in Cushing's syndrome, which we plan to submit in the second half of 2023," said Dr. Guyer. "The Phase 3 GRADIENT trial will produce valuable data about an etiology of Cushing's syndrome that has not been subject to rigorous, controlled study, but affects many patients."

Conference Call

We will hold a conference call on November 3, 2022, at 5:00 p.m. Eastern Time (2:00 p.m. Pacific Time). Participants must register in advance of the conference call by clicking [here](#). Upon registering, each participant will receive a dial-in number, and a unique access PIN. Each access PIN will accommodate one caller. Additionally, a listen-only webcast will be available by clicking [here](#). A replay of the call will be available on the Investors / Events tab of www.corcept.com.

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 patients 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 and can be lethal if not treated effectively. Corcept holds patents directed to the composition of relacorilant and the use of cortisol modulators, including Korlym, in the treatment of patients with hypercortisolism.

About Corcept Therapeutics

Corcept has discovered a large portfolio of proprietary compounds that selectively modulate the effects of cortisol and owns extensive United States and foreign intellectual property covering both their composition and their use to treat a variety of serious disorders. The company is conducting clinical trials of its leading cortisol modulators as potential treatments for patients with Cushing's syndrome, ovarian, prostate and adrenal cancer, ALS, weight gain caused by the use of antipsychotic medications and liver disease. Corcept's drug Korlym® was the first medication approved by the U.S. Food and Drug Administration for the treatment of patients with Cushing's syndrome.

Forward-Looking Statements

Statements in this press release, other than statements of historical fact, are forward-looking statements based on our current plans and expectations that are subject to risks and uncertainties that might cause our 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 operate our business, conduct our clinical trials and achieve our other goals during the COVID-19 pandemic and generate sufficient revenue to fund our activities; the availability of competing treatments for hypercortisolism, including generic versions of Korlym; our ability to obtain acceptable prices and adequate insurance coverage and reimbursement for Korlym; risks related to the development of our product candidates, including their clinical attributes, regulatory approvals, mandates, oversight and other requirements; the timing, cost and outcome of legal disputes and investigations; and the scope and protective power of our intellectual property. 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, among others, those concerning our expectations regarding the course of the COVID-19 pandemic and its effects on our commercial results and clinical activities; the number of eligible patients who have yet to receive Korlym; our continued

revenue growth and 2022 revenue guidance; cortisol modulation's potential to treat many serious diseases; development of relacorilant as a treatment for Cushing's syndrome and ovarian, adrenal and prostate cancer, including relacorilant's clinical attributes, regulatory approvals, mandates and oversight, and other requirements; the potential for relacorilant plus nab-paclitaxel to become a standard of care for patients with recurrent platinum-resistant ovarian cancer; the timing and substance of our results in the GRATITUDE trials of miricorilant in patients with antipsychotic-induced weight gain and our Phase 1b trial in patients with NASH; expectations regarding the GRACE trial as the basis for relacorilant's NDA in Cushing's syndrome; the timing and expectations of our DAZALS trial of dazucorilant in patients with ALS; our other pre-clinical and clinical development programs, including the pace of enrollment, study design and timelines, and the accrual and attributes of clinical data; and the timing of regulatory submissions. We disclaim any intention or duty to update forward-looking statements made in this press release.

CORCEPT THERAPEUTICS INCORPORATED
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands)

	September 30, 2022	December 31, 2021⁽¹⁾
	(Unaudited)	
Assets		
Cash and investments	\$ 401,157	\$ 335,812
Trade receivables, net of allowances	29,414	27,625
Inventory	17,073	17,950
Operating lease right-of-use asset	1,707	514
Deferred tax assets, net	57,342	27,455
Other assets	26,562	14,400
Total assets	\$ 533,255	\$ 423,756
Liabilities and Stockholders' Equity		
Accounts payable	\$ 8,178	\$ 6,908
Operating lease liabilities	1,707	526
Other liabilities	50,006	40,516
Stockholders' equity	473,364	375,806
Total liabilities and stockholders' equity	\$ 533,255	\$ 423,756

⁽¹⁾ Derived from audited financial statements at that date

CORCEPT THERAPEUTICS INCORPORATED
CONDENSED CONSOLIDATED STATEMENTS OF INCOME
(Unaudited)
(In thousands, except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Revenues				
Product revenue, net	\$ 101,728	\$ 96,131	\$ 298,802	\$ 267,156
Operating expenses				
Cost of sales	1,339	1,275	3,905	3,927
Research and development	33,292	28,091	94,237	85,345
Selling, general and administrative	35,163	30,533	110,525	90,071
Total operating expenses	\$ 69,794	\$ 59,899	\$ 208,667	\$ 179,343
Income from operations	31,934	36,232	90,135	87,813
Interest and other income	1,070	72	1,780	457
Income before income taxes	33,004	36,304	91,915	88,270
Income tax benefit (expense)	1,604	(5,833)	(7,098)	(7,811)
Net income	\$ 34,608	\$ 30,471	\$ 84,817	\$ 80,459
Net income attributable to common stockholders	\$ 34,550	\$ 30,471	\$ 84,755	\$ 80,459
Basic net income per common share	\$ 0.32	\$ 0.26	\$ 0.80	\$ 0.69
Diluted net income per common share	\$ 0.30	\$ 0.24	\$ 0.73	\$ 0.63

**Weighted-average shares outstanding used in
computing net income per common share**

Basic	107,125	115,791	106,479	116,297
Diluted	116,620	125,136	115,818	127,173

CONTACT:

Corcept Therapeutics

Investor Relations

ir@corcept.com

www.corcept.com



Source: Corcept Therapeutics Incorporated