



Corcept Therapeutics Announces Third Quarter 2018 Financial Results and Provides Corporate Update

November 1, 2018

MENLO PARK, Calif., Nov. 01, 2018 (GLOBE NEWSWIRE) -- Corcept Therapeutics Incorporated (NASDAQ: CORT), a company engaged in the discovery, development and commercialization 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 September 30, 2018.

Financial Highlights

- Revenue of \$64.4 million, a 51 percent increase from third quarter 2017
- GAAP net income of \$0.14 per share, compared to \$0.11 per share in third quarter 2017
- Non-GAAP net income of \$0.22 per share, compared to \$0.14 per share in third quarter 2017
- Cash and investments of \$196.7 million, a \$36.8 million increase from second quarter 2018
- Reaffirmed 2018 revenue guidance of \$250-270 million

Corcept reported revenue of \$64.4 million for the third quarter, compared to \$42.8 million in the same period last year. GAAP net income was \$17.7 million, compared to \$13.8 million in the third quarter of 2017. Excluding non-cash expenses related to stock-based compensation, use of deferred tax assets, interest on the company's retired royalty financing obligation and related income tax effects, non-GAAP net income in the third quarter was \$27.9 million, compared to \$17.4 million in the third quarter of 2017. A reconciliation of GAAP to non-GAAP net income is set forth below.

Operating expenses for the third quarter were \$41.5 million, compared to \$29.1 million in the third quarter of 2017, primarily due to increased spending to advance relacorilant, CORT118335 and CORT125281 and costs arising from increased sales volume.

Cash and investments were \$196.7 million at September 30, 2018, compared to \$159.9 million at June 30, 2018. The company spent \$8.9 million in the third quarter repurchasing 674,000 shares of its common stock. Under the terms of Corcept's stock repurchase program as currently authorized, \$91.1 million remains available for the repurchase of shares.

Relacorilant to Treat Patients with Cushing's Syndrome

- Enrollment open in relacorilant's 130-patient Phase 3 trial
- Relacorilant designated orphan drug for treatment of Cushing's syndrome

The Phase 3 trial of Corcept's proprietary, selective cortisol modulator, relacorilant, is expected to enroll 130 patients at sites in the United States and Europe. In the trial's initial, open-label phase, patients will receive relacorilant for 22 weeks. Any patients who exhibit clinically meaningful improvements in hypertension or glucose tolerance will then enter a twelve-week, double-blind, placebo-controlled "withdrawal phase," during which half will continue to receive relacorilant and the rest, placebo. The rate and degree of relapse in patients receiving placebo will be measured against the rate and degree of relapse in those continuing relacorilant.

For more information about the trial, go to clinicaltrials.gov.

Because the FDA has designated relacorilant as an orphan drug for the treatment of Cushing's syndrome, Corcept will receive tax credits for clinical trial costs, marketing application filing fee waivers if the drug is approved, as well as assistance from the FDA in the drug development process. Patents covering relacorilant's composition of matter and use to treat Cushing's syndrome expire in 2033.

"We're excited to have started relacorilant's Phase 3 trial," said Joseph K. Belanoff, MD. "Our Cushing's syndrome franchise continues to add new prescribers of our first-generation cortisol modulator, Korlym®, in every region of the country, and we expect it will continue to do so. Relacorilant promises to make the benefits of cortisol modulation even more widely available. Patients in relacorilant's Phase 2 trial experienced significant clinical benefit, but not Korlym's serious off-target effects – endometrial thickening, vaginal bleeding and hypokalemia. If these safety and efficacy results are confirmed in Phase 3, relacorilant will constitute a major clinical and commercial advance."

Oncologic & Metabolic Disorders

- Selective cortisol modulator CORT118335 safe and well-tolerated in Phase 1; Phase 2 trials in antipsychotic-induced weight gain and non-alcoholic steatohepatitis (NASH) planned to start in first quarter 2019
- Further results expected by year-end in Phase 1/2 trial of relacorilant plus Abraxane® (nab-paclitaxel) to treat metastatic

pancreatic cancer; FDA grants relacorilant orphan drug status for that indication

- *Controlled Phase 2 trial of relacorilant plus Abraxane to treat metastatic ovarian cancer planned to start by year-end*
- *Dosing continues in Phase 1/2 trial of CORT125281 plus Xtandi® (enzalutamide) in patients with metastatic castration-resistant prostate cancer*

"Our clinical programs continue to make significant progress," said Robert S. Fishman, MD, Corcept's Chief Medical Officer. "CORT118335 was well-tolerated in its Phase 1 trial. This compound is very potent in animal models of antipsychotic-induced weight gain and NASH – serious, widespread disorders for which patients have no good treatment options. We plan to open placebo-controlled, Phase 2 trials in both indications early next year.

"We are also excited to advance relacorilant as a treatment for solid tumors," said Dr. Fishman. "Our Phase 1/2 trial of relacorilant plus Abraxane® has produced encouraging data. At ASCO earlier this year we reported that four of nine patients with metastatic pancreatic cancer who received the minimum therapeutic dose exhibited durable disease control, as did four of seven patients with metastatic ovarian cancer – notable results in patients with such dire disease, all of whom had progressed on prior taxane-based therapies. By year-end, we plan to open a controlled Phase 2 trial in patients with metastatic ovarian cancer and to have collected sufficient data in patients with metastatic pancreatic cancer to determine if a pivotal trial is warranted."

Conference Call

We will hold a conference call on November 1, 2018, at 5:00 p.m. Eastern Time (2:00 p.m. Pacific Time). To participate, dial 877-260-1479 from the United States or 334-323-0522 internationally approximately ten minutes before the start of the call (passcode: 7489528). A replay will be available through November 15, 2018 at 888-203-1112 from the United States and 719-457-0820 internationally (passcode: 7489528).

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. Our first approved product, Korlym, inhibits the effects of excess cortisol by modulating activity at the glucocorticoid receptor, one of the two receptors to which cortisol binds. Korlym was the first FDA-approved treatment for patients with Cushing's syndrome.

About Corcept Therapeutics Incorporated

Corcept is a pharmaceutical company engaged in the discovery, development and commercialization of drugs that treat severe metabolic, oncologic and psychiatric disorders by modulating the effects of the stress hormone cortisol. Korlym® is the company's first FDA-approved medication. 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 its selective cortisol modulators and 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 measure of net income including the following non-cash items – stock-based compensation, use of deferred tax assets, accreted interest on our retired royalty financing obligation and related income tax effects. We believe this non-GAAP measure helps investors better evaluate our past financial performance and potential future results. Our non-GAAP measure 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 measure 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 protections afforded by Korlym's Orphan Drug designation and our intellectual property; 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 2018 revenue guidance; the progress, timing, design and results of our development programs, including our clinical trials and the therapeutic attributes and clinical and commercial advancement of relacorilant, CORT125281 and CORT118335; potential marketing exclusivity, tax credits, filing fee waivers and assistance from the FDA; patent protection; and the continuing addition of new Korlym prescribers. 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.

(in thousands)

	September 30, 2018 (Unaudited)	December 31, 2017*
ASSETS		
Cash and investments	\$ 196,675	\$ 104,025
Trade receivables, net of allowances	19,360	15,300
Inventory	12,722	8,376
Other receivable	—	12,896
Deferred tax assets	66,126	76,703
Other assets	4,868	3,237
Total assets	\$ 299,751	\$ 220,537
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable	\$ 13,922	\$ 8,579
Other liabilities	26,284	20,990
Stockholders' equity	259,545	190,968
Total liabilities and stockholders' equity	\$ 299,751	\$ 220,537

*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 September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Revenues:				
Product sales, net	\$ 64,445	42,763	\$ 184,416	105,921
Operating expenses:				
Cost of sales	1,308	976	3,636	2,397
Research and development	18,860	11,693	56,453	26,745
Selling, general and administrative	21,308	16,471	59,729	45,621
Total operating expenses	\$ 41,476	\$ 29,140	\$ 119,818	\$ 74,763
Income from operations	22,969	13,623	64,598	31,158
Interest and other income (expense)	759	86	1,615	(237)
Income before income taxes	23,728	13,709	66,213	30,921
Income tax (expense) benefit	(5,981)	48	(12,811)	(129)
Net income	\$ 17,747	\$ 13,757	\$ 53,402	\$ 30,792
Other comprehensive income (loss):				
Net unrealized gain (loss) on available-for-sale securities, net of tax impact of (\$16), \$0, \$25 and \$0, respectively	50	3	(77)	(14)
Total comprehensive income	\$ 17,797	\$ 13,760	\$ 53,325	\$ 30,778
Basic net income per common share	\$ 0.15	\$ 0.12	\$ 0.46	\$ 0.27
Diluted net income per common share	\$ 0.14	\$ 0.11	\$ 0.42	\$ 0.25
Shares used to compute basic net income per share	115,798	113,603	115,394	113,242
Shares used to compute diluted net income per share	126,159	125,651	127,167	123,417

CORCEPT THERAPEUTICS INCORPORATED
RECONCILIATION OF GAAP TO NON-GAAP NET INCOME

(in thousands, except per share amounts)

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
GAAP net income	\$ 17,747	\$ 13,757	\$ 53,402	\$ 30,792
Non-cash expenses (benefits):				
Stock-based compensation				
Research and development	1,961	1,049	5,388	2,552
Selling, general and administrative	4,549	2,574	12,093	6,977
Total stock-based compensation	6,510	3,623	17,481	9,529
Accretion of interest expense related to debt obligation	—	37	—	456
Deferred tax assets	4,960	—	10,603	—
Income tax effect of non-GAAP adjustments ⁽¹⁾	(1,367)	—	(3,671)	—
Non-GAAP net income, as adjusted for non-cash expenses	\$ 27,850	\$ 17,417	\$ 77,815	\$ 40,777
GAAP basic net income per share	\$ 0.15	\$ 0.12	\$ 0.46	\$ 0.27
GAAP diluted net income per share	\$ 0.14	\$ 0.11	\$ 0.42	\$ 0.25
Non-GAAP basic net income per share, as adjusted for non-cash expenses	\$ 0.24	\$ 0.15	\$ 0.67	\$ 0.36
Non-GAAP diluted net income per share, as adjusted for non-cash expenses	\$ 0.22	\$ 0.14	\$ 0.61	\$ 0.33
Shares used to compute basic net income per share	115,798	113,603	115,394	113,242
Shares used to compute diluted net income per share	126,159	125,651	127,167	123,417

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

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