



## Corcept Therapeutics Announces First Quarter 2020 Financial Results And Provides Corporate Update

May 4, 2020

MENLO PARK, Calif. , May 04, 2020 (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 results for the quarter ended March 31, 2020.

### Financial Highlights

- Revenue of \$93.2 million, a 44 percent increase from first quarter 2019
- GAAP diluted net income of \$0.25 per share, compared to \$0.15 per share in first quarter 2019
- Non-GAAP diluted net income of \$0.34 per share, compared to \$0.20 per share in first quarter 2019
- Cash and investments of \$349.0 million, compared to \$315.3 million in fourth quarter 2019
- Reaffirmed 2020 revenue guidance of \$355 – 375 million

Corcept reported quarterly revenue of \$93.2 million in the first quarter, compared to \$64.8 million in the first quarter of 2019. First quarter GAAP net income was \$30.1 million, compared to \$18.3 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 first quarter was \$41.2 million, compared to \$24.3 million in the first quarter of 2019. A reconciliation of GAAP to non-GAAP net income is included below.

First quarter operating expenses were \$55.5 million, compared to \$45.9 million in the first quarter of 2019, primarily due to increased employee recruiting and compensation expense, increased spending to conduct clinical trials in Cushing's syndrome and solid tumors and increased spending to formulate and manufacture relacorilant, miricorilant and exicorilant.

Cash and investments were \$349.0 million at March 31, 2020, an increase of \$33.7 million from December 31, 2019. The company reaffirmed its 2020 revenue guidance of \$355 – 375 million.

"Our commercial and medical affairs teams did an excellent job supporting physicians during this difficult time," said Joseph K. Belanoff, MD, Corcept's Chief Executive Officer. "COVID-19 poses especially grave risks to patients with Cushing's syndrome. Hypercortisolism suppresses the immune system and greatly increases the risk of respiratory infection. Now, more than ever, it is important that patients with Cushing's syndrome receive optimal treatment.

"The COVID-19 pandemic's future impact on Corcept is difficult to estimate," said Dr. Belanoff. "While the heightened vulnerability of patients with Cushing's syndrome and their greater than usual need to adhere to their prescribed regimen tends to increase demand for Korlym, restrictions imposed by public health authorities, hospitals and medical practices make it harder for us to reach physicians and harder for physicians to diagnose and treat new patients. It is difficult to predict how the balance of these countervailing forces will shift as the year progresses. That is why, despite an outstanding first quarter, we have not changed our annual revenue guidance.

"Our clinical development programs continue to advance, although the pandemic has made progress more difficult," Dr. Belanoff continued. "Some clinical trial sites, particularly those at academic centers, have suspended new patient enrollments. Some have stopped initiating new trials. At other sites, patient enrollment and study initiations have continued, but at a slower pace. The effect of these changes varies from trial-to-trial. Slowed enrollment will cause our GRACE trial to take longer to complete. The start of our Phase 3 GRADIENT trial and our planned trials in adrenocortical cancer and non-alcoholic steatohepatitis (NASH) have been delayed one quarter.

"By contrast, we still expect results from our Phase 2 trial in ovarian cancer in the first half of next year and to complete dose-finding in our trial of exicorilant plus enzalutamide (Xtandi®) to treat castration-resistant prostate cancer this year. The planned starts of our Phase 3 trial in pancreatic cancer and our additional Phase 2 trial in antipsychotic-induced weight gain have not changed."

### Cushing's Syndrome

- Phase 3 trial of relacorilant to treat patients with Cushing's syndrome ( [GRACE](#) ) continues at sites in the United States, Europe and Israel; NDA filing planned for second quarter 2022
- Phase 3 trial of relacorilant to treat patients with Cushing's syndrome caused by adrenal adenomas ( [GRADIENT](#) ) expected to start in second quarter 2020

"Although the COVID-19 pandemic has greatly slowed new patient screening and enrollment and delayed the opening of our last few clinical trial sites

in the GRACE study,” said Andreas Grauer, MD, Corcept’s Chief Medical Officer, “patients who have already enrolled have continued to participate and we expect the pace of enrollment to increase as public health restrictions ease. We now plan to submit our relacorilant NDA for Cushing’s syndrome in the second quarter of 2022.

“This quarter, we plan to start our Phase 3 GRADIENT trial of relacorilant in patients with Cushing’s syndrome caused by adrenal adenomas,” said Dr. Grauer. GRADIENT is the first randomized, double-blind, placebo-controlled trial in patients with this etiology of Cushing’s syndrome, with a planned enrollment of 130 patients at sites in the United States and Europe. Half of the patients will receive relacorilant and the other half will receive placebo for six months. The primary endpoints will be improvement in glucose metabolism and hypertension. Many planned GRADIENT sites are currently participating in GRACE.<sup>1</sup>

### **Solid Tumors**

- *Controlled, Phase 2 trial of relacorilant plus nab-paclitaxel (Abraxane®) to treat metastatic ovarian cancer enrolling patients at sites in the United States and Europe; results expected in first half 2021*
- *Phase 3 trial of relacorilant plus nab-paclitaxel in metastatic pancreatic cancer ([RELIANT](#)) to start in second quarter 2020*
- *Selection of optimum dose of exicorilant plus enzalutamide in castration-resistant prostate cancer expected by year-end*
- *Phase 1b trial of relacorilant plus PD-1 checkpoint inhibitor pembrolizumab (Keytruda®) to treat patients with metastatic or unresectable adrenal cancer to start in third quarter 2020*

“While the COVID-19 pandemic has slowed the pace of enrollment and clinical trial site activation, our oncology program continues to advance,” said Dr. Grauer. “We expect results from our Phase 2 trial of relacorilant plus nab-paclitaxel in patients with platinum-resistant, metastatic ovarian cancer in the first half of 2021. This quarter, we plan to start our Phase 3 RELIANT trial of relacorilant plus nab-paclitaxel in patients with metastatic pancreatic cancer.”

RELIANT will be an open-label trial in which 80 patients receive relacorilant plus nab-paclitaxel, with the primary endpoint being the objective response rate, assessed by RECIST criteria. An interim analysis will be performed on data from the first 40 patients. “RELIANT’s design incorporates guidance from the FDA,” said Dr. Grauer. “We believe that sufficiently positive results would support accelerated approval in patients with metastatic pancreatic cancer.”

“Next quarter, we also plan to start a 20-patient, open-label, Phase 1b trial of relacorilant combined with the PD-1 checkpoint inhibitor pembrolizumab in patients with metastatic or unresectable adrenal cancer that produces cortisol. These patients have a poor response to pembrolizumab monotherapy,” Dr. Grauer added. “Patients with adrenal cancer often have Cushing’s syndrome as well, because their tumors produce excess cortisol. We believe relacorilant may treat these patients’ Cushing’s syndrome and, by countering cortisol’s immunosuppressive effect, help pembrolizumab achieve its full effect.”

### **Metabolic Diseases**

- *Results of 900 mg cohort in Phase 1b study confirm miricorilant’s activity in reducing antipsychotic-induced weight gain (APIWG)*
- *Phase 2 trial of miricorilant to reverse long-standing APIWG to start in fourth quarter*
- *Phase 2 trial of miricorilant to treat patients with NASH to start in first quarter 2021*

“Results from the 900 mg cohort in our Phase 1b study of miricorilant to attenuate APIWG confirm the exciting finding from the 600 mg cohort that miricorilant is an active medication,” said Dr. Grauer. Despite being treated for only two weeks and receiving miricorilant at considerably lower exposures than we plan to investigate in future trials, subjects given olanzapine plus miricorilant gained less weight and had lower triglycerides and less sharply elevated liver enzymes than subjects who received olanzapine plus placebo. No side effects, beyond those seen with olanzapine, were observed.

We plan to publish the trial’s full results later this year.

“We hope that our ongoing GRATITUDE trial will confirm our positive Phase 1b results,” added Dr. Grauer. GRATITUDE is a multi-site, double-blind, placebo-controlled, Phase 2 trial of miricorilant in 100 patients with schizophrenia and recent APIWG. Study participants are randomized to receive either miricorilant or placebo in addition to their established antipsychotic medication regimen for 12 weeks.<sup>2</sup>

In the fourth quarter, we plan to test a more potent formulation of miricorilant in a double-blind, placebo-controlled, Phase 2 trial in patients with long-standing APIWG. In the first quarter of 2021, using the same formulation, we plan to start a double-blind, placebo-controlled, Phase 2 trial of miricorilant to treat patients with NASH, a serious liver disorder that afflicts millions of people.

### **Conference Call**

We will hold a conference call on May 4, 2020, at 5:00 p.m. Eastern Time (2:00 p.m. Pacific Time). To participate, dial 1-800-458-4121 from the United States or 1-323-794-2093 internationally approximately ten minutes before the start of the call (passcode 2827359). A replay will be available through May 18, 2020 at 1-888-203-1112 in the United States and 1-719-457-0820 internationally (passcode 2827359).

### **About Corcept Therapeutics**

Corcept is 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. Korlym® was the first drug 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. The company owns extensive United States and foreign intellectual property covering the composition of its selective cortisol modulators and the use of cortisol modulators, including mifepristone, 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 evaluate our financial performance and potential future results. Our non-GAAP measures may be different from, and not directly comparable to, those used by other companies. They are not a substitute for comparable GAAP measures and should not be considered in isolation. Investors should read our non-GAAP presentation in conjunction with our financial statements prepared in accordance with GAAP.

## 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 operate our business and achieve our goals during the COVID-19 pandemic, 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 their clinical attributes, 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 2020 revenue guidance; impact of the COVID-19 pandemic on our operations, financial performance and clinical development programs; the progress, enrollment, timing, design and results of our clinical trials; and the clinical and commercial attributes of relacorilant, exicorilant and miricorilant. We disclaim any intention or duty to update forward-looking statements made in this press release.

*Xtandi® is a registered trademark of Astellas Pharma Inc.*

*Abraxane® is a registered trademark of Abraxis BioScience, LLC.*

*Keytruda® is a registered trademark of Merck Sharp & Dohme Corp.*

## CORCEPT THERAPEUTICS INCORPORATED

### CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands, except per share data)

	March 31, 2020	December 31, 2019 <sup>(1)</sup>
	(Unaudited)	
<b>ASSETS</b>		
Cash and investments	\$ 349,005	\$ 315,314
Trade receivables, net of allowances	26,684	19,928
Inventory	16,147	17,405
Operating lease right-of-use asset	3,082	3,446
Deferred tax assets, net	40,562	45,677
Other assets	10,014	10,542
Total assets	\$ 445,494	\$ 412,312
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Accounts payable	\$ 4,976	\$ 7,537
Operating lease liabilities	3,112	3,461
Other liabilities	27,917	30,132
Stockholders' equity	409,489	371,182
Total liabilities and stockholders' equity	\$ 445,494	\$ 412,312

<sup>(1)</sup>Derived from audited financial statements at that date.

## CORCEPT THERAPEUTICS INCORPORATED

### CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME

(In thousands, except per share data)

	Three Months Ended March 31,	
	2020	2019
Revenues:		
Product revenue, net	\$ 93,247	\$ 64,829

Operating expenses:		
Cost of sales	1,878	1,240
Research and development	26,123	20,244
Selling, general and administrative	27,535	24,389
<b>Total operating expenses</b>	<b>55,536</b>	<b>45,873</b>
Income from operations	37,711	18,956
Interest and other income	1,471	1,097
Income before income taxes	39,182	20,053
Income tax expense	(9,117 )	(1,779 )
<b>Net income</b>	<b>\$ 30,065</b>	<b>\$ 18,274</b>
Other comprehensive income (loss):		
Net unrealized gain on available-for-sale investments, net of tax impact of (\$20) and (\$52) respectively	61	164
Foreign currency translation loss, net of tax	(12 )	—
<b>Total comprehensive income</b>	<b>\$ 30,114</b>	<b>\$ 18,438</b>
<b>Basic net income per share</b>	<b>\$ 0.26</b>	<b>\$ 0.16</b>
<b>Diluted net income per share</b>	<b>\$ 0.25</b>	<b>\$ 0.15</b>
Shares used in computing basic net income per common share	114,575	114,844
Shares used in computing diluted net income per common share	122,226	123,895

## CORCEPT THERAPEUTICS INCORPORATED

### RECONCILIATION OF GAAP TO NON-GAAP NET INCOME

(In thousands, except per share data)

	<b>Three Months Ended March 31,</b>	
	<b>2020</b>	<b>2019</b>
GAAP net income	\$ 30,065	\$ 18,274
Non-cash expenses (benefits):		
Stock-based compensation		
Cost of sales	23	28
Research and development	2,605	1,979
Selling, general and administrative	5,290	4,689
Total stock-based compensation	7,918	6,696
Deferred income taxes	5,095	926
Income tax effect of non-GAAP adjustments	(1,900 )	(1,607 )
Non-GAAP net income, as adjusted for non-cash expenses	\$ 41,178	\$ 24,289
GAAP basic net income per share	\$ 0.26	\$ 0.16
GAAP diluted net income per share	\$ 0.25	\$ 0.15
Non-GAAP basic net income per share, as adjusted for non-cash expenses	\$ 0.36	\$ 0.21
Non-GAAP diluted net income per share, as adjusted for non-cash expenses	\$ 0.34	\$ 0.20
Shares used in computing basic net income per share	114,575	114,844
Shares used in computing diluted net income per share	122,226	123,895

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

<sup>1</sup> For more information, see our 2020 ENDO [poster](#) at the Research & Pipeline / Publications tab of our website.

<sup>2</sup> For more information, see our 2020 APA poster at the Research & Pipeline / Publications tab of our website

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