



## Corcept Therapeutics Announces Fourth Quarter And Full-Year 2019 Audited Financial Results And Provides Corporate Update

February 20, 2020

MENLO PARK, Calif., Feb. 20, 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 December 31, 2019.

### Financial Highlights

- 2019 revenue of \$306.5 million, an increase of 22 percent from 2018
- Fourth quarter revenue of \$87.9 million, an increase of 32 percent from fourth quarter 2018
- Fully diluted 2019 GAAP net income of \$0.77 per share, compared to \$0.60 in 2018
- Fully diluted fourth quarter GAAP net income of \$0.24 per share, compared to \$0.18 in 2018
- Year-end cash and investments of \$315.3 million, compared to \$206.8 million at year-end 2018
- Reiterated 2020 revenue guidance of \$355 - 375 million

### Financial Results

Corcept's 2019 revenue was \$306.5 million, compared to \$251.2 million in 2018. Fourth quarter revenue was \$87.9 million, compared to \$66.8 million in the fourth quarter of 2018. The company reiterated its 2020 revenue guidance of \$355 – 375 million.

GAAP net income was \$94.2 million for the year and \$29.4 million in the fourth quarter of 2019, compared to \$75.4 million for the year and \$22.0 million in the fourth quarter of 2018.

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 was \$40.3 million in the fourth quarter, compared to \$30.4 million in the fourth quarter of 2018. For the full-year, non-GAAP net income was \$133.3 million, compared to \$108.2 million in 2018. A reconciliation of GAAP to non-GAAP net income is included below.

Cash and investments increased by \$48.4 million in the fourth quarter, to \$315.3 million.

"Our Cushing's syndrome business had an excellent 2019," said Joseph K. Belanoff, MD, Corcept's Chief Executive Officer, "and we expect growth to continue in 2020, as more patients with Cushing's syndrome receive Korlym and the number of first-time and repeat prescribers of the medication continues to increase.

"Our commercial success has given us the financial resources to advance our portfolio of selective cortisol modulators. By year-end, we plan to be testing three of our proprietary compounds in Phase 2 or Phase 3 trials in Cushing's syndrome, ovarian cancer, pancreatic cancer, adrenal cancer, antipsychotic-induced weight gain (APIWG) and non-alcoholic steatohepatitis (NASH)."

### Cushing's Syndrome

- Phase 3 trial (GRACE) of relacorilant to treat patients with Cushing's syndrome actively enrolling patients at sites in the United States, Europe and Israel
- Phase 3 trial (GRADIENT) of relacorilant to treat patients with Cushing's syndrome caused by adrenal adenomas expected to start in first quarter

"GRACE is open at fifty-four clinical sites," said Andreas Grauer, MD, Corcept's Chief Medical Officer. "Our investigators are enthusiastic. Patients in relacorilant's Phase 2 trial exhibited meaningful improvements in glucose control and hypertension – two of Cushing's syndrome's most pernicious manifestations – as well as in important secondary endpoints, without instances of Korlym®'s significant off-target effects – vaginal bleeding, endometrial thickening and low potassium.<sup>1</sup> For these physicians, whose patients have few good treatment options, the prospect of confirming these data in a pivotal trial is exciting. As we have said, we plan to complete GRACE in time to submit our NDA in the fourth quarter of 2021.

"Our preparations for opening a double-blind, placebo-controlled, Phase 3 trial (GRADIENT) in patients with Cushing's syndrome caused by adrenal adenomas are nearly complete," added Dr. Grauer. Despite having poor health outcomes, patients with this etiology of Cushing's syndrome have not been rigorously studied." GRADIENT is expected to enroll 130 patients at sites in the United States and Europe. Many of the clinical sites participating in GRADIENT are already participating in GRACE.

## Metabolic Disease

- *Phase 2 trial of miricorilant to reverse recent APIWG actively enrolling patients*
- *Phase 2 trials of miricorilant to reverse long-standing APIWG and to treat patients with NASH planned to start in fourth quarter*

"The exciting recent developments in our program in metabolic disorders build on years of work," said Dr. Grauer. "We know from data with mifepristone that cortisol modulation has the potential to treat APIWG<sup>2</sup> and NASH. Both of these serious disorders afflict millions of people. Last year, our Phase 1b trial showed that our selective cortisol modulator miricorilant at 600 mg was active in mitigating weight gain in healthy volunteers administered olanzapine. Next quarter, we will have results from a 900 mg dose cohort. Our double-blind, placebo-controlled Phase 2 trial of miricorilant in patients with schizophrenia and recent APIWG is now actively enrolling. By year-end, we plan to start testing an improved formulation of miricorilant in two double-blind, placebo-controlled Phase 2 trials – one in patients with long-standing APIWG and another in patients with NASH.

## Solid Tumors

- *Controlled, Phase 2 trial of relacorilant plus nab-paclitaxel to treat metastatic ovarian cancer actively enrolling patients at sites in the United States and Europe, on track to produce results in first half of 2021*
- *Phase 3 trial of relacorilant plus nab-paclitaxel to treat patients with metastatic pancreatic cancer to start in second quarter*
- *Phase 1b trial of relacorilant plus the immunotherapeutic agent pembrolizumab (Keytruda®) to treat patients with metastatic or unresectable adrenocortical cancer to start in second quarter*

"Our oncology program continues to mature," said Dr. Grauer. "At the American Society of Clinical Oncologists (ASCO) annual meeting last June, we presented striking results from our open-label, Phase 1/2 trial of relacorilant plus nab-paclitaxel in patients with ovarian and pancreatic cancers.<sup>3</sup> We are seeking to confirm those findings. Our controlled, Phase 2 trial of relacorilant plus nab-paclitaxel is actively enrolling patients with metastatic ovarian cancer at 22 sites in the United States and Europe. We expect results in the first half of 2021. Next quarter, we plan to begin a Phase 3 trial of relacorilant plus nab-paclitaxel in patients with metastatic pancreatic cancer. Our trial design reflects guidance we have received from the FDA and may enable accelerated approval.

"In the second quarter, we plan to start a Phase 1b trial of relacorilant combined with the PD-1 checkpoint inhibitor pembrolizumab to treat metastatic or unresectable adrenal cancer, a disease with a very poor prognosis. Patients with adrenal cancer often suffer from Cushing's syndrome. Our hypothesis is that by modulating the effects of cortisol, relacorilant can alleviate the symptoms of Cushing's syndrome and, by countering the immunosuppressive effect of cortisol activity, help pembrolizumab achieve its full effect.

"Finally, we expect to conclude by year-end the dose-finding trial of our proprietary cortisol modulator exicorilant in combination with enzalutamide in castration-resistant prostate cancer."

## Conference Call

We will hold a conference call on February 20, 2020, at 5:00 p.m. Eastern Time (2:00 p.m. Pacific Time). To participate, dial 1-800-367-2403 from the United States or 1-334-777-6978 internationally approximately ten minutes before the start of the call (passcode 7085899). A replay will be available through March 5, 2020 at 1-888-203-1112 in the United States and 1-719-457-0820 internationally (passcode 7085899).

## About Corcept Therapeutics

We are 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. We have discovered a large portfolio of proprietary compounds, including relacorilant, exicorilant and miricorilant, that selectively modulate the effects of cortisol but not progesterone. We own extensive United States and foreign intellectual property covering the composition of our 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 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; expected growth in the number of patients receiving Korlym; the financial and managerial resources required to advance our development programs; the progress, enrollment, timing, design and results of our clinical trials; the clinical and commercial attributes of relacorilant, exicorilant and miricorilant; 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.

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

**CORCEPT THERAPEUTICS INCORPORATED**  
**CONDENSED CONSOLIDATED BALANCE SHEETS**

(in thousands)

	December 31, 2019 <sup>(1)</sup>	December 31, 2018 <sup>(1)</sup>
<b>ASSETS</b>		
Cash and investments	\$ 315,314	\$ 206,760
Trade receivables, net of allowances	19,928	17,588
Inventory	17,405	16,242
Right-of-use asset	3,446	—
Deferred tax assets, net	45,677	62,659
Other assets	10,542	8,445
Total assets	\$ 412,312	\$ 311,694
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Accounts payable	\$ 7,537	\$ 8,266
Operating lease liability	3,461	—
Other liabilities	30,132	27,546
Stockholders' equity	371,182	275,882
Total liabilities and stockholders' equity	\$ 412,312	\$ 311,694

<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 December 31,		Year Ended December 31,	
	2019	2018	2019	2018
Revenues:				
Product revenue, net	\$ 87,895	\$ 66,831	\$ 306,486	\$ 251,247
Operating expenses:				
Cost of sales	1,436	1,579	5,504	5,215
Research and development	24,312	18,794	89,017	75,247
Selling, general and administrative	27,131	21,560	100,359	81,289
<b>Total operating expenses</b>	52,879	41,933	194,880	161,751
Income from operations	35,016	24,898	111,606	89,496
Interest and other income	1,444	1,042	5,070	2,657
Income before income taxes	36,460	25,940	116,676	92,153
Income tax expense	(7,079 )	3,932	(22,495 )	16,743
<b>Net income</b>	\$ 29,381	\$ 22,008	\$ 94,181	\$ 75,410
Other comprehensive income (loss):				
Net unrealized income (loss) on available-for-sale investments, net of tax impact of \$20, \$(3), (\$104) and (\$22), respectively	(62 )	7	327	5
Foreign currency translation loss, net of tax	9	—	4	—
<b>Total comprehensive income</b>	\$ 29,328	\$ 22,015	\$ 94,512	\$ 75,415
<b>Basic net income per share</b>	\$ 0.26	\$ 0.19	\$ 0.82	\$ 0.65
<b>Diluted net income per share</b>	\$ 0.24	\$ 0.18	\$ 0.77	\$ 0.60
Shares used in computing basic net income per common share	114,347	115,191	114,349	115,343

Shares used in computing diluted net income  
per common share

122,688    125,152    122,566    126,688

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

(In thousands, except per share data)

	<b>Three Months Ended December 31,</b>		<b>Year Ended December 31,</b>	
	<b>2019</b>	<b>2018</b>	<b>2019</b>	<b>2018</b>
GAAP net income	\$ 29,381	\$ 22,008	\$ 94,181	\$ 75,410
Non-cash expenses (benefits):				
Stock-based compensation				
Cost of sales	39	259	144	259
Research and development	2,707	1,624	9,541	7,012
Selling, general and administrative	4,864	4,383	19,628	16,476
Total stock-based compensation	7,610	6,266	29,313	23,747
Deferred income taxes	5,146	3,464	16,877	14,067
Income tax effect of non-GAAP adjustments <sup>(1)</sup>	(1,826)	(1,316)	(7,035)	(4,987)
Non-GAAP net income, as adjusted for non-cash expenses	\$ 40,311	\$ 30,422	\$ 133,336	\$ 108,237
GAAP basic net income per share	\$ 0.26	\$ 0.19	\$ 0.82	\$ 0.65
GAAP diluted net income per share	\$ 0.24	\$ 0.18	\$ 0.77	\$ 0.60
Non-GAAP basic net income per share, as adjusted for non-cash expenses	\$ 0.35	\$ 0.26	\$ 1.17	\$ 0.94
Non-GAAP diluted net income per share, as adjusted for non-cash expenses	\$ 0.33	\$ 0.24	\$ 1.09	\$ 0.85
Shares used in computing basic net income per share	114,347	115,191	114,349	115,343
Shares used in computing diluted net income per share	122,688	125,152	122,566	126,688

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

<sup>1</sup> For more data, see our 2019 AACE [poster](#) at the Investors/Past Events tab of our website.

<sup>2</sup> Gross et al, Advances in Therapy (2009); Gross et al, Obesity (2010).

<sup>3</sup> Our ASCO [poster](#) is available at the Investors/Past Events tab of our website.

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