



Corcept Therapeutics Announces Second Quarter 2020 Financial Results and Provides Corporate Update

August 4, 2020

MENLO PARK, Calif., Aug. 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 June 30, 2020.

Financial Highlights

- Revenue of \$88.6 million, a 23 percent increase from second quarter 2019
- GAAP diluted net income of \$0.23 per share, compared to \$0.17 per share in second quarter 2019
- Non-GAAP diluted net income of \$0.32 per share, compared to \$0.25 per share in second quarter 2019
- Cash and investments of \$409.6 million, compared to \$349.0 million at March 31, 2020
- Reaffirmed 2020 revenue guidance of \$355 – 375 million

Revenue was \$88.6 million in the second quarter, compared to \$72.3 million in the second quarter of 2019. Second quarter revenue was \$4.7 million lower than in the first quarter, primarily because in March 2020 some patients refilled their prescriptions a few days earlier than usual as a safeguard against pandemic-related delays. These safety stocks were consumed in the second quarter. This shift in refill timing increased shipments of Korlym tablets in the first quarter and decreased them by a similar amount in the second quarter.

We reaffirm our 2020 revenue guidance of \$355 – 375 million.

Second quarter GAAP net income was \$28.3 million, compared to \$20.2 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 \$39.7 million, compared to \$31.0 million in the second quarter of 2019. A reconciliation of GAAP to non-GAAP net income is included below.

Second quarter operating expenses were \$53.3 million, compared to \$47.6 million in the second quarter of 2019, primarily due to increased spending to conduct clinical trials in Cushing's syndrome, antipsychotic-induced weight gain and solid tumors and to formulate and manufacture the company's proprietary, selective cortisol modulators and to increased employee recruiting and compensation expense.

Cash and investments were \$409.6 million at June 30, 2020, an increase of \$60.6 million from March 31, 2020.

"Patients with Cushing's syndrome are at elevated risk of infection with the novel coronavirus," said Joseph K. Belanoff, MD, Corcept's Chief Executive Officer. "Our clinical specialists, medical science liaisons and patient advocates have done an excellent job helping physicians provide the care these patients need, despite the challenges posed by the Covid-19 pandemic.

"The pandemic's impact on Corcept has been varied," Dr. Belanoff added. "As our first and second quarter results showed, pandemic-related changes in patient refill choices can shift revenue from one quarter to another. More fundamentally, while the heightened vulnerability of patients with Cushing's syndrome to Covid-19 has caused patients to stay on therapy, which tends to increase demand for Korlym, it remains difficult for doctors to arrange the tests and on-going monitoring needed to diagnose new patients and optimize their care. In addition, many patients are reluctant to leave their homes, even to visit their doctor. And opportunities for our clinical specialists to meet with physicians in person remain limited, although telephone and video conference contact is becoming more common.

"We expect that these countervailing forces will continue in coming quarters, but also expect any changes to be manageable and reiterate our 2020 revenue guidance of \$355 – 375 million."

Cushing's Syndrome

- Phase 3 trial of relacorilant in patients with all etiologies of Cushing's syndrome (GRACE) continues at 60 sites in the United States, Europe and Israel; NDA submission planned in second quarter 2022
- Enrollment underway in Phase 3 trial of relacorilant in patients with Cushing's syndrome of adrenal origin (GRADIENT)

"Although the Covid-19 pandemic has slowed patient enrollment and clinical site activation, our Cushing's syndrome program continues to make important progress," said Andreas Grauer, MD, Corcept's Chief Medical Officer. "We opened five additional clinical sites in GRACE, our pivotal trial of

relacorilant to treat patients with all etiologies of Cushing's syndrome, bringing the total to 60. Enrollment activity has increased, particularly in Europe, where pandemic-related restrictions have eased. We plan to submit relacorilant's NDA, based on the results of GRACE, in the second quarter of 2022.

"In addition, enrollment has begun in GRADIENT, our double-blind, placebo-controlled, Phase 3 trial with a planned total of 130 patients whose Cushing's syndrome is caused by an adrenal adenoma or adrenal hyperplasia.¹ GRADIENT is the first controlled clinical trial of medical treatment in this etiology of the disease.

Solid Tumors

- *Completed enrollment in controlled, Phase 2 trial of relacorilant plus nab-paclitaxel in patients with metastatic ovarian cancer; results expected in first half 2021*
- *Initiated Phase 3 trial of relacorilant plus nab-paclitaxel in patients with metastatic pancreatic cancer (RELIANT)*
- *Selection of optimum dose of exicorilant plus enzalutamide in patients with castration-resistant prostate cancer expected by year-end*
- *Phase 1b trial of relacorilant plus PD-1 checkpoint inhibitor pembrolizumab in patients with metastatic or unresectable adrenal cancer expected to start in third quarter 2020*

"Our development of relacorilant as a potential treatment for solid tumors recently achieved two important milestones," said Dr. Grauer. "We completed enrollment in our controlled, Phase 2 trial of relacorilant combined with nab-paclitaxel to treat patients with metastatic ovarian cancer. We also initiated RELIANT, our Phase 3 trial of relacorilant plus nab-paclitaxel in patients with metastatic pancreatic cancer. Data from our open-label, Phase 1/2 trial in patients with these tumors were very encouraging.² Replicating those results in these larger, more rigorous trials would be an important medical advance."

Our controlled, Phase 2 trial of relacorilant plus nab-paclitaxel in patients with metastatic, platinum-resistant ovarian cancer has enrolled its goal of 178 patients, at 28 sites in the United States, Canada and Europe. Participants were randomly assigned to receive either relacorilant plus nab-paclitaxel or nab-paclitaxel alone. The trial's primary endpoint is progression free survival, with secondary endpoints including objective response rate and duration of objective response. Data is expected in the first half of next year.

RELIANT has a planned enrollment of 80 patients with metastatic pancreatic cancer, with an interim analysis of data from the first 40 patients. Each patient will receive relacorilant plus nab-paclitaxel. The primary endpoint is objective response rate, with secondary endpoints including progression-free survival and duration of response. RELIANT will be conducted at 20 sites in the United States. We believe sufficiently positive results would support accelerated approval by the FDA.

"In the third quarter, we plan to initiate an open-label, 20-patient, Phase 1b trial of relacorilant combined with the PD-1 checkpoint inhibitor pembrolizumab in patients with metastatic or unresectable adrenal cancer that produces excess cortisol," said Dr. Grauer. "These patients respond poorly to pembrolizumab monotherapy and also suffer from Cushing's syndrome. By modulating the effects of excess cortisol, including cortisol-induced immune suppression, relacorilant may both treat the symptoms of Cushing's syndrome and allow pembrolizumab achieve its full cancer-killing effect."

Metabolic Diseases

- *Enrollment continues in double-blind, placebo-controlled, Phase 2 trial of miricorilant to reverse recent APIWG (GRATITUDE)*
- *Double-blind, placebo-controlled Phase 2 trial (GRATITUDE 2) of miricorilant to reverse long-standing antipsychotic-induced weight gain (APIWG) planned to start in third quarter 2020*
- *Double-blind, placebo-controlled Phase 2 trial of miricorilant in patients with non-alcoholic steatohepatitis (NASH) planned to start in fourth quarter 2020*

"Miricorilant has shown great promise as a treatment for APIWG," said Dr. Grauer. "In our Phase 1b trial, healthy 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 – despite being treated for only two weeks. We hope to confirm and extend these results in the GRATITUDE trials.

"Our on-going GRATITUDE trial is testing the ability of miricorilant to reduce recent weight gain caused by antipsychotic medications in 100 patients with schizophrenia," added Dr. Grauer. "Study participants continue to receive their established dose of antipsychotic medication and either 600 milligrams of miricorilant or placebo for 12 weeks. Our second trial, GRATITUDE 2 will test the same effect in patients with long-standing APIWG.

"Completion of formulation work for miricorilant has allowed us to advance by one quarter the start of our second Phase 2 trial in patients with APIWG and our first Phase 2 trial in patients with NASH," said Dr. Grauer.

Conference Call

We will hold a conference call on August 4th, 2020, at 5:00 p.m. Eastern Time (2:00 p.m. Pacific Time). To participate, dial 1-800-353-6461 from the United States or 1-334-323-0501 internationally approximately ten minutes before the start of the call (passcode 6800706). A replay will be available through August 18, 2020 at 1-888-203-1112 in the United States and 1-719-457-0820 internationally (passcode 6800706).

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 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 that selectively modulate the effects of cortisol. We own extensive United States and foreign intellectual property covering the composition of our 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, basic net income per share and diluted net income per share that exclude the following non-cash expenses – (i) stock-based compensation, (ii) our use of deferred tax assets to offset current tax expense and (iii) 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 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 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 and 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 and 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; the 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.

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CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands, except per share data)

	June 30, 2020 (Unaudited)	December 31, 2019 ⁽¹⁾
Assets		
Cash and investments	\$ 409,558	\$ 315,314
Trade receivables, net of allowances	22,725	19,928
Inventory	16,120	17,405
Operating lease right-of-use asset	3,472	3,446
Deferred tax assets, net	35,470	45,677
Other assets	10,478	10,542
Total assets	\$ 497,823	\$ 412,312
Liabilities and Stockholders' Equity		
Accounts payable	\$ 6,304	\$ 7,537
Operating lease liabilities	3,505	3,461
Other liabilities	34,316	30,132
Stockholders' equity	453,698	371,182
Total liabilities and stockholders' equity	\$ 497,823	\$ 412,312

⁽¹⁾ Derived from audited financial statements at that date

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CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME

(In thousands, except per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Revenues				
Product revenue, net	\$ 88,565	\$ 72,257	\$ 181,812	\$ 137,086
Operating expenses				
Cost of sales	1,234	1,377	3,112	2,617
Research and development	26,497	21,656	52,620	41,900
Selling, general and administrative	25,572	24,591	53,107	48,980
Total operating expenses	\$ 53,303	\$ 47,624	\$ 108,839	\$ 93,497

Income from operations	35,262	24,633	72,973	43,589
Interest and other income	1,010	1,178	2,481	2,275
Income before income taxes	36,272	25,811	75,454	45,864
Income tax expense	(7,945)	(5,625)	(17,062)	(7,404)
Net income	\$ 28,327	\$ 20,186	\$ 58,392	\$ 38,460
Other comprehensive income (loss):				
Net unrealized gain on available-for-sale investments, net of tax impact of \$(170), \$(73), \$(190) and \$(124), respectively	545	227	606	391
Foreign currency translation loss, net of tax	(15)	—	(27)	—
Total comprehensive income	\$ 28,857	\$ 20,413	\$ 58,971	\$ 38,851
Basic net income per share	\$ 0.25	\$ 0.18	\$ 0.51	\$ 0.34
Diluted net income per share	\$ 0.23	\$ 0.17	\$ 0.48	\$ 0.31
Shares used in computing basic net income per common share	115,006	114,340	114,790	114,590
Shares used in computing diluted net income per common share	123,234	121,783	122,756	122,831

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RECONCILIATION OF GAAP TO NON-GAAP NET INCOME

(In thousands, except per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
GAAP net income	\$ 28,327	\$ 20,186	\$ 58,392	\$ 38,460
Non-cash expenses (benefits)				
Stock-based compensation				
Cost of sales	15	55	38	83
Research and development	2,794	2,505	5,399	4,484
Selling, general and administrative	5,680	5,176	10,970	9,865
Total stock-based compensation	8,489	7,736	16,407	14,432
Deferred income taxes	4,922	4,908	10,017	5,834
Income tax effect of non-GAAP adjustments ⁽¹⁾	(2,037)	(1,857)	(3,938)	(3,464)
Non-GAAP net income, adjusted for non-cash expenses	\$ 39,701	\$ 30,973	\$ 80,878	\$ 55,262
GAAP basic net income per share	\$ 0.25	\$ 0.18	\$ 0.51	\$ 0.34
GAAP diluted net income per share	\$ 0.23	\$ 0.17	\$ 0.48	\$ 0.31
Non-GAAP basic net income per share, adjusted for non-cash expenses	\$ 0.35	\$ 0.27	\$ 0.70	\$ 0.48
Non-GAAP diluted net income per share, adjusted for non-cash expenses	\$ 0.32	\$ 0.25	\$ 0.66	\$ 0.45
Shares used in computing basic net income per share	115,006	114,340	114,790	114,590
Shares used in computing diluted net income per share	123,234	121,783	122,756	122,831

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

¹ See our 2020 ENDO [poster](#) at the Research & Pipeline / Publications tab of our website.

² See our ASCO [poster](#) at the Investors / Events tab of our website.

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Source: Corcept Therapeutics Incorporated