



Corcept Therapeutics Announces Second Quarter Financial Results and Provides Corporate Update

July 29, 2021

MENLO PARK, Calif., July 29, 2021 (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 neuropsychiatric disorders by modulating the effects of the hormone cortisol, today reported its results for the quarter ended June 30, 2021.

Financial Results

- *Revenue of \$91.6 million, compared to \$88.6 million in second quarter 2020*
- *GAAP diluted net income of \$0.21 per share, compared to \$0.23 per share in second quarter 2020*
- *Non-GAAP diluted net income of \$0.30 per share, compared to \$0.32 per share in second quarter 2020*
- *Cash and investments of \$471.6 million, compared to \$454.8 million at March 31, 2021*
- *Reiterated 2021 revenue guidance of \$355 – \$385 million*

Second quarter 2021 revenue was \$91.6 million, compared to \$88.6 million in the second quarter of 2020. First quarter 2021 revenue was \$79.4 million. Second quarter 2021 GAAP net income was \$26.5 million, compared to \$28.3 million in the second quarter of 2020. 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 \$38.2 million, compared to \$39.7 million in the second quarter of 2020. A reconciliation of GAAP to non-GAAP net income is included below.

Second quarter operating expenses were \$59.6 million, compared to \$53.3 million in the second quarter of 2020, due to increased employee compensation expenses, commercial spending, spending on clinical trials in Cushing's syndrome and pre-clinical activities.

Cash and investments were \$471.6 million at June 30, 2021, compared to \$454.8 million at March 31, 2021. The balance at June 30, 2021 reflects the acquisition of \$30.8 million of common stock in the second quarter – 1.4 million shares pursuant to the company's stock repurchase program and 0.1 million shares in connection with the net exercise of stock options. Under the repurchase program's current terms, \$127.6 million remains available for the purchase of shares.

The company reiterated its 2021 revenue guidance of \$355 – \$385 million.

"Diminishing COVID-19 public health restrictions and the availability of safe and effective vaccines have allowed our commercial business to resume growing," said Joseph K. Belanoff, MD, Corcept's Chief Executive Officer. "Our second quarter results reflect the fact that physicians are seeing their patients more frequently, which allows them to diagnose and optimally treat those who have Cushing's syndrome. Provided COVID-19 restrictions continue to abate – as we believe they will – we expect growth to continue. Korlym is an excellent treatment for hypercortisolism and there are many eligible patients who have yet to receive it. Our planned successor to Korlym, relacorilant, which is currently in its pivotal trial, promises to be an even better medication."

Clinical Development

"We are enthusiastic about the potential of cortisol modulation to help treat many diseases, not just Cushing's syndrome," added Dr. Belanoff. "Our programs in solid tumors, non-alcoholic steatohepatitis (NASH) and antipsychotic-induced weight gain (AIWG) continue to make progress. We are especially excited about our advancing platinum-resistant ovarian cancer program. Based on the statistically significant and clinically meaningful results of our 178-patient, controlled Phase 2 trial, we plan to initiate a pivotal trial in the first quarter of next year."

Solid Tumors

- *Phase 3 pivotal trial in patients with platinum-resistant ovarian cancer to start in the first quarter of 2022*
- *Selection of the optimum dose of exicorilant plus enzalutamide in patients with castration-resistant prostate cancer (CRPC) expected later this year*
- *Enrollment continues in 20-patient, open-label, Phase 1b trial of relacorilant plus PD-1 checkpoint inhibitor pembrolizumab in patients with adrenal cancer with cortisol excess*

"We look forward to starting a Phase 3 pivotal trial in women with platinum-resistant ovarian cancer," said Andreas Grauer, MD, Corcept's Chief Medical Officer. "Our Phase 2 results illustrated that women who received relacorilant with nab-paclitaxel experienced improved progression free

survival (PFS) without experiencing additional side effects, a welcome finding for women with few good treatment options. We will present detailed results of our Phase 2 trial at the European Society for Medical Oncology (ESMO) meeting in September in a proffered paper oral presentation, with overall survival data expected later in the year. And we continue to evaluate relacorilant as a possible treatment for patients with other glucocorticoid receptor-expressing tumors.”

Metabolic Diseases

- *Phase 1b dose-finding trial in patients with presumed NASH to start in the fourth quarter of 2021*
- *Enrollment continues in GRATITUDE, a 100-patient double-blind, placebo-controlled, Phase 2 trial of miricorilant to reverse recent AIWG*
- *Enrollment continues in GRATITUDE II, a 150-patient, double-blind, placebo-controlled Phase 2 trial of miricorilant to reverse long-standing AIWG*

“We plan to begin a Phase 1b, dose-finding trial of miricorilant in patients with presumed NASH in the fourth quarter of this year,” said Dr. Grauer. “Patients who received miricorilant in our previous trial experienced exceptionally large and rapid reductions in liver fat accompanied by substantial, but transient, elevations of the liver enzymes ALT and AST. Our hypothesis is that the rapidity and magnitude of miricorilant’s fat reducing effect irritated the liver. The objective of our planned study is to identify a dosing regimen that can produce significant reductions in fat without causing liver irritation.”

“Meanwhile, our Phase 2 trials evaluating miricorilant as a treatment for patients with AIWG – GRATITUDE and GRATITUDE II – continue to advance,” added Dr. Grauer. “We expect to complete enrollment in GRATITUDE II by year-end and in GRATITUDE by mid-2022.”

Cushing’s Syndrome

- *Enrollment continues in Phase 3 GRACE trial of relacorilant as a treatment for patients with all etiologies of Cushing’s syndrome; NDA submission expected in the second quarter of 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 based on its extremely promising Phase 2 efficacy and safety data, which we recently published in *Frontiers in Endocrinology* (Pivonello 2021),” said Dr. Grauer. “We expect our GRACE trial, which is accruing patients and generating data, to serve as the basis for relacorilant’s NDA in Cushing’s syndrome. We expect to submit this relacorilant NDA in the second quarter of 2023. The Phase 3 GRADIENT trial will produce valuable data about an etiology of Cushing’s syndrome that affects many patients, but has not been subject to rigorous, controlled study.”

Conference Call

We will hold a conference call on July 29, 2021, at 5:00 p.m. Eastern Time (2:00 p.m. Pacific Time). To participate, [Click this link](#) (listen-only mode) or dial 1-833-693-0540 from the United States or 1-661-407-1581 internationally approximately 15 minutes before the start of the call. The passcode will be 1482035. A replay will be available on the Investors / Past Events tab of our website.

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 covering the composition of relacorilant and the use of cortisol modulators, including Korlym, in the treatment of patients with hypercortisolism.

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. Corcept has discovered a large portfolio of proprietary compounds that selectively modulate the effects of cortisol. The company owns extensive United States and foreign intellectual property covering the composition of its 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 and conduct our clinical trials 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; risks related to the development of our product candidates, including their clinical attributes, regulatory approvals, mandates and oversight, and other requirements; 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 those concerning the clinical attributes of relacorilant and its effects in patients with ovarian cancer, plans to initiate a phase 3 trial in women with platinum-resistant ovarian cancer and continued evaluation of relacorilant as a possible treatment for patients with other glucocorticoid receptor-expressing tumors; the clinical attributes of miricorilant and its effects in patients with NASH and plans to initiate a Phase 1b trial in NASH; 2021 revenue guidance; our expectations regarding growth of our business; our clinical development programs; the progress, enrollment, timing, design and results of our clinical trials, including the timing of enrollment, data and dosing selection; the timing of regulatory submissions; the course of the COVID-19 pandemic and its impact on patients, physicians, medical practice, clinical research activities and our business; and the clinical and commercial attributes of Korlym, relacorilant, exicorilant and miricorilant. 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, except per share data)

	June 30, 2021 (Unaudited)	December 31, 2020 (See Note 1)
Assets		
Cash and investments	\$ 471,639	\$ 476,892
Trade receivables, net of allowances	27,620	26,198
Inventory	19,403	21,157
Operating lease right-of-use asset	1,524	2,509
Deferred tax assets, net	33,741	31,603
Other assets	14,553	13,372
Total assets	\$ 568,480	\$ 571,731
Liabilities and Stockholders' Equity		
Accounts payable	\$ 9,216	\$ 10,554
Operating lease liabilities	1,559	2,551
Other liabilities	35,030	35,288
Stockholders' equity	522,675	523,338
Total liabilities and stockholders' equity	\$ 568,480	\$ 571,731

⁽¹⁾ Derived from audited financial statements at that date

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Revenues				
Product revenue, net	\$ 91,588	\$ 88,565	\$ 171,025	\$ 181,812
Operating expenses				
Cost of sales	1,384	1,234	2,652	3,112
Research and development	28,232	26,497	57,254	52,620
Selling, general and administrative	30,029	25,572	59,538	53,107
Total operating expenses	\$ 59,645	\$ 53,303	\$ 119,444	\$ 108,839
Income from operations	31,943	35,262	51,581	72,973
Interest and other income	110	1,010	385	2,481
Income before income taxes	32,053	36,272	51,966	75,454
Income tax expense	(5,530)	(7,945)	(1,978)	(17,062)
Net income	\$ 26,523	\$ 28,327	\$ 49,988	\$ 58,392
Other comprehensive income:				
Net unrealized (loss) gain on available-for-sale investments, net of tax impact of \$16, \$(170), 77 and (190), respectively	(50)	545	(242)	606

Foreign currency translation gain (loss), net of tax	16	(15)	42	(27)
Total comprehensive income	<u>\$ 26,489</u>	<u>\$ 28,857</u>	<u>\$ 49,788</u>	<u>\$ 58,971</u>
Basic net income per share	<u>\$ 0.23</u>	<u>\$ 0.25</u>	<u>\$ 0.43</u>	<u>\$ 0.51</u>
Diluted net income per share	<u>\$ 0.21</u>	<u>\$ 0.23</u>	<u>\$ 0.39</u>	<u>\$ 0.48</u>
Shares used in computing basic net income per common share	<u>116,294</u>	<u>115,006</u>	<u>116,555</u>	<u>114,790</u>
Shares used in computing diluted net income per common share	<u>126,680</u>	<u>123,234</u>	<u>128,204</u>	<u>122,756</u>

CORCEPT THERAPEUTICS INCORPORATED
RECONCILIATION OF GAAP TO NON-GAAP NET INCOME
(Unaudited)
(In thousands, except per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
GAAP net income	<u>\$ 26,523</u>	<u>\$ 28,327</u>	<u>\$ 49,988</u>	<u>\$ 58,392</u>
Non-cash expenses (benefits)				
Stock-based compensation				
Cost of sales	16	15	26	38
Research and development	3,825	2,794	7,330	5,399
Selling, general and administrative	7,227	5,680	13,813	10,970
Total stock-based compensation	<u>11,068</u>	<u>8,489</u>	<u>21,169</u>	<u>16,407</u>
Deferred income taxes	3,299	4,922	(2,061)	10,017
Income tax effect of non-GAAP adjustments ⁽¹⁾	(2,656)	(2,037)	(5,081)	(3,938)
Non-GAAP net income, adjusted for non-cash expenses	<u>\$ 38,234</u>	<u>\$ 39,701</u>	<u>\$ 64,015</u>	<u>\$ 80,878</u>
GAAP basic net income per share	<u>\$ 0.23</u>	<u>\$ 0.25</u>	<u>\$ 0.43</u>	<u>\$ 0.51</u>
GAAP diluted net income per share	<u>\$ 0.21</u>	<u>\$ 0.23</u>	<u>\$ 0.39</u>	<u>\$ 0.48</u>
Non-GAAP basic net income per share, adjusted for non-cash expenses per share	<u>\$ 0.33</u>	<u>\$ 0.35</u>	<u>\$ 0.55</u>	<u>\$ 0.70</u>
Non-GAAP diluted net income per share, adjusted for non-cash expenses per share	<u>\$ 0.30</u>	<u>\$ 0.32</u>	<u>\$ 0.50</u>	<u>\$ 0.66</u>
Shares used in computing basic net income per common share	<u>116,294</u>	<u>115,006</u>	<u>116,555</u>	<u>114,790</u>
Shares used in computing diluted net income per common share	<u>126,680</u>	<u>123,234</u>	<u>128,204</u>	<u>122,756</u>

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

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