UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

Current Report
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (date of earliest event reported): February 5, 2019

Corcept Therapeutics Incorporated
(Exact name of registrant as specified in its charter)

Delaware	**000-50679**	**77-0487658**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification Number)**

149 Commonwealth Drive
Menlo Park, CA 94025
(Address of principal executive offices, with zip code)

(650) 327-3270
(Registrant's telephone number, including area code)

Not Applicable
(Former name or former, address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 or Rule 12b-2 of the Securities Exchange Act of 1934.

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01 Regulation FD Disclosure.

Corcept Therapeutics Incorporated (the "Company") is disseminating the white paper furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Item 7.01 and Exhibit 99.1 to this Current Report on Form 8-K shall not be deemed filed for purposes of Section 18 of the Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information in this Item 7.01 and Exhibit 99.1 to this Current Report on Form 8-K is not incorporated by reference into any filing with the U.S. Securities and Exchange Commission made by the Company, whether made before or after the date hereof, regardless of any general incorporation language in the filing unless specifically stated so therein.

Forward-Looking Statements

Statements in this Current Report on Form 8-K, other than statements of historical fact, are forward-looking statements for purposes of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, are based on the Company's 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 are set forth in the Company's Securities and Exchange Commission ("SEC") filings, which are available at the Company's website and the SEC's website. Forward-looking statements include, but are not limited to, those concerning the Company's commercial activities related to Korlym®. The Company disclaims any intention or duty to update forward-looking statements made in this Current Report on Form 8-K.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Corcept Therapeutics Incorporated White Paper

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

CORCEPT THERAPEUTICS INCORPORATED

By: /s/ G. Charles Robb
Name: G. Charles Robb
Title: Chief Financial Officer and Secretary

Date: February 5, 2019

Exhibit 99.1

CONTACT:
Charles Robb
Chief Financial Officer
Corcept Therapeutics
650-688-8783
crobb@corcept.com
www.corcept.com

Some Important Facts about Corcept, Physicians and Patients

Our FDA-approved medication, Korlym®, has saved the lives of some patients and greatly improved the health of many more. Our increasingly successful commercial activities, which adhere to the highest ethical standards, fund the development of drug candidates that may benefit patients suffering from cancers and metabolic diseases that currently have no good treatments.

That is the long and the short of it. Or so it should be.

Unfortunately, Corcept's success has attracted speculators who seek to enrich themselves by driving down the price of our stock. These people are not interested in the truth. They use partial and incorrect data to imply, without any basis in truth, that Korlym is dangerous and physicians only prescribe it because we pay them. This is offensive nonsense.

This white paper is meant to help investors ground their analysis in the facts.

- **Speculators wrongly claim** that there are not enough patients with Cushing's syndrome (the life-threatening disease which Korlym treats) to account for our revenue – and so we must be selling for inappropriate, unapproved uses, such as the prevention of weight gain.

  In fact, there at least 10,000 patients in the United States – and according to recent reports in scientific journals, probably several times more than 10,000 patients – in need of medical therapy for the disease. In short, there are a lot more patients with Cushing's syndrome than are required to account for our revenue.[1,2]

- **Speculators wrongly claim** that Korlym is not effective and the FDA should not have approved it.

  In fact, the results of Korlym's pivotal trial were clearly positive, which is why the FDA approved it promptly and without soliciting advice from an advisory committee of third-party experts. All of the trial's results, including an analysis of the rate of adverse events, have been published in peer-reviewed journals.[3]

1 Broder, et al., Pituitary, 2015
2 Guaraldi F, Salvatori R, J Am Board Fam Med, 2012
3 Yuen, et al., Endocr Pract, 2015

- **Speculators wrongly claim** that clusters of Korlym prescriptions in rural and suburban areas mean that Corcept is bribing (or duping) unsophisticated small-town physicians to prescribe Korlym.

  In fact, Cushing's syndrome affects patients in every community. When physicians screen for the disease (which often masquerades as difficult-to-treat cases of hypertension, diabetes and other common disorders), they almost always identify patients. A geographic "cluster" of Korlym prescriptions is merely evidence that physicians in a particular area are diligently diagnosing and treating patients.

- **Speculators wrongly claim,** based on a misrepresentation of government prescription and Sunshine Act payment data, that we pay doctors to prescribe Korlym.

  In fact, we do not. We enlist experienced physicians to educate their colleagues about Cushing's syndrome and Korlym and to provide us with important advice about our clinical trials. We pay fair market rates for these services – nothing more. Our choice of physicians has nothing to do with their prescribing behavior. To insinuate otherwise, as speculators do, is a grotesque slur against skilled, well-meaning physicians.

- **Speculators wrongly claim** that the Veterans Administration (and one VA doctor in particular) account for a suspiciously large portion of our revenue.

  In fact, our sales to hospitals, including all of our sales to the VA, provide a very small part of our revenue – in 2018, less than one percent ($2.5 million). We disclose this data (as reviewed by our auditors) in our quarterly and annual reports to the SEC, which you can find at www.sec.gov and www.corcept.com.

- **Speculators wrongly claim** that we promote Korlym for unapproved, "off-label" uses.

  In fact, we do not. Literally, ninety-nine percent (99%) of the Korlym we sell goes to patients whose diagnosis matches Korlym's FDA-approved label. Insurance companies require proof of this diagnosis before agreeing to cover the cost of Korlym. Patients who do not have a properly documented diagnosis of Cushing's syndrome rarely receive reimbursement.

- **Speculators wrongly claim** that Korlym is causing the death of a large and growing number of patients.

  In fact, it is not. Unfortunately, patients with Cushing's syndrome are very ill, and many of them pass away. We are not aware of any instances where Korlym is the cause. The FDA "FAERS" database upon which speculators base their insinuations does not specify the cause of a patient's death. It also contains many duplicate entries. A single event reported by a Corcept employee, the patient and the patient's physician is listed in FAERS as three events. The FAERS website makes this clear. But speculators cast their aspersions anyway.

- **Speculators wrongly claim** that Korlym is unreasonably costly.

  In fact, we charge for Korlym no more than what we must for a drug for a rare disorder that we developed over many years, at great expense and risk. Even then, Korlym is less expensive than many other orphan drugs. More importantly, we never deny Korlym for financial reasons. And we direct our profits first to the development of our next-generation medications, which we hope will provide treatments for serious oncologic, metabolic and psychiatric disorders. http://www.corcept.com

Detailed Discussion

Background. Corcept was founded in 1998 by Stanford Medical School professors who believed that modulating the effects of the stress hormone cortisol might provide a treatment for a wide variety of serious disorders. At that time, the only drug known to bind to the cortisol receptor was mifepristone, which had been approved in the United States for the termination of pregnancy.

Proving that mifepristone (and cortisol modulation more generally) could be an effective therapy was a long, expensive and challenging task. We began in 1998 by studying mifepristone in the treatment of psychotic major depression, a deadly psychiatric illness. Although our Phase 2 trials provided promising results, our three Phase 3 trials failed to meet their primary endpoints. In 2014, we discontinued the program. All of the results of these studies have been published in peer-reviewed journals.[4,5,6,7,8]

Our accumulated deficit at that point was more than $300 million, mostly due to spending on research and development.

Fortunately, by the time our psychotic depression programs ended, another of our development programs had succeeded. In 2012, the FDA had approved mifepristone (our product, Korlym®) for the treatment of a rare, deadly disease known as Cushing's syndrome. We had begun the pre-clinical and clinical research necessary to support Korlym's approval for this use in 2008.

What is Cushing's syndrome? Cushing's syndrome is caused by a tumor that either produces excess cortisol or causes the body to produce excess cortisol. Because there are receptors for cortisol in nearly every tissue type, excess cortisol activity makes patients sick in many ways. Symptoms include diabetes, high blood pressure, obesity, fat around the neck, thinning arms and legs, weak muscles and severe fatigue. Irritability, anxiety, cognitive disturbances and depression are common.

Cushing's syndrome is deadly. Untreated patients have an average lifespan of 4-5 years.

Why did the FDA approve Korlym? The FDA approved Korlym because our pivotal trial in patients with Cushing's syndrome (known as "SEISMIC") had demonstrated that Korlym was safe and effective for its approved use. You can read Korlym's FDA-approved label at www.Korlym.com.

4 C. DeBattista et al., Biol Psychiatry, 2006
5 C.M. Blasey et al., Contemporary Clinical Trials, 2009
6 C.M. Blasey et al., Journal of Clinical Psychopharmacology, 2011
7 C.M. Blasey et al., Current Psychiatry Reviews, 2013
8 T.S. Block et al., Biol Psychiatry, 2018

SEISMIC had no control arm (meaning every patient received Korlym) because giving patients placebo would have been unethical. Patients with Cushing's syndrome require treatment or they may die. The FDA prospectively agreed that SEISMIC – if it produced positive results – would be sufficient for approval.

SEISMIC's results were clearly positive. Hyperglycemia, one of Cushing's syndrome's most common and pernicious symptoms, improved significantly. Eighty-eight percent of patients experienced significant improvement (as adjudicated by a blinded group of leading academic endocrinologists) across a broad range of symptoms.

In short, Korlym worked exceptionally well. As a consequence, the FDA approved Korlym without delay and without requiring input from an "advisory committee" of third-party experts.

Have you published the results of SEISMIC? Yes. We publish all our clinical results – good, bad or equivocal – in peer-reviewed scientific journals.

- Results of our SEISMIC trial are available at (*Fleseriu et al, J Clin Endocrinol Metab, 2012),* with additional data and analysis published at *(Fein, et al, BMC Endocrine Disorders, 2015, Yuen, et al, Endocr Pract, 2015, Katznelson, et al, Clinical Endocrinology 2014,* and *Fleseriu, et al, J Clin Endocrinol Metab, October 2014).*
- Results from the development of our proprietary, selective cortisol modulator, relacorilant (our candidate to succeed Korlym in Cushing's syndrome and as a treatment for variety of solid tumors), are at *(Hunt, et al, Clin Pharmacol Drug Dev, 2017,* and *Hunt, et al, J Med Chem, 2017).*

Additional information about our development programs is available at the "Research and Pipeline" tab of our website, www.corcept.com.

How many people have Cushing's syndrome? Approximately 20,000 people in the United States have been diagnosed with Cushing's syndrome, and approximately 3,000 more are diagnosed each year.[9] Only about half are cured by surgery.[10] The remaining 10,000 require medical therapy (such as Korlym). Recent peer-reviewed research suggests that the number of Cushing's syndrome patients not cured by surgery is several times higher than 10,000.[11]

Where are patients with Cushing's syndrome treated? Practically every endocrinology practice in the United States has some patients with Cushing's syndrome. Korlym prescriptions are written wherever physicians actively screen patients for the disease. It is the interest and skill of the doctor, not local population density or any other factor that determine where Korlym prescriptions originate. Physician education is a critical component of this process.

9 Guaraldi F, Salvatori R, J Am Board Fam Med, 2012
10 Geer EB, et al., Endocr Pract. 2017
11 Broder, et al., Pituitary, 2015

Patients with Cushing's syndrome often go to major medical centers after they are diagnosed, usually to attempt a surgical cure. If surgery fails (as it does about half the time), these patients return home, where they are often treated by community endocrinologists. Most Korlym prescriptions are not written by doctors practicing at big medical centers or teaching hospitals. Physicians in suburban and rural areas with an interest in screening patients for Cushing's syndrome and expertise in treating it draw patients from many miles away. That is why some physicians in less populous areas treat significant numbers of patients.

Do you promote for diagnoses other than Cushing's syndrome? No. We only promote Korlym for its approved use. Literally, ninety-nine percent (99%) of the Korlym we sell goes to patients whose diagnosis matches Korlym's FDA-approved label. Our vigilance is matched by insurance companies, which in most cases insist on comprehensively reviewing a patient's medical records to confirm the diagnosis of Cushing's syndrome before paying for the drug.

How many physicians prescribe Korlym? Since Korlym's approval in 2012, approximately 1,300 physicians have prescribed Korlym. In the fourth quarter of 2018, more than 580 physicians were treating patients with the medication.

Do you sell Korlym to the Veterans Administration healthcare system? Very little. Korlym shipments to all hospitals, including those run by the VA, are made by our specialty distributor. These shipments accounted for less than one percent of our revenue in 2018, with VA sales being just a portion of that – less than $2.5 million. We report our specialty distributor sales in the quarterly and audited annual financial reports we file with the SEC, which you can find at the SEC'S website www.sec.gov and our website www.corcept.com.

How do you promote Korlym? We employ highly-trained clinical sales specialists to call on physicians across the country. Like other ethical pharmaceutical companies, we also host meetings where a physician who understands Cushing's syndrome and Korlym leads local physicians in a discussion of the disease – its prevalence and how to screen for it, its serious consequences and treatment options.

The "data" speculators cite in casting their slurs actually refutes their case. For example, they report Medicare data so as to create the false impression that each claim represents a new patient, which it does not. Over time, a single patient can make many Medicare claims. The effect of this misrepresentation is to grossly inflate the apparent prescribing activity of some of the physicians with whom we work.

Our educational and promotional efforts adhere to the highest ethical standards. When selecting speakers, the number of Korlym prescriptions he or she has written (or is expected to write) is irrelevant. Speakers are paid fair market rates for their time. The training our speakers receive and the materials they present cover Cushing's syndrome and the FDA-approved use of Korlym – nothing else. We audit these programs regularly to ensure they are fully-compliant with both the letter and the spirit of the law.

Do you pay doctors to prescribe Korlym? Absolutely not. One of the most disturbing rumors spread by speculators is that we use consulting payments to induce physicians to prescribe Korlym. Corcept was founded to help patients, in the expectation that commercial success would follow. We have never deviated from our foundational principle: Patients first. The physicians we work with share our values. They would never put their interests ahead of their patients' health.

Is Korlym dangerous? No. Like any medication, Korlym should be administered in accordance with its FDA-approved label, which describes anticipated side effects. These side effects are also discussed in the scientific literature and, of course, in Korlym's label.[12,13]

Speculators have tried to obscure this truth by misrepresenting information from the FDA's FAERS database of adverse events. Unfortunately, as the FDA's website makes clear, FAERS includes duplicate entries and, crucially, does not identify the causes of adverse events. This is problematic:

- We speak with patients frequently to assist them with the challenges they face living with Cushing's syndrome. This regular contact is highly unusual (and costly). We do it because patients and their doctors request the help and benefit from it. In the course of these conversations, patients discuss the maladies they suffer, which are many, both great and small. We report all of these maladies as adverse events, even though they are rarely caused by Korlym and in many cases have also been reported by the patient' physician.
- Cushing's syndrome patients are very ill. They take many medications and suffer many adverse events, including death, that are unrelated to Korlym. If a patient passes away from adrenal cancer or heart disease or old age, for example, or dies months after taking their last Korlym tablet, their death is reported as associated with Korlym, even though Korlym was not the cause. Because FAERS is silent as to causality, speculators deceptively insinuate that Korlym is to blame.

To the extent the speculators' disinformation campaign succeeds in scaring patients and physicians away from a drug that might help them, the speculators are putting patients' health at risk.

Is Korlym expensive? It is, although less so than many other drugs. Unfortunately, there is no other way to justify investing hundreds of millions of dollars to develop a treatment for such a rare disease. Both public and private insurers understand this, which is why they cover the cost of Korlym.

That being said, we make sure no patient is denied Korlym for financial reasons. We provide the drug at no charge to some patients and provide financial assistance to others. Still, other patients receive help from independent charities we are proud to support. (These organizations pay for all aspects of Cushing's syndrome care, which often does not include Korlym.)

Finally, when determining the optimal use of any profits, our first priority is the development of better therapies for serious disorders – an approach that is aligned with the interests of both patients and our shareholders. Our most advanced compound is relacorilant, which we expect will make Korlym obsolete. Relacorilant's Phase 2 data suggest that it may offer the benefits of Korlym without some of Korlym's most troublesome side effects, including termination of pregnancy, endometrial thickening, vaginal bleeding, and low potassium. We hope to confirm these results in a larger, Phase 3 clinical trial, so that relacorilant can ultimately be approved by the FDA.

12 Yuen, et al., Endocr Pract, 2015

13 http://www.corcept.com/wp-content/uploads/2017/12/KorlymPrescribingInformation.pdf

We have also discovered a large portfolio of selective cortisol modulators that may provide lifesaving benefits to patients in a wide variety of serious disorders, including cancer, liver disease and the weight gain caused by antipsychotic medications.

Conclusion

Korlym has been of great benefit to many patients and will in the future benefit many more. That is why it is a commercial success – a success we have achieved, along with the physicians with whom we work, by adhering to the highest ethical standards and always seeking to put the interests of patients first.