UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2021

or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to

Commission File Number: 000-50679

CORCEPT THERAPEUTICS INCORPORATED

(Exact Name of Corporation as Specified in Its Charter)

Delaware	**77-0487658**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

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

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

Securities registered pursuant to Section 12 (b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.001 par value	CORT	The Nasdaq Stock Market

Securities registered pursuant to Section 12 (g) of the Act:

None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Acts. Yes ☒ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports); and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.:

Large accelerated filer	☒	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
		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. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The aggregate market value of voting and non-voting common equity held by non-affiliates of the Registrant as of June 30, 2021 was $2,122,097,933, based on the closing price of $22.00 for shares of the Registrant's common stock as reported on the Nasdaq Stock Market on June 30, 2021. Shares of common stock beneficially owned by each executive officer, director and holder of more than 10% of our common stock have been excluded, in that such persons may be deemed to be affiliates. This calculation does not reflect a determination that certain persons are affiliates of the Registrant for any other purpose.

On February 8, 2022 there were 105,962,389 shares of common stock outstanding at a par value of $0.001 per share.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's definitive proxy statement for its 2022 Annual Meeting of Stockholders are incorporated by reference in Items 10, 11, 12, 13 and 14 of Part III.

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Form 10-K

For the year ended December 31, 2021

PART I

This Annual Report on Form 10-K ("Form 10-K") contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended ("Exchange Act"), and Section 27A of the Securities Act of 1933, as amended ("Securities Act"). All statements contained in this Form 10-K, other than statements of historical fact, are forward-looking statements. When used in this report, the words "believe," "anticipate," "intend," "plan," "estimate," "expect," "may," "will," "should, "would," "could," "seek" and similar expressions are forward-looking statements based on management's current expectations. The absence of these words does not mean that a statement is not forward-looking. Forward-looking statements include, but are not limited to, statements about:

- our ability to manufacture, market and sell Korlym® (mifepristone) 300 mg Tablets ("Korlym");
- our estimates regarding enrollment in and the completion dates of our clinical trials and the anticipated results of these trials;
- the progress and timing of our research and development programs and the regulatory activities associated with them;
- our ability to realize the benefits of orphan drug designation for Korlym and the impact of possible future competition for Korlym or our product candidates;
- our estimates for future performance, including revenue and profits;
- the timing of regulatory submissions seeking approval of product candidates and the commercialization of any product candidates that are approved;
- our ability to manufacture, market, commercialize and achieve market acceptance for our product candidates;
- uncertainties associated with obtaining and enforcing patents;
- estimates regarding our future revenue, income and capital requirements; and
- the impact of the COVID-19 pandemic and our response to it.

Forward-looking statements involve risks and uncertainties and are not guarantees of future performance. Actual events or results may differ materially for many reasons. For a more detailed discussion of the risks and uncertainties that may affect the accuracy of our forward-looking statements, see the "Risk Factors," "Overview" and "Liquidity and Capital Resources" sections of the "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of this Form 10-K. You should also carefully consider the other reports and documents we file with the Securities and Exchange Commission ("SEC").

Forward-looking statements in this Form 10-K reflect our view only as of the date of this report. Except as required by law, we undertake no obligation to update forward-looking statements.

Unless stated otherwise, all references in this document to "we," "us," "our," "Corcept," the "Company," "our company" and similar words and phrases refer to Corcept Therapeutics Incorporated.

ITEM 1. BUSINESS

Overview

We are a commercial-stage company engaged in the discovery and development of drugs that treat severe metabolic, oncologic and neuropsychiatric disorders by modulating the effects of the hormone cortisol.

Cortisol plays a significant role in the body's response to stress and is essential for survival. Cortisol influences metabolism and the immune system and contributes to emotional stability. Cortisol levels follow a diurnal rhythm that is essential to health, peaking upon awakening and decreasing during the day. Insufficient cortisol activity may lead to dehydration, hypotension, shock, fatigue and hypoglycemia. Excessive cortisol activity, known as hypercortisolism, may lead to a suppressed immune response, impaired glucose tolerance, diabetes, obesity, fatty liver disease, depressed mood, psychosis, wasting of the arms and legs, edema, fatigue, hypertension and other problems.

Pre-clinical and clinical data suggest that cortisol reduces a patient's immune response to oncogenesis, shields certain cancer cells from the apoptotic effects of chemotherapy and facilitates the growth of others. Pre-clinical and clinical data also indicate that modulating cortisol activity may improve outcomes in patients suffering from weight gain caused by antipsychotic

medications (referred to as antipsychotic induced weight gain, or "AIWG"), in patients with fatty liver disease and non-alcoholic steatohepatitis ("NASH"), which are precursors of liver fibrosis and cirrhosis. Pre-clinical data also suggests that modulating cortisol activity may lead to treatments for patients with amyotrophic lateral sclerosis ("ALS").

Since 2012, we have marketed Korlym (mifepristone) in the United States for the treatment of patients with Cushing's syndrome. The challenge in treating a patient with Cushing's syndrome is modulating cortisol's effects without either suppressing them below normal levels or disrupting cortisol's normal diurnal rhythm. Simply reducing or destroying the ability of the body to make cortisol can cause serious harm. Cortisol activity can be modulated effectively by a drug that competes with cortisol as it attempts to bind to the glucocorticoid receptor ("GR").

Because Korlym's active ingredient, mifepristone, reduces the binding of excess cortisol to GR, it can modulate the effects of abnormal levels and release patterns of cortisol without compromising cortisol's healthy functions and rhythms. However, mifepristone also binds to the progesterone receptor ("PR"), thereby terminating pregnancy and causing other adverse effects, including endometrial thickening and vaginal bleeding, a debilitating condition suffered by a significant portion of women who take Korlym.

We have discovered more than 1,000 proprietary cortisol modulators that bind to GR but have no affinity for PR and so do not cause Korlym's PR-related side effects. These novel molecules are "selective" cortisol modulators: they share Korlym's affinity for GR, but, unlike Korlym, do not bind to PR and therefore do not cause effects arising from antagonism of progesterone activity, such as termination of pregnancy, endometrial thickening and vaginal bleeding. The composition of our selective cortisol modulators and their methods of use in a wide range of indications are covered by U.S. and foreign patents.

Our lead compounds have entered the clinic as potential treatments for a variety of serious disorders – Cushing's syndrome, solid tumors (i.e., advanced, high-grade serous ovarian cancer, castration-resistant prostate cancer ("CRPC") and adrenocortical cancer with cortisol excess), AIWG, and NASH.

COVID-19 Pandemic

Much of the world is subject to varying degrees of pandemic-related public health restrictions, including California, where we are headquartered, and the places where we sell Korlym and where we conduct clinical trials. Most of our third-party manufacturers, distributors (including the specialty pharmacy that dispenses Korlym), information technology service providers, law and accounting firms, clinical research organizations and others are also subject to pandemic-related restrictions.

These restrictions, as well as protective measures voluntarily undertaken by patients, physicians, hospitals and medical clinics, have reduced our revenue and made it difficult to grow our Korlym business. Many physicians have reduced the frequency of patient office visits and have barred visits by third parties, including our clinical specialists and medical science liaisons. Many patients have postponed visits to their physicians or the clinical laboratories or imaging centers that are essential for optimal care. These restrictions have made it more difficult for physicians to identify patients who may benefit from Korlym, begin their treatment, titrate to an optimum Korlym dose and maintain their patients' regimens.

The pandemic's impact on the pace of our clinical development programs has been variable. Our trials of indications not considered immediately life-threatening, such as Cushing's syndrome, CRPC and AIWG, have experienced slower enrollment. In addition, some clinical sites have stopped enrolling new patients or have reduced the frequency with which physicians see study participants. Some sites have suspended or halted the initiation of new clinical trials. Our trials in patients with immediately life-threatening diseases, such as advanced ovarian cancer, did not encounter delays.

We expect that pandemic-related impediments to our business will continue so long as there are COVID-19 public health restrictions and risk-reducing behavior by physicians and patients.

Please see the risk factor under Item 1A of this Annual Report, *"The COVID-19 pandemic has adversely affected and is continuing to adversely affect our business. Other public health emergencies, natural disasters, terrorism or other catastrophes could disrupt our activities and render our own or our vendors' facilities and equipment inoperable or inaccessible and require us to curtail or cease operations."*

Cushing's Syndrome

Background. Cushing's syndrome is the clinical manifestation of hypercortisolism. An estimated 10 to 15 of every one million people are diagnosed with Cushing's syndrome each year, resulting in approximately 3,000 new patients per year and a patient population in the United States of about 20,000, approximately half of whom are cured by surgery. Cushing's syndrome most often affects adults between the ages of 20 and 50.

Most people with Cushing's syndrome have one or more of the following symptoms: 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. Cushing's syndrome can affect every organ system in the body and can be lethal if not treated. The preferred treatment is surgery, which, if successful, can cure the disease. In approximately half of patients, surgery is not successful because the tumor cannot be located or removed completely. Depending on the type of tumor, surgery can result in a range of complications.

Korlym. We sell Korlym in the United States, using experienced sales representatives to call on physicians caring for patients with endogenous Cushing's syndrome (hypercortisolism). Because many people who suffer from Cushing's syndrome are undiagnosed or inadequately treated, we have developed and continue to refine and expand programs to educate physicians and patients about screening for hypercortisolism and the role Korlym can play in treating the disorder. We also have a field-based force of medical science liaisons.

We use one specialty pharmacy and one specialty distributor to distribute Korlym and provide logistical support to physicians and patients. Our policy is that no patient with Cushing's syndrome will be denied access to Korlym for financial reasons. To help us achieve that goal, we fund our own patient support programs and donate money to independent charitable foundations that help patients pay for all aspects of their Cushing's syndrome care, whether or not that care includes taking Korlym.

Relacorilant. We are conducting two Phase 3 trials (named GRACE and GRADIENT) of our proprietary, selective cortisol modulator, relacorilant, as a treatment for patients with Cushing's syndrome. Relacorilant was well-tolerated in its Phase 1 and Phase 2 trials. Patients in the Phase 2 trial exhibited meaningful improvements in glucose control, hypertension, weight loss, liver function, coagulopathy, cognition, mood, insulin resistance and quality of life measures. Relacorilant shares Korlym's affinity for GR, but, unlike Korlym, has no affinity for PR and so is not the "abortion pill" and does not cause the effects associated with PR affinity, including endometrial thickening and vaginal bleeding. Relacorilant also does not appear to cause hypokalemia (low potassium), a potentially serious adverse event that is a leading cause of patients stopping treatment with Korlym. Forty-four percent of patients in Korlym's pivotal trial experienced hypokalemia.

In the GRACE trial, each patient receives relacorilant for 22 weeks. Patients who exhibit pre-specified improvements in hypertension and/or glucose metabolism enter a 12-week, double-blind, "randomized withdrawal" phase, in which half of the patients continue receiving relacorilant and half receive placebo. The trial's primary endpoint is the rate and degree of relapse in patients receiving placebo measured against the rate and degree of relapse in those continuing relacorilant. GRACE has a planned enrollment of 130 patients with any etiology of endogenous Cushing's syndrome at sites in the United States, Canada, Europe and Israel. If successful, we expect GRACE to provide the basis for a new drug application ("NDA") for relacorilant as a treatment for patients with any etiology of endogenous Cushing's syndrome.

Our second Phase 3 trial of relacorilant, GRADIENT, is studying patients whose Cushing's syndrome is caused by a benign adrenal tumor. These patients often exhibit less severe symptoms or have a more gradual course of disease than patients with other etiologies of Cushing's syndrome, although their health outcomes are ultimately poor. Half of the patients in GRADIENT will receive relacorilant for 26 weeks and half will receive placebo. The trial's primary endpoints are improvements in glucose metabolism and hypertension. The planned enrollment for this study is 130 patients. Many of the clinical sites in GRACE are participating in GRADIENT.

The United States Food and Drug Association ("FDA") and the European Commission ("EC") have designated relacorilant as an orphan drug for the treatment of Cushing's syndrome. In the United States, relacorilant's orphan designation confers tax credits, reduced regulatory fees and, provided we obtain approval for the treatment of patients with Cushing's syndrome, seven years of exclusive marketing rights. Benefits of orphan drug designation by the EC are similar, but also include protocol assistance from the European Medicines Agency ("EMA"), access to the centralized marketing authorization procedure in the European Union ("EU") and, if we obtain approval, ten years of exclusive marketing rights in the EU for the treatment of patients with Cushing's syndrome.

In neither the United States nor the EU does orphan drug designation shorten the drug approval process, make approval more likely or prevent competitors from marketing other drugs for the treatment of Cushing's syndrome.

FKBP5 Gene Expression Assay. The tests used to diagnose patients with hypercortisolism and optimize their treatment are imprecise and often fail to identify patients with less severe manifestations of the disease. We have developed an assay to measure expression of the gene FKBP5, which is stimulated by cortisol activity, and have completed analytical validation pursuant to the Clinical Laboratory Improvement Amendments ("CLIA"). Clinical data indicate that FKBP5 levels are high in patients suffering from hypercortisolism (i.e., excess cortisol activity), but subside when they are successfully treated. We are testing this hypothesis in the GRACE and GRADIENT trials. We believe successful development of this assay will enable physicians to identify new patients with hypercortisolism more easily and to better treat those already in their care.

Oncology

There is substantial in vitro, in vivo and clinical evidence that cortisol's activity allows certain solid tumors to resist treatment. In some cancers, cortisol retards cellular apoptosis – the tumor-killing effect many treatments are meant to stimulate. In other cancers, cortisol activity promotes tumor growth. Cortisol also suppresses the body's immune response; activating – not suppressing – the immune system is beneficial in fighting certain cancers. Modulating cortisol's activity may help existing anti-cancer treatments achieve their intended effect. Many types of solid tumors express GR and are potential targets for cortisol modulation therapy, among them ovarian, adrenocortical and CRPC.

Relacorilant in Patients with Advanced Ovarian Cancer. In May 2021, we announced preliminary results from our 178-patient, controlled, multi-center, Phase 2 trial of relacorilant combined with nab-paclitaxel in patients with platinum resistant ovarian cancer. Study participants were randomized to one of three treatment arms: 60 women received 150 mg of relacorilant intermittently (the day before, the day of and the day after their weekly nab-paclitaxel infusion) and 58 women received a daily relacorilant dose of 100 mg per day, with titration to 150 mg per day permitted at the investigator's discretion, in addition to nab-paclitaxel. Sixty women received nab-paclitaxel alone. The trial's primary endpoint was progression-free survival ("PFS").

Patients in both relacorilant plus nab-paclitaxel treatment arms experienced longer PFS than did the patients who received nab-paclitaxel alone. Patients who received a higher dose of relacorilant intermittently exhibited a statistically significant improvement in median PFS (5.6 months versus 3.8 months, hazard ratio: 0.66; p-value: <0.05). Patients who received a lower dose of relacorilant daily exhibited a median PFS that was 1.5 months longer than did the patients who received nab-paclitaxel alone (5.3 months versus 3.8 months, hazard ratio: 0.83; p-value: not significant). Patients who received relacorilant intermittently also had a longer median duration of response (5.6 months versus 3.7 months, hazard ratio: 0.36; p-value: 0.006) compared to those who received nab-paclitaxel alone. While the overall survival ("OS") data were only 63% mature at the time of the database cut-off (March 2021), the women who received relacorilant intermittently exhibited a median OS of 12.9 months versus 10.4 months for those who received nab-paclitaxel alone (hazard ratio: 0.63; p-value: 0.12). We expect updated overall survival data from this trial in the first quarter of 2022. Safety and tolerability of relacorilant plus nab-paclitaxel were comparable to nab-paclitaxel monotherapy.

We plan to initiate a pivotal Phase 3 trial in the second quarter of 2022.

Relacorilant in Patients with Advanced Cancer with Cortisol Excess. We are also conducting an open-label, Phase 1b trial of relacorilant plus the PD-1 checkpoint inhibitor pembrolizumab in 20 patients with metastatic or unresectable adrenal cancer with cortisol excess. The trial is examining whether adding relacorilant to pembrolizumab therapy reduces cortisol-activated immune suppression sufficiently to help pembrolizumab achieve its intended tumor-killing effect, while relacorilant treats the Cushing's syndrome caused by excess cortisol activity.

Exicorilant and Relacorilant in Patients with CRPC. Androgen deprivation is the standard treatment for metastatic prostate cancer because androgens stimulate prostate tumor growth. Tumors often escape androgen deprivation therapy when cortisol's activity at GR supplants androgen's in stimulating tumor growth. Combining a cortisol modulator with an androgen modulator may block this escape route.

We are conducting a dose-finding trial of our proprietary, selective cortisol modulator exicorilant in combination with enzalutamide in patients with metastatic CRPC. Investigators at the University of Chicago are conducting a dose-finding trial of relacorilant combined with enzalutamide in the same patient population.

We hold U.S. and international patents covering relacorilant's composition of matter, as well as U.S. patents covering its use to treat patients with ovarian and pancreatic cancer. We also own or have exclusively licensed U.S. and European patents covering the use of GR modulators, including relacorilant, to treat a variety of disorders, including CRPC and other solid tumors. Relacorilant has been designated an orphan drug in both the United States and the EU for the treatment of pancreatic cancer.

Metabolic Disorders

AIWG. In the United States, six million people take antipsychotic medications such as olanzapine and risperidone to treat illnesses such as schizophrenia, bipolar disorder and depression. While these drugs are very effective, they often cause rapid and sustained weight gain, other metabolic disturbances and, ultimately, cardiovascular disease. Patients taking these medications experience a 10 to 25-year reduction in life expectancy, due in large part to increased cardiovascular events, such as heart attacks and strokes. We are studying our selective cortisol modulator miricorilant as a potential treatment for AIWG.

In 2020, we completed a double-blind, placebo-controlled Phase 1b trial, in which 96 healthy subjects received daily doses of the antipsychotic medication olanzapine (10 mg) and either miricorilant (600 mg or 900 mg) or placebo for 14 days.

Study participants who received miricorilant gained less weight than subjects receiving placebo. In addition, markers of liver damage that rise temporarily at the start of olanzapine therapy increased less sharply in subjects receiving miricorilant. The results of this study were published in the *Journal of Clinical Psychopharmacology* (Hunt et al., 2021) and are consistent with the findings of similar studies we conducted in healthy volunteers using mifepristone (published in *Advances in Therapy and Obesity* in 2009 and 2010).

Based on these positive results in healthy subjects and compelling pre-clinical data, we are conducting two double-blind, placebo-controlled, Phase 2 trials of miricorilant – GRATITUDE and GRATITUDE II.

GRATITUDE is evaluating whether a daily dose of miricorilant (600 mg) can reverse recent AIWG. Study participants receive their established antipsychotic medication plus either miricorilant or placebo for 12 weeks. GRATITUDE has planned enrollment of 100 patients with schizophrenia or bipolar disorder and is being conducted at 30 sites in the United States.

GRATITUDE II is evaluating whether miricorilant can reverse long-standing AIWG. Study participants receive their established antipsychotic medication plus either miricorilant (600 mg or 900 mg daily) or placebo for 26 weeks. GRATITUDE II has planned enrollment of 150 patients with schizophrenia and is being conducted at 35 centers in the United States.

The primary endpoint in both the GRATITUDE and GRATITUDE II trials is the change in body weight from baseline, relative to placebo. Other metabolic variables are also being examined.

Liver Disease. We are also studying miricorilant as a potential treatment for NASH. In April 2021, we suspended our Phase 2a trial after observing elevated liver enzymes in four of the five patients who received miricorilant, which resolved after miricorilant was withdrawn. The patients with elevated liver enzymes also exhibited large, rapid reductions in liver fat. We have initiated a Phase 1b dose-finding trial in patients with presumed NASH to see if an alternative dosing regimen can capture this benefit without causing excessive liver irritation.

ALS

Our selective cortisol modulator dazucorilant (formerly, "CORT113176") has shown promise in animal models of ALS and has completed its Phase 1 trial. In 2022, we plan to advance it to Phase 2 as a potential treatment for ALS.

Development of our Other Selective Cortisol Modulators

Our portfolio of proprietary selective cortisol modulators consists of four structurally distinct series totaling more than 1,000 compounds, including relacorilant, exicorilant, miricorilant and dazucorilant. These compounds potently bind to GR but not the progesterone, estrogen or androgen receptors. We hold U.S. and foreign patents covering these compounds and their methods of use in a wide range of indications. We have applied, and will continue to apply, for patents covering the composition and method of use of our products and product candidates. See "Business – Intellectual Property."

We continue to identify selective cortisol modulators and plan to advance the most promising of them towards the clinic.

Studies by Independent Investigators

For many years we have advanced our understanding of cortisol modulation by supporting the work of independent academic investigators. These researchers have studied the potential utility of mifepristone and our proprietary selective cortisol modulators in a wide range of disorders, including central serous retinopathy, post-traumatic stress disorder, anxiety, alcoholism, cocaine addiction, Alzheimer's disease, ALS, Cushing's syndrome, metabolic syndrome, atherosclerosis, fatty liver disease, sarcoma, melanoma and solid tumors, including triple-negative breast, prostate, ovarian and non-small cell lung cancers.

Clinical Trial Agreements

We typically conduct our clinical trials with the assistance of clinical research organizations ("CROs"). ICON plc is helping us conduct our GRACE and GRADIENT trials. IQVIA Inc. is helping us conduct our Phase 2 trial of relacorilant to treat patients with metastatic ovarian cancer and our dose-finding trial of exicorilant to treat patients with CRPC. Medpace, Inc. is helping us conduct our GRATITUDE and GRATITUDE II trials. We may terminate our agreements with ICON and IQVIA on 60 days' written notice. Our agreement with Medpace may be terminated by us without cause at any time.

Research and Development Spending

We incurred $113.9 million, $114.8 million and $89.0 million of research and development expense in the years ended December 31, 2021, 2020 and 2019, respectively, which accounted for 47 percent, 51 percent and 46 percent, respectively, of our total operating expenses in those years.

Manufacturing Korlym

We rely on contract manufacturers to produce Korlym and our product candidates. In March 2014, we entered into an agreement with Produits Chimiques Auxiliaires et de Synthese SA ("PCAS") to produce mifepristone, the active pharmaceutical ingredient ("API") in Korlym. In 2018, we amended this agreement and extended its term to December 31, 2021, with two one-year renewals that will occur automatically unless either party gives 12 months advance written notice of its intent not to renew. The amendment also provides for exclusivity between PCAS and Corcept, unless PCAS is unable to meet our requirements, in which case we may purchase mifepristone from another supplier. At December 31, 2021, the agreement was extended through December 31, 2022.

We have agreements with two third-party manufacturers to produce and bottle Korlym tablets.

Competition for Korlym

Korlym competes with established treatments, including surgery, radiation and other medications, including "off-label" uses of drugs such as ketoconazole, an anti-fungal medication. Korlym also competes with Signifor® (pasireotide) Injection and Isturisa® (osilodrostat). Both of these drugs are approved by the FDA for the treatment of adult patients with Cushing's disease who are not candidates for pituitary surgery or for whom surgery did not work, and both are sold by the Italian pharmaceutical company Recordati S.p.A ("Recordati"). Cushing's disease is a subset of Cushing's syndrome. In the EU, osilodrostat is also approved as a treatment for Cushing's syndrome.

Korlym may also experience competition from new compounds. On December 31, 2021, Xeris Biopharma Holdings, Inc. received approval to market in the United States levoketoconazole, a chiral form of the commonly-prescribed cortisol synthesis inhibitor ketoconazole, as a treatment for patients with Cushing's syndrome. Xeris is also seeking approval in the EU.

The orphan drug marketing exclusivity period for Korlym ended in February 2019, which means a competitor that receives FDA approval for a generic equivalent of Korlym may market its drug to patients with Cushing's syndrome, provided doing so would not infringe any of our patents. We have sued Teva Pharmaceuticals USA, Inc. ("Teva") and Hikma Pharmaceuticals USA Inc. ("Hikma") in federal district court to prevent them from marketing generic versions of Korlym in violation of our patents. In addition, Teva challenged the validity of one of our patents in a post grant review ("PGR") proceeding before the Patent Trial and Appeal Board ("PTAB"). In November 2020, the PTAB decided all of Teva's claims in this PGR in Corcept's favor. On March 12, 2021, Teva appealed its loss to the Federal Circuit Court of Appeals. On December 7, 2021, the Federal Circuit Court of Appeals affirmed the PTAB's decision, upholding the validity of all claims in this PGR in Corcept's favor. See "Part I, Item 3, Legal Proceedings."

Intellectual Property

Overview. Patents and other proprietary rights are important to our business. We own U.S. composition of matter patents related to our next-generation cortisol modulators. Foreign counterparts of some of these patents have issued in Europe. The expiration dates of these patents and their foreign counterparts range from 2025 to 2034.

We also own U.S. and foreign patents directed to the use of our selective cortisol modulators in the treatment of a variety of serious disorders, including Cushing's syndrome, various cancers, fatty liver disease, antipsychotic-induced weight gain, and other disorders.

We continue to file patent applications in the United States and abroad. There can be no guarantee that any of these applications will result in the issuance of patents, that any issued patent will include claims of the breadth we are seeking or that competitors or other third parties will not successfully challenge or circumvent our patents if they are issued.

We believe our patents are valid and that the production and use of our patented compounds and methods do not infringe the proprietary rights of others. Accordingly, we believe we are not obligated to pay royalties relating to the use of intellectual property to any third parties except the University of Chicago, from which we have licensed certain patents, as described below.

Cushing's Syndrome. The composition of matter patent covering Korlym's active ingredient, mifepristone, has expired. We own U.S. method of use patents directed to the use of Korlym in the treatment of patients with Cushing's syndrome, with expiration dates ranging from 2028 to 2038. Furthermore, we own U.S. compound and method of use patents using our selective cortisol modulators directed to the treatment of patients with Cushing's syndrome, with expiration dates ranging from 2033 to 2040.

Oncology. We own U.S. patents covering methods of treating cancer using our selective cortisol modulators with expiration dates ranging from 2023 to 2039. In addition, we have exclusively licensed from the University of Chicago U.S.

patents for (a) the use of cortisol modulators in the treatment of triple-negative breast cancer, and (b) the use of cortisol modulators to treat CRPC. We are required to pay the University of Chicago customary milestone fees and royalties on revenue from products commercialized under the issued patents or patents that may issue pursuant to the pending applications. Our license will end upon expiration of the licensed patents in 2031 and 2033 or upon notification by us to the University of Chicago. See "Business - License Agreements."

Other Indications. In addition to the United States and foreign patents we own or have licensed relating to Cushing's syndrome and various cancers, we also own U.S. and foreign patents for the use of cortisol modulators to treat AIWG, fatty liver disease, mild cognitive impairment, delirium, catatonia, psychosis induced by interferon-alpha therapy, migraine headaches, gastroesophageal reflux disease, neurological damage in premature infants and in the treatment of diseases using combination steroid and GR antagonist therapy. We also own patents covering the prevention and treatment of stress disorders, improvement of therapeutic response to electroconvulsive therapy and inhibition of cognitive deterioration in adults with Down's Syndrome. The expiration dates of these patents and their foreign counterparts range from 2022 to 2039.

Government Regulation

Prescription pharmaceutical products are subject to extensive pre- and post-approval regulation governing the research, development, testing, manufacturing, safety, efficacy, labeling, storage, record keeping, advertising and promotion of the products under the Federal Food, Drug and Cosmetic Act. All of our product candidates require regulatory approval by government agencies prior to commercialization and are subject to continued regulatory oversight thereafter. Before a new drug may be marketed in the United States the FDA generally requires completion of preclinical laboratory and animal testing, performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the proposed drug's intended use and approval by the FDA. Complying with these and other federal and state statutes and regulations involves significant time and expense.

Prior to beginning the first clinical trial with a product candidate in the United States, a sponsor must submit an investigational new drug application ("IND") to the FDA. An IND is a request for authorization from the FDA to administer an investigational new drug product to humans. The central focus of an IND submission is on the general investigational plan and the protocol(s) for clinical studies. The IND also includes results of animal and in vitro studies assessing the toxicology, pharmacokinetics, pharmacology, and pharmacodynamics characteristics of the drug, chemistry, manufacturing, and controls information, and any available human data or literature to support the use of the investigational drug. An IND must become effective before human clinical trials may begin.

Clinical trials involve the administration of the investigational drug to human subjects under the supervision of qualified investigators in accordance with Good Clinical Practice regulations, which include the requirement that all research subjects provide their informed consent for their participation in any clinical study. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. Typically, human clinical trials are conducted in three sequential phases that may overlap.

- Phase 1. The product candidate is administered to a small number of healthy subjects or patients with the target disease or condition to provide preliminary information as to its safety, tolerability and pharmacokinetics and sometimes to provide preliminary information as to its activity and/or efficacy.
- Phase 2. The product candidate is administered to a limited patient population with a specified disease or condition to evaluate its preliminary efficacy, optimal dosages and to identify possible adverse events and safety risks.
- Phase 3. The product candidate is administered to a larger group of patients with the target disease or condition to further evaluate dosage, establish its risk/benefit ratio and to provide an adequate basis for product approval.

The FDA and the institutional review boards associated with clinical trial sites closely monitor the progress of clinical trials conducted in the United States and may reevaluate, alter, suspend or terminate a trial at any time for various reasons, including a belief that the subjects are being exposed to unacceptable risks. The FDA may also require that additional trials be conducted to address and evaluate any potential safety risks.

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, drug developers will submit the results of preclinical studies, clinical trials, formulation studies and data supporting manufacturing to the FDA in the form of an NDA requesting approval to market the drug for one or more indications. The submission of an NDA requires payment of a substantial application user fee to the FDA, unless a waiver or exemption applies. Within 60 days following submission of the application, the FDA reviews an NDA submitted to determine if it is substantially complete before the FDA accepts it for filing. Once filed, the FDA reviews an NDA to determine, among other things, whether a product is safe and effective for its intended use and whether its manufacturing is sufficient to assure and preserve the drug's identity, strength, quality and purity. Under the Prescription Drug User Fee Act, the FDA has a goal of responding to NDAs within ten months of

the filing date for standard review, and six months for priority review, which the FDA may undertake, in its sole discretion, if a sponsor shows that its drug candidate is designed to treat a serious condition, and if approved, would provide a significant improvement in safety or effectiveness compared to marketed drugs. FDA approvals may not be granted on a timely basis or at all.

In addition, under the Orphan Drug Act, the FDA may grant orphan designation to a drug intended to treat a rare disease or condition, defined as a disease or condition with a patient population of fewer than 200,000 individuals in the United States, or a patient population greater than 200,000 individuals in the United States and when there is no reasonable expectation that the cost of developing and making available the drug in the United States will be recovered from sales in the United States for that drug. If a product that has orphan drug designation subsequently receives the first FDA approval for a particular active ingredient for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications, including a full NDA, to market the same drug for the same indication for seven years, except in limited circumstances. Orphan drug exclusivity does not prevent the FDA from approving a different drug for the same disease or condition, or the same drug for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the NDA application user fee.

If the FDA approves the marketing of a new drug, such approval will be granted for particular indications and may entail limitations on the indicated uses for which such product may be marketed. The FDA may withdraw its approval at any time if compliance with regulatory standards is not maintained. The holder of an approved NDA must submit periodic reports to the FDA, including reports of adverse patient experiences, which could cause the FDA to impose marketing restrictions through labeling changes or remove the drug from the market. The FDA may also require post-approval studies, referred to as "Phase 4 studies," to monitor or further explore the effect of approved products, and may limit marketing of the drug based on the results of such studies.

In addition, most changes to an approved drug, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. The FDA imposes complex regulations regarding the promotion and sale of pharmaceuticals, including standards for direct-to-consumer advertising, off-label promotion, and industry-sponsored scientific and educational activities. In addition, facilities involved in the manufacture of drugs must comply with FDA-mandated current Good Manufacturing Practices regulations ("cGMP") and are subject to periodic inspection by the FDA and other regulatory authorities. Failure to abide by these regulations can result in penalties including the issuance of a warning letter or untitled letter directing a company to correct deviations from FDA regulations, mandated modification of promotional materials and labeling, the issuance of corrective information, clinical holds, restrictions on manufacturing, product recalls, product detentions or seizures, refusal to approve pending applications or supplements and injunctions, in addition to state and federal civil and criminal penalties.

Marketing Approvals Outside the United States

If we choose to distribute our product candidates outside the United States, we will have to complete an approval process similar to the one imposed by the FDA. The approval procedure and the time required for approval vary from country to country and may involve additional preclinical and clinical trials. Foreign approvals may not be granted on a timely basis, or at all. Regulatory approval of pricing is required in most countries other than the United States, which pricing may be too low to generate an acceptable return. We are not seeking regulatory approval to market Korlym outside the United States.

Coverage and Reimbursement

Sales of our products will depend, in part, on the extent to which they will be covered by government health care programs and commercial insurance and managed healthcare organizations. Third-party payers are increasingly limiting coverage and reducing reimbursements for medical products and services, although this trend has not to-date had a material impact on the amount or timing of our revenues. In addition, the United States government, state legislatures and foreign governments have continued implementing cost-containment programs, including price controls, restrictions on coverage and reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures and adoption of more restrictive policies in jurisdictions with existing controls and measures could limit our revenue. Decreases in third-party reimbursement for our products or a decision by a third-party payer to not cover our products could reduce our sales and have a material adverse effect on our results of operations and financial condition.

Other Healthcare Laws

We are subject to healthcare regulation and enforcement by the federal government and the states where we conduct business. These laws include, without limitation, state and federal anti-kickback, fraud and abuse, false claims, and physicians' sunshine laws and regulations. Foreign governments have comparable regulations.

The federal Anti-Kickback Statute prohibits, among other things, any person from knowingly and willfully offering, soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs. The Anti-Kickback Statute is subject to evolving interpretations. In the past, the government has enforced the Anti-Kickback Statute to reach large settlements with healthcare companies based on sham consulting and other financial arrangements with physicians. Further, a person or entity does not need to have actual knowledge of these statutes or specific intent to violate them to have committed a violation. The majority of states also have anti-kickback laws which establish similar prohibitions and in some cases may apply to items or services reimbursed by any third-party payor, including commercial insurers.

Additionally, the civil False Claims Act prohibits knowingly presenting or causing the presentation of a false, fictitious or fraudulent claim for payment to the United States government. Actions under the False Claims Act may be brought directly by the government or as a *qui tam* action by a private individual in the name of the government. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act. Violations of the False Claims Act can result in very significant monetary penalties and treble damages. The federal government is using the False Claims Act, and the accompanying threat of significant liability, in its investigation and prosecution of pharmaceutical and biotechnology companies in connection with the promotion of products for unapproved uses and other sales and marketing practices. The government has obtained multi-billion dollar settlements under the False Claims Act in addition to individual criminal convictions under applicable criminal statutes. We expect that the government will continue to devote substantial resources to investigating healthcare providers' and manufacturers' compliance with applicable fraud and abuse laws.

The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, prohibits, among other things, knowingly and willfully executing a scheme to defraud any healthcare benefit program. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of these statutes or specific intent to violate them to have committed a violation.

In addition, there has been increased federal and state regulation of payments made to physicians and other healthcare providers. The Patent Protection and Affordable Care Act ("ACA"), among other things, imposes new reporting requirements on drug manufacturers for payments made by them to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician practitioners (physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists, anesthesiology assistants and certified nurse midwives) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Failure to submit required information may result in significant civil monetary penalties for any payments, transfers of value or ownership or investment interests that are not timely, accurately and completely reported in an annual submission. Drug manufacturers must report such payments to the government by the 90th day of each calendar year. Certain states also mandate implementation of commercial compliance programs, impose restrictions on drug manufacturer marketing practices and/or require the tracking and reporting of gifts, compensation and other remuneration to physicians.

State and foreign laws and regulations restrict business practices in the pharmaceutical industry and complicate our compliance efforts. For example, some states require companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the federal government's compliance guidance or otherwise restrict payments to healthcare providers and other potential referral sources. Some states require manufacturers to file reports relating to pricing and marketing information. Some state and local governments require the public registration of pharmaceutical sales representatives.

The shifting commercial compliance environment and the need to build and maintain robust and expandable systems to comply with different compliance and/or reporting requirements in multiple jurisdictions increase the possibility that a healthcare company may violate one or more of the requirements. If our operations are found to be in violation of any of such laws or any other governmental regulations that apply to us, we may be subject to penalties, including, without limitation, civil and criminal penalties, damages, fines, the curtailment or restructuring of our operations, exclusion from participation in federal and state healthcare programs and imprisonment, any of which could adversely affect our ability to operate our business and our financial results.

Data Privacy and Security

Numerous state, federal and foreign laws and regulations govern the collection of, disclosure of, use of, access to, transfer of, and confidentiality and security of health-related and other personal information, and could apply now or in the future to our operations or the operations of our partners. For example, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their implementing regulations, imposes requirements relating to the privacy, security and transmission of protected health information on HIPAA covered entities, which include

certain healthcare providers, health plans and healthcare clearinghouses, and their business associates who conduct certain activities for or on their behalf involving protected health information on their behalf. Entities that are found to be in violation of HIPAA as the result of a breach of unsecured protected health information, a complaint about privacy practices or an audit by the United States Department of Health and Human Services, or HHS, may be subject to significant civil, criminal and administrative fines and penalties and/or additional reporting and oversight obligations if required to enter into a resolution agreement and corrective action plan with HHS to settle allegations of HIPAA non-compliance. Further, entities that knowingly receive individually identifiable health information from a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA may be subject to criminal penalties.

Even when HIPAA does not apply, according to the Federal Trade Commission or the FTC, failing to take appropriate steps to keep consumers' personal information secure constitutes unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act. The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards.

Certain state and foreign laws also govern the privacy and security of health-related and other personal information in ways that differ significantly from one another and are not preempted by HIPAA. For example, California recently enacted legislation, the California Consumer Privacy Act, or CCPA, which went into effect January 1, 2020. The CCPA, among other things, creates certain data privacy obligations for covered companies and provides privacy rights to California residents, including the right to opt out of certain disclosures of their information. The CCPA also creates a private right of action with statutory damages for certain data breaches, thereby potentially increasing risks associated with a data breach. Although the law includes limited exceptions, including for health-related information, including clinical trial data, it may regulate or impact our processing of personal information depending on the context. Further, the California Privacy Rights Act ("CPRA"), recently passed in California. The CPRA will impose additional data protection obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It will also create a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. The majority of the provisions will go into effect on January 1, 2023, and additional compliance investment and potential business process changes may be required.

In Europe, the General Data Protection Regulation ("GDPR") went into effect in May 2018 and imposes stringent data protection requirements for controllers and processors of personal data of persons within the EU. The GDPR applies to any company established in the EU or the EEA as well as to those outside the EU or the EEA if they collect and use personal data in connection with the offering of goods or services to individuals in the EU or the monitoring of their behavior. In addition, the GDPR increases the scrutiny of transfers of personal data from clinical trial sites located in the EEA to the United States and other jurisdictions that the EC does not recognize as having "adequate" data protection laws; in July 2020, the Court of Justice of the European Union limited how organizations could lawfully transfer personal data from the EEA to the United States by invalidating the EU-US Privacy Shield and imposing further restrictions on use of the standard contractual clauses, which could increase our costs and our ability to efficiently process personal data from the EEA. Companies that must comply with the GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements and potential fines for noncompliance of up to €20 million or 4% of the annual global revenues of the noncompliant company, whichever is greater. In addition, from January 1, 2021, companies have had to comply with both the GDPR and the GDPR as incorporated into United Kingdom national law, the latter regime having the ability to separately fine up to the greater of £17.5 million or 4% of global turnover. The relationship between the United Kingdom and the European Union in relation to certain aspects of data protection law remains unclear, for example around how data can lawfully be transferred between each jurisdiction, which may expose us to further compliance risk. The EC has adopted an adequacy decision in favor of the United Kingdom, enabling data transfers from EU member states to the United Kingdom without additional safeguards. However, the UK adequacy decision will automatically expire in June 2025 unless the EC re-assesses and renews/extends that decision.

Employees

We are managed by experienced pharmaceutical executives and also enlist the expertise of independent advisors with extensive pharmaceutical experience. As of December 31, 2021, we had 238 employees. We consider our employee relations to be good. Our employees are not covered by a collective bargaining agreement.

We seek to hire, retain and motivate smart, ethical, hard-working employees, officers and directors. To achieve this goal, we offer a collegial work environment where creativity, collaboration and initiative are encouraged. We offer competitive salaries, performance bonuses and equity grants, as well as industry-leading health, retirement and childcare benefits. To align our people's goals with Corcept's goals, we offer annual performance-based cash bonuses and stock-based compensation.

About Corcept

We were incorporated in the State of Delaware on May 13, 1998. Our registered trademarks include Corcept® and Korlym®. Other service marks, trademarks and trade names referred to in this document are the property of their respective owners.

Available Information

We are subject to the information requirements of the Securities Exchange Act of 1934, as amended, and we therefore file periodic reports, proxy statements and other information with the SEC relating to our business, consolidated financial statements and other matters. The SEC maintains an Internet site, *www.sec.gov*, that contains reports, proxy statements and other information regarding issuers such as Corcept.

For more information about Corcept, including free access to our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports, visit our website at *www.corcept.com* or the SEC's website, *www.sec.gov*. The information found on or accessible through our website is not incorporated into, and does not form a part of, this Form 10-K.

ITEM 1A. RISK FACTORS

Investing in our common stock involves significant risks. Before investing, carefully consider the risks described below and the other information in this Annual Report on Form 10-K, including our consolidated financial statements and related notes. The risks and uncertainties described below are the ones we believe may materially affect us. Many of them have been or may become exacerbated by the COVID-19 pandemic. There may be others of which we are unaware that could materially harm our business or financial condition and cause the price of our stock to decline, in which case you could lose all or part of your investment.

Summary of Principal Risks

The following bullet points summarize the principal risks we face, each of which could adversely affect our business, operations, and financial results. For clarity of presentation, we have arranged these risks by the part of our business they most directly affect – (i) commercial operations, (ii) research and development, (iii) capital need and financial results, (iv) intellectual property and (v) our stock price. A sixth group of "general risks" lists risks that affect our business as a whole.

Risks Related to our Commercial Activities

- Failure to generate sufficient revenue from the sale of Korlym would harm our financial results and would likely cause our stock price to decline.
- The COVID-19 pandemic has adversely affected and is continuing to adversely affect our business. Other public health emergencies, natural disasters, terrorism or other catastrophes could disrupt our activities and render our own or our vendors' facilities and equipment inoperable or inaccessible and require us to curtail or cease operations.
- If new government regulations or changes to existing regulations make it difficult or impossible for us to obtain acceptable prices or adequate insurance coverage and reimbursement for Korlym, our results of operations and financial position would be adversely affected.
- If generic versions of Korlym are approved and successfully commercialized, our business, results of operations and financial position would be adversely affected.
- Other companies offer or are attempting to develop different medications to treat patients with Cushing's syndrome. The availability of competing treatments could limit our revenue from Korlym.
- We depend on vendors to manufacture Korlym's active ingredient, form it into tablets, package it and dispense it to patients. We also depend on vendors to manufacture the API and capsules or tablets for our product candidates. If our suppliers become unable or unwilling to perform these functions and we cannot transfer these activities to replacement vendors in a timely manner, our business will be harmed.

Risks Related to our Research and Development Activities

- Our efforts to discover, develop and commercialize our product candidates may not succeed. Clinical drug development is lengthy, expensive and often unsuccessful. Results of early studies and trials are often not predictive of later trial results. Failure can occur at any time.
- The COVID-19 pandemic has lengthened the time it takes to initiate and advance some of our clinical trials.
- Vendors perform many of the activities necessary to carry out our clinical trials, including drug product distribution, trial management and oversight and data collection and analysis. Failure of these vendors to perform their duties or meet expected timelines may prevent or delay approval of our product candidates.

- Our products and product candidates may cause undesirable side effects that halt their clinical development, prevent their regulatory approval, limit their commercial potential or cause us significant liability.

Risks Relating to our Intellectual Property

- To succeed, we must secure, maintain and effectively assert adequate patent protection for the composition and methods of use of our proprietary, selective cortisol modulators and for the use of Korlym to treat Cushing's syndrome.

Risks Related to our Stock

- The price of our common stock fluctuates widely and is likely to continue to do so. An investor's ability to sell shares at any particular time may be limited.
- Our stock price may decline if one or more of our clinical development efforts fail or if our financial performance does not meet the guidance we have provided to the public, estimates published by research analysts or other investor expectations.

General Risks

- We are subject to government regulation and other legal obligations relating to privacy and data protection. Compliance with these requirements is complex and costly. Failure to comply could materially harm our business.
- We may be unable to hire and retain the skilled, experienced people we need to grow our business.
- We may be unable to obtain or maintain regulatory approvals for our product or product candidates.
- We rely on information technology systems to conduct our business. A breakdown or breach of these systems or our failure to protect confidential information concerning our business, patients or employees could interrupt the operation of our business and subject us to liability.

Risk Factors - Discussion

The following section discusses the principal risks listed above, as well as other risks we believe to be material.

Risks Related to our Commercial Activities

Failure to generate sufficient revenue from the sale of Korlym would harm our financial results and would likely cause our stock price to decline.

Our ability to generate revenue and to fund our commercial operations and development programs is dependent on the sale of Korlym to treat patients with Cushing's syndrome. Physicians will prescribe Korlym only if they determine that it is preferable to other treatments, even if those treatments are not approved for Cushing's syndrome. Because Cushing's syndrome is rare, most physicians are inexperienced diagnosing or caring for patients with the illness and it can be hard to persuade them to identify appropriate patients and treat them with Korlym.

Many factors could limit our Korlym revenue, including:

- the preference of some physicians for competing treatments for Cushing's syndrome, including off-label treatments and generic versions of Korlym, should any such generic versions be introduced;

- natural disasters or other catastrophes, such as the COVID-19 pandemic, that reduce the ability or willingness of physicians to see patients or of patients to bear the risk of leaving their homes to seek medical care; and

- lack of availability of government or private insurance, the shift of a significant number of patients to Medicaid, which reimburses Korlym at a significantly lower price or the introduction of government price controls or other price-reducing regulations.

Failure to generate sufficient Korlym revenue could prevent us from fully funding our planned commercial and clinical activities and would likely cause our stock price to decline.

The COVID-19 pandemic has adversely affected and is continuing to adversely affect our business. Other public health emergencies, natural disasters, terrorism or other catastrophes could disrupt our activities and render our own or our vendors' facilities and equipment inoperable or inaccessible and require us to curtail or cease operations.

COVID-19, a serious and sometimes fatal illness, has spread to every country in the world and throughout the United States. Many countries, including most states of the United States, reacted by instituting quarantines, "lockdowns" and other

public health restrictions on leisure activities, work and travel. In California, where our headquarters are located, and in the states where our clinical specialists and medical science liaisons live and work, residents have been subject to significant public health restrictions. We have been managing our business with limited in-person activities, supplemented primarily by video conference, teleconference and email. Although pandemic-related restrictions have been eased or removed in certain geographies, including California, our business remains subject to pandemic-related controls, which may become more restrictive at any time. We rely on third-party manufacturers, distributors (including the specialty pharmacy that dispenses Korlym), information technology and software service providers, law and accounting firms, clinical research organizations and consultants who are subject to, or may become subject to, pandemic-related controls. If these third parties cannot perform the services we require in a timely way and we cannot successfully implement replacements or workarounds, our business, results of operations and financial condition could be harmed.

COVID-19 has made it difficult to grow our commercial business. Many physicians have reduced the frequency of patient office visits and barred office visits by third parties, including our clinical specialists and medical science liaisons. In addition, many patients have postponed visits to their physicians or testing at clinical laboratories or imaging centers. These precautions have made it harder for physicians to identify patients who may benefit from Korlym, begin their treatment, titrate to an optimum dose and maintain their patients' regimens.

We cannot predict the duration of these impacts on our business or how severe future impacts may be. If physicians do not prescribe Korlym to new patients or have difficulty increasing a patient's Korlym dose to its optimal level, or if patients already receiving Korlym discontinue treatment, our revenue will be unlikely to grow and may decline.

Other disasters could harm our business, operating results and financial condition. Our headquarters are in the San Francisco Bay Area, which experiences earthquakes. Our specialty pharmacy, tablet manufacturers and warehouses are in areas subject to hurricanes and tornadoes. Political considerations relating to mifepristone put us and our manufacturers at increased risk of protests and disruptive events. If a disaster were to occur, we might not be able to operate our business. Our insurance, if available at all, would likely be insufficient to cover losses resulting from disasters or other business interruptions.

If generic versions of Korlym are approved and successfully commercialized, our business, results of operations and financial position would be adversely affected.

The marketing exclusivity provided by Korlym's orphan drug designation expired in February 2019, which means other companies may now seek to introduce generic equivalents of Korlym for Korlym's approved indication, provided such parties receive FDA approval and can show that they would not infringe our applicable patents or that those patents are invalid or unenforceable. If our patents are successfully challenged and a generic version of Korlym becomes available, our sales of Korlym tablets and their price could decline rapidly and significantly, which would reduce our revenue and materially harm our results of operations and financial position. Competition from a generic version of Korlym may also cause our revenue to be materially less than the public guidance we have provided, which would likely cause the price of our common stock to decline.

Legal action to enforce or defend intellectual property rights is complex, costly and involves significant commitments of management time. There can be no assurance of a successful outcome. We have sued Teva and Hikma in Federal District Court with respect to their proposed generic versions of Korlym. In November 2020, the PTAB ruled against Teva in a challenge Teva had brought to one of our patents, a ruling which Federal Circuit Court of Appeals has affirmed. We had also sued Sun with respect to its proposed generic version of Korlym, although we settled that lawsuit in June 2021. The terms of our settlement with Sun are subject to customary review by the Federal Trade Commission and Department of Justice. Please see "Part I, Item 3, Legal Proceedings." Because Teva has received FDA approval, Teva may choose to begin marketing its generic product at any time, notwithstanding our ongoing litigation. We would seek a court order stopping such a course of action, but even if we were to prevail (i.e., Teva were to withdraw its product and pay us damages), the temporary availability of a generic version of Korlym might materially harm our results of operations and financial condition.

It is likely that other companies will seek FDA approval to market a generic version of Korlym. While we will vigorously protect our intellectual property, there can be no assurance our efforts will be successful.

Other companies offer or are attempting to develop different medications to treat patients with Cushing's syndrome. The availability of competing treatments could limit our revenue from Korlym.

Since 2012, a medication owned by the Italian pharmaceutical company Recordati-S.p.A., the somatostatin analogue Signifor® (pasireotide) Injection, has been marketed in both the United States and the EU for adult patients with Cushing's disease (a subset of Cushing's syndrome). On March 6, 2020, the FDA granted Recordati approval to market another cortisol synthesis inhibitor, Isturisa® (osilodrostat) tablets, to treat patients with Cushing's disease. Osilodrostat is approved in the EU for the treatment of patients with Cushing's syndrome.

On December 31, 2021, Xeris Biopharma Holdings, Inc. ("Xeris") received FDA approval to market the cortisol synthesis inhibitor Recorlev® (levoketoconazole) to treat patients with Cushing's syndrome in the United States. Levoketoconazole is an enantiomer of the generic anti-fungal medication, ketoconazole, that is prescribed off-label to treat patients with Cushing's syndrome.

Osilodrostat and levoketoconazole have been designated orphan drugs in both the EU and the United States.

New laws, government regulations, or changes to existing laws and regulations could make it difficult or impossible for us to obtain acceptable prices or adequate insurance coverage and reimbursement for Korlym, which would adversely affect our results of operations and financial position.

The commercial success of Korlym depends on the availability of acceptable pricing and adequate insurance coverage and reimbursement. Government payers, including Medicare, Medicaid and the Veterans Administration, as well as private insurers and health maintenance organizations, are increasingly attempting to contain healthcare costs by limiting reimbursement for medicines. If government or private payers cease to provide adequate and timely coverage, pricing and reimbursement for Korlym, physicians may not prescribe the medication and patients may not purchase it, even if it is prescribed, or the price we receive may be reduced, which would reduce our revenue.

In many foreign markets, drug prices and the profitability of prescription medications are subject to government control. In the United States, we expect that there will continue to be federal and state proposals for similar controls. Also, the trends toward managed health care in the United States and recent laws and legislation intended to increase the public visibility of drug prices and reduce the cost of government and private insurance programs could significantly influence the purchase of health care services and products and may result in lower prices for Korlym.

In the United States, there have been and continue to be legislative initiatives to contain healthcare costs. The Patient Protection and Affordable Care Act, or ACA, which was passed in 2010, substantially changed the way health care is financed by both governmental and private insurers. The ACA, among other things, expanded Medicaid program eligibility and access to commercial health insurance coverage, increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extended the rebate program to individuals enrolled in Medicaid managed care organizations, established annual fees and taxes on manufacturers of certain branded prescription drugs, and promoted a new Medicare Part D coverage gap discount program. The ACA also appropriated funding to comparative clinical effectiveness research, although it remains unclear how the research will affect Medicare coverage and reimbursement or how new information will influence other third-party payer policies.

Other legislative and regulatory changes have been adopted in the United States since the ACA was enacted. These changes included an aggregate reduction in Medicare payments to providers of 2 percent per fiscal year, which went into effect on April 1, 2013 and will remain in effect through 2030, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022, unless additional Congressional action is taken. In addition, the American Taxpayer Relief Act of 2012, further reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. In March 2021, the American Rescue Plan Act of 2021 was also signed into law, which, among other things, eliminated the statutory cap on drug manufacturers' Medicaid Drug Rebate Program rebate liability, effective January 1, 2024. Under current law enacted as part of the ACA, drug manufacturers' Medicaid Drug Rebate Program rebate liability is capped at 100% of the average manufacturer price for a covered outpatient drug. Moreover, the federal government and the individual states in the United States have become increasingly active in developing proposals, passing legislation and implementing regulations designed to control drug pricing, including price or patient reimbursement constraints, discounts, formulary flexibility, marketing cost disclosure and transparency measures.

There also continue to be federal and state initiatives to contain healthcare costs, in part informed by the current atmosphere of mounting criticism of prescription drug costs in the United States. We expect governmental oversight and scrutiny of pharmaceutical companies will continue to increase and there will continue to be proposals to change the healthcare system in ways that could harm our ability to sell Korlym profitably. We anticipate that the United States Congress, state legislatures, and regulators may implement healthcare policies intended to curb healthcare costs, such as federal and state controls on reimbursement for drugs (including under Medicare and commercial health plans), new or increased requirements to pay prescription drug rebates and penalties to government health care programs and policies that require drug companies to disclose and justify the prices they charge. For example, measures have been introduced in Congress that would impose caps on prescription drug prices and would require manufacturers to negotiate drug pricing with the government.

Recently enacted laws and the regulations and policies implementing them, as well as other healthcare-related measures that may be adopted in the future, could materially reduce our Korlym revenues and our ability to develop and commercialize our product candidates.

We depend on vendors to manufacture Korlym's active ingredient, form it into tablets, package it and dispense it to patients. We also depend on vendors to manufacture the API and capsules or tablets for our product candidates. If our suppliers become unable or unwilling to perform these functions and we cannot transfer these activities to replacement vendors in a timely manner, our business will be harmed.

A single third-party manufacturer, Produits Chimiques Auxiliaires et de Synthese SA ("PCAS"), supplies the API in Korlym. Two other third-party manufacturers produce and bottle Korlym tablets. Our agreement with PCAS automatically renews for two one-year terms, unless either party provides 12-months' written notice of its intent not to renew. A single specialty pharmacy, Optime Care, Inc. ("Optime") dispenses Korlym directly to patients and collects payments from insurers representing approximately 99 percent of our revenue. If Optime does not adhere to its agreements with payers, it may not be able to collect some or all of the payments due to us. Our agreement with Optime has a five-year term and renews upon the written consent of both parties, subject to customary termination provisions, including the right of Optime to terminate in the event of a material breach by us that we do not cure in a reasonable period of time after receiving written notice. In addition, we may terminate the agreement for convenience. In the event any of these vendors fails to perform its contractual obligations to us or is materially impaired in its performance by the COVID-19 pandemic or for any other reason, we may experience disruptions and delays in our supply chain and our ability to deliver Korlym to patients, which would adversely affect our business, results of operations and financial position.

The facilities used by our vendors to manufacture and package the API and drug product for Korlym and our product candidates must be approved by the FDA and, in some cases, the EMA or the Medicines and Healthcare products Regulatory Agency ("MHRA"). We do not control the activities of these vendors, including whether they maintain adequate quality control and hire qualified personnel. We are dependent on them for compliance with the regulatory requirements known as current good manufacturing practices ("cGMPs"). If our vendors cannot manufacture material that conforms to our specifications and the strict requirements of the FDA or others, they will not be able to maintain regulatory authorizations for their facilities and we could be prohibited from using the API or drug product they have provided. If the FDA, EMA, MHRA or other regulatory authorities withdraw regulatory authorizations of these facilities, we may need to find alternative vendors or facilities, which would be time-consuming, complex and expensive and could significantly hamper our ability to develop, obtain regulatory approval for and market our products. Sanctions could be imposed on us, including fines, injunctions, civil penalties, refusal of regulators to approve our product candidates, delays, suspensions or withdrawals of approvals, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could harm our business.

The unfavorable public perception of mifepristone may limit our ability to sell Korlym.

The active ingredient in Korlym, mifepristone, is approved by the FDA in another drug for the termination of early pregnancy. As a result, mifepristone is the subject of considerable debate in the United States and elsewhere. Public perception of mifepristone may limit the acceptance of Korlym by patients and physicians. Even though we have taken measures to minimize the chance that Korlym will accidentally be prescribed to a pregnant woman, physicians may choose not to prescribe Korlym to a woman simply to avoid the risk of terminating a pregnancy.

We may not have adequate insurance to cover our exposure to product liability claims.

We may be subject to product liability or other claims based on allegations that Korlym or one of our product candidates has harmed a patient. Such a claim may damage our reputation by raising questions about Korlym or our product candidates' safety and could prevent or interfere with product development or commercialization. Less common adverse effects of a pharmaceutical product are sometimes not known until long after the product is approved for marketing. Because the active ingredient in Korlym is used to terminate pregnancy, clinicians using Korlym in clinical trials and physicians prescribing the medicine to women must take strict precautions to ensure that it is not administered to pregnant women. Failure to observe these precautions could result in significant product liability claims.

Our insurance may not fully cover our potential product liabilities. Inability to obtain adequate insurance coverage could inhibit development of our product candidates or result in significant uninsured liability. Defending a lawsuit could be costly and divert management from productive activities.

If we are unable to maintain regulatory approval of Korlym or if we fail to comply with other requirements, we will be unable to generate revenue and may be subject to penalties.

We are subject to oversight by the FDA and other regulatory authorities in the United States and elsewhere with respect to our research, testing, manufacturing, labeling, distribution, adverse event reporting, storage, advertising, promotion, recordkeeping and sales and marketing activities. These requirements include submissions of safety information, annual updates on manufacturing activities and continued compliance with FDA regulations, including cGMPs, good laboratory practices and good clinical practices ("GCP"). The FDA enforces these regulations through inspections of us and the laboratories,

manufacturers and clinical sites we use. Foreign regulatory authorities have comparable requirements and enforcement mechanisms. Discovery of previously unknown problems with a product or product candidate, such as adverse events of unanticipated severity or frequency or deficiencies in manufacturing processes or management, as well as failure to comply with FDA or other U.S. or foreign regulatory requirements, may subject us to substantial civil and criminal penalties, injunctions, holds on clinical trials, product seizure, refusal to permit the import or export of products, restrictions on product marketing, withdrawal of the product from the market, product recalls, total or partial suspension of production, refusal to approve pending NDAs or supplemental NDAs, and suspension or revocation of product approvals.

We may be subject to civil or criminal penalties if our marketing of Korlym violates FDA regulations or health care fraud and abuse laws.

We are subject to FDA regulations governing the promotion and sale of medications. Although physicians are permitted to prescribe drugs for any indication they choose, manufacturers may only promote products for their FDA-approved use. All other uses are referred to as "off-label." In the United States, we market Korlym to treat hyperglycemia secondary to hypercortisolism in adult patients with endogenous Cushing's syndrome who have type 2 diabetes mellitus or glucose intolerance and for whom surgery has failed or is not an option. We provide promotional materials and training programs to physicians covering the use of Korlym for this indication. The FDA may change its policies or enact new regulations at any time that restrict our ability to promote our products.

If the FDA were to determine that we engaged in off-label promotion, the FDA could require us to change our practices and subject us to regulatory enforcement actions, including issuance of a public "warning letter," untitled letter, injunction, seizure, civil fine or criminal penalties. Other federal or state enforcement authorities might act if they believe that the alleged improper promotion led to the submission and payment of claims for an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. Even if it is determined that we are not in violation of these laws, we may receive negative publicity, incur significant expenses and be forced to devote management time to defending our position.

In addition to laws prohibiting off-label promotion, we are also subject to federal and state healthcare fraud and abuse laws and regulations designed to prevent fraud, kickbacks, self-dealing, and other abusive practices. The United States healthcare laws and regulations that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal health care programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- federal false claims laws, including, without limitation, the False Claims Act, which prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to get a false claim paid. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act. Pharmaceutical companies have been prosecuted under these laws for a variety of promotional and marketing activities, such as allegedly providing free product to or entering into "sham" consulting arrangements with customers to induce such customers to purchase, order or recommend the company's products in violation of the Anti-Kickback Statute and federal false claims laws and regulations; reporting to pricing services inflated average wholesale prices that were then used by certain governmental programs to set reimbursement rates; engaging in the promotion of "off-label" uses that caused customers to submit claims to and obtain reimbursement from governmental payers for non-covered "off-label" uses; and submitting inflated best price information to the Medicaid Drug Rebate Program; the government may assert that a claim including items and services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;

- the federal Civil Monetary Penalties law, which prohibits, among other things, offering or transferring remuneration to a federal healthcare beneficiary that a person knows or should know is likely to influence the beneficiary's decision to order or receive items or services reimbursable by the government from a particular provider or supplier;

- the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which created federal criminal laws that prohibit executing a scheme to defraud any health care benefit program or making false statements relating to health care matters; similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- federal "sunshine" laws, including the federal Physician Payment Sunshine Act, that require transparency regarding financial arrangements with health care providers, such as the reporting and disclosure requirements imposed by the ACA on drug manufacturers regarding any "transfer of value" made or distributed to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician practitioners (physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists, anesthesiology assistants and certified nurse midwives), teaching hospitals, and ownership or investment interests held by physicians and their immediate family members. Manufacturers are required to submit reports detailing these financial arrangements by the 90th day of each calendar year;

- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and

- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payer, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; and state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and pricing information.

The risk of being found in violation of these laws and regulations is increased by the fact that many of them have not been definitively interpreted by regulatory authorities or the courts and their provisions are open to a variety of interpretations. Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available under them, it is possible that some of our business activities, including our relationships with physicians and other healthcare providers (some of whom recommend, purchase and/or prescribe our products) and the manner in which we promote our products, could be subject to challenge. We are also exposed to the risk that our employees, independent contractors, principal investigators, consultants, vendors, distributors, and contract research organizations ("CROs") may engage in fraudulent or other illegal activity. Although we have policies and procedures prohibiting such activity, it is not always possible to identify and deter misconduct and the precautions we take may not be effective in controlling unknown risks or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with applicable laws and regulations. Please see "Part I, Item 3, Legal Proceedings."

If we are found in violation of any of the laws described above or any other government regulations, we may be subject to civil and criminal penalties, damages, fines, exclusion from governmental health care programs, a corporate integrity agreement or other agreement to resolve allegations of non-compliance, individual imprisonment, and the curtailment or restructuring of our operations, any of which could adversely affect our financial results and ability to operate.

Risks Related to our Research and Development Activities

Our efforts to discover, develop and commercialize our product candidates may not succeed. Clinical drug development is lengthy, expensive and often unsuccessful. Results of early studies and trials are often not predictive of later trial results. Failure can occur at any time.

Clinical development is costly, time-consuming and unpredictable. Positive data from clinical trials are susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. The results from early clinical trials are often not predictive of results in later clinical trials. Product candidates may fail to show the desired safety and efficacy traits despite having produced positive results in preclinical studies and initial clinical trials. Many companies have suffered significant setbacks in late-stage clinical trials due to lack of efficacy or unanticipated or unexpectedly severe adverse events.

Our current clinical trials may prove inadequate to support marketing approvals. Even trials that generate positive results may have to be confirmed in much larger, more expensive and lengthier trials before we could seek regulatory approval.

Clinical trials may take longer to complete, cost more than expected and fail for many reasons, including:

- failure to show efficacy or acceptable safety;

- slow patient enrollment or delayed activation of clinical trial sites due to the COVID-19 pandemic or other factors;

- delays obtaining regulatory permission to start a trial, changes to the size or design of a trial or changes in regulatory requirements for a trial already underway;

- inability to secure acceptable terms with vendors and an appropriate number of clinical trial sites;

- delays or inability to obtain institutional review board ("IRB") approval at prospective trial sites;
- failure of patients or investigators to comply with the clinical trial protocol;
- unforeseen safety issues; and
- negative findings of inspections of clinical sites or manufacturing operations by us, the FDA or other authorities.

A trial may also be suspended or terminated by us, the trial's data safety monitoring board, the IRBs governing the sites where the trial is being conducted or the FDA for many reasons, including failure to comply with regulatory requirements or clinical protocols, negative findings in an inspection of our clinical trial operations or trial sites by the FDA or other authorities, unforeseen safety issues, failure to demonstrate a benefit or changes in government regulations. Disruptions caused by the COVID-19 pandemic increase the likelihood of delays in initiating or completing our planned and ongoing clinical trials, thereby increasing their costs. Please see the risk factor, *"The COVID-19 pandemic has made initiating and advancing our clinical development programs more difficult."*

During the development of a product candidate, we may decide, or the FDA or other regulatory authorities may require us, to conduct more pre-clinical or clinical studies or to change the size or design of a trial already underway, thereby delaying or preventing the completion of development and increase its cost. Even if we conduct the clinical trials and supportive studies that we consider appropriate and the results are positive, we may not receive regulatory approval. Following regulatory approval, there are significant risks to its commercial success, such as development of competing products by other companies or the reluctance of physicians to prescribe it.

The COVID-19 pandemic has lengthened the time it takes to initiate and advance some of our clinical trials.

We conduct clinical trials at sites in the United States, Canada, Europe and Israel. In the United States, Canada and Europe, authorities have imposed significant public health restrictions of varying degrees of severity which are likely to persist as long as COVID-19 public health concerns remain. In addition, physicians, patients and medical institutions have changed their behavior in an attempt to reduce the risk of infection, which makes clinical trials more expensive, time-consuming and risky to initiate and conduct.

Some of the sites where we are conducting clinical trials have from time-to-time stopped enrolling new patients or reduced the frequency with which enrolled patients see their physicians. Some clinical sites have temporarily stopped initiating new trials. Many patients are reluctant to participate in procedures required by our clinical trial protocols because they fear infection. In general, COVID-19 has slowed the pace of our clinical trials, including our studies in Cushing's syndrome and AIWG. Studies of diseases perceived to be acutely life-threatening, such as advanced solid tumors, have not experienced delay or disruption.

We may continue to experience disruptions from the COVID-19 pandemic, which could have a material adverse impact on our clinical trial plans and timelines, including:

- delays in enrolling patients;
- delays in clinical site initiation, including difficulties in recruiting clinical investigators and staff;
- delays in receiving authorizations from local regulatory authorities and internal review boards to initiate clinical trials or amend existing protocols;
- delays in clinical sites receiving necessary supplies and materials due to interruptions in local and global shipping;
- changes in local regulations that require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs or cause us to suspend or discontinue a trial in the affected jurisdiction;
- diversion of healthcare resources, including facilities, supplies and staff, away from the conduct of clinical trials;
- interruption of key clinical trial activities, such as clinical trial site monitoring, patient visits and follow-up, study procedures and data collection, that could affect the integrity of clinical trial data, due to limitations on travel;
- the infection of patients enrolled in our clinical trials with COVID-19, which could affect the results of the clinical trial, including by increasing the number of observed adverse events or by causing patients to drop out of the study;
- patient discontinuations due to fear of infection with COVID-19 or public health restrictions implemented by clinical trial sites which make trial participation more time consuming or difficult;

- interruptions or delays in preclinical studies due to restricted or limited operations at laboratory facilities;
- delays in necessary interactions with local regulators, ethics committees and other third parties and contractors due to limitations in employee resources or the furlough of government employees; and
- limitations caused by the sickness of our employees or their families or the desire of employees to avoid contact with large groups of people.

The extent to which the COVID-19 pandemic affects our business, preclinical studies and clinical trials will depend on future developments, which are highly uncertain and cannot be predicted with confidence.

Vendors perform many of the activities necessary to carry out our clinical trials, including drug product distribution, trial management and oversight and data collection and analysis. Failure of these vendors to perform their duties or meet expected timelines may prevent or delay approval of our product candidates.

Third-party clinical investigators and clinical sites enroll patients and CROs manage many of our trials and perform data collection and analysis. Although we control only certain aspects of these third parties' activities, we are responsible for ensuring that every study adheres to its protocol and meets regulatory and scientific standards. If any of our vendors does not perform its duties or meet expected deadlines or fails to adhere to applicable GCP, or if the quality or accuracy of the data it produces is compromised, affected clinical trials may be extended, delayed or terminated and we may be unable to obtain approval for our product candidates. Failure of our manufacturing vendors to perform their duties or comply with cGMPs may require us to recall drug product or repeat clinical trials, which would delay regulatory approval. If our agreements with any of these vendors terminate, we may not be able to enter into alternative arrangements in a timely manner or on reasonable terms.

Our ability to physically inspect our vendors and clinical sites has been limited by the COVID-19 pandemic and associated public health restrictions, which increases the risk that failures to meet applicable requirements will go undetected.

We may be unable to obtain or maintain regulatory approvals for our product candidates, which would prevent us from commercializing our product candidates.

We cannot sell a product without the approval of the FDA or comparable foreign regulatory authority. Obtaining such approval is difficult, uncertain, lengthy and expensive. Failure can occur at any stage. In order to receive FDA approval for a new drug, we must demonstrate to the FDA's satisfaction that the new drug is safe and effective for its intended use and that our manufacturing processes comply with cGMPs. Our inability or the inability of our vendors to comply with applicable FDA and other regulatory requirements can result in delays in or denials of new product approvals, warning letters, untitled letters, fines, consent decrees restricting or suspending manufacturing operations, injunctions, civil penalties, recall or seizure of products, total or partial suspension of product sales and criminal prosecution. We may seek to commercialize our products in international markets, which would require us to receive a marketing authorization and, in many cases, pricing approval, from the appropriate regulatory authorities. Approval procedures vary between countries and can require additional pre-clinical or clinical studies. Obtaining approval may take longer than it does in the United States. Although approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by others, failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in others. Any of these or other regulatory actions could materially harm our business and financial condition.

If we receive regulatory approval for a product candidate, we will be subject to ongoing requirements and oversight by the FDA and other regulatory authorities, such as continued safety and other reporting requirements, as well as post-approval marketing restrictions and additional costly clinical trials. If we are not able to maintain regulatory compliance, we may be required to stop development of a product candidate or to stop selling a product that has already been approved. We may also be subject to product recalls or seizures. Future governmental action or changes in regulatory authority policy or personnel may also result in delays or rejection of pending or anticipated product approvals.

Our products and product candidates may cause undesirable side effects that halt their clinical development, prevent their regulatory approval, limit their commercial potential or cause us significant liability.

Patients in clinical trials report changes in their health, including new illnesses, injuries, and discomforts, to their study doctor. Often, it is not possible to determine whether or not these conditions were caused by the drug candidate being studied or something else. As we test our product candidates in larger, longer and more extensive clinical trials, or as use of them becomes more widespread if we receive regulatory approval, patients may report serious adverse events that did not occur or went undetected in previous trials. Many times, serious side effects are only detected in large-scale, Phase 3 clinical trials or following commercial approval.

Adverse events reported in clinical trials can slow or stop patient recruitment, prevent enrolled patients from completing a trial and could give rise to liability claims. Regulatory authorities could respond to reported adverse events by interrupting or halting our clinical trials or limiting the scope of, delaying or denying marketing approval. If we elect, or are required by authorities, to delay, suspend or terminate any clinical trial or commercialization efforts, the commercial prospects of such product candidates or products may be harmed, and our ability to generate product revenues from them may be delayed or eliminated.

If one of our product candidates receives marketing approval, and we or others later identify undesirable side effects or adverse events, potentially significant negative consequences could result, including but not limited to:

- regulatory authorities may suspend, limit or withdraw approvals of such product;
- regulatory authorities may require additional warnings on the label, including "boxed" warnings, or issue safety alerts and other safety information about the product;
- we may be required to change the way the product is administered or conduct additional studies or clinical trials;
- we may be required to create a Risk Evaluation and Mitigation Strategy (REMS), which could include a medication guide outlining the risks of such side effects for distribution to patients, a communication plan for healthcare providers and/or other elements to assure safe use;
- the product may become less competitive;
- we may be subject to fines, injunctions or the imposition of criminal penalties; and
- we could be sued and held liable for harm caused to patients;

Any of these events could seriously harm our business.

Risks Related to our Capital Needs and Financial Results

We may need additional capital to fund our operations or for strategic reasons. Such capital may not be available on acceptable terms or at all.

We are dependent on revenue from the sale of Korlym and our cash reserves to fund our commercial operations and development programs. If Korlym revenue declines significantly, we may need to curtail our operations or raise funds to support our plans. We may also choose to raise funds for strategic reasons. We cannot be certain funding will be available on acceptable terms or at all. Equity financing would cause dilution, debt financing may involve restrictive covenants. Neither type of financing may be available to us on attractive terms or at all. If we obtain funds through collaborations with other companies, we may have to relinquish rights to one or more of our product candidates. If our revenue declines and our cash reserves are depleted, and if adequate funds are not available from other sources, we may have to delay, reduce the scope of, or eliminate one or more of our development programs.

Risks Relating to our Intellectual Property

To succeed, we must secure, maintain and effectively assert adequate patent protection for the composition and methods of use of our proprietary, selective cortisol modulators and for the use of Korlym to treat Cushing's syndrome.

Patents are uncertain, involve complex legal and factual questions and are frequently the subject of litigation. The patents issued or licensed to us may be challenged at any time. Competitors may take actions we believe infringe our intellectual property, causing us to take legal action to defend our rights. Intellectual property litigation is lengthy, expensive and requires significant management attention. Outcomes are uncertain. If we do not protect our intellectual property, competitors may erode our competitive advantage. Please see "Part I, Item 3, Legal Proceedings."

Our patent applications may not result in issued patents and patents issued to us may be challenged, invalidated, held unenforceable or circumvented. Our patents may not prevent third parties from producing competing products. The foreign countries where we may someday operate may not protect our intellectual property to the extent the laws of the United States do. If we fail to obtain adequate patent protection in other countries, others may produce products in those countries based on our technology.

Risks Related to our Stock

The price of our common stock fluctuates widely and will continue to do so. Opportunities for investors to sell shares may be limited.

We cannot assure investors that a liquid trading market for our common stock will exist at any particular time. As a result, holders of our common stock may not be able to sell shares quickly or at the current market price. During the 52-week period ended February 8, 2022, our average daily trading volume was approximately 848,907 shares and the intra-day sales prices per share of our common stock on The Nasdaq Stock Market ranged from $15.82 to $31.18. As of February 8, 2022, our officers, directors and principal stockholders beneficially owned approximately 19 percent of our common stock.

Our stock price can experience extreme price and volume fluctuations that are unrelated or disproportionate to our operating performance or prospects. Securities class action lawsuits are often instituted against companies following periods of stock market volatility. Such litigation is costly and diverts management's attention from productive efforts.

Factors that may cause the price of our common stock to fluctuate rapidly and widely include:

- actual or anticipated variations in our operating results or changes to any public guidance we have provided;
- actual or anticipated timing and results of our clinical trials;
- changes in the expected or actual timing of our competitors' development programs;
- general market and economic conditions, including the effects of the COVID-19 pandemic;
- disputes or other developments relating to our intellectual property, including developments in ANDA litigation and proceedings before the PTAB;
- short-selling of our common stock, the publication of speculative opinions about our business or other market manipulation activities that are intended to lower our stock price or increase its volatility;
- changes in estimates or recommendations by securities analysts or the failure of our performance to meet the published expectations of those analysts or public guidance we have provided;
- actual or anticipated regulatory approvals of our product candidates or competing products;
- purchases or sales of our common stock by our officers, directors or stockholders;
- changes in laws or regulations applicable to Korlym, our product candidates or our competitors' products;
- technological innovations by us, our collaborators or our competitors;
- conditions in the pharmaceutical industry, including the market valuations of companies similar to ours;
- additions or departures of key personnel;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments; and
- additional financing activities.

Our stock price may decline if our financial performance does not meet the guidance we have provided to the public, estimates published by research analysts or other investor expectations.

The guidance we provide as to our expected 2022 revenue is only an estimate of what we believe is realizable at the time we give such guidance. It is difficult to predict our revenue and our actual results may vary materially from our guidance. The effect on our business of the COVID-19 pandemic is difficult to forecast. In addition, the rate of physician adoption of Korlym and the actions of government and private payers is uncertain. We may experience competition from generic versions of Korlym, which our public revenue guidance does not anticipate. We may not meet our financial guidance or other investor expectations for other reasons, including those arising from the risks and uncertainties described in this report and in our other public filings and public statements. Research analysts publish estimates of our future revenue and earnings based on their own analysis. The revenue guidance we provide may be one factor they consider when determining their estimates.

General Risk Factors

We need to increase the size of our organization and may experience difficulties in managing growth.

Our commercial and research and development efforts are constrained by our limited administrative, operational and management resources. To date, we have relied on a small management team. Growth will impose significant added responsibilities on members of management, including the need to recruit and retain additional employees. Our financial performance and ability to compete will depend on our ability to manage growth effectively. To that end, we must:

- manage our sales and marketing efforts, clinical trials, research and manufacturing activities effectively;
- hire more management, clinical development, administrative and sales and marketing personnel; and
- continue to develop our administrative systems and controls.

Failure to accomplish any of these tasks, which are more difficult during the COVID-19 pandemic, could harm our business.

If we lose key personnel or are unable to attract more skilled personnel, we may be unable to pursue our product development and commercialization goals.

Our ability to operate successfully and manage growth depends upon hiring and retaining skilled managerial, scientific, sales, marketing and financial personnel. The job market for qualified personnel is intensely competitive and turnover rates have reached record highs within our industry and the geographical areas from which we recruit. We depend on the principal members of our management and scientific staff. Any officer or employee may terminate his or her relationship with us at any time and work for a competitor. We do not have employment insurance covering any of our personnel. The loss of key individuals could delay our research, development and commercialization efforts.

We are subject to government regulation and other legal obligations relating to privacy and data protection. Compliance with these requirements is complex and costly. Failure to comply could materially harm our business.

We and our partners are subject to federal, state and foreign laws and regulations concerning data privacy and security, including HIPAA and the EU General Data Protection Regulation, or the GDPR. These and other regulatory frameworks are evolving rapidly as new rules are enacted and existing ones updated and made more stringent.

In the United States, numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy, laws, and federal and state consumer protection laws and regulations (e.g., Section 5 of the FTC Act), that govern the collection, use, disclosure, and protection of health-related and other personal information could apply to our operations or the operations of our partners. In addition, we may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under HIPAA. Depending on the facts and circumstances, we could be subject to criminal penalties if we knowingly obtain, use, or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA.

Even when HIPAA does not apply, according to the Federal Trade Commission or the FTC, violating consumers' privacy or failing to take appropriate steps to keep consumers' personal information secure may constitute unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act. The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards.

In addition, certain state laws govern the privacy and security of health information in certain circumstances, some of which are more stringent than HIPAA and many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties and private litigation. For example, the California Confidentiality of Medical Information Act imposes restrictive requirements regulating the use and disclosure of health information and other personally identifiable information. Further, on June 28, 2018, California enacted the California Consumer Privacy Act, or the CCPA, which took effect on January 1, 2020. The CCPA creates individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. The CCPA may increase our compliance costs and potential liability. Further, the California Privacy Rights Act, or CPRA, recently passed in California. The CPRA will impose additional data protection obligations on covered businesses, including additional

consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It will also create a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. The majority of the provisions will go into effect on January 1, 2023, and additional compliance investment and potential business process changes may be required. In the event that we are subject to or affected by HIPAA, the CCPA, the CPRA or other domestic privacy and data protection laws, any liability from failure to comply with the requirements of these laws could adversely affect our financial condition. Similar laws have been passed in Virginia and Colorado, and have been proposed at the federal level and in other states, reflecting a trend toward more stringent privacy legislation in the United States.

The GDPR went into effect in 2018 and imposes stringent requirements for controllers and processors of personal data of individuals within the EEA, particularly with respect to clinical trials. The GDPR provides that EEA member states may make their own further laws and regulations limiting the processing of health data, which could limit our ability to use and share personal data or could cause our costs to increase and harm our business and financial condition. In addition, the GDPR increases the scrutiny that clinical trial sites located in the EEA should apply to transfers of personal data from such sites to countries that are considered to lack an adequate level of data protection, such as the United States. Recent legal developments have also created complexity and compliance uncertainty regarding certain transfers of information from the EEA to the United States. For example, on June 16, 2020, the Court of Justice of the European Union, or the CJEU, limited how organizations could lawfully transfer personal data from the EEA to the United States by invalidating the EU-US Privacy Shield Framework for purposes of international transfers and imposing further restrictions on use of the standard contractual clauses, or SCCs. These restrictions include a requirement for companies to carry out a transfer impact assessment which, among other things, assesses the laws governing access to personal data in the recipient country and considers whether supplementary measures that provide privacy protections additional to those provided under SCCs will need to be implemented to ensure an essentially equivalent level of data protection to that afforded in the EEA. The EC issued revised SCCs on June 4, 2021 to account for the decision of the CJEU and recommendations made by the European Data Protection Board. The revised SCCs must be used for relevant new data transfers from September 27, 2021; existing standard contractual clauses arrangements must be migrated to the revised clauses by December 27, 2022. There is some uncertainty around whether the revised clauses can be used for all types of data transfers, particularly whether they can be relied on for data transfers to non-EEA entities subject to the GDPR. As supervisory authorities issue further guidance on personal data export mechanisms, including circumstances where the SCCs cannot be used, and/or start taking enforcement action, we could suffer additional costs, complaints and/or regulatory investigations or fines, and/or if we are otherwise unable to transfer personal data between and among countries and regions in which we operate, it could affect the manner in which we provide our services, the geographical location or segregation of our relevant systems and operations, and could adversely affect our financial results. The GDPR imposes substantial fines for breaches of data protection requirements, which can be up to four percent of global revenue for the preceding financial year or €20 million, whichever is greater, and it also confers a private right of action on data subjects for breaches of data protection requirements. Compliance with European data protection laws is a rigorous and time intensive process that may increase our cost of doing business, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation and reputational harm in connection with our European activities. From January 1, 2021, we have had to comply with the GDPR and separately the United Kingdom GDPR, which, together with the amended United Kingdom Data Protection Act 2018, retains the GDPR in United Kingdom national law, each regime having the ability to fine up to the greater of €20 million/ £17.5 million or 4% of global turnover. It is unclear how United Kingdom data protection laws and regulations will develop in the medium to longer term and these changes may lead to additional costs and increase our overall risk exposure. On June 28, 2021, the EC adopted an adequacy decision in favor of the United Kingdom, enabling data transfers from EU member states to the United Kingdom without additional safeguards. However, the United Kingdom adequacy decision will automatically expire in June 2025 unless the EC renews or extends that decision and remains under review by the Commission during this period.

Complying with U.S. and foreign privacy and security laws and regulations is complex and costly. Failure to comply by us or our vendors could subject us to litigation, government enforcement actions and substantial penalties and fines, which could harm our business.

We rely on information technology systems to conduct our business. A breakdown or breach of these systems or our failure to protect confidential information concerning our business, patients or employees could interrupt the operation of our business and subject us to liability.

We store valuable confidential information relating to our business, patients and employees on our computer networks and on the networks of our vendors. In addition, we rely heavily on internet technology, including video conference, teleconference and file-sharing services, to conduct business. Despite our security measures, our networks and the networks of our vendors are at risk of break-ins, installation of malware or ransomware, denial-of-service attacks, data theft and other forms of malfeasance by persons seeking to commit fraud or theft, which could result in unauthorized access to, and misuse of, our clinical data or other confidential information, including confidential information relating to our patients or employees.

COVID-19 may increase our cybersecurity risks, due to our reliance on internet technology and the number of our employees that are working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities.

We and our vendors have experienced data breaches, theft, "phishing" attacks and other unauthorized access to confidential data and information. There can be no assurance that our cybersecurity systems and processes will prevent unauthorized access in the future that causes serious harm to us, our patients or employees. We may also experience security breaches that remain undetected for an extended period.

Disruptions or security breaches that result in the disclosure of confidential or proprietary information could cause us to incur liability and delay or otherwise harm our research, development and commercialization efforts. We may be liable for losses suffered by patients or employees or other individuals whose confidential information is stolen as a result of a breach of the security of the systems that we or third parties and our vendors store this information on, and any such liability could be material. Even if we are not liable for such losses, any breach of these systems could expose us to material costs in notifying affected individuals, as well as regulatory fines or penalties. In addition, any breach of these systems could disrupt our normal business operations and expose us to reputational damage and harm our business, operating results and financial condition. Any insurance we maintain against the risk of this type of loss may not be sufficient to cover actual losses, or may not apply to the circumstances relating to any particular loss.

We are dependent on the continued functioning of the FDA and other federal instrumentalities. Their partial or complete closure, whether due to public health concerns or a budgetary dispute, or their diversion of significant resources to advance pandemic-related issues could materially harm our business.

The government's ability to carry out its mandated functions is affected by a variety of factors, including diversion of resources and limited operating capacity caused by the COVID-19 pandemic, as well as other events that may reduce the government's ability to perform routine functions, such as inadequate funding, the inability to hire and retain key personnel, and statutory, regulatory and policy changes. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Similarly, disruptions at the Securities and Exchange Commission ("SEC") could temporarily stop its ability to review and approve proposed financing transactions.

In March 2020, the FDA announced that in response to the COVID-19 pandemic, it would postpone most inspections of foreign manufacturing facilities and was postponing routine surveillance inspections of domestic manufacturing facilities. In July 2020, the FDA resumed certain on-site inspections of domestic manufacturing facilities subject to a risk-based prioritization system, which it used to determine when and where it was safest to conduct prioritized domestic inspections. In April 2021, the FDA issued a guidance document in which it described its plans to conduct voluntary remote interactive evaluations of certain drug manufacturing facilities and clinical research sites, among other facilities. According to the guidance, the FDA may request such remote interactive evaluations where it determines that remote evaluation would be appropriate based on mission needs and travel limitations. In July 2021, the FDA resumed standard inspections of domestic facilities. The FDA has continued to monitor and implement changes to its inspection practices to ensure the safety of its employees and those of the firms it regulates. Regulatory authorities outside the United States may adopt similar changes.

Changes in federal, state and local tax laws may reduce our net earnings.

Our earnings are subject to federal, state and local taxes. We offset a portion of our earnings using net operating losses and our taxes using research and development tax credits, which reduces the amount of tax we pay. Some jurisdictions require that we pay taxes or fees calculated as a percentage of sales, payroll expense, or other indicia of our activities. Please see "Part IV, Item 15, Notes to Consolidated Financial Statements - Income Taxes." Changes to existing tax laws could materially increase the amounts we pay, which would reduce our after tax net income. Beginning in 2022, the Tax Cuts and Jobs Act of 2017 ("TCJA") eliminates the option to deduct research and development expenditures currently and requires taxpayers to amortize them over five years pursuant to IRC Section 174. Although Congress is considering legislation that would defer the amortization requirement to later years, it is not certain that the provision will be repealed or otherwise modified. If the requirement is not modified, it will reduce our cash flows beginning in 2022.

We may face competition from companies with greater financial, technical and marketing resources than our own.

The pharmaceutical industry is competitive and subject to rapid technological change. Our potential competitors include large pharmaceutical companies and innovative biotechnology companies, many of which have greater clinical, marketing and sales resources than our own and may develop and commercialize medications that are superior to and less expensive than ours, which could negatively affect our financial results and the prospects of our product candidates.

Research analysts may not continue to provide or initiate coverage of our common stock or may issue negative reports.

The market for our common stock may be affected by the reports financial analysts publish about us. If any of the analysts covering us downgrades or discontinues coverage of our stock, the price of our common stock could decline rapidly and significantly. Paucity of research coverage may also adversely affect our stock price.

Sale of a substantial number of shares of our common stock may cause its price to decline.

Sales of a substantial number of shares of our stock in the public market could reduce its price. As additional shares of our stock become available for public resale, whether by the exercise of stock options by employees or directors or because of an equity financing by us, the supply of our stock will increase, which could cause its price to fall. Substantially all of the shares of our stock are eligible for sale, subject to applicable volume and other resale restrictions.

Changes in laws and regulations may significantly increase our costs or reduce our revenue, which could harm our financial results.

New laws and regulations, as well as changes to existing laws and regulations, including statutes and regulations concerning taxes and the development, approval, marketing and pricing of medications, the provisions of the ACA requiring the reporting of aggregate spending related to health care professionals, the provisions of the Sarbanes-Oxley Act of 2002 and rules adopted by the SEC and by The Nasdaq Stock Market have and will likely continue to increase our cost of doing business and divert management's attention from revenue-generating activities.

If we acquire products or product candidates, we will incur significant costs and may not realize the benefits we anticipate.

We may acquire a product or product candidate that complements our strategic plan. Such an acquisition may give rise to unforeseen difficulties and costs and may absorb significant management attention. We may not realize the anticipated benefits of any acquisition, which could dilute our stockholders' ownership interest or cause us to incur significant expenses and debt.

We may fail to comply with our public company obligations, including securities laws and regulations. Such compliance is costly and requires significant management attention.

The federal securities laws and regulations, including the corporate governance and other requirements of the Sarbanes-Oxley Act of 2002, impose complex and continually changing regulatory requirements on our operations and reporting. These developing requirements will continue to increase our compliance costs. Section 404 of the Sarbanes-Oxley Act of 2002 requires that we evaluate the effectiveness of, and provide a management report with respect to, our internal controls over financial reporting. It also requires that the independent registered public accounting firm auditing our consolidated financial statements must attest to and report on the effectiveness of our internal controls over financial reporting. If we are unable to complete the required assessment and report or if our independent registered public accounting firm is unable to issue an unqualified opinion as to the effectiveness of our internal control over financial reporting, investors could lose confidence in our financial reporting and our stock price would likely decline.

Anti-takeover provisions in our charter and bylaws and under Delaware law may make an acquisition of us or a change in our management more expensive or difficult, even if an acquisition or a management change would be beneficial to our stockholders.

Provisions in our charter and bylaws may delay or prevent an acquisition of us or a change in our management. Some of these provisions allow us to issue preferred stock without any vote or further action by the stockholders, require advance notification of stockholder proposals and nominations of candidates for election as directors and prohibit stockholders from acting by written consent. In addition, a supermajority vote of stockholders is required to amend our bylaws. Our bylaws provide that special meetings of the stockholders may be called only by our Chairman, President or the Board of Directors and that the authorized number of directors may be changed only by resolution of the Board of Directors. These provisions may prevent or delay a change in our Board of Directors or our management, which our Board of Directors appoints. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law. Section 203 may prohibit large stockholders, in particular those owning 15 percent or more of our outstanding voting stock, from merging or combining with us. These provisions in our charter and bylaws and under Delaware law could reduce the price that investors would be willing to pay for shares of our common stock.

Our officers, directors and principal stockholders, acting as a group, could significantly influence corporate actions.

As of February 8, 2022, our officers and directors beneficially owned approximately 19 percent of our common stock. Acting together, these stockholders could significantly influence any matter requiring approval by our stockholders, including

the election of directors and the approval of mergers or other business combinations. The interests of this group may not always coincide with our interests or the interests of other stockholders and may prevent or delay a change in control. This significant concentration of share ownership may adversely affect the trading price of our common stock because many investors perceive disadvantages to owning stock in companies with controlling stockholders.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

We lease 36,062 square feet of office space in Menlo Park, California for our corporate facilities. Our current lease expires in March 2022.

ITEM 3. LEGAL PROCEEDINGS

Teva ANDA Litigation

In February 2018, we received a Paragraph IV Notice Letter advising that Teva had submitted an Abbreviated New Drug Application ("ANDA") to the FDA seeking authorization to manufacture, use or sell a generic version of Korlym in the United States prior to the expiration of patents related to Korlym that are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"). Teva's February 5, 2018 Notice Letter alleged that our patents would not be infringed by Teva's proposed product, were invalid and/or were unenforceable. On March 15, 2018, we filed a lawsuit in the United States District Court for the District of New Jersey against Teva for infringement of our patents. On October 12, 2018, Teva received tentative approval from the FDA for its ANDA. In accordance with the Hatch-Waxman Act, however, FDA final approval of Teva's ANDA was stayed for 30 months, until August 1, 2020.

On July 6, 2018, we filed an amended complaint and on February 8, 2019, we filed a separate lawsuit against Teva, asserting infringement of several patents, including U.S. Patent No. 10,195,214 (the "'214 patent"). On December 13, 2019, we filed a third lawsuit against Teva, asserting infringement of U.S. Patent Nos. 10,500,216 (the "'216 patent"). The District Court consolidated our lawsuits against Teva into a single action and set a trial date of February 2, 2021. On September 24, 2020, the Court vacated the February 2, 2021 trial date. A new trial date has not been set.

Our current lawsuit against Teva asserts the '214 patent and the '216 patent. The parties have completed briefing cross-motions for summary judgment regarding infringement of the '214 patent. There is no timetable as to when the Court will rule on these motions and there are currently no further calendared dates for the litigation.

We will vigorously enforce our intellectual property rights relating to Korlym but cannot predict the outcome of this matter.

On May 7, 2019, Teva submitted to the PTAB a petition for post-grant review ("PGR") of the '214 patent. On November 20, 2019, the PTAB agreed to initiate the PGR, and on November 19, 2020 issued a decision upholding the validity of the '214 patent in its entirety. Teva appealed its loss to the Federal Circuit Court of Appeals, which on December 7, 2021, ruled in Corcept's favor.

The time for Teva to appeal or seek reconsideration of these adverse decisions has passed. This matter is closed.

Sun ANDA Litigation and Settlement

On June 10, 2019, we received a Paragraph IV Notice Letter advising that Sun had submitted an ANDA to the FDA seeking authorization to manufacture, use or sell a generic version of Korlym in the United States prior to the expiration of certain of our patents related to Korlym listed in the Orange Book.

On July 22, 2019, we filed a lawsuit in the United States District Court for the District of New Jersey against Sun for infringement of our patents. On January 23, 2020, we filed an amended complaint against Sun asserting infringement of two additional patents.

On June 9, 2021, we entered into an agreement with Sun resolving this litigation. Pursuant to the agreement, we have granted Sun the right to sell a generic version of Korlym in the United States beginning October 1, 2034 or earlier under circumstances customary for settlement agreements of this type. As required by law, we and Sun have submitted the settlement agreement to the United States Federal Trade Commission and the United States Department of Justice for review.

Hikma ANDA Litigation

On February 1, 2021, we received a Paragraph IV Notice Letter advising that Hikma Pharmaceuticals USA Inc. ("Hikma") had submitted an ANDA to the FDA seeking authorization to manufacture, use or sell a generic version of Korlym in the United States.

The Notice Letter contains Paragraph IV certifications against certain of our patents related to Korlym, alleging that these patents will not be infringed by Hikma's proposed product, are invalid and/or are unenforceable.

On March 12, 2021, we filed a lawsuit in the United States District Court for the District of New Jersey against Hikma for infringement of the '214 patent, the '216 patent, U.S. Patent Nos. 10,842,800, and U.S. Patent Nos. 10,842,801. The 30-month stay of FDA approval of Hikma's ANDA expires on August 1, 2023. Hikma responded to our complaint on May 17, 2021, denying our claims. On July 13, 2021, the Court entered a schedule for the case setting a fact discovery deadline of July 1, 2022.

We intend to vigorously enforce our intellectual property rights relating to Korlym but cannot predict the outcome of this matter.

Other Matters

On March 14, 2019, a purported securities class action complaint was filed in the United States District Court for the Northern District of California by Nicholas Melucci (*Melucci v. Corcept Therapeutics Incorporated, et al.*, Case No. 5:19-cv-01372-LHK) (the "Melucci litigation"). The complaint named us and certain of our executive officers as defendants asserting violations of Sections 10(b) and 20(a) of the Exchange Act and Rule 10b-5 promulgated thereunder and alleges that the defendants made false and materially misleading statements and failed to disclose adverse facts about our business, operations, and prospects. The complaint asserts a putative class period extending from August 2, 2017 to February 5, 2019 and seeks unspecified monetary relief, interest and attorneys' fees. On October 7, 2019, the Court appointed a lead plaintiff and lead counsel. The lead plaintiff's consolidated complaint was filed on December 6, 2019.

We moved to dismiss the consolidated complaint on January 27, 2020. Rather than oppose our motion to dismiss, on March 20, 2020, the lead plaintiff withdrew its consolidated complaint and filed a second amended complaint. On May 11, 2020, we moved to dismiss the second amended complaint. On November 20, 2020, the Court granted our motion to dismiss, while granting plaintiff leave to file a third amended complaint, which plaintiff did on December 21, 2020. On February 19, 2021, we moved to dismiss this third amended complaint. Plaintiff filed its opposition to our motion on April 20, 2021 and we filed our reply on June 4, 2021.

On August 24, 2021, the Court granted our motion in part, but also denied it in part, which means certain of plaintiff's claims may proceed to discovery.

We will respond vigorously to plaintiff's claims but cannot predict the outcome of this matter.

On September 30, 2019, a purported shareholder derivative complaint was filed in the United States District Court for the District of Delaware by Lauren Williams, captioned *Lauren Williams v. G. Leonard Baker, et al.*, Civil Action No. 1:19-cv-01830. The complaint named our board of directors, Chief Executive Officer and current Chief Business Officer as defendants, and us as nominal defendant. The complaint alleges breach of fiduciary duty, violation of Section 14(a) of the Exchange Act, insider selling, misappropriation of insider information and waste of corporate assets and seeks damages in an amount to be proved at trial. On October 23, 2019, this action was stayed pending a resolution of our motions to dismiss the Melucci litigation. On December 20, 2020, the case was further stayed pending a resolution of our motion to dismiss the third amended complaint in the Melucci litigation. On September 30, 2021, the case was further stayed pending a resolution of the Melucci litigation.

We will respond to this complaint vigorously but cannot predict the outcome of this matter.

On December 19, 2019, a second purported shareholder derivative complaint was filed in the United States District Court for the District of Delaware by Jeweltex Pension Plan, captioned *Jeweltex Pension Plan v. James N. Wilson, et al.*, Civil Action No. 1:19-cv-02308. The complaint named our board of directors, Chief Executive Officer and current Chief Business Officer as defendants, and us as nominal defendant. The complaint alleges causes of action for breach of fiduciary duty, violation of section 14(a) of the Exchange Act, waste of corporate assets, contribution and indemnification, aiding and abetting, and gross mismanagement. The complaint seeks damages in an amount to be proved at trial. On April 6, 2020, this action was stayed pending a resolution of our motions to dismiss the Melucci litigation. On December 20, 2020, the case was further stayed pending a resolution of our motion to dismiss the third amended complaint in the Melucci litigation. On September 30, 2021, the case was further stayed pending a resolution of the Melucci litigation.

We will respond to this complaint vigorously but cannot predict the outcome of this matter.

On January 31, 2022, a purported shareholder derivative complaint was filed in the Delaware Court of Chancery by Joel B. Ritchie, captioned Joel B. Ritchie v. G. Leonard Baker, et al., Case No. 2022-0102-SG. The complaint named our board of directors, Chief Executive Officer, current Chief Business Officer, and Chief Commercial Officer as defendants, and us as nominal defendant. The complaint alleges a single cause of action for breach of fiduciary duty. The complaint seeks damages in an amount to be proved at trial.

We will respond to this complaint vigorously but cannot predict the outcome of this matter.

In November 2021, we received a records subpoena from the United States Attorney's Office for the District of New Jersey (the "NJ USAO") pursuant to Section 248 of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) seeking information relating to the sale and promotion of Korlym, Corcept's relationships with and payments to health care professionals who can prescribe or recommend Korlym and prior authorizations and reimbursement for Korlym. The NJ USAO has informed Corcept that it is investigating whether any criminal or civil violations by Corcept occurred in connection with the matters referenced in the subpoena. It has also informed Corcept that it does not currently consider Corcept a defendant but rather an entity whose conduct is within the scope of the government's investigation.

From time-to-time, in the ordinary course of business, we are involved in legal proceedings in addition to the matters described above. Although the outcome of any such matters and the amount, if any, of our liability with respect to them cannot be predicted with certainty, we do not believe that they will have a material adverse effect on our business, results of operations or financial position.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

Our common stock is traded on The Nasdaq Capital Market under the symbol "CORT."

Stockholders of Record and Dividends

As of February 8, 2022, we had 105,962,389 shares of common stock outstanding held by 28 stockholders of record. Because almost all of our common stock is held by brokers, nominees and other institutions on behalf of stockholders, we are unable to estimate the actual number of our stockholders. We have never declared or paid cash dividends. We do not anticipate paying cash dividends in the foreseeable future.

Sale of Unregistered Securities

None.

Repurchases of Securities

The following table contains information relating to the purchases of our common stock in the three months ended December 31, 2021 as part of a publicly announced tender offer (in thousands, except average price per share):

Fiscal Period	Total Number of Shares Repurchased	Average Price Paid Per Share	Dollar Amount of Shares Purchased Under the Tender Offer[1]
October 1, 2021 to October 31, 2021	—	$ —	$ —
November 1, 2021 to November 30, 2021	—	—	—
December 1, 2021 to December 31, 2021	10,000	20.75	207,500
Total	10,000	$ 20.75	$ 207,500

[1] On November 8, 2021, we announced a tender offer to purchase up to 10 million shares of our common stock. The tender offer commenced on that date and expired on December 15, 2021.

The following table contains information relating to the purchases of our common stock in the three months ended December 31, 2021 as part of the cashless net exercises of stock options (in thousands, except average price per share):

Fiscal Period	Total Number of Shares Purchased[2]	Average Price Paid Per Share	Total Purchase Price of Shares[3]
October 1, 2021 to October 31, 2021	230	$ 21.26	$ 4,900
November 1, 2021 to November 30, 2021	111	22.82	2,529
December 1, 2021 to December 31, 2021	63	18.68	1,178
Total	404	$ 21.28	$ 8,607

(2) In October 2021, we issued 304,166 shares of common stock as part of a net-share settlement of a cashless option exercise, of which 230,489 shares were surrendered to us in satisfaction of related exercise cost and tax obligations. In November 2021, we issued 190,851 shares of common stock as part of a net-share settlement of a cashless option exercise, of which 110,858 shares were surrendered to us. In December 2021, we issued 84,388 shares of common stock as part of a net-share settlement of a cashless option exercise, of which 63,041 shares were surrendered to us.

(3) We paid $2.5 million to satisfy the tax withholding obligations associated with the net-share settlement of these cashless option exercises.

Market Performance Graph

The graph and the accompanying text below is not "soliciting material," is not deemed filed with the SEC and is not to be incorporated by reference in any filings by us under the Securities Act or the Exchange Act, whether made before or after the date hereof and irrespective of any general incorporation language in such filing.

We have elected to use the Nasdaq US Benchmark TR Index and Nasdaq Biotechnology Index (consisting of a group of 120 companies in the biotechnology sector, including us) for purposes of the performance comparison that appears below,

which shows the cumulative stockholder return assuming the investment of $100 and the reinvestment of any dividends and is based on the returns of the component companies weighted according to their market capitalizations.

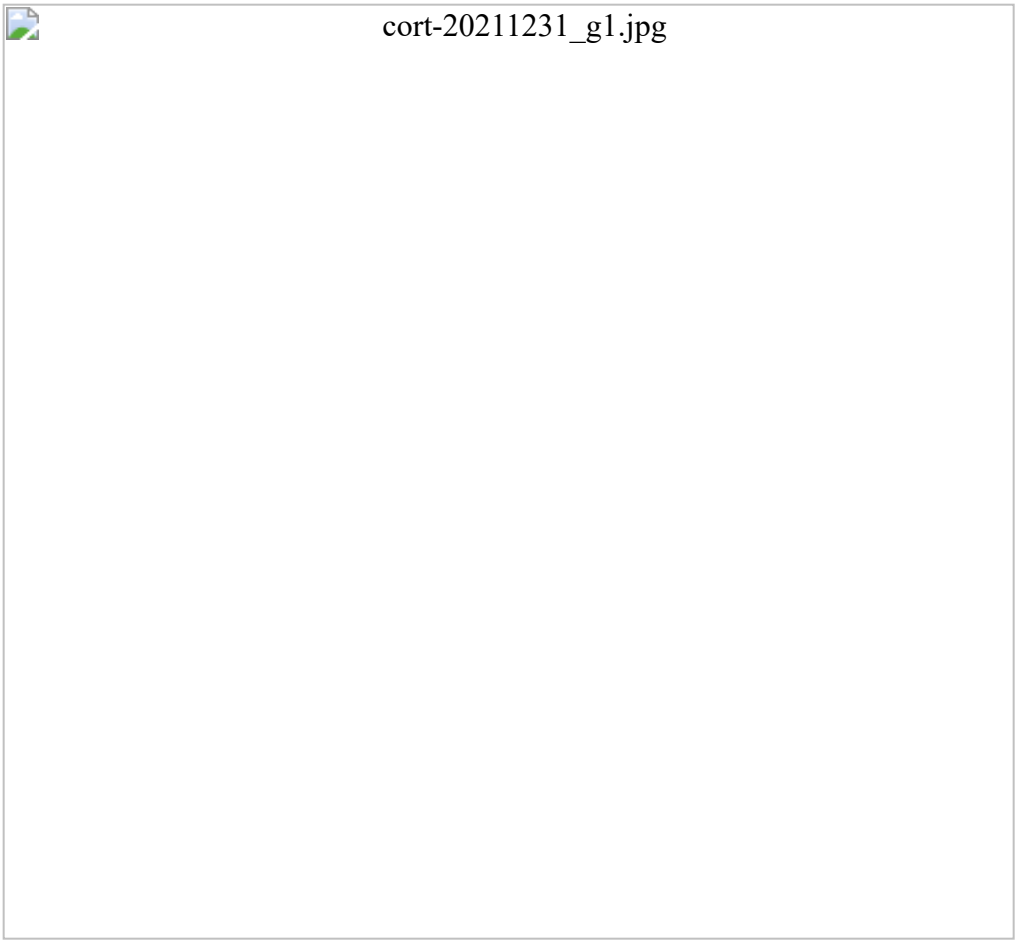
The graph shows the cumulative total stockholder return assuming the investment of $100 and the reinvestment of any dividends and is based on the returns of the component companies weighted according to their market capitalizations as of the end of the period for which returns are indicated. We have never paid dividends on our common stock.

The return shown in the graph below for our common stock is not necessarily indicative of future performance. We do not make or endorse any predictions as to future stockholder returns.

Five-Year Cumulative Total Returns of our Common Stock (CORT),

the Nasdaq US Benchmark TR Index (NQUSBT) and

the Nasdaq Biotechnology Index (NBI)



ITEM 6. [RESERVED]

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following Management's Discussion and Analysis of Financial Condition and Results of Operations ("MD&A") is intended to help the reader understand our results of operations and financial condition and is provided as a supplement to, and should be read in conjunction with, our audited consolidated financial statements and the accompanying notes to financial statements, risk factors and other disclosures included in this Form 10-K. Our consolidated financial statements have been prepared in accordance with U.S. Generally Accepted Accounting Principles ("U.S. GAAP").

We make statements in this section that are forward-looking statements within the meaning of the federal securities laws. For a complete discussion of such forward-looking statements and the potential risks and uncertainties that may affect their accuracy, see "Forward-Looking Statements" included in "Risk Factors" in this Form 10-K and the "Overview" and "Liquidity and Capital Resources" sections of this MD&A.

Overview

We are a commercial-stage company engaged in the discovery and development of drugs that treat severe metabolic, oncologic and neuropsychiatric disorders by modulating the effects of the hormone cortisol. Since 2012, we have marketed Korlym (mifepristone) for the treatment of patients suffering from Cushing's syndrome. Our portfolio of proprietary selective cortisol modulators consists of four structurally distinct series totaling more than 1,000 compounds.

Cushing's Syndrome

Korlym. We sell Korlym in the United States, using experienced clinical sales representatives to call on physicians caring for patients with endogenous Cushing's syndrome (hypercortisolism). Because many people who suffer from Cushing's syndrome are undiagnosed or inadequately treated, we have developed and continue to refine and expand programs to educate physicians and patients about screening for hypercortisolism and the role Korlym can play in treating patients with the disorder. We also have a field-based force of medical science liaisons.

We use one specialty pharmacy and one specialty distributor to distribute Korlym and provide logistical support to physicians and patients. Our policy is that no patient with Cushing's syndrome will be denied access to Korlym for financial reasons. To help us achieve that goal, we fund our own patient support programs and donate money to independent charitable foundations that help patients pay for all aspects of their Cushing's syndrome care, whether or not that care includes taking Korlym.

Relacorilant. We are conducting two Phase 3 trials (named GRACE and GRADIENT) of our proprietary, selective cortisol modulator, relacorilant, as a treatment for patients with Cushing's syndrome.

Each patient in GRACE receives relacorilant for 22 weeks. Patients who exhibit pre-specified improvements in hypertension or glucose metabolism enter a 12-week, double-blind, "randomized withdrawal" phase, in which half of the patients continue receiving relacorilant and half receive placebo. The trial's primary endpoint is the rate and degree of relapse in patients receiving placebo measured against the rate and degree of relapse in those continuing relacorilant. GRACE has a planned enrollment of 130 patients with any etiology of endogenous Cushing's syndrome at sites in the United States, Canada, Europe and Israel.

Our GRADIENT trial is studying patients whose Cushing's syndrome is caused by a benign adrenal tumor. Half of the patients in GRADIENT will receive relacorilant for 26 weeks and half will receive placebo. The trial's primary endpoints are improvement in glucose metabolism and hypertension. The planned enrollment for this study is 130 patients. Many of the clinical sites in GRACE are participating in GRADIENT.

The FDA and the EC have designated relacorilant as an orphan drug for the treatment of Cushing's syndrome.

Oncology

There is substantial in vitro, in vivo and clinical evidence that cortisol's activity allows certain types of solid tumors to resist treatment. Many types of solid tumors express GR and are potential targets for cortisol modulation therapy.

Relacorilant in Patients with Advanced Ovarian Cancer. In May 2021, we announced positive preliminary results from our 178-patient, controlled, multi-center, Phase 2 trial of relacorilant combined with nab-paclitaxel in patients with platinum resistant ovarian cancer.

Based on these positive results, we plan to initiate a pivotal Phase 3 trial in the second quarter of 2022.

Exicorilant and Relacorilant in Patients with Castration-Resistant Prostate Cancer ("CRPC"). Androgen deprivation is the standard treatment for metastatic prostate cancer. Tumors often escape androgen deprivation therapy when cortisol activity at GR supplants androgen activity at its receptor in stimulating tumor growth. We are conducting a dose-finding trial of our proprietary, selective cortisol modulator exicorilant in combination with enzalutamide in patients with metastatic CRPC. Investigators at the University of Chicago are conducting a dose-finding trial of relacorilant combined with enzalutamide in the same patient population.

Relacorilant in Patients with Adrenal Cancer with Cortisol Excess. We are conducting an open-label, Phase 1b trial of relacorilant plus the PD-1 checkpoint inhibitor pembrolizumab in 20 patients with metastatic or unresectable adrenal cancer with cortisol excess. The trial is examining whether adding relacorilant to pembrolizumab therapy reduces cortisol-activated immune suppression sufficiently to help pembrolizumab achieve its intended tumor-killing effect, while relacorilant treats the Cushing's syndrome caused by excess cortisol activity.

Metabolic Diseases

AIWG. We are conducting two double-blind, placebo-controlled, Phase 2 trials of miricorilant in patients with AIWG – GRATITUDE and GRATITUDE II.

GRATITUDE is evaluating whether a daily dose of miricorilant can reverse recent AIWG. Study participants receive their established antipsychotic medication plus either miricorilant or placebo for 12 weeks. GRATITUDE has planned enrollment of 100 patients with schizophrenia or bipolar disorder and is being conducted at 30 sites in the United States.

GRATITUDE II is evaluating whether miricorilant can reverse long-standing AIWG. Study participants receive their established antipsychotic medication plus either miricorilant or placebo for 26 weeks. GRATITUDE II has planned enrollment of 150 patients with schizophrenia and is being conducted at 35 centers in the United States.

The primary endpoint in both the GRATITUDE and GRATITUDE II trials is the change in body weight from baseline, relative to placebo.

Liver Disease. We are also studying miricorilant as a potential treatment for nonalcoholic steatohepatitis ("NASH"). In April 2021, we suspended our Phase 2a trial after observing elevated liver enzymes in four of the five patients who received miricorilant, which resolved after miricorilant was withdrawn. The patients with elevated liver enzymes exhibited large, rapid reductions in liver fat. We are conducting a Phase 1b dose-finding trial in patients with presumed NASH to see if an alternative dosing regimen can capture this benefit without causing excessive liver irritation.

Neurological Disorders

Our selective cortisol modulator dazucorilant (formerly "CORT113176"), which has shown promise in animal models of amyotrophic lateral sclerosis ("ALS"), has completed its Phase 1 trial. We plan to advance it to Phase 2 as a potential treatment for that disease.

COVID-19 Pandemic

Much of the world is subject to varying degrees of pandemic-related public health restrictions, including California, where we are headquartered, and in the jurisdictions where our vendors are located and where we sell Korlym and conduct clinical trials.

These restrictions, as well as measures voluntarily undertaken by patients, physicians, hospitals and medical clinics, have reduced our revenue and make it difficult to grow our Korlym business.

The pandemic's impact on the pace of our clinical development programs has been variable. Our trials of indications not considered immediately life-threatening, such as Cushing's syndrome, CRPC and AIWG have experienced slower enrollment. In addition, some clinical sites have stopped enrolling new patients or have reduced the frequency with which physicians see study participants. Some sites have suspended or halted the initiation of new clinical trials. Our trials in patients with immediately life-threatening diseases, such as advanced pancreatic and ovarian cancer, did not encounter delays.

We expect that pandemic-related impediments to our business will continue so long as there are COVID-19 public health restrictions and risk-reducing behavior by physicians and patients in the locations where we do business and conduct our clinical trials.

Please see "COVID-19 Pandemic" under Item 1 of this Annual Report and the risk factor under Item 1A of this Annual Report, *"The COVID-19 pandemic has adversely affected and is continuing to adversely affect our business. Other public*

health emergencies, natural disasters, terrorism or other catastrophes could disrupt our activities and render our own or our vendors' facilities and equipment inoperable or inaccessible and require us to curtail or cease operations."

Results of Operations

Net Product Revenue – Net product revenue is gross product revenue from sales to our customers less deductions for estimated government rebates and chargebacks.

Net product revenue was $366.0 million for the year ended December 31, 2021, compared to $353.9 million and $306.5 million for the years ended December 31, 2020 and 2019, respectively. For the years ended December 31, 2021 and 2020, higher sales volumes accounted for 20.7 percent and 31.9 percent of the increases, respectively, as we shipped Korlym to more patients. Increases in the average price of Korlym accounted for the remaining growth. The increase in Korlym's price for the year ended December 31, 2021 was primarily due to a price increase effective March 1, 2021.

Cost of sales – Cost of sales includes the cost of API, tableting, packaging, personnel, overhead, stability testing and distribution.

Cost of sales was $5.3 million for the year ended December 31, 2021, compared to $5.6 million and $5.5 million for the years ended December 31, 2020 and 2019, respectively. Cost of sales as a percentage of revenue was 1.4 percent, 1.6 percent and 1.8 percent for the years ended December 31, 2021, 2020 and 2019, respectively. The decreases in cost of sales as a percentage of revenue are due to the increased average price of Korlym and reduced manufacturing costs.

Research and development expense – Research and development expense includes the cost of (1) recruiting and compensating development personnel, (2) clinical trials, (3) drug product and preclinical studies in support of clinical trials and regulatory submissions, (4) discovery research and (5) the development of drug formulations and manufacturing processes.

Research and development expense was $113.9 million for the year ended December 31, 2021, compared to $114.8 million for the comparable period in 2020. The decrease was primarily due to a decline in spending on our oncology program due to timing and completion of patient enrollments in our clinical trials, partially offset by increased spending on employee recruiting and compensation expenses and the advancement of our other development programs.

Research and development expense was $114.8 million for the year ended December 31, 2020, compared to $89.0 million for the comparable period in 2019. The increase was due to increased spending on the advancement of our development programs and employee recruiting and compensation expenses.

	Year Ended December 31,		
	2021	2020[1]	2019[1]
	(in thousands)		
Development programs:			
Oncology	$ 17,984	$ 34,207	$ 20,657
Cushing's syndrome	28,639	26,821	24,010
Metabolic diseases	20,594	20,408	19,545
Pre-clinical and early-stage selective cortisol modulators	21,924	14,726	10,546
Unallocated activities, including manufacturing and regulatory activities	10,617	7,380	4,718
Stock-based compensation	14,106	11,222	9,541
Total research and development expense	$ 113,864	$ 114,764	$ 89,017

[1] Beginning in the first quarter of 2021, expenses for the years ended December 31, 2020 and 2019 previously allocated to oncology and endocrinology were re-allocated between Cushing's syndrome, metabolic diseases and pre-clinical development programs.

It is difficult to predict the timing and cost of development activities, which are subject to many uncertainties and risks, including inconclusive or negative results, slow patient enrollment, adverse side effects, difficulties in the formulation or manufacture of study drugs and the lack of drug-candidate efficacy. In addition, clinical development is subject to government oversight and regulations that may change without notice. We expect our research and development expense to be higher in 2022 than in 2021 as our clinical programs advance. Research and development spending in future years will depend on the outcome of our pre-clinical and clinical trials and our development plans.

Selling, general and administrative expense - Selling, general and administrative expense includes (1) compensation of employees, consultants and contractors engaged in commercial and administrative activities, (2) the cost of vendors supporting commercial activities and (3) legal and accounting fees.

Selling, general and administrative expense was $122.4 million for the year ended December 31, 2021, compared to $105.3 million for the comparable period in 2020. The increase was primarily due to increases in employee recruiting and compensation expenses, sales and marketing expenses and professional services.

Selling, general and administrative expense was $105.3 million for the year ended December 31, 2020, compared to $100.4 million for the comparable period in 2019. The increase was primarily due to increases in employee recruiting and compensation expenses, legal and marketing costs, volume-related pharmacy and other distribution costs and professional service fees.

We expect our selling, general and administrative expense to be higher in 2022 than in 2021 due to increased commercial and administrative activities, including litigation and administrative support for increased research and development.

Interest and other income - Interest and other income for the years ended December 31, 2021, 2020 and 2019 was $0.5 million, $3.4 million and $5.1 million, respectively, and consisted primarily of interest income from marketable securities. Interest and other income decreased for the year ended December 31, 2021 from the comparable periods in 2020 and 2019 primarily due to market-wide reductions in interest rates.

Income tax expense - Income tax expense was $12.5 million for the year ended December 31, 2021, compared to $25.6 million for the comparable period in 2020. The decrease in income tax expense was due to a decrease in our effective tax rate from 10 percent for the year ended December 31, 2021 compared to 19.4 percent for the comparable period in 2020. The decrease in the effective tax rate in 2021 as compared to 2020 and 2019 is primarily due to increased excess tax benefits from stock-based compensation in 2021. While our core effective tax rate has remained relatively consistent throughout the years, the tax rate can vary based upon the timing of provisions related to discrete tax items, including current and future excess tax benefits from stock-based compensation.

Liquidity and Capital Resources

Since 2015, we have relied on revenues from the sale of Korlym to fund our operations.

Based on our current plans and expectations, we expect to fund our operations and planned research and development activities over the next 12 months and beyond without needing to raise additional funds, although we may choose to raise additional funds for other reasons. If we were to raise funds, equity financing would be dilutive, debt financing could involve restrictive covenants and funds raised through collaborations with other companies may require us to relinquish certain rights in our product candidates.

As of December 31, 2021, we had cash, cash equivalents and marketable securities of $335.8 million, consisting of cash and cash equivalents of $77.6 million and marketable securities of $258.2 million, compared to cash, cash equivalents and marketable securities of $476.9 million, consisting of cash and cash equivalents of $76.2 million and marketable securities of $400.7 million as of December 31, 2020.

The cash in our bank accounts and our marketable securities could be affected if the financial institutions holdings them were to fail or severely adverse conditions were to rise in the markets for public or private debt securities. We have never experienced a loss or lack of access to cash.

Net cash provided by operating activities for the years ended December 31, 2021, 2020 and 2019 was $167.9 million, $152.0 million and $136.1 million, respectively. These increases were primarily due to higher revenue as a result of increases in Korlym's price and shipping volume.

Net cash provided by investing activities for the year ended December 31, 2021 was $136.1 million. Net cash used in investing activities for the years ended December 31, 2020 and 2019 was $119.3 million and $117.8 million, respectively. The change in net cash from investing activities for the year ended December 31, 2021 compared to 2020 was primarily due to our use of cash for financing activities (specifically, the repurchase of our common stock) instead of increasing our investment in marketable securities. The change in net cash used in investing activities for the years ended December 31, 2020 compared to 2019 was primarily due to increased purchases of marketable securities with cash generated by our operating activities.

In the year ended December 31, 2021, we spent $318.8 million acquiring shares of our common stock ($207.5 million pursuant to our tender offer, $88.5 million pursuant to our Stock Repurchase Program that expired on September 31, 2021 and $22.8 million in connection with the net exercise of employee and director stock options), offset by $16.2 million received from

the exercise of stock options, resulting in net cash used in financing activities of $302.6 million. In the comparable periods in 2020 and 2019, we spent $11.0 million and $37.1 million, respectively, acquiring shares of our common stock, offset by $23.2 million and $8.4 million received from the exercise of stock options, respectively, resulting in net cash provided by financing activities of $12.2 million for the year ended December 31, 2020 and net cash used in financing activities of $28.6 million for the year ended December 31, 2019.

As of December 31, 2021, we had retained earnings of $195.0 million.

Manufacturing Purchase Commitments

We have other contractual payment obligations and purchase commitments, the timing of which are contingent on future events, including the initiation and completion of manufacturing projects. In March 2014, we entered into a long-term agreement with one contract manufacturer, PCAS to produce mifepristone, the API for Korlym. On July 25, 2018, we amended this agreement to add a second manufacturing site and extend its term to December 31, 2021, with two one-year automatic renewals, unless either party provides 12 months advance written notice of its intent not to renew. The amendment provides exclusivity between PCAS and Corcept. If PCAS is unable to meet our requirements, we may purchase mifepristone from another supplier.

We have agreements with two third-party manufacturers to produce and bottle Korlym tablets.

As of December 31, 2021, we had $2.0 million remaining in commitments to purchase API from PCAS and have a $0.1 million commitment to purchase Korlym tablets.

Net Operating Loss Carryforwards

See Note 9*, Income Taxes* in our audited consolidated financial statements.

Critical Accounting Policies and Estimates

Our consolidated financial statements have been prepared in accordance with U.S. GAAP, which requires us to make estimates and judgments that affect the amount of assets, liabilities and expenses we report. We base our estimates on historical experience and on other assumptions we believe to be reasonable. Actual results may differ from our estimates. Our significant accounting policies are described in Note 1, ***Basis of Presentation and Summary of Significant Accounting Policies***, of the Notes to Consolidated Financial Statements included in Part IV of this Annual Report on Form 10-K. We believe the following accounting estimates and policies to be critical:

Net Product Revenue

To determine net product revenue, we deduct from sales the cost of our patient co-pay assistance program and our estimates of (i) government chargebacks and rebates, (ii) discounts provided to our specialty distributor ("SD") for prompt payment and (iii) reserves for expected returns. We record these estimates at the time we recognize revenue and update them as new information becomes available. Our estimates take into account our understanding of the range of possible outcomes. If results differ from our estimates, we adjust our estimates, which changes our net product revenue and earnings. We report any changes in the period they become known, even if they concern transactions occurring in prior periods.

Government Rebates

Korlym is eligible for purchase by, or qualifies for reimbursement from, Medicaid and other government programs that are eligible for rebates on the price they pay for Korlym. To determine the appropriate amount to reserve against these rebates, we identify Korlym sold to patients covered by government-funded programs, apply the applicable government discount to these sales, then estimate the portion of total rebates we expect will be claimed. We (i) deduct this reserve from revenue in the period to which the rebates relate and (ii) include in accrued expenses on our consolidated balance sheet a current liability of equal amount.

Chargebacks

Although we sell Korlym to the SD at full price, some of the government entities to which the SD sells receive a discount. The SD recovers the full amount of any related discounts by reducing its payment to us (this reduction is called a "chargeback"). Chargebacks sometimes relate to Korlym sold to the SD in prior periods. We deduct from our revenue in each period chargebacks claimed by the SD for Korlym we sold to the SD that period. We also create a reserve for chargebacks we estimate the SD will claim in future periods against Korlym it purchased in the current period but has not yet resold. We determine the amount of this reserve based on our experience with SD chargebacks and our understanding of the SD's customer

base and business practices. We deduct this reserve from revenue and include in accrued expenses on our consolidated balance sheet a current liability of equal amount.

Patient Assistance Program and Charitable Support

It is our policy that no patient be denied Korlym due to inability to pay. We provide financial assistance to eligible patients whose insurance policies have high deductibles or co-payments and deduct the amount of such assistance from gross revenue. We determine the assistance we provide each patient by applying our program guidelines to that patient's financial position and their insurance policy's co-payment and deductible requirements. We also donate cash to charities that help patients with financial need pay for the treatment of Cushing's syndrome (which treatment may not include Korlym). We do not include in our revenue payments these charities make on behalf of patients receiving Korlym. We provide Korlym at no cost to uninsured patients who do not qualify for charitable support.

Sales Returns

Federal law prohibits the return of Korlym sold to patients. Sales to our SD are subject to return. We deduct the amount of Korlym we estimate the SD will return from each period's gross revenue. We base our estimates on quantitative and qualitative information including, but not limited to, historical return rates, the amount of Korlym held by the SD and projected demand. To date, returns have not been material.

Inventory and Cost of Sales

We value inventory at the lower of cost or net realizable value and determine the cost of inventory we sell using the specific identification method, which approximates a first-in, first-out basis. We assess our inventory levels at each reporting period and write down inventory that is either expected to be at risk of expiration prior to sale, has a cost basis in excess of its expected net realizable value, or for which there are inventory quantities in excess of expected requirements. We destroy expired inventory and recognize the related costs as cost of sales in that period's statement of comprehensive income.

Cost of sales includes the cost of manufacturing Korlym, including materials, third-party manufacturing costs and indirect personnel and other overhead costs, based on the number of Korlym tablets for which we recognize revenue, as well as costs of stability testing, logistics and distribution.

Recently Issued Accounting Pronouncements

See Note 1, *Basis of Presentation and Summary of Significant Accounting Policies* in our audited consolidated financial statements.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

The primary objective of our investment activities is to preserve capital. As of December 31, 2021, the fair value of our cash and cash equivalents and marketable securities was $335.8 million. Our marketable securities consisted of corporate notes, commercial paper, asset-backed securities, U.S. Treasury securities and a money market fund invested in short-term U.S. Treasury securities maintained at a major U.S. financial institution. To minimize our exposure to interest rate and other market risks, we have limited the maturities of our investments to less than three years, with the duration of our portfolio not to exceed two years. Additionally, except for securities issued by the United States government or its agencies, securities of any one issuer may not make up more than ten percent of our portfolio's market value. Due to the short-term nature and high liquidity of these instruments, an increase or decrease in market interest rates by 25 basis points would not have a material impact on the total value of our portfolio as of December 31, 2021.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The consolidated financial statements required by this item are set forth beginning at page F-1 and are incorporated herein by reference.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

(a) Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in the reports we file with the SEC is recorded, processed, summarized and filed within the time periods specified in the SEC's rules and forms and that such information is accumulated and discussed with our management, including our Chief Executive Officer and Chief Financial Officer, so as to allow timely decisions regarding disclosure. Management recognizes that controls and procedures, no matter how well designed and operated, can only provide reasonable, not absolute, assurance the desired control objectives will be met. In reaching a reasonable level of assurance, management has weighed the cost of contemplated controls against their intended benefits. The design of any system of controls is based on management's assumptions about the likelihood of future events. We cannot assure you that our controls will achieve their stated goals under all possible conditions. Changes in future conditions may render our controls inadequate or may cause our degree of compliance with them to deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

As of December 31, 2021, our Chief Executive Officer and Chief Financial Officer evaluated our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act). Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level.

During the quarter ended March 31, 2021, we completed the implementation of an enterprise resource planning ("ERP") system, which we expect will improve the efficiency of certain financial and related transactional processes. We changed our internal controls so that they continue to operate effectively following the ERP implementation. Our Chief Financial Officer and other members of management evaluated the changes in our internal control over financial reporting during the quarter ended December 31, 2021 and concluded that there was no change during the quarter that materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

(b) Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rule 13a-15(f). Our internal control system is designed to provide reasonable assurance regarding the preparation and fair presentation of externally-reported consolidated financial statements in accordance with U.S. GAAP. As discussed in Item 9A(a) above, internal control systems, no matter how well designed, have inherent limitations and can provide only reasonable assurance that their objectives have been met.

As of December 31, 2021, our management conducted an evaluation, under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer, of the effectiveness of our internal control over financial reporting based upon the framework in "Internal Control-Integrated Framework (2013)" issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our internal control over financial reporting was effective as of December 31, 2021.

Our independent registered public accounting firm has issued an attestation report on our internal control over financial reporting. It is set forth below.

(c) Report of Independent Registered Public Accounting Firm

To the Stockholders and Board of Directors of Corcept Therapeutics Incorporated

Opinion on Internal Control over Financial Reporting

We have audited Corcept Therapeutics Incorporated's internal control over financial reporting as of December 31, 2021, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). In our opinion, Corcept Therapeutics Incorporated (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2021, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets as of December 31, 2021 and 2020, the related consolidated statements comprehensive income, cash flows and stockholders' equity for each of the three years in the period ended December 31, 2021, and the related notes and our report dated February 15, 2022 expressed an unqualified opinion thereon.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control Over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ Ernst & Young LLP

Redwood City, California

February 15, 2022

ITEM 9B. OTHER INFORMATION

None.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

PART III

Certain information required by Part III is omitted from this Form 10-K because we expect to file with the United States Securities and Exchange Commission, not later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K, a definitive proxy statement ("Proxy Statement"), pursuant to Regulation 14A in connection with the solicitation of proxies for our 2022 Annual Meeting of Stockholders, and certain information included therein is incorporated herein by reference.

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this Item will be included in the Proxy Statement and is incorporated herein by reference.

ITEM 11. EXECUTIVE COMPENSATION

Compensation Discussion and Analysis

The information required by this Item will be included in the Proxy Statement and is incorporated herein by reference.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this Item will be included in the Proxy Statement and is incorporated herein by reference.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by this Item will be included in the Proxy Statement and is incorporated herein by reference.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required by this Item will be included in the Proxy Statement and is incorporated herein by reference.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

The following documents are filed as part of this Form 10-K

(1) Financial Statements:

(2) Financial Statement Schedules:

All schedules have been omitted because the information required to be set forth therein is not applicable or is shown in the financial statements or notes thereto.

(3) Exhibits:

Item 601 of Regulation S-K requires the exhibits listed below. Each management contract or compensatory plan or arrangement required to be filed as an exhibit to this Form 10-K has been identified.

(A) EXHIBITS

Exhibit Number	Description of Document
3.1	Amended and Restated Certificate of Incorporation, as amended (incorporated by reference to Exhibit 3.1 to the registrant's Quarterly Report on Form 10-Q filed on August 9 2012).
3.2	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.1 to the registrant's Current Report on Form 8-K filed on February 13, 2017).
4.1	Specimen Common Stock Certificate (incorporated by reference to Exhibit 4.1 to the registrant's Registration Statement on Form S-1 (Registration No. 333-112676) filed on February 10, 2004).
4.2	Description of Common Stock (incorporated by reference to Exhibit 4.2 to the registrant's Annual Report on Form 10-K filed on February 23, 2021)
4.3	Registration Rights Agreement by and among Corcept Therapeutics Incorporated and the investors signatory thereto, dated March 14, 2008 (incorporated by reference to Exhibit 10.25 to the registrant's Annual Report on Form 10-K filed on March 31, 2008).
4.4	Amendment to Registration Rights Agreement by and among Corcept Therapeutics Incorporated and the investors signatory thereto, dated November 11, 2008 (incorporated by reference to Exhibit 10.30 to the registrant's Annual Report on Form 10-K filed on March 31, 2009).
4.5	Registration Rights Agreement dated as of April 21, 2010 by and among Corcept Therapeutics Incorporated and the investors signatory thereto (incorporated by reference to Exhibit 4.2 to the registrant's Current Report on Form 8-K filed on April 23, 2010).
4.6	Registration Rights Agreement, dated as of March 29, 2012, by and among Corcept Therapeutics Incorporated and the investors signatory thereto (incorporated by reference to Exhibit 4.2 to the registrant's Current Report on Form 8-K filed on March 29, 2012).

Exhibit Number	Description of Document
10.1	License Agreement by and between The Board of Trustees of the Leland Stanford Junior University and Corcept Therapeutics Incorporated, dated as of July 1, 1999 (incorporated by reference to Exhibit 10.6 to the registrant's Registration Statement on Form S-1 (Registration No. 333-112676) filed on February 10, 2004).
10.2#	Manufacturing Agreement with Produits Chimiques Auxiliaires et de Synthese SA, dated November 8, 2006 (incorporated by reference to Exhibit 10.15 to the registrant's Annual Report on Form 10-K filed on April 2, 2007).
10.3†	Form of Indemnification Agreement for directors and officers approved by the Board of Directors on September 24, 2007 (incorporated by reference to Exhibit 10.7 to the registrant's Quarterly Report on Form 10-Q filed on November 14, 2007).
10.4	Securities Purchase Agreement by and among Corcept Therapeutics Incorporated and the purchasers named therein, dated March 14, 2008 (incorporated by reference to Exhibit 10.24 to the registrant's Annual Report on Form 10-K filed on March 31, 2008).
10.5†	Amended and Restated Severance and Change in Control Agreement by and between Corcept Therapeutics Incorporated and Joseph K. Belanoff, M. D., dated September 19, 2008 (incorporated by reference to Exhibit 10.25 to the registrant's Annual Report on Form 10-K filed on March 31, 2009).
10.6†	Amended and Restated Severance and Change in Control Agreement by and between Corcept Therapeutics Incorporated and James N. Wilson, dated September 19, 2008 (incorporated by reference to Exhibit 10.28 to the registrant's Annual Report on Form 10-K filed on March 31, 2009).
10.7†	Amended and Restated 2004 Equity Incentive Plan (incorporated by reference to the registrant's Proxy Statement on Schedule 14A filed on May 7, 2009).
10.8	Securities Purchase Agreement by and among Corcept Therapeutics Incorporated and the purchasers named therein, dated October 12, 2009 (incorporated by reference to Exhibit 10.1 to the registrant's Quarterly Report on Form 10-Q filed on November 12, 2009).
10.9†	Form of Option Agreement for options granted pursuant to the Amended and Restated 2004 Equity Incentive Plan (incorporated by reference to Exhibit 10.25 to the registrant's Annual Report on Form 10-K filed on March 15, 2011).
10.10†	Severance and Change in Control Agreement by and between Corcept Therapeutics Incorporated and Charles Robb, dated September 1, 2011 (incorporated by reference to Exhibit 10.2 to the registrant's Quarterly Report on Form 10-Q filed on November 8, 2011).
10.11†	Employment offer letter to Charles Robb dated August 12, 2011 (incorporated by reference to Exhibit 10.1 to the registrant's Quarterly Report on Form 10-Q filed on November 8, 2011).
10.12†	Corcept Therapeutics Incorporated 2012 Incentive Award Plan (incorporated by reference to Appendix A to the registrant's Definitive Proxy Statement on Schedule 14A filed with the SEC on May 21, 2012).
10.13#	Commercial Outsourcing Services Agreement with Integrated Commercialization Solutions, Inc., dated as of April 14, 2011 (incorporated by reference to Exhibit 10.1 to the registrant's Quarterly Report on Form 10-Q filed on August 9, 2012).
10.14†	Form of 2012 Incentive Award Plan Stock Option Grant Notice and Agreement
10.15	Amendment to Manufacturing Agreement with Produits Chimiques Auxiliaires et de Synthese SA, dated February 21, 2013 (incorporated by reference to Exhibit 10.31 to the registrant's Annual Report on Form 10-K filed on March 15, 2013).
10.16#	Pharmaceutical Manufacturer Services Agreement with Centric Health Resources, Inc., dated May 21, 2013 (incorporated by reference to Exhibit 10.1 to the registrant's Quarterly Report on Form 10-Q filed on August 9, 2013).
10.17#	Amendment to Pharmaceutical Manufacturer Services Agreement with Centric Health Resources, Inc., dated July 22, 2013 (incorporated by reference to Exhibit 10.3 to the registrant's Quarterly Report on Form 10-Q filed on August 9, 2013).
10.18	Amendment to Manufacturing Agreement with Produits Chimiques Auxiliaires et de Synthese SA, dated August 1, 2013 (incorporated by reference to Exhibit 10.4 to the registrant's Quarterly Report on Form 10-Q filed on August 9, 2013).

Exhibit Number	Description of Document
10.19	Amendment to Manufacturing Agreement with Produits Chimiques Auxiliaires et de Synthese SA, dated November 7, 2013 (incorporated by reference to Exhibit 10.1 to the registrant's Quarterly Report on Form 10-Q filed on November 12, 2013).
10.20	Amendment to Manufacturing Agreement with Produits Chimiques Auxiliaires et de Synthese SA, dated January 27, 2014 (incorporated by reference to Exhibit 10.34 to the registrant's Annual Report on Form 10-K filed on March 14, 2014).
10.21#	Manufacturing and Supply Agreement with Produits Chimiques Auxiliaires et de Synthese SA, dated March 20, 2014 (incorporated by reference to Exhibit 10.2 to the registrant's Quarterly Report on Form 10-Q filed on May 12, 2014).
10.22	First Amendment to the Commercial Outsourcing Services Agreement with Integrated Commercialization Solutions, Inc., effective as of April 14, 2014 (incorporated by reference to Exhibit 10.1 to the registrant's Quarterly Report on Form 10-Q filed on August 8, 2014).
10.23#	Manufacturing Agreement with AAI Pharma Services Corp., dated April 7, 2014 (incorporated by reference to Exhibit 10.2 to the registrant's Quarterly Report on Form 10-Q filed on August 8, 2014).
10.24	Second Amendment to the Commercial Outsourcing Services Agreement with Integrated Commercialization Solutions, Inc., effective as of June 11, 2014 (incorporated by reference to Exhibit 10.3 to the registrant's Quarterly Report on Form 10-Q filed on August 8, 2014).
10.25	Third Amendment to the Commercial Outsourcing Services Agreement with Integrated Commercialization Solutions, Inc., effective as of August 11, 2014 (incorporated by reference to Exhibit 10.1 to the registrant's Quarterly Report on Form 10-Q filed on November 7, 2014).
10.26#	Second Amendment to Pharmaceutical Manufacturer Services Agreement with Dohmen Life Science Services, LLC (as successor in interest to Centric Health Resources, Inc.) dated October 6, 2014 (incorporated by reference to Exhibit 10.41to the registrant's Annual Report on Form 10K filed on March 13, 2015).
10.27†	Employment offer letter to Robert S. Fishman dated September 16, 2015 (incorporated by reference to Exhibit 10.2 to the registrant's Quarterly Report on Form 10-Q filed on November 6, 2015).
10.28†	Severance and Change in Control Agreement by and between Corcept Therapeutics Incorporated and Robert S. Fishman, dated September 28, 2015 (incorporated by reference to Exhibit 10.3 to the registrant's Quarterly Report on Form 10-Q filed on November 6, 2015).
10.29#	Distribution Services Agreement, dated August 4, 2017, between Corcept Therapeutics Incorporated and Optime Care, Inc. (incorporated by reference to Exhibit 10.1 to the registrant's Quarterly Report on Form 10-Q filed on November 3, 2017).
10.30#	Task Order Number One to Distribution Services Agreement, dated August 4, 2017, between Corcept Therapeutics Incorporated and Optime Care, Inc. (incorporated by reference to Exhibit 10.2 to the registrant's Quarterly Report on Form 10-Q filed on November 3, 2017.
10.31#	Amendment N°1 to the Manufacturing and Supply Agreement effective 19 March 2014 with PCAS SA, dated July 25, 2018
10.32†	Severance and Change in Control Agreement by and between Corcept Therapeutics Incorporated and Andreas Grauer, M.D. dated March 18, 2019 (incorporated by reference to Exhibit 10.1 to the registrant's Quarterly Report on Form 10-Q filed on May 9, 2019).
10.33†	Employment offer letter to Andreas Grauer, M.D. dated March 18, 2019 (incorporated by reference to Exhibit 10.2 to the registrant's Quarterly Report on Form 10-Q filed on May 9, 2019).
10.34	Office Lease Agreement by and between Exponent Realty, LLC and Corcept Therapeutics Incorporated, effective as of April 1, 2016.
10.35	First Amendment to Office Lease Agreement by and between Exponent Realty, LLC and Corcept Therapeutics Incorporated, made and entered into as of June 1, 2017.
10.36	Second Amendment to Office Lease Agreement by and between Exponent Realty, LLC and Corcept Therapeutics Incorporated, made and entered into as of March 12, 2018.
10.37	Third Amendment to Office Lease Agreement by and between Exponent Realty, LLC and Corcept Therapeutics Incorporated, made and entered into as of November 8, 2018.

Exhibit Number	Description of Document
10.38	Fourth Amendment to Office Lease Agreement by and between Exponent Realty, LLC and Corcept Therapeutics Incorporated, made and entered into as of October 23, 2019.
10.39†	Severance and Change in Control Agreement by and between Corcept Therapeutics Incorporated and Hazel Hunt, dated August 3, 2020 (incorporated by reference to Exhibit 10.1 to the registrant's Quarterly Report on Form 10-Q filed on August 4, 2020).
10.40†	Severance and Change in Control Agreement by and between Corcept Therapeutics Incorporated and Joseph Douglas ("J.D.") Lyon, dated August 3, 2020 (incorporated by reference to Exhibit 10.2 to the registrant's Quarterly Report on Form 10-Q filed on August 4, 2020).
10.41†	Severance and Change in Control Agreement by and between Corcept Therapeutics Incorporated and Sean Maduck, dated August 3, 2020 (incorporated by reference to Exhibit 10.3 to the registrant's Quarterly Report on Form 10-Q filed on August 4, 2020).
10.42	Fifth Amendment to Office Lease Agreement by and between Exponent Realty, LLC and Corcept Therapeutics Incorporated, made and entered into as of June 17, 2020 (incorporated by reference to Exhibit 10.4 to the registrant's Quarterly Report on Form 10-Q filed on August 4, 2020).
10.43	Sixth Amendment to Office Lease Agreement by and between Exponent Realty, LLC and Corcept Therapeutics Incorporated, made and entered into as of July 22, 2020 (incorporated by reference to Exhibit 10.1 to the registrant's Quarterly Report on Form 10-Q filed on November 3, 2020).
10.44†	Employment offer letter to Atabak Mokari, dated March 1, 2021 (incorporated by reference to Exhibit 10.1 to the registrant's Current Report on Form 8-K filed on March 1, 2021).
10.45†	Severance and Change in Control Agreement by and between Corcept Therapeutics Incorporated and Atabak Mokari, dated March 1, 2021 (incorporated by reference to Exhibit 10.2 to the registrant's Current Report on Form 8-K filed on March 1, 2021).
10.46†	Separation Agreement by and between Corcept Therapeutics Incorporated and Andreas Grauer, M.D., dated August 11, 2021 (incorporated by reference to Exhibit 10.1 to the registrant's Current Report on Form 8-K filed on August 10, 2021).
10.1	Employment offer letter to William Guyer, dated July 2, 2021.
10.2	Severance and Change in Control Agreement by and between Corcept Therapeutics Incorporated and William Guyer, dated February 9, 2022.
23.1	Consent of Independent Registered Public Accounting Firm
24.1	Power of Attorney (See signature page)
31.1	Certification pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934 of Joseph K. Belanoff, M.D.
31.2	Certification pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934 of Atabak Mokari
32.1	Certification pursuant to 18 U.S.C. Section 1350 of Joseph K. Belanoff, M.D.
32.2	Certification pursuant to 18 U.S.C. Section 1350 of Atabak Mokari
101.INS	XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document
101.SCH	XBRL Schema Document
101.CAL	XBRL Calculation Linkbase Document
101.DEF	XBRL Definition Linkbase Document
101.LAB	XBRL Labels Linkbase Document
101.PRE	XBRL Presentation Linkbase Document

Exhibit Number	Description of Document
104	Cover Page Interactive Data File - the cover page interactive data file does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL Document

Confidential treatment granted

† Management contract or compensatory plan or arrangement

ITEM 16. FORM 10-K SUMMARY

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

CORCEPT THERAPEUTICS INCORPORATED

By: /s/ JOSEPH K. BELANOFF

Joseph K. Belanoff, M.D.,
Chief Executive Officer and President

Date: February 15, 2022

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints Joseph K. Belanoff and Atabak Mokari, and each of them acting individually, as his or her true and lawful attorneys-in-fact and agents, each with full power of substitution, for him or her in any and all capacities, to sign any and all amendments to this report on Form 10-K and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, with full power of each to act alone, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully for all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or his or their substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Exchange Act, this Annual Report on Form 10-K has been signed by the following persons on behalf of the registrant and in the capacities and on the dates indicated:

Signature	Title	Date
/s/ JOSEPH K. BELANOFF **Joseph K. Belanoff, M.D.**	Chief Executive Officer, President and Director (Principal Executive Officer)	February 15, 2022
/s/ ATABAK MOKARI **Atabak Mokari**	Chief Financial Officer (Principal Financial Officer)	February 15, 2022
/s/ JOSEPH DOUGLAS LYON **Joseph Douglas Lyon**	Chief Accounting Officer (Principal Accounting Officer)	February 15, 2022
/s/ JAMES N. WILSON **James N. Wilson**	Director and Chairman of the Board of Directors	February 15, 2022
/s/ GREGG ALTON **Gregg Alton**	Director	February 15, 2022
/s/ G. LEONARD BAKER, JR. **G. Leonard Baker, Jr.**	Director	February 15, 2022
/s/ GILLIAN CANNON **Gillian Cannon**	Director	February 15, 2022
/s/ DAVID L. MAHONEY **David L. Mahoney**	Director	February 15, 2022
/s/ JOSHUA MURRAY **Joshua Murray**	Director	February 15, 2022
/s/ KIMBERLY PARK **Kimberly Park**	Director	February 15, 2022
/s/ DANIEL N. SWISHER, JR **Daniel N. Swisher, Jr.**	Director	February 15, 2022

CORCEPT THERAPEUTICS INCORPORATED

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and Board of Directors of Corcept Therapeutics Incorporated

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Corcept Therapeutics Incorporated (the Company) as of December 31, 2021 and 2020, the related consolidated statements of comprehensive income, cash flows and stockholders' equity for each of the three years in the period ended December 31, 2021, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2021 and 2020, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2021, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2021, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) and our report dated February 15, 2022 expressed an unqualified opinion thereon.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the account or disclosure to which it relates.

Inventory Excess and Obsolescence Reserve

Description of the matter	As of December 31, 2021, the Company had $18 million of inventory which included $11.5 million of work in progress and $6.5 million of finished goods. As disclosed in Note 1, inventories are stated at the lower of cost or net realizable value. The Company assesses its inventory levels each reporting period and writes down inventory that is either expected to be at risk of expiration prior to sale, or has a cost basis in excess of its expected net realizable value, or for which there are inventory quantities in excess of expected requirements. Auditing management's estimates for excess and obsolete inventory involved subjective auditor judgment because the estimates rely on a number of factors that are affected by market and economic conditions outside the Company's control. In particular, the obsolete and excess inventory calculations are sensitive to significant assumptions, including the expected demand for the Company's products, assumptions about the drug's life cycle, the effect on demand of competitive products and the Company's purchase commitments.
How we addressed the matter in our audit	We obtained an understanding, evaluated the design, and tested the operating effectiveness of internal controls over the Company's excess and obsolete inventory reserve process including management's review of the significant assumptions described above and controls over the completeness and accuracy of the information used to develop the estimate. Our substantive audit procedures included, among others, evaluating methodologies used and data utilized in the analysis for inventory expected to be at risk for expiration or excess. We evaluated purchase commitments or alternative uses, compared forecasted demand to historical trends, compared actual inventory levels to forecasted demand requirements and evaluated the sensitivity of sales forecast assumptions on the amount of inventory reserves recorded.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2001.

Redwood City, California
February 15, 2022

CORCEPT THERAPEUTICS INCORPORATED

CONSOLIDATED BALANCE SHEETS
(In thousands, except per share data)

	December 31,	
	2021	**2020**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 77,617	$ 76,190
Short-term marketable securities	145,918	364,506
Trade receivables, net of allowances	27,625	26,198
Inventory	4,988	4,910
Prepaid expenses and other current assets	10,315	6,697
Total current assets	266,463	478,501
Strategic inventory	12,962	16,247
Operating lease right-of-use asset	514	2,509
Property and equipment, net of accumulated depreciation	1,002	1,675
Long-term marketable securities	112,277	36,196
Other assets	3,083	5,000
Deferred tax assets, net	27,455	31,603
Total assets	$ 423,756	$ 571,731
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 6,908	$ 10,554
Accrued clinical expenses	12,442	13,704
Accrued and other liabilities	27,665	21,186
Short-term operating lease liability	526	2,050
Total current liabilities	47,541	47,494
Long-term operating lease liability	—	501
Long-term accrued income taxes	409	398
Total liabilities	47,950	48,393
Commitments and contingencies (Note 10)		
Stockholders’ equity:		
Preferred stock, par value $0.001 per share, 10,000 shares authorized and no shares outstanding at December 31, 2021 and December 31, 2020	—	—
Common stock, par value $0.001 per share, 280,000 shares authorized and 127,218 issued and 105,940 outstanding at December 31, 2021 and 122,586 shares issued and 116,735 outstanding at December 31, 2020	127	122
Treasury stock; at cost; 21,278 shares of common stock at December 31, 2021 and 5,851 shares of common stock at December 31, 2020	(410,411)	(75,795)
Additional paid-in capital	591,349	516,140
Accumulated other comprehensive (loss) gain	(227)	415
Retained earnings	194,968	82,456
Total stockholders’ equity	375,806	523,338
Total liabilities and stockholders’ equity	$ 423,756	$ 571,731

The accompanying notes are an integral part of these consolidated financial statements.

CORCEPT THERAPEUTICS INCORPORATED

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME
(In thousands, except per share data)

	Year Ended December 31,		
	2021	**2020**	**2019**
Product revenue, net	$ 365,978	$ 353,874	$ 306,486
Operating expenses:			
Cost of sales	5,281	5,582	5,504
Research and development	113,864	114,764	89,017
Selling, general and administrative	122,356	105,326	100,359
Total operating expenses	241,501	225,672	194,880
Income from operations	124,477	128,202	111,606
Interest and other income	529	3,400	5,070
Income before income taxes	125,006	131,602	116,676
Income tax expense	12,494	25,591	22,495
Net income	$ 112,512	$ 106,011	$ 94,181
Other comprehensive income:			
Net unrealized (loss) gain on available-for-sale investments, net of tax impact of $198, $15 and $(104)	(621)	(50)	327
Foreign currency translation (loss) gain, net of tax	(21)	204	4
Total comprehensive income	$ 111,870	$ 106,165	$ 94,512
Basic net income per share	$ 0.97	$ 0.92	$ 0.82
Diluted net income per share	$ 0.89	$ 0.85	$ 0.77
Weighted average shares outstanding used in computing net income per share			
Basic	115,653	115,412	114,349
Diluted	125,963	124,194	122,566

The accompanying notes are an integral part of these consolidated financial statements.

CORCEPT THERAPEUTICS INCORPORATED

CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	Year Ended December 31,		
	2021	**2020**	**2019**
Cash flows from operating activities:			
Net income	$ 112,512	$ 106,011	$ 94,181
Adjustments to reconcile net income to net cash provided by operations:			
Stock-based compensation	42,931	33,539	29,313
Amortization (accretion) of interest income	5,083	1,303	(1,738)
Depreciation and amortization of property and equipment	1,072	525	703
Deferred income taxes	4,346	14,089	16,877
Non-cash amortization of right-of-use asset	1,995	1,712	1,468
Others	10	148	—
Changes in operating assets and liabilities:			
Trade receivables	(1,427)	(6,270)	(2,340)
Inventory	3,444	(3,514)	(1,044)
Prepaid expenses and other current assets	(3,597)	(653)	1,696
Other assets	1,917	(1,552)	(3,398)
Accounts payable	(3,597)	3,161	(735)
Accrued clinical expenses	(1,262)	7,227	2,956
Accrued and other liabilities	6,479	(2,083)	(517)
Long-term accrued income taxes	11	12	147
Operating lease liability	(2,025)	(1,685)	(1,452)
Net cash provided by operating activities	167,892	151,970	136,117
Cash flows from investing activities:			
Purchases of property and equipment	(469)	(1,238)	(1,088)
Proceeds from maturities of marketable securities	398,937	302,089	182,295
Proceeds from sales of marketable securities	50,463	—	—
Purchases of marketable securities	(312,805)	(420,114)	(299,035)
Net cash provided by (used in) investing activities	136,126	(119,263)	(117,828)
Cash flows from financing activities:			
Proceeds from exercise of stock options, net of issuance costs	16,229	23,226	8,419
Repurchase of common stock in connection with Tender Offer	(207,500)	—	—
Repurchases of common stock in connection with Stock Repurchase Program	(88,485)	(9,945)	(30,975)
Cash paid to satisfy statutory withholding requirement for the net settlement of cashless option exercises	(22,835)	(1,067)	(6,089)
Net cash (used in) provided by financing activities	(302,591)	12,214	(28,645)
Net increase (decrease) in cash and cash equivalents	1,427	44,921	(10,356)
Cash and cash equivalents, at beginning of period	76,190	31,269	41,625
Cash and cash equivalents, at end of period	$ 77,617	$ 76,190	$ 31,269
Supplemental disclosure:			
Income taxes paid	$ 9,104	$ 10,856	$ 6,744
Cost of shares repurchased for net settlement of cashless option exercise	$ 15,796	$ 2,079	$ 1,983
Recognition of right-of-use asset and lease liability	$ —	$ 775	$ 4,913

The accompanying notes are an integral part of these consolidated financial statements

CORCEPT THERAPEUTICS INCORPORATED

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

(In thousands)

	Common Stock		Additional Paid-in Capital	Treasury Stock	Accumulated Other Comprehensive Income (Loss)	Retained Earnings (Accumulated Deficit)	Total Stockholders' Equity
	Shares	Amount					
Balance at December 31, 2018	115,031	$ 117	$ 417,228	$ (23,657)	$ (70)	$ (117,736)	$ 275,882
Issuance of common stock upon exercise of options	2,929	3	10,399	—	—	—	10,402
Shares tendered to satisfy cost and statutory withholding requirements for net settlement of cashless option exercises	(631)	—	—	(8,072)	—	—	(8,072)
Stock-based compensation related to employee and director options	—	—	29,201	—	—	—	29,201
Stock-based compensation related to non-employee options	—	—	232	—	—	—	232
Other comprehensive loss, net of tax	—	—	—	—	331	—	331
Purchase of treasury stock	(2,780)	—	—	(30,975)	—	—	(30,975)
Net income	—	—	—	—	—	94,181	94,181
Balance at December 31, 2019	114,549	120	457,060	(62,704)	261	(23,555)	371,182
Issuance of common stock upon exercise of options	2,819	2	25,303	—	—	—	25,305
Shares tendered to satisfy cost and statutory withholding requirements for net settlement of cashless option exercises	(154)	—	—	(3,146)	—	—	(3,146)
Stock-based compensation related to employee and director options	—	—	33,777	—	—	—	33,777
Other comprehensive income, net of tax	—	—	—	—	154	—	154
Purchase of treasury stock	(479)	—	—	(9,945)	—	—	(9,945)
Net income	—	—	—	—	—	106,011	106,011
Balance at December 31, 2020	116,735	122	516,140	(75,795)	415	82,456	523,338
Issuance of common stock upon exercise of options	4,632	5	32,041	—	—	—	32,046
Shares tendered to satisfy cost and statutory withholding requirements for net settlement of cashless option exercises	(1,560)	—		(38,631)	—	—	(38,631)
Stock-based compensation related to employee and director options	—	—	43,168	—	—	—	43,168
Other comprehensive income, net of tax	—	—	—	—	(642)	—	(642)
Purchase of treasury stock in connection with Stock Repurchase Program	(3,867)	—	—	(88,485)	—	—	(88,485)
Purchase of treasury stock in connection with Tender Offer	(10,000)	—	—	(207,500)	—	—	(207,500)
Net income	—	—	—	—	—	112,512	112,512
Balance at December 31, 2021	105,940	$ 127	$ 591,349	$ (410,411)	$ (227)	$ 194,968	$ 375,806

The accompanying notes are an integral part of these consolidated financial statements

CORCEPT THERAPEUTICS INCORPORATED

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Basis of Presentation and Summary of Significant Accounting Policies

Description of Business and Basis of Presentation

Corcept Therapeutics Incorporated is a commercial-stage pharmaceutical company engaged in the discovery and development of medications that treat severe metabolic, oncologic and neuropsychiatric disorders by modulating the effect of the hormone cortisol. In 2012, the United States Food and Drug Administration ("FDA") approved Korlym ("mifepristone") 300 mg tablets, as a once-daily oral medication for the treatment of hyperglycemia secondary to hypercortisolism in adult patients with endogenous Cushing's syndrome who have type 2 diabetes mellitus or glucose intolerance and have failed surgery or are not candidates for surgery. We have discovered and patented four structurally distinct series of selective cortisol modulators, consisting of more than 1,000 compounds. We are developing compounds from these series as potential treatments for a broad range of serious disorders.

We were incorporated in the State of Delaware in May 1998. Our headquarters are located in Menlo Park, California.

Basis of Presentation

The consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles ("U.S. GAAP").

Principles of Consolidation

Our consolidated financial statements include the financial position and results of operations of Corcept Therapeutics UK Limited, our wholly owned subsidiary, which we incorporated in the United Kingdom in March 2017.

Use of Estimates

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. Actual results could differ materially from those estimates.

We reevaluate our estimates and assumptions each quarter, including those related to revenue recognition, recognition and measurement of income tax assets and liabilities, inventory, allowances for doubtful accounts and other accrued liabilities, including our bonus accrual, clinical trial accruals and stock-based compensation.

Fair Value Measurements

We value financial instruments using assumptions we believe third-party market participants would use. When choosing which assumptions to make when determining the value of a financial instrument, we look first for quoted prices in active markets for identical instruments ("Level 1 inputs"). If no Level 1 inputs are available, we consider (i) quoted prices in non-active markets for identical instruments; (ii) active markets for similar instruments; (iii) inputs other than quoted prices for the instrument; and (iv) inputs that are not directly observable, but that can be corroborated by observable data ("Level 2 inputs"). In the absence of Level 2 inputs, we rely on unobservable inputs, such as our estimates of the assumptions market participants would use in pricing the instrument ("Level 3 inputs").

Cash and Cash Equivalents and Marketable Securities

We consider highly liquid investments that will mature in three months or less from the time we purchase them to be cash equivalents. Cash equivalents are valued using Level 1 inputs, which approximate our cost.

We invest the majority of our funds in marketable securities, primarily corporate notes, U.S. Treasury securities, asset-backed securities and commercial paper. We classify our marketable securities as available-for-sale securities and report them at fair value as "cash equivalents" or "marketable securities" on our consolidated balance sheet, with related unrealized gains and losses included in stockholders' equity. Realized gains and losses and permanent declines in value are included in "interest and other income (expense)" on our consolidated statement of comprehensive income.

Credit and Concentration Risks

Our cash, cash equivalents and marketable securities are held in one financial institution. We are subject to credit risk from our cash equivalents and marketable securities. We limit our investments to U.S. Treasury obligations and high-grade corporate debt and asset-backed securities with less than a 36-month maturity at the time of purchase. These investments are diversified and do not expose us to concentrations of credit risk. We have never experienced a loss in, or lack of access to, our operating or investment accounts.

We have a single-source manufacturer of mifepristone, the active pharmaceutical ingredient ("API"), in Korlym - Produits Chimiques Auxiliaires et de Synthèse SA ("PCAS," a member of the Seqens Group). If PCAS is unable or unwilling to manufacture API in the amounts and time frames required, we may not be able to manufacture Korlym in a timely manner. In order to mitigate this risk, we have purchased and hold in inventory a reserve quantity of mifepristone.

We have a concentration of risk in regard to the distribution of our product. A single specialty pharmacy, Optime Care, Inc. ("Optime"), dispenses Korlym to patients for us. Optime is an independent third party. Its unwillingness or inability to dispense Korlym to patients in a timely manner would harm our business.

We sell Korlym that Optime dispenses directly to patients, with title to the medicine passing directly from us to the patient upon the patient's receipt of the drug. Our receivables risk is spread among various third-party payers - pharmacy benefit managers, insurance companies, government programs and private charities. We monitor our exposure and record an allowance against uncollectible trade receivables as necessary. To date, we have not incurred any credit losses.

Inventory and Cost of Sales

Regulatory approval of product candidates is uncertain. Because product manufactured prior to regulatory approval may not be sold unless regulatory approval is obtained, we record the cost of manufacturing our product candidates as research and development expense at the time such costs are incurred. We capitalize to inventory manufacturing costs related to Korlym.

We value inventory at the lower of cost or net realizable value and determine the cost of inventory we sell using the specific identification method, which approximates a first-in, first-out basis. We assess our inventory levels at each reporting period and write down inventory that is either expected to be at risk of expiration prior to sale, has a cost basis in excess of its expected net realizable value, or for which there are inventory quantities in excess of expected requirements. We destroy expired inventory and recognize the related costs as cost of sales in that period's statement of comprehensive income.

Cost of sales also includes the cost of manufacturing Korlym, including materials, third-party manufacturing costs and indirect personnel and other overhead costs, based on the number of Korlym tablets for which we recognize revenue, as well as costs of stability testing, logistics and distribution.

We classify inventory we do not expect to sell within 12 months of the balance sheet date as strategic inventory, a non-current asset.

Net Product Revenue

We sell Korlym directly to patients through a single specialty pharmacy. We also sell Korlym to a specialty distributor ("SD"), for which we recognize revenue at the time the SD receives Korlym. SD sales were less than one percent of our net revenue in each of the years ended December 31, 2021, 2020 and 2019.

To determine our revenue from the sale of Korlym, we (i) identify our contract with each customer; (ii) identify the obligations of Corcept and the customer under the contract; (iii) determine the contracted transaction price; (iv) allocate the transaction price to the contract's performance obligations, which in our case consists of delivering Korlym to the customer; and (v) recognize revenue once Korlym has been delivered, provided we deem it probable that we will collect the payment due to us.

Confirmation of coverage by private or government insurance or by a third-party charity is a prerequisite for selling Korlym to a patient.

To determine net product revenue, we deduct from sales the cost of our patient co-pay assistance program and our estimates of (a) government chargebacks and rebates, (b) discounts provided to our SD for prompt payment and (c) reserves for expected returns. We record these estimates at the time we recognize revenue and update them as new information becomes available. Our estimates take into account our understanding of the range of possible outcomes. If results differ from our

estimates, we adjust our estimates, which changes our net product revenue and earnings. We report any changes in the period they become known, even if they concern transactions occurring in prior periods.

Government Rebates: Korlym is eligible for purchase by, or qualifies for reimbursement from, Medicaid and other government programs that are eligible for rebates on the price they pay for Korlym. To determine the appropriate amount to reserve against these rebates, we identify Korlym sold to patients covered by government-funded programs, apply the applicable government discount to these sales, then estimate the portion of total rebates we expect will be claimed. We (i) deduct this reserve from revenue in the period to which the rebates relate and (ii) include in accrued expenses on our consolidated balance sheet a current liability of an equal amount.

Chargebacks: Although we sell Korlym to the SD at full price, some of the government entities to which the SD sells receive a discount. The SD recovers the full amount of any related discounts by reducing its payment to us (this reduction is called a "chargeback"). Chargebacks sometimes relate to Korlym purchased by the SD in prior periods. We deduct from our revenue in each period chargebacks claimed by the SD for Korlym it purchased in that period. We also create a reserve for chargebacks we estimate the SD will claim in future periods against Korlym it purchased in the current period but has not yet resold. We determine the amount of this reserve based on our experience with SD chargebacks and our understanding of the SD's customer base and business practices. We deduct this reserve from revenue and include in accrued expenses on our consolidated balance sheet a current liability of equal amount.

Patient Assistance Program and Charitable Support: It is our policy that no patient be denied Korlym due to inability to pay. We provide financial assistance to eligible patients whose insurance policies have high deductibles or co-payments and deduct the amount of such assistance from gross revenue. We determine the assistance we provide each patient by applying our program guidelines to that patient's financial position and their insurance policy's co-payment and deductible requirements for the purchase of Korlym. We donate cash to charities that help patients with financial need pay for the treatment of Cushing's syndrome. We do not include payments from these charities in revenue, but as a deduction to selling, general and administrative expenses. We provide Korlym at no cost to uninsured patients who do not qualify for charitable support.

Sales Returns: Federal law prohibits the return of Korlym sold to patients. Sales to our SD are subject to return. We deduct the amount of Korlym we estimate the SD will return from each period's gross revenue. We base our estimates on quantitative and qualitative information including, but not limited to, historical return rates, the amount of Korlym held by the SD and projected demand. If we cannot reasonably estimate returns with respect to a particular sale, we defer recognition of revenue until we can make a reasonable estimate. To date, returns have not been significant.

The following table summarizes activity in each of the product revenue allowance and reserve categories for the years ended December 31, 2021, 2020 and 2019:

	Chargebacks	Government Rebates	Total
		(in thousands)	
Balance at December 31, 2018:	$ 346	$ 11,133	$ 11,479
Provision related to current period sales	783	24,374	25,157
Provision related to prior period sales	—	(95)	(95)
Credit or payments made during the period	(852)	(27,203)	(28,055)
Balance at December 31, 2019:	277	8,209	8,486
Provision related to current period sales	519	27,698	28,217
Provision related to prior period sales	(3)	(631)	(634)
Credit or payments made during the period	(630)	(25,864)	(26,494)
Balance at December 31, 2020:	163	9,412	9,575
Provision related to current period sales	394	33,709	34,103
Provision related to prior period sales	(29)	(1,047)	(1,076)
Credit or payments made during the period	(478)	(30,900)	(31,378)
Balance at December 31, 2021:	$ 50	$ 11,174	$ 11,224

Leases

We determine whether an arrangement contains a lease at inception. A contract is or contains a lease if the contract conveys the right to control the use of an identified asset for a period of time in exchange for consideration. To determine whether a contract is or contains a lease, we consider all relevant facts and circumstances to assess whether the customer has the right to both (i) obtain substantially all of the economic benefits from use of the identified asset and (ii) direct the use of the identified asset.

We recognize right-of-use assets and lease liabilities at lease commencement. We measure lease liabilities based on the present value of lease payments over the lease term discounted by the rate equal to the rate we would pay on a collateralized loan with monthly payments and a term equal to the monthly payments and remaining term of our lease. We estimate our incremental borrowing rate based on non-tender bank quotes and an analysis of public companies with debt and credit carrying terms similar to our lease term. We do not include in the lease term options to extend or terminate the lease unless it is reasonably certain at commencement that we will exercise any such options. We account for the lease components separately from non-lease components for our operating leases.

We measure right-of-use assets based on the corresponding lease liabilities adjusted for (i) prepayments made to the lessor at or before the commencement date, (ii) initial direct costs we incur, and (iii) tenant incentives under the lease. We evaluate the recoverability of our right-of-use assets for possible impairment in accordance with our long-lived assets policy. We do not recognize right-of-use assets or lease liabilities for leases with a term of twelve months or less; rather, we recognize the associated lease payments in the consolidated statements of comprehensive income on a straight-line basis over the lease term.

Operating leases are reflected on our consolidated balance sheets as operating lease right-of-use assets, short-term operating lease liabilities and long-term operating lease liabilities.

We begin recognizing operating lease expense when the lessor makes the underlying asset available to us. We recognize operating lease expense under our operating leases on a straight-line basis. Variable lease payments are expensed as incurred.

The Company did not have any finance leases at either December 31, 2021 or 2020.

Research and Development

Research and development expense includes the direct cost of discovering and screening new compounds, pre-clinical studies, clinical trials, manufacturing development, submissions to regulatory agencies and related overhead costs. We expense nonrefundable payments and the cost of technologies and materials used in research and development as we incur them.

We base our accruals for discovery research, preclinical studies and clinical trials on our estimates of work completed, milestones achieved, patient enrollment and past experience with similar activities. Our estimates include assessments of information from contract research organizations and the status of our own research, development and administrative activities.

Segment Reporting

We determine our operating segments based on the way we organize our business, make decisions and assess performance. We have one operating segment, which is the discovery, development and commercialization of pharmaceutical products.

Stock-Based Compensation

We account for stock-based compensation under the fair value method, based on the value of the award at the grant date. To date, our stock-based compensation has consisted entirely of option grants, which we value using the Black-Scholes model. We recognize stock-based compensation expense over the applicable vesting period, net of estimated forfeitures. If actual forfeitures differ from our estimates, we adjust stock-based compensation expense accordingly.

Income Taxes

We account for income taxes in accordance with ASC 740, *Income Taxes* (“ASC 740”), which requires recognition of deferred tax assets and liabilities for the expected tax consequences of our future financial and operating activities. Under ASC 740, we determine deferred tax assets and liabilities based on the temporary difference between the financial statement and tax bases of assets and liabilities using the tax rates in effect for the year in which we expect such differences to reverse. If we determine that it is more likely than not that we will not generate sufficient taxable income to realize the value of some or all of

our deferred tax assets (net of our deferred tax liabilities), we establish a valuation allowance offsetting the amount we do not expect to realize. We perform this analysis each reporting period and reduce our measurement of deferred taxes if the likelihood we will realize them becomes uncertain.

The deferred tax assets that we record each period depend primarily on our ability to generate future taxable income in the United States. Each period, we evaluate the need for a valuation allowance against our deferred tax assets and, if necessary, adjust the valuation allowance so that net deferred tax assets are recorded only to the extent we conclude it is more likely than not that these deferred tax assets will be realized. If our outlook for future taxable income changes significantly, our assessment of the need for, and the amount of, a valuation allowance may also change.

We are also required to evaluate and quantify other sources of taxable income, such as the possible reversal of future deferred tax liabilities, should any arise, and the implementation of tax planning strategies. Evaluating and quantifying these amounts is difficult and involves significant judgment, based on all of the available evidence and assumptions about our future activities.

We account for uncertain tax positions in accordance with ASC 740, which requires us to adjust our consolidated financial statements to reflect only those tax positions that are more-likely-than-not to be sustained upon review by federal or state examiners. We recognize in the consolidated financial statements the largest expected tax benefit that has a greater than 50 percent likelihood of being sustained on examination by the taxing authorities. We report interest and penalties related to unrecognized tax benefits as income tax expense.

Recently Adopted Accounting Pronouncements

In December 2019, the FASB issued ASU No. 2019-12 (ASC Topic 740), “Simplifying the Accounting for Income Taxes.” This standard simplifies and clarifies existing guidance, and is effective for fiscal years, and interim periods within those years, beginning after December 15, 2020. We adopted this standard on January 1, 2021. The adoption had no impact on our consolidated financial statements.

2. Significant Agreements

Commercial Agreements

In August 2017, we entered into a distribution services agreement with an independent third party, Optime, to provide exclusive specialty pharmacy and patient services programs for Korlym beginning August 10, 2017. Under the terms of this agreement, Optime acts as the exclusive specialty pharmacy distributor of Korlym in the United States, subject to certain exceptions. Optime provides services related to pharmacy operations; patient intake, access and reimbursement; patient support; claims management and accounts receivable; and data and reporting. We provide Korlym to Optime, which it dispenses to patients. Optime does not purchase Korlym from us and it does not take title to the product. Title passes directly from us to the patient at the time the patient receives the medicine.

The initial term of our agreement with Optime is five years, unless terminated earlier by us upon 90 days’ notice. The agreement contains additional customary termination provisions, representations, warranties and covenants. Subject to certain limitations, we have agreed to indemnify Optime for certain third-party claims related to the product, and we have each agreed to indemnify the other for certain breaches of representations, warranties, covenants and other specified matters.

Manufacturing Agreements Related to Korlym

We purchase all of our API for Korlym from PCAS. On July 25, 2018, we amended our agreement with PCAS to add a second manufacturing site and extend its term to December 31, 2021, with two one-year automatic renewals, unless either party provides 12 months advance written notice of its intent not to renew. The agreement was renewed through December 31, 2022. The amendment provides exclusivity between PCAS and Corcept. In the event PCAS cannot meet our requirements, we may purchase API from another supplier. As of December 31, 2021, we had non-cancelable commitments to purchase $2.0 million worth of API from PCAS over the next 12 months.

We have agreements with two third-party manufacturers to produce and bottle Korlym tablets.

Lease Agreement

See discussion below in Note 5, ***Leases***, regarding our office lease.

3. Available for Sale Securities and Fair Value Measurements

The available-for-sale securities in our Consolidated Balance Sheets are as follows:

	Year Ended December 31,	
	2021	2020
	(in thousands)	
Cash equivalents	$ 45,088	$ 50,524
Short-term marketable securities	145,918	364,506
Long-term marketable securities	112,277	36,196
Total marketable securities	$ 303,283	$ 451,226

The following table presents our available-for-sale securities grouped by asset type:

		December 31, 2021				December 31, 2020			
	Fair Value Hierarchy Level	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
				(in thousands)					
Corporate bonds	Level 2	$ 125,370	$ 3	$ (276)	$ 125,097	$ 96,999	$ 74	$ (9)	$ 97,064
Commercial paper	Level 2	30,963	—	—	30,963	139,791	—	—	139,791
Asset-backed securities	Level 2	57,801	—	(67)	57,734	39,243	15	(1)	39,257
U.S. Treasury securities	Level 1	44,473	—	(72)	44,401	124,461	131	(2)	124,590
Money market funds	Level 1	45,088	—	—	45,088	50,524	—	—	50,524
Total Marketable securities		$ 303,695	$ 3	$ (415)	$ 303,283	$ 451,018	$ 220	$ (12)	$ 451,226

We estimate the fair value of marketable securities classified as Level 1 using quoted market prices for these or identical investments obtained from a commercial pricing service. We estimate the fair value of marketable securities classified as Level 2 using inputs that may include benchmark yields, reported trades, broker/dealer quotes and issuer spreads.

We periodically review our debt securities to determine if any of our investments is impaired due to credit-related or other issues. If the fair value of our investment in any debt security is less than our amortized cost basis, we determine whether an allowance for credit losses is appropriate by assessing quantitative and subjective factors including, but not limited to, the nature of security, changes in credit ratings, analyst reports concerning the security's issuer and industry, interest rate fluctuations and general market conditions.

Unrealized losses on our available-for-sale debt securities as of December 31, 2021 were not material. Accordingly, we have not recorded an allowance for credit losses associated with these investments.

During the three months ended December 31, 2021, we sold $50.5 million of investments to fund the tender offer. We recognized realized losses of less than $0.1 million from these sales. We do not intend to sell our remaining investments that are currently in an unrealized loss position, and it is highly unlikely that we will be required to sell the investments before recovery of their amortized cost basis, which may be at maturity.

We classified accrued interest on our marketable securities of $1.4 million and $1.3 million as of December 31, 2021 and 2020, respectively, as prepaid and other current assets on our consolidated balance sheets.

As of December 31, 2021, all our marketable securities had original maturities of less than two years. The weighted-average maturity of our holdings was eight months. As of December 31, 2021, our long-term marketable securities had remaining maturities ranging from 13 to 19 months. None of our marketable securities changed from one fair value hierarchy to another during the year ended December 31, 2021.

4. Composition of Certain Balance Sheet Items

Inventory

	Year Ended December 31,	
	2021	2020
	(in thousands)	
Raw materials	$ —	$ 1,685
Work in progress	11,450	12,916
Finished goods	6,500	6,556
Total inventory	17,950	21,157
Less strategic inventory classified as non-current	(12,962)	(16,247)
Total inventory classified as current	$ 4,988	$ 4,910

Because we rely on a single manufacturer to produce Korlym's API, we have purchased and hold significant quantities of API, included in work in progress inventory. We classify inventory we do not expect to sell within 12 months of the balance sheet date as "Strategic Inventory," a long-term asset.

Property and Equipment

	Year Ended December 31,	
	2021	2020
	(in thousands)	
Furniture and equipment	$ 1,157	$ 810
Software	1,508	1,485
Leasehold improvements	1,262	1,233
	3,927	3,528
Less accumulated depreciation	(2,925)	(1,853)
Property and equipment, net of accumulated depreciation	$ 1,002	$ 1,675

Accrued and other liabilities

	Year Ended December 31,	
	2021	2020
	(in thousands)	
Accrued compensation	$ 13,339	$ 10,144
Government rebates	11,174	9,412
Accrued selling and marketing costs	1,351	665
Legal fees	842	612
Income taxes payable	513	—
Professional fees	150	151
Other	296	202
Total accrued and other liabilities	$ 27,665	$ 21,186

Other assets

As of December 31, 2021 and 2020, other assets included $2.9 million and $4.8 million of deposits for clinical trials, respectively.

5. Leases

We lease our office facilities in Menlo Park, California. In October 2019, we amended the lease to extend its term from March 31, 2020 to March 31, 2022 and to add more space beginning April 1, 2020. In June 2020, we amended our lease commencement date for additional space to June 15, 2020. As a result of this amendment, we recognized an additional right-of-use asset and corresponding lease liability of $0.8 million. The right-of-use asset and lease liability recognized equals the present value of the remaining payments due under our amended lease.

As the operating lease for our facilities does not include an expressly stated interest rate, we calculated the present value of remaining lease payments using a discount rate equal to the interest rate we would pay on a collateralized loan with monthly payments and a term equal to the monthly payments and remaining term of our lease. We recognize operating lease payments as expenses using the straight-line method over the term of the lease.

Operating lease expense for the years ended December 31, 2021, 2020 and 2019 was approximately $2.1 million, $1.9 million and $1.5 million, respectively.

Our right-of-use assets and related lease liabilities were as follows:

	Year Ended December 31,	
	2021	2020
	(in thousands)	
Cash paid for operating lease liabilities	$ 2,104	$ 1,840
Right-of-use assets obtained in connection with operating lease obligations	$ —	$ 775
Weighted-average remaining lease term (months)	3 months	15 months
Weighted-average discount rate	4.8 %	4.8 %

As of December 31, 2021, future minimum lease payments under non-cancelable operating leases were as follows *(in thousands)*:

2022	$ 530
	530
Less imputed interest	(4)
Total operating lease liabilities	$ 526

6. Related Party Transactions

In February 2020, we purchased from our Chief Executive Officer $0.3 million of our common stock at a price of $13.54 per share, which was the last quoted price per share on the Nasdaq Capital Market on the date of purchase. We purchased the shares in order to provide him with liquidity to satisfy the tax liability arising from his net (cashless) exercise in 2019 of stock options that were about to expire.

There were no other related party transactions during the years ended December 31, 2021, 2020, and 2019.

7. Preferred Stock and Stockholders' Equity

Preferred Stock

Our Board of Directors is authorized, subject to any limitations prescribed by law, without stockholder approval, to issue up to an aggregate of 10,000,000 shares of preferred stock at $0.001 par value in one or more series and to fix the rights, preferences, privileges and restrictions granted to or imposed upon the preferred stock, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences. The rights of the holders of common stock will be subject to the rights of holders of any preferred stock that may be issued in the future. As of December 31, 2021 and 2020, we had no outstanding shares of preferred stock.

Common Stock

On November 3, 2020, we announced that our Board of Directors approved a program to repurchase up to $200 million of our common stock (the "Stock Repurchase Program"). The terms of this program did not require us to acquire any shares and allowed for repurchases by a variety of methods, including open market purchases, privately negotiated transactions, block trades, accelerated share repurchase transactions or any combination of such methods. The Stock Repurchase Program expired by its terms on September 30, 2021.

During the years ended December 31, 2021 and 2020, we purchased 3.9 million and 0.5 million shares of common stock under the Stock Repurchase Program in open market transactions at an average price of $22.88 and $21.08 per share, for an aggregate purchase price of $88.5 million and $9.7 million, respectively. Over the term of the Stock Repurchase Program, we repurchased 4.3 million shares at an average price of $22.69 per share and a total cost of $98.2 million.

During the year ended December 31, 2019, we purchased 2.8 million shares of common stock at a cost of $31.0 million under a stock repurchase program that expired on June 30, 2019.

On November 8, 2021, we announced that our Board of Directors approved a tender offer to purchase up to 10 million shares of our common stock. The tender offer commenced on November 8, 2021 and expired on December 15, 2021. We repurchased 10 million shares through the tender offer at a price of $20.75 per share for an aggregate purchase price of $207.5 million, excluding fees and expenses relating to the tender offer.

We recorded purchased shares as treasury stock on our consolidated balance sheets, at cost. It has not been determined whether purchased shares will be retired or sold.

During the years ended December 31, 2021, 2020 and 2019, we issued 4.6 million, 2.8 million and 2.9 million shares, respectively, of our common stock upon the exercise of stock options.

We have never declared or paid any dividends.

Shares of common stock reserved for future issuance as of December 31, 2021 are as follows:

Common stock:	*(in thousands)*
Exercise of outstanding options	24,453
Shares available for grant under stock option plans	9,571
	34,024

On February 4, 2021, our Board of Directors authorized an increase of 4.7 million shares in the number of shares available under the 2012 Equity Incentive Plan (the "2012 Plan"), which was equivalent to 4% of the shares of our common stock outstanding at December 31, 2020. On December 2, 2021, our Board of Directors authorized, effective January 1, 2022, an additional increase of 4.2 million shares available under the 2012 Plan, which is equivalent to 4% of the shares of our common stock outstanding at December 31, 2021.

Stock Option Plans

We have two stock option plans – the 2004 Equity Incentive Plan (the "2004 Plan") and the 2012 Plan.

In 2004, our Board of Directors and stockholders approved the 2004 Plan, which became effective upon the completion of our initial public offering. Under the 2004 Plan, options, stock purchase and stock appreciation rights and restricted stock awards can be issued to our employees, officers, directors and consultants. The 2004 Plan provided that the exercise price for incentive stock options will be no less than 100% of the fair value of the Company's common stock, as of the date of grant. Options granted under the 2004 Plan vest over periods ranging from one year to five years. The vesting period of the options is generally equivalent to the requisite service period.

In 2012, our Board of Directors and stockholders approved the 2012 Plan. As of the effective date of the 2012 Plan, 5.3 million shares that remained available for issuance of new grants under the 2004 Plan were transferred to the 2012 Plan. After that date, no additional options were or will be issued under the 2004 Plan. Vested options under the 2004 Plan that are not exercised within the

remaining contractual life and any options under the 2004 Plan that do not vest because of terminations after the effective date of the 2012 Plan will be added to the pool of shares available for future grants under the 2012 Plan.

Under the 2012 Plan, we can issue options, stock purchase and stock appreciation rights and restricted stock awards to our employees, officers, directors and consultants. The 2012 Plan provides that the exercise price for incentive stock options will be no less than 100 percent of the fair value of our common stock as of the date of grant. Options granted under the 2012 Plan carry a contractual term of ten years and are expected to vest over periods ranging from one year to four years. We assume the vesting period of the options that we grant under the 2012 Plan to be equal to the option grantee's period of service.

Upon exercise of options, new shares are issued.

Option activity during 2021

The following table summarizes all activity under the 2004 Plan and the 2012 Plan:

		Outstanding Options			
	Shares Available For Future Grant	Options Shares Subject to Options Outstanding	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life	Aggregate Intrinsic Value
	(in thousands)	*(in thousands)*		*(in years)*	*(in thousands)*
Balance at December 31, 2020	9,041	24,946	$ 9.62		
Increase in shares authorized for grant	4,669	—			
Shares granted	(5,460)	5,460	$ 26.75		
Shares exercised	—	(4,632)	$ 6.92		
Shares canceled and forfeited	1,321	(1,321)	$ 18.07		
Balance at December 31, 2021	9,571	24,453	$ 13.50	6.39	$ 188,820
Options exercisable at December 31, 2021		16,532	$ 10.20	5.33	$ 165,487
Options fully vested and expected to vest at December 31, 2021		23,868	$ 13.31	6.34	$ 187,250

The total intrinsic value of options exercised during the years ended December 31, 2021, 2020 and 2019 was $78.9 million, $28.8 million and $26.6 million, respectively, based on the difference between the closing price of our common stock on the date of exercise of the options and the exercise price.

The total fair value of options that vested during the years ended December 31, 2021, 2020 and 2019 was $40.4 million, $34.0 million and $30.2 million, respectively.

Stock-Based Compensation related to Employee and Director Options

The following table summarizes the weighted-average assumptions and resultant fair value-based measurements for options granted to employees and directors.

	Year Ended December 31,		
	2021	2020	2019
Weighted-average assumptions for stock options granted:			
Risk-free interest rate	0.76%	1.20%	2.34%
Expected term	6.3 years	6.0 years	6.0 years
Expected volatility of stock price	60.7%	59.1%	67.4%
Dividend rate	0%	0%	0%
Weighted-average grant date fair value-based measurement	$15.06	$7.55	$7.09

The expected term of options reflected in the table above has been based on a formula that considers the expected service period and expected post-vesting termination behavior depending on whether the option holder is an employee, officer or director.

The expected volatility of our stock used in determining the fair value-based measurement of option grants to employees, officers and directors is based on the volatility of our stock price. The volatility is based on historical data of the price for our common stock for periods of time equal to the expected term of these grants.

We calculate employee stock-based compensation expense using the number of options we expect to vest, based on our estimate of the option grantees' average length of employment, and reduced by our estimate of option forfeitures. We estimate forfeitures at the time of option grant and revise this estimate in subsequent periods if actual forfeitures differ from our estimates.

As of December 31, 2021, we had $80.0 million of unrecognized compensation expense for employee and director options outstanding, which had a weighted-average remaining vesting period of 2.76 years.

Summary of Stock-based Compensation

The following table presents a summary of stock-based compensation by financial statement classification.

	Year Ended December 31,		
	2021	2020	2019
	(in thousands)		
Stock-based compensation capitalized in inventory	$ 237	$ 238	$ 120
Cost of sales	59	66	144
Research and development	14,106	11,222	9,541
Selling, general and administrative	28,766	22,251	19,628
Total stock-based compensation	$ 43,168	$ 33,777	$ 29,433

8. Net Income Per Share

We compute basic and diluted net income per share by dividing our net income by the weighted-average number of common shares outstanding during the period. We used the treasury stock method to determine the number of dilutive shares of common stock resulting from the potential exercise of stock options. The statements of consolidated comprehensive income show the computation of net income per share for each period, including the number of weighted-average shares outstanding.

The following table shows the computation of net income per share for each period:

	Year Ended December 31,		
	2021	2020	2019
	(in thousands, except per share data)		
Numerator:			
Net income	$ 112,512	$ 106,011	$ 94,181
Denominator:			
Weighted-average shares used to compute basic net income per share	115,653	115,412	114,349
Dilutive effect of employee stock options	10,310	8,782	8,217
Weighted-average shares used to compute diluted net income per share	125,963	124,194	122,566
Net income per share			
Basic	$ 0.97	$ 0.92	$ 0.82
Diluted	$ 0.89	$ 0.85	$ 0.77

Because including them would have reduced dilution, we excluded from the computation of diluted net income per share, on a weighted-average basis 4.5 million, 11.2 million and 9.9 million stock options outstanding during the years ended December 31, 2021, 2020, and 2019, respectively,

9. Income Taxes

The domestic and foreign components of income before income taxes were as follows:

	Year Ended December 31,		
	2021	**2020**	**2019**
	(in thousands)		
Domestic	$ 126,308	$ 131,634	$ 116,676
Foreign	(1,302)	(32)	—
Income before income taxes	$ 125,006	$ 131,602	$ 116,676

The income tax expense for the years ended December 31, 2021, 2020, and 2019 consisted of the following:

	Year Ended December 31,		
	2021	**2020**	**2019**
	(in thousands)		
U.S. federal taxes:			
Current	$ 4,675	$ 6,094	$ 1,716
Deferred	5,066	14,418	15,944
Total U.S. federal taxes	9,741	20,512	17,660
State taxes:			
Current	3,432	5,368	3,900
Deferred	(274)	520	935
Total state taxes	3,158	5,888	4,835
Foreign taxes:			
Current	$ 41	$ 41	$ —
Deferred	$ (446)	$ (850)	$ —
Total foreign taxes	(405)	(809)	—
Total provision for income taxes	$ 12,494	$ 25,591	$ 22,495

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of our deferred tax assets are as follows:

	Year Ended December 31,	
	2021	2020
Deferred tax assets:	*(in thousands)*	
Federal and state net operating losses	$ 5,377	$ 5,412
Capitalized research and patent costs	3,412	5,139
Research credits	9,953	15,107
Stock-based compensation costs	17,831	14,043
Operating lease liability	130	630
Other	3,851	3,473
Total deferred tax assets	40,554	43,804
Valuation allowance	(12,972)	(11,581)
Deferred tax liabilities		
Operating lease right-of-use asset	(127)	(620)
Total deferred tax liabilities	(127)	(620)
Net deferred tax assets	$ 27,455	$ 31,603

Each quarter, we assess the likelihood that we will generate sufficient taxable income to use our federal and state deferred tax assets. If we believe that recovery of these deferred tax assets is not more likely than not, we will establish a valuation allowance. Significant judgment is required in determining any valuation allowance recorded against deferred tax assets. In assessing the need for a valuation allowance, we consider all available evidence, including recent operating results, projections of future taxable income, our ability to utilize net operating losses and tax credit carryforwards, and the feasibility of tax planning strategies. Other than valuation allowances against our California net deferred tax assets, we have determined that it is more likely than not we will realize the benefit related to all other deferred tax assets. If we increase a valuation allowance, we will include an expense of equal amount in the Condensed Consolidated Statement of Comprehensive Income in the period in which such determination is made.

The valuation allowance increased by $1.4 million, $0.2 million and $0.2 million for the years ended December 31, 2021, 2020 and 2019, respectively.

At December 31, 2021, we had California net operating loss carryforwards of $75.2 million, which will begin to expire in the year 2031, and net operating loss carryforwards from other states of $2.2 million, which will begin to expire in the year 2035 if not utilized. On June 29, 2020, the California governor signed Assembly Bill 85 (“AB 85”) into law. AB 85 limits the use of business incentive tax credits and suspends the use of California net operating losses for 2020, 2021 and 2022 for companies with California-sourced taxable income of $1 million or more. AB 85 will not have a material impact on our consolidated financial statements.

At December 31, 2021, we also had federal research and development tax credits of $5.7 million and orphan drug tax credits of $3.8 million, respectively, and California research and development credits of $10.5 million. The federal research credits will expire in the years 2040 through 2041 and the California research credits have no expiration date.

The following table presents a reconciliation from the statutory federal income tax rate to the effective rate.

	Year Ended December 31,		
	2021	2020	2019
	(in thousands)		
U.S. federal taxes at statutory rate	$ 26,251	$ 27,636	$ 24,502
R&D and other credits	(7,579)	(6,666)	(4,504)
State income taxes, net of federal benefit	2,495	4,651	3,819
Non-deductible compensation	990	1,508	657
Stock-based compensation	(9,568)	(1,551)	(2,107)
Other	(95)	13	128
Total	$ 12,494	$ 25,591	$ 22,495

We maintain liabilities for uncertain tax positions. The measurement of these liabilities involves considerable judgment and estimation and are continuously monitored by management based on the best information available, including changes in tax regulations, the outcome of relevant court cases, and other pertinent information.

The aggregate annual changes in the balance of gross unrecognized tax benefits are as follows:

	Year Ended December 31,		
	2021	2020	2019
	(in thousands)		
Beginning balance	$ 7,471	$ 6,029	$ 4,756
Increase in tax positions for prior years	103	158	261
Decreases in tax positions for prior years	—	—	—
Increase in tax positions for current year	1,663	1,284	1,012
Decrease in tax positions for current year	—	—	—
Ending balance	$ 9,237	$ 7,471	$ 6,029

As of December 31, 2021, the amount of unrecognized tax benefits that would favorably impact the effective tax rate were approximately $7.5 million, and approximately $1.7 million of unrecognized tax benefits would be offset by a change in the valuation allowance. A valuation allowance is maintained on the remaining tax benefits related to California deferred tax assets and would not impact the effective tax rate. We had no or immaterial amounts of accrued interest and no accrued penalties related to unrecognized tax benefits as of December 31, 2021, 2020 and 2019. We do not expect our unrecognized tax benefits to change materially over the next 12 months.

While we believe we have adequately provided for all tax positions, amounts asserted by tax authorities could be greater or less than the recorded position. Accordingly, our provisions on federal and state tax-related matters to be recorded in the future may change as revised estimates are made or the underlying matters are settled or otherwise resolved.

The Company's primary tax jurisdiction is the United States. For federal and state tax purposes, the years 1999 through 2021 remain open and subject to tax examination by the appropriate federal or state taxing authorities.

10. Commitments and contingencies

We have entered into a number of agreements to purchase API for the manufacturing of relacorilant, miricorilant and exicorilant. We have also entered into agreements to perform clinical studies on miricorilant and dazucorilant (formerly, "CORT113176"). See the discussion in Note 2, ***Significant Agreements***, for further discussion regarding the commitments under these agreements.

In December 2021, to ensure we have sufficient API to meet future demand for Korlym tablets, we committed to purchase 150 kilograms of API from PCAS for a total price of $2.0 million. As of December 31, 2021, there remained a $2.0 million obligation in connection with this purchase commitment.

In January 2022, we committed to purchase an additional 75 kilograms of API from PCAS for a total price of $0.9 million.

In the ordinary course of business, we may be subject to legal claims and regulatory actions that could have a material adverse effect on our business or financial position. We assess our potential liability in such situations by analyzing the possible outcomes of various litigation, regulatory and settlement strategies. If we determine a loss is probable and its amount can be reasonably estimated, we accrue an amount equal to the estimated loss.

No losses and no provision for a loss contingency have been recorded to date.