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**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, 2022**

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**

(State or other jurisdiction of incorporation or organization)

**77-0487658**

(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:

<b>Title of each class</b>	<b>Trading Symbol(s)</b>	<b>Name of each exchange on which registered</b>
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	<input checked="" type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

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. ☒

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant’s executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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, 2022 was \$2,058,080,161, based on the closing price of \$23.78 for shares of the Registrant’s common stock as reported on the Nasdaq Stock Market on June 30, 2022. 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 21, 2023 there were 107,899,316 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 2023 Annual Meeting of Stockholders are incorporated by reference in Items 10, 11, 12, 13 and 14 of Part III.

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## 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<sup>®</sup> (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;
- 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 medications to treat severe endocrine, oncologic, metabolic and neurological 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 with fatty liver disease and non-alcoholic steatohepatitis (“NASH”), which are precursors of liver fibrosis and cirrhosis, and in patients at risk of weight gain caused by

antipsychotic medications (referred to as antipsychotic induced weight gain, or “AIWG”). Pre-clinical data also suggest 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 suffering from 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 the 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 the GR but have no affinity for the 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 the GR, but, unlike Korlym, do not bind to the 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, advanced ovarian cancer, adrenal cancer with cortisol excess, prostate cancer, ALS and NASH.

## **COVID-19 Pandemic**

Public health restrictions put in place to reduce the impact of the global COVID-19 pandemic, as well as measures voluntarily undertaken by patients, physicians, hospitals and medical clinics, have reduced our revenue growth and make it difficult to grow our Korlym business.

The pandemic’s impact on the pace of our clinical development programs has been variable. Some of our trials of indications not considered immediately life-threatening, such as Cushing’s syndrome, have experienced slower enrollment. In addition, some clinical sites have reduced the frequency with which physicians see study participants. Our trials in patients with immediately life-threatening diseases, such as our Phase 2 trial in women with platinum-resistant ovarian cancer, have not encountered delays.

We expect that pandemic-related impediments to our business will continue so long as there are COVID-19 public health restrictions and/or 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.”*

## **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 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. 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, 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 other effects associated with PR affinity, including endometrial thickening and vaginal bleeding. Relacorilant also does not appear to cause hypokalemia (low potassium), a potentially serious condition 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 of hypertension in patients receiving placebo measured against the rate and degree of relapse of hypertension in those continuing relacorilant. GRACE has a planned enrollment of 130 patients with 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 22 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 Administration ("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 evidence that cortisol activity at the GR reduces the efficacy of certain anti-cancer therapies and that modulating cortisol's activity may help anti-cancer treatments achieve their intended effect. 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. Many types of solid tumors express the GR and are potential targets for cortisol modulation therapy, among them ovarian, adrenal and prostate cancer.

*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 in addition to nab-paclitaxel. Sixty women received nab-paclitaxel alone. The trial's primary endpoint was progression-free survival (i.e., the time from random assignment in a clinical trial to disease progression or death from any cause or "PFS").

Patients in both of the 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: 0.038). 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 ("DoR") (5.6 months versus 3.7 months, hazard ratio: 0.36; p-value: 0.006) compared to those who received nab-paclitaxel alone. Patients who received relacorilant intermittently also lived longer (median OS: 13.9 months versus 12.2 months, hazard ratio: 0.67; p-value: 0.066) compared to those who received nab-paclitaxel alone.

Safety and tolerability of relacorilant plus nab-paclitaxel were comparable to nab-paclitaxel monotherapy.

In June 2022, we initiated a pivotal Phase 3 trial ("ROSELLA") that seeks to replicate the positive results observed in our Phase 2 study. ROSELLA has a planned enrollment of 360 women with recurrent, platinum-resistant ovarian cancer, randomized 1:1 to receive either relacorilant plus nab-paclitaxel or nab-paclitaxel monotherapy. The primary endpoint is PFS, with overall survival as a key secondary endpoint. Patients in ROSELLA will have received prior bevacizumab therapy, which is the standard of care in the United States for patients with platinum-resistant ovarian cancer. Women with a history of tumors that do not respond to initial platinum-based treatments (i.e., women with "primary platinum-refractory" disease) and those who have received more than three prior lines of therapy will be excluded.

In our Phase 2 trial, women who met the entry criteria for ROSELLA and received relacorilant intermittently experienced significantly improved PFS (median: 7.3 months versus 3.7 months, hazard ratio: 0.40; p-value: 0.005) and OS (median: 17.9 months versus 12.6 months, hazard ratio: 0.38; p-value: 0.011) relative to patients in the comparator arm. The patients in the intermittent arm also experienced a significant improvement in DoR relative to those in the comparator arm (median: 5.6 months versus 3.1 months, hazard ratio: 0.29; p-value: 0.016).

*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 patients with metastatic or unresectable adrenal cancer whose tumors produce cortisol. 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. Relacorilant is also expected to treat the patients' Cushing's syndrome generated by their tumors' excess production of cortisol.

*Relacorilant in Patients with Prostate Cancer.* Androgen deprivation is the standard treatment for prostate cancer because androgens stimulate prostate tumor growth. Tumors often escape androgen deprivation therapy when cortisol's activity at the GR stimulates tumor growth. Combining a cortisol modulator with an androgen modulator may block this escape route. Our collaborators at the University of Chicago plan to initiate a randomized, placebo-controlled Phase 2 trial of relacorilant plus enzalutamide in patients with prostate cancer, pre-prostatectomy. We are providing relacorilant and placebo for the study and have licensed patents covering the use of relacorilant combined with anticancer agents such as enzalutamide in the treatment of patients with this indication.

## ALS

ALS, also known as Lou Gehrig's disease, is a devastating neuromuscular illness. Our selective cortisol modulator dazucorilant improved motor performance and reduced neuroinflammation and muscular atrophy in animal models of ALS. Following these compelling results, in October 2022 we initiated a Phase 2 trial of dazucorilant (the "DAZALS" trial) in patients with ALS. DAZALS has a planned enrollment of 198 patients, randomized 1:1:1 to receive either 150 mg or 300 mg of dazucorilant or placebo daily for 24 weeks. The primary endpoint is the difference between dazucorilant and placebo demonstrated by patients on the ALS Functional Rating Scale-Revised (ALSFRRS-R).

## Metabolic Diseases

*Liver Disease.* NASH is an advanced form of nonalcoholic fatty liver disease that afflicts millions of patients and is a leading cause of liver-related mortality. In April 2021, we suspended our Phase 2a trial of our selective cortisol modulator miricorilant as a potential treatment for NASH after four of the five patients who received miricorilant exhibited both elevated liver enzymes and large rapid reductions in liver fat. Liver enzyme levels in all affected patients returned to baseline or below baseline after miricorilant was withdrawn. Our ongoing Phase 1b dose-finding trial in patients with presumed NASH has

identified a range of doses that appear to cause large reductions in liver fat without causing excessive liver irritation. We plan to start a Phase 2 trial in the fourth quarter of 2023.

**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 largely to increased cardiovascular events, such as heart attacks and strokes. Patients in our two double-blind, placebo-controlled, Phase 2 trials of miricorilant (GRATITUDE and GRATITUDE II) did not experience reversal of AIWG. However, multiple replicated pre-clinical results as well as the results of our double-blind, placebo-controlled trial (published in the *Journal of Clinical Psychopharmacology* (Hunt et al., 2021)) suggest that miricorilant has the potential to significantly reduce weight gain caused by the administration of olanzapine. Accordingly, we plan to further study miricorilant's potential to prevent AIWG.

### **Development of our Other Selective Cortisol Modulators**

Our portfolio of proprietary selective cortisol modulators consists of four structurally distinct series. More than 1,000 of these compounds, including relacorilant, exicorilant, miricorilant and dazucorilant, potently bind to the 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. Syneos Health is helping us conduct our ROSELLA trial. Julius Clinical is helping us conduct our DAZALS trial. We may terminate our agreements with ICON, Syneos Health and Julius Clinical on 60 days' written notice.

### **Research and Development Spending**

We incurred \$131.0 million, \$113.9 million and \$114.8 million of research and development expense in the years ended December 31, 2022, 2021 and 2020, respectively, which accounted for 45 percent, 47 percent and 51 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 Synthèse 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. At December 31, 2022, the agreement was further extended through December 31, 2023.

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, and metyrapone, which is approved for testing hypothalamic-

pituitary function. Korlym also competes with Signifor<sup>®</sup> (pasireotide) Injection and Isturisa<sup>®</sup> (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 also competes with Recorlev<sup>®</sup> (levoketoconazole), a chiral form of the commonly-prescribed cortisol synthesis inhibitor ketoconazole, that is sold by Xeris Biopharma Holdings, Inc. ("Xeris"), as a treatment for patients with Cushing's syndrome.

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 sued Teva Pharmaceuticals USA, Inc. ("Teva") 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, Japan, China, Canada, Australia and other countries. The expiration dates of these patents and their foreign counterparts range from 2025 to 2039.

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 proprietary 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 proprietary selective cortisol modulators with expiration dates ranging from 2023 to 2041. 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 castration resistant prostate cancer ("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."

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.

*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, 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 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 2023 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, and 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.

Examples of legislation in this area include the Patient Protection and Affordable Care Act (“ACA”) which was passed in 2010, and the Inflation Reduction Act of 2022 (the “IRA”). The ACA 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. More recently, the Inflation Reduction Act of 2022 (the “IRA”) was signed into law on August 16, 2022, which, among other things, requires the Secretary of the U.S. Department of Health and Human Services (“HHS”) to negotiate the price of a set number of high Medicare spend drugs starting in 2026, requires rebates from manufacturers who increase their drug prices above inflation, and makes several changes to the Medicare Part D benefit that will increase manufacturer liability for drug costs previously borne by the government and beneficiaries under the program. We also expect there to be other healthcare reform measures that could impact coverage, reimbursement, and drug prices.

### **Other Healthcare Laws**

In addition to the laws and regulations outlined in the “Government Regulations” section, 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 (e.g. transparency) laws and regulations. Foreign governments have comparable regulations, and violating these laws and regulations in any jurisdiction could result in significant criminal, civil, and administrative sanctions.

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. 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 and other third parties. The Anti-Kickback Statute is subject to evolving interpretations, and in the absence of substantive guidance, it is possible for future initiatives or engagements with healthcare professionals to be challenged under this Statute, which could adversely impact our operations. While this Statute has a number of exceptions and regulatory safe harbors that safeguard certain common, industry practices from prosecution, these exceptions and safe harbors are narrowly defined, and parties must satisfy all elements of an available exception or safe harbor to avoid scrutiny. 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. For example, through legislative action, the government may assert that an Anti-Kickback Statute violation could implicate the federal civil False Claims Act. 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.

The civil False Claims Act prohibits knowingly presenting or causing the presentation of a false, fictitious or fraudulent claim for payment to federal programs (including Medicare and Medicaid). Actions under the False Claims Act may be brought directly by the government or as a *qui tam* action by a private individual (acting as a "whistleblower") in the name of the government. In addition, as noted directly above, 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 significant monetary penalties including treble damages, and carry the potential for exclusion from participation in federal healthcare programs. The federal government has and continues to use 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 potential or actual false claims resulting from promotion of products for unapproved uses or other sales and marketing practices. The government has obtained multi-billion dollar settlements under the False Claims Act and individual criminal convictions under applicable criminal statutes. We expect that the government will continue to devote substantial resources to investigating potential or actual violations of the False Claims Act.

The federal criminal statute on false statements makes it a crime to knowingly and willfully (in connection with the delivery of or payment for health care benefits, items, or services): (i) falsify, conceal, or cover up any material fact, (ii) make any materially false, fictitious, or fraudulent statements or representations, or (iii) make or use any materially false writing or document while knowing such writings or documents contain materially false, fictitious, or fraudulent statements.

The Civil Monetary Penalties Law provides the government the ability to impose civil monetary penalties against any party or entity who offers or transfers anything of value to a federal health care program beneficiary when a party or entity knows or should know that providing a transfer of value is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier for the order or receipt of any item or service reimbursable by a federal health care program. Notably, while pharmaceutical and biotech companies are generally not considered "providers, practitioners, or suppliers," offering anything of value to a beneficiary that is likely to influence the beneficiary to select a particular provider, practitioner, or supplier (e.g., a physician or pharmacy) could implicate the Civil Monetary Penalties Law.

The federal Health Insurance Portability and Accountability Act of 1996 ("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.

The federal physician Payments Sunshine Act (generally referred to as the Open Payments™ Program) is a provision under the Patient Protection and Affordable Care Act ("ACA"). The Open Payments Program imposes reporting requirements on covered entities (e.g., drug manufacturers) for payments made or transfers of value provided by them to certain healthcare organizations (e.g., teaching hospitals) and physicians, which is broadly defined to include doctors, dentists, optometrists, podiatrists and chiropractors, and certain non-physician practitioners (e.g., physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists, anesthesiology assistants and certified nurse midwives). Covered entities are also required to report ownership and investment interests held by physicians and their immediate family members (as it relates to the Covered entities). This information is then analyzed and made public, available via searchable databases. 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. Similarly, certain states also mandate the tracking and reporting of gifts, compensation and other remuneration to physicians. Some of these states also require the implementation of commercial compliance programs and impose restrictions on drug manufacturer marketing practices.

Federal and state agencies continue to spend time, energy and resources combating healthcare fraud and abuse. This regulatory environment, taken together with the evolving commercial compliance environment and the need to build, enhance and maintain robust and expandable systems and controls 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.

In addition to the above “fraud and abuse” laws and regulations, we must also account for other applicable state and foreign laws and regulations that could impact our business activities. For example, some states require pharmaceutical companies to certify that they are in compliance with the pharmaceutical industry’s voluntary compliance guidelines and certain federal government compliance guidance, while other states (and some local governments) require the public registration of pharmaceutical sales representatives.

### **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 (“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. In 2022, the FTC also began a rulemaking proceeding to develop additional data privacy rules and requirements, which may add additional complexity to compliance obligations going forward.

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, the California Consumer Privacy Act (“CCPA”) which took effect on January 1, 2020, created individual privacy rights for California consumers and increased 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 (“CPRA”) revised and expanded the CCPA, adding 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 also created a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. The CPRA is in full effect as of January 1, 2023, and similar laws passed in Virginia, Colorado, Connecticut, and Utah will take effect starting in 2023. As a result, 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. Additional legislation

proposed at the federal level and in other states, along with increased regulatory action, reflect a trend toward more stringent privacy legislation in the United States.

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 European Economic Area (“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. 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, 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. Transfers of personal information out of the European Union face a constantly shifting set of requirements, as courts in Europe have invalidated intergovernmental agreements and European regulators have required changes to standard contracting terms, which themselves do not fit all situations. As a result, significant uncertainty exists with respect to GDPR compliance and the attendant obligations going forward as the regulatory environment is rapidly developing. 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 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. Outside Europe, significant data privacy regulatory regimes exist in major markets including Brazil, India, China, and elsewhere. The ever-shifting landscape of global data privacy regulation requires significant investment and attention to avoid significant noncompliance liabilities.

## **Employees**

We are managed by experienced pharmaceutical executives and also enlist the expertise of independent advisors with extensive pharmaceutical experience. As of December 31, 2022, we had 299 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](http://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](http://www.corcept.com) or the SEC’s website, [www.sec.gov](http://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.
- If generic versions of Korlym are successfully commercialized, our business, results of operations and financial position would be adversely affected.
- 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.

### 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.
- We may be unable to obtain or maintain regulatory approvals for our product or product candidates, which would prevent us from commercializing 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. Opportunities for investors to sell shares may be limited.
- 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.

### General Risks

- We rely on information technology to conduct our business. A breakdown or breach of our information technology 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, such as the Inflation Reduction Act of 2022, that may significantly limit Medicare reimbursement rates.

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.**

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. Although pandemic-related restrictions have been eased or removed in some places, 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, arrive at 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, including supply-chain disruptions and inflationary impacts. 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.

**If generic versions of Korlym are 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 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 the Federal Circuit Court of Appeals has affirmed. We had also sued Sun and Hikma with respect to their proposed generic version of Korlym, although we settled those lawsuits in June 2021 and December 2022, respectively. The terms of our settlement with Sun and Hikma 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 and 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.

**Natural disasters, some possibly related to the increasing effects of climate change, could damage or destroy clinical trial sites, our office spaces, the residences of our employees or the facilities or residences of our vendors, contractors or consultants, which could significantly harm our operations.**

We are vulnerable to natural disasters, including earthquakes, fires, hurricanes, floods, blizzards and the extended periods of extreme heat, cold and precipitation made more frequent and severe by global warming. For example, our headquarters are in the San Francisco Bay Area, which experiences earthquakes, wildfires and flooding. Our specialty pharmacy, tablet manufacturers and warehouses are in areas subject to hurricanes and tornadoes. All our activities, as well as the activities of our vendors, consultants, clinical investigators, patients, physicians and regulators, are subject to the risks posed by global warming.

The loss of life, property damage and disruptions to electrical power distribution, communications, travel and shipping caused by natural disasters could make it difficult or impossible to conduct our commercial activities or complete our drug discovery activities or clinical trials. Patients may be unwilling or unable to travel to clinical trial sites, for example, or clinical materials or data may be lost.

Our insurance, if available at all, would likely be insufficient to cover losses resulting from disasters or other business interruptions.

**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 30, 2021, 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.

Physician preference for any of these medications, or for the off-label use of generic medications such as ketoconazole, to treat patients with Cushing's syndrome could reduce our revenue materially and harm our results of operations, which would cause our stock price to decline.

**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. 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. 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 the United States, there have been and continue to be legislative initiatives to contain healthcare costs. The Patient Protection and Affordable Care Act ("ACA") which was passed in 2010, substantially changed the way health care is financed



by both governmental and private insurers. The Inflation Reduction Act of 2022, or IRA, introduced some of the most significant changes to Medicare payment for prescription drugs since the ACA. Among its many provisions, the IRA requires the Secretary of the U.S. Department of Health and Human Services (“HHS”) to negotiate Medicare prices for selected drugs and biologicals, including both physician-administered products covered under Medicare’s Part B benefit and self-administered drugs covered under the Part D benefit. Each year, the Secretary will select for price negotiation a specified number of negotiation-eligible drugs with the highest total Part B or D expenditures over a preceding 12-month period. To be eligible for price negotiation a drug must have been on the market for at least seven years without generic competition. Orphan drugs indicated for only one rare disease or condition and drugs with less than \$200 million in annual Medicare expenditures are exempt from the negotiation program. For the first two years of the program, 2026 and 2027, only Part D drugs are eligible. The Secretary will publish the negotiated price, known as the “Maximum Fair Price”, or MFP, for each of the selected products. Manufacturers of selected drugs would be required to offer the drug for Medicare recipients at the MFP. Manufacturers who fail to negotiate or offer the MFP can face significant civil money penalties or excise tax liability on sales of that drug. Depending on the share of Medicare spending each year that is attributed to Korlym or any other drug candidate that we develop and whether or not those drugs become eligible for Medicare negotiation, those drugs and our revenue may be adversely impacted by this provision.

The IRA also establishes an inflation rebate program that requires manufacturers to pay rebates to the Medicare program if any of the medications they provide Medicare recipients increase in price faster than the rate of inflation. The Part D inflation rebate provision went into effect on October 1, 2022. Although manufacturers are generally familiar with inflation rebates under the Medicaid program, where they have existed for decades, the IRA represents the first time that inflation rebates have been extended to the Medicare program.

Beginning in 2025, the IRA will also shift a significant portion of the Medicare beneficiary costs from the government and beneficiaries to manufacturers. We anticipate that this provision will significantly limit the revenue Corcept receives and may materially reduce our revenue and profits.

There continues 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.

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 active pharmaceutical ingredient (“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 are approved to produce and bottle Korlym tablets. The current term of our agreement with PCAS continues until December 31, 2023. We use a single specialty pharmacy, Optime, to dispense Korlym and perform related pharmacy operations, patient support and related services, including the collection of 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 extends to March 31, 2024, 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 our 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 European Medicines Agency (“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. On June 24, 2022, the United States Supreme Court published its decision in the case of *Dobbs v. Jackson Women’s Health Organization* (“Dobbs”), which overturned *Roe v. Wade*, the 1973 Supreme Court decision establishing a woman’s right to terminate her pregnancy, subject to certain limitations. *Dobbs* has stimulated many states to enact laws making abortion illegal in virtually every circumstance, including during early pregnancy. More laws banning or heavily restricting termination of pregnancy may be adopted and existing laws may be made more restrictive. Heightened public perception of mifepristone as an abortifacient may draw the attention of hostile state government officials or political activists to Korlym – even though Korlym is not approved for the termination of pregnancy, we do not promote it for that use and we have taken measures to minimize the chance that it will accidentally be prescribed to a pregnant woman. In addition, physicians and patients may choose not to use Korlym as a treatment for Cushing’s syndrome 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 (“GCPs”). 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 new drug applications (“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,” manufacturers are prohibited from engaging in any of “off-label” promotion. 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. Among other activities, 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 may restrict our ability to promote our products, which could adversely impact our business.

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. And, although we structure our applicable business arrangements in accordance with the safe harbors, it is difficult to determine exactly how the law will be applied in specific circumstances. Accordingly, it is possible that certain practices of ours may be challenged under the federal Anti-Kickback Statute. From a liability perspective, 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. The federal False Claims Act is unique in that it allows private individuals (whistleblowers) to bring actions on behalf of the federal government via qui tam actions. Importantly, under the False Claims Act 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;
- 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;
- 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 (or sometimes referred to as the Open Payments<sup>TM</sup> Program), 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, certain non-physician practitioners, teaching hospitals, and ownership or investment interests held by physicians and their immediate family members;
- 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 and scrutiny. 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.

In November 2021, we received a records subpoena from the United States Attorney’s Office for the District of New Jersey (the “NJ USAO”) seeking information relating to the sale and promotion of Korlym, our 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 us that it is investigating whether any criminal or civil violations by us occurred in connection with the matters referenced in the subpoena. It has also informed us that it does not currently consider us a defendant but rather an entity whose conduct is within the scope of the government’s investigation. We are cooperating with the investigation. 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 lengthened the time it takes to initiate and advance some of our clinical trials.”*

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. Studies of diseases perceived to be acutely life-threatening, such as our Phase 2 trial in women with platinum-resistant ovarian cancer, did not experience 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 or the loss of enrolled patients due to COVID-19 related restrictions;
- 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 GCPs, 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. Outside parties may have staffing difficulties, may undergo changes in priorities or may become financially distressed, adversely affecting their willingness or ability to conduct our clinical trials. Problems with the timeliness or quality of the work of a CRO may lead us to seek to terminate the relationship and use an alternative service provider. However, making this change may be costly and may delay our trials, and it may be challenging to find a replacement organization that can conduct our trials in an acceptable manner and at an acceptable cost. 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 or 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 and possibly 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 a clinical trial or commercialization efforts, the commercial prospects of the affected 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, 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 is likely to 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 21, 2023, our average daily trading volume was approximately 736,105 shares and the intra-day sales prices per share of our common stock on The Nasdaq Stock Market ranged from \$17.19 to \$30.14. As of February 21, 2023, 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;
- 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 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 Federal Trade Commission 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 (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 2022, the FTC also began a rulemaking proceeding to develop additional data privacy rules and requirements, which may add additional complexity to compliance obligations going forward.

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, the California Consumer Privacy Act, or the CCPA, which took effect on January 1, 2020, created individual privacy rights for California consumers and increased 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, revised and expanded the CCPA, adding 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 also created a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. The CPRA is in full effect as of January 1, 2023, and similar laws passed in Virginia, Colorado, Connecticut and Utah will take effect starting in 2023. As a result, 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. Additional legislation proposed at the federal level and in other states, along with increased regulatory action, reflect a trend toward more stringent privacy legislation in the United States.

Outside the United States, many jurisdictions have or are in the process of enacting sweeping data privacy regulatory regimes. In Europe, the GDPR took effect in 2018, and is imposing 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 added complexity and compliance uncertainty regarding certain transfers of information from the EEA to the United States. Following EU court decisions, updated standard contractual clauses (“SCCs”) were adopted to account for these judicial decisions, imposing new requirements on data transfers. The revised SCCs must be used for relevant new data transfers from September 27, 2021, and existing SCC arrangements were required to be migrated 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 to conduct our business. A breakdown or breach of our information technology 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/or misuse of, our clinical data or other confidential information, including confidential information relating to our patients or employees. COVID-19 may continue to 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. Russia’s invasion of Ukraine or another war of international dispute may cause an increase in the number and severity of such malicious incidents. 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.

**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.” Certain provisions of the recently enacted Inflation Reduction Act of 2022, effective January 1, 2023, including a 1% excise tax on share repurchases and a 15% corporate alternative minimum tax, may impact our income tax expense, profitability and capital allocation decisions. Changes to existing tax laws could materially increase the amounts we pay, which would reduce our after tax net income.

**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 our outstanding shares are eligible for sale, subject to applicable volume and certain 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, the Dodd Frank Act of 2010 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.

**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 and the governance and other requirements of the Dodd Frank Act of 2010, 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 21, 2023, 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.

**We have in the past and may in the future be subject to short selling strategies that may drive down the market price of our common stock.**

Short sellers have in the past and may attempt in the future to drive down the market price of our common stock. Short selling is the practice of selling securities that the seller does not own but may have borrowed with the intention of buying identical securities back at a later date. The short seller hopes to profit from a decline in the value of the securities between the time the securities are borrowed and the time they are replaced. As it is in the short seller's best interests for the price of the stock to decline, many short sellers (sometime known as "disclosed shorts") publish, or arrange for the publication of, negative opinions regarding the relevant issuer and its business prospects to create negative market momentum. Although traditionally these disclosed shorts were limited in their ability to access mainstream business media or to otherwise create negative market rumors, the rise of the Internet and technological advancements regarding document creation, videotaping and publication by weblog ("blogging") have allowed many disclosed shorts to publicly attack a company's credibility, strategy and veracity by means of so-called "research reports" that mimic the type of investment analysis performed by large Wall Street firms and independent research analysts. These short attacks have, in the past, led to selling of shares in the market. Further, these short seller publications are not regulated by any governmental, self-regulatory organization or other official authority in the U.S. and they are not subject to certification requirements imposed by the SEC. Accordingly, the opinions they express may be based on distortions, omissions or fabrications. Companies that are subject to unfavorable allegations, even if untrue, may have to expend a significant amount of resources to investigate such allegations and/or defend themselves, including shareholder suits against the company that may be prompted by such allegations. We may in the future be the subject of shareholder suits that we believe were prompted by allegations made by short sellers.

**ITEM 1B. UNRESOLVED STAFF COMMENTS**

None.

**ITEM 2. PROPERTIES**

We lease 47,022 square feet of office space in Menlo Park, California for our corporate facilities. Our current lease expires in June 2023.

**ITEM 3. LEGAL PROCEEDINGS**

*Teva Litigation*

In February 2018, we received a Paragraph IV Notice Letter advising that Teva Pharmaceuticals USA, Inc. ("Teva") had submitted an Abbreviated New Drug Application ("ANDA") to the FDA seeking authorization to manufacture and sell a generic version of Korlym 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"). 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 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, which it later vacated. A new trial date has not been set.

On May 7, 2019, Teva submitted to the Patent Trial and Appeal Board (“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 our favor.

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

This lawsuit against Teva currently asserts the ‘214 patent and the ‘216 patent. The parties have completed briefing cross-motions for summary judgment regarding infringement of the ‘214 patent. On February 27, 2023, the Court denied both motions without prejudice. No trial date has been set.

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

#### *Hikma ANDA Litigation and Settlement*

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.

On December 7, 2022, we entered into an agreement with Hikma resolving this litigation. Pursuant to the agreement, we have granted Hikma 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 Hikma have submitted the settlement agreement to the United States Federal Trade Commission and the United States Department of Justice for review.

#### *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.

On February 8, 2023, we reached an agreement in principle (the “Proposed Settlement”) to resolve all claims in the Melucci litigation. Under the Proposed Settlement, we have agreed to make a one-time payment of \$14.0 million, which will be covered in full by our insurers. The Proposed Settlement is subject to the final approval of the United States District Court for the Northern District of California.

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.

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.

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 President of Corcept Endocrinology 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. On April 20, 2022, the case was further stayed pending a resolution of the Melucci litigation.

We will respond vigorously to the above allegations but cannot predict the outcome of these matters.

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, our 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 us that it is investigating whether any criminal or civil violations by us occurred in connection with the matters referenced in the subpoena. It has also informed us that it does not currently consider us a defendant but rather an entity whose conduct is within the scope of the government's investigation.

In addition to the above-described matters, we are involved from time-to-time in other legal proceedings arising in the ordinary course of our business. 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 21, 2023, we had 107,899,316 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, 2022 as part of the cashless net exercises of stock options (in thousands, except average price per share):

Fiscal Period	Total Number of Shares Purchased <sup>(1)</sup>	Average Price Per Share	Total Purchase Price of Shares <sup>(2)</sup>
October 1, 2022 to October 31, 2022	19	\$ 27.75	\$ 536
November 1, 2022 to November 30, 2022	81	25.74	2,079
December 1, 2022 to December 31, 2022	24	22.55	532
Total	124	\$ 25.45	\$ 3,147

(1) In October 2022, we issued 29,584 shares of common stock as part of net-share settlement of cashless option exercises, of which 19,306 shares were surrendered to us in satisfaction of related exercise cost and tax obligations. In November 2022, we issued 120,595 shares of common stock as part of net-share settlement of cashless option exercises, of which 80,770 shares were surrendered to us. In December 2022, we issued 60,480 shares of common stock as part of net-share settlement of cashless option exercises, of which 23,590 shares were surrendered to us.

(2) We paid \$0.7 million to satisfy the tax withholding obligations associated with the net-share settlement of these cashless option exercises.

#### Market Performance Graph

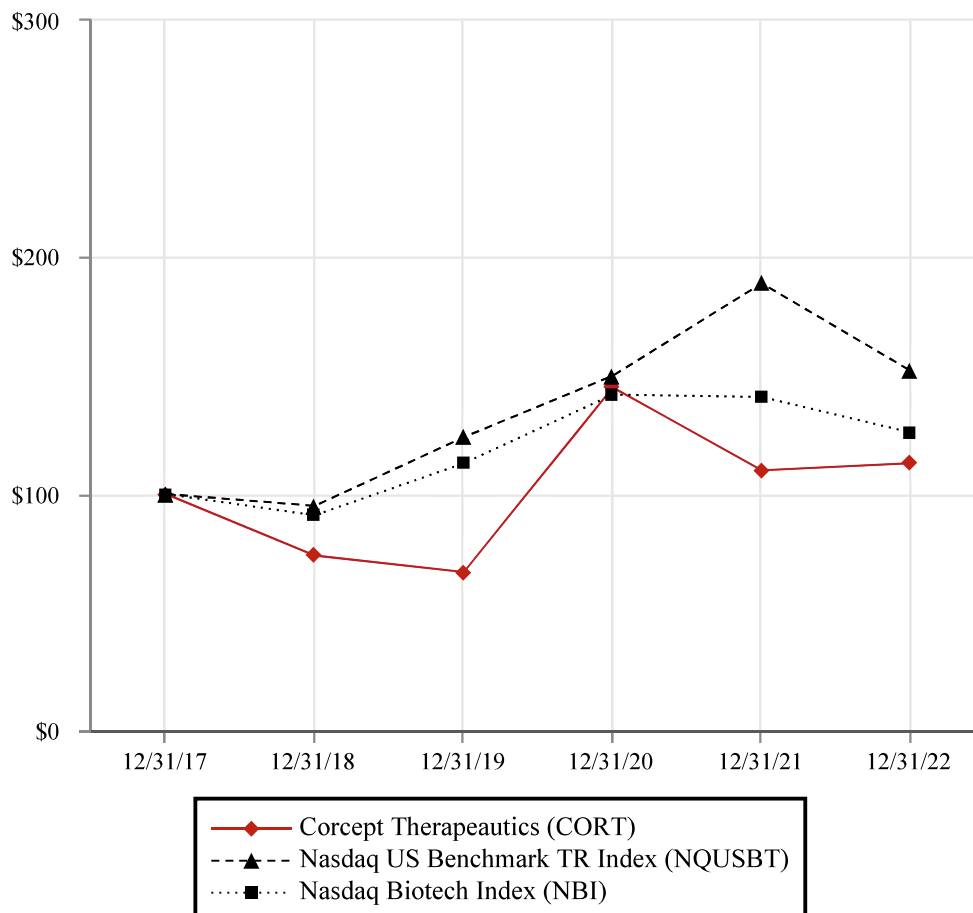
*The graph and the accompanying text below is not "soliciting material," is not deemed filed with the SEC and is not to be incorporated by reference in any filings by us under the Securities Act or the Exchange Act, whether made before or after the date hereof and irrespective of any general incorporation 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" within the meaning of the federal securities laws. For a complete discussion of such statements and the potential risks and uncertainties that may affect their accuracy, see the "Risk Factors" section of 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 medications to treat severe endocrine, oncologic, metabolic and neurological disorders by modulating the effects of the hormone cortisol.

#### *Cushing's Syndrome*

**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 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. 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, liver function, coagulopathy, cognition, mood, insulin resistance and quality of life measures. Relacorilant shares Korlym's affinity for the glucocorticoid receptor ("GR"), but, unlike Korlym, has no affinity for the progesterone receptor ("PR"), and so is not the "abortion pill" and does not cause other effects associated with PR affinity, including endometrial thickening and vaginal bleeding. Relacorilant also does not appear to cause hypokalemia (low potassium), a potentially serious condition 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 of hypertension in patients receiving placebo measured against the rate and degree of relapse of hypertension in those continuing relacorilant. GRACE has a planned enrollment of 130 patients with 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 22 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 Administration ("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.

### *Oncology*

There is substantial evidence that cortisol activity at the GR reduces the efficacy of certain anti-cancer therapies and that modulating cortisol’s activity may help anti-cancer treatments achieve their intended effect. 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. Many types of solid tumors express the GR and are potential targets for cortisol modulation therapy, among them ovarian, adrenal and prostate cancer.

*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 in addition to nab-paclitaxel. Sixty women received nab-paclitaxel alone. The trial’s primary endpoint was progression-free survival (i.e., the time from random assignment in a clinical trial to disease progression or death from any cause or “PFS”).

Patients in both of the 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: 0.038). 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 (“DoR”) (5.6 months versus 3.7 months, hazard ratio: 0.36; p-value: 0.006) compared to those who received nab-paclitaxel alone. Patients who received relacorilant intermittently also lived longer (median OS: 13.9 months versus 12.2 months, hazard ratio: 0.67; p-value: 0.066) compared to those who received nab-paclitaxel alone.

Safety and tolerability of relacorilant plus nab-paclitaxel were comparable to nab-paclitaxel monotherapy.

In June 2022, we initiated a pivotal Phase 3 trial (“ROSELLA”) that seeks to replicate the positive results observed in our Phase 2 study. ROSELLA has a planned enrollment of 360 women with recurrent, platinum-resistant ovarian cancer, randomized 1:1 to receive either relacorilant plus nab-paclitaxel or nab-paclitaxel monotherapy. The primary endpoint is PFS, with overall survival as a key secondary endpoint. Patients in ROSELLA will have received prior bevacizumab therapy, which is the standard of care in the United States for patients with platinum-resistant ovarian cancer. Women with a history of tumors that do not respond to initial platinum-based treatments (i.e., women with “primary platinum-refractory” disease) and those who have received more than three prior lines of therapy will be excluded.

In our Phase 2 trial, women who met the entry criteria for ROSELLA and received relacorilant intermittently experienced significantly improved PFS (median: 7.3 months versus 3.7 months, hazard ratio: 0.40; p-value: 0.005) and OS (median: 17.9 months versus 12.6 months, hazard ratio: 0.38; p-value: 0.011) relative to patients in the comparator arm. The patients in the intermittent arm also experienced a significant improvement in DoR relative to those in the comparator arm (median: 5.6 months versus 3.1 months, hazard ratio: 0.29; p-value: 0.016).

*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 patients with metastatic or unresectable adrenal cancer whose tumors produce cortisol. 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. Relacorilant is also expected to treat the patients’ Cushing’s syndrome generated by their tumors’ excess production of cortisol.

*Relacorilant in Patients with Prostate Cancer.* Androgen deprivation is the standard treatment for prostate cancer because androgens stimulate prostate tumor growth. Tumors often escape androgen deprivation therapy when cortisol’s activity at the GR stimulates tumor growth. Combining a cortisol modulator with an androgen modulator may block this escape route. Our collaborators at the University of Chicago plan to initiate a randomized, placebo-controlled Phase 2 trial of relacorilant plus enzalutamide in patients with prostate cancer, pre-prostatectomy. We are providing relacorilant and placebo for the study and have licensed patents covering the use of relacorilant combined with anticancer agents such as enzalutamide in the treatment of patients with this indication.

### *Amyotrophic Lateral Sclerosis (“ALS”)*

ALS, also known as Lou Gehrig’s disease, is a devastating neuromuscular illness. Our selective cortisol modulator dazucorilant improved motor performance and reduced neuroinflammation and muscular atrophy in animal models of ALS. Following these compelling results, in October 2022 we initiated a Phase 2 trial of dazucorilant (the “DAZALS” trial) in patients with ALS. DAZALS has a planned enrollment of 198 patients, randomized 1:1:1 to receive either 150 mg or 300 mg of dazucorilant or placebo daily for 24 weeks. The primary endpoint is the difference between dazucorilant and placebo demonstrated by patients on the ALS Functional Rating Scale-Revised (ALSFRS-R).

### *Metabolic Diseases*

*Liver Disease.* NASH is an advanced form of nonalcoholic fatty liver disease that afflicts millions of patients and is a leading cause of liver-related mortality. In April 2021, we suspended our Phase 2a trial of our selective cortisol modulator miricorilant as a potential treatment for NASH after four of the five patients who received miricorilant exhibited both elevated liver enzymes and large rapid reductions in liver fat. Liver enzyme levels in all affected patients returned to baseline or below baseline after miricorilant was withdrawn. Our ongoing Phase 1b dose-finding trial in patients with presumed NASH has identified a range of doses that appear to cause large reductions in liver fat without causing excessive liver irritation. We plan to start a Phase 2 trial in the fourth quarter of 2023.

*Antipsychotic-Induced Weight Gain (“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 largely to increased cardiovascular events, such as heart attacks and strokes. Patients in our two double-blind, placebo-controlled, Phase 2 trials of miricorilant (GRATITUDE and GRATITUDE II) did not experience reversal of AIWG. However, multiple replicated pre-clinical results as well as the results of our double-blind, placebo-controlled trial (published in the *Journal of Clinical Psychopharmacology* (Hunt et al., 2021)) suggest that miricorilant has the potential to significantly reduce weight gain caused by the administration of olanzapine. Accordingly, we plan to further study miricorilant’s potential to prevent AIWG.

### *COVID-19 Pandemic*

Public health restrictions put in place to reduce the impact of the global COVID-19 pandemic, as well as measures voluntarily undertaken by patients, physicians, hospitals and medical clinics, have reduced our revenue growth and make it difficult to grow our Korlym business.

The pandemic’s impact on the pace of our clinical development programs has been variable. Some of our trials of indications not considered immediately life-threatening, such as Cushing’s syndrome, have experienced slower enrollment. In addition, some clinical sites have reduced the frequency with which physicians see study participants. Our trials in patients with immediately life-threatening diseases, such as our Phase 2 trial in women with platinum-resistant ovarian cancer, have not encountered delays.

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

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.*”

### *Inflation Reduction Act of 2022*

The Inflation Reduction Act of 2022 (“IRA”) was enacted on August 16, 2022. The IRA includes provisions imposing a 1% excise tax on share repurchases that occur after December 31, 2022 and introduces a 15% corporate alternative minimum tax (“CAMT”) on adjusted financial statement income. The CAMT will be effective for us beginning on January 1, 2024. We do not expect the CAMT to have a significant effect on our consolidated financial statements.

## **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 \$401.9 million for the year ended December 31, 2022, compared to \$366.0 million and \$353.9 million for the years ended December 31, 2021 and 2020, respectively. For the years ended December 31, 2022 and 2021, sales

volume accounted for 54.6 percent and 20.7 percent of the increases, respectively. Increases in the average price of Korlym accounted for the remaining growth due to price increases effective January 1, 2022 and 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 \$5.4 million for the year ended December 31, 2022, compared to \$5.3 million and \$5.6 million for the years ended December 31, 2021 and 2020, respectively. Cost of sales as a percentage of revenue was 1.3 percent, 1.4 percent and 1.6 percent for the years ended December 31, 2022, 2021 and 2020, respectively. The decreases in cost of sales as a percentage of revenue are due to reduced manufacturing costs and increased price of Korlym.

*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 \$131.0 million for the year ended December 31, 2022, compared to \$113.9 million for the comparable period in 2021. The increase was primarily due to the advancement of our development programs and increased spending on employee compensation expenses.

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.

	Year Ended December 31,		
	2022	2021	2020 <sup>(1)</sup>
	(in thousands)		
Development programs:			
Oncology	\$ 20,987	\$ 17,984	\$ 34,207
Cushing's syndrome	30,031	28,639	26,821
Metabolic diseases	24,270	20,594	20,408
Pre-clinical and early-stage selective cortisol modulators and ALS	26,084	21,924	14,726
Unallocated activities, including manufacturing and regulatory activities	16,819	10,617	7,380
Stock-based compensation	12,800	14,106	11,222
Total research and development expense	<u>\$ 130,991</u>	<u>\$ 113,864</u>	<u>\$ 114,764</u>

<sup>(1)</sup> Beginning in the first quarter of 2021, expenses for the year ended December 31, 2020 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 2023 than in 2022 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 \$152.8 million for the year ended December 31, 2022, compared to \$122.4 million for the comparable period in 2021. The increase was primarily due to increased sales and marketing activities, employee compensation expenses, and legal 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.

We expect our selling, general and administrative expense to be higher in 2023 than in 2022 due to increased commercial and administrative activities, including litigation and administrative support for increased research and development and marketing efforts.

*Settlement expense and insurance recovery related to Melucci litigation* – In connection with the Proposed Settlement of the Melucci litigation, we recorded a settlement expense of \$14.0 million and corresponding insurance recovery of \$14.0 million in Operating Expenses on our Consolidated Statement of Income in the fourth quarter of 2022.

*Interest and other income* – Interest and other income for the years ended December 31, 2022, 2021 and 2020 was \$3.6 million, \$0.5 million and \$3.4 million, respectively, and consisted primarily of interest income from marketable securities. Interest and other income increased for the year ended December 31, 2022 from the comparable periods in 2021 and 2020 due to a higher cash and investment balance and market-wide increases in interest rates.

*Income tax expense* – Income tax expense was \$14.8 million for the year ended December 31, 2022, compared to \$12.5 million for the comparable period in 2021. Income tax expense increased for the year ended December 31, 2022 from the comparable period in 2021 due to decreased excess tax benefits for stock option exercises compared to 2021. 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. Income tax expense decreased for the year ended December 31, 2021 from the comparable period in 2020 primarily due to increases in excess tax benefits for stock option exercises compared to 2020. 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, 2022, we had cash, cash equivalents and marketable securities of \$436.6 million, consisting of cash and cash equivalents of \$66.3 million and marketable securities of \$370.3 million, compared to 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 as of December 31, 2021.

The cash in our bank accounts and our marketable securities could be reduced or our access to them restricted if the financial institutions holding them were to fail or severely adverse conditions were to arise in the markets for public or private debt securities. We have never experienced a lack of access to cash or material realized losses.

Net cash provided by operating activities for the years ended December 31, 2022, 2021 and 2020 was \$120.3 million, \$167.9 million and \$152.0 million, respectively. The decrease for the year ended December 31, 2022 compared to 2021 was primarily due to higher current income taxes resulting from the capitalization of research and development costs for tax purposes. The increase for the year ended December 31, 2021 compared to 2020 was primarily due to higher revenue.

Net cash (used in) provided by investing activities for the year ended December 31, 2022, 2021 and 2020 was \$(114.3) million, \$136.1 million and \$(119.3) million, respectively. The change for the year ended December 31, 2022 compared to 2021 was primarily due to allocation of cash generated from our operating activities towards marketable securities rather than share repurchases. The change for the years ended December 31, 2021 compared to 2020 was primarily due to our use of cash for the repurchase of our common stock instead of increasing our investment in marketable securities.

In the year ended December 31, 2022, we spent \$21.7 million acquiring shares of our common stock in connection with the net exercise of employee and director stock options and vesting of restricted stock grants, offset by \$4.4 million received from the exercise of stock options and purchases through our Employee Stock Purchase Plan, resulting in net cash used in financing activities of \$17.3 million. In the comparable periods in 2021 and 2020, we spent \$318.8 million and \$11.0 million, respectively, acquiring shares of our common stock, offset by \$16.2 million and \$23.2 million received from the exercise of stock options, respectively, resulting in net cash used in financing activities of \$302.6 million for the year ended and net cash provided by financing activities of \$12.2 million for the year ended December 31, 2020.

As of December 31, 2022, we had retained earnings of \$296.4 million.

### *Manufacturing Purchase Commitments*

We have 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, 2022, we had \$1.5 million remaining in commitments to purchase API from PCAS and have a \$0.2 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, Medicare 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.

#### *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 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.

### **ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

The primary objective of our investment activities is to preserve capital. As of December 31, 2022, the fair value of our cash and cash equivalents and marketable securities was \$436.6 million. Our marketable securities consisted of corporate notes, commercial paper, asset-backed securities, U.S. Treasury and government agency 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, 2022.

### **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.

As of December 31, 2022, 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.

There were no changes in our internal controls over financial reporting during the quarter ended December 31, 2022 that materially affected, or are 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, 2022, 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, 2022.

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

**(c) Inherent Limitations on Effectiveness of Controls**

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.

**(d) 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, 2022, 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, 2022, 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, 2022 and 2021, the related consolidated statements of income, comprehensive income, cash flows and stockholders’ equity for each of the three years in the period ended December 31, 2022, and the related notes and our report dated February 28, 2023 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

San Mateo, California

February 28, 2023

**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 2023 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:

	<b>Page</b>
<a href="#"><u>Report of Independent Registered Public Accounting Firm</u></a>	<a href="#"><u>2</u></a>
Audited Consolidated Financial Statements	
<a href="#"><u>Consolidated Balance Sheets</u></a>	<a href="#"><u>4</u></a>
<a href="#"><u>Consolidated Statements of Income</u></a>	<a href="#"><u>5</u></a>
<a href="#"><u>Consolidated Statements of Comprehensive Income</u></a>	<a href="#"><u>6</u></a>
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<a href="#"><u>Notes to Consolidated Financial Statements</u></a>	<a href="#"><u>11</u></a>

(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

<b>Exhibit Number</b>	<b>Description of Document</b>
3.1	<a href="#"><u>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).</u></a>
3.2	<a href="#"><u>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).</u></a>
4.1	<a href="#"><u>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).</u></a>
4.2	<a href="#"><u>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)</u></a>
10.1#	<a href="#"><u>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).</u></a>
10.2†	<a href="#"><u>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).</u></a>
10.3†	<a href="#"><u>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).</u></a>
10.4†	<a href="#"><u>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).</u></a>
10.5†	<a href="#"><u>Amended and Restated 2004 Equity Incentive Plan (incorporated by reference to the registrant's Proxy Statement on Schedule 14A filed on May 7, 2009).</u></a>

Exhibit Number	Description of Document
10.6†	<a href="#"><u>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).</u></a>
10.7†	<a href="#"><u>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).</u></a>
10.8†	<a href="#"><u>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).</u></a>
10.9†	<a href="#"><u>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).</u></a>
10.10†	<a href="#"><u>Form of 2012 Incentive Award Plan Stock Option Grant Notice and Agreement</u></a>
10.11†	<a href="#"><u>Form of 2012 Incentive Award Plan Restricted Stock Unit Grant Notice and Agreement</u></a>
10.12†	<a href="#"><u>Form of 2012 Incentive Award Plan Restricted Stock Award Grant Notice and Agreement</u></a>
10.13	<a href="#"><u>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).</u></a>
10.14#	<a href="#"><u>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).</u></a>
10.15#	<a href="#"><u>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).</u></a>
10.16	<a href="#"><u>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).</u></a>
10.17	<a href="#"><u>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).</u></a>
10.18	<a href="#"><u>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).</u></a>
10.19#	<a href="#"><u>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).</u></a>
10.20#	<a href="#"><u>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).</u></a>
10.21#	<a href="#"><u>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 10.41 to the registrant's Annual Report on Form 10K filed on March 13, 2015).</u></a>
10.22#	<a href="#"><u>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).</u></a>
10.23##	<a href="#"><u>Amendment No. 1 to Distribution Services Agreement by and between Optime Care, Inc. and Corcept Therapeutics Incorporated, made and entered into as of August 1, 2022. (incorporated by reference to Exhibit 10.3 to the registrant's Quarterly Report on Form 10-Q filed on November 3, 2022).</u></a>
10.24##	<a href="#"><u>Amendment No. 2 to Distribution Services Agreement by and between Optime Care, Inc. and Corcept Therapeutics Incorporated, made and entered into as of August 1, 2022. (incorporated by reference to Exhibit 10.4 to the registrant's Quarterly Report on Form 10-Q filed on November 3, 2022).</u></a>

Exhibit Number	Description of Document
10.25#	<a href="#"><u>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.</u></a>
10.26#	<a href="#"><u>Amendment No. 1 to the Manufacturing and Supply Agreement effective March 19, 2014 with PCAS SA, dated July 25, 2018</u></a>
10.27	<a href="#"><u>Office Lease Agreement by and between Exponent Realty, LLC and Corcept Therapeutics Incorporated, effective as of April 1, 2016.</u></a>
10.28	<a href="#"><u>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.</u></a>
10.29	<a href="#"><u>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.</u></a>
10.30	<a href="#"><u>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.</u></a>
10.31	<a href="#"><u>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.</u></a>
10.32†	<a href="#"><u>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).</u></a>
10.33†	<a href="#"><u>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).</u></a>
10.34†	<a href="#"><u>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).</u></a>
10.35	<a href="#"><u>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).</u></a>
10.36	<a href="#"><u>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).</u></a>
10.37†	<a href="#"><u>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).</u></a>
10.38†	<a href="#"><u>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).</u></a>
10.39†	<a href="#"><u>Employment offer letter to William Guyer, dated July 2, 2021.</u></a>
10.40†	<a href="#"><u>Severance and Change in Control Agreement by and between Corcept Therapeutics Incorporated and William Guyer, dated February 9, 2022.</u></a>
10.41	<a href="#"><u>Seventh Amendment to Office Lease Agreement by and between Exponent Realty, LLC and Corcept Therapeutics Incorporated, made and entered into as of March 18, 2022.</u></a>
23.1	<a href="#"><u>Consent of Independent Registered Public Accounting Firm</u></a>
24.1	<a href="#"><u>Power of Attorney (See signature page)</u></a>
31.1	<a href="#"><u>Certification pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934 of Joseph K. Belanoff, M.D.</u></a>
31.2	<a href="#"><u>Certification pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934 of Atabak Mokari</u></a>
32.1	<a href="#"><u>Certification pursuant to 18 U.S.C. Section 1350 of Joseph K. Belanoff, M.D.</u></a>

Exhibit Number	Description of Document
32.2	<a href="#">Certification pursuant to 18 U.S.C. Section 1350 of Atabak Mokari</a>
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
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
##	Certain identified information has been omitted pursuant to Item 601(b)(10) of Regulation S-K because such information is both (i) not material and (ii) information that the registrant treats as private or confidential. The Registrant hereby undertakes to furnish supplemental copies of the unredacted exhibit upon request by the SEC.
†	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 28, 2023

## 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
<u>/s/ JOSEPH K. BELANOFF</u> <b>Joseph K. Belanoff, M.D.</b>	Chief Executive Officer, President and Director (Principal Executive Officer)	February 28, 2023
<u>/s/ ATABAK MOKARI</u> <b>Atabak Mokari</b>	Chief Financial Officer (Principal Financial Officer)	February 28, 2023
<u>/s/ JOSEPH DOUGLAS LYON</u> <b>Joseph Douglas Lyon</b>	Chief Accounting Officer (Principal Accounting Officer)	February 28, 2023
<u>/s/ JAMES N. WILSON</u> <b>James N. Wilson</b>	Director and Chairman of the Board of Directors	February 28, 2023
<u>/s/ GREGG ALTON</u> <b>Gregg Alton</b>	Director	February 28, 2023
<u>/s/ G. LEONARD BAKER, JR.</u> <b>G. Leonard Baker, Jr.</b>	Director	February 28, 2023
<u>/s/ GILLIAN CANNON</u> <b>Gillian Cannon</b>	Director	February 28, 2023
<u>/s/ DAVID L. MAHONEY</u> <b>David L. Mahoney</b>	Director	February 28, 2023
<u>/s/ JOSHUA MURRAY</u> <b>Joshua Murray</b>	Director	February 28, 2023
<u>/s/ KIMBERLY PARK</u> <b>Kimberly Park</b>	Director	February 28, 2023
<u>/s/ DANIEL N. SWISHER, JR</u> <b>Daniel N. Swisher, Jr.</b>	Director	February 28, 2023

**CORCEPT THERAPEUTICS INCORPORATED**  
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## **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, 2022 and 2021, the related consolidated statements of income, comprehensive income, cash flows and stockholders' equity for each of the three years in the period ended December 31, 2022, 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, 2022 and 2021, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2022, 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, 2022, 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 28, 2023 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, 2022, the Company had \$17.0 million of inventory which included \$7.8 million of work in progress and \$9.2 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.

San Mateo, California

February 28, 2023

**CORCEPT THERAPEUTICS INCORPORATED**

**CONSOLIDATED BALANCE SHEETS**

(In thousands, except per share data)

	<b>December 31,</b>	
	<b>2022</b>	<b>2021</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 66,329	\$ 77,617
Short-term marketable securities	365,343	145,918
Trade receivables, net of allowances	31,057	27,625
Insurance recovery receivable related to Melucci litigation (Note 10)	14,000	—
Inventory	6,100	4,988
Prepaid expenses and other current assets	16,424	10,315
Total current assets	499,253	266,463
Strategic inventory	10,931	12,962
Operating lease right-of-use asset	1,143	514
Property and equipment, net of accumulated depreciation and amortization	633	1,002
Long-term marketable securities	4,947	112,277
Other assets	5,058	3,083
Deferred tax assets, net	61,465	27,455
Total assets	\$ 583,430	\$ 423,756
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 11,976	\$ 6,908
Accrued research and development expenses	14,573	12,442
Accrued and other liabilities	30,799	27,665
Accrued settlement related to Melucci litigation (Note 10)	14,000	—
Short-term operating lease liability	1,143	526
Total current liabilities	72,491	47,541
Long-term accrued income taxes payable	9,097	409
Total liabilities	81,588	47,950
Commitments and contingencies (Note 10)		
Stockholders' equity:		
Preferred stock, par value \$0.001 per share, 10,000 shares authorized and no shares outstanding as of December 31, 2022 and December 31, 2021	—	—
Common stock, par value \$0.001 per share, 280,000 shares authorized and 130,959 issued and 107,835 outstanding as of December 31, 2022 and 127,218 shares issued and 105,940 outstanding as of December 31, 2021	131	127
Treasury stock; at cost; 23,124 shares of common stock as of December 31, 2022 and 21,278 shares of common stock as of December 31, 2021	(456,148)	(410,411)
Additional paid-in capital	662,342	591,349
Accumulated other comprehensive loss	(869)	(227)
Retained earnings	296,386	194,968
Total stockholders' equity	501,842	375,806
Total liabilities and stockholders' equity	\$ 583,430	\$ 423,756

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

**CORCEPT THERAPEUTICS INCORPORATED**

**CONSOLIDATED STATEMENTS OF INCOME**

(In thousands, except per share data)

	Year Ended December 31,		
	2022	2021	2020
Product revenue, net	\$ 401,858	\$ 365,978	\$ 353,874
Operating expenses:			
Cost of sales	5,385	5,281	5,582
Research and development	130,991	113,864	114,764
Selling, general and administrative	152,848	122,356	105,326
Settlement expense related to Melucci litigation	14,000	—	—
Insurance recovery related to Melucci litigation	(14,000)	—	—
<b>Total operating expenses</b>	<b>289,224</b>	<b>241,501</b>	<b>225,672</b>
Income from operations	112,634	124,477	128,202
Interest and other income	3,557	529	3,400
Income before income taxes	116,191	125,006	131,602
Income tax expense	(14,773)	(12,494)	(25,591)
<b>Net income</b>	<b>\$ 101,418</b>	<b>\$ 112,512</b>	<b>\$ 106,011</b>
<b>Net income attributable to common stockholders</b>	<b>\$ 101,288</b>	<b>\$ 112,512</b>	<b>\$ 106,011</b>
<b>Basic net income per common share</b>	<b>\$ 0.95</b>	<b>\$ 0.97</b>	<b>\$ 0.92</b>
<b>Diluted net income per common share</b>	<b>\$ 0.87</b>	<b>\$ 0.89</b>	<b>\$ 0.85</b>
<b>Weighted-average shares outstanding used in computing net income per common share</b>			
Basic	106,787	115,653	115,412
Diluted	115,966	125,963	124,194

*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)

	<b>Year Ended December 31,</b>		
	<b>2022</b>	<b>2021</b>	<b>2020</b>
<b>Net income</b>	<b>\$ 101,418</b>	<b>\$ 112,512</b>	<b>\$ 106,011</b>
Other comprehensive income (loss):			
Unrealized loss on available-for-sale investments, net of tax impact of \$105, \$198, and \$15	(331)	(621)	(50)
Foreign currency translation loss, net of tax	(311)	(21)	204
<b>Total comprehensive income</b>	<b>100,776</b>	<b>111,870</b>	<b>106,165</b>

*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,		
	2022	2021	2020
<b>Cash flows from operating activities:</b>			
Net income	\$ 101,418	\$ 112,512	\$ 106,011
Adjustments to reconcile net income to net cash provided by operations:			
Stock-based compensation	42,442	42,931	33,539
Amortization of interest income	1,383	5,083	1,303
Depreciation and amortization of property and equipment	782	1,072	525
Deferred income taxes	(33,905)	4,346	14,089
Non-cash amortization of right-of-use asset	2,187	1,995	1,712
Other	—	10	148
Changes in operating assets and liabilities:			
Trade receivables	(3,432)	(1,427)	(6,270)
Insurance recovery receivable related to Melucci litigation	(14,000)	—	—
Inventory	1,199	3,444	(3,514)
Prepaid expenses and other current assets	(6,080)	(3,597)	(653)
Other assets	(1,975)	1,917	(1,552)
Accounts payable	4,757	(3,597)	3,161
Accrued research and development expenses	2,131	(1,262)	7,227
Accrued and other liabilities	2,927	6,479	(2,083)
Accrued settlement related to Melucci litigation	14,000	—	—
Long-term accrued income taxes	8,688	11	12
Operating lease liability	(2,199)	(2,025)	(1,685)
Net cash provided by operating activities	120,323	167,892	151,970
<b>Cash flows from investing activities:</b>			
Purchases of property and equipment	(413)	(469)	(1,238)
Proceeds from maturities of marketable securities	241,152	398,937	302,089
Proceeds from sales of marketable securities	—	50,463	—
Purchases of marketable securities	(355,066)	(312,805)	(420,114)
Net cash (used in) provided by investing activities	(114,327)	136,126	(119,263)
<b>Cash flows from financing activities:</b>			
Proceeds from issuance of common stock under our incentive award plan, net of issuance costs	4,381	16,229	23,226
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)
Cash paid to satisfy statutory withholding requirement for net settlement of cashless option exercises and vesting of restricted stock grants	(21,665)	(22,835)	(1,067)
Net cash (used in) provided by financing activities	(17,284)	(302,591)	12,214
Net (decrease) increase in cash and cash equivalents	(11,288)	1,427	44,921
Cash and cash equivalents, at beginning of period	77,617	76,190	31,269
Cash and cash equivalents, at end of period	\$ 66,329	\$ 77,617	\$ 76,190
<b>Supplemental disclosure:</b>			
Income taxes paid	\$ 39,747	\$ 9,104	\$ 10,856
Exercise cost of shares repurchased for net settlement of cashless option exercises	\$ 24,388	\$ 15,796	\$ 2,079
Recognition of right-of-use asset and lease liability	\$ 2,816	\$ —	\$ 775

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



**CORCEPT THERAPEUTICS INCORPORATED**

**CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY**

(In thousands)

	<b>Common Stock</b>		<b>Additional Paid-in Capital</b>	<b>Treasury Stock</b>	<b>Accumulated Other Comprehensive Income (Loss)</b>	<b>Retained Earnings (Accumulated Deficit)</b>	<b>Total Stockholders' Equity</b>
	<b>Shares</b>	<b>Amount</b>					
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	—	—	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	—	—	43,168	—	—	—	43,168
Other comprehensive loss, 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
Issuance of common stock under our incentive award plan	3,741	4	28,478	—	—	—	28,482
Shares tendered to satisfy cost and statutory withholding requirements for net settlement of cashless option exercises	(1,846)	—	—	(45,737)	—	—	(45,737)
Stock-based compensation	—	—	42,515	—	—	—	42,515
Other comprehensive loss, net of tax	—	—	—	—	(642)	—	(642)
Net income	—	—	—	—	—	101,418	101,418
Balance at December 31, 2022	107,835	\$ 131	\$ 662,342	\$ (456,148)	\$ (869)	\$ 296,386	\$ 501,842

*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 (collectively, “Corcept,” the “Company,” “we,” “us” and “our”) is a commercial-stage pharmaceutical company engaged in the discovery and development of medications to treat severe endocrine, oncologic, metabolic and neurological disorders by modulating the effects 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 and government agency 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 statements of income.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS, Continued

**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 recorded an allowance for 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. Once a product candidate is approved by the FDA, we begin capitalizing manufacturing costs. 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 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, 2022, 2021 and 2020.

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

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS, Continued

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, Medicare 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, 2022, 2021 and 2020:

	Chargebacks	Government Rebates	Total
	(in thousands)		
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
Provision related to current period sales	557	38,745	39,302
Provision related to prior period sales	78	(68)	10
Credit or payments made during the period	(455)	(38,753)	(39,208)
Balance at December 31, 2022	<u>\$ 230</u>	<u>\$ 11,098</u>	<u>\$ 11,328</u>

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS, Continued

**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 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, 2022 or 2021.

**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 recognize stock-based compensation expense for stock options, restricted stock awards (“RSAs”) and restricted stock units (“RSUs”), net of estimated forfeitures, on a straight-line basis over the period during which an employee is required to provide services in exchange for the award (the vesting period of the award). We estimate future forfeitures during the first quarter of each fiscal year, and revise the estimates, if necessary, in subsequent periods if actual forfeitures differ significantly from those estimates.

We determine the fair value of stock options based on the value of the award at the grant date, 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.

In addition, we have issued RSAs in connection with our Employee Stock Purchase Plan (“ESPP”) that vest on the condition that the participating employee hold the corresponding shares purchased under the ESPP for one year from the purchase date. The participating employee is granted one RSA for each share purchased in the ESPP. We initially measure the

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS, Continued

fair value of these RSAs based on the grant date fair value determined using the closing price of our common stock on the date the purchase of the corresponding ESPP shares is made. This fair value of the RSA is amortized over the one-year holding period. As a result of the RSA's being reported as liability-classified awards, they must be remeasured at each reporting date until settlement. Ultimately, the compensation cost recognized for the RSA award will equal the fair value of the Company's common stock on the date the RSA is fully vested and settled. See Note 7, *Preferred Stock and Stockholders' Equity* regarding our ESPP.

**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.

**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 was five years. In August 2022, we amended our agreement to extend its term to September 30, 2022. In September 2022, we amended our agreement to further extend its term to March 31, 2024, 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 to 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, 2023. The amendment provides exclusivity between PCAS and Corcept. In the event PCAS cannot meet our requirements, we

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS, Continued

may purchase API from another supplier. As of December 31, 2022, we had non-cancelable commitments to purchase \$1.5 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,	
	2022	2021
	(in thousands)	
Cash equivalents	\$ 36,380	\$ 45,088
Short-term marketable securities	365,343	145,918
Long-term marketable securities	4,947	112,277
Total marketable securities	<u>\$ 406,670</u>	<u>\$ 303,283</u>

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

	Fair Value Hierarchy Level	December 31, 2022				December 31, 2021			
		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	\$ 151,069	\$ —	\$ (625)	\$ 150,444	\$ 125,370	\$ 3	\$ (276)	\$ 125,097
Commercial paper	Level 2	136,132	—	—	136,132	30,963	—	—	30,963
U.S. government agency securities	Level 2	25,113	23	—	25,136	—	—	—	—
Asset-backed securities	Level 2	185	—	—	185	57,801	—	(67)	57,734
U.S. Treasury securities	Level 1	58,536	—	(142)	58,394	44,473	—	(72)	44,401
Money market funds	Level 1	36,379	—	—	36,379	45,088	—	—	45,088
Total marketable securities		<u>\$ 407,414</u>	<u>\$ 23</u>	<u>\$ (767)</u>	<u>\$ 406,670</u>	<u>\$ 303,695</u>	<u>\$ 3</u>	<u>\$ (415)</u>	<u>\$ 303,283</u>

We estimate the fair value of marketable securities classified as Level 1 using quoted market prices obtained from a commercial pricing service for these or identical investments. 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 the issuer's poor credit or other reasons. If the fair value of our investment is less than our amortized cost, we evaluate quantitative and subjective factors – including, but not limited to, the nature of security, changes in credit ratings and analyst reports concerning the security's issuer and industry, and interest rate fluctuations and general market conditions to determine whether an allowance for credit losses is appropriate.

None of our investments, including those with unrealized losses, are impaired. Unrealized losses on our investments are due to interest rate fluctuations. We do not intend to sell investments that currently have unrealized losses and it is highly unlikely that we will sell any investment before recovery of its amortized cost basis, which may be at maturity. Accordingly, we have not recorded an allowance for credit losses for these investments.

We classified accrued interest on our marketable securities of \$1.8 million and \$1.4 million as of December 31, 2022 and 2021, respectively, as prepaid and other current assets on our consolidated balance sheets.

As of December 31, 2022, all our marketable securities had original maturities of less than two years and all our marketable securities classified as short-term have maturities of less than one year. The weighted-average maturity of our holdings was four months. As of December 31, 2022, our long-term marketable securities had remaining maturities of 15



## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS, Continued

months. None of our marketable securities changed from one fair value hierarchy to another during the year ended December 31, 2022.

## 4. Composition of Certain Balance Sheet Items

*Inventory*

	<b>Year Ended December 31,</b>	
	<b>2022</b>	<b>2021</b>
	<i>(in thousands)</i>	
Work in progress	\$ 7,827	\$ 11,450
Finished goods	9,204	6,500
Total inventory	17,031	17,950
Less strategic inventory classified as non-current	(10,931)	(12,962)
Total inventory classified as current	<u>\$ 6,100</u>	<u>\$ 4,988</u>

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, net of accumulated depreciation and amortization*

	<b>Year Ended December 31,</b>	
	<b>2022</b>	<b>2021</b>
	<i>(in thousands)</i>	
Furniture and equipment	\$ 1,235	\$ 1,157
Software	1,508	1,508
Leasehold improvements	1,597	1,262
Total property and equipment	4,340	3,927
Less accumulated depreciation and amortization	(3,707)	(2,925)
Property and equipment, net of accumulated depreciation and amortization	<u>\$ 633</u>	<u>\$ 1,002</u>

*Accrued and other liabilities*

	<b>Year Ended December 31,</b>	
	<b>2022</b>	<b>2021</b>
	<i>(in thousands)</i>	
Accrued compensation	\$ 15,511	\$ 13,339
Government rebates	11,098	11,174
Legal fees	2,673	842
Accrued selling and marketing costs	434	1,351
Professional fees	211	150
Income taxes payable	89	513
Other	783	296
Total accrued and other liabilities	<u>\$ 30,799</u>	<u>\$ 27,665</u>

*Other assets*

As of December 31, 2022 and 2021, other assets included \$4.9 million and \$2.9 million of deposits for clinical trials, respectively.



## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS, Continued

**5. Leases**

We lease our office facilities in Menlo Park, California. In March 2022, we amended our lease to extend its term from March 31, 2022 to June 30, 2023. As a result of this amendment, we recognized an additional right-of-use asset and corresponding lease liability of \$2.8 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 expressly state an 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, 2022, 2021 and 2020 was \$2.3 million, \$2.1 million and \$1.9 million, respectively.

Our right-of-use assets and related lease liabilities were as follows (in thousands, except weighted average amounts):

	Year Ended December 31,	
	2022	2021
Cash paid for operating lease liabilities	\$ 2,265	\$ 2,104
Right-of-use assets obtained in connection with operating lease obligations	\$ 2,816	\$ —
Weighted-average remaining lease term	6 months	3 months
Weighted-average discount rate	4.0 %	4.8 %

As of December 31, 2022, future minimum lease payments under non-cancelable operating leases were as follows (in thousands):

2023	\$ 1,157
Total operating lease payments	1,157
Less imputed interest	(14)
Present value of operating lease liabilities	<u>\$ 1,143</u>

**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, 2022, 2021, and 2020.

**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 10.0 million 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, 2022 and 2021, 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

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS, Continued

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.

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.

We have never declared or paid any dividends.

**Incentive Award Plan**

We have one stock option plan – the Corcept Therapeutics Incorporated 2012 Incentive Award Plan (the “2012 Plan”).

In 2012, our Board of Directors and stockholders approved 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.

As of December 31, 2022, we had 10.9 million shares available for future issuance under the 2012 plan.

*Option activity during 2022*

The following table summarizes option activity under the 2012 Plan:

	Outstanding Options			
	Number of Options <i>(in thousands)</i>	Weighted- Average Exercise Price	Weighted- Average Remaining Contractual Life <i>(in years)</i>	Aggregate Intrinsic Value <i>(in thousands)</i>
Balance at December 31, 2021	24,453	\$ 13.50		
Options granted	2,958	\$ 20.38		
Options exercised	(3,681)	\$ 7.56		
Options cancelled and forfeited	(532)	\$ 21.79		
Balance at December 31, 2022	<u>23,198</u>	\$ 15.13	6.20	\$ 152,681
Options exercisable at December 31, 2022	<u>16,850</u>	\$ 12.74	5.38	\$ 141,743
Options fully vested and expected to vest at December 31, 2022	<u>22,789</u>	\$ 15.00	6.16	\$ 152,179

The total intrinsic value of options exercised during the years ended December 31, 2022, 2021 and 2020 was \$63.4 million, \$78.9 million and \$28.8 million, respectively, based on the difference between the closing price of our common stock on the date of exercise and the exercise price.

# CORCEPT THERAPEUTICS INCORPORATED

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS, Continued

The total fair value of options that vested during the years ended December 31, 2022, 2021 and 2020 was \$43.2 million, \$40.4 million and \$34.0 million, respectively.

As of December 31, 2022, we had \$68.7 million of unrecognized compensation expense for options outstanding, which had a weighted-average remaining vesting period of 2.36 years.

### *RSA and RSU (collectively, “restricted stock”) activity during 2022*

The following table summarizes restricted stock activity under the 2012 Plan:

	Outstanding Restricted Stock			
	Number of Restricted Stock	Weighted- Average Grant Date Fair Value	Weighted- Average Remaining Vesting Life	Aggregate Intrinsic Value
	(in thousands)		(in years)	(in thousands)
Balance at December 31, 2021	—	\$ —		
Restricted stock granted	534	\$ 23.37		
Restricted stock vested	(34)	\$ 19.49		
Restricted stock cancelled and forfeited	(45)	\$ 20.87		
Balance at December 31, 2022	<u>455</u>	<u>\$ 23.91</u>	3.35	\$ 896

As of December 31, 2022, we had \$7.8 million of unrecognized compensation expense for restricted stock outstanding, which had a weighted-average remaining vesting period of 3.32 years.

### *ESPP*

In February 2022, we adopted an ESPP that allows employees to set aside, by means of payroll deductions, up to ten percent of their annual cash compensation for the purchase of our common stock. Shares are issued to participating employees from the 2012 Plan on March 1st and September 1st of each year (or, if those dates fall on holidays or weekends, on the first business day thereafter) at the then-current fair market value of our stock, as determined at the close of trading on those days. Payroll deductions for participating employees began April 1, 2022, and the first purchase under the plan took place on September 1, 2022.

In January 2023, we increased the number of ESPP purchase dates to occur quarterly on March 1st, June 1st, September 1st and December 1st (or, if those dates fall on holidays or weekends, on the first business day thereafter).

For each purchased share, the participating employee will receive one matching share, also issued from the 2012 Plan, if certain conditions are met. There is no vesting requirement for shares issued pursuant to the ESPP purchase. The matching share will be granted in the form of a RSA that will vest on the one-year anniversary of the respective ESPP purchase date, net of any applicable tax withholding. The vesting condition on the RSA is that the participating employee hold the corresponding share purchased under the ESPP for one year from the purchase date. Shares purchased pursuant to the ESPP and any matching shares issued upon satisfaction of the one-year holding requirement may be held, sold or transferred at the employee’s discretion.

As of December 31, 2022, we recorded \$0.2 million of stock-based compensation related to RSAs granted in connection with our ESPP in “Accrued and other liabilities” on our consolidated balance sheet.

# CORCEPT THERAPEUTICS INCORPORATED

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS, Continued

### Option Valuation Assumptions

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

	Year Ended December 31,		
	2022	2021	2020
Weighted-average assumptions for options granted:			
Risk-free interest rate	1.97%	0.76%	1.20%
Expected term	6.4 years	6.3 years	6.0 years
Expected volatility of stock price	56.5%	60.7%	59.1%
Dividend rate	0%	0%	0%
Weighted-average grant date fair value-based measurement	\$11.27	\$15.06	\$7.55

The expected term of options reflected in the table above is 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.

### Stock-based Compensation

The following table summarizes our stock-based compensation by financial statement classification.

	Year Ended December 31,		
	2022	2021	2020
	<i>(in thousands)</i>		
Stock-based compensation capitalized in inventory	\$ 280	\$ 237	\$ 238
Cost of sales	70	59	66
Research and development	12,800	14,106	11,222
Selling, general and administrative	29,572	28,766	22,251
Total stock-based compensation	<u>\$ 42,722</u>	<u>\$ 43,168</u>	<u>\$ 33,777</u>

### 8. Net Income Per Share

We compute our basic and diluted net income per share in conformity with the two-class method required for companies with participating shares. Under the two-class method, net income is determined by allocating net income between common stock and unvested RSAs. We compute basic net income per share by dividing our net income attributable to common stockholders by the weighted-average number of common shares outstanding during the period. We compute diluted net income per share by dividing our net income attributable to common stockholders by the weighted-average number of common shares outstanding during the period, including potentially dilutive stock options and unvested RSUs, less unvested RSAs. We use the treasury stock method to determine the number of dilutive shares of common stock resulting from stock options and unvested RSUs.

**CORCEPT THERAPEUTICS INCORPORATED**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS, Continued**

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

	<b>Year Ended December 31,</b>		
	<b>2022</b>	<b>2021</b>	<b>2020</b>
	<i>(in thousands, except per share data)</i>		
<b>Numerator:</b>			
Net income attributable to common stockholders	\$ 101,288	\$ 112,512	\$ 106,011
<b>Denominator:</b>			
Weighted-average shares used to compute basic net income per common share	106,787	115,653	115,412
Dilutive effect of employee stock options and unvested RSUs	9,179	10,310	8,782
Weighted-average shares used to compute diluted net income per common share	115,966	125,963	124,194
<b>Net income per share attributable to common stockholders</b>			
Basic	\$ 0.95	\$ 0.97	\$ 0.92
Diluted	\$ 0.87	\$ 0.89	\$ 0.85

We excluded from the computation of diluted net income per share, on a weighted-average basis, 7.3 million stock options and unvested RSUs outstanding during the year ended December 31, 2022, and 4.5 million and 11.2 million stock options outstanding during the years ended December 31, 2021 and 2020, respectively, because including them would have reduced dilution.

**9. Income Taxes**

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

	<b>Year Ended December 31,</b>		
	<b>2022</b>	<b>2021</b>	<b>2020</b>
	<i>(in thousands)</i>		
Domestic	\$ 116,871	\$ 126,308	\$ 131,634
Foreign	(680)	(1,302)	(32)
Income before income taxes	\$ 116,191	\$ 125,006	\$ 131,602

**CORCEPT THERAPEUTICS INCORPORATED**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS, Continued**

The income tax expense for the years ended December 31, 2022, 2021, and 2020 consisted of the following:

	<b>Year Ended December 31,</b>		
	<b>2022</b>	<b>2021</b>	<b>2020</b>
	<i>(in thousands)</i>		
<b>U.S. federal taxes:</b>			
Current	\$ 39,132	\$ 4,675	\$ 6,094
Deferred	(28,122)	5,066	14,418
Total U.S. federal taxes	11,010	9,741	20,512
<b>State taxes:</b>			
Current	9,515	3,432	5,368
Deferred	(5,313)	(274)	520
Total state taxes	4,202	3,158	5,888
<b>Foreign taxes:</b>			
Current	30	41	41
Deferred	(469)	(446)	(850)
Total foreign taxes	(439)	(405)	(809)
<b>Total provision for income taxes</b>	<b>\$ 14,773</b>	<b>\$ 12,494</b>	<b>\$ 25,591</b>

Beginning in 2022, the Tax Cuts and Jobs Act of 2017 eliminates the right to deduct research and development expenditures for tax purposes in the period the expenses were incurred and instead requires all U.S. and foreign research and development expenditures to be amortized over five and fifteen tax years, respectively. Congress has considered legislation that would defer the amortization requirement to later years, but as of December 31, 2022, the requirement has not been modified. Accordingly, we have capitalized our research and development expenses for tax purposes, resulting in higher cash paid for taxes as compared to prior years.

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:

	<b>Year Ended December 31,</b>	
	<b>2022</b>	<b>2021</b>
	<i>(in thousands)</i>	
<b>Deferred tax assets:</b>		
Federal and state net operating losses	\$ 4,882	\$ 5,377
Capitalized research and patent costs	1,911	3,412
Capitalized research expenditures	36,465	—
Research credits	9,963	9,953
Stock-based compensation costs	17,956	17,831
Operating lease liability	280	130
Other	5,127	3,851
Total deferred tax assets	76,584	40,554
Valuation allowance	(14,839)	(12,972)
<b>Deferred tax liabilities</b>		
Operating lease right-of-use asset	(280)	(127)
Total deferred tax liabilities	(280)	(127)
<b>Net deferred tax assets</b>	<b>\$ 61,465</b>	<b>\$ 27,455</b>

Each quarter, we assess the likelihood that we will generate sufficient taxable income to use our federal and state deferred tax assets. Except for the valuation allowances that offset the value of our California net deferred tax assets, we have determined that it is more likely than not we will realize the benefit related to our deferred tax assets. To the extent we increase

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS, Continued

a valuation allowance, we will include an expense in the Consolidated Statement of Income in the period in which such determination is made.

The valuation allowance increased by \$1.9 million, \$1.4 million and \$0.2 million for the years ended December 31, 2022, 2021 and 2020, respectively.

As of December 31, 2022, we had California net operating loss carryforwards of \$68.6 million, which will begin to expire in the year 2032, and net operating loss carryforwards from other states of \$1.5 million, which will begin to expire in the year 2035 if not utilized.

As of December 31, 2022, we also had California research and development credits of \$14.1 million, which 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,		
	2022	2021	2020
	<i>(in thousands)</i>		
U.S. federal taxes at statutory rate	\$ 24,400	\$ 26,251	\$ 27,636
R&D and other credits	(9,114)	(7,579)	(6,666)
State income taxes, net of federal benefit	3,320	2,495	4,651
Non-deductible compensation	4,354	990	1,508
Stock-based compensation	(7,980)	(9,568)	(1,551)
Other	(207)	(95)	13
Total	<u>\$ 14,773</u>	<u>\$ 12,494</u>	<u>\$ 25,591</u>

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,		
	2022	2021	2020
	<i>(in thousands)</i>		
Beginning balance	\$ 9,237	\$ 7,471	\$ 6,029
Increase in tax positions for prior years	53	103	158
Decreases in tax positions for prior years	—	—	—
Increase in tax positions for current year	2,135	1,663	1,284
Decrease in tax positions for current year	—	—	—
Ending balance	<u>\$ 11,425</u>	<u>\$ 9,237</u>	<u>\$ 7,471</u>

As of December 31, 2022, the amount of unrecognized tax benefits that would favorably impact the effective tax rate were approximately \$9.3 million, and approximately \$2.2 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 insignificant amounts of accrued interest and no accrued penalties related to unrecognized tax benefits as of December 31, 2022, 2021 and 2020. 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 2022 remain open and subject to tax examination by the appropriate federal or state taxing authorities.



## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS, Continued

## 10. Commitments and Contingencies

**Manufacturing Agreements**

We have entered into a number of agreements to purchase API for the manufacturing of relacorilant, miricorilant and exicorilant. 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 162 kilograms of API from PCAS for a total price of \$2.3 million. In January 2022, we committed to purchase an additional 75 kilograms of API from PCAS for a total price of \$0.9 million. As of December 31, 2022, there remained a \$1.5 million obligation in connection with this purchase commitment.

**Taxes**

As of December 31, 2022, we have recorded non-current taxes payable of \$9.1 million related to uncertain tax positions.

**Legal Proceedings**

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.

*Melucci Litigation and Settlement*

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.

On February 8, 2023, we reached an agreement in principle (the “Proposed Settlement”) to resolve all claims in the Melucci litigation. Under the Proposed Settlement, we have agreed to make a one-time payment of \$14.0 million, which will be covered in full by our insurers. In connection with the Proposed Settlement, we recorded a settlement expense of \$14.0 million and corresponding insurance recovery of \$14.0 million in Operating Expenses on our Consolidated Statement of Income in the fourth quarter of 2022. Accordingly, we recorded an accrued liability of \$14.0 million for this settlement and a corresponding insurance recovery receivable of \$14.0 million on our Consolidated Balance Sheet. The Proposed Settlement is subject to the final approval of the United States District Court for the Northern District of California.

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



