
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, 2024

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.)

101 Redwood Shores Parkway
Redwood City, CA 94065
(Address of principal executive offices) (zip code)

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

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

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

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

None

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

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

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

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

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

Large accelerated filer	<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, 2024 was \$2,691,187,787, based on the closing price of \$32.49 for shares of the Registrant’s common stock as reported on the Nasdaq Stock Market on June 30, 2024. 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 18, 2025 there were 105,503,432 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 2025 Annual Meeting of Stockholders are incorporated by reference in Items 10, 11, 12, 13 and 14 of Part III.

TABLE OF CONTENTS
Form 10-K
For the year ended December 31, 2024

		Page
PART I		
ITEM 1.	<u>Business</u>	<u>1</u>
ITEM 1A.	<u>Risk Factors</u>	<u>12</u>
ITEM 1B.	<u>Unresolved Staff Comments</u>	<u>27</u>
ITEM 1C.	<u>Cybersecurity</u>	<u>27</u>
ITEM 2.	<u>Properties</u>	<u>25</u>
ITEM 3.	<u>Legal Proceedings</u>	<u>27</u>
ITEM 4.	<u>Mine Safety Disclosures</u>	<u>29</u>
PART II		
ITEM 5.	<u>Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	<u>30</u>
ITEM 6.	<u>[Reserved]</u>	<u>31</u>
ITEM 7.	<u>Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>	<u>32</u>
ITEM 7A.	<u>Quantitative and Qualitative Disclosures About Market Risk</u>	<u>38</u>
ITEM 8.	<u>Financial Statements and Supplementary Data</u>	<u>38</u>
ITEM 9.	<u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>	<u>38</u>
ITEM 9A.	<u>Controls and Procedures</u>	<u>39</u>
ITEM 9B.	<u>Other Information</u>	<u>40</u>
ITEM 9C.	<u>Disclosure Regarding Foreign Jurisdictions That Prevent Inspections</u>	<u>40</u>
PART III		
ITEM 10.	<u>Directors, Executive Officers and Corporate Governance</u>	<u>41</u>
ITEM 11.	<u>Executive Compensation</u>	<u>41</u>
ITEM 12.	<u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	<u>41</u>
ITEM 13.	<u>Certain Relationships and Related Transactions, and Director Independence</u>	<u>41</u>
ITEM 14.	<u>Principal Accounting Fees and Services</u>	<u>41</u>
PART IV		
ITEM 15.	<u>Exhibits and Financial Statement Schedules</u>	<u>42</u>
ITEM 16.	<u>Form 10-K Summary</u>	<u>45</u>
	<u>Signatures and Power of Attorney</u>	<u>46</u>

PART I

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

- our ability to manufacture, market and sell Korlym[®] (mifepristone) 300 mg Tablets (“Korlym”) and an authorized generic version of Korlym (collectively, our “Products”);
- the impact of possible future competition on our Products or our product candidates;
- 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 timing of regulatory submissions seeking approval of product candidates and the commercialization of any product candidates that are approved;
- our estimates for future performance, including revenue, income and capital requirements;
- our ability to manufacture, market, commercialize and achieve market acceptance for our product candidates; and
- uncertainties associated with obtaining and enforcing patents.

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 endocrinologic, oncologic, metabolic and neurologic 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 hypertension, diabetes, impaired glucose tolerance, obesity, fatty liver disease, depressed mood, psychosis, wasting of the arms and legs, edema, fatigue, insomnia and other problems.

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 indicate that modulating cortisol activity may improve outcomes in patients with fatty liver disease and metabolic dysfunction-associated steatohepatitis (“MASH”), which are precursors of liver fibrosis and cirrhosis. Pre-clinical and 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 in the United States for the treatment of patients suffering from hypercortisolism (also known as “Cushing’s syndrome”). In June 2024, we made available an authorized generic version of Korlym for the same indication. The challenge in treating a patient with hypercortisolism is modulating cortisol’s effects without either inappropriately suppressing them 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’s binding 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. On December 30, 2024, we submitted to the United States Food and Drug Administration (“FDA”) a New Drug Application (“NDA”) for a proprietary cortisol modulator we have developed, relacorilant, that, like Korlym, modulates the effects of cortisol by binding at the GR, but has no affinity for the PR and so does not cause PR-related side effects.

In addition to relacorilant, we have discovered more than 1,000 proprietary cortisol modulators that bind to the GR but have no affinity for 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 these “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 are being evaluated in clinical trials as potential treatments for a variety of serious disorders – hypercortisolism, advanced ovarian cancer, prostate cancer, ALS and MASH.

Hypercortisolism (Cushing’s Syndrome)

Background. Hypercortisolism is the result of a tumor that produces either cortisol or adrenal corticotrophic hormone, a hormone that causes the adrenal glands to produce cortisol. Abnormally high levels of cortisol lead to overstimulation of the GR, which gives rise to a wide range of serious adverse effects. Most people with hypercortisolism have one or more of the following symptoms: hypertension, diabetes, impaired glucose tolerance, obesity, fatty liver disease, wasting of the arms and legs, edema, fatigue and insomnia. Irritability, anxiety, cognitive disturbances and depression are also common. Hypercortisolism can affect every organ system in the body and can be lethal if not treated. If the tumor can be found, the preferred treatment is surgery, which, if successful, can cure the disease. In approximately half of patients who receive surgery, the procedure is not successful. Depending on the type of tumor, surgery can also result in a range of complications and recurrence of the disease is common.

Our Products. We sell Korlym and a generic version of Korlym in the United States (our “Products”), using sales representatives to call on physicians caring for patients with hypercortisolism. We also have a field-based force of medical science liaisons. We use a specialty pharmacy and a specialty distributor to distribute our Products and provide logistical support to physicians and patients. Our policy is that no patient with hypercortisolism will be denied access to our Products for financial reasons. To help us achieve that goal, we have patient support programs and donate money to independent charitable foundations that help patients pay for all aspects of their hypercortisolism care, whether or not that care includes taking our Products.

Because most people who suffer from hypercortisolism 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 our Products can play in treating patients with the disorder. In 2024, we conducted the CATALYST study to determine the prevalence of hypercortisolism in patients with difficult-to-control diabetes (defined as HbA1c of 7.5 percent or higher) despite receiving optimum treatment. Of the 1,057 patients enrolled in the first phase of CATALYST, 23.8 percent were found to have hypercortisolism. These patients were offered the chance to enter CATALYST’s second phase, in which 136 eligible patients were randomized 2:1 to receive either Korlym or placebo for 24 weeks. CATALYST’s primary endpoint was the difference in HbA1c in patients who received Korlym compared to patients who received placebo. Patients who received Korlym exhibited a clinically meaningful and statistically significant improvement in hemoglobin A1c, with a decrease from baseline of 1.47 percent, compared to a decrease of 0.15 percent in patients who received placebo (p-value: < 0.0001). The safety profile of Korlym in CATALYST was consistent with the medication’s label: No new side effects or adverse events were identified.

The CATALYST data will help physicians better identify patients with hypercortisolism and determine their optimal treatment.

Relacorilant. We are developing our proprietary, selective cortisol modulator, relacorilant, as a treatment for patients with hypercortisolism. Relacorilant shares Korlym’s affinity for the GR but, unlike Korlym, has no affinity for the PR and so is

not the “abortion pill” and does not cause other effects associated with PR affinity, including endometrial thickening and vaginal bleeding. Because relacorilant does not meaningfully increase cortisol levels, it does not 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. Unlike all other medications used to treat hypercortisolism, relacorilant does not prolong the heart’s QT interval, a potentially deadly off-target effect.

In December 2024, we submitted an NDA to the FDA seeking approval to market relacorilant as a treatment for patients with endogenous hypercortisolism. The NDA is based on positive results from our pivotal trial “GRACE”, as well as confirmatory evidence from our Phase 3 “GRADIENT” trial, our Phase 3 long-term extension study and our Phase 2 study. In all of these trials, patients exhibited clinically meaningful improvements in a wide range of hypercortisolism signs and symptoms, including hypertension, glucose control, weight and body composition. Relacorilant was well-tolerated in all of the trials. Notably, patients did not experience some of the serious adverse events that can arise in patients taking Korlym or other currently approved treatments.

The GRACE trial had two parts. The first, open-label phase enrolled 152 patients with any etiology of hypercortisolism. Each patient received relacorilant for 22 weeks. Patients who exhibited pre-specified improvements in either hypertension, hyperglycemia or both symptoms proceeded to GRACE’s second, double-blind, randomized withdrawal phase, in which half of the patients continued to receive relacorilant and half received placebo for 12 weeks. GRACE’s primary endpoint was the number of patients in the relacorilant group who lost blood pressure control compared to the number who lost blood pressure control in the placebo group.

In the open-label phase, patients experienced clinically meaningful and statistically significant improvements in a wide-array of hypercortisolism signs and symptoms, including hypertension, hyperglycemia, weight, waist circumference, fat and lean body mass, cognition and Cushing’s Quality of Life score. Rapid and sustained improvements in systolic blood pressure (“SBP”) and diastolic blood pressure (“DBP”) were observed in all patients with hypertension, with an improvement in mean SBP of 7.9 mm Hg and mean DBP of 5.4 mm Hg at 22 weeks (p-values: <0.0001). During the open-label phase, 63 percent of patients with hypertension met the study’s response criteria. The improvements were even greater in the patients with hypertension who entered the randomized withdrawal phase, with reductions in SBP of 12.6 mm Hg and DBP of 8.3 mm Hg (p-values: <0.0001). To ensure accuracy, hypertension was measured by 24-hour ambulatory blood pressure monitoring (“ABPM”).

Glucose metabolism was measured by several diagnostic tests, including the oral glucose tolerance test (glucose area under the curve or AUCglucose), hemoglobin A1c (HbA1c) and fasting glucose. In the open-label phase, clinically meaningful and statistically significant improvements in glucose metabolism were observed in patients with diabetes or impaired glucose tolerance (i.e., pre-diabetes), with reductions in AUCglucose of 3.3 h*mmol/L, HbA1c of 0.3 percent and fasting glucose of 12.4 mg/dL at 22 weeks (p-values: <0.0001, 0.03, 0.03, respectively). During the open-label phase, 50 percent of patients with hyperglycemia met the study’s response criteria. Patients with hyperglycemia who entered the randomized withdrawal phase exhibited more pronounced improvements, with reductions in AUCglucose of 6.2 h*mmol/L, HbA1c of 0.7 percent and fasting glucose of 25.2 mg/dL at 22 weeks (p-values: <0.0001, <0.0001, 0.006, respectively).

GRACE met its primary endpoint. Patients with hypertension who were switched to placebo in the randomized withdrawal phase were significantly more likely to lose blood pressure control than were patients who continued to receive relacorilant (odds ratio: 0.17; p-value: 0.02). Patients who continued to receive relacorilant also maintained their improvements in hyperglycemia, waist circumference, fat and lean tissue mass, while patients who received placebo experienced a significant worsening of hypercortisolism signs and symptoms.

Our Phase 3 GRADIENT study enrolled patients with hypercortisolism caused by adrenal adenomas or adrenal hyperplasia. These patients have a more gradual decline than patients with other etiologies of hypercortisolism, although their health outcomes are ultimately poor. GRADIENT enrolled 137 patients with hypercortisolism and either hypertension, hyperglycemia or both. Patients were randomized on a double-blind basis 1:1 to receive either relacorilant or placebo for 22 weeks. The trial’s primary endpoint was the improvement compared to placebo in systolic blood pressure with glycemic control, weight and body composition as secondary endpoints.

Patients in GRADIENT who received relacorilant exhibited clinically meaningful and statistically significant improvements in hypertension, hyperglycemia, weight and body composition compared to baseline, while patients who received placebo did not.

GRADIENT patients with hypertension who received relacorilant experienced a reduction in systolic blood pressure of 6.6 mm Hg (p-value 0.012) compared to baseline. The reduction in patients who received placebo was 2.1 mm Hg (p-value: ns) compared to baseline. The comparison between those who received relacorilant and placebo was not statistically significant. During the study, five patients who received placebo required rescue therapy with anti-hypertension medications, compared to

one patient who received relacorilant. To ensure accuracy, hypertension was measured by 24-hour ambulatory blood pressure monitoring.

GRADIENT patients with hyperglycemia who received relacorilant experienced clinically meaningful and statistically significant improvements in glucose metabolism, including fasting glucose (placebo-adjusted reduction of 22.2 mg/dL; p-value 0.002), area under the curve of the oral glucose tolerance test (placebo-adjusted reduction of 2.6 h*mmol/L; p-value 0.046) and hemoglobin A1c (placebo-adjusted reduction of 0.3 percent; p-value 0.019), compared to those who received placebo.

Patients in GRADIENT who received relacorilant experienced clinically meaningful and statistically significant improvements in body weight (placebo-adjusted reduction of 3.9 kg; p-value: 0.0001) and visceral adipose fat mass and volume (p-values: 0.018 and 0.016, respectively), compared to patients who received placebo.

Relacorilant was well-tolerated in GRADIENT, with side effects consistent with its other clinical trials. The most common adverse events were mild-to-moderate nausea, edema, pain in the extremities and back, and fatigue – all symptoms associated with the “cortisol withdrawal” many patients experience when cortisol activity reverts to a more normal level, following surgery or the start of medical therapy for hypercortisolism. Importantly, there were no relacorilant-induced instances of hypokalemia, endometrial hypertrophy or drug-induced vaginal bleeding, adrenal insufficiency or QT prolongation.

Patients who completed our Phase 2 study or the GRACE or GRADIENT trials were eligible to enter our open-label, long-term extension study. Of the 116 patients who chose to do so, the duration of the treatment has been up to six years. In December 2024, we announced that patients who remained in the study for 24 months exhibited, at that time, further clinically meaningful and statistically significant reductions in systolic (10.0 mm Hg; p-value: 0.012) and diastolic blood pressure (7.3 mm Hg; p-value: 0.016), compared to their blood pressure at entry into the long-term extension study. These patients had also maintained response in other cardiometabolic measures, such as glycemic control and body weight. Consistent with its known safety profile, relacorilant was well-tolerated.

The FDA and the European Commission (“EC”) have designated relacorilant as an orphan drug for the treatment of hypercortisolism. 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 hypercortisolism, 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 hypercortisolism.

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 Platinum-Resistant Ovarian Cancer. We are conducting a pivotal Phase 3 trial (“ROSELLA”) of our proprietary, selective cortisol modulator, relacorilant combined with nab-paclitaxel as a treatment for patients with platinum-resistant ovarian cancer. Enrollment in ROSELLA is complete. Three hundred eighty-one women with recurrent, platinum-resistant ovarian cancer were randomized 1:1 to receive either 150 mg of relacorilant intermittently in addition to nab-paclitaxel or nab-paclitaxel monotherapy. ROSELLA has dual primary endpoints – progression free survival (“PFS”) and overall survival (“OS”). ROSELLA will have a statistically positive outcome if either endpoint is met. Patients enrolled in ROSELLA were required to have received prior bevacizumab therapy, which is the approved standard of care 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 were excluded.

ROSELLA seeks to replicate the positive results of our Phase 2 trial, a 178-patient, controlled, multi-center, trial of relacorilant combined with nab-paclitaxel in patients with platinum-resistant ovarian cancer. Phase 2 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 PFS.

Patients in both of the relacorilant plus nab-paclitaxel treatment arms of the Phase 2 trial 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.

Notably, the addition of relacorilant to treatment with nab-paclitaxel did not create an additional adverse event burden for patients. Safety and tolerability of relacorilant and nab-paclitaxel combination treatment were comparable to the safety and tolerability of nab-paclitaxel monotherapy.

The final analysis from our Phase 2 trial was published in the *Journal of Clinical Oncology* (Colombo et al., 2023), the premiere journal of the American Society of Clinical Oncology (ASCO).

Relacorilant in Patients with Adrenal Cancer with Cortisol Excess. We have completed an open-label, Phase 1b trial of relacorilant plus the PD-1 checkpoint inhibitor pembrolizumab in 14 patients with metastatic or unresectable adrenal cancer whose tumors produce cortisol. Patients with this form of adrenal cancer virtually never respond to immunotherapy and their disease progresses very rapidly. Our trial sought to test whether adding relacorilant to pembrolizumab therapy would reduce cortisol-activated immune suppression sufficiently to help the patient’s immune system reduce or eradicate the patient’s tumors while also reducing the symptoms of hypercortisolism caused by the tumors’ hypersecretion of cortisol. Although patients exhibited significant improvements in their symptoms of hypercortisolism, such as reductions in hypertension and hyperglycemia, their tumor progression did not slow. The combination of relacorilant with pembrolizumab was well-tolerated. We are evaluating next steps to better understand the role cortisol modulation may play in combination with immunotherapies directed to other tumor types and earlier stages of cancer.

Relacorilant in Patients with Prostate Cancer. Androgen deprivation is the standard treatment for prostate cancer because androgens stimulate prostate tumor growth. Prostate cancer tumors eventually escape androgen deprivation therapy; one of the prime reasons is that these tumors begin to be stimulated by cortisol’s activity. Combining a cortisol modulator with an androgen modulator may block this escape route. Our collaborators at the University of Chicago have initiated 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. Patents we have licensed from the University of Chicago cover the use of relacorilant combined with anticancer agents, including enzalutamide, to treat patients with this disease.

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 an animal model of ALS. Following these compelling results, we initiated a Phase 2 trial (“DAZALS”) of dazucorilant in patients with ALS. Two hundred forty-nine patients were randomized on a double-blind basis 1:1:1 to receive either 150 mg of dazucorilant, 300 mg of dazucorilant or placebo daily for 24 weeks. Upon completion of the trial, patients were eligible to enter an open-label, long-term extension study, in which they receive 300 mg of dazucorilant for up to 132 weeks. DAZALS did not meet its primary endpoint, which was the change from baseline in the ALS Functional Rating Scale-Revised (ALSFRS-R) in patients who received dazucorilant compared to those who received placebo. Patients who received dazucorilant also experienced substantially more gastrointestinal upset at the onset of treatment than did those who received placebo. During the 24-week study, no deaths (0/83) were observed in the 300 mg dazucorilant arm, compared to 5 deaths (5/82) in the placebo group (p-value: 0.02). The open-label, long-term extension study, which enrolled 118 patients, will continue. Pursuant to the study protocol, overall survival will be assessed again in March 2025. The FDA has granted dazucorilant Fast Track Designation and orphan drug status for the treatment of ALS in the United States.

Metabolic Diseases

Liver Disease. Metabolic dysfunction-associated steatohepatitis (“MASH”) is an advanced form of metabolic dysfunction-associated fatty liver disease that afflicts millions of patients and is a leading cause of liver-related mortality. Our Phase 1b trial of the selective cortisol modulator miricorilant as a potential treatment for MASH identified a dosing regimen that reduced liver fat, improved liver health and key metabolic and lipid measures and was well-tolerated. Following these compelling results, we initiated a randomized, double-blind, placebo-controlled, Phase 2b trial (“MONARCH”) of miricorilant in patients with MASH in October 2023. MONARCH has two patient cohorts. Cohort A has a planned enrollment of 120 patients with biopsy-confirmed MASH, randomized 2:1 to receive either 100 mg of miricorilant twice weekly or placebo for 48 weeks. The primary endpoint of Cohort A is reduction in liver fat, with MASH resolution and fibrosis improvement as key

secondary endpoints. Cohort B has a planned enrollment of 75 patients with presumed MASH, randomized 2:1 to receive either 100 mg of miricorilant twice weekly for 6 weeks and then 200 mg of miricorilant twice weekly for 18 weeks or placebo for 24 weeks. The primary endpoint of Cohort B is reduction in liver fat.

Development of 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, 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” for additional information.

We continue to create new selective cortisol modulators, the most promising of which we advance 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, hypercortisolism, 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”). Syneos Health is helping us conduct our ROSELLA trial. Medpace Research is helping us conduct our MONARCH trial. We may terminate our agreements with Syneos Health on 60 days’ written notice and with Medpace Research without cause at any time.

Research and Development Spending

We incurred \$246.9 million, \$184.4 million and \$131.0 million of research and development expense in the years ended December 31, 2024, 2023 and 2022, respectively, which accounted for 46 percent, 49 percent and 45 percent, respectively, of our total operating expenses in those years.

Manufacturing

We rely on contract manufacturers to produce our Products and product candidates.

We have agreements with manufacturers to supply mifepristone, the active pharmaceutical ingredient (“API”) in our Products, and to produce and bottle tablets of our Products. We have purchased and hold significant quantities of API.

Competition

Our Products compete 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. Our Products also compete with Signifor[®] (pasireotide) Injection and Isturisa[®] (osilodrostat). Both of these drugs are approved by the FDA for the treatment of adult patients with Cushing’s disease who are not candidates for pituitary surgery or for whom surgery did not work, and both are sold by the Italian pharmaceutical company Recordati S.p.A (“Recordati”). Cushing’s disease is a subset of hypercortisolism. In the EU, osilodrostat is also approved as a treatment for hypercortisolism. Our Products also compete with Recorlev[®] (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 hypercortisolism.

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 hypercortisolism, provided doing so would not infringe any of our patents. In January 2024, Teva launched a generic version of Korlym. 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 response, Teva separately 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 rejected Teva’s claims, affirming the validity of our patent in its entirety. Teva appealed to the Court of Appeals for the Federal Circuit, which affirmed the PTAB’s decision. On December 29, 2023, the federal district in which we had sued Teva issued a ruling finding

that Teva’s proposed product would not infringe the two patents we had asserted against it. We have appealed that decision to the Court of Appeals for the Federal Circuit. See “Part I, Item 3, Legal Proceedings” for additional information.

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 been issued in Europe, Japan, China, Canada, Australia and other countries. The expiration dates of these patents and their foreign counterparts range from 2025 to 2041.

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 hypercortisolism, various cancers, fatty liver disease, 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.

Hypercortisolism. 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 hypercortisolism, with expiration dates ranging from 2028 to 2038. Furthermore, we own U.S. composition of matter and method of use patents using our proprietary selective cortisol modulators directed to the treatment of patients with hypercortisolism, with expiration dates ranging from 2033 to 2041. We have asserted two patents directed to patients with hypercortisolism in a lawsuit against Teva Pharmaceuticals USA, Inc. (“Teva”) in a lawsuit filed in Federal District Court. On December 29, 2023, the Court found that Teva’s proposed generic version of Korlym would not infringe either patent. We are appealing that decision to the Court of Appeals for the Federal Circuit. We do not know when our appeal will be resolved. See “Part I, Item 3, Legal Proceedings” for additional details.

Oncology. We own U.S. patents covering methods of treating cancer using our proprietary selective cortisol modulators with expiration dates ranging from 2033 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” for additional information.

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, miricorilant, dazucorilant, and other of our proprietary compounds 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 hypercortisolism and various cancers, we also own U.S. and foreign patents for the use of cortisol modulators to treat ALS, fatty liver disease, delirium, catatonia, psychosis induced by interferon-alpha therapy, migraine headaches, gastroesophageal reflux disease, neurological damage in premature infants, for the improvement of therapeutic response to electroconvulsive therapy, and in the treatment of diseases using combined steroid and GR modulator therapy. The expiration dates of these patents and their foreign counterparts range from 2025 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.

The FDA also has the authority to grant Fast Track designation for drugs intended to fill an unmet need in the treatment of a serious or life-threatening condition. When a drug receives Fast Track designation, among other things, the manufacturer is eligible for more frequent communication with the FDA regarding the drug’s NDA, and for the FDA to review parts of the application as they are submitted, rather than waiting until every section of the NDA is completed.

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.

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. The IRA was enacted on August 16, 2022. The IRA includes provisions requiring manufacturers to pay a rebate to the Centers for Medicare & Medicaid Services (“CMS”) if the price of a Medicare Part B or Part D drug increases faster than the rate of inflation. In addition, beginning in 2025, the IRA will also shift a significant portion of the Medicare beneficiary costs currently borne by the government and beneficiaries to manufacturers. The IRA permits CMS to negotiate prices for certain high-expenditure Medicare Part B or Part D drugs. 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 Patent 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 (“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 (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 2024, the FTC finalized updates to the Health Breach Notification Rule that, among other things, clarified its applicability to health apps and other similar technologies and expanded the information the breach notification requirements for entities subject to the rule, 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 which took effect on January 1, 2020, and was later revised and expanded by the California Privacy Rights Act (collectively, “CCPA”), created individual privacy rights for California consumers and increased the privacy and security obligations of entities handling certain personal information as well as limitations on data uses, audit requirements for higher risk data, and opt outs for certain uses of sensitive data. 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. 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 CCPA may increase our compliance costs and potential liability. Similar laws passed in Virginia, Colorado, Connecticut, Montana, Oregon, Texas, and Utah took effect in 2023 and 2024. Additionally, Delaware, Indiana, Iowa, Kentucky, Maryland, Minnesota, Nebraska, New Hampshire, New Jersey, Rhode Island and Tennessee have adopted privacy laws, which take effect from January 1, 2025 through 2026. In addition, some of these laws (including the CPRA), along with other standalone health privacy laws, subject health-related information to additional safeguards and disclosures and some specifically regulate consumer health data. For example, Washington’s My Health My Data Act, effective as of March 31, 2024, imposes similar requirements specific to consumer health data. Similar laws have also passed in Connecticut and Nevada, which came into effect in 2023 and 2024. 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 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. As a result, 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 (“UK GDPR”), 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, 2024, we had 500 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 other benefits. To align our employees’ goals with Corcept’s goals, we offer annual performance-based cash bonuses and stock-based compensation.

About Corcept

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

Available Information

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

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

ITEM 1A. RISK FACTORS

Investing in our common stock involves significant risks. Before investing, carefully consider the risks described below and the other information in this Annual Report on Form 10-K, including our consolidated financial statements and related notes. The risks and uncertainties described below are the ones we believe may materially affect us. 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. Below, we have arranged these risks by the part of our business they most directly affect.

Risks Related to our Commercial Activities

- Failure to generate sufficient revenue from the sale of our Products would harm our financial results and would likely cause our stock price to decline.
- The availability of generic versions of Korlym could adversely affect our business, results of operations and financial position.
- Public perception of mifepristone or legislation limiting or barring its distribution or use for termination of early pregnancy may limit our ability to sell our Products.
- 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 our Products, which would adversely affect our results of operations and financial position.

Risks Related to our Research and Development Activities

- Vendors perform many of the activities necessary to carry out our clinical trials, including drug product distribution, trial management and oversight and data collection and analysis. Failure of these vendors to perform their duties or meet expected timelines may prevent or delay approval of our product candidates.
- Our 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. Even if we deem that our product candidates' clinical trial results demonstrate safety and efficacy, regulatory authorities may not agree. Failure to obtain or maintain regulatory approvals for our product candidates would prevent us from commercializing them.

Risks Related to our Intellectual Property

- We may not be able to secure, maintain or effectively assert patent protection for the composition, manufacture, or methods of use of our proprietary, selective cortisol modulators and for the use of our Products to treat hypercortisolism. Litigation is slow and expensive and its outcome is uncertain and subject to challenge on appeal.

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 performance does not meet the guidance we have provided to the public, estimates published by research analysts or other investor expectations.

General Risk Factors

- 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 our Products 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 our Products to treat patients with hypercortisolism. Physicians will prescribe our Products if they determine that it is preferable to other treatments, even if those treatments are not approved for hypercortisolism. Most physicians are

inexperienced diagnosing or caring for patients with hypercortisolism and it can be hard to persuade them to identify appropriate patients and treat them with our Products.

Many factors could limit our product revenue, including:

- the preference of physicians or payors for competing treatments for hypercortisolism, including a lower-priced generic version of Korlym and off-label treatments; 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 product revenue could prevent us from fully funding our planned commercial and clinical activities and would likely cause our stock price to decline.

The availability of generic versions of Korlym could adversely affect our business, results of operations and financial position.

In January 2024, Teva launched a generic version of Korlym. We have sued Teva in Federal District Court with respect to its generic version of Korlym. On December 29, 2023, the Court issued a ruling in that case finding that Teva's generic product would not infringe the patents we have asserted against it. We have appealed this adverse decision to the Court of Appeals for the Federal Circuit, but there can be no assurance our appeal will be successful. If Teva's commercial efforts are successful, they may materially harm our results of operations and financial condition, even if our appeal is successful and Teva is required to withdraw its product and pay us damages. We have made available our own generic version of Korlym.

We also have litigation settlements with Sun and Hikma that allow them to begin selling mifepristone, with customary restrictions, provided the FDA has approved their products and Teva's generic product remains commercially available. The availability of generic versions of Korlym from Sun or Hikma could materially harm our results of operations and financial condition, even if our on-going appeal against Teva is successful and Teva, Sun and Hikma were required to withdraw their products and pay us damages. Please see "*Part I, Item 3, Legal Proceedings*" for additional details.

The availability of generic Korlym could cause our revenue to decline and materially harm our results of operations and financial position, by reducing the number of tablets we sell or lowering their price. It 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. Other companies may seek FDA approval to market generic versions of Korlym, in which case we will vigorously protect our intellectual property. However, there can be no assurance our efforts will be successful.

Public perception of mifepristone or legislation limiting or barring its distribution or use for termination of early pregnancy may limit our ability to sell our Products.

The active ingredient in our Products, mifepristone, is approved by the FDA in another drug for the termination of early pregnancy. In 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 that had established a woman's right to terminate her pregnancy, subject to certain limitations. Dobbs has stimulated many states to enact laws restricting the legality of abortion and mifepristone, including during early pregnancy and under specific conditions of use. More laws banning or heavily restricting termination of pregnancy may be adopted and existing laws may be made more restrictive. On June 13, 2024, in a highly publicized case, the Supreme Court ruled against plaintiffs seeking to restrict access to mifepristone for terminating pregnancy, holding that they lacked standing (i.e., the right to sue), thus preserving current access to mifepristone. Because the Supreme Court's decision was made solely on procedural grounds, the ruling does not necessarily foreclose other challenges to the continued availability of mifepristone. The timing and outcome of any subsequent cases, as well as additional legislative changes are uncertain. In addition, heightened public awareness of mifepristone as an abortifacient may draw the attention of hostile state government officials or political activists to our Products – as could additional public debate concerning current or proposed restrictions on the distribution of mifepristone. This may be the case even though (i) our Products are not approved for the termination of pregnancy, (ii) we do not promote it for that use and (iii) we have taken measures to minimize the chance that it will accidentally be prescribed to a pregnant woman.

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 our Products, which would adversely affect our results of operations and financial position.

The commercial success of our Products 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 our Products. If government or private payers cease to provide adequate and timely coverage, pricing and reimbursement for our Products, 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 IRA significantly changed the way Medicare pays for prescription drugs. 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 such as our Products that are 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 the 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” (“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 with the Secretary or offer their drug to Medicare recipients at the MFP can face significant civil money penalties or excise tax liability on sales of that drug. If our Products or any drug we commercialize becomes eligible for Medicare negotiation, the revenue we generate from sales of that drug may be significantly reduced.

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. The inflation rebate provision applies to any medication sold to Medicare recipients, whether or not that medication is subject to Medicare price negotiation.

Beginning in 2025, the IRA also shifts 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 we receive and may materially reduce our revenue and profits.

We make grants to independent charitable foundations that help financially needy patients with their premium, co-pay, and co-insurance obligations with respect to their hypercortisolism treatment, regardless of whether that treatment includes one of our Products. There has been enhanced scrutiny of company-sponsored patient assistance programs, including insurance premium and co-pay assistance programs and donations to third-party charities that provide such assistance. As a result of this scrutiny, these assistance programs and charities may decide to reduce or eliminate entirely the assistance they provide to patients, which could result in fewer patients receiving the financial support they need to cover the cost of their hypercortisolism care, including the cost of medication, which may include one of our Products.

We expect governmental oversight and scrutiny of pharmaceutical companies to increase and that there will be additional attempts to change the healthcare system in ways that could harm our ability to sell our Products and any other drugs we commercialize profitably, including new 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.

Other companies offer different medications to treat patients with hypercortisolism. The availability of competing treatments could limit our product revenue.

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 hypercortisolism). 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 hypercortisolism.

On December 30, 2021, Xeris received FDA approval to market the cortisol synthesis inhibitor Recorlev® (levoketoconazole) to treat patients with hypercortisolism in the United States. Levoketoconazole is an enantiomer of the generic anti-fungal medication, ketoconazole, that is prescribed off-label to treat patients with hypercortisolism.

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 hypercortisolism could reduce our revenue materially and harm our results of operations, which would cause our stock price to decline.

We depend on vendors to manufacture the active pharmaceutical ingredient ("API") and capsules or tablets for our commercialized products as well as our product candidates. We also depend on vendors to package our products and dispense them to patients. If our vendors become unable or unwilling to perform these functions and we cannot transfer these activities to other vendors in a timely manner, our business will be harmed.

In the event any of our vendors fails to perform its contractual obligations to us or is materially impaired in its performance, we may experience disruptions and delays in our ability to deliver our commercialized products to patients or investigational drugs to patients in our clinical trials, which would adversely affect our business, results of operations and financial position.

Our single specialty pharmacy, Optime, dispenses our Products and performs related pharmacy and patient support services, including the collection of payments from insurers representing more than 99 percent of our revenue. If Optime does not adhere to its agreements with payers or does not continue to meet regulatory requirements concerning pharmacy operations, it may not be able to collect on our behalf some or all of the payments due to us. In addition, if Optime becomes unable or unwilling to perform its obligations under our agreement, we may not be able to dispense our Products in a timely manner to some or all of our patients. Effective April 1, 2024, we extended our agreement with Optime through March 31, 2027, with automatic renewal for successive three-year terms. The agreement is 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.

The facilities used by our vendors to manufacture and package the API and drug product for our Products and product candidates and distribute them to hospitals, clinics and patients, must be approved by government regulators in the United States, Europe, and elsewhere. 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"), which are subject to change at the regulators' discretion. 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, European Medicines Agency ("EMA"), the Medicines and Healthcare products Regulatory Agency ("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. In addition, our reputation as a reliable sponsor of clinical studies would be harmed, which would make it more difficult for us to develop our drug candidates.

Natural disasters, such as earthquakes, fires, extreme weather events or widespread outbreaks of a deadly disease such as COVID-19, could disrupt our commercial and clinical activities or 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.

A resurgence of COVID-19 or the widespread occurrence of another deadly illness could adversely affect our business, operations and financial results. The COVID-19 pandemic made it difficult to grow our commercial business and slowed the pace of some of our clinical trials.

We are also 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.

If we are unable to maintain regulatory approval of our Products 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”), all of which are subject to change without notice and at the regulators’ sole discretion. Foreign regulatory authorities have comparable requirements and enforcement mechanisms, which are also subject to change. The FDA and other regulators enforce these regulations through inspections of us and the laboratories, manufacturers and clinical sites we use. 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 current or future 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 our Products violates FDA regulations or health care fraud and abuse laws.

We are subject to statutes and regulations governing the promotion and sale of medicine. 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 “off-label” promotion. In the United States, we market our Products to treat hyperglycemia secondary to hypercortisolism in adult patients with endogenous hypercortisolism 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 our Products 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 or a law enforcement agency were to determine that we engaged in off-label promotion, we could be required to change our practices and be subject to regulatory enforcement actions, including issuance of a public “warning letter,” untitled letter, injunction, seizure, civil fine or criminal penalties. Federal or state enforcement authorities may 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 PaymentsTM Program), that require transparency regarding financial arrangements with health care providers, such as the reporting and disclosure requirements imposed by the Patient Protection and Affordable Care Act ("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;
- 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 documents 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" for additional details.

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

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 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. Even if we deem that our product candidates' clinical trial results demonstrate safety and efficacy, regulatory authorities may not agree. Failure to obtain or maintain regulatory approvals for our product candidates would prevent us from commercializing them.

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;
- 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.

At any time prior to the regulatory approval 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, provide additional analysis of existing data or change the size or design of a trial already underway. Such additional or changed requirements, which regulators may impose in their sole discretion, may delay or prevent the completion of development, submission of an NDA or the completion of regulatory review, which would increase our costs and adversely impact future revenue. 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 is no assurance of commercial success.

We may be unable to obtain or maintain regulatory approvals for our Products 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 our Products and our cash reserves to fund our commercial operations and development programs. If our 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 Related to our Intellectual Property

We may not be able to secure, maintain or effectively assert patent protection for the composition, manufacture, or methods of use of our proprietary, selective cortisol modulators and for the use of our Products to treat hypercortisolism. Litigation is slow and expensive and its outcome is uncertain and subject to challenge on appeal.

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” for additional information.

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 18, 2025, our average daily trading volume was approximately 970,395 shares and the intra-day sales prices per share of our common stock on The Nasdaq Stock Market ranged from \$20.84 to \$74.61. As of February 18, 2025, our officers, directors and principal stockholders beneficially owned approximately 21 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;
- actual or anticipated regulatory approvals of our product candidates;
- disputes or other developments relating to our intellectual property, including developments in generic-related litigation;
- changes in laws or regulations applicable to the pricing, availability of insurance reimbursement, or approved uses of our commercialized products, our product candidates or our competitors' products;
- short-selling of our common stock, the publication of negative opinions about our business or other market manipulation activities that are intended to lower our stock price or increase its volatility;
- sales of a substantial number of shares of our stock in the public market, leading to reductions in its price;
- 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;
- purchases of our common stock pursuant to our stock repurchase program (the "Stock Repurchase Program") or changes to that program;
- general market and economic conditions;
- changes in the expected or actual timing of our competitors' development programs and the approval of competing products;
- purchases or sales of our common stock by our officers, directors or stockholders;
- 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. Our revenue depends on many factors, including, without limitation, the efficacy of our sales and marketing efforts, the price we receive from private and government payors, competition from alternate treatments for patients with hypercortisolism, including from generic versions of Korlym and changes in government regulations. Our guidance estimate considers all of these factors, but they are difficult to predict. As a result, our revenue may vary materially from our guidance. 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. If our revenue is materially less than the guidance we or the research analysts who cover our stock provide investors, our stock price may decline.

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 and increase its volatility.

Short sellers have, and likely will continue to, attempt to drive down the price of our common stock. Short selling is the practice of selling stock the seller does not own with the intention of buying it back later at a lower price, thereby profiting

from any decline in the price of the stock between the time it is sold and the time it is repurchased. To support their efforts, short sellers often publish, or arrange for others to publish, negative opinions regarding the relevant issuer and its business prospects. These publications are often made to appear as if they were objective journalism or unbiased “research reports” of the type distributed by credible Wall Street firms and independent research analysts. Short seller publications are not regulated by any governmental, self-regulatory organization or other authority in the United States and the opinions they express are often based on distortions, omissions or fabrications. Short attacks supported by such publications have, in the past, led to selling of our stock and at least temporary reductions in its price. 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 have been, and may in the future be, the subject of shareholder suits prompted by allegations made by short sellers.

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:

- continue to add talented, experienced personnel to our endocrine, oncology and emerging markets businesses;
- manage our clinical trials, research and manufacturing activities effectively;
- hire more general 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 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 regulations and other legal obligations relating to drug development and commercialization, the conduct of business as an issuer of publicly traded securities and individual privacy and data protection. Compliance with these obligations is complex and costly. Failure to comply could materially harm our business.

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 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 (“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. Requirements for compliance under HIPAA are also subject to change,

as the U.S. Department of Health and Human Services Office of Civil Rights issued a proposed rule that would amend certain security compliance requirements for covered entities and business associates.

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 2024, the FTC also finalized its rulemaking on 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, which took effect on January 1, 2020, and was later revised and expanded by the California Privacy Rights Act, collectively the CCPA, created individual privacy rights for California consumers and increased the privacy and security obligations of entities handling certain personal information as well as limitation on data uses, audit requirements for higher risk data, and opt outs for certain uses of sensitive data. 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. It also created a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. Similar laws passed in Virginia, Colorado, Connecticut, Montana, Oregon, Texas and Utah have taken effect in 2023 and 2024 and other states, including Delaware, Indiana, Iowa, Kentucky, Maryland, Minnesota, Nebraska, New Hampshire, New Jersey, Rhode Island, and Tennessee, have passed similar laws that will take effect in or after 2025. In addition, along with the CPRA, some of these laws, along with other standalone health privacy laws, subject health-related information to additional safeguards and disclosures and some specifically regulate consumer health data, such as the Washington My Health My Data Privacy Law, which became effective in 2024, Nevada’s Consumer Health Data Privacy Law, which became effective in 2024, and Connecticut’s amendments to its privacy law to address health data, which became effective 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 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. 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. As supervisory authorities issue further guidance on personal data export mechanisms, 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. Further, on July 10, 2023, the European Commission adopted its adequacy decision on the E.U.-U.S. Data Privacy Framework or DPF. The decision, which took effect on the day of its adoption, concludes that the United States ensures an adequate level of protection for personal data transferred from the EEA to companies certified to the DPF. It is currently unclear how the future of DPF will evolve and what impact it will have on our international activities. 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 UK 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 percent 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. Further, 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.

Preparing for and complying with U.S. and foreign privacy and security laws and regulations is complex and costly as it is rigorous and time intensive and requires significant resources and a review of our technologies, systems and practices, as well as those of any third-party collaborators, service providers, CROs, contractors or consultants that process or transfer personal data collected in the EU. The GDPR and other changes in laws or regulations associated with the enhanced protection of certain types of sensitive data, such as healthcare data or other personal data from our clinical trials, and access to certain data such as the European Health Data Space Regulation, could require us to change our business practices and put in place additional compliance mechanisms, may interrupt or delay our development, regulatory and commercialization activities and increase our cost of doing business, and could lead to government enforcement actions, private litigation and significant fines and penalties against us and could have a material adverse effect on our business, financial condition or results of operations. Similarly, failure to comply with federal and state laws regarding privacy and security of personal data could expose us to fines and penalties under such laws. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could harm our reputation and 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. We 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. 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.” Changes to existing tax laws could materially increase the amounts we pay, which would reduce our after tax net income.

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.

Any acquisition of Corcept shares through our stock repurchase program or, in certain cases, pursuant to the exercise of stock options, will reduce our cash reserves.

In January 2024, our Board of Directors authorized the repurchase of up to \$200 million of our common stock pursuant to the Stock Repurchase Program. In addition, we sometimes accept, in our sole discretion, shares equal in value to any tax and exercise price liability due from option holders at the time of exercise and remit the applicable tax amounts to the tax authorities. Neither our Stock Repurchase Program nor the acceptance of shares at the time of options exercise require us to acquire shares. Furthermore, the Stock Repurchase Program may be modified, suspended or discontinued at any time without notice. It is possible that other uses of our capital would have been more advantageous or that our future capital requirements increase unexpectedly. By reducing our cash balance, our repurchases of common stock could hamper our ability to execute our plans, meet financial obligations or access financing.

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 18, 2025, our officers and directors beneficially owned approximately 21 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 face unprecedented political, legal, governmental, regulatory and economic uncertainty and risks that may adversely affect our business.

Steps taken by the presidential administration in the United States have caused great uncertainty regarding the continuity of government funding, policies and operations. The scope and direction of the administration's policies and their implementation are unpredictable. New policies may be adopted or actions taken, without notice, that adversely affect our commercial efforts or make it more challenging or costly to develop our product candidates. Significant cuts or disruptions to government employment and spending may delay review of our NDA for relacorilant as a treatment for patients with hypercortisolism or constrain our ability to advance our other clinical development programs and the development programs of our academic collaborators. The imposition of tariffs such as the administration has threatened to impose on materials we or our vendors use to conduct experiments or to make our Products or product candidates would increase our cost of doing business. Additionally, the laws and regulations governing our operations, as well as the application of such laws and regulations, may change abruptly. Failure to comply with new laws or regulations, whether by us or by our vendors, as well as changes in the application of existing laws and regulations, could adversely affect our operations, cash flow and financial condition or otherwise harm our business.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 1C. CYBERSECURITY

In the normal course of business, we collect and store personal information and other sensitive information, including proprietary and confidential business information, intellectual property, information regarding patients and clinical trial participants, sensitive third-party information and employee information. To protect this information, we use managed detection and response services to monitor our network infrastructure and associated endpoints for possible cybersecurity threats. In addition, we use multi-factor authentication, perform penetration testing and engage third parties to assess the effectiveness of our cybersecurity practices. We conduct a thorough risk assessment by identifying critical assets, recognizing potential threats and vulnerabilities, and implement strategies to mitigate these risks and their possible impacts. We establish incidence response plans and provide cybersecurity training to our employees and monitor their activity to ensure adherence to our security protocols.

No risks from cybersecurity threats have occurred that have affected our business strategy, results of operations, or financial condition.

The Corporate Governance and Nominating Committee of our Board of Directors oversees management of risks associated with corporate governance, including cybersecurity. This committee meets regularly with Corcept management and reports to the full Board of Directors.

See “*Risk Factors – General Risk Factors*” for additional information about the risks to our business associated with a breach or compromise to our information security systems.

ITEM 2. PROPERTIES

We lease 50,632 square feet of office space in Redwood City, California for our corporate facilities. Our current lease expires in June 2030.

ITEM 3. LEGAL PROCEEDINGS

Teva Patent 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”). In March 2018, we filed a lawsuit in the United States District Court for the District of New Jersey (“D.N.J.”) against Teva for infringement of our patents. In August 2020, Teva received final approval from the FDA for its ANDA in accordance with the Hatch-Waxman Act.

In May 2019, Teva submitted to the Patent Trial and Appeal Board (“PTAB”) a petition for post-grant review (“PGR”) of U.S. Patent No. 10,195,214 (the “’214 patent”). In November 2020, the PTAB issued a decision upholding the validity of the ’214 patent in its entirety, which decision the Court of Appeals for the Federal Circuit upheld. This matter is closed.

The patents currently at issue in the D.N.J matter are the ’214 patent and U.S. Patent No. 10,842,800 (the “’800 patent”). Trial was held from September 26, 2023 through September 28, 2023 before Judge Renee Marie Bumb. On December 29, 2023, Judge Bumb ruled that Teva’s proposed generic product would not infringe either the ’214 or ’800 patent. We have appealed that ruling to the United States Court of Appeals for the Federal Circuit. Teva launched its generic product in January 2024.

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

Antitrust Litigation

On June 13, 2024, Teva filed a complaint in the Northern District of California, captioned *Teva Pharmaceuticals USA, Inc. v. Corcept Therapeutics, Inc., et al.* (N.D. Cal.), Case No. 3:24-cv-03567-BLF (the “Teva Antitrust Litigation”). This lawsuit names Corcept and Optime Care, Inc. (“Optime”), our single specialty pharmacy that dispenses Korlym and the authorized generic version of Korlym and performs related pharmacy and patient support services, as defendants. The lawsuit alleges, among other things, that Corcept has violated federal and state laws related to antitrust and unfair business practices.

On August 26, 2024, Corcept and Optime filed motions to dismiss the complaint. On September 13, 2024, Teva filed a First Amended Complaint, and on October 14, 2024, Corcept and Optime moved to dismiss the First Amended Complaint.

On February 10, 2025, several named plaintiffs filed a complaint against Corcept in the Alameda County Superior Court for the State of California, captioned, *Aetna Inc., Health Care Service Corporation, Humana Inc. and Molina Healthcare Inc. vs. Corcept Therapeutics, Inc.*, Case No. 25CV110493. This lawsuit names Corcept as the sole defendant and includes allegations substantially similar to those made in the Teva Antitrust Litigation. Corcept's response to the Complaint is due on March 17, 2025.

Other Litigation

In March 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 alleged that the defendants made false and materially misleading statements and failed to disclose adverse facts about our business, operations and prospects. The complaint asserted a putative class period extending from August 2, 2017 to February 5, 2019 and sought unspecified monetary relief, interest and attorneys' fees. On June 6, 2024, Judge James Donato of the United States District Court for the Northern District of California granted final approval of a settlement resolving all claims in the Melucci litigation (the "Melucci Settlement"). As previously disclosed, the Melucci Settlement required us to make a one-time payment of \$14 million for which our insurers reimbursed us in full. On September 6, 2024, Judge Donato approved the Plan of Allocation for payment of the settlement funds to eligible members of the class of plaintiffs. This matter is closed.

In September 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. A second nearly identical lawsuit was filed in December 2019 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. These complaints named the then-existing members of our board of directors, our Chief Executive Officer and our current Chief Business Officer as defendants, and Corcept as a nominal defendant. The complaints allege 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 seek damages in an amount to be proved at trial. These actions had been stayed pending resolution of the Melucci litigation. On June 21, 2024, the United States District Court for the District of Delaware lifted the stays on the Williams and Jeweltex cases and consolidated these two cases into one case.

In January 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 certain members of our Board of Directors, our Chief Executive Officer, our current Chief Business Officer and our President of Corcept Endocrinology as defendants, and Corcept 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 March 22, 2024, the Court lifted a previously-entered stay, which had been pending the resolution of the Melucci litigation, and on May 3, 2024, we filed a Motion to Dismiss this complaint. We cannot predict when the Court will rule on this motion.

Given the overlapping allegations in these shareholder derivative actions, we and the individual defendants have filed a One Forum Motion in both the United States District Court for the District of Delaware and the Delaware Court of Chancery requesting that the Courts coordinate to determine in which jurisdiction (Federal or Chancery Court) these matters should first proceed. The matters pending in the Federal Court have been stayed pending the Chancery Court's ruling on our Motion to Dismiss.

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

Records Subpoena

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 18, 2025, we had 105,503,432 shares of common stock outstanding held by 522 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, 2024 as part of the cashless net exercises of stock options and vesting of restricted stock (in thousands, except average price per share):

Fiscal Period	Total Number of Shares Purchased ⁽¹⁾	Average Price Per Share	Total Purchase Price of Shares ⁽²⁾
October 1, 2024 to October 31, 2024	11	\$ 46.78	\$ 520
November 1, 2024 to November 30, 2024	122	54.79	6,716
December 1, 2024 to December 31, 2024	128	52.92	6,760
Total	261	\$ 53.53	\$ 13,996

(1) In October 2024, we issued 7,574 shares of common stock as part of net-share settlement of cashless option exercises, of which 3,448 shares were surrendered to us in satisfaction of related exercise cost and tax obligations. In November 2024, we issued 212,261 shares of common stock as part of net-share settlement of cashless option exercises, of which 104,456 shares were surrendered to us. In December 2024, we issued 197,059 shares of common stock as part of net-share settlement of cashless option exercises, of which 113,449 shares were surrendered to us.

In October 2024, we issued 21,847 shares of common stock as part of restricted stock vesting, of which 7,661 shares were surrendered to us in satisfaction of related tax obligations. In November 2024, we issued 51,391 shares of common stock as part of restricted stock vesting, of which 18,122 shares were surrendered to us. In December 2024, we issued 42,230 shares of common stock as part of restricted stock vesting, of which 14,303 shares were surrendered to us.

(2) We paid \$7.0 million to satisfy the tax withholding obligations associated with the net-share settlement of these cashless option exercises and restricted stock vesting.

Market Performance Graph

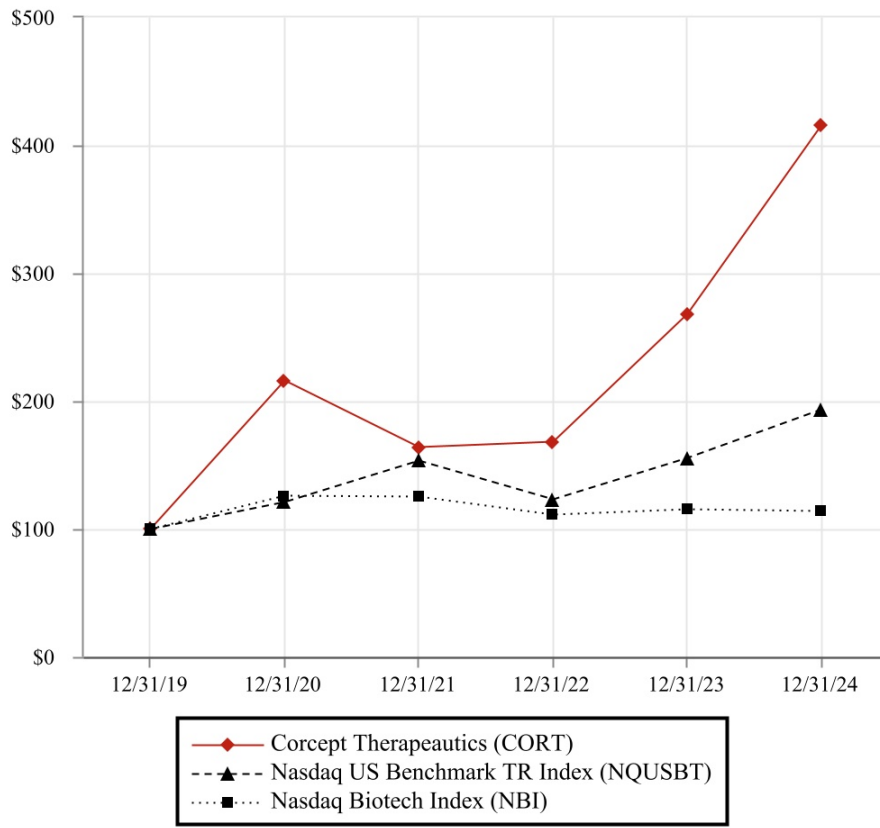
The graph and the accompanying text below is not "soliciting material," is not deemed filed with the SEC and is not to be incorporated by reference in any filings by us under the Securities Act or the Exchange Act, whether made before or after the date hereof and irrespective of any general incorporation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

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. Discussions of 2022 items and year-to-year comparisons between 2023 and 2022 are not included, and can be found in "Management's Discussion and Analysis of Financial Condition and Results of Operations" in Part II, Item 7 of the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2023.

Overview

We are a commercial-stage company engaged in the discovery and development of medications to treat severe endocrinologic, oncologic, metabolic and neurologic disorders by modulating the effects of the hormone cortisol. Since 2012, we have marketed Korlym in the United States for the treatment of patients suffering from hypercortisolism (also known as "Cushing's syndrome"). In June 2024, we made available an authorized generic version of Korlym for the same indication. Our portfolio of proprietary selective cortisol modulators consists of four structurally distinct series totaling more than 1,000 compounds.

Hypercortisolism (Cushing's Syndrome)

Our Products. We sell Korlym and a generic version of Korlym in the United States (our "Products"), using sales representatives to call on physicians caring for patients with hypercortisolism. We also have a field-based force of medical science liaisons. We use a specialty pharmacy and a specialty distributor to distribute our Products and provide logistical support to physicians and patients. Our policy is that no patient with hypercortisolism will be denied access to our Products for financial reasons. To help us achieve that goal, we have patient support programs and donate money to independent charitable foundations that help patients pay for all aspects of their hypercortisolism care, whether or not that care includes taking our Products.

Because most people who suffer from hypercortisolism 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 our Products can play in treating patients with the disorder. In 2024, we conducted the CATALYST study to determine the prevalence of hypercortisolism in patients with difficult-to-control diabetes (defined as HbA1c of 7.5 percent or higher) despite receiving optimum treatment. Of the 1,057 patients enrolled in the first phase of CATALYST, 23.8 percent were found to have hypercortisolism. These patients were offered the chance to enter CATALYST's second phase, in which 136 eligible patients were randomized 2:1 to receive either Korlym or placebo for 24 weeks. CATALYST's primary endpoint was the difference in HbA1c in patients who received Korlym compared to patients who received placebo. Patients who received Korlym exhibited a clinically meaningful and statistically significant improvement in hemoglobin A1c, with a decrease from baseline of 1.47 percent, compared to a decrease of 0.15 percent in patients who received placebo (p-value: < 0.0001). The safety profile of Korlym in CATALYST was consistent with the medication's label: No new side effects or adverse events were identified.

The CATALYST data will help physicians better identify patients with hypercortisolism and determine their optimal treatment.

Relacorilant. We are developing our proprietary, selective cortisol modulator, relacorilant, as a treatment for patients with hypercortisolism. Relacorilant shares Korlym's affinity for the GR but, unlike Korlym, has no affinity for the PR and so is not the "abortion pill" and does not cause other effects associated with PR affinity, including endometrial thickening and vaginal bleeding. Because relacorilant does not meaningfully increase cortisol levels, it does not 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. Unlike all other medications used to treat hypercortisolism, relacorilant does not prolong the heart's QT interval, a potentially deadly off-target effect.

In December 2024, we submitted an NDA to the FDA seeking approval to market relacorilant as a treatment for patients with endogenous hypercortisolism. The NDA is based on positive results from our pivotal trial "GRACE", as well as confirmatory evidence from our Phase 3 "GRADIENT" trial, our Phase 3 long-term extension study and our Phase 2 study. In

all of these trials, patients exhibited clinically meaningful improvements in a wide range of hypercortisolism signs and symptoms, including hypertension, glucose control, weight and body composition. Relacorilant was well-tolerated in all of the trials. Notably, patients did not experience some of the serious adverse events that can arise in patients taking Korlym or other currently approved treatments.

The GRACE trial had two-parts. The first, open-label phase enrolled 152 patients with any etiology of hypercortisolism. Each patient received relacorilant for 22 weeks. Patients who exhibited pre-specified improvements in either hypertension, hyperglycemia or both symptoms proceeded to GRACE's second, double-blind, randomized withdrawal phase, in which half of the patients continued to receive relacorilant and half received placebo for 12 weeks. GRACE's primary endpoint was the number of patients in the relacorilant group who lost blood pressure control compared to the number who lost blood pressure control in the placebo group.

In the open-label phase, patients experienced clinically meaningful and statistically significant improvements in a wide-array of hypercortisolism signs and symptoms, including hypertension, hyperglycemia, weight, waist circumference, fat and lean body mass, cognition and Cushing's Quality of Life score. Rapid and sustained improvements in systolic blood pressure ("SBP") and diastolic blood pressure ("DBP") were observed in all patients with hypertension, with an improvement in mean SBP of 7.9 mm Hg and mean DBP of 5.4 mm Hg at 22 weeks (p-values: <0.0001). During the open-label phase, 63 percent of patients with hypertension met the study's response criteria. The improvements were even greater in the patients with hypertension who entered the randomized withdrawal phase, with reductions in SBP of 12.6 mm Hg and DBP of 8.3 mm Hg (p-values: <0.0001). To ensure accuracy, hypertension was measured by 24-hour ambulatory blood pressure monitoring ("ABPM").

Glucose metabolism was measured by several diagnostic tests, including the oral glucose tolerance test (glucose area under the curve or AUCglucose), hemoglobin A1c (HbA1c) and fasting glucose. In the open-label phase, clinically meaningful and statistically significant improvements in glucose metabolism were observed in patients with diabetes or impaired glucose tolerance (i.e., pre-diabetes), with reductions in AUCglucose of 3.3 h*mmol/L, HbA1c of 0.3 percent and fasting glucose of 12.4 mg/dL at 22 weeks (p-values: <0.0001, 0.03, 0.03, respectively). During the open-label phase, 50 percent of patients with hyperglycemia met the study's response criteria. Patients with hyperglycemia who entered the randomized withdrawal phase exhibited more pronounced improvements, with reductions in AUCglucose of 6.2 h*mmol/L, HbA1c of 0.7 percent and fasting glucose of 25.2 mg/dL at 22 weeks (p-values: <0.0001, <0.0001, 0.006, respectively).

GRACE met its primary endpoint. Patients with hypertension who were switched to placebo in the randomized withdrawal phase were significantly more likely to lose blood pressure control than were patients who continued to receive relacorilant (odds ratio: 0.17; p-value: 0.02). Patients who continued to receive relacorilant also maintained their improvements in hyperglycemia, waist circumference, fat and lean tissue mass, while patients who received placebo experienced a significant worsening of hypercortisolism signs and symptoms.

Our Phase 3 GRADIENT study enrolled patients with hypercortisolism caused by adrenal adenomas or adrenal hyperplasia. These patients have a more gradual decline than patients with other etiologies of hypercortisolism, although their health outcomes are ultimately poor. GRADIENT enrolled 137 patients with hypercortisolism and either hypertension, hyperglycemia or both. Patients were randomized on a double-blind basis 1:1 to receive either relacorilant or placebo for 22 weeks. The trial's primary endpoint was the improvement compared to placebo in systolic blood pressure with glycemic control, weight and body composition as secondary endpoints.

Patients in GRADIENT who received relacorilant exhibited clinically meaningful and statistically significant improvements in hypertension, hyperglycemia, weight and body composition compared to baseline, while patients who received placebo did not.

GRADIENT patients with hypertension who received relacorilant experienced a reduction in systolic blood pressure of 6.6 mm Hg (p-value 0.012) compared to baseline. The reduction in patients who received placebo was 2.1 mm Hg (p-value: ns) compared to baseline. The comparison between those who received relacorilant and placebo was not statistically significant. During the study, five patients who received placebo required rescue therapy with anti-hypertension medications, compared to one patient who received relacorilant. To ensure accuracy, hypertension was measured by 24-hour ambulatory blood pressure monitoring.

GRADIENT patients with hyperglycemia who received relacorilant experienced clinically meaningful and statistically significant improvements in glucose metabolism, including fasting glucose (placebo-adjusted reduction of 22.2 mg/dL; p-value 0.002), area under the curve of the oral glucose tolerance test (placebo-adjusted reduction of 2.6 h*mmol/L; p-value 0.046) and hemoglobin A1c (placebo-adjusted reduction of 0.3 percent; p-value 0.019), compared to those who received placebo.

Patients in GRADIENT who received relacorilant experienced clinically meaningful and statistically significant improvements in body weight (placebo-adjusted reduction of 3.9 kg; p-value: 0.0001) and visceral adipose fat mass and volume (p-values: 0.018 and 0.016, respectively), compared to patients who received placebo.

Relacorilant was well-tolerated in GRADIENT, with side effects consistent with its other clinical trials. The most common adverse events were mild-to-moderate nausea, edema, pain in the extremities and back, and fatigue – all symptoms associated with the “cortisol withdrawal” many patients experience when cortisol activity reverts to a more normal level, following surgery or the start of medical therapy for hypercortisolism. Importantly, there were no relacorilant-induced instances of hypokalemia, endometrial hypertrophy or drug-induced vaginal bleeding, adrenal insufficiency or QT prolongation.

Patients who completed our Phase 2 study or the GRACE or GRADIENT trials were eligible to enter our open-label, long-term extension study. Of the 116 patients who chose to do so, the duration of the treatment has been up to six years. In December 2024, we announced that patients who remained in the study for 24 months exhibited, at that time, further clinically meaningful and statistically significant reductions in systolic (10.0 mm Hg; p-value: 0.012) and diastolic blood pressure (7.3 mm Hg; p-value: 0.016), compared to their blood pressure at entry into the long-term extension study. These patients had also maintained response in other cardiometabolic measures, such as glycemic control and body weight. Consistent with its known safety profile, relacorilant was well-tolerated.

The FDA and the EC have designated relacorilant as an orphan drug for the treatment of hypercortisolism. 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 hypercortisolism, seven years of exclusive marketing rights. Benefits of orphan drug designation by the EC are similar, but also include protocol assistance from the EMA, access to the centralized marketing authorization procedure in the EU and, if we obtain approval, ten years of exclusive marketing rights in the EU for the treatment of patients with hypercortisolism.

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 Platinum-Resistant Ovarian Cancer. We are conducting a pivotal Phase 3 trial (“ROSELLA”) of our proprietary, selective cortisol modulator, relacorilant combined with nab-paclitaxel as a treatment for patients with platinum-resistant ovarian cancer. Enrollment in ROSELLA is complete. Three hundred eighty-one women with recurrent, platinum-resistant ovarian cancer were randomized 1:1 to receive either 150 mg of relacorilant intermittently in addition to nab-paclitaxel or nab-paclitaxel monotherapy. ROSELLA has dual primary endpoints – progression free survival (“PFS”) and overall survival (“OS”). ROSELLA will have a statistically positive outcome if either endpoint is met. Patients enrolled in ROSELLA were required to have received prior bevacizumab therapy, which is the approved standard of care 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 were excluded.

ROSELLA seeks to replicate the positive results of our Phase 2 trial, a 178-patient, controlled, multi-center, trial of relacorilant combined with nab-paclitaxel in patients with platinum-resistant ovarian cancer. Phase 2 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 PFS.

Patients in both of the relacorilant plus nab-paclitaxel treatment arms of the Phase 2 trial 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.

Notably, the addition of relacorilant to treatment with nab-paclitaxel did not create an additional adverse event burden for patients. Safety and tolerability of relacorilant and nab-paclitaxel combination treatment were comparable to the safety and tolerability of nab-paclitaxel monotherapy.

The final analysis from our Phase 2 trial was published in the *Journal of Clinical Oncology* (Colombo et al., 2023), the premiere journal of the American Society of Clinical Oncology (ASCO).

Relacorilant in Patients with Adrenal Cancer with Cortisol Excess. We have completed an open-label, Phase 1b trial of relacorilant plus the PD-1 checkpoint inhibitor pembrolizumab in 14 patients with metastatic or unresectable adrenal cancer whose tumors produce cortisol. Patients with this form of adrenal cancer virtually never respond to immunotherapy and their disease progresses very rapidly. Our trial sought to test whether adding relacorilant to pembrolizumab therapy would reduce cortisol-activated immune suppression sufficiently to help the patient's immune system reduce or eradicate the patient's tumors while also reducing the symptoms of hypercortisolism caused by the tumors' hypersecretion of cortisol. Although patients exhibited significant improvements in their symptoms of hypercortisolism, such as reductions in hypertension and hyperglycemia, their tumor progression did not slow. The combination of relacorilant with pembrolizumab was well-tolerated. We are evaluating next steps to better understand the role cortisol modulation may play in combination with immunotherapies directed to other tumor types and earlier stages of cancer.

Relacorilant in Patients with Prostate Cancer. Androgen deprivation is the standard treatment for prostate cancer because androgens stimulate prostate tumor growth. Prostate cancer tumors eventually escape androgen deprivation therapy; one of the prime reasons is that these tumors begin to be stimulated by cortisol's activity. Combining a cortisol modulator with an androgen modulator may block this escape route. Our collaborators at the University of Chicago have initiated 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. Patents we have licensed from the University of Chicago cover the use of relacorilant combined with anticancer agents, including enzalutamide, to treat patients with this disease.

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 an animal model of ALS. Following these compelling results, we initiated a Phase 2 trial ("DAZALS") of dazucorilant in patients with ALS. Two hundred forty-nine patients were randomized on a double-blind basis 1:1:1 to receive either 150 mg of dazucorilant, 300 mg of dazucorilant or placebo daily for 24 weeks. Upon completion of the trial, patients were eligible to enter an open-label, long-term extension study, in which they receive 300 mg of dazucorilant for up to 132 weeks. DAZALS did not meet its primary endpoint, which was the change from baseline in the ALS Functional Rating Scale-Revised (ALSFRS-R) in patients who received dazucorilant compared to those who received placebo. Patients who received dazucorilant also experienced substantially more gastrointestinal upset at the onset of treatment than did those who received placebo. During the 24-week study, no deaths (0/83) were observed in the 300 mg dazucorilant arm, compared to 5 deaths (5/82) in the placebo group (p-value: 0.02). The open-label, long-term extension study, which enrolled 118 patients, will continue. Pursuant to the study protocol, overall survival will be assessed again in March 2025. The FDA has granted dazucorilant Fast Track Designation and orphan drug status for the treatment of ALS in the United States.

Metabolic Diseases

Liver Disease. Metabolic dysfunction-associated steatohepatitis ("MASH") is an advanced form of metabolic dysfunction-associated fatty liver disease that afflicts millions of patients and is a leading cause of liver-related mortality. Our Phase 1b trial of the selective cortisol modulator miricorilant as a potential treatment for MASH identified a dosing regimen that reduced liver fat, improved liver health and key metabolic and lipid measures and was well-tolerated. Following these compelling results, we initiated a randomized, double-blind, placebo-controlled, Phase 2b trial ("MONARCH") of miricorilant in patients with MASH in October 2023. MONARCH has two patient cohorts. Cohort A has a planned enrollment of 120 patients with biopsy-confirmed MASH, randomized 2:1 to receive either 100 mg of miricorilant twice weekly or placebo for 48 weeks. The primary endpoint of Cohort A is reduction in liver fat, with MASH resolution and fibrosis improvement as key secondary endpoints. Cohort B has a planned enrollment of 75 patients with presumed MASH, randomized 2:1 to receive either 100 mg of miricorilant twice weekly for 6 weeks and then 200 mg of miricorilant twice weekly for 18 weeks or placebo for 24 weeks. The primary endpoint of Cohort B is reduction in liver fat.

Development of Other Selective Cortisol Modulators

We continue to create new selective cortisol modulators, the most promising of which we advance towards the clinic.

Inflation Reduction Act of 2022

The Inflation Reduction Act of 2022 (“IRA”) was enacted on August 16, 2022. The IRA includes provisions requiring manufacturers to pay a rebate to the Centers for Medicare & Medicaid Services (“CMS”) if the price of a Medicare Part B or Part D drug increases faster than the rate of inflation. In addition, beginning in 2025, the IRA will also shift a significant portion of the Medicare beneficiary costs currently borne by the government and beneficiaries to manufacturers. We anticipate this provision will limit the revenue we receive from Medicare patients and may materially reduce our profits. The IRA permits CMS to negotiate prices for certain high-expenditure Medicare Part B or Part D drugs.

The IRA also imposes a one percent excise tax on certain share repurchases and introduces a 15 percent corporate alternative minimum tax on adjusted financial statement income. The corporate alternative minimum tax became effective for us on January 1, 2024. We do not expect either of these provisions to significantly affect our consolidated financial statements.

Please see the risk factor under Item 1A of this Annual Report on Form 10-K, “*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 our Products, which would adversely affect our results of operations and financial position.*”

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, patient co-pay assistance program, discounts provided to our specialty distributor for prompt payment and reserves for expected returns.

Net product revenue was \$675.0 million for the year ended December 31, 2024, compared to \$482.4 million and \$401.9 million for the years ended December 31, 2023 and 2022, respectively. Higher sales volume accounted for 79.4 percent of the increase for the year ended December 31, 2024, with the remaining growth due to a price increase effective January 1, 2024.

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

Cost of sales was \$10.9 million for the year ended December 31, 2024, compared to \$6.5 million and \$5.4 million for the years ended December 31, 2023 and 2022, respectively. Cost of sales as a percentage of revenue was 1.6 percent, 1.3 percent and 1.3 percent for each of the years ended December 31, 2024, 2023 and 2022, respectively. The increase of cost of sales as a percentage of revenue for the year ended December 31, 2024 compared to 2023 was primarily due to increased manufacturing and distribution costs.

Research and development expense – Research and development expense includes the cost of (1) clinical trials, (2) recruiting and compensating development personnel, (3) manufacturing investigational drug product (4) preclinical studies, (5) drug discovery research and (6) the development of new drug formulations and manufacturing processes.

Research and development expense was \$246.9 million for the year ended December 31, 2024, compared to \$184.4 million and \$131.0 million for the years ended December 31, 2023 and 2022, respectively. The increase for the year ended December 31, 2024 compared to 2023 was primarily due to increased spending on the advancement and completion of our Cushing’s syndrome and Oncology development programs and increased employee compensation expense to support these activities.

	Year Ended December 31,		
	2024	2023	2022
	<i>(in thousands)</i>		
Development programs:			
Oncology	\$ 52,699	\$ 41,433	\$ 20,987
Cushing’s syndrome	65,215	41,196	30,031
Metabolic diseases	40,124	36,104	24,270
Pre-clinical and early-stage selective cortisol modulators and ALS	41,048	30,852	26,084
Unallocated activities, including manufacturing and regulatory activities	30,072	19,366	16,819
Stock-based compensation	17,729	15,402	12,800
Total research and development expense	<u>\$ 246,887</u>	<u>\$ 184,353</u>	<u>\$ 130,991</u>

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 and difficulties in the formulation or manufacture of study drugs and 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 2025 than in 2024 as we add new clinical trials, assuming success in our existing trials, and our existing trials enroll more patients. 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 for the years ended December 31, 2024, 2023 and 2022 was \$280.3 million, \$184.3 million and \$152.8 million, respectively. The increase for the year ended December 31, 2024 compared to 2023 was primarily due to increased employee compensation expenses and sales and marketing activities.

We expect our selling, general and administrative expense to be higher in 2025 than in 2024 due to increased commercial and administrative activities to support our increased research and development and marketing efforts.

Interest and other income – Interest and other income for the years ended December 31, 2024, 2023 and 2022 was \$24.5 million, \$17.3 million and \$3.6 million, respectively, and consisted primarily of interest income from marketable securities. The increase for the year ended December 31, 2024 compared to 2023 was due to higher cash and investment balances.

Income tax expense – Income tax expense for the years ended December 31, 2024, 2023, and 2022 was \$20.3 million, \$18.4 million, and \$14.8 million, respectively. The increase for the year ended December 31, 2024 compared to 2023 was primarily due to increased income before income taxes.

Liquidity and Capital Resources

Since 2015, we have relied on revenues from the sale of our Products 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, 2024, we had cash, cash equivalents and marketable securities of \$603.2 million, consisting of cash and cash equivalents of \$127.7 million and marketable securities of \$475.5 million, compared to cash, cash equivalents and marketable securities of \$425.4 million, consisting of cash and cash equivalents of \$135.6 million and marketable securities of \$289.8 million as of December 31, 2023.

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 material lack of access to cash or material realized losses.

Net cash provided by operating activities for the years ended December 31, 2024, 2023 and 2022 was \$198.1 million, \$127.0 million and \$120.3 million, respectively. The increase for the year ended December 31, 2024 compared to 2023 was primarily due to higher revenue.

Net cash (used in) provided by investing activities for the years ended December 31, 2024, 2023 and 2022 was \$(177.6) million, \$90.9 million and \$(114.3) million, respectively. The change for the year ended December 31, 2024 compared to 2023 was primarily due to investments in marketable securities during 2024 compared to allocation of cash proceeds from maturities of marketable securities towards cash equivalents in anticipation of the closing of our tender offer during 2023.

Net cash used in financing activities was \$28.3 million, \$148.7 million and \$17.3 million for the years ended December 31, 2024, 2023 and 2022, respectively. In the year ended December 31, 2024, we spent \$38.0 million acquiring shares of our common stock, comprised of \$15.7 million pursuant to our Stock Repurchase Program, \$17.0 million acquiring shares of our common stock in connection with the net exercise of employee and director stock options and \$5.3 million to satisfy tax withholding requirements from vesting of restricted stock grants, offset by \$5.5 million received in connection with our ESPP and \$4.2 million net cash received from the exercise of stock options. For the year ended December 31, 2023, we spent \$154.5 million acquiring shares of our common stock, comprised of \$145.4 million pursuant to our tender offer, \$7.4

million acquiring shares of our common stock in connection with the net exercise of employee and director stock options and \$1.7 million to satisfy tax withholding requirements from vesting of restricted stock grants, offset by \$3.8 million received in connection with our ESPP and \$2.0 million net cash received from the exercise of stock options.

As of December 31, 2024, we had retained earnings of \$543.7 million.

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

Our Products are 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 our Products. To determine the appropriate amount to reserve against these rebates, we identify our Products sold to patients covered by government-funded programs, apply the applicable government discount to these sales, then estimate utilization of such programs by government payors. 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.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

The primary objective of our investment activities is to preserve capital. As of December 31, 2024, the fair value of our cash and cash equivalents and marketable securities was \$603.2 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, 2024.

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, 2024, 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, 2024 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, 2024, 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, 2024.

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, 2024, 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, 2024, 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, 2024 and 2023, 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, 2024, and the related notes and our report dated February 26, 2025 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 26, 2025

ITEM 9B. OTHER INFORMATION

Insider Trading Arrangements

During the quarter ended December 31, 2024, none of directors and officers (as defined in Rule 16a-1(f) under the Exchange Act) adopted or terminated any contract, instruction or written plan for the purchase or sales of our securities that are intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) of the Securities Exchange Act of 1934, as amended, or any "non-Rule 10b5-1 trading arrangement," as defined in Item 408(a) of Regulation S-K, other than as set forth in the table below.

Name	Position	Action	Adoption Date	Total Shares of Common Stock to be Sold	Expiration Date⁽¹⁾
Joseph K. Belanoff, M.D.	Chief Executive Officer	Adoption	11/26/2024	Up to 400,000	8/31/2026
William Guyer	Chief Development Officer	Adoption	11/27/2024	Up to 360,000	8/31/2026

(1) Each trading arrangement permits transactions through and including the earlier to occur of (a) the completion of all sales or (b) the date listed in the table.

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 2025 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:

	Page
Report of Independent Registered Public Accounting Firm	F-2
Audited Consolidated Financial Statements	
Consolidated Balance Sheets	F-4
Consolidated Statements of Income	F-5
Consolidated Statements of Comprehensive Income	F-6
Consolidated Statements of Cash Flows	F-7
Consolidated Statement of Stockholders' Equity	F-9
Notes to Consolidated Financial Statements	F-10

(2) Financial Statement Schedules:

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

(3) Exhibits:

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

(A) EXHIBITS

Exhibit Number	Description of Document
3.1	Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the registrant's Current Report on Form 8-K filed on May 24, 2023).
3.2	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.1 to the registrant's Current Report on Form 8-K filed on December 11, 2023).
4.1	Specimen Common Stock Certificate (incorporated by reference to Exhibit 4.1 to the registrant's Registration Statement on Form S-1 (Registration No. 333-112676) filed on February 10, 2004).
4.2	Description of Common Stock (incorporated by reference to Exhibit 4.2 to the registrant's Annual Report on Form 10-K filed on February 23, 2021).
10.1†	Form of Indemnification Agreement for directors and officers approved by the Board of Directors on September 24, 2007 (incorporated by reference to Exhibit 10.7 to the registrant's Quarterly Report on Form 10-Q filed on November 14, 2007).
10.2†	Amended and Restated Severance and Change in Control Agreement by and between Corcept Therapeutics Incorporated and Joseph K. Belanoff, M. D., dated September 19, 2008 (incorporated by reference to Exhibit 10.25 to the registrant's Annual Report on Form 10-K filed on March 31, 2009).
10.3†	Amended and Restated Severance and Change in Control Agreement by and between Corcept Therapeutics Incorporated and James N. Wilson, dated September 19, 2008 (incorporated by reference to Exhibit 10.28 to the registrant's Annual Report on Form 10-K filed on March 31, 2009).
10.4†	Severance and Change in Control Agreement by and between Corcept Therapeutics Incorporated and Charles Robb, dated September 1, 2011 (incorporated by reference to Exhibit 10.2 to the registrant's Quarterly Report on Form 10-Q filed on November 8, 2011).
10.5†	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).

Exhibit Number	Description of Document
10.6†	<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>
10.7†	<u>Corcept Therapeutics Incorporated 2024 Incentive Award Plan (incorporated by reference to Appendix A to the registrant’s Definitive Proxy Statement on Schedule 14A filed on April 10, 2024).</u>
10.8†	<u>Form of 2024 Incentive Award Plan Stock Option Grant Notice and Agreement (incorporated by reference to Exhibit 4.3 to the Company’s Registration Statement on Form S-1 (File No. 333-279862) filed on May 31, 2024).</u>
10.9†	<u>Form of 2024 Incentive Award Plan Restricted Stock Award Grant Notice and Agreement (incorporated by reference to Exhibit 4.4 to the Company’s Registration Statement on Form S-1 (File No. 333-279862) filed on May 31, 2024).</u>
10.10#	<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>
10.11##	<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>
10.12##	<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>
10.13##	<u>Third Amendment to Distribution Services Agreement by and between Optime Care, Inc. and Corcept Therapeutics Incorporated, effective as of April 1, 2024 (incorporated by reference to Exhibit 10.2 to the registrant’s Quarterly Report on Form 10-Q filed on May 1, 2024).</u>
10.14#	<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>
10.15†	<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>
10.16†	<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>
10.17†	<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>
10.18	<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>
10.19	<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>
10.20†	<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>
10.21†	<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>
10.22†	<u>Employment offer letter to William Guyer, dated July 2, 2021 (incorporated by reference to Exhibit 10.1 to the registrant’s Annual Report on Form 10-K filed on February 15, 2022).</u>
10.23†	<u>Severance and Change in Control Agreement by and between Corcept Therapeutics Incorporated and William Guyer, dated February 9, 2022 (incorporated by reference to Exhibit 10.2 to the registrant’s Annual Report on Form 10-K filed on February 15, 2022).</u>

Exhibit Number	Description of Document
10.24	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 (incorporated by reference to Exhibit 10.1 to the registrant's Quarterly Report on Form 10-Q filed on May 5, 2022).
10.25	Eighth Amendment to Office Lease Agreement by and between Exponent Realty, LLC and Corcept Therapeutics Incorporated, made and entered into as of April 1, 2023 (incorporated by reference to Exhibit 10.1 to the registrant's Quarterly Report on Form 10-Q filed on May 3, 2023).
10.26	Ninth Amendment to Office Lease Agreement by and between Exponent Realty, LLC and Corcept Therapeutics Incorporated, made and entered into as of March 19, 2024 (incorporated by reference to Exhibit 10.1 to the registrant's Quarterly Report on Form 10-Q filed on May 1, 2024).
10.27	Sublease by and between Zuora, Inc. and Corcept Therapeutics Incorporated, entered into as of April 12, 2024 (incorporated by reference to Exhibit 10.3 to the registrant's Quarterly Report on Form 10-Q filed on May 1, 2024).
10.28	Tenth Amendment to Office Lease Agreement by and between Exponent Realty, LLC and Corcept Therapeutics Incorporated, made and entered into as of May 13, 2024 (incorporated by reference to Exhibit 10.1 to the registrant's Quarterly Report on Form 10-Q filed on July 29, 2024).
19	Corcept Therapeutics Incorporated Insider Trading Policy and 10b5-1 Trading Plan Guidelines (incorporated by reference to Exhibit 10.36 to the registrant's Annual Report on Form 10-K filed on February 15, 2024).
97	Corcept Therapeutics Incorporated Compensation Clawback Policy (incorporated by reference to Exhibit 97 to the registrant's Annual Report on Form 10-K filed on February 15, 2024).
23.1	Consent of Independent Registered Public Accounting Firm
24.1	Power of Attorney (See signature page)
31.1	Certification pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934 of Joseph K. Belanoff, M.D.
31.2	Certification pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934 of Atabak Mokari
32.1	Certification pursuant to 18 U.S.C. Section 1350 of Joseph K. Belanoff, M.D.
32.2	Certification pursuant to 18 U.S.C. Section 1350 of Atabak Mokari
101.INS	XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document
101.SCH	XBRL Schema Document
101.CAL	XBRL Calculation Linkbase Document
101.DEF	XBRL Definition Linkbase Document
101.LAB	XBRL Labels Linkbase Document
101.PRE	XBRL Presentation Linkbase Document
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.

Signature	Title	Date
<u>/s/ JOSEPH K. BELANOFF</u> Joseph K. Belanoff, M.D.	Chief Executive Officer, President and Director (Principal Executive Officer)	February 26, 2025
<u>/s/ ATABAK MOKARI</u> Atabak Mokari	Chief Financial Officer (Principal Financial Officer)	February 26, 2025
<u>/s/ JOSEPH DOUGLAS LYON</u> Joseph Douglas Lyon	Chief Accounting and Technology Officer (Principal Accounting Officer)	February 26, 2025
<u>/s/ JAMES N. WILSON</u> James N. Wilson	Director and Chairman of the Board of Directors	February 26, 2025
<u>/s/ GREGG ALTON</u> Gregg Alton	Director	February 26, 2025
<u>/s/ G. LEONARD BAKER, JR.</u> G. Leonard Baker, Jr.	Director	February 26, 2025
<u>/s/ GILLIAN CANNON</u> Gillian Cannon	Director	February 26, 2025
<u>/s/ DAVID L. MAHONEY</u> David L. Mahoney	Director	February 26, 2025
<u>/s/ JOSHUA MURRAY</u> Joshua Murray	Director	February 26, 2025
<u>/s/ KIMBERLY PARK</u> Kimberly Park	Director	February 26, 2025
<u>/s/ DANIEL N. SWISHER, JR</u> Daniel N. Swisher, Jr.	Director	February 26, 2025

CORCEPT THERAPEUTICS INCORPORATED
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

	Page
Report of Independent Registered Public Accounting Firm (EY US PCAOB #42)	F-2
Audited Financial Statements	
Consolidated Balance Sheets	F-4
Consolidated Statements of Income	F-5
Consolidated Statements of Comprehensive Income	F-6
Consolidated Statements of Cash Flows	F-7
Consolidated Statement of Stockholders' Equity	F-9
Consolidated Notes to Financial Statements	F-10

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, 2024 and 2023, 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, 2024, 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, 2024 and 2023, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2024, 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, 2024, 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 26, 2025, 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.

Net Product Revenue - Accounting for Government Rebates

Description of the matter

As of December 31, 2024, accrued government rebates were \$41.6 million, and the Company recognized \$87.7 million in revenue reductions associated with rebates during the year-ended December 31, 2024. As discussed in Note 1 to the consolidated financial statements, the Company recognizes revenues net of government rebates and accrues for rebates in the same period the product is sold. However, third-party reporting and payment of the rebate amount occur on a time lag. Allowances for rebates include mandated discounts due to the Company's participation in various government health care programs. The Company estimates accrued rebates, considering actual revenue, formulaic rebate rates, historical payment experience and expected utilization under each program, and changes in product pricing and information regarding changes in program regulations and guidelines.

Auditing government rebates was complex due to the time lag associated with third-party reporting of rebate amounts, complexity in the calculations of government pricing used to determine the rebate price, and the judgmental nature of the utilization assumptions. The complexities associated with government pricing calculations required the involvement of specialists.

How we addressed the matter in our audit

We obtained an understanding, evaluated the design and tested the operating effectiveness of controls that address the risks of material misstatement relating to the measurement and valuation of government rebates. For example, we tested controls over management's review of the government rebate accrual, including the significant assumptions and data inputs provided by third parties.

To test government rebates, our audit procedures included, among others, evaluating the methodologies, key assumptions, and testing the underlying data used by the Company. We performed analytics on the Company's net product revenue. We evaluated the reasonableness of management's assumptions by comparing against historical trends, evaluated the change in estimated accruals from the prior periods, and assessed the historical accuracy of the Company's estimates against actual results. We utilized government pricing specialists in evaluating the Company's application of government rebate program regulations and calculations of government prices used to estimate rebates during the year ended December 31, 2024.

/s/ Ernst & Young LLP

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

San Mateo, California
February 26, 2025

CORCEPT THERAPEUTICS INCORPORATED

CONSOLIDATED BALANCE SHEETS

(In thousands, except per share data)

	December 31,	
	2024	2023
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 127,665	\$ 135,551
Short-term marketable securities	255,669	232,670
Trade receivables, net of allowances	53,976	41,123
Insurance recovery receivable related to Melucci litigation (Note 10)	—	14,000
Inventory	12,412	7,730
Prepaid expenses and other current assets	21,880	27,562
Total current assets	471,602	458,636
Strategic inventory	3,583	8,244
Operating lease right-of-use asset	5,324	120
Property and equipment, net	2,689	195
Long-term marketable securities	219,831	57,176
Other assets	6,610	6,541
Deferred tax assets, net	130,914	90,605
Total assets	\$ 840,553	\$ 621,517
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 15,376	\$ 17,396
Accrued research and development expenses	33,868	21,330
Accrued and other liabilities	90,700	51,628
Accrued settlement related to Melucci litigation (Note 10)	—	14,000
Short-term operating lease liability	829	151
Total current liabilities	140,773	104,505
Long-term operating lease liability	6,107	—
Long-term accrued income taxes payable	14,084	10,307
Total liabilities	160,964	114,812
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, 2024 and December 31, 2023	—	—
Common stock, par value \$0.001 per share, 280,000 shares authorized and 137,753 issued and 105,113 outstanding as of December 31, 2024 and 134,344 shares issued and 103,405 outstanding as of December 31, 2023	136	133
Treasury stock; at cost; 32,640 shares of common stock as of December 31, 2024 and 30,938 shares of common stock as of December 31, 2023	(696,173)	(635,078)
Additional paid-in capital	832,108	738,515
Accumulated other comprehensive (loss) income	(217)	609
Retained earnings	543,735	402,526
Total stockholders' equity	679,589	506,705
Total liabilities and stockholders' equity	\$ 840,553	\$ 621,517

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,		
	2024	2023	2022
Product revenue, net	\$ 675,040	\$ 482,375	\$ 401,858
Operating expenses:			
Cost of sales	10,882	6,481	5,385
Research and development	246,887	184,353	130,991
Selling, general and administrative	280,320	184,259	152,848
Settlement expense related to Melucci litigation	—	—	14,000
Insurance recovery related to Melucci litigation	—	—	(14,000)
Total operating expenses	538,089	375,093	289,224
Income from operations	136,951	107,282	112,634
Interest and other income	24,542	17,275	3,557
Income before income taxes	161,493	124,557	116,191
Income tax expense	(20,284)	(18,417)	(14,773)
Net income	\$ 141,209	\$ 106,140	\$ 101,418
Net income attributable to common stockholders	\$ 139,733	\$ 105,496	\$ 101,288
Basic net income per common share	\$ 1.35	\$ 1.02	\$ 0.95
Diluted net income per common share	\$ 1.23	\$ 0.94	\$ 0.87
Weighted-average shares outstanding used in computing net income per common share			
Basic	103,232	103,560	106,787
Diluted	113,480	111,742	115,966

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

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

	Year Ended December 31,		
	2024	2023	2022
Net income	\$ 141,209	\$ 106,140	\$ 101,418
Other comprehensive income (loss):			
Unrealized (loss) gain on available-for-sale investments, net of tax effect of \$118, \$(353), and \$105, respectively	(598)	1,120	(331)
Foreign currency translation (loss) gain	(228)	358	(311)
Total comprehensive income	140,383	107,618	100,776

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,		
	2024	2023	2022
Cash flows from operating activities:			
Net income	\$ 141,209	\$ 106,140	\$ 101,418
Adjustments to reconcile net income to net cash provided by operating activities:			
Stock-based compensation	61,354	48,940	42,442
(Accretion) of discount and Amortization of premium on marketable securities, net	(10,938)	(9,128)	1,383
Depreciation and amortization	795	1,042	1,259
Deferred income taxes	(40,191)	(29,493)	(33,905)
Amortization of right-of-use asset	541	1,320	2,187
Changes in operating assets and liabilities:			
Trade receivables	(12,853)	(10,066)	(3,432)
Insurance recovery receivable related to Melucci litigation	14,000	—	(14,000)
Inventory	305	1,265	1,199
Prepaid expenses and other current assets	5,422	(11,603)	(6,557)
Other assets	(69)	(1,483)	(1,975)
Accounts payable	(2,248)	5,778	4,757
Accrued research and development expenses	12,538	6,757	2,131
Accrued and other liabilities	38,242	17,649	2,927
Accrued settlement related to Melucci litigation	(14,000)	—	14,000
Long-term accrued income taxes	3,777	1,210	8,688
Operating lease liability	183	(1,289)	(2,199)
Net cash provided by operating activities	<u>198,067</u>	<u>127,039</u>	<u>120,323</u>
Cash flows from investing activities:			
Purchases of property and equipment	(2,172)	(139)	(413)
Proceeds from maturities of marketable securities	412,878	419,793	241,152
Purchases of marketable securities	(588,310)	(328,748)	(355,066)
Net cash (used in) provided by investing activities	<u>(177,604)</u>	<u>90,906</u>	<u>(114,327)</u>
Cash flows from financing activities:			
Proceeds from stock option exercises, net of issuance costs	4,157	1,977	3,391
Proceeds from purchases under the Employee Stock Purchase Program	5,459	3,834	990
Repurchases of common stock in connection with Stock Repurchase Program	(15,664)	—	—
Repurchase of common stock in connection with Tender Offer	—	(145,428)	—
Cash paid to satisfy statutory withholding requirement for net settlement of cashless option exercises and vesting of restricted stock grants	(22,301)	(9,106)	(21,665)
Net cash used in financing activities	<u>(28,349)</u>	<u>(148,723)</u>	<u>(17,284)</u>
Net (decrease) increase in cash and cash equivalents	<u>(7,886)</u>	<u>69,222</u>	<u>(11,288)</u>
Cash and cash equivalents, at beginning of period	135,551	66,329	77,617
Cash and cash equivalents, at end of period	<u>\$ 127,665</u>	<u>\$ 135,551</u>	<u>\$ 66,329</u>
Supplemental disclosure:			
Income taxes paid	\$ 60,267	\$ 47,602	\$ 39,747
Exercise cost of shares repurchased for net settlement of cashless option exercises	\$ 21,195	\$ 25,032	\$ 24,388

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

CORCEPT THERAPEUTICS INCORPORATED
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(In thousands)

	Common Stock		Additional Paid-in Capital	Treasury Stock	Accumulated Other Comprehensive (Loss) Income	Retained Earnings	Total Stockholders' Equity
	Shares	Amount					
Balance at December 31, 2021	105,940	\$ 127	\$ 591,349	\$ (410,411)	\$ (227)	\$ 194,968	\$ 375,806
Issuance of common stock under 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
Issuance of common stock under incentive award plan	3,383	2	29,126	—	—	—	29,128
Shares tendered to satisfy cost and statutory withholding requirements for net settlement of cashless option exercises	(1,203)	—	—	(32,424)	—	—	(32,424)
Repurchase of common stock in connection with Tender Offer	(6,610)	—	—	(145,428)	—	—	(145,428)
Excise tax related to net share repurchases	—	—	—	(1,078)	—	—	(1,078)
Stock-based compensation	—	—	45,977	—	—	—	45,977
Vesting of RSAs in connection with ESPP	—	—	1,070	—	—	—	1,070
Other comprehensive income, net of tax	—	—	—	—	1,478	—	1,478
Net income	—	—	—	—	—	106,140	106,140
Balance at December 31, 2023	103,405	133	738,515	(635,078)	609	402,526	506,705
Issuance of common stock under incentive award plan	3,332	3	30,810	—	—	—	30,813
Shares tendered to satisfy cost and statutory withholding requirements for net settlement of cashless option exercises and vesting of restricted stock	(1,138)	—	2,032	(45,528)	—	—	(43,496)
Repurchase of common stock in connection with Stock Repurchase Program	(486)	—	—	(15,664)	—	—	(15,664)
Excise tax related to net share repurchases	—	—	—	97	—	—	97
Stock-based compensation	—	—	55,710	—	—	—	55,710
Vesting of RSAs in connection with ESPP	—	—	5,041	—	—	—	5,041
Other comprehensive loss, net of tax	—	—	—	—	(826)	—	(826)
Net income	—	—	—	—	—	141,209	141,209
Balance at December 31, 2024	105,113	\$ 136	\$ 832,108	\$ (696,173)	\$ (217)	\$ 543,735	\$ 679,589

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 biopharmaceutical company engaged in the discovery and development of medications to treat severe endocrinologic, oncologic, metabolic and neurologic 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, and in June 2024, we made available an authorized generic version of Korlym for the same indication (collectively, our “Products”). 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 Redwood City, 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. All material intercompany balances and transactions have been eliminated in consolidation.

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.

Credit and Concentration Risks

Our cash, cash equivalents and marketable securities are held in four financial institutions. 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 minimize concentrations of credit risk. We have never experienced a loss in, or lack of access to, our operating or investment accounts.

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

We sell our Products 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 our Products.

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

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

Net Product Revenue

We sell our Products directly to patients through a single specialty pharmacy. We also sell our Products to a specialty distributor (“SD”), for which we recognize revenue at the time the SD receives our Products. SD sales were less than one percent of our net revenue in each of the years ended December 31, 2024, 2023 and 2022.

To determine our revenue from the sale of our Products, 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 our Products to the customer; and (v) recognize revenue once our Products have 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 our Products to a patient.

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

Government Rebates: Our Products are 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 our Products. To determine the

CORCEPT THERAPEUTICS INCORPORATED

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS, Continued

appropriate amount to reserve against these rebates, we identify our Products sold to patients covered by government-funded programs, apply the applicable government discount to these sales, then estimate utilization of such programs by government payors. 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 our Products 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 our Products purchased by the SD in prior periods. We deduct from our revenue in each period chargebacks claimed by the SD for our Products it purchased in that period. We also create a reserve for chargebacks we estimate the SD will claim in future periods against our Products 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 our Products 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 our Products. 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 our Products at no cost to uninsured patients who do not qualify for charitable support.

Sales Returns: Federal law prohibits the return of our Products sold to patients. Sales to our SD are subject to return. We deduct the amount of our Products 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 our Products held by the SD and projected demand. 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, 2024, 2023 and 2022:

	<u>Chargebacks</u>	<u>Government Rebates</u>	<u>Total</u>
	<i>(in thousands)</i>		
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	230	11,098	11,328
Provision related to current period sales	346	52,825	53,171
Provision related to prior period sales	(88)	(555)	(643)
Credit or payments made during the period	(266)	(44,900)	(45,166)
Balance at December 31, 2023	222	18,468	18,690
Provision related to current period sales	241	86,336	86,577
Provision related to prior period sales	11	1,404	1,415
Credit or payments made during the period	(366)	(64,628)	(64,994)
Balance at December 31, 2024	<u>\$ 108</u>	<u>\$ 41,580</u>	<u>\$ 41,688</u>

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.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS, Continued

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, allocate resources and assess performance. Joseph K. Belanoff, M.D., Chief Executive Officer, is our Chief Operating Decision Maker (“CODM”) who reviews our consolidated balance sheets and statements of income. We view our operations and manage our business as 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 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, *Stockholders’ Equity* for more information.

Income Taxes

We account for income taxes in accordance with ASC 740, *Income Taxes* (“ASC 740”), which requires recognition of deferred tax assets and liabilities for the expected tax consequences of our future financial and operating activities. Under ASC 740, we determine deferred tax assets and liabilities based on the temporary difference between the financial statement and tax bases of assets and liabilities using the tax rates in effect for the year in which we expect such differences to reverse. If we determine that it is more likely than not that we will not generate sufficient taxable income to realize the value of some or all of our deferred tax assets (net of our deferred tax liabilities), we establish a valuation allowance offsetting the amount we do not expect to realize. We perform this analysis each reporting period and reduce our measurement of deferred taxes if the likelihood we will realize them becomes uncertain.

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

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

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

Recently Issued Accounting Pronouncements Not Yet Adopted

In December 2023, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) No. 2023-09, which requires disaggregated information about a reporting entity’s effective tax rate reconciliation as well as information on income taxes paid. The standard is intended to benefit investors by providing more detailed income tax disclosures that would be useful in making capital allocation decisions. This ASU is effective for public companies with annual periods beginning after December 15, 2024, with early adoption permitted. We plan to adopt this guidance for the fiscal year ending December 31, 2025. We are currently evaluating the effects adoption of this guidance will have on the consolidated financial statements.

In November 2024, the FASB issued ASU No. 2024-03, which requires additional information about specific expense categories in the notes to financial statements. This ASU is effective for public companies with annual periods beginning after December 15, 2026, with early adoption permitted. We plan to adopt this guidance for the fiscal year ending December 31, 2027. We are currently evaluating the effects adoption of this guidance will have on the consolidated financial statements.

Recently Adopted Accounting Pronouncements

In November 2023, the FASB issued ASU No. 2023-07, to improve the disclosures about a public entity’s reportable segments and address requests from investors for additional, more detailed information about a reportable segment’s expenses. The standard is effective for public companies with annual periods beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024, with early adoption permitted. We adopted this guidance for the annual period ended December 31, 2024.

2. Significant Agreements**Commercial Agreement**

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 our Products 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 our Products to Optime, which it dispenses to patients. Optime does not purchase our Products 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 and September 2022, we amended our agreement to extend its term to September 30, 2022 and March 31, 2024, respectively. In March 2024, we amended our agreement to further extend its term to March 31, 2027 with automatic renewal for successive three-year terms, 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.

3. Available for Sale Marketable Securities and Fair Value Measurements

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

	December 31,	
	2024	2023
	<i>(in thousands)</i>	
Cash equivalents	\$ 98,436	\$ 97,170
Short-term marketable securities	255,669	232,670
Long-term marketable securities	219,831	57,176
Total marketable securities	<u>\$ 573,936</u>	<u>\$ 387,016</u>

CORCEPT THERAPEUTICS INCORPORATED

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS, Continued

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

	Fair Value Hierarchy Level	December 31, 2024				December 31, 2023			
		Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
<i>(in thousands)</i>									
Corporate bonds	Level 2	\$ 373,440	\$ 333	\$ (529)	\$ 373,244	\$ 120,508	\$ 307	\$ —	\$ 120,815
Commercial paper	Level 2	9,771	6	(2)	9,775	75,308	20	(9)	75,319
U.S. government agency securities	Level 2	7,999	—	(2)	7,997	—	—	—	—
U.S. Treasury securities	Level 1	84,458	27	(1)	84,484	93,655	61	(4)	93,712
Money market funds	Level 1	98,436	—	—	98,436	97,170	—	—	97,170
Total marketable securities		<u>\$ 574,104</u>	<u>\$ 366</u>	<u>\$ (534)</u>	<u>\$ 573,936</u>	<u>\$ 386,641</u>	<u>\$ 388</u>	<u>\$ (13)</u>	<u>\$ 387,016</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 \$4.1 million and \$1.7 million as of December 31, 2024 and 2023, respectively, as prepaid and other current assets on our consolidated balance sheets.

As of December 31, 2024, all of our long-term marketable securities had original maturities of no more than 24 months and all of our marketable securities classified as short-term have maturities of less than one year. The weighted-average maturity of our short-term and long-term marketable securities was nine months. As of December 31, 2024, our long-term marketable securities had remaining maturities between 12 months and 23 months. None of our marketable securities changed from one fair value hierarchy to another during the year ended December 31, 2024.

4. Composition of Certain Balance Sheet Items

Inventory

	Year Ended December 31,	
	2024	2023
<i>(in thousands)</i>		
Work in progress	\$ 7,789	\$ 8,233
Finished goods	8,206	7,741
Total inventory	15,995	15,974
Less strategic inventory classified as non-current	(3,583)	(8,244)
Total inventory classified as current	<u>\$ 12,412</u>	<u>\$ 7,730</u>

We have purchased and hold significant quantities of API, included in work in progress inventory. We classify inventory we do not expect to utilize within 12 months of the balance sheet date as “Strategic inventory,” a non-current asset.

CORCEPT THERAPEUTICS INCORPORATED
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS, Continued

Prepaid expenses and other current assets

	Year Ended December 31,	
	2024	2023
	<i>(in thousands)</i>	
Prepaid expenses	\$ 9,492	\$ 4,319
Deferred clinical materials	4,493	13,496
Clinical deposits	1,817	3,865
Other current assets	6,078	5,882
Total prepaid expenses and other current assets	\$ 21,880	\$ 27,562

Accrued and other liabilities

	Year Ended December 31,	
	2024	2023
	<i>(in thousands)</i>	
Accrued compensation	\$ 41,731	\$ 25,457
Government rebates	41,580	18,468
Accrued selling and marketing costs	3,345	1,771
Legal fees	824	542
Accounting and financial services fees	648	389
Income taxes payable	191	1,814
Accrued manufacturing costs	109	1,455
Excise tax payable	—	1,078
Other	2,272	654
Total accrued and other liabilities	\$ 90,700	\$ 51,628

Other assets

As of December 31, 2024 and 2023, other assets included \$5.6 million and \$6.4 million of deposits for clinical trials, respectively.

5. Leases

In April 2024, we entered into a six-year sublease (the “Sublease”) with Zuora, Inc. for office space located at 101 Redwood Shores Parkway, Redwood City, California, effective from July 1, 2024. The leased property became our new headquarters effective August 1, 2024. The portion of the premises subject to the Sublease is 50,632 rentable square feet. The Sublease commenced on June 1, 2024 due to early access rights and will end on June 30, 2030. We are obligated to pay a base rent of an average of \$1.5 million annually over the term of the lease. As a result of the agreement, we recorded a right-of-use asset and corresponding lease liability related to the leased property based on the present value of future lease payments.

The lease for our previous headquarters in Menlo Park, California ended on August 31, 2024. We do not recognize right-of-use assets or lease liabilities for leases with a term of 12 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. Therefore, we did not record an additional right of use asset and corresponding lease liability related to our previous headquarters, as the remaining lease term was less than 12 months.

As the operating leases for our facilities do not provide sufficient information to determine the implicit borrowing 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. Operating lease right-of-use assets also include any rent paid prior to the commencement date, less any lease incentives received. We recognize operating lease payments as expenses using the straight-line method over the term of the lease.

CORCEPT THERAPEUTICS INCORPORATED

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS, Continued

Operating lease expense, including variable lease costs for the years ended December 31, 2024, 2023 and 2022 was \$3.0 million, \$2.4 million and \$2.3 million, respectively.

Supplemental information related to operating leases was as follows (in thousands, except weighted average amounts):

	Year Ended December 31,		
	2024	2023	2022
Cash paid for operating lease liabilities	\$ 1,358	\$ 2,391	\$ 2,265
Recognition of right-of-use asset in exchange for lease liability	\$ 5,745	\$ 297	\$ 2,816
Weighted-average remaining lease term	66 months	6 months	6 months
Weighted-average discount rate	8.5 %	8.0 %	4.0 %

As of December 31, 2024, future minimum lease payments under non-cancelable operating leases were as follows (in thousands):

2025	\$	1,382
2026		1,551
2027		1,598
2028		1,646
2029		1,695
2030		860
Total operating lease payments		8,732
Less imputed interest		(1,796)
Present value of operating lease liabilities	\$	6,936

6. Related Party Transactions

There were no related party transactions during the years ended December 31, 2024, 2023, and 2022.

7. 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, 2024 and 2023, we had no outstanding shares of preferred stock.

Treasury Stock

In January 2024, our Board of Directors approved a program authorizing the repurchase of up to \$200 million of our common stock (the "Stock Repurchase Program"). Purchases under this program may be made in the open market, in privately negotiated transactions or otherwise. The timing and amount of any repurchases will be determined based on market conditions, our stock price and other factors. The program does not require us to repurchase any specific number of shares and may be modified, suspended or discontinued at any time without notice. During the year ended December 31, 2024, we purchased 0.5 million shares of common stock under the Stock Repurchase Program in open market transactions at an average price of \$32.25 per share, for aggregate purchase price of \$15.7 million.

In March 2023, we announced that our Board of Directors approved a tender offer to purchase up to 7.5 million shares of our common stock. The tender offer commenced on March 6, 2023 and expired on March 31, 2023. On April 5, 2023, we purchased 6.6 million shares through the tender offer at a price of \$22.00 per share for an aggregate purchase price of

CORCEPT THERAPEUTICS INCORPORATED

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS, Continued

\$145.4 million, excluding related fees and expenses. We recorded purchased shares as treasury stock on our consolidated balance sheet at cost.

During the years ended December 31, 2024, 2023 and 2022, we issued 2.3 million, 2.4 million and 3.7 million shares, respectively, of our common stock upon the exercise of stock options. Some option holders exercised their options on a “net exercise” basis, pursuant to which they surrendered to us, and we purchased from them, at the then current market price, shares equal in value to the associated exercise price and tax withholding obligations. During the years ended December 31, 2024, 2023 and 2022, we purchased 1.1 million, 1.2 million and 1.8 million shares, respectively, in connection with such option net exercises and vesting of restricted stock and paid \$22.3 million, \$9.1 million and \$21.7 million, respectively, to satisfy associated tax withholding obligations.

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 equity award plan – the Corcept Therapeutics Incorporated 2024 Incentive Award Plan (the “2024 Plan”).

In February 2024, our Board of Directors approved the 2024 Plan, which became effective upon its approval by our stockholders at our 2024 Annual Meeting of Stockholders on May 17, 2024 and replaced the Corcept Therapeutics Incorporated 2012 Incentive Award Plan (the “2012 Plan”). The aggregate number of shares which may be issued or transferred pursuant to awards under the 2024 Plan is equal to the sum of (i) 8.0 million shares, (ii) 4.1 million shares, which equals the number of shares available for future grant under the 2012 Plan as of May 17, 2024, and (iii) any shares underlying awards outstanding under the 2012 Plan that, on or after May 17, 2024, terminate, expire or lapse for any reason without the delivery of shares to the holder thereof. After May 17, 2024, no additional awards were or will be issued under the 2012 Plan.

Under the 2024 Plan, we can issue stock options, stock purchase and stock appreciation rights and restricted stock awards to our employees, officers, directors and consultants.

As of December 31, 2024, we had 11.0 million shares available for future issuance under the 2024 plan.

Stock Options

The following table summarizes option activity and related information:

	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, 2023	23,370	\$ 16.47		
Options granted	3,813	\$ 25.28		
Options exercised	(2,306)	\$ 11.01		
Options cancelled and forfeited	(164)	\$ 24.42		
Balance at December 31, 2024	<u>24,713</u>	\$ 18.29	5.64	\$ 793,378
Options exercisable at December 31, 2024	<u>19,021</u>	\$ 16.46	4.78	\$ 645,388
Options fully vested and expected to vest at December 31, 2024	<u>24,413</u>	\$ 18.15	5.60	\$ 786,966

The total intrinsic value of options exercised during the years ended December 31, 2024, 2023 and 2022 was \$60.1 million, \$36.0 million and \$63.4 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

As of December 31, 2024, we had \$71.3 million of unrecognized compensation expense for options outstanding, which had a weighted-average remaining vesting period of 2.5 years.

RSAs and RSUs (collectively, "restricted stock")

The following table summarizes restricted stock activity and related information:

	Outstanding Restricted Stock	
	Number of Restricted Stock <i>(in thousands)</i>	Weighted-Average Grant Date Fair Value
Balance at December 31, 2023	827	\$ 24.10
Restricted stock granted	916	\$ 31.35
Restricted stock vested	(416)	\$ 23.73
Restricted stock cancelled and forfeited	(84)	\$ 25.71
Balance at December 31, 2024	<u>1,243</u>	<u>\$ 29.47</u>

The total fair value of restricted stock vested during the years ended December 31, 2024, 2023 and 2022 was \$14.8 million, \$4.9 million and \$0.9 million, respectively.

As of December 31, 2024, we had \$27.4 million of unrecognized compensation expense for restricted stock outstanding, which had a weighted-average remaining vesting period of 2.66 years.

ESPP

Our ESPP allows employees to set aside, by means of payroll deductions, up to ten percent of their annual compensation for the purchase of our common stock. Shares are issued to participating employees from the 2024 Plan 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) at the then-current fair market value of our stock, as determined at the close of trading on those days.

For each purchased share, the participating employee receives one matching share, also issued from the 2024 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 an RSA that will vest on the one-year anniversary of the respective ESPP purchase date, net of 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 may be held, sold or transferred at the employee's sole discretion.

As of December 31, 2024 and 2023, we had a liability of \$3.2 million and \$2.3 million, respectively, of stock-based compensation related to RSAs granted in connection with our ESPP in "Accrued and other liabilities" on our consolidated balance sheet.

Option Valuation Assumptions

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

	Year Ended December 31,		
	2024	2023	2022
Weighted-average assumptions for options granted:			
Risk-free interest rate	4.14%	3.87%	1.97%
Expected term	6.7 years	6.7 years	6.4 years
Expected volatility of stock price	54.6%	53.0%	56.5%
Dividend rate	0%	0%	0%
Weighted-average grant date fair value-based measurement	\$14.65	\$13.65	\$11.27

CORCEPT THERAPEUTICS INCORPORATED

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS, Continued

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,		
	2024	2023	2022
	<i>(in thousands)</i>		
Stock-based compensation capitalized in inventory	\$ 326	\$ 208	\$ 280
Cost of sales	75	52	70
Research and development	17,729	15,402	12,800
Selling, general and administrative	43,550	33,486	29,572
Total stock-based compensation	\$ 61,680	\$ 49,148	\$ 42,722

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.

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

	Year Ended December 31,		
	2024	2023	2022
	<i>(in thousands, except per share data)</i>		
Numerator:			
Net income attributable to common stockholders	\$ 139,733	\$ 105,496	\$ 101,288
Denominator:			
Weighted-average shares used to compute basic net income per common share	103,232	103,560	106,787
Dilutive effect of employee stock options and unvested RSUs	10,248	8,182	9,179
Weighted-average shares used to compute diluted net income per common share	113,480	111,742	115,966
Net income per share attributable to common stockholders			
Basic	\$ 1.35	\$ 1.02	\$ 0.95
Diluted	\$ 1.23	\$ 0.94	\$ 0.87

We excluded from the computation of diluted net income per share, on a weighted-average basis, 2.7 million stock options and unvested RSUs outstanding during the year ended December 31, 2024, and 9.1 million and 7.3 million stock

CORCEPT THERAPEUTICS INCORPORATED
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS, Continued

options outstanding during the years ended December 31, 2023 and 2022, respectively, because including them would have reduced dilution.

9. Income Taxes

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

	Year Ended December 31,		
	2024	2023	2022
	<i>(in thousands)</i>		
Domestic	\$ 159,623	\$ 125,691	\$ 116,871
Foreign	1,870	(1,134)	(680)
Income before income taxes	<u>\$ 161,493</u>	<u>\$ 124,557</u>	<u>\$ 116,191</u>

The income tax expense for the years ended December 31, 2024, 2023, and 2022 consisted of the following:

	Year Ended December 31,		
	2024	2023	2022
	<i>(in thousands)</i>		
U.S. federal taxes:			
Current	\$ 49,716	\$ 40,265	\$ 39,132
Deferred	(35,845)	(25,613)	(28,122)
Total U.S. federal taxes	13,871	14,652	11,010
State taxes:			
Current	10,504	7,590	9,515
Deferred	(3,783)	(2,645)	(5,313)
Total state taxes	6,721	4,945	4,202
Foreign taxes:			
Current	256	56	30
Deferred	(564)	(1,236)	(469)
Total foreign taxes	(308)	(1,180)	(439)
Total provision for income taxes	<u>\$ 20,284</u>	<u>\$ 18,417</u>	<u>\$ 14,773</u>

Beginning in 2022, the Tax Cuts and Jobs Act of 2017 eliminated 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, 2024, 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.

CORCEPT THERAPEUTICS INCORPORATED

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS, Continued

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

	Year Ended December 31,	
	2024	2023
Deferred tax assets:	<i>(in thousands)</i>	
Federal and state net operating losses	\$ 3,470	\$ 3,942
Capitalized research and patent costs	293	908
Capitalized research expenditures	93,010	61,760
Research credits	13,326	11,682
Stock-based compensation costs	25,295	21,676
Operating lease liability	1,695	37
Accruals and Reserves	10,358	7,996
Other	2,228	—
Total deferred tax assets	149,675	108,001
Valuation allowance	(17,460)	(15,947)
Deferred tax liabilities		
Operating lease right-of-use asset	(1,301)	(30)
Other	—	(1,419)
Total deferred tax liabilities	(1,301)	(1,449)
Net deferred tax assets	\$ 130,914	\$ 90,605

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 our California net deferred tax assets, we have determined that it is more likely than not we will realize the benefit related to all other deferred tax assets. To the extent we increase 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 \$1.5 million, \$1.1 million and \$1.9 million for the years ended December 31, 2024, 2023 and 2022, respectively.

As of December 31, 2024, we had California net operating loss carryforwards of \$49.4 million, which will begin to expire in the year 2035.

As of December 31, 2024, we also had California research and development credits of \$19.3 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,		
	2024	2023	2022
	<i>(in thousands)</i>		
U.S. federal taxes at statutory rate	\$ 33,914	\$ 26,157	\$ 24,400
R&D and other credits	(16,002)	(11,508)	(9,114)
State income taxes, net of federal benefit	5,288	3,897	3,320
Non-deductible compensation	4,431	3,295	4,354
Stock-based compensation	(8,464)	(2,951)	(7,980)
Other	1,117	(473)	(207)
Total	\$ 20,284	\$ 18,417	\$ 14,773

CORCEPT THERAPEUTICS INCORPORATED

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS, Continued

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,		
	2024	2023	2022
	<i>(in thousands)</i>		
Beginning balance	\$ 13,022	\$ 11,425	\$ 9,237
Increase in tax positions for prior years	86	112	53
Decreases in tax positions for prior years	(399)	(205)	—
Decrease in tax positions for expirations of statute of limitations	—	(750)	—
Increase in tax positions for current year	3,740	2,440	2,135
Decrease in tax positions for current year	—	—	—
Ending balance	\$ 16,449	\$ 13,022	\$ 11,425

As of December 31, 2024, the amount of unrecognized tax benefits that would favorably impact the effective tax rate were approximately \$13.1 million, and approximately \$3.4 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 \$1.0 million of accrued interest and no accrued penalties related to unrecognized tax benefits as of December 31, 2024. We had no or insignificant amounts of accrued interest and no accrued penalties related to unrecognized tax benefits as of December 31, 2023 and 2022. 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 tax purposes, the years 2021 through 2024 remain open and subject to tax examination. For US state tax purposes, the years 2004 through 2024 generally remain open and subject to tax examination by the appropriate state taxing authorities.

10. Commitments and Contingencies

Manufacturing Agreements

We have agreements with manufacturers to supply mifepristone, the active pharmaceutical ingredient ("API") in our Products, and to produce and bottle tablets of our Products.

As of December 31, 2024, we had a \$17.4 million remaining obligation in connection with commitments to purchase API from these manufacturers.

Taxes

As of December 31, 2024, we have recorded non-current taxes payable of \$14.1 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.

CORCEPT THERAPEUTICS INCORPORATED

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS, Continued

Melucci Litigation and Settlement

In March 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 alleged that the defendants made false and materially misleading statements and failed to disclose adverse facts about our business, operations and prospects. The complaint asserted a putative class period extending from August 2, 2017 to February 5, 2019 and sought unspecified monetary relief, interest and attorneys’ fees. On June 6, 2024, Judge James Donato of the United States District Court for the Northern District of California granted final approval of a settlement resolving all claims in the Melucci litigation (the “Melucci Settlement”). As previously disclosed, the Melucci Settlement required us to make a one-time payment of \$14.0 million for which our insurers reimbursed us in full. On September 6, 2024, Judge Donato approved the Plan of Allocation for payment of the settlement funds to eligible members of the class of plaintiffs. This matter is closed.

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

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements

1. Registration Statements (Form S-8 Nos. 333-183284, 333-187316, 333-194663, 333-202753, 333-210076, 333-216658, 333-223318, 333-229857, 333-236601, 333-253413 and 333-262752) pertaining to the Corcept Therapeutics Incorporated 2012 Incentive Award Plan
2. Registration Statements (Form S-8 No. 333-279862) pertaining to the Corcept Therapeutics Incorporated 2024 Equity Incentive Plan

of our reports dated February 26, 2025, with respect to the consolidated financial statements of Corcept Therapeutics Incorporated and the effectiveness of internal control over financial reporting of Corcept Therapeutics Incorporated included in this Annual Report (Form 10-K) of Corcept Therapeutics Incorporated for the year ended December 31, 2024.

/s/ Ernst & Young LLP

San Mateo, California

February 26, 2025

CERTIFICATION

I, Joseph K. Belanoff, M.D., certify that:

1. I have reviewed this Annual Report on Form 10-K for the period ended December 31, 2024 of Corcept Therapeutics Incorporated;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Joseph K. Belanoff

Joseph K. Belanoff, M.D.
Chief Executive Officer and President
(Principal Executive Officer)
February 26, 2025

CERTIFICATION

I, Atabak Mokari, certify that:

1. I have reviewed this Annual Report on Form 10-K for the period ended December 31, 2024 of Corcept Therapeutics Incorporated;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Atabak Mokari

Atabak Mokari
Chief Financial Officer
(Principal Financial Officer)
February 26, 2025

Corcept Therapeutics Incorporated

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Corcept Therapeutics Incorporated (the "Company") on Form 10-K for the period ended December 31, 2024, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Joseph K. Belanoff, M.D., Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Joseph K. Belanoff

Joseph K. Belanoff, M.D.

Chief Executive Officer and President

(Principal Executive Officer)

February 26, 2025

This certification is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Corcept Therapeutics Incorporated under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, irrespective of any general incorporation language contained in such filing.

Corcept Therapeutics Incorporated

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Corcept Therapeutics Incorporated (the "Company") on Form 10-K for the period ended December 31, 2024, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Atabak Mokari, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Atabak Mokari

Atabak Mokari

Chief Financial Officer

(Principal Financial Officer)

February 26, 2025

This certification is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Corcept Therapeutics Incorporated under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, irrespective of any general incorporation language contained in such filing.