

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 10-Q**

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

For the quarterly period ended March 31, 2023

or

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

For the transition period from            to

Commission File Number:

000-50679

**CORCEPT THERAPEUTICS INCORPORATED**

(Exact Name of Corporation as Specified in Its Charter)

Delaware  
(State or other jurisdiction of  
incorporation or organization)

77-0487658  
(I.R.S. Employer  
Identification No.)

149 Commonwealth Drive  
Menlo Park, CA 94025  
(Address of principal executive offices, including 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

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 is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  No

On April 26, 2023, there were 101,577,897 shares of common stock outstanding at a par value of \$0.001 per share.

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**PART I. FINANCIAL INFORMATION**

**ITEM 1. FINANCIAL STATEMENTS**

**CORCEPT THERAPEUTICS INCORPORATED**  
**CONDENSED CONSOLIDATED BALANCE SHEETS**  
(In thousands)

	<b>March 31, 2023</b>	<b>December 31, 2022</b>
	(Unaudited)	(See Note 1)
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 299,942	\$ 66,329
Short-term marketable securities	165,115	365,343
Trade receivables, net of allowances	32,557	31,057
Insurance recovery receivable related to Melucci litigation (Note 4)	14,000	14,000
Inventory	6,409	6,100
Prepaid expenses and other current assets	15,870	16,424
Total current assets	533,893	499,253
Strategic inventory	10,156	10,931
Operating lease right-of-use asset	575	1,143
Property and equipment, net	461	633
Long-term marketable securities	—	4,947
Other assets	4,764	5,058
Deferred tax assets, net	67,999	61,465
Total assets	\$ 617,848	\$ 583,430
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 11,216	\$ 11,976
Accrued research and development expenses	13,981	14,573
Accrued and other liabilities	39,093	30,799
Accrued settlement related to Melucci litigation (Note 4)	14,000	14,000
Short-term operating lease liability	575	1,143
Total current liabilities	78,865	72,491
Long-term accrued income taxes payable	9,399	9,097
Total liabilities	88,264	81,588
Commitments and contingencies (Note 4)		
Stockholders' equity:		
Preferred stock	—	—
Common stock	131	131
Treasury stock	(462,507)	(456,148)
Additional paid-in capital	679,848	662,342
Accumulated other comprehensive loss	(153)	(869)
Retained earnings	312,265	296,386
Total stockholders' equity	529,584	501,842
Total liabilities and stockholders' equity	\$ 617,848	\$ 583,430

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

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

	<b>Three Months Ended March 31,</b>	
	<b>2023</b>	<b>2022</b>
Product revenue, net	\$ 105,654	\$ 93,688
Operating expenses:		
Cost of sales	1,386	1,250
Research and development	40,851	28,120
Selling, general and administrative	48,564	37,549
<b>Total operating expenses</b>	<b>90,801</b>	<b>66,919</b>
Income from operations	14,853	26,769
Interest and other income	3,581	80
Income before income taxes	18,434	26,849
Income tax expense	(2,555)	(4,052)
<b>Net income</b>	<b>\$ 15,879</b>	<b>\$ 22,797</b>
<b>Net income attributable to common stockholders</b>	<b>15,807</b>	<b>22,797</b>
<b>Basic net income per common share</b>	<b>\$ 0.15</b>	<b>\$ 0.22</b>
<b>Diluted net income per common share</b>	<b>\$ 0.14</b>	<b>\$ 0.20</b>
<b>Weighted-average shares outstanding used in computing net income per common share</b>		
Basic	107,885	106,012
Diluted	115,425	115,037

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

**CORCEPT THERAPEUTICS INCORPORATED**

**CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME**

(Unaudited)  
(In thousands)

	<b>Three Months Ended March 31,</b>	
	<b>2023</b>	<b>2022</b>
<b>Net income</b>	\$ 15,879	\$ 22,797
Other comprehensive income (loss):		
Unrealized gain (loss) on available-for-sale investments, net of tax effect of \$(192) and \$323, respectively	605	(1,019)
Foreign currency translation gain (loss), net of tax	111	(105)
<b>Total comprehensive income</b>	<b>\$ 16,595</b>	<b>\$ 21,673</b>

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

**CORCEPT THERAPEUTICS INCORPORATED**  
**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**  
(Unaudited)  
(In thousands)

	<b>Three Months Ended March 31,</b>	
	<b>2023</b>	<b>2022</b>
<b>Cash flows from operating activities:</b>		
Net income	\$ 15,879	\$ 22,797
Adjustments to reconcile net income to net cash provided by operations:		
Stock-based compensation	11,141	10,761
(Accretion) amortization of interest income	(1,503)	1,106
Depreciation and amortization of property and equipment	172	288
Deferred income taxes	(6,726)	(9,935)
Non-cash amortization of right-of-use asset	568	514
Changes in operating assets and liabilities:		
Trade receivables	(1,500)	447
Inventory	558	(163)
Prepaid expenses and other assets	848	(9)
Accounts payable	(649)	2,256
Accrued research and development expenses	(592)	609
Accrued and other liabilities	8,027	4,995
Long-term accrued income taxes	302	2,107
Operating lease liability	(568)	(526)
Net cash provided by operating activities	<u>25,957</u>	<u>35,247</u>
<b>Cash flows from investing activities:</b>		
Purchases of property and equipment	—	(12)
Proceeds from maturities of marketable securities	207,475	42,127
Purchases of marketable securities	—	(92,611)
Net cash provided by (used in) investing activities	<u>207,475</u>	<u>(50,496)</u>
<b>Cash flows from financing activities:</b>		
Proceeds from issuance of common stock under our incentive award plan, net of issuance costs	1,409	1,382
Cash paid to satisfy statutory withholding requirement for net settlement of cashless option exercises and vesting of restricted stock grants	(1,228)	(1,888)
Net cash provided by (used in) financing activities	<u>181</u>	<u>(506)</u>
Net increase (decrease) in cash and cash equivalents	233,613	(15,755)
Cash and cash equivalents, at beginning of period	66,329	77,617
Cash and cash equivalents, at end of period	<u>\$ 299,942</u>	<u>\$ 61,862</u>
<b>Supplemental disclosure:</b>		
Exercise cost of shares repurchased for net settlement of cashless option exercises	\$ 5,246	\$ 5,149
Recognition of right-of-use asset and lease liability	\$ —	\$ 2,816

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

**CORCEPT THERAPEUTICS INCORPORATED**

**CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY**

(Unaudited)  
(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, 2022	107,835	\$ 131	\$ 662,342	\$ (456,148)	\$ (869)	\$ 296,386	\$ 501,842
Issuance of common stock under our incentive award plan	618	—	6,540	—	—	—	6,540
Shares purchased to satisfy cost and statutory withholding requirements for net settlement of cashless option exercises	(297)	—	—	(6,359)	—	—	(6,359)
Stock-based compensation	—	—	10,966	—	—	—	10,966
Other comprehensive gain, net of tax	—	—	—	—	716	—	716
Net income	—	—	—	—	—	15,879	15,879
Balance at March 31, 2023	108,156	\$ 131	\$ 679,848	\$ (462,507)	\$ (153)	\$ 312,265	\$ 529,584

	Common Stock		Additional Paid-in Capital	Treasury Stock	Accumulated Other Comprehensive Loss	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 upon exercise of options	586	1	6,543	—	—	—	6,544
Shares purchased to satisfy cost and statutory withholding requirements for net settlement of cashless option exercises	(305)	—	—	(7,037)	—	—	(7,037)
Stock-based compensation	—	—	10,825	—	—	—	10,825
Other comprehensive loss, net of tax	—	—	—	—	(1,124)	—	(1,124)
Net income	—	—	—	—	—	22,797	22,797
Balance at March 31, 2022	106,221	\$ 128	\$ 608,717	\$ (417,448)	\$ (1,351)	\$ 217,765	\$ 407,811

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

## CORCEPT THERAPEUTICS INCORPORATED

### NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

#### 1. Basis of Presentation and Summary of Significant Accounting Policies

##### Description of Business and Basis of Presentation

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

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

##### Basis of Presentation

We have prepared the following in accordance with U.S. generally accepted accounting principles (“GAAP”) for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X: (i) condensed consolidated balance sheet as of March 31, 2023 and (ii) condensed consolidated statements of income, comprehensive income, cash flows and stockholders’ equity for the three-month periods ended March 31, 2023 and 2022. These do not include all of the information and footnotes required by GAAP for complete financial statements. In the opinion of management, all adjustments considered necessary for a fair presentation (which in the applicable periods consist only of normal, recurring adjustments) have been included. Operating results for the three-month period ended March 31, 2023 are not necessarily indicative of the results for the remainder of 2023 or any other period. These financial statements and notes should be read in conjunction with the financial statements for the year ended December 31, 2022 included in our Annual Report on Form 10-K. The December 31, 2022 balance sheet was derived from audited financial statements at that date.

There have been no material changes to the significant accounting policies described in our Annual Report on Form 10-K for the year ended December 31, 2022.

#### 2. Composition of Certain Balance Sheet Items

##### Inventory

	March 31, 2023	December 31, 2022
	<i>(in thousands)</i>	
Work in progress	\$ 8,514	\$ 7,827
Finished goods	8,051	9,204
Total inventory	16,565	17,031
Less strategic inventory classified as non-current	(10,156)	(10,931)
Total inventory classified as current	\$ 6,409	\$ 6,100

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



*Property and equipment, net*

	<b>March 31, 2023</b>	<b>December 31, 2022</b>
	<i>(in thousands)</i>	
Furniture and equipment	\$ 1,235	\$ 1,235
Software	1,508	1,508
Leasehold improvements	1,597	1,597
Total property and equipment	4,340	4,340
Less accumulated depreciation and amortization	(3,879)	(3,707)
Property and equipment, net	<u>\$ 461</u>	<u>\$ 633</u>

*Accrued and other liabilities*

	<b>March 31, 2023</b>	<b>December 31, 2022</b>
	<i>(in thousands)</i>	
Government rebates	\$ 15,478	\$ 11,098
Income taxes payable	8,589	89
Accrued compensation	7,806	15,511
Legal fees	3,421	2,673
Professional fees	1,498	211
Accrued selling and marketing costs	1,081	434
Other	1,220	783
Total accrued and other liabilities	<u>\$ 39,093</u>	<u>\$ 30,799</u>

*Other assets*

As of March 31, 2023 and December 31, 2022, other assets included \$4.6 million and \$4.9 million of deposits for clinical trials, respectively.

**3. Available-for-Sale Securities and Fair Value Measurements**

The available-for-sale securities in our condensed consolidated balance sheets are as follows:

	<b>March 31, 2023</b>	<b>December 31, 2022</b>
	<i>(in thousands)</i>	
Cash equivalents	\$ 259,936	\$ 36,380
Short-term marketable securities	165,115	365,343
Long-term marketable securities	—	4,947
Total marketable securities	<u>\$ 425,051</u>	<u>\$ 406,670</u>

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

	Fair Value Hierarchy Level	March 31, 2023				December 31, 2022			
		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	\$ 30,832	\$ —	\$ (134)	\$ 30,698	\$ 151,069	\$ —	\$ (625)	\$ 150,444
Commercial paper	Level 2	94,301	—	—	94,301	136,132	—	—	136,132
U.S. government agency securities	Level 2	25,398	—	(2)	25,396	25,113	23	—	25,136
Asset-backed securities	Level 2	—	—	—	—	185	—	—	185
U.S. Treasury securities	Level 1	14,723	—	(3)	14,720	58,536	—	(142)	58,394
Money market funds	Level 1	259,936	—	—	259,936	36,379	—	—	36,379
<b>Total marketable securities</b>		<b>\$ 425,190</b>	<b>\$ —</b>	<b>\$ (139)</b>	<b>\$ 425,051</b>	<b>\$ 407,414</b>	<b>\$ 23</b>	<b>\$ (767)</b>	<b>\$ 406,670</b>

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

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

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

We classified accrued interest on our marketable securities of \$1.1 million and \$1.8 million as of March 31, 2023 and December 31, 2022, respectively, as prepaid and other current assets on our condensed consolidated balance sheets.

As of March 31, 2023, all our marketable securities had original maturities of less than two years and all our marketable securities classified as short-term have maturities of less than one year. The weighted-average maturity of our holdings was one month. None of our marketable securities changed from one fair value hierarchy to another during the three months ended March 31, 2023.

#### 4. Commitments and Contingencies

There have been no material changes in our obligations under contractual agreements described in our Annual Report on Form 10-K for the year ended December 31, 2022.

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 potential outcomes under various litigation, regulatory and settlement strategies. If we determine a loss is probable and its amount can be reasonably estimated, we accrue an amount equal to the estimated loss.

##### *Melucci Litigation and Settlement*

On March 14, 2019, a purported securities class action complaint was filed in the United States District Court for the Northern District of California by Nicholas Melucci (Melucci v. Concept Therapeutics Incorporated, et al., Case No. 5:19-cv-01372-LHK) (the "Melucci litigation"). The complaint named us and certain of our executive officers as defendants asserting violations of Sections 10(b) and 20(a) of the Exchange Act and Rule 10b-5 promulgated thereunder and alleges that the defendants made false and materially misleading statements and failed to disclose adverse facts about our business, operations and prospects. The complaint asserts a putative class period extending from August 2, 2017 to February 5, 2019 and seeks unspecified monetary relief, interest and attorneys' fees. On October 7, 2019, the Court appointed a lead plaintiff and lead counsel. The lead plaintiff's consolidated complaint was filed on December 6, 2019. With respect to these allegations, we have stated, from the beginning, that we have done nothing wrong.

On February 8, 2023, we reached an agreement in principle (the “Proposed Settlement”) to resolve all claims in the Melucci litigation. Under the Proposed Settlement, we have agreed to make a one-time payment of \$14.0 million, which will be covered in full by our insurers. In connection with the Proposed Settlement, we recorded a settlement expense of \$14.0 million and corresponding insurance recovery of \$14.0 million in operating expenses on our consolidated statement of income in the fourth quarter of 2022. Accordingly, we recorded an accrued liability of \$14.0 million and a corresponding insurance recovery receivable of \$14.0 million on our condensed consolidated balance sheet as of March 31, 2023. The Proposed Settlement is subject to the final approval of the Court.

No losses and no provision for a loss contingency have been recorded to date. For further information about our ongoing legal matters, see *Part II, Item 1, Legal Proceedings*.

## 5. Leases

We lease our office facilities in Menlo Park, California. On April 1, 2023, we signed an amendment to extend our lease through June 30, 2024. Refer to Note 9 “Subsequent Events” for further details.

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

Operating lease expense for the three months ended March 31, 2023 and 2022 was \$0.6 million and \$0.5 million, respectively.

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

	<b>Three Months Ended March 31,</b>	
	<b>2023</b>	<b>2022</b>
Cash paid for operating lease liabilities	\$ 578	\$ 530
Right-of-use assets obtained in connection with new operating lease obligations	\$ —	\$ 2,816
Weighted-average remaining lease term	3 months	15 months
Weighted-average discount rate	4.0 %	4.0 %

As of March 31, 2023, future minimum lease payments under non-cancelable operating leases were as follows (in thousands):

2023 (remainder)	578
Total operating lease payments	578
Less imputed interest	(3)
Present value of operating lease liabilities	<u>\$ 575</u>

## 6. Stockholders' Equity

### *Incentive Award Plan*

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

### *Stock Options*

During the three months ended March 31, 2023, we issued 0.5 million shares 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 current market price, shares equal in value to the associated exercise price and tax withholding obligations. During the three months ended March 31, 2023, we purchased 0.3 million shares in connection with option net exercises and paid \$1.1 million to satisfy associated tax withholding obligations.

During the three months ended March 31, 2022, we issued 0.6 million shares of our common stock upon the exercise of stock options. We purchased 0.3 million shares in connection with option net exercises and paid \$1.9 million to satisfy associated tax withholding obligations.

We recorded purchased shares as treasury stock on our condensed consolidated balance sheets at cost. As of March 31, 2023 and December 31, 2022, we had 23.4 million and 23.1 million treasury shares outstanding, respectively.

*Restricted Stock Units (“RSUs”)*

During the three months ended March 31, 2022, we granted employees 0.2 million RSUs with a weighted-average grant date fair value of \$19.34 per share. No RSUs were granted during the three months ended March 31, 2023.

*Restricted Stock Awards (“RSAs”)*

During the three months ended March 31, 2023, we granted employees 0.3 million RSAs with a weighted-average grant date fair value of \$22.39 per share. No RSAs were granted during the three months ended March 31, 2022. RSAs include voting and dividend rights and are therefore “participating” shares for the purpose of calculating basic and diluted net income per share. See “Note 7” below.

*Employee Stock Purchase Plan (“ESPP”)*

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

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

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

During the three months ended March 31, 2023 and 2022, we issued 0.1 million and no shares of our common stock in connection with our ESPP, respectively. As of March 31, 2023 and December 31, 2022, we had a liability of \$0.5 million and \$0.2 million, respectively, related to RSAs granted in connection with our ESPP in “Accrued and other liabilities” on our condensed consolidated balance sheets.

*Stock-based Compensation*

Stock-based compensation expense associated with stock options and awards of restricted stock is measured at the grant date based on the fair value of the award, and is recognized, net of forfeitures, as expense over the remaining requisite service period on a straight-line basis.

We value restricted stock at the closing market price of the our common stock on the date of grant.

The following table summarizes our stock-based compensation by account:

	<b>Three Months Ended March 31,</b>	
	<b>2023</b>	<b>2022</b>
	<i>(in thousands)</i>	
Stock-based compensation capitalized in inventory	\$ 92	\$ 64
Cost of sales	23	16
Research and development	3,484	3,371
Selling, general and administrative	7,634	7,374
<b>Total stock-based compensation</b>	<b>\$ 11,233</b>	<b>\$ 10,825</b>

## 7. 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:

	Three Months Ended March 31,	
	2023	2022
	<i>(in thousands)</i>	
<b>Numerator:</b>		
Net income attributable to common stockholders	\$ 15,807	\$ 22,797
<b>Denominator:</b>		
Weighted-average shares used to compute basic net income per common share	107,885	106,012
Dilutive effect of employee stock options and unvested RSUs	<u>7,540</u>	<u>9,025</u>
Weighted-average shares used to compute diluted net income per common share	<u>115,425</u>	<u>115,037</u>
<b>Net income per share attributable to common stockholders</b>		
Basic	<u>\$ 0.15</u>	<u>\$ 0.22</u>
Diluted	<u>\$ 0.14</u>	<u>\$ 0.20</u>

As of March 31, 2023, we had 24.6 million stock options, 0.1 million RSUs and 0.6 million RSAs outstanding. As of March 31, 2022, we had 26.0 million stock options, 0.2 million RSUs and no RSAs outstanding.

We excluded from the computation of diluted net income per share, on a weighted-average basis, 10.4 million stock options and unvested RSUs outstanding during the three months ended March 31, 2023 and 6.9 million stock options outstanding and unvested RSUs during the three months ended March 31, 2022, because including them would have reduced dilution.

## 8. Income Taxes

We recorded income tax expense of \$2.6 million for the three months ended March 31, 2023, compared to \$4.1 million for the comparable period in 2022. The decrease during the three months ended March 31, 2023 was primarily due to decreased income before income taxes compared to the corresponding period in 2022.

Our effective tax rate differs from the federal statutory rate due to state income taxes and the non-deductible portion of our stock-based compensation, which increased our tax expense, offset by research and development credits and the excess tax deduction arising from the exercise of employee stock options, which reduced our taxable income.

During the three months ended March 31, 2023, unrecognized tax benefits increased by \$0.4 million. As of March 31, 2023, the Company had unrecognized tax benefits of \$9.3 million that, if recognized, would affect the Company's effective tax rate and approximately \$2.5 million of unrecognized tax benefits that would not impact the effective tax rate as they would be offset by a corresponding change in valuation allowance.

Each quarter, we assess the likelihood that we will generate sufficient taxable income to use our federal and state deferred tax assets. Except for the valuation allowances that offset the value of our California net deferred tax assets, we have determined that it is more likely than not we will realize the benefit related to all other deferred tax assets. To the extent we increase a valuation allowance, we will include an expense in the Condensed Consolidated Statement of Income in the period in which such determination is made.

Beginning in 2022, the Tax Cuts and Jobs Act of 2017 eliminates the right to deduct research and development expenditures for tax purposes in the period the expenses were incurred and instead requires all U.S. and foreign research and development expenditures to be amortized over five and fifteen tax years, respectively. Congress has considered legislation that would defer the amortization requirement to later years, but as of March 31, 2023, the requirement has not been modified.

## **9. Subsequent Events**

### *Lease Amendment*

On April 1, 2023, we amended our office lease to extend its terms from July 1, 2023 through June 30, 2024 and we leased an additional space beginning April 1, 2023 through June 30, 2024. As a result of the amendment, we expect to record a right-of-use asset and corresponding lease liability of approximately \$0.3 million related to the additional space. The remaining space has an extended lease term of 12 months, for which we do not expect to record an additional right of use asset. We will record \$2.5 million of rent expense on a straight-line basis throughout the lease term in connection with this lease amendment.

### *Tender Offer*

On March 6, 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 repurchased 6.6 million shares through the tender offer at a price of \$22.00 per share for an aggregate purchase price of \$145.4 million, excluding related fees and expenses. We recorded purchased shares as treasury stock on our condensed consolidated balance sheet at cost.

## ITEM 2. 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 condensed consolidated financial statements and the accompanying notes to financial statements, risk factors and other disclosures included in this Form 10-Q. Our condensed 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-Q and the "Overview" and "Liquidity and Capital Resources" sections of this MD&A.

### Overview

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

#### *Cushing's Syndrome*

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

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

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

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

Our second Phase 3 trial of relacorilant, GRADIENT, is studying patients whose Cushing's syndrome is caused by a benign adrenal tumor. These patients often exhibit less severe symptoms or have a more gradual course of disease than patients with other etiologies of Cushing's syndrome, although their health outcomes are ultimately poor. Half of the patients in GRADIENT will receive relacorilant for 22 weeks and half will receive placebo. The trial's primary endpoints are improvements in glucose metabolism and hypertension. The planned enrollment for this study is 130 patients. Many of the clinical sites in GRACE are participating in GRADIENT.

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

### *Oncology*

There is substantial evidence that cortisol activity at the GR reduces the efficacy of certain anti-cancer therapies and that modulating cortisol’s activity may help anti-cancer treatments achieve their intended effect. In some cancers, cortisol retards cellular apoptosis – the tumor-killing effect many treatments are meant to stimulate. In other cancers, cortisol activity promotes tumor growth. Cortisol also suppresses the body’s immune response; activating – not suppressing – the immune system is beneficial in fighting certain cancers. Many types of solid tumors express the GR and are potential targets for cortisol modulation therapy, among them ovarian, adrenal and prostate cancer.

*Relacorilant in Patients with Advanced Ovarian Cancer.* In May 2021, we announced preliminary results from our 178-patient, controlled, multi-center, Phase 2 trial of relacorilant combined with nab-paclitaxel in patients with platinum-resistant ovarian cancer. Study participants were randomized to one of three treatment arms: 60 women received 150 mg of relacorilant intermittently (the day before, the day of and the day after their weekly nab-paclitaxel infusion) and 58 women received a daily relacorilant dose of 100 mg per day in addition to nab-paclitaxel. Sixty women received nab-paclitaxel alone. The trial’s primary endpoint was progression-free survival (i.e., the time from random assignment in a clinical trial to disease progression or death from any cause or “PFS”).

Patients in both of the relacorilant plus nab-paclitaxel treatment arms experienced longer PFS than did the patients who received nab-paclitaxel alone. Patients who received a higher dose of relacorilant intermittently exhibited a statistically significant improvement in median PFS (5.6 months versus 3.8 months, hazard ratio: 0.66; p-value: 0.038). Patients who received a lower dose of relacorilant daily exhibited a median PFS that was 1.5 months longer than did the patients who received nab-paclitaxel alone (5.3 months versus 3.8 months, hazard ratio: 0.83; p-value: not significant). Patients who received relacorilant intermittently also had a longer median duration of response (“DoR”) (5.6 months versus 3.7 months, hazard ratio: 0.36; p-value: 0.006) compared to those who received nab-paclitaxel alone. Patients who received relacorilant intermittently also lived longer (median OS: 13.9 months versus 12.2 months, hazard ratio: 0.67; p-value: 0.066) compared to those who received nab-paclitaxel alone.

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

In June 2022, we initiated a pivotal Phase 3 trial (“ROSELLA”) that seeks to replicate the positive results observed in our Phase 2 study. ROSELLA has a planned enrollment of 360 women with recurrent, platinum-resistant ovarian cancer, randomized 1:1 to receive either 150 mg of relacorilant intermittently in addition to nab-paclitaxel or nab-paclitaxel monotherapy. The primary endpoint is PFS, with overall survival as a key secondary endpoint. Patients in ROSELLA will have received prior bevacizumab therapy, which is the standard of care in the United States for patients with platinum-resistant ovarian cancer. Women with a history of tumors that do not respond to initial platinum-based treatments (i.e., women with “primary platinum-refractory” disease) and those who have received more than three prior lines of therapy will be excluded.

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

*Relacorilant in Patients with Adrenal Cancer with Cortisol Excess.* We are conducting an open-label, Phase 1b trial of relacorilant plus the PD-1 checkpoint inhibitor pembrolizumab in patients with metastatic or unresectable adrenal cancer whose tumors produce cortisol. The trial is examining whether adding relacorilant to pembrolizumab therapy reduces cortisol-activated immune suppression sufficiently to help pembrolizumab achieve its intended tumor-killing effect. Relacorilant is also expected to treat the patients’ Cushing’s syndrome generated by their tumors’ excess production of cortisol.

*Relacorilant in Patients with Prostate Cancer.* Androgen deprivation is the standard treatment for prostate cancer because androgens stimulate prostate tumor growth. Tumors often escape androgen deprivation therapy when cortisol’s activity at the GR stimulates tumor growth. Combining a cortisol modulator with an androgen modulator may block this escape route. Our collaborators at the University of Chicago plan to initiate a randomized, placebo-controlled Phase 2 trial of relacorilant plus



enzalutamide in patients with prostate cancer, pre-prostatectomy. We are providing relacorilant and placebo for the study and have licensed patents covering the use of relacorilant combined with anticancer agents such as enzalutamide in the treatment of patients with this indication.

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

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

#### *Metabolic Diseases*

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

*Antipsychotic-Induced Weight Gain (“AIWG”).* In the United States, six million people take antipsychotic medications such as olanzapine and risperidone to treat illnesses such as schizophrenia, bipolar disorder and depression. While these drugs are very effective, they often cause rapid and sustained weight gain, other metabolic disturbances and, ultimately, cardiovascular disease. Patients taking these medications experience a 10 to 25-year reduction in life expectancy, due largely to increased cardiovascular events, such as heart attacks and strokes. Patients in our two double-blind, placebo-controlled, Phase 2 trials of miricorilant (GRATITUDE and GRATITUDE II) did not experience reversal of AIWG. However, multiple replicated pre-clinical results as well as the results of our double-blind, placebo-controlled trial (published in the *Journal of Clinical Psychopharmacology* (Hunt et al., 2021)) suggest that miricorilant has the potential to significantly reduce weight gain caused by the administration of olanzapine. Accordingly, we plan to further study miricorilant’s potential to prevent AIWG.

#### *COVID-19 Pandemic*

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

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

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

Please see the risk factor under Item 1A of this Quarterly Report, “*The COVID-19 pandemic has adversely affected and is continuing to adversely affect our business.*”

#### *Inflation Reduction Act of 2022*

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

Additionally, the IRA permits CMS to negotiate prices for certain high-expenditure Medicare Part B or Part D drugs. The IRA also requires manufacturers to pay a rebate to CMS if the price of a Medicare Part B or Part D drug increases faster than the rate of inflation. Beginning in 2025, the IRA will also shift to manufacturers a significant portion of the Medicare beneficiary costs currently borne by the government and beneficiaries. We anticipate that this provision will significantly limit

the revenue Concept receives from Medicare patients and may materially reduce our profits. Please see the risk factor under Item 1A of this Quarterly Report, “New laws, government regulations, or changes to existing laws and regulations could make it difficult or impossible for us to obtain acceptable prices or adequate insurance coverage and reimbursement for Korlym, which would adversely affect our results of operations and financial position.”

## Results of Operations

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

Net product revenue was \$105.7 million for the three months ended March 31, 2023, compared to \$93.7 million for the comparable period in 2022. For the three months ended March 31, 2023, higher sales volumes accounted for 42.9 percent of the increase, with the remaining growth due to a price increase effective January 1, 2023.

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

Cost of sales was \$1.4 million for the three months ended March 31, 2023, compared to \$1.3 million for the comparable period in 2022. Cost of sales as a percentage of revenue was 1.3 percent for each of the three months ended March 31, 2023 and 2022.

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

Research and development expense was \$40.9 million for the three months ended March 31, 2023, compared to \$28.1 million for the comparable period in 2022. The increase was primarily due to increased spending on the advancement of our development programs and employee compensation expenses.

	<b>Three Months Ended March 31,</b>	
	<b>2023</b>	<b>2022</b>
	<i>(in thousands)</i>	
Development programs:		
Oncology	\$ 7,250	\$ 3,823
Cushing’s syndrome	10,974	7,107
Metabolic diseases	7,172	5,377
Pre-clinical and early-stage selective cortisol modulators and ALS	7,464	5,306
Unallocated activities, including manufacturing and regulatory activities	4,507	3,136
Stock-based compensation	3,484	3,371
Total research and development expense	<u>\$ 40,851</u>	<u>\$ 28,120</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 2023 than in 2022 as our clinical programs advance. Research and development spending in future years will depend on the outcome of our pre-clinical and clinical trials and our development plans.

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

Selling, general and administrative expense was \$48.6 million for the three months ended March 31, 2023, compared to \$37.5 million for the comparable period in 2022. The increase was primarily due to increased sales and marketing activities and employee compensation expenses.

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

*Interest and other income* – Interest and other income was \$3.6 million for the three months ended March 31, 2023, compared to \$0.1 million for the comparable period in 2022. The increase was due to a higher cash and investment balance and market-wide increases in interest rates.

*Income tax expense* – Income tax expense was \$2.6 million for the three months ended March 31, 2023, compared to \$4.1 million for the comparable period in 2022. The change was primarily due to a decrease in income before income taxes.

### **Liquidity and Capital Resources**

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

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

As of March 31, 2023, we had cash, cash equivalents and marketable securities of \$465.1 million, consisting of cash and cash equivalents of \$299.9 million and marketable securities of \$165.1 million, compared to cash, cash equivalents and marketable securities of \$436.6 million, consisting of cash and cash equivalents of \$66.3 million and marketable securities of \$370.3 million as of December 31, 2022.

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 was \$26.0 million for the three months ended March 31, 2023, compared to \$35.2 million for the comparable period in 2022. This decrease was primarily due to increases in operating expenses supporting advancement of our development programs.

Net cash provided by investing activities was \$207.5 million for the three months ended March 31, 2023, compared to net cash used in investing activities of \$50.5 million for the comparable period in 2022. The increase was primarily due to allocation of cash proceeds from maturities of marketable securities towards cash equivalents in anticipation of the closing of our tender offer in April 2023.

Net cash provided by financing activities was \$0.2 million for the three months ended March 31, 2023, compared to net cash used in financing activities of \$0.5 million for the comparable period in 2022. In the three months ended March 31, 2023, we spent \$1.1 million acquiring shares of our common stock in connection with the net exercise of employee and director stock options and \$0.1 million to satisfy tax withholding requirements from vesting of restricted stock grants, offset by \$0.2 million received from the exercise of stock options and \$1.2 million received in connection with our ESPP. In the comparable period in 2022, we spent \$1.9 million acquiring shares of our common stock in connection with the net exercise of employee and director stock options, offset by \$1.4 million received from the exercise of stock options.

As of March 31, 2023, we had retained earnings of \$312.3 million.

### **Contractual Obligations and Commitments**

Our contractual payment obligations and purchase commitments are disclosed in our Annual Report on Form 10-K for the year ended December 31, 2022. Our payment obligations and purchase commitments did not change materially during the three months ended March 31, 2023. See Note 4 to our Unaudited Condensed Consolidated Financial Statements for more information regarding our purchase commitments.

### **Off-Balance Sheet Arrangements**

None.

### **Critical Accounting Policies and Estimates**

Our condensed 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 our Annual Report on Form 10-K for the fiscal year ended December 31, 2022.

There were no changes that occurred during the fiscal quarter covered by this report that materially affected, or are reasonably likely to materially affect, our critical accounting policies and estimates.

### **ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

Our market risks as of March 31, 2023 are disclosed in our Annual Report on Form 10-K for the year ended December 31, 2022. The market risks associated with our cash, cash equivalents and marketable securities, which consist entirely of debt instruments with original maturities of less than 24 months, did not change materially during the three months ended March 31, 2023.

### **ITEM 4. CONTROLS AND PROCEDURES**

***Evaluation of disclosure controls and procedures.*** As of March 31, 2023, 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 the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934 (the “Exchange Act”). Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of March 31, 2023, our disclosure controls and procedures were effective to provide reasonable assurance that the information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms and that such information is accumulated and communicated to the officers who certify our financial reports and to the members of the Company’s senior management and board of directors as appropriate to allow timely decisions regarding required disclosure at the reasonable assurance level.

***Changes in internal control over financial reporting.*** Our Chief Financial Officer and other members of management evaluated the changes in our internal control over financial reporting during the quarter ended March 31, 2023 and concluded that there was no change during the quarter that materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

## PART II. OTHER INFORMATION

### ITEM 1. LEGAL PROCEEDINGS

#### *Teva Litigation*

In February 2018, we received a Paragraph IV Notice Letter advising that Teva Pharmaceuticals USA, Inc. (“Teva”) had submitted an Abbreviated New Drug Application (“ANDA”) to the FDA seeking authorization to manufacture and sell a generic version of Korlym prior to the expiration of patents related to Korlym that are listed in the FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations (the “Orange Book”). In March 2018, we filed a lawsuit in the United States District Court for the District of New Jersey 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. The patents currently at issue in the original lawsuit against Teva are U.S. Patent No. 10,195,214 (the “’214 patent”) and U.S. Patent Nos. 10,500,216 (the “’216 patent”). The parties completed briefing on cross-motions for summary judgment regarding infringement of the ’214 patent in July 2021. On February 27, 2023, the Court denied both motions without prejudice.

In May 2019, Teva submitted to the Patent Trial and Appeal Board (“PTAB”) a petition for post-grant review (“PGR”) of the ’214 patent. The PTAB agreed to initiate the PGR, and, in November 2020, issued a decision upholding the validity of the ’214 patent in its entirety. Teva appealed its loss to the Federal Circuit Court of Appeals, which in December 2021, ruled in our favor. The time for Teva to appeal or seek reconsideration of these adverse decisions has passed. This matter is closed.

On March 17, 2023, we filed a separate lawsuit in the United States District Court for the District of New Jersey against Teva for infringement of U.S. patents 10,842,800 and 10,842,801.

The Court has set a trial date of September 27, 2023 for both pending matters.

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

#### *Hikma ANDA Litigation and Settlement*

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

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

In March 2021, we filed a lawsuit in the United States District Court for the District of New Jersey against Hikma for infringement of the ’214 patent, the ’216 patent, U.S. Patent Nos. 10,842,800 and U.S. Patent Nos. 10,842,801.

On December 7, 2022, we entered into an agreement with Hikma resolving this litigation. Pursuant to the agreement, we have granted Hikma the right to sell a generic version of Korlym in the United States beginning October 1, 2034 or earlier under circumstances customary for settlement agreements of this type. As required by law, we and Hikma have submitted the settlement agreement to the United States Federal Trade Commission and the United States Department of Justice for review.

#### *Other Matters*

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 alleges that the defendants made false and materially misleading statements and failed to disclose adverse facts about our business, operations and prospects. The complaint asserts a putative class period extending from August 2, 2017 to February 5, 2019 and seeks unspecified monetary relief, interest and attorneys’ fees. In October 2019, the Court appointed a lead plaintiff and lead counsel. The lead plaintiff’s consolidated complaint was filed in December 2019. With respect to these allegations, we have stated, from the beginning, that we have done nothing wrong.

On February 8, 2023, we reached an agreement in principle (the “Proposed Settlement”) to resolve all claims in the Melucci litigation. Under the Proposed Settlement, we have agreed to make a one-time payment of \$14.0 million, which will be covered in full by our insurers. The Proposed Settlement does not include an admission of liability on our part. The Proposed Settlement is subject to the final approval of the Court.

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. The complaint named our board of directors, Chief Executive Officer and current Chief Business Officer as defendants, and us as nominal defendant. The complaint alleges breach of fiduciary duty, violation of Section 14(a) of the Exchange Act, insider selling, misappropriation of insider information and waste of corporate assets and seeks damages in an amount to be proved at trial. In October 2019, this action was stayed pending a resolution of our motions to dismiss the Melucci litigation. In December 2020, the case was further stayed pending a resolution of our motion to dismiss the third amended complaint in the Melucci litigation. In September 2021, the case was further stayed pending a resolution of the Melucci litigation.

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

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 our board of directors, Chief Executive Officer, current Chief Business Officer and President of Corcept Endocrinology as defendants, and us as nominal defendant. The complaint alleges a single cause of action for breach of fiduciary duty. The complaint seeks damages in an amount to be proved at trial. In April 2022, the case was further stayed pending a resolution of the Melucci litigation.

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

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

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

## **ITEM 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 quarterly report, including our condensed consolidated financial statements and related notes. The risks and uncertainties described below are the ones we believe may materially affect us. Many of them have been or may become exacerbated by the COVID-19 pandemic. There may be others of which we are unaware that could materially harm our business or financial condition and cause the price of our stock to decline, in which case you could lose all or part of your investment.*

### **Summary of Principal Risks**

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

### **Risks Related to our Commercial Activities**

- Failure to generate sufficient revenue from the sale of Korlym would harm our financial results and would likely cause our stock price to decline.
- The COVID-19 pandemic has adversely affected and is continuing to adversely affect our business.
- If generic versions of Korlym are successfully commercialized, our business, results of operations and financial position would be adversely affected.
- New laws, government regulations, or changes to existing laws and regulations could make it difficult or impossible for us to obtain acceptable prices or adequate insurance coverage and reimbursement for Korlym, which would adversely affect our results of operations and financial position.

### **Risks Related to our Research and Development Activities**

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

### **Risks Relating to our Intellectual Property**

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

### **Risks Related to our Stock**

- The price of our common stock fluctuates widely and is likely to continue to do so. Opportunities for investors to sell shares may be limited.
- Our stock price may decline if our financial performance does not meet the guidance we have provided to the public, estimates published by research analysts or other investor expectations.

### **General Risks**

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

### **Risk Factors – Discussion**

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

### **Risks Related to our Commercial Activities**

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

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

Many factors could limit our Korlym revenue, including:

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

- natural disasters or other catastrophes, such as the COVID-19 pandemic, that reduce the ability or willingness of physicians to see patients or of patients to bear the risk of leaving their homes to seek medical care; and
- lack of availability of government or private insurance, the shift of a significant number of patients to Medicaid, which reimburses Korlym at a significantly lower price, or the introduction of government price controls or other price-reducing regulations, such as the IRA, that may significantly limit Medicare reimbursement rates.

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

**The COVID-19 pandemic has adversely affected and is continuing to adversely affect our business.**

COVID-19, a serious and sometimes fatal illness, has spread to every country in the world and throughout the United States. Many countries, including most states of the United States, reacted by instituting quarantines, “lockdowns” and other public health restrictions on leisure activities, work and travel. Although pandemic-related restrictions have been eased or removed in some places, including California, our business remains subject to pandemic-related controls, which may become more restrictive at any time. We rely on third-party manufacturers, distributors (including the specialty pharmacy that dispenses Korlym), information technology and software service providers, law and accounting firms, clinical research organizations and consultants who are subject to, or may become subject to, pandemic-related controls. If these third parties cannot perform the services we require in a timely way and we cannot successfully implement replacements or workarounds, our business, results of operations and financial condition could be harmed.

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

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

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

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

Legal action to enforce or defend intellectual property rights is complex, costly and involves significant commitments of management time. There can be no assurance of a successful outcome. We have sued Teva in Federal District Court with respect to their proposed generic versions of Korlym. In November 2020, the PTAB ruled against Teva in a challenge Teva had brought to one of our patents, a ruling which the Federal Circuit Court of Appeals has affirmed. We had also sued Sun and Hikma with respect to their proposed generic version of Korlym, although we settled those lawsuits in June 2021 and December 2022, respectively. The terms of our settlement with Sun and Hikma are subject to customary review by the Federal Trade Commission and Department of Justice. Please see “Part II, Item 1, Legal Proceedings.” Because Teva has received FDA approval, Teva may choose to begin marketing its generic product at any time, notwithstanding our ongoing litigation. We would seek a court order stopping such a course of action, but even if we were to prevail and Teva were to withdraw its product and pay us damages the temporary availability of a generic version of Korlym might materially harm our results of operations and financial condition.

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



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

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

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

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

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

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

The commercial success of Korlym depends on the availability of acceptable pricing and adequate insurance coverage and reimbursement. Government payers, including Medicare, Medicaid and the Veterans Administration, as well as private insurers and health maintenance organizations, are increasingly attempting to contain healthcare costs by limiting reimbursement for medicines. In many foreign markets, drug prices and the profitability of prescription medications are subject to government control. In the United States, we expect that there will continue to be federal and state proposals for similar controls. Also, the trends toward managed health care in the United States and recent laws and legislation intended to increase the public visibility of drug prices and reduce the cost of government and private insurance programs could significantly influence the purchase of health care services and products and may result in lower prices for Korlym. If government or private payers cease to provide adequate and timely coverage, pricing and reimbursement for Korlym, physicians may not prescribe the medication and patients may not purchase it, even if it is prescribed, or the price we receive may be reduced, which would reduce our revenue.

In the United States, there have been and continue to be legislative initiatives to contain healthcare costs. The Patient Protection and Affordable Care Act (“ACA”) which was passed in 2010, substantially changed the way health care is financed by both governmental and private insurers. The IRA introduced some of the most significant changes to Medicare payment for prescription drugs since the ACA. Among its many provisions, the IRA requires the Secretary of the U.S. Department of Health and Human Services (“HHS”) to negotiate Medicare prices for selected drugs and biologicals, including both physician-administered products covered under Medicare’s Part B benefit and self-administered drugs covered under the Part D benefit. Each year, the Secretary will select for price negotiation a specified number of negotiation-eligible drugs with the highest total Part B or D expenditures over a preceding 12-month period. To be eligible for price negotiation a drug must have been on the market for at least seven years without generic competition. Orphan drugs indicated for only one rare disease or condition and drugs with less than \$200 million in annual Medicare expenditures are exempt from the negotiation program. For the first two years of the program, 2026 and 2027, only Part D drugs are eligible. The Secretary will publish the negotiated price, known as the “Maximum Fair Price”, or MFP, for each of the selected products. Manufacturers of selected drugs would be required to offer the drug for Medicare recipients at the MFP. Manufacturers who fail to negotiate or offer the MFP can face significant civil money penalties or excise tax liability on sales of that drug. Depending on the share of Medicare spending each year that is attributed to Korlym or any other drug candidate that we develop and whether or not those drugs become eligible for Medicare negotiation, those drugs and our revenue may be adversely impacted by this provision.

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

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

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

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

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

A single third-party manufacturer, Produits Chimiques Auxiliaires et de Synthèse SA (“PCAS”), supplies the API in Korlym. Two other third-party manufacturers are approved to produce and bottle Korlym tablets. The current term of our agreement with PCAS continues until December 31, 2023. We use a single specialty pharmacy, Optime, to dispense Korlym and perform related pharmacy operations, patient support and related services, including the collection of payments from insurers representing approximately 99 percent of our revenue. If Optime does not adhere to its agreements with payers, it may not be able to collect some or all of the payments due to us. Our agreement with Optime extends to March 31, 2024, subject to customary termination provisions, including the right of Optime to terminate in the event of a material breach by us that we do not cure in a reasonable period of time after receiving written notice. In addition, we may terminate the agreement for convenience.

In the event any of our vendors fails to perform its contractual obligations to us or is materially impaired in its performance by the COVID-19 pandemic or for any other reason, we may experience disruptions and delays in our supply chain and our ability to deliver Korlym to patients, which would adversely affect our business, results of operations and financial position.

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

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

The active ingredient in Korlym, mifepristone, is approved by the FDA in another drug for the termination of early pregnancy. On June 24, 2022, the United States Supreme Court published its decision in the case of *Dobbs v. Jackson Women’s Health Organization* (“*Dobbs*”), which overturned *Roe v. Wade*, the 1973 Supreme Court decision establishing a woman’s right to terminate her pregnancy, subject to certain limitations. *Dobbs* has stimulated many states to enact laws making abortion illegal in virtually every circumstance, including during early pregnancy. More laws banning or heavily restricting termination of pregnancy may be adopted and existing laws may be made more restrictive. Two highly publicized cases regarding mifepristone have been filed in the U.S. since the *Dobbs* decision, one of which seeks to invalidate the FDA’s approval of mifepristone and the other of which seeks to uphold the FDA’s approval in certain jurisdictions. On April 7, 2023, the United

States District Court for the Northern District of Texas Amarillo Division issued a preliminary injunction blocking the FDA's approval of mifepristone, and on the same day, the United States District Court in the Eastern District of Washington issued a ruling ordering the FDA to maintain the current availability of mifepristone in 17 states and Washington, D.C. On April 21, 2023, the U.S. Supreme Court granted an emergency request from the U.S. Department of Justice and the manufacturer of mifepristone to permit the continued availability of mifepristone. The ultimate outcome of these cases and any further consideration by the U.S. Supreme Court, as well as the timing of any outcome, is uncertain. In addition, heightened public perception of mifepristone as an abortifacient may draw the attention of hostile state government officials or political activists to Korlym – even though Korlym is not approved for the termination of pregnancy, we do not promote it for that use and we have taken measures to minimize the chance that it will accidentally be prescribed to a pregnant woman. In addition, physicians and patients may choose not to use Korlym as a treatment for Cushing's syndrome simply to avoid the risk of terminating a pregnancy.

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

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

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

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

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

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

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

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

We are subject to oversight by the FDA and other regulatory authorities in the United States and elsewhere with respect to our research, testing, manufacturing, labeling, distribution, adverse event reporting, storage, advertising, promotion, recordkeeping and sales and marketing activities. These requirements include submissions of safety information, annual updates on manufacturing activities and continued compliance with FDA regulations, including cGMPs, good laboratory practices and good clinical practices ("GCPs"). The FDA enforces these regulations through inspections of us and the laboratories, manufacturers and clinical sites we use. Foreign regulatory authorities have comparable requirements and enforcement mechanisms. Discovery of previously unknown problems with a product or product candidate, such as adverse events of unanticipated severity or frequency or deficiencies in manufacturing processes or management, as well as failure to comply with FDA or other U.S. or foreign regulatory requirements, may subject us to substantial civil and criminal penalties, injunctions, holds on clinical trials, product seizure, refusal to permit the import or export of products, restrictions on product marketing, withdrawal of the product from the market, product recalls, total or partial suspension of production, refusal to approve pending new drug applications ("NDAs") or supplemental NDAs, and suspension or revocation of product approvals.

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

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

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

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

- the federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal health care programs such as Medicare and Medicaid. And, although we structure our applicable business arrangements in accordance with the safe harbors, it is difficult to determine exactly how the law will be applied in specific circumstances. Accordingly, it is possible that certain practices of ours may be challenged under the federal Anti-Kickback Statute. From a liability perspective, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- federal false claims laws, including, without limitation, the False Claims Act, which prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to get a false claim paid. The federal False Claims Act is unique in that it allows private individuals (whistleblowers) to bring actions on behalf of the federal government via qui tam actions. Importantly, under the False Claims Act the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;
- the federal Civil Monetary Penalties law, which prohibits, among other things, offering or transferring remuneration to a federal healthcare beneficiary that a person knows or should know is likely to influence the beneficiary’s decision to order or receive items or services reimbursable by the government from a particular provider or supplier;
- HIPAA, which created federal criminal laws that prohibit executing a scheme to defraud any health care benefit program or making false statements relating to health care matters; similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- federal “sunshine” laws, including the federal Physician Payment Sunshine Act (or sometimes referred to as the Open Payments™ Program), that require transparency regarding financial arrangements with health care providers, such as the reporting and disclosure requirements imposed by the ACA on drug manufacturers regarding any “transfer of value” made or distributed to physicians, certain non-physician practitioners, teaching hospitals, and ownership or investment interests held by physicians and their immediate family members;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payer, including commercial insurers; state laws that require

pharmaceutical companies to comply with the pharmaceutical industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; and state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and pricing information.

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

In November 2021, we received a records subpoena from the United States Attorney’s Office for the District of New Jersey (the “NJ USAO”) seeking information relating to the sale and promotion of Korlym, our relationships with and payments to health care professionals who can prescribe or recommend Korlym and prior authorizations and reimbursement for Korlym. The NJ USAO has informed us that it is investigating whether any criminal or civil violations by us occurred in connection with the matters referenced in the subpoena. It has also informed us that it does not currently consider us a defendant but rather an entity whose conduct is within the scope of the government’s investigation. We are cooperating with the investigation. Please see “Part II, Item 1, Legal Proceedings.”

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

#### **Risks Related to our Research and Development Activities**

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

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

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

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

- failure to show efficacy or acceptable safety;
- slow patient enrollment or delayed activation of clinical trial sites due to the COVID-19 pandemic or other factors;
- delays obtaining regulatory permission to start a trial, changes to the size or design of a trial or changes in regulatory requirements for a trial already underway;
- inability to secure acceptable terms with vendors and an appropriate number of clinical trial sites;
- delays or inability to obtain institutional review board (“IRB”) approval at prospective trial sites;
- failure of patients or investigators to comply with the clinical trial protocol;
- unforeseen safety issues; and

- negative findings of inspections of clinical sites or manufacturing operations by us, the FDA or other authorities.

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

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

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

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

Some of the sites where we are conducting clinical trials have, from time-to-time, stopped enrolling new patients or reduced the frequency with which enrolled patients see their physicians. Some clinical sites have temporarily stopped initiating new trials. Many patients are reluctant to participate in procedures required by our clinical trial protocols because they fear infection. In general, COVID-19 has slowed the pace of our clinical trials, including our studies in Cushing’s syndrome. Studies of diseases perceived to be acutely life-threatening, such as our Phase 2 trial in women with platinum-resistant ovarian cancer, did not experience delay or disruption.

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

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

- limitations caused by the sickness of our employees or their families or the desire of employees to avoid contact with large groups of people.

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

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

Third-party clinical investigators and clinical sites enroll patients and CROs manage many of our trials and perform data collection and analysis. Although we control only certain aspects of these third parties' activities, we are responsible for ensuring that every study adheres to its protocol and meets regulatory and scientific standards. If any of our vendors does not perform its duties or meet expected deadlines or fails to adhere to applicable GCPs, or if the quality or accuracy of the data it produces is compromised, affected clinical trials may be extended, delayed or terminated and we may be unable to obtain approval for our product candidates. Outside parties may have staffing difficulties, may undergo changes in priorities or may become financially distressed, adversely affecting their willingness or ability to conduct our clinical trials. Problems with the timeliness or quality of the work of a CRO may lead us to seek to terminate the relationship and use an alternative service provider. However, making this change may be costly and may delay our trials, and it may be challenging to find a replacement organization that can conduct our trials in an acceptable manner and at an acceptable cost. Failure of our manufacturing vendors to perform their duties or comply with cGMPs may require us to recall drug product or repeat clinical trials, which would delay regulatory approval. If our agreements with any of these vendors terminate, we may not be able to enter into alternative arrangements in a timely manner or on reasonable terms.

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

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

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

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

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

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

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

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

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

Any of these events could seriously harm our business.

#### **Risks Related to our Capital Needs and Financial Results**

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

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

#### **Risks Relating to our Intellectual Property**

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

Patents are uncertain, involve complex legal and factual questions and are frequently the subject of litigation. The patents issued or licensed to us may be challenged at any time. Competitors may take actions we believe infringe our intellectual property, causing us to take legal action to defend our rights. Intellectual property litigation is lengthy, expensive and requires significant management attention. Outcomes are uncertain. If we do not protect our intellectual property, competitors may erode our competitive advantage. Please see “Part II, Item 1, Legal Proceedings.”

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



## Risks Related to our Stock

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

We cannot assure investors that a liquid trading market for our common stock will exist at any particular time. As a result, holders of our common stock may not be able to sell shares quickly or at the current market price. During the 52-week period ended April 26, 2023, our average daily trading volume was approximately 740,650 shares and the intra-day sales prices per share of our common stock on The Nasdaq Stock Market ranged from \$17.19 to \$30.14. As of April 26, 2023, our officers, directors and principal stockholders beneficially owned approximately 20 percent of our common stock.

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

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

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

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

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

## General Risk Factors

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

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

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

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

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

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

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

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

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

Even when HIPAA does not apply, according to the Federal Trade Commission (the "FTC"), violating consumers' privacy or failing to take appropriate steps to keep consumers' personal information secure may constitute unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act. The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards. In 2022, the FTC also began a rulemaking proceeding to develop additional data privacy rules and requirements, which may add additional complexity to compliance obligations going forward.

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

liability. Further, the California Privacy Rights Act, or CPRA, revised and expanded the CCPA, adding additional data protection obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It also created a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. The CPRA is in full effect as of January 1, 2023, and similar laws passed in Virginia, Colorado, Connecticut and Utah will take effect starting in 2023. As a result, additional compliance investment and potential business process changes may be required. In the event that we are subject to or affected by HIPAA, the CCPA, the CPRA or other domestic privacy and data protection laws, any liability from failure to comply with the requirements of these laws could adversely affect our financial condition. Additional legislation proposed at the federal level and in other states, along with increased regulatory action, reflect a trend toward more stringent privacy legislation in the United States.

Outside the United States, many jurisdictions have or are in the process of enacting sweeping data privacy regulatory regimes. In Europe, the GDPR took effect in 2018, and is imposing stringent requirements for controllers and processors of personal data of individuals within the EEA, particularly with respect to clinical trials. The GDPR provides that EEA member states may make their own further laws and regulations limiting the processing of health data, which could limit our ability to use and share personal data or could cause our costs to increase and harm our business and financial condition. In addition, the GDPR increases the scrutiny that clinical trial sites located in the EEA should apply to transfers of personal data from such sites to countries that are considered to lack an adequate level of data protection, such as the United States. Recent legal developments have added complexity and compliance uncertainty regarding certain transfers of information from the EEA to the United States. Following EU court decisions, updated standard contractual clauses (“SCCs”) were adopted to account for these judicial decisions, imposing new requirements on data transfers. The revised SCCs must be used for relevant new data transfers from September 27, 2021, and existing SCC arrangements were required to be migrated by December 27, 2022. There is some uncertainty around whether the revised clauses can be used for all types of data transfers, particularly whether they can be relied on for data transfers to non-EEA entities subject to the GDPR. As supervisory authorities issue further guidance on personal data export mechanisms, including circumstances where the SCCs cannot be used, and/or start taking enforcement action, we could suffer additional costs, complaints and/or regulatory investigations or fines, and/or if we are otherwise unable to transfer personal data between and among countries and regions in which we operate, it could affect the manner in which we provide our services, the geographical location or segregation of our relevant systems and operations, and could adversely affect our financial results. The GDPR imposes substantial fines for breaches of data protection requirements, which can be up to four percent of global revenue for the preceding financial year or €20 million, whichever is greater, and it also confers a private right of action on data subjects for breaches of data protection requirements. Compliance with European data protection laws is a rigorous and time intensive process that may increase our cost of doing business, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation and reputational harm in connection with our European activities. From January 1, 2021, we have had to comply with the GDPR and separately the United Kingdom GDPR, which, together with the amended United Kingdom Data Protection Act 2018, retains the GDPR in United Kingdom national law, each regime having the ability to fine up to the greater of €20 million/ £17.5 million or 4 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. On June 28, 2021, the EC adopted an adequacy decision in favor of the United Kingdom, enabling data transfers from EU member states to the United Kingdom without additional safeguards. However, the United Kingdom adequacy decision will automatically expire in June 2025 unless the EC renews or extends that decision and remains under review by the Commission during this period.

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

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

We store valuable confidential information relating to our business, patients and employees on our computer networks and on the networks of our vendors. In addition, we rely heavily on internet technology, including video conference, teleconference and file-sharing services, to conduct business. Despite our security measures, our networks and the networks of our vendors are at risk of break-ins, installation of malware or ransomware, denial-of-service attacks, data theft and other forms of malfeasance by persons seeking to commit fraud or theft, which could result in unauthorized access to, and/or misuse of, our clinical data or other confidential information, including confidential information relating to our patients or employees. COVID-19 may continue to increase our cybersecurity risks, due to our reliance on internet technology and the number of our employees that are working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities.

We and our vendors have experienced data breaches, theft, “phishing” attacks and other unauthorized access to confidential data and information. Russia’s invasion of Ukraine or another war of international dispute may cause an increase in the number and severity of such malicious incidents. There can be no assurance that our cybersecurity systems and processes will prevent unauthorized access in the future that causes serious harm to us, our patients or employees. We may also experience security breaches that remain undetected for an extended period.

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

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

Our earnings are subject to federal, state and local taxes. We offset a portion of our earnings using net operating losses and our taxes using research and development tax credits, which reduces the amount of tax we pay. Some jurisdictions require that we pay taxes or fees calculated as a percentage of sales, payroll expense, or other indicia of our activities. Please see “Part I, Item 1, Notes to Unaudited Condensed Consolidated Financial Statements – Income Taxes.” Certain provisions of the recently enacted IRA, effective January 1, 2023, including a 1 percent excise tax on share repurchases and a 15 percent corporate alternative minimum tax, may impact our income tax expense, profitability and capital allocation decisions. In April 2023, we completed an issuer tender offer pursuant to which we accepted for tender 6,610,369 shares of our common stock for an aggregate purchase price of \$145,428,118. Changes to existing tax laws could materially increase the amounts we pay, which would reduce our after tax net income.

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

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

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

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

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

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

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

New laws and regulations, as well as changes to existing laws and regulations, including statutes and regulations concerning taxes and the development, approval, marketing and pricing of medications, the provisions of the ACA requiring the reporting of aggregate spending related to health care professionals, the provisions of the Sarbanes-Oxley Act of 2002, the Dodd Frank Act of 2010 and rules adopted by the SEC and by The Nasdaq Stock Market have and will likely continue to increase our cost of doing business and divert management’s attention from revenue-generating activities.

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

The federal securities laws and regulations, including the corporate governance and other requirements of the Sarbanes-Oxley Act of 2002 and the governance and other requirements of the Dodd Frank Act of 2010, impose complex and continually

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

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

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

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

As of April 26, 2023, our officers and directors beneficially owned approximately 20 percent of our common stock. Acting together, these stockholders could significantly influence any matter requiring approval by our stockholders, including the election of directors and the approval of mergers or other business combinations. The interests of this group may not always coincide with our interests or the interests of other stockholders and may prevent or delay a change in control. This significant concentration of share ownership may adversely affect the trading price of our common stock because many investors perceive disadvantages to owning stock in companies with controlling stockholders.

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

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

**ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS**

There were no unregistered sales of equity securities during the period covered by this report.

### Issuer Purchases of Equity Securities

The following table contains information relating to the purchases of our common stock in the three months ended March 31, 2023 as part of the cashless net exercises of stock options (in thousands, except average price per share):

<b>Fiscal Period</b>	<b>Total Number of Shares Purchased<sup>(1)</sup></b>	<b>Average Price Per Share</b>	<b>Total Purchase Price of Shares<sup>(2)</sup></b>
January 1, 2023 to January 31, 2023	40	\$ 22.10	\$ 887
February 1, 2023 to February 28, 2023	11	23.03	244
March 1, 2023 to March 31, 2023	246	21.21	5,228
Total	297	\$ 21.40	\$ 6,359

(1) In January 2023, we issued 76,066 shares of common stock as part of net-share settlement of cashless option exercises, of which 40,146 shares were surrendered to us in satisfaction of related exercise cost and tax obligations. In February 2023, we issued 16,168 shares of common stock as part of net-share settlement of cashless option exercises, of which 10,584 shares were surrendered to us. In March 2023, we issued 378,456 shares of common stock as part of net-share settlement of cashless option exercises, of which 246,463 shares were surrendered to us.

(2) We paid \$1.1 million to satisfy the tax withholding obligations associated with the net-share settlement of these cashless option exercises.

### ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

### ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

### ITEM 5. OTHER INFORMATION

None.

**ITEM 6. EXHIBITS**

<b>Exhibit Number</b>	<b>Description of Document</b>
3.1	<a href="#"><u>Amended and Restated Certificate of Incorporation, as amended (incorporated by reference to Exhibit 3.1 to the registrant's Quarterly Report on Form 10-Q filed on August 9, 2012).</u></a>
3.2	<a href="#"><u>Amended and Restated Bylaws (incorporated by reference to Exhibit 3.1 to the registrant's Current Report on Form 8-K filed on February 13, 2017).</u></a>
10.1	<a href="#"><u>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.</u></a>
31.1	<a href="#"><u>Rule 13a-14(a)/15d-14(a) Certifications of Joseph K. Belanoff, M.D., Chief Executive Officer of the registrant.</u></a>
31.2	<a href="#"><u>Rule 13a-14(a)/15d-14(a) Certifications of Atabak Mokari, Chief Financial Officer of the registrant.</u></a>
32.1	<a href="#"><u>18 U.S.C. Section 1350 Certifications of Joseph K. Belanoff, M.D., Chief Executive Officer of the registrant.</u></a>
32.2	<a href="#"><u>18 U.S.C. Section 1350 Certifications of Atabak Mokari, Chief Financial Officer of the registrant.</u></a>
101	The following materials from the registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2023, formatted in Extensible Business Reporting Language (XBRL): (i) Unaudited Condensed Consolidated Balance Sheets at March 31, 2023 and December 31, 2022, (ii) Unaudited Condensed Consolidated Statements of Income for the three month periods ended March 31, 2023 and 2022, (iii) Unaudited Condensed Consolidated Statements of Comprehensive Income for the three month periods ended March 31, 2023 and 2022, (iv) Unaudited Condensed Consolidated Statements of Cash Flows for the three month periods ended March 31, 2023 and 2022, (v) Unaudited Condensed Consolidated Statement of Stockholders' Equity and (vi) Notes to Unaudited Condensed Consolidated Financial Statements.
104	Cover Page Interactive Data File - the cover page XBRL tags are embedded within the Inline XBRL document.

## SIGNATURES

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

### CORCEPT THERAPEUTICS INCORPORATED

Date: May 3, 2023

/s/ Joseph K. Belanoff

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**Joseph K. Belanoff, M.D.**  
**Chief Executive Officer**

Date: May 3, 2023

/s/ Atabak Mokari

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**Atabak Mokari**  
**Chief Financial Officer**

Date: May 3, 2023

/s/ Joseph D. Lyon

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**Joseph D. Lyon**  
**Chief Accounting Officer**



## EIGHTH AMENDMENT TO LEASE

THIS EIGHTH AMENDMENT TO LEASE (the “**Eighth Amendment**”) is made and entered into as of April 1, 2023 by and between Exponent Realty, LLC, a Delaware limited liability company (“**Landlord**”), and Corcept Therapeutics Incorporated, a Delaware corporation (“**Tenant**”).

## RECITALS

- A. Landlord and Tenant are parties to that certain lease dated April 1, 2016 (the “**Lease**”), the first amendment (the “**First Amendment**”) dated June 1, 2017, the second amendment (the “**Second Amendment**”) dated March 12, 2018, the third amendment (the “**Third Amendment**”) dated November 8, 2018, the Fourth Amendment dated October 23, 2019 (the “**Fourth Amendment**”) the Fifth Amendment dated June 17, 2020 (the “**Fifth Amendment**”), the Sixth Amendment dated July 22, 2020 (the “**Sixth Amendment**”), and the Seventh Amendment (the “**Seventh Amendment**”) dated March 18, 2022. Pursuant to the Lease, the First Amendment, the Second Amendment, the Third Amendment, the Fourth Amendment, the Fifth Amendment, the Sixth Amendment, and the Seventh Amendment, Landlord has leased to Tenant space currently containing approximately 47,022 rentable square feet (the “**Premises**”) on the first and second floor of the building, located at 149 Commonwealth Dr., Menlo Park, CA 94025 (the “**Building**”).
- B. Tenant and Landlord now desire to amend the Lease on the following terms and conditions:

**NOW, THEREFORE**, in consideration of the above recitals which by this reference are incorporated herein, the mutual covenants and conditions contained herein and other valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Landlord and Tenant agree as follows:

1. **Tenant Improvements.** Landlord shall not provide any allowance for Tenant Improvements in the Premises.
2. **Lease Term.** The Term of the Lease shall be extended through June 30, 2024.
3. **Revision of Premises.** The Premises shall be revised as follows:
  - a. Effective June 30, 2023, Suite 1014 (2,617 rentable square feet), shown on Exhibit A, shall no longer be part of the Premises and all rights to that portion of the Premises shall revert to Landlord.
  - b. Effective immediately, Suite 2060 (6,372 rentable square feet), shown on Exhibit A, shall be added to the Premises, provided, however, that no base rent shall be due with respect to that portion of the Premises until July 1, 2023.
4. **Base Rent.** The Base Rent for the Premises shall be as shown in the schedule below. Tenant shall continue to pay its proportionate share of the Operating Expenses and Real Estate Taxes on the Premises. As of July 1, 2023, the schedule of Base Rent payable with respect to the Premises is the following:

DATE	PERIOD	RENTABLE SQ. FT.	BASE RENT PER RSF* PER YEAR	MONTHLY AMOUNT	PERIODIC AMOUNT
07/01/2023 to 06/30/2024	12 months	50,777	\$48.60	\$205,646.85	\$2,467,762.20

\*RSF is defined as Rentable Square Foot/Feet

5. **Option to Extend Lease.** Tenant shall have one option to extend the Term of the Lease by 12 months. In order to extend the Term, Tenant must notify Landlord in writing, by September 30, 2023 of Tenant’s exercise of this option. In the event that Tenant exercises this option, Tenant shall continue to pay its proportionate share of the Operating Expenses and Real Estate Taxes on the Premises through the extended Term and the schedule of Base Rent payable with respect to the Premises shall be the following:

DATE	PERIOD	RENTABLE SQ. FT.	BASE RENT PER RSF* PER YEAR	MONTHLY AMOUNT	PERIODIC AMOUNT
07/01/2024 to 06/30/2025	12 months	50,777	\$48.60	\$205,646.85	\$2,467,762.20

6. **Miscellaneous.**

6.1 This Eighth Amendment, which is hereby incorporated into and made a part of the Lease, sets forth the entire agreement between the parties with respect to the matters herein. There have been no additional oral or written representations or agreements. Under no circumstances shall Tenant be entitled to any Rent abatement, improvement allowance, leasehold improvements, or other work to the Premises, or any similar economic incentives that may have been provided Tenant in connection with entering into the Lease, unless specifically set forth in this Eighth Amendment. Tenant agrees that neither Tenant nor its agents or any other parties acting on behalf of Tenant shall disclose any matters set forth in this Eighth Amendment or disseminate or distribute any information concerning the terms, details or conditions hereof to any person, firm, entity, broker or other tenants in the Building without obtaining the express written consent of Landlord.

6.2 Except as herein modified or amended, the provisions, conditions and terms of the Lease shall remain unchanged and in full force and effect.

6.3 In the case of any inconsistency between the provisions of the Lease and the Eighth Amendment, the provisions of this Eighth Amendment shall govern and control.

6.4 Submission of this Eighth Amendment by Landlord is not an offer to enter into this Eighth Amendment but rather is a solicitation for such an offer by Tenant. Landlord shall not be bound by this Eighth Amendment until Tenant and Landlord have executed and Landlord delivered the same to Tenant.

6.5 Tenant hereby represents to Landlord that Tenant has dealt with no real estate brokers or agents in connection with this Eighth Amendment. Tenant agrees to indemnify and hold Landlord, its members, principals, beneficiaries, partners, officers, directors, employees, mortgagee(s) and agents, and the respective principals and members of any such real estate brokers or agents (collectively, the "**Landlord Related Parties**") harmless from all claims of any real estate brokers or agents claiming to have represented Tenant in connection with this Eighth Amendment. Landlord hereby represents to Tenant that Landlord has dealt with no real estate brokers or agents in connection with this Eighth Amendment. Landlord agrees to indemnify and hold Tenant, its members, principals, beneficiaries, partners, officers, directors, employees, and agents, and the respective principals and members of any such real estate brokers or agents (collectively, the "**Tenant Related Parties**") harmless from all claims of any real estate brokers or agents claiming to have represented Landlord in connection with this Eighth Amendment.

6.6 Each signatory of this Eighth Amendment represents hereby that he or she has the authority to execute and deliver the same on behalf of the party hereto for which such signatory is acting.

SIGNATURES APPEAR ON NEXT PAGE

IN WITNESS WHEREOF, Landlord and Tenant have duly executed this Eighth Amendment as of the day and year first above written.

**LANDLORD:**

**EXPONENT REALTY, L.L.C.,  
a Delaware limited liability company**

Date: April 1, 2023

By: /s/ Richard L. Schlenker

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Name: Richard L. Schlenker

Title: Executive Vice President & CFO

**TENANT:**

**Corcept Therapeutics Incorporated,  
a Delaware corporation**

Date: April 1, 2023

By: /s/ J.D. Lyon

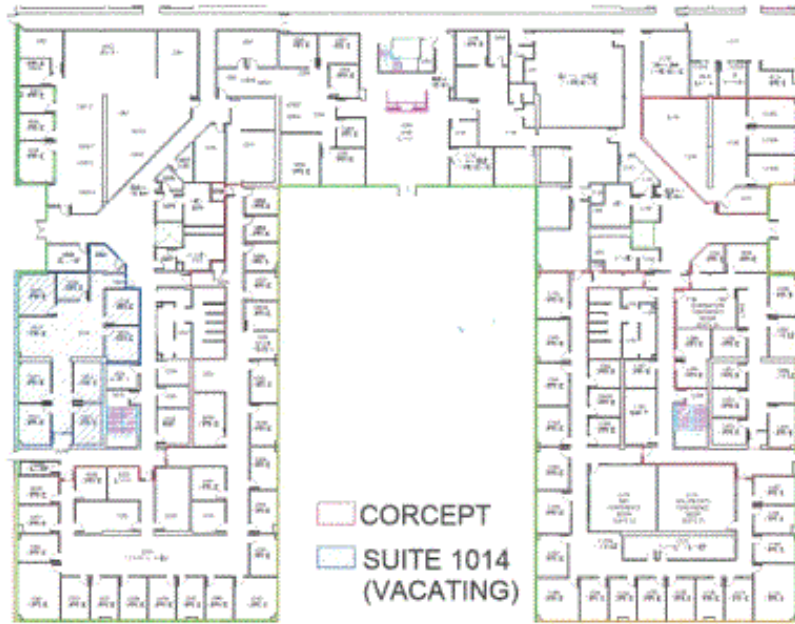
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Name: J.D. Lyon

Title: Chief Accounting Officer

EXHIBIT A

1ST FLOOR PLAN



2ND FLOOR PLAN



**CERTIFICATION**

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

1. I have reviewed this Quarterly Report on Form 10-Q for the period ended March 31, 2023 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 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 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)  
May 3, 2023

**CERTIFICATION**

I, Atabak Mokari, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the period ended March 31, 2023 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 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 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)  
May 3, 2023

**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 Quarterly Report of Corcept Therapeutics Incorporated (the "Company") on Form 10-Q for the period ended March 31, 2023, 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)  
May 3, 2023

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 Quarterly Report of Corcept Therapeutics Incorporated (the "Company") on Form 10-Q for the period ended March 31, 2023, 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)  
May 3, 2023

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.