

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 September 30, 2024

or

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

For the transition period from to

Commission File Number:  
000-50679

CORCEPT THERAPEUTICS INCORPORATED

(Exact Name of Corporation as Specified in Its Charter)

Delaware  
(State or other jurisdiction of  
incorporation or organization)

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

101 Redwood Shores Parkway  
Redwood City, CA 94065  
(Address of principal executive offices, 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 LLC

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

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

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

Large accelerated filer  Accelerated filer   
Non-accelerated filer  Smaller reporting company   
Emerging growth company

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

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

On October 23, 2024, there were 104,775,137 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>September 30, 2024</b>	<b>December 31, 2023</b>
	(Unaudited)	(See Note 1)
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 137,289	\$ 135,551
Short-term marketable securities	243,047	232,670
Trade receivables, net of allowances	59,717	41,123
Insurance recovery receivable related to Melucci litigation (Note 4)	—	14,000
Inventory	8,050	7,730
Prepaid expenses and other current assets	18,875	27,562
<b>Total current assets</b>	<b>466,978</b>	<b>458,636</b>
Strategic inventory	7,764	8,244
Operating lease right-of-use asset	5,503	120
Property and equipment, net	2,930	195
Long-term marketable securities	167,310	57,176
Other assets	6,973	6,541
Deferred tax assets, net	126,799	90,605
<b>Total assets</b>	<b>\$ 784,257</b>	<b>\$ 621,517</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 18,584	\$ 17,396
Accrued research and development expenses	27,736	21,330
Accrued and other liabilities	79,464	51,628
Accrued settlement related to Melucci litigation (Note 4)	—	14,000
Short-term operating lease liability	432	151
<b>Total current liabilities</b>	<b>126,216</b>	<b>104,505</b>
Long-term operating lease liability	6,359	—
Long-term accrued income taxes payable	12,847	10,307
<b>Total liabilities</b>	<b>145,422</b>	<b>114,812</b>
Commitments and contingencies (Note 4)		
Stockholders' equity:		
Preferred stock	—	—
Common stock	135	133
Treasury stock	(682,177)	(635,078)
Additional paid-in capital	806,317	738,515
Accumulated other comprehensive income	1,571	609
Retained earnings	512,989	402,526
<b>Total stockholders' equity</b>	<b>638,835</b>	<b>506,705</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 784,257</b>	<b>\$ 621,517</b>

*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)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Product revenue, net	\$ 182,546	\$ 123,601	\$ 493,150	\$ 346,970
Operating expenses:				
Cost of sales	2,867	1,645	7,926	4,604
Research and development	59,336	45,517	176,587	129,646
Selling, general and administrative	73,745	45,262	196,948	137,107
Total operating expenses	135,948	92,424	381,461	271,357
Income from operations	46,598	31,177	111,689	75,613
Interest and other income	6,345	5,208	17,844	12,135
Income before income taxes	52,943	36,385	129,533	87,748
Income tax expense	(5,730)	(5,007)	(19,070)	(12,963)
Net income	47,213	31,378	110,463	74,785
Net income attributable to common stockholders	46,690	31,172	109,344	74,353
Basic net income per common share	\$ 0.45	\$ 0.31	\$ 1.06	\$ 0.72
Diluted net income per common share	\$ 0.41	\$ 0.28	\$ 0.98	\$ 0.66
Weighted-average shares outstanding used in computing net income per common share				
Basic	103,371	102,014	103,094	103,933
Diluted	113,723	111,099	111,571	112,054

*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)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Net income	47,213	31,378	110,463	74,785
Other comprehensive income (loss):				
Unrealized gain (loss) on available-for-sale investments, net of tax effect of \$(256), \$31, \$(139) and \$(184), respectively	951	(95)	432	586
Foreign currency translation gain (loss)	536	(184)	530	49
<b>Total comprehensive income</b>	<b>\$ 48,700</b>	<b>\$ 31,099</b>	<b>\$ 111,425</b>	<b>\$ 75,420</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>Nine Months Ended September 30,</b>	
	<b>2024</b>	<b>2023</b>
<b>Cash flows from operating activities:</b>		
Net income	\$ 110,463	\$ 74,785
Adjustments to reconcile net income to net cash provided by operating activities:		
Stock-based compensation	44,558	35,875
Accretion of discount on marketable securities, net	(8,747)	(5,933)
Depreciation and amortization	514	828
Deferred income taxes	(36,333)	(25,821)
Amortization of right-of-use asset	362	1,262
Changes in operating assets and liabilities:		
Trade receivables	(18,594)	(3,569)
Insurance recovery receivable related to Melucci litigation	14,000	—
Inventory	383	936
Prepaid expenses and other current assets	8,462	(5,579)
Other assets	(432)	—
Accounts payable	1,616	4,783
Accrued research and development expenses	6,406	6,732
Accrued and other liabilities	27,531	36,695
Accrued settlement related to Melucci litigation	(14,000)	—
Long-term accrued income taxes	2,540	1,373
Operating lease liability	38	(1,215)
Net cash provided by operating activities	<u>138,767</u>	<u>121,152</u>
<b>Cash flows from investing activities:</b>		
Purchases of property and equipment	(2,051)	(139)
Proceeds from maturities of marketable securities	332,545	372,793
Purchases of marketable securities	(443,738)	(298,846)
Net cash (used in) provided by investing activities	<u>(113,244)</u>	<u>73,808</u>
<b>Cash flows from financing activities:</b>		
Proceeds from stock option exercises, net of issuance costs	3,268	1,091
Proceeds from purchases under the Employee Stock Purchase Program	3,927	2,959
Repurchase of common stock in connection with Stock Repurchase Program	(15,664)	—
Repurchase of common stock in connection with Tender Offer	—	(145,428)
Cash paid to satisfy statutory withholding requirement for net settlement of cashless option exercises and vesting of restricted stock grants	(15,316)	(8,111)
Net cash used in financing activities	<u>(23,785)</u>	<u>(149,489)</u>
Net increase in cash and cash equivalents	1,738	45,471
Cash and cash equivalents, at beginning of period	135,551	66,329
Cash and cash equivalents, at end of period	<u>\$ 137,289</u>	<u>\$ 111,800</u>

**Supplemental disclosure:**

Exercise cost of shares repurchased for net settlement of cashless option exercises	\$	14,184	\$	22,199
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*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 Income (Loss)	Retained Earnings	Total Stockholders' Equity
	Shares	Amount					
Balance at December 31, 2023	103,405	\$ 133	\$ 738,515	\$ (635,078)	\$ 609	\$ 402,526	\$ 506,705
Issuance of common stock under incentive award plan	786	—	3,485	—	—	—	3,485
Shares tendered to satisfy cost and statutory withholding requirements for net settlement of cashless option exercises and vesting of restricted stock	(143)	—	2,032	(5,586)	—	—	(3,554)
Repurchase of common stock in connection with Stock Repurchase Program	(20)	—	—	(476)	—	—	(476)
Excise tax related to net share repurchases	—	—	—	81	—	—	81
Stock-based compensation	—	—	12,929	—	—	—	12,929
Vesting of RSAs in connection with ESPP	—	—	1,283	—	—	—	1,283
Other comprehensive loss, net of tax	—	—	—	—	(351)	—	(351)
Net income	—	—	—	—	—	27,762	27,762
Balance at March 31, 2024	104,028	\$ 133	\$ 758,244	\$ (641,059)	\$ 258	\$ 430,288	\$ 547,864
Issuance of common stock under incentive award plan	700	1	7,573	—	—	—	7,574
Shares tendered to satisfy cost and statutory withholding requirements for net settlement of cashless option exercises and vesting of restricted stock	(208)	—	—	(6,242)	—	—	(6,242)
Repurchase of common stock in connection with Stock Repurchase Program	(122)	—	—	(3,478)	—	—	(3,478)
Excise tax related to net share repurchases	—	—	—	16	—	—	16
Stock-based compensation	—	—	13,881	—	—	—	13,881
Vesting of RSAs in connection with ESPP	—	—	1,314	—	—	—	1,314
Other comprehensive loss, net of tax	—	—	—	—	(174)	—	(174)
Net income	—	—	—	—	—	35,488	35,488
Balance at June 30, 2024	104,398	\$ 134	\$ 781,012	\$ (650,763)	\$ 84	\$ 465,776	\$ 596,243
Issuance of common stock under incentive award plan	1,175	1	10,321	—	—	—	10,322
Shares tendered to satisfy cost and statutory withholding requirements for net settlement of cashless option exercises and vesting of restricted stock	(526)	—	—	(19,704)	—	—	(19,704)
Repurchase of common stock in connection with Stock Repurchase Program	(344)	—	—	(11,710)	—	—	(11,710)
Stock-based compensation	—	—	14,286	—	—	—	14,286
Vesting of RSAs in connection with ESPP	—	—	698	—	—	—	698
Other comprehensive income, net of tax	—	—	—	—	1,487	—	1,487
Net income	—	—	—	—	—	47,213	47,213
Balance at September 30, 2024	104,703	\$ 135	\$ 806,317	\$ (682,177)	\$ 1,571	\$ 512,989	\$ 638,835

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



	Common Stock		Additional Paid-in Capital	Treasury Stock	Accumulated Other Comprehensive Income (Loss)	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 incentive award plan	618	—	6,540	—	—	—	6,540
Shares tendered 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 income, 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
Issuance of common stock under incentive award plan	1,168	1	4,496	—	—	—	4,497
Shares tendered to satisfy cost and statutory withholding requirements for net settlement of cashless option exercises	(202)	—	—	(4,823)	—	—	(4,823)
Repurchase of common stock in connection with Tender Offer	(6,610)	—	—	(145,428)	—	—	(145,428)
Excise tax related to net share repurchases	—	—	—	(1,316)	—	—	(1,316)
Stock-based compensation	—	—	11,374	—	—	—	11,374
Other comprehensive income, net of tax	—	—	—	—	198	—	198
Net income	—	—	—	—	—	27,528	27,528
Balance at June 30, 2023	102,512	\$ 132	\$ 695,718	\$ (614,074)	\$ 45	\$ 339,793	\$ 421,614
Issuance of common stock under incentive award plan	1,068	1	13,949	—	—	—	13,950
Shares purchased to satisfy cost and statutory withholding requirements for net settlement of cashless option exercises	(584)	—	—	(17,866)	—	—	(17,866)
Excise tax related to net share repurchases	—	—	—	152	—	—	152
Stock-based compensation	—	—	11,660	—	—	—	11,660
Vesting of RSAs in connection with ESPP	—	—	1,070	—	—	—	1,070
Other comprehensive loss, net of tax	—	—	—	—	(279)	—	(279)
Net income	—	—	—	—	—	31,378	31,378
Balance at September 30, 2023	102,996	\$ 133	\$ 722,397	\$ (631,788)	\$ (234)	\$ 371,171	\$ 461,679

*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 endocrinologic, oncologic, metabolic and neurologic disorders by modulating the effects of the hormone cortisol. In 2012, the United States Food and Drug Administration (“FDA”) approved Korlym® (“mifepristone”) 300 mg tablets, as a once-daily oral medication for the treatment of hyperglycemia secondary to hypercortisolism in adult patients with endogenous Cushing’s syndrome who have type 2 diabetes mellitus or glucose intolerance and have failed surgery or are not candidates for surgery. In June 2024, we made available an authorized generic version of Korlym for the same indication. We have discovered and patented four structurally distinct series of selective cortisol modulators, consisting of more than 1,000 compounds. We are developing compounds from these series as potential treatments for a broad range of serious disorders.

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

##### Basis of Presentation

We have prepared the following interim financial statements in accordance with U.S. generally accepted accounting principles (“GAAP”) and with the instructions to Form 10-Q and Article 10 of Regulation S-X: (i) condensed consolidated balance sheet as of September 30, 2024 and (ii) condensed consolidated statements of income, comprehensive income and stockholders’ equity for the three- and nine-month periods ended September 30, 2024 and 2023 and (iii) condensed consolidated statements of cash flows for the nine-month periods ended September 30, 2024 and 2023. 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- and nine-month periods ended September 30, 2024 are not necessarily indicative of the results for the remainder of 2024 or any other period. These financial statements and notes should be read in conjunction with the financial statements for the year ended December 31, 2023 included in our Annual Report on Form 10-K. The December 31, 2023 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, 2023.

##### Recently Issued Accounting Pronouncements Not Yet Adopted

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

In November 2023, the FASB issued ASU No. 2023-07, to improve the disclosures about a public entity’s reportable segments and address requests from investors for additional, more detailed information about a reportable segment’s expenses. The standard is effective for public companies with annual periods beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024 with early adoption permitted. We will adopt this guidance for the annual period ending December 31, 2024 and for interim periods thereafter. The Chief Executive Officer is our Chief Operating Decision Maker and we view our operations and manage our business as one operating segment.

## 2. Composition of Certain Balance Sheet Items

### *Inventory*

	<b>September 30, 2024</b>	<b>December 31, 2023</b>
	<i>(in thousands)</i>	
Work in progress	7,764	8,233
Finished goods	8,050	7,741
<b>Total inventory</b>	<b>15,814</b>	<b>15,974</b>
Less strategic inventory classified as non-current	(7,764)	(8,244)
<b>Total inventory classified as current</b>	<b>\$ 8,050</b>	<b>\$ 7,730</b>

We rely on two manufacturers to produce the active pharmaceutical ingredient (“API”) for our medications. 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 non-current asset.

### *Prepaid expenses and other current assets*

	<b>September 30, 2024</b>	<b>December 31, 2023</b>
	<i>(in thousands)</i>	
Prepaid expenses	\$ 5,817	\$ 4,319
Deferred clinical materials	5,707	13,496
Clinical deposits	2,771	3,865
Other current assets	4,580	5,882
<b>Total prepaid expenses and other current assets</b>	<b>\$ 18,875</b>	<b>\$ 27,562</b>

### *Accrued and other liabilities*

	<b>September 30, 2024</b>	<b>December 31, 2023</b>
	<i>(in thousands)</i>	
Government rebates	\$ 38,799	\$ 18,468
Accrued compensation	27,568	25,457
Accrued selling and marketing costs	3,959	1,771
Legal fees	1,836	542
Other	7,302	5,390
<b>Total accrued and other liabilities</b>	<b>\$ 79,464</b>	<b>\$ 51,628</b>

### *Other assets*

As of September 30, 2024 and December 31, 2023, other assets included \$6.0 million and \$6.4 million of deposits for clinical trials, respectively.

### 3. Available-for-Sale Marketable Securities and Fair Value Measurements

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

	September 30, 2024	December 31, 2023
	<i>(in thousands)</i>	
Cash equivalents	\$ 110,789	\$ 97,170
Short-term marketable securities	243,047	232,670
Long-term marketable securities	167,310	57,176
Total marketable securities	<u>\$ 521,146</u>	<u>\$ 387,016</u>

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

	Fair Value Hierarchy Level	September 30, 2024				December 31, 2023			
		Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
		<i>(in thousands)</i>							
Corporate bonds	Level 2	\$ 300,504	\$ 836	\$ (87)	\$ 301,253	\$ 120,508	\$ 307	\$ —	\$ 120,815
Commercial paper	Level 2	4,875	12	—	4,887	75,308	20	(9)	75,319
U.S. Treasury securities	Level 1	104,171	46	—	104,217	93,655	61	(4)	93,712
Money market funds	Level 1	110,789	—	—	110,789	97,170	—	—	97,170
Total marketable securities		<u>\$ 520,339</u>	<u>\$ 894</u>	<u>\$ (87)</u>	<u>\$ 521,146</u>	<u>\$ 386,641</u>	<u>\$ 388</u>	<u>\$ (13)</u>	<u>\$ 387,016</u>

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

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

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

We classified accrued interest on our marketable securities of \$2.9 million and \$1.7 million as of September 30, 2024 and December 31, 2023, respectively, as prepaid and other current assets on our condensed consolidated balance sheets.

As of September 30, 2024, all of our long-term marketable securities had original maturities of no more than 26 months and all our marketable securities classified as short-term have maturities of less than one year. The weighted-average maturity of our short-term and long-term marketable securities was ten months. As of September 30, 2024, our long-term marketable securities had remaining maturities between 13 months and 24 months. None of our marketable securities changed from one fair value hierarchy to another during the three and nine months ended September 30, 2024.

### 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, 2023.

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

On February 8, 2023, we reached an agreement in principle (the “Proposed Settlement”) to resolve all claims in the Melucci litigation. As previously disclosed, we made a one-time payment of \$14.0 million into escrow as required by the Proposed Settlement and our insurers have since reimbursed us in full for this payment. On June 6, 2024, Judge James Donato of the United States District Court for the Northern District of California granted final approval of the Proposed Settlement which will govern administration of payments to eligible members of the plaintiff class.

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**

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

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

As the operating leases for our facilities do not provide sufficient information to determine the implicit borrowing rate, we calculated the present value of remaining lease payments using a discount rate equal to the interest rate we would pay on a collateralized loan with monthly payments and a term equal to the monthly payments and remaining term of our lease. Operating lease right-of-use assets also include any rent paid prior to the commencement date, less any lease incentives received. We recognize operating lease payments as expenses using the straight-line method over the term of the lease.

Operating lease expense for the three and nine months ended September 30, 2024 was \$0.7 million and \$2.1 million, respectively, compared to \$0.6 million and \$1.8 million, respectively, for the comparable periods in 2023.

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

	Three months ended September 30,		Nine months ended September 30,	
	2024	2023	2024	2023
Cash paid for operating lease liabilities	\$ —	\$ 617	\$ 1,358	\$ 1,774
Recognition of right-of-use asset in exchange for lease liability	\$ —	\$ 297	\$ 5,745	\$ 297
Weighted-average remaining lease term			69 months	9 months
Weighted-average discount rate			8.5 %	8.0 %

As of September 30, 2024, future minimum lease payments under non-cancelable capitalized operating leases were as follows (in thousands):

2024 (remainder)	\$	—
2025		1,382
2026		1,551
2027		1,598
2028		1,646
Thereafter		2,555
Total operating lease payments		8,732
Less imputed interest		(1,941)
Present value of operating lease liabilities	\$	<u>6,791</u>

## 6. Stockholders' Equity

### *Treasury Stock*

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

During the three and nine months ended September 30, 2024, we purchased 0.3 million and 0.5 million, respectively shares of our common stock under the Stock Repurchase Program in open market transactions at an average price of \$34.02 and \$32.25 per share, respectively, for aggregate purchase prices of \$11.7 million and \$15.7 million, respectively. As of September 30, 2024, \$184.3 million of the current authorization remained available for the repurchase of shares of our common stock.

We recorded purchased shares as treasury stock on our condensed consolidated balance sheets at cost. As of September 30, 2024 and December 31, 2023, we had 32.4 million and 30.9 million treasury shares outstanding, respectively.

### *Incentive Award Plan*

We have one equity award plan – the Corcept Therapeutics Incorporated 2024 Incentive Award Plan (the "2024 Plan").

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

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

### *Stock Options*

During the three and nine months ended September 30, 2024, we issued 1.0 million and 1.8 million, respectively, 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 then current market price, shares equal in value to the associated exercise price and tax withholding obligations. During the three and nine months ended September 30, 2024, we purchased 0.5 million and 0.8 million shares, respectively, in connection with such option net exercises and paid \$10.5 million and \$12.2 million, respectively, to satisfy associated tax withholding obligations.

During the three and nine months ended September 30, 2023, we issued 1.0 million and 2.0 million, respectively, 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 then current market price, shares equal in value to the associated exercise price and tax withholding obligations. During the three and nine months ended September 30, 2023, we

purchased 0.6 million and 1.1 million shares, respectively, in connection with such option net exercises and paid \$4.2 million and \$6.8 million, respectively, to satisfy associated tax withholding obligations.

### ***Restricted Stock Awards (“RSAs”)***

During the three and nine months ended September 30, 2024, we granted employees 0.2 million and 0.8 million RSAs, respectively, with a weighted-average grant date fair value of \$34.58 and \$27.07 per share, respectively. During the three and nine months ended September 30, 2023, we granted employees 0.1 million and 0.5 million RSAs with a weighted-average grant date fair value of \$26.96 and \$23.26 per share, respectively. 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”)***

Our ESPP allows employees to set aside, by means of payroll deductions, up to ten percent of their annual compensation for the purchase of our common stock. Shares are issued to participating employees from the 2024 Plan on March 1st, June 1st, September 1st and December 1st (or, if those dates fall on holidays or weekends, on the first business day thereafter) at the then-current fair market value of our stock, as determined at the close of trading on those days.

For each purchased share, the participating employee receives one matching share, also issued from the 2024 Plan if certain conditions are met. There is no vesting requirement for shares issued pursuant to the ESPP purchase. The matching share will be granted in the form of an RSA that will vest on the one-year anniversary of the respective ESPP purchase date, net of applicable tax withholding. The vesting condition on the RSA is that the participating employee hold the corresponding share purchased under the ESPP for one year from the purchase date. Shares purchased pursuant to the ESPP and any matching shares may be held, sold or transferred at the employee’s sole discretion.

As of September 30, 2024 and December 31, 2023, we had a liability of \$2.7 million and \$2.3 million, respectively, of stock-based compensation related to RSAs granted in connection with our ESPP in “Accrued and other liabilities” on our unaudited condensed consolidated balance sheets.

### ***Stock-based Compensation***

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

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2024</b>	<b>2023</b>	<b>2024</b>	<b>2023</b>
	<i>(in thousands)</i>			
Capitalized stock-based compensation	\$ 95	\$ 44	\$ 223	\$ 170
Cost of sales	24	11	49	43
Research and development	4,660	4,023	13,018	11,169
Selling, general and administrative	11,418	8,841	31,491	24,663
<b>Total stock-based compensation</b>	<b>\$ 16,197</b>	<b>\$ 12,919</b>	<b>\$ 44,781</b>	<b>\$ 36,045</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 restricted stock units (“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 September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
	<i>(in thousands, except per share amounts)</i>			
<b>Numerator:</b>				
Net income attributable to common stockholders	\$ 46,690	\$ 31,172	\$ 109,344	\$ 74,353
<b>Denominator:</b>				
Weighted-average shares used to compute basic net income per common share	103,371	102,014	103,094	103,933
Dilutive effect of employee stock options and unvested RSUs	10,352	9,085	8,477	8,121
Weighted-average shares used to compute diluted net income per common share	113,723	111,099	111,571	112,054
Basic net income per common share	\$ 0.45	\$ 0.31	\$ 1.06	\$ 0.72
Diluted net income per common share	\$ 0.41	\$ 0.28	\$ 0.98	\$ 0.66

As of September 30, 2024, we had 25.0 million stock options, 1.2 million RSAs and 0.1 million RSUs outstanding. As of September 30, 2023, we had 23.3 million stock options, 0.7 million RSAs and 0.1 million RSUs outstanding.

We excluded from the computation of diluted net income per share, on a weighted-average basis, 1.0 million and 8.6 million stock options outstanding during the three and nine months ended September 30, 2024, respectively, and 6.3 million and 9.0 million stock options outstanding during the three and nine months ended September 30, 2023, respectively, because including them would have reduced dilution.

## 8. Income Taxes

We recorded income tax expense of \$5.7 million and \$19.1 million for the three and nine months ended September 30, 2024, respectively, as compared to an income tax expense of \$5.0 million and \$13.0 million for the three and nine months ended September 30, 2023. The increases during the three and nine months ended September 30, 2024 were primarily due to increased pretax book income compared to the corresponding periods in 2023.

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 and nine months ended September 30, 2024, unrecognized tax benefits increased by \$1.3 million and \$3.4 million, respectively.

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 September 30, 2024, the requirement has not been modified.



## 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 endocrinologic, oncologic, metabolic and neurologic disorders by modulating the effects of the hormone cortisol. Since 2012, we have marketed Korlym® for the treatment of patients suffering from Cushing's syndrome. In June 2024, we made available an authorized generic version of Korlym for the same indication. Our portfolio of proprietary selective cortisol modulators consists of four structurally distinct series totaling more than 1,000 compounds.

#### *Cushing's Syndrome*

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

Because most 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 are conducting a study ("CATALYST") to determine the prevalence of Cushing's syndrome in patients with difficult-to-control diabetes (i.e., HbA1c of 7.5 percent or higher) despite receiving optimum treatment. In the 1,055 patients enrolled in the first phase of CATALYST, 24 percent were found to have hypercortisolism. These patients were offered the chance to enter CATALYST'S second phase, in which eligible patients were randomized 2:1 to receive either Korlym or placebo for 24 weeks. We expect that the prevalence and treatment data from CATALYST will help physicians better identify patients with Cushing's syndrome and determine their optimal treatment.

*Relacorilant.* We are developing our proprietary, selective cortisol modulator, relacorilant, as a treatment for patients with Cushing's syndrome. 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. Because relacorilant also does not meaningfully increase cortisol levels, it does not cause hypokalemia (low potassium), a potentially serious condition that is a leading cause of patients stopping treatment with Korlym. Forty-four percent of patients in Korlym's pivotal trial experienced hypokalemia. Unlike all other medications used to treat Cushing's syndrome, relacorilant does not prolong the heart's QT interval, a potentially deadly off-target effect.

We have completed two Phase 3 trials of relacorilant in patients with Cushing's syndrome – our pivotal trial "GRACE" and our "GRADIENT" trial. In both trials, patients exhibited clinically meaningful improvements in hypertension, glucose control, weight and body composition, as well as other Cushing's syndrome signs and symptoms. Relacorilant was well-tolerated. Notably, patients did not experience some of the serious adverse events that can arise in patients taking Korlym or other currently approved treatments.

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

In the open-label phase, patients experienced clinically meaningful and statistically significant improvements in a wide-array of Cushing's syndrome signs and symptoms, including hypertension, hyperglycemia, weight, waist circumference, fat and lean body mass, cognition and Cushing's Quality of Life score.

Rapid and sustained improvements in systolic blood pressure ("SBP") and diastolic blood pressure ("DBP") were observed in all patients with hypertension, with an improvement in mean SBP of 7.9 mm Hg and mean DBP of 5.4 mm Hg at 22 weeks (p-values: <0.0001). During the open-label phase, 63 percent of patients with hypertension met the study's response criteria. For the patients that entered the randomized withdrawal phase, the observed improvements in hypertension were even greater, with improvements in mean SBP of 12.6 mm Hg and mean DBP of 8.3 mm Hg at 22 weeks (p-values: <0.0001). To ensure accuracy, hypertension was measured by 24-hour ambulatory blood pressure monitoring ("ABPM").

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

GRACE met its primary endpoint of loss of blood pressure control in the randomized withdrawal phase among patients who continued to receive relacorilant as compared to patients who were switched to placebo (odds ratio: 0.17; p-value: 0.02). Patients that continued to receive relacorilant also maintained their improvements in hyperglycemia, waist circumference and fat and lean body mass. Patients who received placebo experienced a significant worsening of Cushing's syndrome signs and symptoms.

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

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

GRADIENT patients with hypertension who received relacorilant experienced a reduction in mean systolic blood pressure of 6.6 mm Hg (p-value 0.012) compared to baseline. The reduction in patients who received placebo was 2.1 mm Hg (p-value: ns) compared to baseline. The comparison between those who received relacorilant and placebo was not statistically significant. During the study, 5 patients who received placebo compared to 1 patient who received relacorilant required rescue therapy with anti-hypertension medications. To ensure accuracy, hypertension was measured by 24-hour ambulatory blood pressure monitoring.

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

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

Relacorilant was well tolerated in GRADIENT, with side effects consistent with those seen in its Phase 2 and GRACE trials. Across all of these studies, the most common adverse events were mild-to-moderate nausea, edema, pain in extremities and back, and fatigue – all symptoms associated with the "cortisol withdrawal" many patients experience following surgery or start of medical therapy for Cushing's syndrome. Importantly, there were no relacorilant-induced instances of hypokalemia, endometrial hypertrophy or related vaginal bleeding, adrenal insufficiency or QT prolongation.

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 Platinum-Resistant Ovarian Cancer.* We are conducting a pivotal Phase 3 trial (“ROSELLA”) of our proprietary, selective cortisol modulator, relacorilant combined with nab-paclitaxel as a treatment for patients with platinum-resistant ovarian cancer. Enrollment in ROSELLA is complete. Three hundred eighty-one women with recurrent, platinum-resistant ovarian cancer were randomized 1:1 to receive either 150 mg of relacorilant intermittently in addition to nab-paclitaxel or nab-paclitaxel monotherapy. ROSELLA’s primary endpoint is progression free survival (“PFS”), with overall survival a key secondary endpoint. Patients enrolled in ROSELLA were required to have received prior bevacizumab therapy, which is the approved standard of care for patients with platinum-resistant ovarian cancer. Women with a history of tumors that do not respond to initial platinum-based treatments (i.e., women with “primary platinum-refractory” disease) and those who have received more than three prior lines of therapy were excluded.

ROSELLA seeks to replicate the positive results of our Phase 2 trial, a 178-patient, controlled, multi-center, trial of relacorilant combined with nab-paclitaxel in patients with platinum-resistant ovarian cancer. Phase 2 study participants were randomized to one of three treatment arms: 60 women received 150 mg of relacorilant intermittently (the day before, the day of and the day after their weekly nab-paclitaxel infusion) and 58 women received a daily relacorilant dose of 100 mg per day in addition to nab-paclitaxel. Sixty women received nab-paclitaxel alone. The trial’s primary endpoint was PFS.

Patients in both of the relacorilant plus nab-paclitaxel treatment arms of the Phase 2 trial experienced longer PFS than did the patients who received nab-paclitaxel alone. Patients who received a higher dose of relacorilant intermittently exhibited a statistically significant improvement in median PFS (5.6 months versus 3.8 months, hazard ratio: 0.66; p-value: 0.038). Patients who received a lower dose of relacorilant daily exhibited a median PFS that was 1.5 months longer than did the patients who received nab-paclitaxel alone (5.3 months versus 3.8 months, hazard ratio: 0.83; p-value: not significant). Patients who received relacorilant intermittently also had a longer median duration of response (“DoR”) (5.6 months versus 3.7 months, hazard ratio: 0.36; p-value: 0.006) compared to those who received nab-paclitaxel alone. Patients who received relacorilant intermittently also lived longer (median OS: 13.9 months versus 12.2 months, hazard ratio: 0.67; p-value: 0.066) compared to those who received nab-paclitaxel alone.

In the Phase 2 trial, the addition of relacorilant to treatment with nab-paclitaxel did not create an additional adverse event burden for patients. Safety and tolerability of relacorilant plus nab-paclitaxel were comparable to nab-paclitaxel monotherapy.

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

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

*Relacorilant in Patients with Prostate Cancer.* Androgen deprivation is the standard treatment for prostate cancer because androgens stimulate prostate tumor growth. Cortisol also stimulates prostate tumor growth and cortisol's activity at the GR can cause tumors to escape androgen deprivation therapy. Combining a cortisol modulator with an androgen modulator may block this escape route. Our collaborators at the University of Chicago have initiated a randomized, placebo-controlled Phase 2 trial of relacorilant plus enzalutamide in patients with prostate cancer, pre-prostatectomy. We are providing relacorilant and placebo for the study. Patents we have licensed from the University of Chicago cover the use of relacorilant combined with anticancer agents, including enzalutamide, to treat patients with this 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 an animal model of ALS. Following these compelling results, we initiated a Phase 2 trial ("DAZALS") of dazucorilant in patients with ALS. Two hundred forty-nine patients were randomized on a double-blind basis 1:1:1 to receive either 150 mg of dazucorilant, 300 mg of dazucorilant or placebo daily for 24 weeks. DAZALS' primary endpoint is the difference on the ALS Functional Rating Scale-Revised (ALSFRS-R) between patients receiving dazucorilant and patients receiving placebo. Enrollment is complete. The FDA has designated dazucorilant as an orphan drug for the treatment of ALS in the United States.

#### *Metabolic Diseases*

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

*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. We conducted two Phase 2 trials of miricorilant in patients with weight gain stimulated by anti-psychotic medication. However, patients receiving miricorilant in these studies did not lose weight. In October 2023, we initiated a Phase 1 trial to study miricorilant's potential to prevent AIWG, which we discontinued for lack of efficacy in June 2024.

#### *Drug Discovery and Pre-clinical Development*

We continue to identify new compounds from our portfolio of selective cortisol modulators and advance the most promising of them towards the clinic.

#### *Inflation Reduction Act of 2022*

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

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

Please see the risk factor under Item 1A of this Quarterly Report on Form 10-Q, "*New laws, government regulations, or changes to existing laws and regulations could make it difficult or impossible for us to obtain acceptable prices or adequate*

insurance coverage and reimbursement for our medications, which would adversely affect our results of operations and financial position.”

## Results of Operations

*Net Product Revenue* – Net product revenue is gross product revenue from sales to our customers less deductions for estimated government rebates and chargebacks, patient co-pay assistance program, discounts provided to our specialty distributor for prompt payment and reserves for expected returns.

Net product revenue was \$182.5 million and \$493.2 million for the three and nine months ended September 30, 2024, respectively, compared to \$123.6 million and \$347.0 million for the comparable periods in 2023. Higher sales volumes accounted for 89.0 percent and 78.6 percent of the increases in the three and nine months ended September 30, 2024, respectively, with the remaining growth due to a price increase effective January 1, 2024.

*Cost of sales* – Cost of sales includes the cost of the active pharmaceutical ingredient (“API”), tableting, packaging, personnel, overhead, stability testing and distribution.

Cost of sales was \$2.9 million and \$7.9 million for the three and nine months ended September 30, 2024, respectively, compared to \$1.6 million and \$4.6 million for the comparable periods in 2023. Cost of sales as a percentage of revenue was 1.6 percent for each of the three and nine months ended September 30, 2024, compared to 1.3 percent for each of the comparable periods in 2023. The increases were primarily due to increased manufacturing, shipping and distribution costs.

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

Research and development expense was \$59.3 million and \$176.6 million for the three and nine months ended September 30, 2024, respectively, compared to \$45.5 million and \$129.6 million for the comparable periods in 2023. The increases were due to increased spending on the advancement and completion of our development programs and increased employee compensation expense.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
	<i>(in thousands)</i>			
Clinical development programs:				
Oncology	\$ 13,007	\$ 11,493	\$ 42,237	\$ 27,925
Cushing’s syndrome	14,273	8,980	39,930	27,747
Metabolic diseases	10,406	8,122	29,914	24,597
Pre-clinical and early-stage selective cortisol modulators	9,583	7,871	30,028	23,594
Unallocated activities, including manufacturing and regulatory activities	7,407	5,028	21,460	14,614
Stock-based compensation	4,660	4,023	13,018	11,169
Total research and development expense	<u>\$ 59,336</u>	<u>\$ 45,517</u>	<u>\$ 176,587</u>	<u>\$ 129,646</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 2024 than in 2023 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 \$73.7 million and \$196.9 million for the three and nine months ended September 30, 2024, respectively, compared to \$45.3 million and \$137.1 million for the comparable periods in 2023. The increases were primarily due to increased employee compensation expenses and sales and marketing activities.

We expect our selling, general and administrative expense to be higher in 2024 than in 2023 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 \$6.3 million and \$17.8 million for the three and nine months ended September 30, 2024, respectively, compared to \$5.2 million and \$12.1 million for the comparable periods in 2023. The increases were due to higher cash and investment balances and market-wide increases in interest rates.

*Income tax expense* - Income tax expense was \$5.7 million and \$19.1 million for the three and nine months ended September 30, 2024, respectively, compared to income tax expense of \$5.0 million and \$13.0 million for the comparable periods in 2023. The increases were primarily due to increased pretax book income.

## **Liquidity and Capital Resources**

We rely on revenues from the sale of our medications 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 September 30, 2024, we had cash, cash equivalents and marketable securities of \$547.6 million, consisting of cash and cash equivalents of \$137.3 million and marketable securities of \$410.4 million, compared to cash, cash equivalents and marketable securities of \$425.4 million, consisting of cash and cash equivalents of \$135.6 million and marketable securities of \$289.8 million as of December 31, 2023.

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

Net cash provided by operating activities was \$138.8 million for the nine months ended September 30, 2024, compared to \$121.2 million for the comparable period in 2023. The increase was primarily due to higher revenue.

Net cash used in investing activities was \$113.2 million for the nine months ended September 30, 2024, compared to net cash provided by investing activities of \$73.8 million for the comparable period in 2023. The change 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 during the comparable period in 2023.

Net cash used in financing activities was \$23.8 million for the nine months ended September 30, 2024, compared to \$149.5 million for the comparable period in 2023. In the nine months ended September 30, 2024, we spent \$31.0 million acquiring shares of our common stock, comprised of \$15.7 million pursuant to our Stock Repurchase Program, \$12.2 million acquiring shares of our common stock in connection with the net exercise of employee and director stock options, and \$3.1 million to satisfy tax withholding requirements from vesting of restricted stock grants, offset by \$3.9 million received in connection with our ESPP and \$3.3 million net cash received from the exercise of stock options. In the comparable period in 2023, we spent \$153.5 million acquiring shares of our common stock, comprised of \$145.4 million pursuant to our tender offer, \$6.8 million acquiring shares of our common stock in connection with the net exercise of employee and director stock options and \$1.3 million to satisfy tax withholding requirements from vesting of restricted stock grants, offset by \$3.0 million received in connection with our ESPP and \$1.1 million net cash received from the exercise of stock options.

As of September 30, 2024, we had retained earnings of \$513.0 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, 2023. Other than future minimum lease payments with respect to our sublease for office space with Zuora, our payment obligations and purchase commitments did not change materially during the nine months ended September 30, 2024. See Notes 4 and 5 to our Unaudited Condensed Consolidated Financial Statements for more information regarding our purchase commitments and future minimum lease payments, respectively.

## **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, 2023. 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 September 30, 2024 are disclosed in our Annual Report on Form 10-K for the year ended December 31, 2023. The market risks associated with our cash, cash equivalents and marketable securities, which consist entirely of debt instruments with original maturities of less than 26 months did not change materially during the nine months ended September 30, 2024.

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

***Evaluation of disclosure controls and procedures.*** As of September 30, 2024, our management conducted an evaluation, under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer, of the effectiveness of 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 September 30, 2024, 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 September 30, 2024 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 Patent Litigation*

In February 2018, we received a Paragraph IV Notice Letter advising that Teva Pharmaceuticals USA, Inc. (“Teva”) had submitted an Abbreviated New Drug Application (“ANDA”) to the FDA seeking authorization to manufacture and sell a generic version of Korlym prior to the expiration of patents related to Korlym that are listed in the FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations (the “Orange Book”). In March 2018, we filed a lawsuit in the United States District Court for the District of New Jersey (“D.N.J.”) against Teva for infringement of our patents. In August 2020, Teva received final approval from the FDA for its ANDA in accordance with the Hatch-Waxman Act.

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

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

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

#### *Teva Antitrust Litigation*

On June 13, 2024, Teva filed a complaint in the Northern District of California, captioned *Teva Pharmaceuticals USA, Inc. v. Corcept Therapeutics, Inc., et al.* (N.D. Cal.), Case No. 3:24-cv-03567-BLF (the “Teva Antitrust Litigation”). This lawsuit names Corcept and Optime Care, Inc. (“Optime”), our single specialty pharmacy that dispenses Korlym and performs related pharmacy and patient support services, as defendants and alleges, among other things, that Corcept has violated federal and state laws related to antitrust and unfair business practices. On August 26, 2024, Corcept and Optime filed motions to dismiss the complaint. On September 13, 2024, Teva filed a First Amended Complaint, and on October 14, 2024, Corcept and Optime moved to dismiss the First Amended Complaint. A hearing on the motion to dismiss has been scheduled for February 20, 2025.

#### *Other Litigation*

In March 2019, a purported securities class action complaint was filed in the United States District Court for the Northern District of California by Nicholas Melucci (*Melucci v. Corcept Therapeutics Incorporated, et al.*, Case No. 5:19-cv-01372-LHK) (the “Melucci litigation”). The complaint named us and certain of our executive officers as defendants asserting violations of Sections 10(b) and 20(a) of the Exchange Act and Rule 10b-5 promulgated thereunder and alleged that the defendants made false and materially misleading statements and failed to disclose adverse facts about our business, operations and prospects. The complaint asserted a putative class period extending from August 2, 2017 to February 5, 2019 and sought unspecified monetary relief, interest and attorneys’ fees. On June 6, 2024, Judge James Donato of the United States District Court for the Northern District of California granted final approval of a settlement resolving all claims in the Melucci litigation (the “Melucci Settlement”). As previously disclosed, the Melucci Settlement required us to make a one-time payment of \$14 million for which our insurers reimbursed us in full. On September 6, 2024, Judge Donato approved the Plan of Allocation for payment of the settlement funds to eligible members of the class of plaintiffs. This matter is closed.

In September 2019, a purported shareholder derivative complaint was filed in the United States District Court for the District of Delaware by Lauren Williams, captioned *Lauren Williams v. G. Leonard Baker, et al.*, Civil Action No. 1:19-cv-01830. A second nearly identical lawsuit was filed in December 2019 in the United States District Court for the District of Delaware by Jeweltex Pension Plan, captioned *Jeweltex Pension Plan v. James N. Wilson, et al.*, Civil Action No. 1:19-cv-02308. These complaints named the then-existing members of our board of directors, our Chief Executive Officer and our current Chief Business Officer as defendants, and Corcept as a nominal defendant. The complaints allege breach of fiduciary duty, violation of Section 14(a) of the Exchange Act, insider selling, misappropriation of insider information and waste of corporate assets and seek damages in an amount to be proved at trial. These actions had been stayed pending resolution of the Melucci litigation. On June 21, 2024, the United States District Court for the District of Delaware lifted the stays on the Williams and Jeweltex cases and consolidated these two cases into one case.



In January 2022, a purported shareholder derivative complaint was filed in the Delaware Court of Chancery by Joel B. Ritchie, captioned *Joel B. Ritchie v. G. Leonard Baker, et al.*, Case No. 2022-0102-SG. The complaint named certain members of our Board of Directors, our Chief Executive Officer, our current Chief Business Officer and our President of Corcept Endocrinology as defendants, and Corcept as nominal defendant. The complaint alleges a single cause of action for breach of fiduciary duty. The complaint seeks damages in an amount to be proved at trial. On March 22, 2024, the Court lifted a previously-entered stay, which had been pending the resolution of the Melucci litigation, and on May 3, 2024, we filed a Motion to Dismiss this complaint. We cannot predict when the Court will rule on this motion.

Given the overlapping allegations in these shareholder derivative actions, we and the individual defendants have filed a One Forum Motion in both the United States District Court for the District of Delaware and the Delaware Court of Chancery requesting that the Courts coordinate to determine in which jurisdiction (Federal or Chancery Court) these matters should first proceed. The Courts have not yet ruled on that Motion.

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

#### *Records Subpoena*

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

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

### **ITEM 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. There may be others of which we are unaware that could materially harm our business or financial condition and cause the price of our stock to decline, in which case you could lose all or part of your investment.*

#### **Summary of Principal Risks**

The following bullet points summarize the principal risks we face, each of which could adversely affect our business, operations and financial results. Below, we have arranged these risks by the part of our business they most directly affect.

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

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

- Vendors perform many of the activities necessary to carry out our clinical trials, including drug product distribution, trial management and oversight and data collection and analysis. Failure of these vendors to perform their duties or meet expected timelines may prevent or delay approval of our product candidates.
- Our efforts to discover, develop and commercialize our product candidates may not succeed. Clinical drug development is lengthy, expensive and often unsuccessful. Results of early studies and trials are often not predictive of

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

#### **Risks 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. Litigation is slow and expensive and its outcome is uncertain and subject to challenge on appeal.

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

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

#### **General Risk Factors**

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

#### **Risk Factors – Discussion**

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

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

##### **Failure to generate sufficient revenue from the sale of 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 if they determine that it is preferable to other treatments, even if those treatments are not approved for Cushing's syndrome. Most physicians are inexperienced diagnosing or caring for patients with Cushing's syndrome 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 physicians or payors for competing treatments for Cushing's syndrome, including a lower-priced generic version of Korlym and off-label treatments; and
- lack of availability of government or private insurance, the shift of a significant number of patients to Medicaid, which reimburses Korlym at a significantly lower price, or the introduction of government price controls or other price-reducing regulations, such as the Inflation Reduction Act of 2022, that may significantly limit Medicare reimbursement rates.

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

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

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

We also have litigation settlements with Sun and Hikma that allow them to begin selling mifepristone, with customary restrictions, provided the FDA has approved their products and Teva's generic product remains commercially available. The

availability of generic versions of Korlym from Sun or Hikma could materially harm our results of operations and financial condition, even if our on-going appeal against Teva is successful and Teva, Sun and Hikma were required to withdraw their products and pay us damages. Please see “Part II, Item 1, Legal Proceedings” for additional details.

The availability of generic Korlym could cause our revenue to decline and materially harm our results of operations and financial position, by reducing the number of tablets we sell or lowering their price. It may also cause our revenue to be materially less than the public guidance we have provided, which would likely cause the price of our common stock to decline.

Legal action to enforce or defend intellectual property rights is complex, costly and involves significant commitments of management time. Other companies may seek FDA approval to market generic versions of Korlym, in which case we will vigorously protect our intellectual property. However, there can be no assurance our efforts will be successful.

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

The active ingredient in Korlym, mifepristone, is approved by the FDA in another drug for the termination of early pregnancy. In 2022, the United States Supreme Court published its decision in the case of *Dobbs v. Jackson Women’s Health Organization* (“Dobbs”), which overturned *Roe v. Wade*, the 1973 Supreme Court decision that had established a woman’s right to terminate her pregnancy, subject to certain limitations. Dobbs has stimulated many states to enact laws restricting the legality of abortion and mifepristone, including during early pregnancy and under specific conditions of use. More laws banning or heavily restricting termination of pregnancy may be adopted and existing laws may be made more restrictive. On June 13, 2024, in a highly publicized case, the Supreme Court ruled against plaintiffs seeking to restrict access to mifepristone for terminating pregnancy, holding that they lacked standing (i.e., the right to sue), thus preserving current access to mifepristone. Because the Supreme Court’s decision was made solely on procedural grounds, the ruling does not necessarily foreclose other challenges to the continued availability of mifepristone. The timing and outcome of any subsequent cases, as well as additional legislative changes are uncertain. In addition, heightened public awareness of mifepristone as an abortifacient may draw the attention of hostile state government officials or political activists to Korlym – as could additional public debate concerning current or proposed restrictions on the distribution of mifepristone. This may be the case even though (i) Korlym is not approved for the termination of pregnancy, (ii) we do not promote it for that use and (iii) we have taken measures to minimize the chance that it will accidentally be prescribed to a pregnant woman.

**New laws, government regulations, or changes to existing laws and regulations could make it difficult or impossible for us to obtain acceptable prices or adequate insurance coverage and reimbursement for 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 IRA significantly changed the way Medicare pays for prescription drugs. The IRA requires the Secretary of the U.S. Department of Health and Human Services (“HHS”) to negotiate Medicare prices for selected drugs and biologicals, including both physician-administered products covered under Medicare’s Part B benefit and self-administered drugs such as Korlym that are covered under the Part D benefit. Each year, the Secretary will select for price negotiation a specified number of negotiation-eligible drugs with the highest total Part B or D expenditures over the preceding 12-month period. To be eligible for price negotiation a drug must have been on the market for at least seven years without generic competition. Orphan drugs indicated for only one rare disease or condition and drugs with less than \$200 million in annual Medicare expenditures are exempt from the negotiation program. For the first two years of the program, 2026 and 2027, only Part D drugs are eligible. The Secretary will publish the negotiated price, known as the “Maximum Fair Price” (“MFP”), for each of the selected products. Manufacturers of selected drugs would be required to offer the drug for Medicare recipients at the MFP. Manufacturers who fail to negotiate with the Secretary or offer their drug to Medicare recipients at the MFP can face significant civil money penalties or excise tax

liability on sales of that drug. If Korlym or any drug we commercialize becomes eligible for Medicare negotiation, the revenue we generate from sales of that drug may be significantly reduced.

The IRA also establishes an inflation rebate program that requires manufacturers to pay rebates to the Medicare program if any of the medications they provide Medicare recipients increase in price faster than the rate of inflation. The Part D inflation rebate provision went into effect on October 1, 2022. Although manufacturers are generally familiar with inflation rebates under the Medicaid program, where they have existed for decades, the IRA represents the first time that inflation rebates have been extended to the Medicare program. The inflation rebate provision applies to any medication sold to Medicare recipients, whether or not that medication is subject to Medicare price negotiation.

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

We make grants to independent charitable foundations that help financially needy patients with their premium, co-pay, and co-insurance obligations with respect to their Cushing's syndrome treatment, whether that treatment includes Korlym or not. There has been enhanced scrutiny of company-sponsored patient assistance programs, including insurance premium and co-pay assistance programs and donations to third-party charities that provide such assistance. As a result of this scrutiny, these assistance programs and charities may decide to reduce or eliminate entirely the assistance they provide to patients, which could result in fewer patients receiving the financial support they need to cover the cost of their Cushing's syndrome care, including the cost of medication, which may include Korlym.

We expect governmental oversight and scrutiny of pharmaceutical companies to increase and that there will be additional attempts to change the healthcare system in ways that could harm our ability to sell Korlym and any other drugs we commercialize profitably, including new policies intended to curb healthcare costs, such as federal and state controls on reimbursement for drugs (including under Medicare and commercial health plans), new or increased requirements to pay prescription drug rebates and penalties to government health care programs and policies that require drug companies to disclose and justify the prices they charge.

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

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

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

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

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

**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 other vendors in a timely manner, our business will be harmed.**

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

Our single specialty pharmacy, Optime, dispenses Korlym and performs related pharmacy and patient support services, including the collection of payments from insurers representing more than 99 percent of our revenue. If Optime does not adhere to its agreements with payers or does not continue to meet regulatory requirements concerning pharmacy operations, it may not be able to collect on our behalf some or all of the payments due to us. In addition, if Optime becomes unable or unwilling to perform its obligations under our agreement, we may not be able to dispense Korlym in a timely manner to some or all of our

patients. Effective April 1, 2024, we extended our agreement with Optime through March 31, 2027, with automatic renewal for successive three-year terms. The agreement is subject to customary termination provisions, including the right of Optime to terminate in the event of a material breach by us that we do not cure in a reasonable period of time after receiving written notice. In addition, we may terminate the agreement for convenience.

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

**Natural disasters, such as earthquakes, fires, extreme weather events or widespread outbreaks of a deadly disease such as COVID-19, could disrupt our commercial and clinical activities or damage or destroy clinical trial sites, our office spaces, the residences of our employees or the facilities or residences of our vendors, contractors or consultants, which could significantly harm our operations.**

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

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

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

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

**If we are unable to maintain regulatory approval of 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”), all of which are subject to change without notice and at the regulators’ sole discretion. Foreign regulatory authorities have comparable requirements and enforcement mechanisms, which are also subject to change. The FDA and other regulators enforce these regulations through inspections of us and the laboratories, manufacturers and clinical sites we use. Discovery of previously unknown problems with a product or product candidate, such as adverse events of unanticipated severity or frequency or deficiencies in manufacturing processes or management, as well as failure to comply with current or future FDA or other U.S. or foreign regulatory requirements, may subject us to substantial civil and criminal penalties, injunctions, holds on clinical trials, product seizure, refusal to permit the import or export of products, restrictions on product marketing, withdrawal of the product from the market, product recalls, total or partial suspension of production, refusal

to approve pending new drug applications (“NDAs”) or supplemental NDAs, and suspension or revocation of product approvals.

**We may be subject to civil or criminal penalties if our marketing of 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 “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 Patient Protection and Affordable Care Act (“ACA”) on drug manufacturers regarding any “transfer of value” made or distributed to physicians, certain non-physician practitioners, teaching hospitals, and ownership or investment interests held by physicians and their immediate family members;

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

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

In November 2021, we received a records subpoena from the United States Attorney’s Office for the District of New Jersey (the “NJ USAO”) seeking 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*” for additional details.

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

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

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

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

**Our efforts to discover, develop and secure regulatory approval for our product candidates may not succeed. Clinical drug development is lengthy, expensive and often unsuccessful. Results of early studies and trials are often not predictive of later trial results. Failure can occur at any time. Even if we deem that our product candidates’ clinical trial**

**results demonstrate safety and efficacy, regulatory authorities may not agree. Failure to obtain or maintain regulatory approvals for our product candidates would prevent us from commercializing them.**

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

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

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

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

A trial may also be suspended or terminated by us, the trial’s data safety monitoring board, the IRBs governing the sites where the trial is being conducted or the FDA for many reasons, including failure to comply with regulatory requirements or clinical protocols, negative findings in an inspection of our clinical trial operations or trial sites by the FDA or other authorities, unforeseen safety issues, failure to demonstrate a benefit or changes in government regulations.

At any time prior to the regulatory approval of a product candidate, we may decide, or the FDA or other regulatory authorities may require us, to conduct more pre-clinical or clinical studies, provide additional analysis of existing data or change the size or design of a trial already underway. Such additional or changed requirements, which regulators may impose in their sole discretion, may delay or prevent the completion of development, submission of an NDA or the completion of regulatory review, which would increase our costs and adversely impact future revenue. Even if we conduct the clinical trials and supportive studies that we consider appropriate and the results are positive, we may not receive regulatory approval. Following regulatory approval, there is no assurance of commercial success.

**We may be unable to obtain or maintain regulatory approvals for our 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*” for additional information.

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

## Risks Related to our Stock

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

We cannot assure investors that a liquid trading market for our common stock will exist at any particular time. As a result, holders of our common stock may not be able to sell shares quickly or at the current market price. During the 52-week period ended October 23, 2024, our average daily trading volume was 1,105,185 shares and the intra-day sales prices per share of our common stock on The Nasdaq Stock Market ranged from \$20.84 to \$50.07. As of October 23, 2024, our officers, directors and principal stockholders beneficially owned 21 percent of our common stock.

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

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

- actual or anticipated variations in our operating results or changes to any public guidance we have provided;
- actual or anticipated timing and results of our clinical trials;
- actual or anticipated regulatory approvals of our product candidates;
- disputes or other developments relating to our intellectual property, including developments in generic-related litigation;
- changes in laws or regulations applicable to the pricing, availability of insurance reimbursement, or approved uses of Korlym, our product candidates or our competitors’ products;
- short-selling of our common stock, the publication of negative opinions about our business or other market manipulation activities that are intended to lower our stock price or increase its volatility;
- sales of a substantial number of shares of our stock in the public market, leading to reductions in its price;
- changes in estimates or recommendations by securities analysts or the failure of our performance to meet the published expectations of those analysts or public guidance we have provided;
- purchases of our common stock pursuant to our stock repurchase program (the “Stock Repurchase Program”) or changes to that program;
- general market and economic conditions;
- changes in the expected or actual timing of our competitors’ development programs and the approval of competing products;
- purchases or sales of our common stock by our officers, directors or stockholders;

- technological innovations by us, our collaborators or our competitors;
- conditions in the pharmaceutical industry, including the market valuations of companies similar to ours;
- additions or departures of key personnel;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments; and
- additional financing activities.

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

The guidance we provide as to our expected revenue is only an estimate of what we believe is realizable at the time we give such guidance. Our revenue depends on many factors, including, without limitation, the efficacy of our sales and marketing efforts, the price we receive from private and government payors, competition from alternate treatments for patients with Cushing’s syndrome, including from generic versions of Korlym and changes in government regulations. Our guidance estimate considers all of these factors, but they are difficult to predict. As a result, our revenue may vary materially from our guidance. Research analysts publish estimates of our future revenue and earnings based on their own analysis. The revenue guidance we provide may be one factor they consider when determining their estimates. If our revenue is materially less than the guidance we or the research analysts who cover our stock provide investors, our stock price may decline.

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

Short sellers have, and likely will continue to, attempt to drive down the price of our common stock. Short selling is the practice of selling stock the seller does not own with the intention of buying it back later at a lower price, thereby profiting from any decline in the price of the stock between the time it is sold and the time it is repurchased. To support their efforts, short sellers often publish, or arrange for others to publish, negative opinions regarding the relevant issuer and its business prospects. These publications are often made to appear as if they were objective journalism or unbiased “research reports” of the type distributed by credible Wall Street firms and independent research analysts. Short seller publications are not regulated by any governmental, self-regulatory organization or other authority in the United States and the opinions they express are often based on distortions, omissions or fabrications. Short attacks supported by such publications have, in the past, led to selling of our stock and at least temporary reductions in its price. Companies that are subject to unfavorable allegations, even if untrue, may have to expend a significant amount of resources to investigate such allegations and/or defend themselves, including shareholder suits against the company that may be prompted by such allegations. We have been, and may in the future be, the subject of shareholder suits prompted by allegations made by short sellers.

#### **General Risk Factors**

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

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

- continue to add talented, experienced personnel to our endocrine, oncology and emerging markets businesses;
- manage our clinical trials, research and manufacturing activities effectively;
- hire more general management, clinical development, administrative and sales and marketing personnel; and
- continue to develop our administrative systems and controls.

Failure to accomplish any of these tasks could harm our business.

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

Our ability to operate successfully and manage growth depends upon hiring and retaining skilled managerial, scientific, sales, marketing and financial personnel. The job market for qualified personnel is intensely competitive and turnover rates

have reached record highs within our industry and the geographical areas from which we recruit. We depend on the principal members of our management and scientific staff. Any officer or employee may terminate his or her relationship with us at any time and work for a competitor. We do not have employment insurance covering any of our personnel. The loss of key individuals could delay our research, development and commercialization efforts.

**We are subject to regulations and other legal obligations relating to drug development and commercialization, the conduct of business as an issuer of publicly traded securities and individual privacy and data protection. Compliance with these obligations is complex and costly. Failure to comply could materially harm our business.**

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

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

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

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 have taken effect and other states, including Texas, Florida, Oregon and Montana, have passed similar laws that will take effect in or after 2024. As a result, additional compliance investment and potential business process changes may be required. In the event that we are subject to or affected by HIPAA, the CCPA, 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. We may continue to increase our cybersecurity risks, due to our reliance on internet technology and the number of our employees that are working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities.

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

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

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

Our earnings are subject to federal, state and local taxes. We offset a portion of our earnings using net operating losses and our taxes using research and development tax credits, which reduces the amount of tax we pay. Some jurisdictions require that we pay taxes or fees calculated as a percentage of sales, payroll expense, or other indicia of our activities. Please see “*Part I, Item 1, Notes to Unaudited Condensed Consolidated Financial Statements – Income Taxes.*” Changes to existing tax laws could materially increase the amounts we pay, which would reduce our after tax net income.

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

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

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

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

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

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

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

As of October 23, 2024, our officers and directors beneficially owned 21 percent of our common stock. Acting together, these stockholders could significantly influence any matter requiring approval by our stockholders, including the election of directors and the approval of mergers or other business combinations. The interests of this group may not always coincide with our interests or the interests of other stockholders and may prevent or delay a change in control. This significant concentration of share ownership may adversely affect the trading price of our common stock because many investors perceive disadvantages to owning stock in companies with controlling stockholders.

**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 repurchases of our common stock in the three months ended September 30, 2024 as part of our publicly announced stock repurchase program (in thousands, except average price per share):

<b>Fiscal Period</b>	<b>Total Number of Shares Repurchased</b>	<b>Average Price Paid Per Share</b>	<b>Dollar Amount of Shares That May Yet be Purchased Under the Program<sup>(1)</sup></b>
July 1, 2024 to July 31, 2024	—	\$ —	\$ —
August 1, 2024 to August 31, 2024	270	34.03	186,842
September 1, 2024 to September 30, 2024	74	33.97	184,329
Total	344	\$ 34.02	\$ 184,329

(1) On January 8, 2024, our Board of Directors authorized the repurchase of up to \$200 million of our common stock pursuant to our Stock Repurchase Program. The program may be modified, suspended or discontinued at any time without notice.

The following table contains information relating to the purchases of our common stock in the three months ended September 30, 2024 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>
July 1, 2024 to July 31, 2024	322	\$ 37.82	\$ 12,175
August 1, 2024 to August 31, 2024	116	36.23	4,218
September 1, 2024 to September 30, 2024	88	37.82	3,311
Total	526	\$ 37.47	\$ 19,704

(1) In July 2024, we issued 518,670 shares of common stock as part of a net-share settlement of a cashless option exercise, of which 315,870 shares were surrendered to us in satisfaction of related exercise cost and tax obligations. In August 2024, we issued 217,081 shares of common stock as part of a net-share settlement of a cashless option exercise, of which 99,831 shares were surrendered to us. In September 2024, we issued 156,227 shares of common stock as part of a net-share settlement of a cashless option exercise, of which 78,239 shares were surrendered to us.

In July 2024, we issued 17,023 shares of common stock as part of restricted stock vesting, of which 6,070 shares were surrendered to us in satisfaction of related tax obligations. In August 2024, we issued 46,575 shares of common stock as part of restricted stock vesting, of which 16,601 shares were surrendered to us. In September 2024, we issued 26,924 shares of common stock as part of restricted stock vesting, of which 9,323 shares were surrendered to us.

(2) We paid \$11.7 million to satisfy the tax withholding obligations associated with the net-share settlement of these cashless option exercises and vesting of restricted stock.

### ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

### ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

## ITEM 5. OTHER INFORMATION

### Insider Trading Arrangements

During the quarter ended September 30, 2024, none of our directors and officers (as defined in Rule 16a-1(f) under the Exchange Act) adopted or terminated any contract, instruction or written plan for the purchase or sale of our securities that are intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) of the Securities Exchange Act of 1934, as amended, or any “non-Rule 10b5-1 trading arrangement,” as defined in Item 408(a) of Regulation S-K, other than as set forth in the table below.

Name	Position	Action	Adoption Date	Total Shares of Common Stock to be Sold	Expiration Date <sup>(1)</sup>
Daniel Swisher	Director	Adoption	8/1/2024	Up to 26,400	10/13/2025
Joseph D. Lyon	Chief Accounting and Technology Officer	Adoption	8/30/2024	Up to 260,000	12/31/2025
Sean Maduck	President, Endocrinology	Adoption	9/5/2024	Up to 340,000	12/31/2025

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



**ITEM 6. EXHIBITS**

<b>Exhibit Number</b>	<b>Description of Document</b>
3.1	<a href="#"><u>Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the registrant's Current Report on Form 8-K filed on May 24, 2023).</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 December 11, 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 September 30, 2024, formatted in Extensible Business Reporting Language (XBRL): (i) Unaudited Condensed Consolidated Balance Sheets at September 30, 2024 and December 31, 2023, (ii) Unaudited Condensed Consolidated Statements of Income for the three and nine month periods ended September 30, 2024 and 2023, (iii) Unaudited Condensed Consolidated Statements of Comprehensive Income for the three and nine month periods ended September 30, 2024 and 2023, (iv) Unaudited Condensed Consolidated Statements of Cash Flows for the nine month periods ended September 30, 2024 and 2023, (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: October 30, 2024

/s/ Joseph K. Belanoff

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

Date: October 30, 2024

/s/Atabak Mokari

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

Date: October 30, 2024

/s/Joseph D. Lyon

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

**CERTIFICATION**

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

1. I have reviewed this Quarterly Report on Form 10-Q for the period ended September 30, 2024 of Corcept Therapeutics Incorporated;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer 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  
October 30, 2024

**CERTIFICATION**

I, Atabak Mokari, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the period ended September 30, 2024 of Corcept Therapeutics Incorporated;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer 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  
October 30, 2024

**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 September 30, 2024, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Joseph K. Belanoff, M.D., Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

/s/ Joseph K. Belanoff

Joseph K. Belanoff, M.D.  
Chief Executive Officer and President  
October 30, 2024

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 September 30, 2024, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Atabak Mokari, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

/s/ Atabak Mokari

Atabak Mokari  
Chief Financial Officer  
October 30, 2024

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.