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, 2021

or

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

For the transition period from to

Commission File Number:
000-50679

CORCEPT THERAPEUTICS INCORPORATED

(Exact Name of Corporation as Specified in Its Charter)

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

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

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

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

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

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

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

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

Large accelerated filer	☒	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 27, 2021, there were 115,451,895 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)

	September 30, 2021	December 31, 2020
	(Unaudited)	(See Note 1)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 94,688	$ 76,190
Short-term marketable securities	266,643	364,506
Trade receivables, net of allowances	26,508	26,198
Inventory	4,994	4,910
Prepaid expenses and other current assets	9,067	6,697
Total current assets	401,900	478,501
Strategic inventory	13,659	16,247
Operating lease right-of-use asset	1,022	2,509
Property and equipment, net of accumulated depreciation	1,226	1,675
Long-term marketable securities	133,845	36,196
Other assets	4,106	5,000
Deferred tax assets, net	29,641	31,603
Total assets	$ 585,399	$ 571,731
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 6,558	$ 10,554
Accrued clinical expenses	12,844	13,704
Accrued and other liabilities	24,309	21,186
Short-term operating lease liability	1,046	2,050
Total current liabilities	44,757	47,494
Long-term operating lease liability	—	501
Long-term accrued income taxes	413	398
Total liabilities	45,170	48,393
Commitments and contingencies (Note 4)		
Stockholders' equity:		
Preferred stock	—	—
Common stock	126	122
Additional paid-in capital	571,377	516,140
Treasury stock	(194,304)	(75,795)
Accumulated other comprehensive income	115	415
Retained earnings	162,915	82,456
Total stockholders' equity	540,229	523,338
Total liabilities and stockholders' equity	$ 585,399	$ 571,731

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, except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	**2020**	**2021**	**2020**
Product revenue, net	$ 96,131	$ 86,327	$ 267,156	$ 268,139
Operating expenses:				
Cost of sales	1,275	1,216	3,927	4,328
Research and development	28,091	33,869	85,345	86,489
Selling, general and administrative	30,533	26,523	90,071	79,630
Total operating expenses	59,899	61,608	179,343	170,447
Income from operations	36,232	24,719	87,813	97,692
Interest and other income	72	622	457	3,103
Income before income taxes	36,304	25,341	88,270	100,795
Income tax expense	(5,833)	(3,716)	(7,811)	(20,778)
Net income	30,471	21,625	80,459	80,017
Other comprehensive income:				
Net unrealized gain (loss) on available-for-sale investments, net of tax effect of $8, $109, $85 and $(81), respectively	(23)	(347)	(265)	259
Foreign currency translation gain (loss), net of tax	(77)	84	(35)	57
Total comprehensive income	$ 30,371	$ 21,362	$ 80,159	$ 80,333
Basic net income per share	$ 0.26	$ 0.19	$ 0.69	$ 0.70
Diluted net income per share	$ 0.24	$ 0.17	$ 0.63	$ 0.65
Weighted-average shares outstanding used in computing net income per share				
Basic	115,791	115,734	116,297	115,107
Diluted	125,136	124,464	127,173	123,337

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)

	Nine Months Ended September 30,	
	2021	**2020**
Cash flows from operating activities:		
Net income	$ 80,459	$ 80,017
Adjustments to reconcile net income to net cash provided by operations:		
Stock-based compensation	32,121	25,109
Deferred income taxes	2,047	11,778
Amortization of interest income	3,805	404
Depreciation and amortization of property and equipment	783	447
Non-cash amortization of right-of-use asset	1,487	1,228
Others	—	148
Changes in operating assets and liabilities:		
Trade receivables	(310)	(2,029)
Inventory	2,655	694
Prepaid expenses and other current assets	(2,288)	(1,882)
Other assets	894	(1,562)
Accounts payable	(3,961)	(988)
Accrued clinical expenses	(860)	9,055
Accrued and other liabilities	3,138	(4,315)
Operating lease liability	(1,505)	(1,205)
Net cash provided by operating activities	118,465	116,899
Cash flows from investing activities:		
Purchases of property and equipment	(404)	(807)
Proceeds from maturities of marketable securities	308,864	193,418
Purchases of marketable securities	(312,805)	(323,094)
Net cash used in investing activities	(4,345)	(130,483)
Cash flows from financing activities:		
Proceeds from exercise of stock options, net of issuance costs	13,182	13,240
Repurchase of common stock	(88,485)	(275)
Cash paid to satisfy statutory withholding requirement for net settlement of cashless option exercises	(20,319)	(90)
Net cash (used in) provided by financing activities	(95,622)	12,875
Net increase (decrease) in cash and cash equivalents	18,498	(709)
Cash and cash equivalents, at beginning of period	76,190	31,269
Cash and cash equivalents, at end of period	$ 94,688	$ 30,560
Supplemental disclosure:		
Cost of shares repurchased for net settlement of cashless option exercises	$ 9,705	$ 900
Recognition of right-of-use asset and lease liability	$ —	$ 775

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	Retained Earnings (Accumulated Deficit)	Total Stockholders' Equity
	Shares	Amount					
Balance at December 31, 2019	114,549	$ 120	$ 457,060	$ (62,704)	$ 261	$ (23,555)	$ 371,182
Issuance of common stock upon exercise of options	67	—	480	—	—	—	480
Purchases of treasury stock	(20)	—	—	(275)	—	—	(275)
Stock-based compensation	—	—	7,988	—	—	—	7,988
Other comprehensive income, net of tax	—	—	—	—	49	—	49
Net income	—	—	—	—	—	30,065	30,065
Balance at March 31, 2020	114,596	120	465,528	(62,979)	310	6,510	409,489
Issuance of common stock upon exercise of options	1,011	1	7,638	—	—	—	7,639
Shares purchased to satisfy cost and statutory withholding requirements for net settlement of cashless option exercises	(54)	—	—	(835)	—	—	(835)
Stock-based compensation	—	—	8,548	—	—	—	8,548
Other comprehensive income, net of tax	—	—	—	—	530	—	530
Net income	—	—	—	—	—	28,327	28,327
Balance at June 30, 2020	115,553	121	481,714	(63,814)	840	34,837	453,698
Issuance of common stock upon exercise of options	626	—	6,020	—	—	—	6,020
Shares purchased to satisfy cost and statutory withholding requirements for net settlement of cashless option exercises	(11)	—	—	(155)	—	—	(155)
Stock-based compensation	—	—	8,755	—	—	—	8,755
Other comprehensive income, net of tax	—	—	—	—	(263)	—	(263)
Net income	—	—	—	—	—	21,625	21,625
Balance at September 30, 2020	116,168	$ 121	$ 496,489	$ (63,969)	$ 577	$ 56,462	$ 489,680
Balance at December 31, 2020	116,735	$ 122	$ 516,140	$ (75,795)	$ 415	$ 82,456	$ 523,338
Issuance of common stock upon exercise of options	1,832	2	10,081	—	—	—	10,083
Purchases of treasury stock	(1,282)	—	—	(33,540)	—	—	(33,540)
Shares purchased to satisfy cost and statutory withholding requirements for net settlement of cashless option exercises	(808)	—	—	(22,520)	—	—	(22,520)
Stock-based compensation	—	—	10,142	—	—	—	10,142
Other comprehensive loss, net of tax	—	—	—	—	(166)	—	(166)
Net income	—	—	—	—	—	23,465	23,465
Balance at March 31, 2021	116,477	124	536,363	(131,855)	249	105,921	510,802
Issuance of common stock upon exercise of options	855	1	6,660	—	—	—	6,661
Purchases of treasury stock	(1,365)	—	—	(29,170)	—	—	(29,170)
Shares purchased to satisfy cost and statutory withholding requirements for net settlement of cashless option exercises	(146)	—	—	(3,238)	—	—	(3,238)
Stock-based compensation	—	—	11,131	—	—	—	11,131
Other comprehensive loss, net of tax	—	—	—	—	(34)	—	(34)
Net income	—	—	—	—	—	26,523	26,523
Balance at June 30, 2021	115,821	125	554,154	(164,263)	215	132,444	522,675
Issuance of common stock upon exercise of options	904	1	6,224	—	—	—	6,225
Purchases of treasury stock	(1,220)	—	—	(25,775)	—	—	(25,775)
Shares purchased to satisfy cost and statutory withholding requirements for net settlement of cashless option exercises	(202)	—	—	(4,266)	—	—	(4,266)

Stock-based compensation	—	—	10,999	—	—	—	10,999
Other comprehensive loss, net of tax	—	—	—	—	(100)	—	(100)
Net income	—	—	—	—	—	30,471	30,471
Balance at September 30, 2021	115,303	$ 126	$ 571,377	$ (194,304)	$ 115	$ 162,915	$ 540,229

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

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

Basis of Presentation

We have prepared the following in accordance with U.S. generally accepted accounting principles ("GAAP") for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X: (i) condensed consolidated balance sheet as of September 30, 2021, (ii) condensed consolidated statements of comprehensive income and stockholders' equity for the three- and nine-month periods ended September 30, 2021 and 2020 and (iii) condensed consolidated statements of cash flows for the nine-month periods ended September 30, 2021 and 2020. 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, 2021 are not necessarily indicative of the results for the remainder of 2021 or any other period. These financial statements and notes should be read in conjunction with the consolidated financial statements for the year ended December 31, 2020 included in our Annual Report on Form 10-K. The December 31, 2020 consolidated balance sheet was derived from audited financial statements at that date.

There have been no material changes in the significant accounting policies described in our Annual Report on Form 10-K for the year ended December 31, 2020.

Recently Adopted Accounting Pronouncement

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

2. Composition of Certain Balance Sheet Items

Inventory

	September 30, 2021	December 31, 2020
	(in thousands)	
Raw materials	$ —	$ 1,685
Work in progress	13,727	12,916
Finished goods	4,926	6,556
Total inventory	18,653	21,157
Less strategic inventory classified as non-current	(13,659)	(16,247)
Total inventory classified as current	$ 4,994	$ 4,910

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

Property and Equipment

	September 30, 2021	December 31, 2020
	(in thousands)	
Furniture and equipment	$ 1,093	$ 810
Software	1,508	1,485
Leasehold improvements	1,261	1,233
Total property and equipment	3,862	3,528
Less accumulated depreciation	(2,636)	(1,853)
Property and equipment, net of accumulated depreciation	$ 1,226	$ 1,675

Accrued and other liabilities

	September 30, 2021	December 31, 2020
	(in thousands)	
Government rebates	$ 11,146	$ 9,412
Accrued compensation	10,474	10,144
Accrued selling and marketing costs	871	665
Legal fees	756	612
Professional fees	544	151
Other	518	202
Total accrued and other liabilities	$ 24,309	$ 21,186

Other assets

As of September 30, 2021 and December 31, 2020, other assets included $3.9 million and $4.8 million of deposits for clinical trials, respectively.

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

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

	September 30, 2021	December 31, 2020
	(in thousands)	
Cash equivalents	$ 73,180	$ 50,524
Short-term marketable securities	266,643	364,506
Long-term marketable securities	133,845	36,196
Total marketable securities	$ 473,668	$ 451,226

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

		September 30, 2021				December 31, 2020			
	Fair Value Hierarchy Level	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
		(in thousands)							
Corporate bonds	Level 2	$ 135,204	$ 15	$ (37)	$ 135,182	$ 96,999	$ 74	$ (9)	$ 97,064
Commercial paper	Level 2	127,395	—	—	127,395	139,791	—	—	139,791
Asset-backed securities	Level 2	63,220	6	(49)	63,177	39,243	15	(1)	39,257
U.S. treasury securities	Level 1	74,726	9	(1)	74,734	124,461	131	(2)	124,590
Money market funds	Level 1	73,180	—	—	73,180	50,524	—	—	50,524
Total marketable securities		$ 473,725	$ 30	$ (87)	$ 473,668	$ 451,018	$ 220	$ (12)	$ 451,226

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

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

Unrealized losses on our available-for-sale debt securities as of September 30, 2021 were not material. Accordingly, we have not recorded an allowance for credit losses associated with these investments.

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.

We classified accrued interest on our marketable securities of $1.4 million and $1.3 million as of September 30, 2021 and December 31, 2020, respectively, as prepaid and other current assets on our condensed consolidated balance sheets.

As of September 30, 2021, all our marketable securities had original maturities of less than two years. The weighted-average maturity of our holdings was eight months. As of September 30, 2021, our long-term marketable securities had remaining maturities ranging from 13 to 22 months. None of our marketable securities changed from one fair value hierarchy to another during the three and nine months ended September 30, 2021.

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, 2020.

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.

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

5. Stockholders' Equity

Stock Option Plans

We have two stock option plans – the 2004 Equity Incentive Plan (the "2004 Plan") and the 2012 Incentive Award Plan (the "2012 Plan"). In February 2021, our Board of Directors authorized a 4.7 million increase in the shares available for grant under the 2012 Plan.

During the three and nine months ended September 30, 2021, we issued 0.9 million and 3.6 million shares of our common stock, respectively, upon the exercise of stock options. Certain option holders exercised their options on a "net exercise" basis, pursuant to which they surrendered to us, and we purchased from them at the current market price, enough shares to cover the exercise price and tax withholding requirements arising from the exercise. During the three and nine months ended September 30, 2021, we purchased 0.2 million and 1.2 million shares, respectively, in connection with such option net exercises. In connection with the shares purchased, during the three and nine months ended September 30, 2021, we paid $2.3 million and $20.3 million, respectively, to satisfy the tax withholding obligations associated with the net-share settlement of these cashless option exercises. We recorded these shares as treasury stock on our condensed consolidated balance sheets, at cost.

During the three and nine months ended September 30, 2020, we issued 0.6 million and 1.7 million shares of our common stock upon the exercise of stock options, respectively.

Stock Repurchase Program

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

The Stock Repurchase Program expired by its terms on September 30, 2021.

During the three and nine months ended September 30, 2021, we repurchased 1.2 million and 3.9 million shares of common stock under the Stock Repurchase Program in open market transactions at an average price of $21.13 and $22.88 per share, for an aggregate purchase price of $25.8 million and $88.5 million, respectively. Over the term of the Stock Repurchase Program, we repurchased 4.3 million shares at an average price of $22.69 per share and a total cost of $98.2 million.

We recorded repurchased shares as treasury stock on our condensed consolidated balance sheets, at cost. As of September 30, 2021 and December 31, 2020 we had 10.9 million and 5.3 million treasury shares outstanding, respectively.

Stock-based compensation

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
		(in thousands)		
Stock-based compensation capitalized in inventory	$ 47	$ 53	$ 151	$ 182
Cost of sales	12	13	38	51
Research and development	3,434	2,958	10,764	8,357
Selling, general and administrative	7,506	5,731	21,319	16,701
Total stock-based compensation	$ 10,999	$ 8,755	$ 32,272	$ 25,291

6. Net Income Per Share

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
	(in thousands)			
Numerator:				
Net income	$ 30,471	$ 21,625	$ 80,459	$ 80,017
Denominator:				
Weighted-average shares used to compute basic net income per share	115,791	115,734	116,297	115,107
Dilutive effect of employee stock options	9,345	8,730	10,876	8,230
Weighted-average shares used to compute diluted net income per share	125,136	124,464	127,173	123,337
Net income per share				
Basic	$ 0.26	$ 0.19	$ 0.69	$ 0.70
Diluted	$ 0.24	$ 0.17	$ 0.63	$ 0.65

As of September 30, 2021 and 2020, we had 25.5 million and 26.0 million stock options outstanding, respectively.

Because including them would have reduced dilution, we excluded from the computation of diluted net income per share 5.3 million and 4.1 million stock options outstanding, on a weighted-average basis, during the three and nine months ended September 30, 2021, respectively, and 10.5 million and 12.7 million stock options outstanding during the three and nine months ended September 30, 2020, respectively.

7. Income Taxes

We recorded income tax expense of $5.8 million and $7.8 million for the three and nine months ended September 30, 2021, respectively. In the three and nine months ended September 30, 2020, respectively, our income tax expense was $3.7 million and $20.8 million. The increase in income tax expense during the three months ended September 30, 2021 was primarily due to increased net income compared to the corresponding period in 2020. The decrease in income tax expense during the nine months ended September 30, 2021 compared to the corresponding period in 2020 was primarily due to increased excess tax benefits for stock option exercises.

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 tax benefits for research and development tax 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, 2021, unrecognized tax benefits increased by $0.6 million and $1.4 million, respectively. As of September 30, 2021, the Company had unrecognized tax benefits of $7.2 million that, if recognized, would affect the Company’s effective tax rate and approximately $1.8 million of unrecognized tax benefits that would not impact the effective tax rate as they would be offset by a corresponding change in valuation allowance.

Each quarter, we assess the likelihood that we will generate sufficient taxable income to make use of our federal and state deferred tax assets. If we believe that recovery of these deferred tax assets is not more likely than not, we establish a valuation allowance offsetting such assets on our balance sheet. Significant judgment is required in assessing the need for a valuation allowance. We consider all available evidence, including our recent operating results and our forecasts of future taxable income. Other than valuation allowances against our California net deferred tax assets, we have determined that it is more likely than not we will realize the benefit related to all other deferred tax assets. To the extent we increase a valuation allowance, we include an expense in the Condensed Consolidated Statement of Comprehensive Income in the period in which we make that determination.

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 statements within the meaning of the federal securities laws. For a complete discussion of such forward-looking statements and the potential risks and uncertainties that may affect their accuracy, see 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 drugs that treat severe metabolic, oncologic and psychiatric disorders by modulating the effects of the hormone cortisol. Since 2012, we have marketed Korlym (mifepristone) for the treatment of patients suffering from Cushing's syndrome. Our portfolio of proprietary selective cortisol modulators consists of four structurally distinct series totaling more than 1,000 compounds.

Cushing's Syndrome

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

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

We hold patents listed in the United States Food and Drug Administration's ("FDA's") Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") covering uses of Korlym in the treatment of patients with Cushing's syndrome, with additional patent applications that may be suitable for listing in the Orange Book under review by the U.S. Patent and Trademark Office. Our Orange Book patents have expiration dates ranging from 2028 to 2038.

Relacorilant. We are conducting two Phase 3 trials (named GRACE and GRADIENT) of our proprietary, selective cortisol modulator, relacorilant, as a treatment for patients with Cushing's syndrome. Relacorilant was well-tolerated in its Phase 1 and Phase 2 trials. Patients in the Phase 2 trial exhibited meaningful improvements in glucose control, hypertension, weight loss, liver function, coagulopathy, cognition, mood, insulin resistance and quality of life measures. Relacorilant shares Korlym's affinity for 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 the effects associated with PR affinity, including endometrial thickening and vaginal bleeding. Relacorilant also does not appear to cause hypokalemia (low potassium), a potentially serious adverse event that is a leading cause of patients stopping treatment with Korlym. Forty-four percent of patients in Korlym's pivotal trial experienced hypokalemia.

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

Our second Phase 3 trial of relacorilant, GRADIENT, is studying patients whose Cushing's syndrome is caused by a benign adrenal tumor. These patients often exhibit less severe symptoms or have a more gradual course of disease than patients with other etiologies of Cushing's syndrome, although their health outcomes are ultimately poor. Half of the patients in

GRADIENT will receive relacorilant for 26 weeks and half will receive placebo. The trial's primary endpoints are improvement in glucose metabolism and hypertension. The planned enrollment for this study is 130 patients. Many of the clinical sites in GRACE are participating in GRADIENT.

The FDA and the 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

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

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

Patients in both of the relacorilant plus nab-paclitaxel treatment arms experienced longer PFS than did the patients who received nab-paclitaxel alone. Patients who received a higher dose of relacorilant intermittently exhibited a statistically significant improvement in median PFS (5.6 months versus 3.8 months, hazard ratio: 0.66; p-value: <0.05). Patients who received a lower dose of relacorilant daily exhibited a median PFS that was 1.5 months longer than did the patients who received nab-paclitaxel alone (5.3 months versus 3.8 months, hazard ratio: 0.83; p-value: not significant). Patients who received relacorilant intermittently also had a longer median duration of response (5.6 months versus 3.7 months, hazard ratio: 0.36; p-value: 0.006) compared to those who received nab-paclitaxel alone. While the overall survival ("OS") data was only 63% mature at the time of the database cut-off (March 2021), the women who received relacorilant intermittently exhibited a median OS of 12.9 months versus 10.4 months for those who received nab-paclitaxel alone (hazard ratio: 0.63; p-value: 0.12). We expect updated overall survival data from the Phase 2 trial in the first quarter of 2022. Safety and tolerability of relacorilant plus nab-paclitaxel was comparable to nab-paclitaxel monotherapy. Based on these positive results, we plan to initiate a pivotal Phase 3 trial in the first quarter of 2022.

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

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

Metabolic Diseases

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

In 2020, we completed a double-blind, placebo-controlled Phase 1b trial, in which 96 healthy subjects received daily doses of the antipsychotic medication olanzapine (10 mg) and either miricorilant (600 mg or 900 mg) or placebo for 14 days. Study participants who received miricorilant gained less weight than subjects receiving placebo. In addition, markers of liver damage that rise temporarily at the start of olanzapine therapy increased less sharply in subjects receiving miricorilant. The results of this study were published in the *Journal of Clinical Psychopharmacology* (Hunt et al., 2021) and are consistent with the findings of similar studies we conducted in healthy volunteers using mifepristone (published in *Advances in Therapy and Obesity* in 2009 and 2010).

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

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

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

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

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

Continued Discovery and Development

Our selective cortisol modulator CORT113176, which has shown promise in animal models of amyotrophic lateral sclerosis (“ALS”), has completed its Phase 1 trial. We plan to advance it to Phase 2 as a potential treatment for that disease. In addition, we continue to identify selective cortisol modulators and plan to advance the most promising of them towards the clinic.

COVID-19 Pandemic

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

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

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

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

Please see the risk factor under Item 1A of this Quarterly Report, “*The COVID-19 pandemic has adversely affected and is continuing to adversely affect our business. Other public health emergencies, natural disasters, terrorism or other*

catastrophes could disrupt our activities and render our own or our vendors' facilities and equipment inoperable or inaccessible and require us to curtail or cease operations."

Results of Operations

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

Net product revenue was $96.1 million and $267.2 million for the three and nine months ended September 30, 2021, respectively, compared to $86.3 million and $268.1 million for the comparable periods in 2020. For the three months ended September 30, 2021, higher sales volume accounted for 60.7% of the increase as we shipped Korlym to more patients. An increase in the average price of Korlym, due to a price increase effective March 1, 2021, accounted for the remaining growth. For the nine months ended September 30, 2021, the decrease in net product revenue was due to lower sales volume, partially offset by an increase in the Korlym's average price. The decrease in tablet shipments was primarily due to the effects of the COVID-19 pandemic on our business in the three months ended March 31, 2021.

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

Cost of sales was $1.3 million and $3.9 million for the three and nine months ended September 30, 2021, respectively, compared to $1.2 million and $4.3 million for the comparable periods in 2020. Cost of sales as a percentage of revenue was 1.3 percent and 1.5 percent for the three and nine months ended September 30, 2021, respectively, compared to 1.4 percent and 1.6 percent for the comparable periods in 2020. The decrease in cost of sales as a percentage of revenue for the nine months ended September 30, 2021 was due to reduced manufacturing costs.

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

Research and development expense was $28.1 million and $85.3 million for the three and nine months ended September 30, 2021, respectively, compared to $33.9 million and $86.5 million for the comparable period in 2020. The decreases were primarily due to a decline in spending on our oncology program due to timing and completion of patient enrollments in our clinical trials. The decreases were partially offset by increased spending on the advancement of our pre-clinical programs and on the compensation of development personnel.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020[1]	2021	2020[1]
	(in thousands)			
Development programs:				
Oncology	$ 4,521	$ 9,375	$ 12,549	$ 27,712
Cushing's syndrome	5,779	6,827	21,893	19,011
Metabolic diseases	5,009	7,823	16,129	15,399
Pre-clinical and early-stage selective cortisol modulators	6,379	5,071	16,736	10,645
Unallocated activities, including manufacturing and regulatory activities	2,969	1,815	7,274	5,365
Stock-based compensation	3,434	2,958	10,764	8,357
Total research and development expense	$ 28,091	$ 33,869	$ 85,345	$ 86,489

[1] Beginning in the first quarter of 2021, expenses for the three and nine months ended September 30, 2020 previously allocated to oncology and endocrinology were re-allocated between Cushing's syndrome, metabolic diseases and pre-clinical development programs.

It is difficult to predict the timing and cost of development activities, which are subject to many uncertainties and risks, including inconclusive or negative results, slow patient enrollment, adverse side effects, difficulties in the formulation or manufacture of study drugs and 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 in 2021 to be

approximately the same as our research and development expense in 2020. 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 expenses - Selling, general and administrative expenses include (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 $30.5 million and $90.1 million for the three and nine months ended September 30, 2021, respectively, compared to $26.5 million and $79.6 million for the comparable periods in 2020. The increases were due to increased employee compensation and sales and marketing expenses.

We expect our selling, general and administrative expenses in 2021 to be higher than in 2020 due to increased commercial and administrative activities, including litigation and administrative support for increased research and development.

Interest and other income - Interest and other income was $0.1 million and $0.5 million for the three and nine months ended September 30, 2021, respectively, compared to $0.6 million and $3.1 million for the comparable periods in 2020. The decreases in interest and other income were due to market wide reductions in interest rates.

Income tax expense - We recorded income tax expense of $5.8 million and $7.8 million for the three and nine months ended September 30, 2021, respectively, compared to $3.7 million and $20.8 million for the comparable periods in 2020. The increase in income tax expense during the three months ended September 30, 2021 was primarily due to an increase in net income compared to the corresponding period in 2020. The decrease in income tax expense during the nine months ended September 30, 2021 was primarily due to increased excess tax benefits for stock option exercises, compared to the corresponding period in 2020.

Liquidity and Capital Resources

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

Based on our current plans and expectations, we expect to fund our operations and planned research and development activities 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, 2021, we had cash, cash equivalents and marketable securities of $495.2 million, consisting of cash and cash equivalents of $94.7 million and marketable securities of $400.5 million, compared to cash, cash equivalents and marketable securities of $476.9 million, consisting of cash and cash equivalents of $76.2 million and marketable securities of $400.7 million as of December 31, 2020.

The cash in our bank accounts and our marketable securities could be affected if the financial institutions 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 loss or lack of access to cash.

Net cash provided by operating activities was $118.5 million for the nine months ended September 30, 2021, compared to $116.9 million for the comparable period in 2020. The increase was primarily due to higher net income as a result of lower income tax expense.

Net cash used in investing activities was $4.3 million for the nine months ended September 30, 2021, compared to $130.5 million for the comparable period in 2020. The change in net cash from investing activities was primarily due to our use of cash for financing activities (specifically, the repurchase of our common stock) instead of increasing our investment in marketable securities.

In the nine months ended September 30, 2021, we spent $108.8 million acquiring shares of our common stock ($88.5 million pursuant to our Stock Repurchase Program and $20.3 million in connection with the net exercise of employee and director stock options), offset by $13.2 million received from the exercise of stock options, resulting in net cash used in financing activities of $95.6 million. In the comparable period in 2020, we spent $0.3 million to acquire from our Chief Executive Officer shares of our common stock at the then-current market price to provide him with liquidity to satisfy the tax liability arising from his net exercise in 2019 of stock options, offset by $13.2 million received from the exercise of stock options, resulting in net cash provided by financing activities of $12.9 million.

As of September 30, 2021, we had retained earnings of $162.9 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, 2020. Our payment obligations and purchase commitments did not change materially during the nine months ended September 30, 2021. See Note 4 to our Unaudited Condensed Consolidated Financial Statements for more information regarding our purchase commitments.

Off-Balance Sheet Arrangements

None.

Critical Accounting Policies and Estimates

Our condensed consolidated financial statements have been prepared in accordance with U.S. GAAP, which requires us to make estimates and judgments that affect the amount of assets, liabilities and expenses we report. We base our estimates on historical experience and on other assumptions we believe to be reasonable. Actual results may differ from our estimates. Our significant accounting policies are discussed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2020. 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, 2021 are disclosed in our Annual Report on Form 10-K for the year ended December 31, 2020. The market risks associated with our cash, cash equivalents and marketable securities, which consist entirely of debt instruments with original maturities of less than 24 months, did not change materially during the nine months ended September 30, 2021.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of disclosure controls and procedures. As of September 30, 2021, our management conducted an evaluation, under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer, of the effectiveness of 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, 2021, 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. During the quarter ended March 31, 2021, we completed the implementation of an enterprise resource planning ("ERP") system, which we expect will improve the efficiency of certain financial and related transactional processes. We have changed our internal controls so that they continue to operate effectively following the ERP implementation. Our Chief Financial Officer and other members of management have evaluated the changes in our internal control over financial reporting during the quarter ended September 30, 2021 and concluded that there was no change during the quarter that materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

Teva ANDA Litigation

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

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

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

On May 7, 2019, Teva submitted to the PTAB a petition for post-grant review ("PGR") of the '214 patent. On November 20, 2019, the PTAB agreed to initiate the PGR, and issued a decision upholding the validity of the '214 patent against all of Teva's claims on November 19, 2020. On March 12, 2021, Teva appealed its loss to the Federal Circuit Court of Appeals. Oral argument in this case was heard October 5, 2021. There is no timetable for the Federal Circuit to issue its decision.

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

Sun ANDA Litigation and Settlement

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

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

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

Hikma ANDA Litigation

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

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

On March 12, 2021, we filed a lawsuit in the U.S. District Court for the District of New Jersey against Hikma for infringement of the '214 patent, the '216 patent, U.S. Patent Nos. 10,842,800, and U.S. Patent Nos. 10,842,801. The 30-month stay of FDA approval of Hikma's ANDA expires on August 1, 2023. Hikma responded to our complaint on May 17, 2021,

denying our claims. On July 13, 2021, the Court entered a schedule for the case setting a fact discovery deadline of July 1, 2022.

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

Other matters

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

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

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

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

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

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

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

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

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

ITEM 1A. RISK FACTORS

Investing in our common stock involves significant risks. Before investing, carefully consider the risks described below and the other information in this quarterly report, including our condensed consolidated financial statements and related notes. The risks and uncertainties described below are the ones we believe may materially affect us. Many of them have been or may

become exacerbated by the COVID-19 pandemic. There may be others of which we are unaware that could materially harm our business or financial condition and cause the price of our stock to decline, in which case you could lose all or part of your investment.

Summary of Principal Risks

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

Risks Related to our Commercial Activities

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

Risks Related to our Research and Development Activities

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

Risks 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.

Risks Relating to our Intellectual Property

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

Risks Related to our Stock

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

General Risks

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

Risk Factors - Discussion

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

Risks Related to our Commercial Activities

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

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

Many factors could limit our Korlym revenue, including:

- the preference of some physicians for competing treatments for Cushing's syndrome, including off-label treatments and generic versions of Korlym, should any be introduced;
- natural disasters or other catastrophes, such as the COVID-19 pandemic, that reduce the ability or willingness of physicians to see patients or of patients to bear the risk of leaving their homes to seek medical care; and
- lack of availability of government or private insurance, the shift of a significant number of patients to Medicaid, which reimburses Korlym at a significantly lower price or the introduction of government price controls or other price-reducing regulations.

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

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

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

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

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

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

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

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

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

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

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

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

Xeris Biopharma Holdings, Inc. ("Xeris") has received orphan drug designation in the United States and the EU for the use of the cortisol synthesis inhibitor levoketoconazole to treat patients with Cushing's syndrome. Levoketoconazole is an enantiomer of the generic anti-fungal medication, ketoconazole, that is prescribed off-label to treat patients with Cushing's syndrome. Xeris completed two Phase 3 trials, which met their primary endpoints of reducing cortisol synthesis, and submitted a new drug application ("NDA") to the FDA on March 2, 2021.

Crinetics Pharmaceuticals, Inc. is conducting a Phase 1 trial of CRN04894, an oral adrenocorticotrophic hormone antagonist, for the treatment of Cushing's disease.

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

The commercial success of Korlym depends on the availability of acceptable pricing and adequate insurance coverage and reimbursement. Government payers, including Medicare, Medicaid and the Veterans Administration, as well as private insurers and health maintenance organizations, are increasingly attempting to contain healthcare costs by limiting

reimbursement for medicines. If government or private payers cease to provide adequate and timely coverage, pricing and reimbursement for Korlym, physicians may not prescribe the medication and patients may not purchase it, even if it is prescribed, or the price we receive may be reduced, which would reduce our revenue.

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

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

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

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

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

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

A single third-party manufacturer, Produits Chimiques Auxiliaires et de Synthese SA ("PCAS"), supplies the API in Korlym. Two other third-party manufacturers produce and bottle Korlym tablets. Our agreement with PCAS automatically renews for two one-year terms, unless either party provides 12-months' written notice of its intent not to renew. A single specialty pharmacy, Optime Care, Inc. ("Optime") dispenses Korlym directly to patients and collects payments from insurers representing approximately 99 percent of our revenue. If Optime does not adhere to its agreements with payers, it may not be able to collect some or all of the payments due to us. Our agreement with Optime has a five-year term and renews upon the written consent of both parties, subject to customary termination provisions, including the right of Optime to terminate in the

event of a material breach by us that we do not cure in a reasonable period of time after receiving written notice. In addition, we may terminate the agreement for convenience. In the event any of these vendors fails to perform its contractual obligations to us or is materially impaired in its performance by the COVID-19 pandemic or for any other reason, we may experience disruptions and delays in our supply chain and our ability to deliver Korlym to patients, which would adversely affect our business, results of operations and financial position.

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

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

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

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

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

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

If we are unable to maintain regulatory approval of Korlym for the treatment of patients with Cushing's syndrome or if we fail to comply with other requirements, we will be unable to generate revenue and may be subject to penalties.

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

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

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

If the FDA were to determine that we engaged in off-label promotion, the FDA could require us to change our practices and subject us to regulatory enforcement actions, including issuance of a public "warning letter," 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 restricting 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 U.S. healthcare laws and regulations that may affect our ability to operate include, but are not limited to:

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

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

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

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

- federal "sunshine" laws, including the federal Physician Payment Sunshine Act, that require transparency regarding financial arrangements with health care providers, such as the reporting and disclosure requirements imposed by the ACA on drug manufacturers regarding any "transfer of value" made or distributed to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain health care professionals beginning in 2022, teaching hospitals, and ownership or investment interests held by physicians and their immediate family members. Manufacturers are required to submit reports detailing these financial arrangements by the 90th day of each calendar year;

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

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

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

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

Risks Related to our Research and Development Activities

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

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

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

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

- failure to show efficacy or acceptable safety;

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

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

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

- delays or inability to obtain institutional review board ("IRB") approval at prospective trial sites;

- failure of patients or investigators to comply with the clinical trial protocol;

- unforeseen safety issues; and

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

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

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

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

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

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

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

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

- the possible refusal of the FDA or other regulatory authorities to accept data from clinical trials in affected geographies.

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

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

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

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

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

We cannot sell a product without the approval of the FDA or comparable foreign regulatory authority. Obtaining such approval is difficult, uncertain, lengthy and expensive. Failure can occur at any stage. In order to receive FDA approval, 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, fines, consent decrees restricting or suspending manufacturing operations, injunctions, civil penalties, recall or seizure of products, total or partial suspension of product sales and criminal prosecution. We may seek to commercialize our products in international markets, which would require us to receive a marketing authorization and, in many cases, pricing approval, from the appropriate regulatory authorities. Approval procedures vary between countries and can require additional pre-clinical or clinical studies. Obtaining approval may take longer than it does in the United States. Although approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by others, failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in others. Any of these or other regulatory actions could materially harm our business and financial condition.

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

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

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

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

product candidates or products may be harmed, and our ability to generate product revenues from them may be delayed or eliminated.

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

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

Any of these events could seriously harm our business.

Risks Related to our Capital Needs and Financial Results

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

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

Risks Relating to our Intellectual Property

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

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

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

Our patents concerning mifepristone cover its use, not its composition, which may make it harder to prevent patent infringement.

We own or have exclusively licensed issued U.S. patents covering the use of cortisol modulators, including mifepristone, to treat a variety of disorders. A method of use patent covers only a particular use of a compound, not its composition. Because our patents do not cover the composition of mifepristone, we cannot prevent others from commercializing mifepristone to treat disorders not covered by our method of use patents. The availability of mifepristone for these disorders may enable patients to

obtain mifepristone from other companies for indications covered by our patents. Although such "off-label" use would violate our patents, effectively monitoring compliance and enforcing our rights may be difficult and costly.

Third parties may allege that our patents infringe their rights. Defending against such allegations may result in costly litigation and may require us to obtain a license or bar us from commercializing our product candidates or Korlym for a new indication.

Our development and commercialization of Korlym or our selective cortisol modulators may give rise to claims that our patents or the patents we have licensed infringe the rights of others, which may require us to engage in costly, time-consuming and possibly unsuccessful litigation. If it is determined that one of our products or product candidates infringe others' patent rights, we may have to obtain licenses to those rights or delay or suspend commercial activity while we attempt to design around the infringed patent. If our efforts fail, we may be unable to commercialize the infringing product or product candidate. We do not have liability insurance for patent infringement.

We do not believe that we infringe any patents or other proprietary rights. We are not obligated to pay royalties relating to the use of intellectual property except to the University of Chicago. To maintain our licenses from the University of Chicago, we must make milestone and royalty payments. If we do not comply with our obligations under these licenses, we may lose the right to commercialize cortisol modulators, including mifepristone, for the treatment of Triple-Negative Breast Cancer ("TNBC") and CRPC.

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 27, 2021, our average daily trading volume was approximately 632,308 shares and the intra-day sales prices per share of our common stock on The Nasdaq Stock Market ranged from $16.52 to $31.18. As of October 27, 2021, our officers, directors and principal stockholders beneficially owned approximately 17 percent of our common stock.

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

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

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

- additions or departures of key personnel;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments; and
- additional financing activities.

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

The guidance we provide as to our expected 2021 revenue is only an estimate of what we believe is realizable at the time we give such guidance. It is difficult to predict our revenue and our actual results may vary materially from our guidance. The effect on our business of the COVID-19 pandemic is difficult to forecast. In addition, the rate of physician adoption of Korlym and the actions of government and private payers is uncertain. We may experience competition from generic versions of Korlym, which our public revenue guidance does not anticipate. We may not meet our financial guidance or other investor expectations for other reasons, including those arising from the risks and uncertainties described in this report and in our other public filings and public statements. Research analysts publish estimates of our future revenue and earnings based on their own analysis. The revenue guidance we provide may be one factor they consider when determining their estimates.

General Risk Factors

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

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

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

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

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

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

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

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

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

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

In addition, certain state laws govern the privacy and security of health information in certain circumstances, some of which are more stringent than HIPAA and many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties and private litigation. For example, the California Confidentiality of Medical Information Act imposes restrictive requirements regulating the use and disclosure of health information and other personally identifiable information. Further, on June 28, 2018, California enacted the California Consumer Privacy Act, or the CCPA, which took effect on January 1, 2020. The CCPA creates individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. The CCPA may increase our compliance costs and potential liability. Further, the California Privacy Rights Act, or CPRA, recently passed in California. The CPRA will impose additional data protection obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It will also create a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. The majority of the provisions will go into effect on January 1, 2023, and additional compliance investment and potential business process changes may be required. In the event that we are subject to or affected by HIPAA, the CCPA, the CPRA or other domestic privacy and data protection laws, any liability from failure to comply with the requirements of these laws could adversely affect our financial condition. Similar laws have also been proposed at the federal level and in other states.

The GDPR went into effect in 2018 and imposes stringent requirements for controllers and processors of personal data of individuals within the EEA, particularly with respect to clinical trials. The GDPR provides that EEA member states may make their own further laws and regulations limiting the processing of health data, which could limit our ability to use and share personal data or could cause our costs to increase and harm our business and financial condition. In addition, the GDPR increases the scrutiny that clinical trial sites located in the EEA should apply to transfers of personal data from such sites to countries that are considered to lack an adequate level of data protection, such as the United States. Recent legal developments have also created complexity and compliance uncertainty regarding certain transfers of information from the EEA to the United States. For example, on June 16, 2020, the Court of Justice of the European Union, or the CJEU, limited how organizations could lawfully transfer personal data from the EEA to the United States by invalidating the EU-US Privacy Shield Framework for purposes of international transfers and imposing further restrictions on use of the standard contractual clauses, or SCCs. These restrictions include a requirement for companies to carry out a transfer impact assessment which, among other things, assesses the laws governing access to personal data in the recipient country and considers whether supplementary measures that provide privacy protections additional to those provided under SCCs will need to be implemented to ensure an essentially equivalent level of data protection to that afforded in the EEA. The European Commission issued revised SCCs on June 4, 2021 to account for the decision of the CJEU and recommendations made by the European Data Protection Board. The revised SCCs must be used for relevant new data transfers from September 27, 2021; existing standard contractual clauses arrangements must be migrated to the revised clauses by December 27, 2022. There is some uncertainty around whether the revised clauses can be used for all types of data transfers, particularly whether they can be relied on for data transfers to non-EEA entities subject to the GDPR. As supervisory authorities issue further guidance on personal data export mechanisms, including circumstances where the SCCs cannot be used, and/or start taking enforcement action, we could suffer additional costs, complaints and/or regulatory investigations or fines, and/or if we are otherwise unable to transfer personal data between and among countries and regions in which we operate, it could affect the manner in which we provide our services, the geographical location or segregation of our relevant systems and operations, and could adversely affect our financial results. The GDPR imposes substantial fines for breaches of data protection requirements, which can be up to four percent of global revenue for the preceding financial year or €20 million, whichever is greater, and it also confers a private right of action on data subjects for breaches of data protection requirements. Compliance with European data protection laws is a rigorous and time intensive process that may increase our cost of doing business, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation and reputational harm in connection with our European activities. From January 1, 2021, we have had to comply with the GDPR and separately the United Kingdom GDPR, which, together with the amended United Kingdom Data Protection Act 2018, retains the GDPR in United Kingdom national law, each regime having the ability to fine up to the greater of €20 million/ £17.5 million or 4% of global turnover. It is unclear how United Kingdom data protection laws and regulations will develop in the medium to longer term and these changes may lead to additional costs and increase our overall risk exposure. On June 28, 2021, the European Commission 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 European Commission renews or extends that decision and remains under review by the Commission during this period.

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

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

We store valuable confidential information relating to our business, patients and employees on our computer networks and on the networks of our vendors. In addition, we rely heavily on internet technology, including video conference, teleconference and file-sharing services, to conduct business during the COVID-19 pandemic. Despite the implementation of security measures, our networks and the networks of our vendors are subject to the risk of cyberattacks, "phishing" attacks, computer hackers, service provider or vendor error, or malfeasance or other intentional or unintentional acts by third parties and bad actors, including vendors, computer viruses, unauthorized access, natural disasters, terrorism, war and internet and electrical failures. They may also be manipulated by criminals seeking to commit fraud or theft.

COVID-19 may increase our cybersecurity risks, due to our reliance on internet technology and the number of our employees that are working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities. In addition, system failures could cause the loss, theft, exposure, or unauthorized access or use of valuable clinical trial data as a result of accidents, errors or malfeasance by our employees, independent contractors or others working with us or on our behalf or otherwise disrupt our clinical and commercial activities and be expensive and time-consuming to remedy. Our servers and systems, and those of our vendors, may be vulnerable to computer malware, break-ins, denial-of-service attacks, and similar disruptions from unauthorized tampering with our computer systems, which could result in someone obtaining unauthorized access to our confidential information, including our clinical data, or the confidential information of our patients or employees.

The computer systems of the CRO that managed one of our early-stage clinical trials was breached and confidential information, including information about some of the patients who participated in our trial, was exposed. Under applicable law, this breach is the responsibility of the CRO, which has notified the affected patients and is cooperating closely with regulatory and law enforcement authorities. We do not expect this breach to have any impact on our development programs or financial performance.

We have experienced "phishing" attacks and other unauthorized access to certain data and information. There is no assurance that our cybersecurity systems and processes will be effective in preventing unauthorized access in the future. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may also experience security breaches that remain undetected for an extended period.

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

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

The government's ability to carry out its mandated functions is affected by a variety of factors, including adequate government funding, the ability to hire and retain key personnel, statutory, regulatory and policy changes, possible diversion of resources and limited operating capacity and diversion of resources caused by the COVID-19 pandemic or other events that may reduce the government's ability to perform routine functions. Disruptions at the FDA and other agencies may slow the time to review new drug applications and respond to other inquiries. Disruptions at the Securities and Exchange Commission ("SEC") may temporarily stop its ability to review and approve proposed financing transactions. Several times in the last few

years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down and many regulatory agencies, including the FDA and SEC, have had to furlough employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impair the FDA, SEC and other authorities' ability to process our submissions, which could materially harm our business.

Separately, in response to the COVID-19 pandemic, on March 10, 2020 the FDA announced its intention to postpone most inspections of foreign manufacturing facilities, and on March 18, 2020, the FDA temporarily postponed routine surveillance inspections of domestic manufacturing facilities. Subsequently, on July 10, 2020 the FDA announced its intention to resume certain on-site inspections of domestic manufacturing facilities subject to a risk-based prioritization system. The FDA intends to use this risk-based assessment system to identify the categories of regulatory activity that can occur within a given geographic area, ranging from mission critical inspections to resumption of all regulatory activities. Additionally, on April 15, 2021, the FDA issued a guidance document in which the FDA described its plans to conduct voluntary remote interactive evaluations of certain drug manufacturing facilities and clinical research sites. According to the guidance, the FDA intends to request such remote interactive evaluations in situations where an in-person inspection would not be prioritized, deemed mission-critical, or where direct inspection is otherwise limited by travel restrictions, but where the FDA determines that remote evaluation would be appropriate. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

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 I, Notes to Unaudited Condensed Consolidated Financial Statements - Income Taxes." Changes to existing tax laws could materially increase the amounts we must pay, which would reduce our net income.

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

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

Our ability to compete could be diminished if we are unable to protect our trade secrets and proprietary information.

In addition to patents, we rely on a combination of confidentiality, nondisclosure and other contractual provisions, laws protecting trade secrets and security measures to protect our proprietary information. These measures may not be adequate, in which case competitors could exploit our proprietary information to our disadvantage. If employees, consultants or anyone else breaches their agreements with us regarding our proprietary information, we may not have adequate remedies for the breach.

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

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

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

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

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

New laws and regulations, as well as changes to existing laws and regulations, including statutes and regulations concerning taxes and the development, approval, marketing and pricing of medications, the provisions of the ACA requiring the reporting of aggregate spending related to health care professionals, the provisions of the Sarbanes-Oxley Act of 2002 and rules

adopted by the SEC and by The Nasdaq Stock Market have and will likely continue to increase our cost of doing business and divert management's attention from revenue-generating activities.

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

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

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

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

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

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

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

As of October 27, 2021, our officers and directors beneficially owned approximately 17 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, 2021 as part of our publicly announced Stock Repurchase Program (in thousands, except average price per share):

Fiscal Period	Total Number of Shares Repurchased	Average Price Paid Per Share	Dollar Amount of Shares That May Yet be Purchased Under the Program[1]
July 1, 2021 to July 31, 2021	—	$ —	$ 127,620
August 1, 2021 to August 31, 2021	493	21.26	117,139
September 1, 2021 to September 30, 2021	727	21.04	101,845
Total	1,220	$ 21.13	$ 101,845

(1) On November 3, 2020, our Board of Directors authorized the repurchase of up to $200 million of our common stock pursuant to our Stock Repurchase Program. The Stock Repurchase Program expired on September 30, 2021.

The following table contains information relating to the purchase of shares of our common stock as part of the cashless net exercises of stock options in the three months ended September 30, 2021 (in thousands, except average price per share):

Fiscal Period	Total Number of Shares Purchased[2]	Average Price Per Share	Total Purchase Price of Shares[3]
July 1, 2021 to July 31, 2021	31	$ 20.61	$ 636
August 1, 2021 to August 31, 2021	167	21.22	3,538
September 1, 2021 to September 30, 2021	4	20.46	92
Total	202	$ 21.11	$ 4,266

(2) In July 2021, we issued 50,521 shares of common stock as part of a net-share settlement of a cashless option exercise, of which 30,833 shares were surrendered to us in satisfaction of related exercise cost and tax obligations. In August 2021, we issued 260,184 shares of common stock as part of a net-share settlement of a cashless option exercise, of which 166,708 shares were surrendered to us. In September 2021, we issued 5,884 shares of common stock as part of a net-share settlement of a cashless option exercise, of which 4,519 shares were surrendered to us.

(3) We paid $2.3 million to satisfy the tax withholding obligations associated with the net-share settlement of these cashless option exercises.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

Exhibit Number	Description of Document
3.1	Amended and Restated Certificate of Incorporation, as amended (incorporated by reference to Exhibit 3.1 to the registrant's Quarterly Report on Form 10-Q filed on August 9, 2012).
3.2	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.1 to the registrant's Current Report on Form 8-K filed on February 13, 2017).
10.1	Separation Agreement by and between the registrant and Andreas Grauer, M.D. (incorporated by reference to Exhibit 10.1 to the registrant's Current Report on Form 8-K filed on August 10, 2021).
31.1	Rule 13a-14(a)/15d-14(a) Certifications of Joseph K. Belanoff, M.D., Chief Executive Officer of the registrant.
31.2	Rule 13a-14(a)/15d-14(a) Certifications of Atabak Mokari, Chief Financial Officer of the registrant.
32.1	18 U.S.C. Section 1350 Certifications of Joseph K. Belanoff, M.D., Chief Executive Officer of the registrant.
32.2	18 U.S.C. Section 1350 Certifications of Atabak Mokari, Chief Financial Officer of the registrant.
101	The following materials from the registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2021, formatted in Extensible Business Reporting Language (XBRL): (i) Unaudited Condensed Consolidated Balance Sheets at September 30, 2021 and December 31, 2020, (ii) Unaudited Condensed Consolidated Statements of Comprehensive Income for the three and nine month periods ended September 30, 2021 and 2020, (iii) Unaudited Condensed Consolidated Statements of Cash Flows for the nine month periods ended September 30, 2021 and 2020, (iv) Unaudited Condensed Consolidated Statement of Stockholders' Equity and (v) 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: November 3, 2021

/s/ Joseph K. Belanoff

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

Date: November 3, 2021

/s/Atabak Mokari

Atabak Mokari
Chief Financial Officer

Date: November 3, 2021

/s/Joseph D. Lyon

Joseph D. Lyon
Chief Accounting Officer

Exhibit 31.1

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, 2021 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
November 3, 2021

Exhibit 31.2

CERTIFICATION

I, Atabak Mokari, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the period ended September 30, 2021 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
November 3, 2021

Exhibit 32.1

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, 2021, 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
November 3, 2021

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.

Exhibit 32.2

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, 2021, 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
November 3, 2021

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.