

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended March 31, 2020
or

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

For the transition period from to

Commission File Number:
000-50679

CORCEPT THERAPEUTICS INCORPORATED

(Exact Name of Corporation as Specified in Its Charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

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

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

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

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

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

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

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

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

Large accelerated filer	<input checked="" type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

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

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

On April 30, 2020, there were 114,601,708 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, except per share data)

	March 31, 2020	December 31, 2019
	(Unaudited)	(See Note 1)
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 84,477	\$ 31,269
Short-term marketable securities	222,838	244,693
Trade receivables, net of allowances	26,684	19,928
Inventory	5,084	5,424
Prepaid expenses and other current assets	5,693	6,044
Total current assets	344,776	307,358
Strategic inventory	11,063	11,981
Operating lease right-of-use asset	3,082	3,446
Property and equipment, net of accumulated depreciation	880	1,050
Long-term marketable securities	41,690	39,352
Other assets	3,441	3,448
Deferred tax assets, net	40,562	45,677
Total assets	<u>\$ 445,494</u>	<u>\$ 412,312</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 4,976	\$ 7,537
Accrued clinical expenses	7,938	6,477
Accrued and other liabilities	19,590	23,269
Short-term operating lease liability	1,571	1,558
Total current liabilities	34,075	38,841
Long-term operating lease liability	1,541	1,903
Long-term accrued income taxes	389	386
Total liabilities	36,005	41,130
Commitments and contingencies (Note 5)		
Stockholders' equity:		
Preferred stock	—	—
Common stock	120	120
Additional paid-in capital	465,528	457,060
Treasury stock	(62,979)	(62,704)
Accumulated other comprehensive income	310	261
Retained earnings (accumulated deficit)	6,510	(23,555)
Total stockholders' equity	409,489	371,182
Total liabilities and stockholders' equity	<u>\$ 445,494</u>	<u>\$ 412,312</u>

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 March 31,	
	2020	2019
Product revenue, net	\$ 93,247	\$ 64,829
Operating expenses:		
Cost of sales	1,878	1,240
Research and development	26,123	20,244
Selling, general and administrative	27,535	24,389
Total operating expenses	55,536	45,873
Income from operations	37,711	18,956
Interest and other income	1,471	1,097
Income before income taxes	39,182	20,053
Income tax expense	(9,117)	(1,779)
Net income	\$ 30,065	\$ 18,274
Other comprehensive income (loss):		
Net unrealized gain on available-for-sale investments, net of tax impact of \$(20) and \$(52), respectively	61	164
Foreign currency translation loss, net of tax	(12)	—
Total comprehensive income	\$ 30,114	\$ 18,438
Basic net income per share	\$ 0.26	\$ 0.16
Diluted net income per share	\$ 0.25	\$ 0.15
Weighted-average shares outstanding used in computing net income per share		
Basic	114,575	114,844
Diluted	122,226	123,895

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)

	Three Months Ended March 31,	
	2020	2019
Cash flows from operating activities:		
Net income	\$ 30,065	\$ 18,274
Adjustments to reconcile net income to net cash generated from operations:		
Stock-based compensation	7,918	6,696
Deferred income taxes	5,095	926
Accretion of interest income	(177)	(634)
Depreciation and amortization of property and equipment	238	96
Non-cash amortization of right-of-use asset	364	413
Changes in operating assets and liabilities:		
Trade receivables	(6,756)	(1,630)
Inventory	1,328	910
Prepaid expenses and other current assets	351	1,999
Other assets	7	(25)
Accounts payable	(2,600)	953
Accrued clinical expenses	1,461	1,016
Accrued and other liabilities	(3,676)	(4,956)
Operating lease liabilities	(349)	(357)
Net cash provided by operating activities	33,269	23,681
Cash flows from investing activities:		
Purchases of property and equipment	(42)	(257)
Proceeds from maturities of marketable securities	68,245	70,825
Purchases of marketable securities	(48,469)	(70,935)
Net cash provided by (used in) investing activities	19,734	(367)
Cash flows from financing activities:		
Proceeds from issuance of common stock upon exercise of options, net of issuance costs	480	2,435
Repurchase of common stock	(275)	(13,555)
Cash paid to satisfy statutory withholding requirement for net settlement of cashless option exercise	—	(4,169)
Net cash provided by (used in) financing activities	205	(15,289)
Net increase in cash and cash equivalents	53,208	8,025
Cash and cash equivalents, at beginning of period	31,269	41,625
Cash and cash equivalents, at end of period	\$ 84,477	\$ 49,650
Supplemental disclosure:		
Exercise price of shares tendered in net settlement of cashless option exercise	\$ —	\$ 931
Recognition of right-of-use asset and lease liability	\$ —	\$ 1,878

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

CORCEPT THERAPEUTICS INCORPORATED

CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

(Unaudited)
(in thousands)

	Common Stock		Additional Paid-in Capital	Treasury Stock	Accumulated Other Comprehensive Income (Loss)	Retained Earnings (Accumulated Deficit)	Total Stockholders' Equity
	Shares	Amount					
Balance at December 31, 2018	115,031	\$ 117	\$ 417,228	\$ (23,657)	\$ (70)	\$ (117,736)	\$ 275,882
Issuance of common stock upon exercise of options	1,497	1	3,365	—	—	—	3,366
Shares tendered to satisfy cost and statutory withholding requirements for net settlement of cashless option exercise	(428)	—	—	(5,100)	—	—	(5,100)
Stock-based compensation related to employee and director options	—	—	6,724	—	—	—	6,724
Other comprehensive income, net of tax	—	—	—	—	164	—	164
Purchases of treasury stock	(1,168)	—	—	(13,555)	—	—	(13,555)
Net income	—	—	—	—	—	18,274	18,274
Balance at March 31, 2019	<u>114,932</u>	<u>\$ 118</u>	<u>\$ 427,317</u>	<u>\$ (42,312)</u>	<u>\$ 94</u>	<u>\$ (99,462)</u>	<u>\$ 285,755</u>
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 related to employee and director options	—	—	7,988	—	—	—	7,988
Other comprehensive income, net of tax	—	—	—	—	49	—	49
Net income	—	—	—	—	—	30,065	30,065
Balance at March 31, 2020	<u>114,596</u>	<u>\$ 120</u>	<u>\$ 465,528</u>	<u>\$ (62,979)</u>	<u>\$ 310</u>	<u>\$ 6,510</u>	<u>\$ 409,489</u>

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 and patented four structurally distinct series of selective cortisol modulators, consisting of more than 1,000 compounds. We are developing compounds from these series as potential treatments for a broad range of serious disorders.

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

Basis of Presentation

We have prepared the following in accordance with U.S. generally accepted accounting principles (“GAAP”) for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X: (i) condensed consolidated balance sheet as of March 31, 2020, (ii) statements of comprehensive income and stockholders’ equity for the three months ended March 31, 2020 and 2019 and (iii) statements of cash flows for the three months ended March 31, 2020 and 2019. 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 months ended March 31, 2020 are not necessarily indicative of the results for the remainder of 2020 or any other period. These financial statements and notes should be read in conjunction with the financial statements for the year ended December 31, 2019 included in our Annual Report on Form 10-K. The December 31, 2019 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, 2019 except for the adoption of the accounting pronouncements set forth below.

Recently Adopted Accounting Pronouncements

In June 2016, the FASB issued ASU No. 2016-13, “Financial Instruments—Credit Losses (Topic 326), Measurement of Credit Losses on Financial Instruments,” which changes the methodology for measuring credit losses on financial instruments and when such losses are recorded. This standard is effective for fiscal years, and interim periods within those years, beginning after December 15, 2019. We adopted this standard on January 1, 2020 using the modified retrospective approach with the cumulative effect of the adoption recorded as an adjustment to retained earnings. It had no impact on our condensed consolidated financial statements.

In August 2018, the FASB issued ASU No. 2018-13, “Fair Value Measurements (Topic 820),” which eliminates or modifies certain disclosure requirements for fair value measurements and requires disclosure of additional information. This standard is effective for fiscal years, and interim periods within those years, beginning after December 15, 2019. We adopted this standard on January 1, 2020 using the modified retrospective approach with the cumulative effect of the adoption recorded as an adjustment to retained earnings. It had no impact on our condensed consolidated financial statements.

In August 2018, the FASB issued ASU No. 2018-15, “Intangibles—Goodwill and Other—Internal-Use Software (Subtopic 350-40): Customer’s Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract,” which requires a customer that is a party to a cloud computing service contract to follow the internal-use software guidance in ASC 350-40 to determine which implementation costs to recognize as assets. This standard is effective for fiscal years, and interim periods within those years, beginning after December 15, 2019. We adopted this standard on January 1, 2020 using the modified retrospective approach with the cumulative effect of the adoption recorded as an adjustment to retained earnings. It had no impact on our condensed consolidated financial statements.

Recently Issued Accounting Pronouncements Not Yet Adopted

In December 2019, the FASB issued ASU No. 2019-12 (ASC Topic 740), “Simplifying the Accounting for Income Taxes.” This standard simplifies accounting for income taxes by removing certain exceptions to the general principles and

amending existing guidance to improve consistent application. This standard will be effective for fiscal years, and interim periods within those years, beginning after December 15, 2021. Early adoption is permitted. We are in the process of assessing the impact of this standard on our consolidated financial statements.

2. Composition of Certain Balance Sheet Items

Inventory

	March 31, 2020	December 31, 2019
	<i>(in thousands)</i>	
Raw materials	\$ —	\$ 1,389
Work in progress	10,024	10,086
Finished goods	6,123	5,930
Total inventory	16,147	17,405
Less strategic inventory classified as non-current	(11,063)	(11,981)
Total inventory classified as current	\$ 5,084	\$ 5,424

Because we rely on a single manufacturer for the active pharmaceutical ingredient (“API”) for Korlym, we have purchased and hold significant quantities of API. 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

	March 31, 2020	December 31, 2019
	<i>(in thousands)</i>	
Furniture and equipment	\$ 304	\$ 304
Software	1,609	1,541
Leasehold improvements	533	533
	2,446	2,378
Less accumulated depreciation	(1,566)	(1,328)
	\$ 880	\$ 1,050

Accrued and other liabilities

	March 31, 2020	December 31, 2019
	<i>(in thousands)</i>	
Government rebates	\$ 9,275	\$ 8,209
Income taxes payable	4,210	472
Accrued compensation	3,837	12,331
Accrued selling and marketing costs	707	491
Legal fees	697	1,087
Professional fees	421	367
Accrued manufacturing costs	180	33
Other	263	279
Total accrued and other liabilities	\$ 19,590	\$ 23,269

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

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

	March 31, 2020	December 31, 2019
	<i>(in thousands)</i>	
Cash equivalents	\$ 67,227	\$ 18,461
Short-term marketable securities	222,838	244,693
Long-term marketable securities	41,690	39,352
Total marketable securities	<u>\$ 331,755</u>	<u>\$ 302,506</u>

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

	Fair Value Hierarchy Level	March 31, 2020				December 31, 2019			
		Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
		<i>(in thousands)</i>							
Corporate bonds	Level 2	\$ 115,877	\$ 22	\$ (300)	\$ 115,599	\$ 109,780	\$ 136	\$ (6)	\$ 109,910
Commercial paper	Level 2	34,191	—	—	34,191	41,237	—	—	41,237
Asset-backed securities	Level 2	39,803	9	(93)	39,719	57,195	63	(5)	57,253
Repurchase agreements	Level 2	—	—	—	—	18,000	—	—	18,000
U.S. treasury securities	Level 1	74,337	682	—	75,019	75,574	71	—	75,645
Money market funds	Level 1	67,227	—	—	67,227	461	—	—	461
Total Marketable securities		<u>\$ 331,435</u>	<u>\$ 713</u>	<u>\$ (393)</u>	<u>\$ 331,755</u>	<u>\$ 302,247</u>	<u>\$ 270</u>	<u>\$ (11)</u>	<u>\$ 302,506</u>

We estimate the fair value of marketable securities classified as Level 1 using quoted market prices for these or similar 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 March 31, 2020 were not significant and were primarily due to changes in interest rates, and not increased credit risk. Accordingly, we have not recorded an allowance for credit losses associated with these investments.

We do not intend to sell the investments that are currently in an unrealized loss position, and it is highly unlikely that we will be required to sell the investments before recovery of their full amortized cost basis, which will most likely be at maturity.

We classified accrued interest on our marketable securities of \$1.4 million and \$1.0 million as of March 31, 2020 and December 31, 2019, respectively, within prepaid and other current assets on our condensed consolidated balance sheet.

As of March 31, 2020, all our marketable securities had original maturities of less than two years. The weighted-average maturity of our holdings was five months. As of March 31, 2020, our long-term marketable securities had remaining maturities ranging from 13 to 16 months. None of our marketable securities changed from one fair value hierarchy to another during the three months ended March 31, 2020.

4. Leases

We lease our office facilities in Menlo Park, California. On January 1, 2019, we recognized a right-of-use asset and a corresponding lease liability of \$1.9 million. Effective October 1, 2019, we amended the lease to extend its term from March

31, 2020 to March 31, 2022 and to add more space beginning April 1, 2020. As a result of this amendment, we recognized an additional right-of-use asset and corresponding lease liability of \$3.0 million. The right-of-use asset and lease liability recognized equals the present value of the remaining payments due under our amended lease.

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

Operating lease expense for each of the three months ended March 31, 2020 and 2019 was approximately \$0.4 million.

For any future operating lease transactions, we will recognize operating lease right-of-use assets and liabilities equal to the present value of the expected lease payments at the lease commencement date.

Our right-of-use assets and related lease liabilities were as follows:

	Three Months Ended March 31, 2020	Three Months Ended March 31, 2019
	<i>(in thousands)</i>	
Cash paid for operating lease liability	\$ 391	\$ 379
Right-of-use assets obtained in exchange for new operating lease liability	\$ —	\$ 1,878
Weighted-average remaining lease term	24 months	12 months
Weighted-average discount rate	5.0 %	5.0 %

As of March 31, 2020, future minimum lease payments under non-cancelable operating leases were as follows *(in thousands)*:

2020 (remainder)	\$ 1,598
2021	2,130
2022	535
	<u>4,263</u>
Less imputed interest	(1,151)
Total lease liabilities	<u>\$ 3,112</u>

These payments exclude impact of any leases and modifications executed after March 31, 2020.

5. Commitments and Contingencies

In March 2020, to ensure we have sufficient API to meet future demand for Korlym tablets, we committed to purchase an additional 400 kilograms of API from Produits Chimiques Auxiliaires et de Synthèse SA ("PCAS," a member of the Seqens Group) for a total price of \$5.9 million.

There have been no other material changes in our obligations under contractual agreements described in our Annual Report on Form 10-K for the year ended December 31, 2019.

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.

6. 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 2020, our Board of Directors authorized a 4.6 million increase in the shares available for grant under the 2012 Plan.

During the three months ended March 31, 2020, we issued 0.1 million shares of our common stock upon the exercise of stock options, compared to 1.5 million shares during the same period of 2019.

The following table summarizes our stock-based compensation:

	Three Months Ended March 31,	
	2020	2019
	<i>(in thousands)</i>	
Stock-based compensation capitalized in inventory	\$ 70	\$ 28
Cost of sales	23	28
Research and development	2,605	1,979
Selling, general and administrative	5,290	4,689
Total stock-based compensation	<u>\$ 7,988</u>	<u>\$ 6,724</u>

Related Party Transaction

On February 26, 2020, we purchased from our Chief Executive Officer \$0.3 million of our common stock at a purchase price of \$13.54 per share, which was the last quoted price per share on the Nasdaq Capital Market on the date of purchase. We purchased the shares in order to provide him with liquidity to satisfy tax liability arising from his net (cashless) exercise in 2019 of stock options that were about to expire.

7. 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. 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 statements of condensed consolidated comprehensive income show the computation of net income per share for each period, including the number of weighted-average shares outstanding.

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

	Three Months Ended March 31,	
	2020	2019
	<i>(in thousands)</i>	
Numerator:		
Net income	\$ 30,065	\$ 18,274
Denominator:		
Weighted-average shares used to compute basic net income per share	114,575	114,844
Dilutive effect of employee stock options	7,651	9,051
Weighted-average shares used to compute diluted net income per share	122,226	123,895
Net income per share		
Basic	<u>\$ 0.26</u>	<u>\$ 0.16</u>
Diluted	<u>\$ 0.25</u>	<u>\$ 0.15</u>

As of March 31, 2020 and 2019, we had 27.0 million and 24.4 million stock options outstanding, respectively.

Because including them would have reduced dilution, we excluded from the computation of diluted net income per share, on a weighted-average basis, 12.5 million and 8.5 million stock options outstanding during the three months ended March 31, 2020 and 2019, respectively.

8. Income taxes

We recorded income tax expense of \$9.1 million for the three months ended March 31, 2020, net of discrete benefits related to stock option exercises and dispositions of \$0.1 million. Income tax expense for the three months ended March 31, 2020 consisted primarily of reductions in our deferred tax assets of \$5.1 million caused by utilization of our federal and state net operating losses and research tax credits, and income tax expense of \$4.0 million for federal and in states where we do not have net operating loss carryforwards.

In the three months ended March 31, 2019, our income tax expense was \$1.8 million, consisting primarily of reductions of \$0.9 million in our deferred tax assets caused by utilization of our federal and state net operating losses, and income tax expense of \$0.9 million in states where we do not have net operating loss carryforwards.

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

Each quarter, we assess the likelihood that we will generate sufficient taxable income to use our federal and state deferred tax assets. If we believe that recovery of these deferred tax assets is not more likely than not, we will establish a valuation allowance. Significant judgment is required in determining any valuation allowance recorded against deferred tax assets. In assessing the need for a valuation allowance, we consider all available evidence, including recent operating results, projections of future taxable income, our ability to utilize net operating losses and tax credit carryforwards, and the feasibility of tax planning strategies. 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 will include an expense in the Condensed Consolidated Statement of Comprehensive Income in the period in which such determination is made.

On March 27, 2020, President Trump signed into U.S. federal law the CARES Act, which provides emergency assistance and health care for individuals, families, and businesses affected by the COVID-19 pandemic. Based on our preliminary analysis, the relief provisions will not have a material impact on our condensed consolidated financial statements.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Forward-Looking Statements

This Management's Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with the financial statements and accompanying notes in this report. Statements in this section are "forward-looking" within the meaning of the federal securities laws and are subject to known and unknown risks and uncertainties that might cause actual results to differ materially from those the statements express or imply. For a discussion of such risks and uncertainties, see the "Risk Factors" section of this Form 10-Q and the "Overview" and "Liquidity and Capital Resources" sections of this Management's Discussion and Analysis of Financial Condition and Results of Operations.

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 who suffer from endogenous Cushing's syndrome, a disease caused by excess cortisol activity.

We have discovered more than 1,000 proprietary, selective cortisol modulators in four structurally distinct series. Our lead compounds have entered the clinic as potential treatments for a variety of serious disorders – Cushing's syndrome, solid tumors (including advanced, high-grade serous ovarian cancer, metastatic pancreatic cancer and castration-resistant prostate cancer), weight-gain caused by antipsychotic medications, and non-alcoholic steatohepatitis ("NASH").

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 12 method of use patents listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") covering various 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 by the U.S. Patent and Trademark Office ("USPTO"). Our Orange Book patents have expiration dates ranging from 2028 to 2037.

Relacorilant. We are conducting a Phase 3 trial of our proprietary, selective cortisol modulator, relacorilant, as a treatment for hypercortisolism. Relacorilant's Phase 3 trial ("GRACE"), is expected to enroll 130 patients at sites in the United States, Canada, Europe and Israel. Each patient in GRACE will receive relacorilant for 22 weeks. Those who exhibit pre-specified improvements in hypertension or glucose metabolism will then enter a twelve-week, double-blind, "randomized withdrawal" phase, in which half of the patients will continue receiving relacorilant and the rest will receive placebo. GRACE's primary endpoints are the rate and degree of relapse in patients receiving placebo compared to those continuing treatment with relacorilant.

We also plan to conduct a placebo-controlled, double-blind, Phase 3 trial ("GRADIANT") of relacorilant to treat patients whose Cushing's syndrome is caused by an adrenal tumor. Patients with this etiology of Cushing's syndrome have a more indolent course of disease, although their health outcomes are poor. We plan for GRADIANT to enroll 130 patients, half of whom will receive relacorilant and half of whom will receive placebo for 26 weeks. GRADIANT's primary endpoints will be improvement in hypertension and glucose metabolism. We expect many of the clinical sites in GRACE will participate in GRADIANT.

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, orphan designation confers tax credits, reduced regulatory fees and, provided we obtain approval, seven years of exclusive marketing rights for relacorilant in the treatment of Cushing's syndrome, with limited

exceptions. Benefits of orphan drug designation by the EC are similar, and include reduced regulatory fees and, if we obtain approval, ten years of exclusive marketing rights in the European Union (“EU”) for the treatment of Cushing’s syndrome. Additional benefits in the EU include protocol assistance from the European Medicines Agency (“EMA”) and access to the EU’s centralized marketing authorization procedure.

In neither the United States nor the EU does orphan drug designation shorten the drug approval process, make approval more likely or prevent competitors from marketing other drugs for the treatment of Cushing’s syndrome.

FKBP5 Gene Expression Assay. The tests used to diagnose patients with hypercortisolism and optimize their treatment are imprecise and often fail to identify patients with less severe manifestations of the disease. We have developed an assay to measure expression of the gene FKBP5, which is stimulated by cortisol activity, and have completed analytical validation pursuant to the Clinical Laboratory Improvement Amendments (“CLIA”). Clinical data indicate that FKBP5 levels are high in patients suffering from hypercortisolism (i.e., excess cortisol activity), but subside when they are successfully treated. We are testing this hypothesis in the GRACE and GRADIENT trials. We believe successful development of this assay will enable physicians to identify new patients with hypercortisolism more easily and to better treat those already in their care.

Oncology

Many types of solid tumors express GR and are potential targets for cortisol modulation therapy, among them pancreatic, ovarian, castration-resistant prostate and adrenocortical cancer.

Relacorilant in Patients with Solid Tumors. We are conducting a controlled Phase 2 trial of relacorilant in combination with Abraxane in patients with advanced, high-grade serous ovarian tumors. The trial is expected to enroll 180 patients at sites in the United States and Europe. Two thirds of the patients will receive relacorilant plus Abraxane. The rest will receive Abraxane alone. The primary endpoint is progression-free survival, as measured using the Response Evaluation Criteria in Solid Tumors.

We plan to conduct a Phase 3 trial of relacorilant plus Abraxane to treat patients with metastatic pancreatic cancer. Relacorilant has been designated an orphan drug by both the FDA and the EC for the treatment of pancreatic cancer.

We have exclusively licensed from the University of Chicago U.S. patents for (a) the use of cortisol modulators in the treatment of triple-negative breast cancer, and (b) the use of cortisol modulators to treat castration-resistant prostate cancer.

Cortisol Modulators in Patients with Castration-Resistant Prostate Cancer. We are conducting an open label, dose-finding trial of our proprietary, selective cortisol modulator exicorilant combined with Xtandi in patients with metastatic CRPC. Investigators at the University of Chicago are conducting a dose-finding trial of relacorilant combined with Xtandi in the same patient population. We are providing relacorilant. In addition to patents covering its composition of matter, we own U.S. patents covering the use of exicorilant to treat CRPC.

Metabolic Diseases

Antipsychotic-Induced Weight Gain. We are conducting a double-blind, placebo-controlled Phase 1b trial testing miricorilant’s activity in attenuating antipsychotic-induced weight gain. The first part of this trial enrolled 66 healthy subjects, each of whom received a daily dose of olanzapine (10 mg) and either placebo or miricorilant (600 mg). The duration of the trial was 14 days. Study participants who received miricorilant gained less weight than subjects receiving placebo. In addition, markers of liver damage that often rise temporarily at the start of olanzapine therapy increased less sharply in subjects receiving miricorilant, suggesting that miricorilant may have protective effects in the liver.

The trial’s second stage is testing a miricorilant dose of 900 mg.

We are also conducting a Phase 2, double-blind, placebo-controlled trial (“GRATITUDE”) of miricorilant in the reversal of antipsychotic-induced weight gain. GRATITUDE is expected to enroll 100 patients with schizophrenia at 20 sites in the United States. Study participants will receive their established antipsychotic medication and will have either miricorilant or placebo added to their regimen for 12 weeks. The trial’s primary endpoint is reduction in weight. We are also planning to conduct a double-blind placebo-controlled Phase 2 trial in patents with long-standing antipsychotic-induced weight gain.

Liver Disease. Miricorilant is potent in animal models of fatty liver and liver fibrosis. We plan to conduct a double-blind, placebo-controlled Phase 2 trial evaluating miricorilant as a treatment for NASH.

Continued Discovery and Development

We plan to continue identifying selective cortisol modulators and advancing the most promising of them towards the clinic. We are conducting a Phase 1 trial of our proprietary, selective cortisol modulator CORT113176. This molecule has shown promise in animal models of amyotrophic lateral sclerosis (or “ALS”).

COVID-19 Pandemic

Due to the COVID-19 pandemic, in California, where our headquarters are located, and in the states where most of our clinical specialists and medical science liaisons live, residents are subject to “shelter-in-place” orders with no announced end date. We are exempt from some quarantine requirements in some jurisdictions because pharmaceutical companies are typically deemed “essential businesses.” Nonetheless, to protect the public health and the health of our employees, we are conducting our business primarily by means of video and teleconferences and e-mail. We rely on third-party manufacturers, distributors (including the specialty pharmacy that dispenses Korlym), information technology service providers, law and accounting firms and clinical research organizations, most of which are also subject to pandemic-related restrictions.

The effect of the COVID-19 pandemic on our 2020 revenue and expenses is uncertain. Physicians have taken steps to reduce the risk of coronavirus infection in their practices that will reduce the effectiveness of our sales and marketing efforts, including temporarily suspending office visits by pharmaceutical company representatives. To maintain physician engagement, we have implemented a program of teleconference and video meetings. Although it is too early to know how effective these measures will be, we believe they will not work as well as in-person visits to educate physicians about Cushing’s syndrome and the potential of Korlym to benefit their patients. In addition, many physicians have reduced the frequency of patient visits, which, together with pandemic-related closures of laboratory facilities and imaging centers and the reluctance of some patients to leave their homes, make diagnosing and optimally treating patients with Cushing’s syndrome more difficult. All of these factors will make it more difficult for us to increase the number of patients who receive Korlym, even though we believe there are many who could benefit from the medication and who have not yet received it.

The pandemic’s impact on our clinical development programs is also difficult to estimate. Some of the sites at which we are conducting trials 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. At other clinical sites, new patient enrollment and new study initiations continue, but at a slower pace. These changes are likely to lengthen the time it takes us to complete our development programs.

Please see the risk factor under Item 1A of this Quarterly Report, “*The COVID-19 pandemic or another public health emergency, as well as natural disasters, terrorism and other catastrophes, could disrupt our activities and render our own or our vendors’ facilities and equipment inoperable or inaccessible and require us to cease or curtail 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 \$93.2 million for the three months ended March 31, 2020, compared to \$64.8 million for the corresponding period in 2019. Higher sales volume accounted for 51.2 percent of the increase, as we shipped Korlym to more patients, while an increase in the average price of Korlym tablets accounted for the rest of the increase as compared to the three months ended March 31, 2019. Korlym’s average price increased due to (i) price increases that took effect on August 1, 2019 and January 1, 2020, (ii) a decrease in the percentage of patients taking Korlym who are covered by Medicaid (which reimburses for Korlym at a lower rate than private insurers and other government programs) and (iii) statutorily-mandated increases in the price paid by certain government programs.

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

Cost of sales was \$1.9 million for the three months ended March 31, 2020, as compared to \$1.2 million for the corresponding period in 2019. Cost of sales as a percentage of revenue was 2.0 percent for the three months ended March 31, 2020 compared to 1.9 percent for the corresponding period in 2019.

Research and development expenses – Research and development expenses include the cost of (1) clinical trials, (2) recruiting and compensating development personnel, (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 expenses increased to \$26.1 million for the three months ended March 31, 2020 from \$20.2 million for the comparable period in 2019. The increase was primarily due to increased spending on the recruitment and compensation of development personnel and on the advancement of our oncology and endocrinology development programs.

	Three Months Ended March 31,	
	2020	2019
	<i>(in thousands)</i>	
Development programs:		
Oncology	\$ 12,316	\$ 5,214
Endocrinology	10,007	6,846
Pre-clinical and clinical selective cortisol modulators ⁽¹⁾	—	3,559
Unallocated activities, including pre-clinical, manufacturing and regulatory activities	1,195	2,646
Stock-based compensation	2,605	1,979
Total research and development expense	\$ 26,123	\$ 20,244

(1) Expenses for the three months ended March 31, 2020 relating to pre-clinical and clinical selective cortisol modulators were allocated between their respective development programs.

It is difficult to predict the timing and cost of development activities, which are subject to many uncertainties and risks, including the effects of the COVID-19 pandemic, inconclusive or negative results, slow patient enrollment, adverse side effects and difficulties in the formulation or manufacture of study drugs and the lack of drug-candidate efficacy. In addition, clinical development is subject to intensive government oversight and regulations that may change unpredictably and without notice. We expect our research and development expense in 2020 to be higher than it was in 2019 as our clinical programs advance. Research and development spending in future years will depend on the outcome of our pre-clinical and clinical trials and our development plans.

Selling, general and administrative 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 expenses for the three months ended March 31, 2020 increased to \$27.5 million, from \$24.4 million for the comparable period in 2019. The increase was primarily due to increases in employee recruiting and compensation expenses, increased legal costs, volume-related pharmacy and other distribution costs and professional service fees.

We expect our selling, general and administrative expenses to be higher in 2020 than in 2019, due to increased commercial and administrative activities arising from increased sales volumes, litigation and support for increased research and development activity. Selling, general and administrative activities in future years will depend on the cost and extent of our commercial activities, the scope of our research and development programs and the progress of our litigation.

Interest and other income - Interest and other income for the three months ended March 31, 2020 was \$1.5 million, compared to \$1.1 million for the comparable period in 2019. The increase in interest and other income was due to growth in our holdings of cash and marketable securities.

Income tax expense - Income tax expense for the three months ended March 31, 2020 was \$9.1 million compared to \$1.8 million for the comparable period in 2019. The increase in income tax expense was primarily due to decreased discrete benefits from the exercises of non-qualified stock options during the three months ended March 31, 2020, as compared to the comparable period in 2019.

Liquidity and Capital Resources

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

Based on our current plans, which include fully funding our Cushing's syndrome commercial operations, advancing relacorilant in Cushing's syndrome and solid tumors, the development of miricorilant to treat patients with antipsychotic-induced weight gain and NASH and of exicorilant to treat patients with CRPC, we expect to fund our operations 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 to stockholders. Debt financing could involve restrictive covenants. Funds raised through collaborations with other companies may require us to relinquish certain rights in our product candidates.

At March 31, 2020, we had cash, cash equivalents and marketable securities of \$349.0 million, consisting of cash and cash equivalents of \$84.5 million and marketable securities of \$264.5 million, compared to cash and cash equivalents of \$31.3 million and marketable securities of \$284.0 million at December 31, 2019.

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 for the three months ended March 31, 2020 was \$33.3 million, compared to \$23.7 million for the comparable period in 2019. This increase was primarily due to greater revenue, as we shipped Korlym to more patients.

Net cash provided by investing activities for the three months ended March 31, 2020 was \$19.7 million, compared to net cash used in investing activities of \$0.4 million for the comparable period in 2019. This increase was primarily due to fewer purchases of marketable securities as we increased our cash reserves in response to the uncertainties associated with the COVID-19 pandemic.

Net cash provided by financing activities for the three months ended March 31, 2020 was \$0.2 million compared to net cash used in financing activities of \$15.3 million for the comparable period in 2019. Stock option exercises provided \$0.5 million in the three months ended March 31, 2020, compared to \$2.4 million in the comparable period in 2019. In the first quarter of 2020, we purchased from our Chief Executive Officer \$0.3 million of our common stock in order to provide him liquidity to satisfy tax liability arising from his net (cashless) exercise in 2019 of stock options that were about to expire.

In the first quarter of 2019, we repurchased an aggregate of \$13.6 million of our common stock in accordance with our now-terminated stock repurchase program and paid an additional \$4.2 million to satisfy statutory withholding requirements for the net settlement of a cashless option exercise in March 2019.

At March 31, 2020, we had retained earnings of \$6.5 million.

Contractual Obligations and Purchase Commitments

Our contractual payment obligations and purchase commitments as of December 31, 2019 are disclosed in our Annual Report on Form 10-K for the year ended December 31, 2019. Other than our additional commitment to purchase \$5.9 million of API from PCAS, our payment obligations and purchase commitments have not changed materially during the three months ended March 31, 2020. See Note 5 to our Unaudited Condensed Consolidated Financial Statements for more information regarding our purchase commitments.

Off-Balance Sheet Arrangements

None.

Critical Accounting Policies and Estimates

We have prepared our financial statements in accordance with GAAP, which requires us to make estimates regarding our assets, liabilities and expenses. We base our estimates on assumptions we believe to be reasonable. Actual results may differ if our assumptions are incorrect or the conditions in which we do business change in ways we did not anticipate. Our critical accounting policies and estimates are discussed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2019. 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 internal control over financial reporting.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our market risks as of March 31, 2020 are disclosed in our Annual Report on Form 10-K for the year ended December 31, 2019. Although the COVID-19 pandemic has significantly increased volatility in the equity markets, the market risks associated with our cash, cash equivalents and marketable securities, which consists entirely of debt instruments with maturities of less than 18 months, have not changed materially during the three months ended March 31, 2020.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of disclosure controls and procedures. Our management, under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated our disclosure controls and procedures, as defined under Rules 13a-15(e) and 15d-15(e) of the Exchange Act as of March 31, 2020. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures provide a reasonable level of assurance that the information required to be disclosed in this Quarterly Report on Form 10-Q was (i) recorded, processed, summarized and reported within the time periods specified in the SEC's rules and (ii) communicated to our management, including our Chief Executive Officer and Chief Financial Officer, so as to allow timely decisions regarding required disclosure. Our disclosure controls and procedures are designed to provide reasonable, not absolute, assurance that our disclosures are accurate and timely.

Changes in internal control over financial reporting. Our Chief Financial Officer and other members of management have evaluated the changes in our internal control over financial reporting during the quarter ended March 31, 2020 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.

On February 5, 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 certain of our patents related to Korlym - U.S. Patent No. 8,921,348 (the “’348 patent”) and U.S. Patent No. 9,829,495 (the “’495 patent”) - which are listed in the Orange Book. Teva’s February 5, 2018 Notice Letter alleges that the ’348 patent, with an expiration date in August 2028, and the ’495 patent, with an expiration date in August 2036, will not be infringed by Teva’s proposed product, are invalid and/or are 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 these 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 having filed a timely lawsuit against Teva, FDA final approval of Teva’s ANDA will be stayed until the earlier of (i) August 1, 2020 (i.e., 30 months from our February 1, 2018 receipt of Teva’s Paragraph IV Notice Letter) or (ii) a District Court decision finding that the identified patents are invalid, unenforceable or not infringed.

On July 6, 2018, we filed an amended complaint against Teva, asserting infringement of U.S. Patent No. 9,943,526 (the “’526 patent”). On February 8, 2019, we filed a second lawsuit against Teva, asserting infringement of U.S. Patent Nos. 10,166,242 (the “’242 patent”), 10,166,243 (the “’243 patent”) and 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”).

No new 30-month stay results from the filing of the amended complaint or new lawsuits.

The District Court has consolidated our lawsuits against Teva into a single action at a set trial date of February 2, 2021.

On May 7, 2019, Teva submitted to the PTAB a petition for post-grant review of the ’214 patent, which we opposed. On November 20, 2019 the PTAB granted Teva’s petition. A PTAB decision regarding the ’214 patent is expected on or about November 20, 2020, subject to appeal to the United States Court of Appeals for the Federal Circuit.

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

Sun ANDA Litigation

On June 10, 2019, we received a Paragraph IV Notice Letter advising that Sun 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 certain of our patents related to Korlym listed in the Orange Book (the “Korlym Patents”).

The Notice Letter alleges that the Korlym Patents will not be infringed by Sun Ltd.’s proposed product, are invalid and/or are unenforceable. On July 22, 2019, we filed a lawsuit in the U.S. District Court for the District of New Jersey against Sun Pharma Global FZE (“Sun FZE”), Sun Pharma Global Inc. (“Sun Pharma”), Sun Pharmaceutical Industries, Inc. (“Sun Inc.”), and Sun Ltd. (collectively, “Sun”) for infringement of the ’348, ’214, and ’495 patents. Sun has denied our allegations.

In accordance with the Hatch-Waxman Act, as a result of having filed a timely lawsuit against Sun, FDA approval of Sun Ltd.’s ANDA will be stayed until the earlier of (i) 30 months from our June 10, 2019 receipt of Sun Ltd.’s Paragraph IV Notice Letter or (ii) a District Court decision finding that the ’348, ’214, and ’495 patents are invalid, unenforceable or not infringed.

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

Inter Partes Review at the PTAB

In August 2018, Neptune Generics, LLC (“Neptune”) submitted a petition for Inter Partes Review (“IPR”) at the PTAB of the ’348 patent. Neptune is backed by Burford Capital Ltd., a U.K.-based litigation finance company, and does not have regulatory approval to sell any drug in the United States. A PTAB decision finding all claims of the ’348 patent to be valid was issued on February 10, 2020. Neptune did not appeal the PTAB’s decision. The matter is now closed.

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 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 stemming 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 filed an amended complaint. We will respond to this amended complaint vigorously 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, and captioned *Lauren Williams v. G. Leonard Baker, et al.*, Civil Action No. 1:19-cv-01830. The complaint named our board of directors, including our Chief Executive Officer and Chief Financial Officer as defendants and us as nominal defendant. The complaint alleges breach of fiduciary duty, violation of Section 14(a) of the Exchange Act, insider selling, misappropriation of inside 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. 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, and captioned *Jeweltex Pension Plan v. James N. Wilson, et al.*, Civil Action No. 1:19-cv-02308. The complaint named our board of directors, including our Chief Executive Officer, as well as our Chief Financial Officer as defendants and Corcept Therapeutics Incorporated as nominal defendant. The complaint seeks to allege 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 an amount of damages to be proved at trial. On April 6, 2020, this action was stayed pending a resolution of our motions to dismiss the Melucci litigation. We will respond to this complaint vigorously but cannot predict the outcome of this matter.

In addition to the matters described above, we are involved from time to time in other legal proceedings in the ordinary course of business. Although the outcome of any pending matters and the amount, if any, of our ultimate liability with respect to them cannot be predicted with certainty, we do not believe that the ultimate outcome of such matters 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.

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 off-label treatments for Cushing's syndrome, such as ketoconazole;
- competition from non-medical treatments, such as surgery and radiation;

- the potential introduction of a competitor for Korlym, including a generic version of Korlym;
- natural disasters or other catastrophic events, such as the COVID-19 pandemic, which may reduce the ability or willingness of physicians to see patients and of patients to bear the risk of leaving their homes to seek medical care;
- the lack of availability of adequate private and government insurance coverage;
- negative publicity and political concerns about Korlym’s active ingredient, mifepristone, which is approved in another drug for the termination of pregnancy; and
- technological change that makes Korlym obsolete.

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

The COVID-19 pandemic or another public health emergency, as well as natural disasters, terrorism and other catastrophes, could disrupt our activities and render our own or our vendors’ facilities and equipment inoperable or inaccessible and require us to cease or curtail operations.

Since being reported in December 2019, COVID-19, a serious and sometimes fatal illness, has spread globally, including to every state in the United States. Many countries, including most states of the United States, have reacted by instituting quarantines and restrictions on work and travel. In California, where our headquarters are located, and in the states where most of our clinical specialists and medical science liaisons live and work, residents are subject to “shelter-in-place” orders and other restrictions. Although many of these orders designate pharmaceutical companies as “essential businesses” with some freedom to operate, we have been managing our business primarily by video conference, teleconference and email, because we believe the public good and the safety of our employees requires it. In addition, 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 which 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, operating results and financial condition could be harmed.

COVID-19 has made it more difficult to interact with physicians who treat patients with Cushing’s syndrome. Steps physicians have taken to reduce the risk of COVID-19 infection in their practices include reducing the frequency of patient office visits and barring office visits by third parties, including our clinical specialists and medical science liaisons. Pandemic-related closures of clinical laboratories and imaging centers, as well as the reluctance of patients to leave the safety of their homes, has made it difficult or impossible for many physicians to identify patients who may benefit from Korlym, begin their treatment, titrate to an optimum dose and maintain their regimen. If physicians do not prescribe Korlym to new patients or patients already receiving Korlym discontinue treatment, our revenue will be reduced.

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 suspended the initiation of new trials. Many patients are reluctant to participate in procedures required by our clinical trial protocols because they fear infection. If COVID-19 remains prevalent, we may experience additional disruptions, 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, patient discontinuations, 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;
- 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.

In addition, other natural or man-made 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. 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 patents covering Korlym’s use to treat patients with Cushing’s syndrome or that our 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 Sun in Federal District Court with respect to their proposed generic versions of Korlym. Teva has challenged the validity of one of our patents in a proceeding before the Patent Trial and Appeals Board. 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 II, Item 1, Legal Proceedings.” Furthermore, on August 1, 2020, after the 30-month stay provided by the Hatch-Waxman Act has expired, Teva may choose to market a generic version of Korlym, notwithstanding any ongoing litigation or administrative disputes with us. Even if we prevail in our legal actions and Teva withdraws its product and pays us damages, the temporary availability of a generic version of Korlym could materially harm our results of operations and financial condition.

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.

Strongbridge Biopharma plc (“Strongbridge”) 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. Strongbridge has completed one Phase 3 trial, which met its primary endpoint of reducing cortisol synthesis, and is conducting a second Phase 3 trial.

If we cannot continue to obtain acceptable prices or adequate insurance coverage and reimbursement for Korlym, we will be unable to generate significant revenues.

The commercial success of Korlym depends on the availability of 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 and reimbursement for Korlym, physicians may not prescribe the medication and patients may not purchase it, even if it is prescribed. In addition, delays in coverage for individual patients may reduce our revenues.

The COVID-19 pandemic has already caused a global economic contraction that may last a long time. Significant increases in unemployment stemming from the pandemic may cause some patients to lose access to employer-sponsored insurance, which pays significantly more for Korlym than do state Medicaid plans, and may increase patient reliance on our financial assistance and free drug programs and on the independent charities we support. In addition, there may be delays in coverage as patients secure authorization for Korlym treatment from their new insurer. If the pandemic causes any of these effects, our charitable donation expenses would increase and our revenue would decline.

In some 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 (“PPACA”), which was passed in 2010, substantially changed the way health care is financed by both governmental and private insurers. The PPACA, 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 PPACA 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.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the PPACA, and we expect there will be additional challenges and amendments to the PPACA in the future. For example, the Tax Cuts and Jobs Acts (the “Tax Act”) was enacted, which, among other things, removed penalties for not complying with the individual mandate to carry health insurance. On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, ruled that the individual mandate is a critical and inseparable feature of the PPACA, and therefore, because it was repealed as part of the Tax Act, the remaining provisions of the PPACA are invalid as well. On December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the district court’s decision that the individual mandate was unconstitutional but remanded the case back to the District Court to determine whether the remaining provisions of the Affordable Care Act are invalid as well. On March 2, 2020, the U.S. Supreme Court granted the petitions for writs of certiorari to review the case, although it is unclear when a decision will be made or how these decisions, subsequent appeals, if any, and the Supreme Court will rule. In addition, there may be other efforts to challenge, replace or repeal the PPACA that may affect the law or our business. Any new limitations on, changes to, or uncertainty with respect to the ability of individuals to enroll in governmental reimbursement programs or other third-party payer insurance plans could reduce Korlym sales, which in turn could affect our ability to successfully develop and commercialize new products.

Other legislative and regulatory changes have been proposed and adopted in the United States since the PPACA 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 2029 unless additional Congressional action is taken. These reductions will be suspended from May 1, 2020 through December 31, 2020 due to the COVID-19 pandemic. The American Taxpayer Relief Act of 2012, which 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. 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.

These new 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 ability to develop and commercialize our product candidates.

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 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, 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 of Korlym and our product candidates must be approved by the FDA and, in some cases, the European Medicines Agency ("EMA"). 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 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.

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 cannot predict how government regulations may change. The Trump administration has taken actions that could impose significant burdens on or materially delay the FDA’s ability to implement new rules, issue guidance and review and approve marketing applications. It is difficult to predict how these executive actions will be implemented, if at all, and the extent to which they will affect the FDA’s ability to exercise its authority. If these executive actions impair the FDA’s ability to carry out its regulatory responsibilities or if we are slow or unable to adapt to sudden changes in regulatory requirements, our regulatory compliance may lapse and we may lose marketing approval for Korlym or face enforcement action.

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.

Although we believe our marketing materials and training programs do not constitute “off-label” promotion, the FDA may disagree. If the FDA determines that our promotional materials, training or other activities by our employees or agents constitute “off-label” promotion, it could require us to change them. The FDA could also 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.

We are subject to federal and state healthcare fraud and abuse regulations, including:

- 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;
- 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 PPACA 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.

We rely heavily 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. As a result of COVID-19, we may face increased 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.

We have experienced “phishing” attacks, hacking incidents and other unauthorized access to certain data and information, and 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 may remain undetected for an extended period.

If a disruption or security breach resulted in the disclosure of confidential or proprietary information, we could incur liability and our research, development and commercialization efforts could be delayed or otherwise harmed. 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 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 are subject to statutes concerning data privacy and security, including HIPAA and the EU’s General Data Protection Regulation (“GDPR”). These and other regulatory frameworks are evolving rapidly as new rules are enacted and existing ones updated and made more stringent.

In the United States, HIPAA imposes privacy, security and breach reporting obligations with respect to individually identifiable health information upon “covered entities” (health plans, health care clearinghouses and certain health care providers), and their respective business associates, individuals or entities that create, received, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity. HIPAA mandates the reporting of certain breaches of health information to HHS, affected individuals and if the breach is large enough, the media. Entities that are found to be in violation of HIPAA as the result of a breach of unsecured protected health information, a complaint about privacy practices or an audit by HHS, may be subject to significant civil, criminal and administrative fines and penalties and/or additional reporting and oversight obligations if required to enter into a resolution agreement and corrective action plan with HHS to settle allegations of HIPAA non-compliance. Even when HIPAA does not apply, according to the Federal Trade Commission or the FTC, failing to take appropriate steps to keep consumers’ personal information secure constitutes unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act, or the FTCA, 15 U.S.C § 45(a). 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. The FTC’s guidance for appropriately securing consumers’ personal information is similar to what is required by the HIPAA Security Rule.

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 instance, on June 28, 2018, California enacted the California Consumer Privacy Act, or 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. Similar laws have been proposed at the federal level and in other states.

The GDPR went into effect in 2018 and has become binding against all EEA member states. It imposes several stringent requirements for controllers and processors of personal data, particularly with respect to clinical trials. The GDPR provides that EU 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. There are currently a number of legal challenges to the validity of EU mechanisms for adequate data transfers (such as the commonly-

used EU-Commission-approved model clauses) or review of these mechanisms (such as the U.S. Privacy Shield), and our business could be impacted by changes in law as a result of a future review of these transfer mechanisms by EU regulators under the GDPR, as well as current challenges to these mechanisms in the EU courts. 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 EU data protection law 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. Additionally, following the United Kingdom's withdrawal from the EU, we will have to comply with the GDPR and the United Kingdom GDPR, each regime having the ability to fine up to the greater of €20 million/ £17.5 million or 4% of global turnover. The relationship between the United Kingdom and the EU in relation to certain aspects of data protection law remains unclear, for example around how data can lawfully be transferred between each jurisdiction, which exposes us to further compliance risk.

Complying with HIPAA, the GDPR and other data privacy and security requirements 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 are dependent on the continued functioning of the FDA and other federal instrumentalities. Inadequate funding of these instrumentalities, their partial or complete closure, or their inability to hire and retain talented professionals 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 caused by the COVID-19 pandemic or other events that may affect governmental authorities' 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.

In response to the COVID-19 pandemic, the FDA announced on March 10, 2020 its intention to postpone most foreign inspections of manufacturing facilities and products through April 2020, and subsequently, on March 18, 2020, the FDA announced its intention to temporarily postpone routine surveillance inspections of domestic manufacturing facilities. On April 16, 2020, the FDA announced that the amount of time it takes to complete its review of new drug candidates and generic drug applications may increase, as it diverts workers to pandemic-related projects. Regulatory authorities outside the United States have adopted similar restrictions and may experience delays in response. 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 tax. 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 that we cannot control or predict could materially increase the amount of taxes and fees we must pay. For example, an increase in income tax rates or a reduction or elimination of net operating losses and research and development tax credits could significantly increase our tax expense, which would reduce our net income and adversely affecting our results of operations.

Risks Related to our Research and Development Activities

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 stage of drug development. Our efforts to discover, develop and commercialize our product candidates may not succeed.

Clinical development is expensive, lengthy and often unsuccessful. 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 realistically seek regulatory approval of a product candidate.

Clinical trials may be delayed by many factors, including:

- 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. Please see the risk factor *“The COVID-19 pandemic or another public health emergency, as well as natural disasters, terrorism and other catastrophes, could disrupt our activities and render our own or our vendors’ facilities and equipment inoperable or inaccessible and require us to cease or curtail operations.”*

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, which could delay or prevent the completion of development and increase its cost. Even if we conduct all of the clinical trials and supportive studies that we consider appropriate and the results are positive, we may not receive regulatory approval.

Vendors manufacture and distribute the drug product we use in our trials, conduct and manage some of our clinical trials and perform 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 would go undetected.

We may be unable to obtain or maintain regulatory approvals for our product or product candidates.

We cannot promote a product candidate unless the FDA or comparable foreign regulatory authorities approves it, which may not happen. Obtaining regulatory approval of a drug 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. 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 FDA requirements and oversight, such as continued safety and other reporting requirements and post-marketing restrictions. If we are not able to maintain regulatory compliance, we may not be permitted to develop our product candidates or market our products and may be subject to product recalls or seizures. Any regulatory approvals for our product candidates may require costly post-marketing studies. Future governmental action or changes in FDA policy or personnel may also result in delays or rejection of an NDA or supplemental NDA.

Obtaining regulatory approval of product candidates in foreign jurisdictions would be costly and difficult. Failure to obtain such approvals would prevent us from commercializing our product candidates outside the United States.

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. These approval processes include all of the risks associated with the FDA's approval process and, in some cases, more. 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.

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 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.

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, which have greater 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.

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 will be 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.

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. The COVID-19 pandemic has caused extreme volatility in the equity markets, which makes raising additional capital more difficult. 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.

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.

If we are unable to obtain or maintain orphan designation for our product candidates, our financial results may be negatively affected.

In the United States and the EU, orphan drug designation confers financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages, and reduction of fees or fee waivers. Although we have received orphan drug designation for relacorilant for the treatment of patients with Cushing's syndrome and patients with pancreatic cancer in both the United States and EU, we may be unable to maintain these designations or to obtain designations for our other product candidates, which may negatively affect our financial results.

Risks Relating to Our Intellectual Property

To succeed, we must secure and maintain 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 and other disorders.

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

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

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 TNBC and CRPC.

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.

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. Mifepristone is sold in the United States by Danco Laboratories for the termination of pregnancy. We cannot be certain that patients with Cushing’s syndrome will not be able to obtain mifepristone from Danco or from another company, should it receive approval to market mifepristone for any indication.

Risks Related to Our Stock

The price of our common stock fluctuates widely and is likely to continue to do so. Opportunities for the sale of shares at any particular time may be limited.

We cannot assure investors that a liquid trading market for our common stock will exist at any particular time. As a result, holders of our common stock may not be able to sell shares quickly or at the current market price. During the 52-week period ended April 30, 2020, our average daily trading volume was approximately 869,102 shares and the intra-day sales prices per

share of our common stock on The Nasdaq Stock Market ranged from \$9.55 to \$17.48. As of April 30, 2020, our officers, directors and principal stockholders beneficially owned approximately 16 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:

- changes in the expected or actual timing of our competitors' potential development programs, including developments in ANDA litigation and proceedings before the PTAB and the announcement of ANDA filings seeking approval for generic versions of Korlym;
- general market and economic conditions, including the economic, social and emotional costs and dislocations arising from the COVID-19 pandemic;
- 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;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- short selling of our common stock, the publication of speculative opinions about our business or other market manipulation activities by third parties 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 any public guidance we have provided;
- actual or anticipated regulatory approvals of our product candidates or of competing products;
- purchases or sales of our common stock by our officers, directors or stockholders;
- changes in laws or regulations applicable to our product candidates or our competitors' products;
- technological innovations by us, our collaborators or our competitors;
- changes in the trading volume of our common stock;
- conditions in the pharmaceutical industry, including the market valuations of companies similar to Corcept;
- additions or departures of key personnel;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;
- additional financing activities; and
- our cash and short-term investment position.

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 2020 revenue is only an estimate of what we believe is realizable at the time we give such guidance. Our actual results may vary materially. It is difficult to predict our revenue. Most obviously, the ultimate effect on our business of the COVID-19 pandemic is difficult to estimate. 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.

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.

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

As of April 30, 2020, our officers and directors beneficially owned approximately 16 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.

Changes in laws and regulations may significantly increase our costs, 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, and marketing of medications, the provisions of the PPACA 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.

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.

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

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

Issuer Purchases of Equity Securities

The following table contains information relating to the purchases of our common stock made by us during the three months ended March 31, 2020 (in thousands, except per share data):

Fiscal Period	Total Number of Shares Purchased (1)	Average Price Paid Per Share	Approximate Dollar Amount of Shares
January 1, 2020 to January 31, 2020	—	\$ —	\$ —
February 1, 2020 to February 29, 2020	20	\$ 13.54	275
March 1, 2020 to March 31, 2020	—	—	—
Total	20	\$ 13.54	\$ 275

(1) On February 26, 2020, we purchased 20,338 shares at an aggregate purchase price of \$0.3 million of our common stock from our Chief Executive Officer to satisfy tax liability arising from his cashless option exercise in 2019 of stock options that were set to expire.

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	<u>Amended and Restated Certificate of Incorporation, as amended (incorporated by reference to Exhibit 3.1 to the registrant's Quarterly Report on Form 10-Q filed on August 9, 2012).</u>
3.2	<u>Amended and Restated Bylaws (incorporated by reference to Exhibit 3.1 to the registrant's Current Report on Form 8-K filed on February 13, 2017).</u>
31.1	<u>Rule 13a-14(a)/15d-14(a) Certifications of Joseph K. Belanoff, M.D., Chief Executive Officer of the registrant.</u>
31.2	<u>Rule 13a-14(a)/15d-14(a) Certifications of Charles Robb, Chief Financial Officer of the registrant.</u>
32.1	<u>18 U.S.C. Section 1350 Certifications of Joseph K. Belanoff, M.D., Chief Executive Officer of the registrant.</u>
32.2	<u>18 U.S.C. Section 1350 Certifications of Charles Robb, Chief Financial Officer of the registrant.</u>
101	The following materials from the registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2020, formatted in Extensible Business Reporting Language (XBRL): (i) Unaudited Condensed Consolidated Balance Sheets at March 31, 2020 and December 31, 2019, (ii) Unaudited Condensed Consolidated Statements of Comprehensive Income for the three month periods ended March 31, 2020 and 2019, (iii) Unaudited Condensed Consolidated Statements of Cash Flows for the three month periods ended March 31, 2020 and 2019, (iv) Unaudited Condensed Consolidated Statement of Stockholder's 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: May 4, 2020

/s/ Joseph K. Belanoff

Joseph K. Belanoff, M.D.

Chief Executive Officer

Date: May 4, 2020

/s/Charles Robb

Charles Robb

Chief Financial Officer

CERTIFICATION

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

1. I have reviewed this Quarterly Report on Form 10-Q for the period ended March 31, 2020 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 we 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
May 4, 2020

CERTIFICATION

I, Charles Robb, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the period ended March 31, 2020 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 we 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/ Charles Robb

Charles Robb

Chief Financial Officer and Secretary

May 4, 2020

Corcept Therapeutics Incorporated

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

In connection with the Quarterly Report of Corcept Therapeutics Incorporated (the "Company") on Form 10-Q for the period ended March 31, 2020, 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

May 4, 2020

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

Corcept Therapeutics Incorporated

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

In connection with the Quarterly Report of Corcept Therapeutics Incorporated (the "Company") on Form 10-Q for the period ended March 31, 2020, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Charles Robb, 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/ Charles Robb

Charles Robb

Chief Financial Officer and Secretary

May 4, 2020

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.