

**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 June 30, 2019

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 July 29, 2019, there were 113,688,837 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)

	June 30, 2019	December 31, 2018
	(Unaudited)	(See Note 1)
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 58,141	\$ 41,625
Short-term marketable securities	143,396	165,135
Trade receivables, net of allowances	19,774	17,588
Inventory	5,142	4,732
Prepaid expenses and other current assets	6,202	7,740
Total current assets	232,655	236,820
Strategic inventory	12,726	11,510
Operating lease right-of-use asset	1,106	—
Property and equipment, net of accumulated depreciation	1,177	655
Long-term marketable securities	24,165	—
Other assets	150	50
Deferred tax assets, net	56,700	62,659
Total assets	<u>\$ 328,679</u>	<u>\$ 311,694</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 7,026	\$ 8,266
Accrued clinical expenses	5,770	3,521
Accrued and other liabilities	16,437	23,786
Operating lease liability	1,148	—
Total current liabilities	30,381	35,573
Long-term accrued income taxes	245	239
Total liabilities	30,626	35,812
Commitments and contingencies (Note 5)		
Stockholders' equity:		
Preferred stock	—	—
Common stock	118	117
Additional paid-in capital	436,622	417,228
Treasury stock	(59,732)	(23,657)
Accumulated other comprehensive gain (loss)	321	(70)
Accumulated deficit	(79,276)	(117,736)
Total stockholders' equity	298,053	275,882
Total liabilities and stockholders' equity	<u>\$ 328,679</u>	<u>\$ 311,694</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 June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Product revenue, net	\$ 72,257	\$ 62,312	\$ 137,086	\$ 119,971
Operating expenses:				
Cost of sales	1,377	1,154	2,617	2,328
Research and development	21,656	20,543	41,900	37,593
Selling, general and administrative	24,591	19,981	48,980	38,421
Total operating expenses	47,624	41,678	93,497	78,342
Income from operations	24,633	20,634	43,589	41,629
Interest and other income	1,178	562	2,275	856
Income before income taxes	25,811	21,196	45,864	42,485
Income tax expense	(5,625)	(3,000)	(7,404)	(6,830)
Net income	\$ 20,186	\$ 18,196	\$ 38,460	\$ 35,655
Other comprehensive income (loss):				
Net unrealized income (loss) on available-for-sale investments, net of tax impact of \$(73), \$(7), \$(124) and \$41, respectively	227	25	391	(127)
Total comprehensive income	\$ 20,413	\$ 18,221	\$ 38,851	\$ 35,528
Basic net income per share	\$ 0.18	\$ 0.16	\$ 0.34	\$ 0.31
Diluted net income per share	\$ 0.17	\$ 0.14	\$ 0.31	\$ 0.28
Weighted-average shares outstanding used in computing net income per share				
Basic	114,340	115,492	114,590	115,189
Diluted	121,783	127,515	122,831	127,610

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)

	Six Months Ended June 30,	
	2019	2018
Cash flows from operating activities:		
Net income	\$ 38,460	\$ 35,655
Adjustments to reconcile net income to net cash generated from operations:		
Stock-based compensation	14,432	10,971
Deferred income taxes	5,834	5,642
Accretion of interest income	(1,053)	(546)
Depreciation and amortization of property and equipment	263	105
Amortization of right-of-use asset	772	—
Changes in operating assets and liabilities:		
Trade receivables	(2,186)	(13,404)
Other receivable	—	12,896
Inventory	(1,543)	(2,071)
Prepaid expenses and other current assets	1,538	(910)
Other assets	(100)	(3)
Accounts payable	(1,299)	(2,214)
Accrued clinical expenses	2,197	3,150
Accrued and other liabilities	(7,349)	370
Operating lease liability	(730)	—
Net cash provided by operating activities	<u>49,236</u>	<u>49,641</u>
Cash flows from investing activities:		
Purchases of property and equipment	(667)	(140)
Proceeds from maturities of marketable securities	130,145	40,300
Purchases of marketable securities	(131,001)	(95,664)
Net cash used in investing activities	<u>(1,523)</u>	<u>(55,504)</u>
Cash flows from financing activities:		
Proceeds from issuance of common stock upon exercise of options, net of issuance costs	3,947	5,966
Repurchase of common stock	(30,975)	—
Cash paid to satisfy statutory withholding requirement for net settlement of cashless option exercise	(4,169)	—
Net cash (used in) provided by financing activities	<u>(31,197)</u>	<u>5,966</u>
Net increase in cash and cash equivalents	16,516	103
Cash and cash equivalents, at beginning of period	41,625	31,062
Cash and cash equivalents, at end of period	<u>\$ 58,141</u>	<u>\$ 31,165</u>
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)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount					
Balance at December 31, 2017	114,717	\$ 115	\$ 384,074	\$ —	\$ (75)	\$ (193,146)	\$ 190,968
Issuance of common stock upon exercise of options	479	—	1,922	—	—	—	1,922
Stock-based compensation related to employee and director options	—	—	4,954	—	—	—	4,954
Net unrealized gain on marketable securities, net of tax	—	—	—	—	(77)	—	(77)
Net income	—	—	—	—	—	17,459	17,459
Balance at March 31, 2018	115,196	115	390,950	—	(152)	(175,687)	215,226
Issuance of common stock upon exercise of options	821	1	4,043	—	—	—	4,044
Stock-based compensation related to employee and director options	—	—	6,017	—	—	—	6,017
Net unrealized gain on marketable securities, net of tax	—	—	—	—	24	—	24
Net income	—	—	—	—	—	18,196	18,196
Balance at June 30, 2018	116,017	\$ 116	\$ 401,010	\$ —	\$ (128)	\$ (157,491)	\$ 243,507
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
Net unrealized gain on marketable securities, 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	114,932	118	427,317	(42,312)	94	(99,462)	285,755
Issuance of common stock upon exercise of options	317	—	1,514	—	—	—	1,514
Stock-based compensation related to employee and director options	—	—	7,791	—	—	—	7,791
Net unrealized gain on marketable securities, net of tax	—	—	—	—	227	—	227
Purchases of treasury stock	(1,612)	—	—	(17,420)	—	—	(17,420)
Net income	—	—	—	—	—	20,186	20,186
Balance at June 30, 2019	113,637	\$ 118	\$ 436,622	\$ (59,732)	\$ 321	\$ (79,276)	\$ 298,053

The accompanying notes are an integral part of these 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 was incorporated in the State of Delaware in May 1998. Our headquarters are in Menlo Park, California. We are 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 three structurally distinct series of selective cortisol modulators, consisting of more than 500 compounds. We are developing compounds from these series as potential treatments for a broad range of serious disorders.

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 June 30, 2019, (ii) statements of comprehensive income and stockholders' equity for the three and six months ended June 30, 2019 and 2018 and (iii) statements of cash flows for the six months ended June 30, 2019 and 2018. These do not include all of the information and footnotes required by GAAP for complete financial statements. In the opinion of management, all adjustments considered necessary for a fair presentation (which in the applicable periods consist only of normal, recurring adjustments) have been included. Operating results for the three and six months ended June 30, 2019 are not necessarily indicative of the results for the remainder of 2019 or any other period. These financial statements and notes should be read in conjunction with the financial statements for the year ended December 31, 2018 included in our Annual Report on Form 10-K. The December 31, 2018 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, 2018 except for the adoption of the accounting pronouncements set forth below.

Recently Adopted Accounting Pronouncements

In February 2016, the FASB issued ASU No. 2016-02, “Leases”, which requires lease transactions with terms longer than 12 months to be recognized on the balance sheet as a liability (“lease liabilities”), offset by an asset of equal amount (“right-of-use assets”). ASU No. 2016-02 supersedes the lease accounting requirements of ASC Topic 840, “Leases” and creates Topic 842, “Leases.” We adopted this standard using the modified retrospective approach on January 1, 2019. Prior comparative periods are not adjusted under this approach. We have reviewed all contracts that may contain leases and have determined that the only impact is to the accounting for our leased office space. We have elected to apply the practical expedients in Topic 842 that allow us not to reassess lease classification for any expired or existing lease contracts. On the date of adoption, we increased our “operating right-of-use assets” and “operating lease liability” by approximately \$1.9 million, an amount equal to the present value of our expected payments over the remaining term of the lease. There was no change to our retained earnings. See Note 4 for more information regarding our leased office space.

In February 2018, the FASB issued ASU No. 2018-02, “Income Statement - Reporting Comprehensive Income (Topic 220): Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income.” The standard allows companies to reclassify to retained earnings tax effects related to items that have been stranded in accumulated other comprehensive income as a result of the Tax Cuts and Jobs Act (the “Act”). A company that elects to reclassify these amounts must reclassify stranded tax effects related to the Act’s change in US federal tax rate for all items accounted for in other comprehensive income. These entities can also elect to reclassify other stranded effects that relate to the Act but do not directly relate to the change in the federal rate. This standard is effective for fiscal years, and interim periods within those years, beginning after December 15, 2018. We adopted this standard on January 1, 2019. It had no impact on our consolidated financial statements.

In June 2018, the FASB issued ASU No. 2018-07, “Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting,” which expands the scope of ASC 718 to include all share-based payment arrangements related to the acquisition of goods and services from nonemployees. This standard is effective for fiscal years and interim periods within those years beginning after December 15, 2018. We adopted ASC 718 on January 1, 2019. It had no impact on our consolidated financial statements.

Recently Issued Accounting Pronouncements Not Yet Adopted

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 will be effective for fiscal years, and interim periods within those years, beginning after December 15, 2019. Early adoption is permitted beginning after December 15, 2018. We plan to adopt this standard on January 1, 2020. Although we have not concluded our analysis, we do not expect adoption of this standard to have a material impact on our 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 new information. This standard will be effective for fiscal years, and interim periods within those years, beginning after December 15, 2019. We plan to adopt this standard on January 1, 2020. We are evaluating the likely impact of this new standard on our 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 deferred assets. This standard will be effective for fiscal years, and interim periods within those years, beginning after December 15, 2019. We plan to adopt this standard on January 1, 2020. We are evaluating the likely impact of this new standard on our consolidated financial statements.

2. Composition of Certain Balance Sheet Items

Inventory

	June 30, 2019	December 31, 2018
	<i>(in thousands)</i>	
Raw materials	\$ 7,395	\$ 4,195
Work in progress	5,271	5,624
Finished goods	5,202	6,423
Total inventory	17,868	16,242
Less strategic inventory classified as non-current	(12,726)	(11,510)
Total inventory classified as current	<u>\$ 5,142</u>	<u>\$ 4,732</u>

Because we rely on single manufacturers of both the active pharmaceutical ingredient (“API”) for Korlym and Korlym tablets, we have purchased and hold significant quantities of these materials. We classify inventory we do not expect to sell within 12 months of the balance sheet date as “Strategic Inventory,” a long-term asset.

Accrued and other liabilities

	June 30, 2019	December 31, 2018
	<i>(in thousands)</i>	
Government rebates	\$ 7,688	\$ 11,132
Accrued compensation	5,083	7,879
Accrued selling and marketing costs	1,275	261
Legal fees	967	314
Professional fees	694	240
Accrued manufacturing costs	261	2,032
Income taxes payable	—	1,542
Other	469	386
Total accrued and other liabilities	<u>\$ 16,437</u>	<u>\$ 23,786</u>

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

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

	June 30, 2019	December 31, 2018
	<i>(in thousands)</i>	
Cash equivalents	\$ 43,269	\$ 27,075
Short-term marketable securities	143,396	165,135
Long-term marketable securities	24,165	—
Total marketable securities	\$ 210,830	\$ 192,210

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

	Fair Value Hierarchy Level	June 30, 2019				December 31, 2018				
		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	\$ 91,501	\$ 183	\$ (2)	\$ 91,682	\$ 54,513	\$ 2	\$ (46)	\$ 54,469	
Commercial paper	Level 2	17,881	—	—	17,881	67,906	—	—	67,906	
Asset-backed securities	Level 2	38,452	106	—	38,558	10,970	—	(5)	10,965	
Repurchase agreements	Level 2	30,000	—	—	30,000	15,000	—	—	15,000	
U.S. treasury securities	Level 1	19,406	34	—	19,440	39,308	—	(21)	39,287	
Money market funds	Level 1	13,269	—	—	13,269	4,583	—	—	4,583	
Total Marketable securities		\$ 210,509	\$ 323	\$ (2)	\$ 210,830	\$ 192,280	\$ 2	\$ (72)	\$ 192,210	

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.

As of June 30, 2019, all our marketable securities had original maturities of less than two years. The weighted-average maturity of our holdings was six months. As of June 30, 2019, our long-term marketable securities had a remaining maturity of 12 to 14 months. None of our marketable securities changed from one fair value hierarchy to another during the three and six months ended June 30, 2019.

4. Leases

We lease our office facilities in Menlo Park, California. Our lease expires on March 31, 2020. On January 1, 2019, we recognized a right-of-use asset and a corresponding lease liability of \$1.9 million, which equals the present value of the remaining payments due under our lease. Because the discount rate implicit in our lease is not readily determinable, 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 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. For any future 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 time the lease is executed. Operating lease expense for the three and six months ended June 30, 2019 was approximately \$0.4 million and \$0.8 million, respectively.

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

	Three Months Ended June 30, 2019	Six Months Ended June 30, 2019
	<i>(in thousands)</i>	
Cash paid for operating lease liability	\$ 391	\$ 769
Right-of-use assets obtained in exchange for new operating lease liability	\$ —	\$ 1,878
Weighted-average remaining lease term	9 months	9 months
Weighted-average discount rate	5.0%	5.0%

As of June 30, 2019, future minimum lease payments under non-cancelable operating leases due in each of the next two years were as follows (*in thousands*):

2019 (remainder)	\$ 781
2020	391
	<u>1,172</u>
Less imputed interest	(24)
Total lease liability	<u>\$ 1,148</u>

5. Commitments and Contingencies

There have been no material changes in our obligations under contractual agreements described in our Annual Report on Form 10-K for the year ended December 31, 2018.

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 2019, our Board of Directors authorized a 4.6 million increase in the shares available for grant under the 2012 Plan.

During the three and six months ended June 30, 2019, we issued 0.3 million and 1.8 million shares, respectively, of our common stock upon the exercise of stock options, compared to 0.8 million and 1.3 million shares during the same periods of 2018, respectively.

The following table summarizes our stock-based compensation:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
	<i>(in thousands)</i>		<i>(in thousands)</i>	
Stock-based compensation capitalized in inventory	\$ 55	\$ —	\$ 83	\$ —
Cost of sales	55	—	83	—
Research and development	2,505	1,963	4,484	3,427
Selling, general and administrative	5,176	4,054	9,865	7,544
Total stock-based compensation	<u>\$ 7,791</u>	<u>\$ 6,017</u>	<u>\$ 14,515</u>	<u>\$ 10,971</u>

Stock Repurchase Program

On August 9, 2018, we announced a program to repurchase up to \$100 million of our common stock (the “Stock Repurchase Program”). The terms of this program did not require us to acquire any shares and allowed for repurchases by a variety of methods, including in the open market, in block trades, through privately negotiated transactions, accelerated share repurchase transactions or any combination of such methods.

During the three and six months ended June 30, 2019, we repurchased 1.6 million and 2.8 million shares of common stock under the Stock Repurchase Program in open market transactions at costs of \$17.4 million and \$31.0 million (average prices of \$10.81 and \$11.14 per share), respectively. In total, we repurchased 4.6 million shares under the Program at a cost of \$54.6 million (an average price of \$11.91 per share). We recorded shares repurchased as treasury stock at cost on our consolidated balance sheet.

The Stock Repurchase Program expired on June 30, 2019.

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 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 June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
	<i>(in thousands)</i>		<i>(in thousands)</i>	
Numerator:				
Net income	\$ 20,186	\$ 18,196	\$ 38,460	\$ 35,655
Denominator:				
Weighted-average shares used to compute basic net income per share	114,340	115,492	114,590	115,189
Dilutive effect of employee stock options	7,443	12,023	8,241	12,421
Weighted-average shares used to compute diluted net income per share	121,783	127,515	122,831	127,610
Net income per share				
Basic	<u>\$ 0.18</u>	<u>\$ 0.16</u>	<u>\$ 0.34</u>	<u>\$ 0.31</u>
Diluted	<u>\$ 0.17</u>	<u>\$ 0.14</u>	<u>\$ 0.31</u>	<u>\$ 0.28</u>

As of June 30, 2019 and 2018, we had 24.7 million and 23.0 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, 10.8 million and 9.8 million stock options outstanding during the three and six months

ended June 30, 2019, respectively, and 5.0 million and 3.9 million stock options outstanding during the three and six months ended June 30, 2018, respectively.

8. Income taxes

We recorded income tax expense of \$5.6 million and \$7.4 million for the three and six months ended June 30, 2019, respectively, net of discrete benefits related to stock option exercises and dispositions of \$0.3 million and \$3.2 million, respectively. Income tax expense in these periods consisted primarily of reductions in our deferred tax assets of \$4.9 million and \$5.8 million, respectively, caused by utilization of our federal and state net operating losses, and income tax expense of \$0.7 million and \$1.6 million, respectively, in states where we do not have net operating loss carryforwards.

In the three and six month ended June 30, 2018, our income tax expense was \$3.0 million and \$6.8 million, respectively, consisting primarily of reductions of \$2.5 million and \$5.6 million, respectively, in our deferred tax assets caused by utilization of our federal and state net operating losses, and income tax expense of \$0.5 million and \$1.2 million, respectively, in states where we do not have net operating loss carryforwards.

Our effective tax rate differed from the federal statutory rate in these periods 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 taxable income.

Each quarter, we assess the likelihood that we will generate sufficient taxable income to use our federal and state deferred tax assets. In the fourth quarter of 2017, we determined that it was more likely than not that we would generate sufficient taxable income to utilize all of our federal deferred tax assets and all of our state deferred tax assets in every state except California. We therefore included in our balance sheet at December 31, 2017 the net value of our federal deferred tax assets and all of state deferred tax assets except those related to California income tax.

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 Cushing's syndrome, a disease caused by excess cortisol activity.

We are also developing compounds from our portfolio of more than 500 proprietary, selective cortisol modulators. We have discovered and patented three structurally distinct series of such molecules, all of which share Korlym's affinity for the glucocorticoid receptor ("GR") but, unlike Korlym, do not bind to the progesterone receptor ("PR") and therefore do not cause effects arising from antagonism of progesterone activity, such as termination of pregnancy, endometrial thickening and vaginal bleeding. We are developing compounds from these series as potential treatments for a wide range 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 and diagnosis of 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.

Prior to its approval, the FDA designated Korlym an orphan drug for the treatment of endogenous Cushing's syndrome, which conferred seven years of exclusive marketing rights in the United States. This exclusivity expired in February 2019, which means a competitor who receives FDA approval for a generic equivalent of Korlym may market its drug to patients with Cushing's syndrome, provided doing so would not infringe any of our patents. We have eight patents listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book, that we believe would be infringed by a generic competitor for Korlym. These patents have terms ranging from 2028 to 2037. Additional applications for patents we believe would qualify for the Orange Book are under examination by the U.S. Patent and Trademark Office ("USPTO").

Relacorilant. We are conducting a Phase 3 trial of our proprietary, selective cortisol modulator, relacorilant, as a treatment for hypercortisolism. Patients in relacorilant's Phase 2 trial exhibited meaningful improvements in the trial's primary endpoints of glucose control and hypertension, as well as in a variety of secondary endpoints, including weight loss, liver function, coagulopathy, cognition, mood, insulin resistance, and quality of life. Relacorilant was well-tolerated in its Phase 1 and Phase 2 trials. Importantly, relacorilant shares Korlym's affinity for GR, but unlike Korlym has no affinity for PR, and so does not cause the effects associated with PR affinity, including termination of pregnancy, endometrial thickening and vaginal bleeding. Relacorilant also does not appear to cause hypokalemia (low potassium), a potentially serious adverse event that is the leading cause of patients stopping treatment with Korlym. Forty-four percent of patients in Korlym's pivotal trial experienced hypokalemia.

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 then enter a twelve-week, double-blind, "randomized withdrawal" phase, in which half of the patients will continue receiving relacorilant and the rest receive placebo. GRACE's primary endpoints are the rate and degree of relapse in patients receiving placebo compared to those continuing treatment with relacorilant.

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 for relacorilant in the designation orphan indication, seven years of exclusive marketing rights for 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 approved for the orphan designation indication, 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. The EC based its orphan designation on its finding that there was plausible evidence of relacorilant's efficacy and of its potential to confer significant clinical benefit compared to already-approved treatments.

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 diagnosing patients with hypercortisolism and optimizing 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 believe 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, triple-negative breast, cervical and vulvar cancers, as well as sarcoma and melanoma.

Relacorilant in Patients with Solid Tumors. At the June 2019 annual meeting of the American Society of Clinical Oncology ("ASCO"), we presented data from our Phase 1/2 trial of relacorilant plus nab-paclitaxel (Celgene Corporation's Abraxane®) to treat patients with advanced solid tumors. Eleven of the evaluable patients in that trial suffered from advanced, high-grade serous ovarian cancer. As determined using the Response Evaluation Criteria in Solid Tumors ("RECIST"), one of these patients exhibited a complete response, two exhibited a partial response and five had stable disease. Patients with metastatic pancreatic cancer demonstrated similarly encouraging responses to treatment. Of the trial's twenty-five evaluable patients with pancreatic tumors, four exhibited partial responses and eight exhibited stable disease.

These are striking results in such ill patients, all of whom had failed earlier courses of taxane-based treatment, and merit further investigation. We have begun a Phase 2, controlled 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 will be progression-free survival ("PFS"), as measured by RECIST. We also plan to start a phase 3 study in patients with metastatic pancreatic cancer.

Relacorilant has been designated an orphan drug by the EC for the treatment of pancreatic cancer. In addition, we own United States and European patents covering relacorilant's composition of matter and its use to treat a variety of disorders, including pancreatic cancer.

Korlym in Patients with Solid Tumors. University of Chicago investigators have initiated three trials of Korlym plus anticancer agents in the treatment of solid tumors: With funding from Celgene, they are leading a 64-patient double-blind, placebo-controlled, multi-center, Phase 2 trial of Korlym combined with Abraxane in patients with triple-negative breast cancer ("TNBC"). They are conducting a 74-patient, open label trial of Korlym combined with Merck's drug Keytruda® (pembrolizumab) in patients with advanced HER2-negative and triple-negative breast cancer. Merck is funding this trial and providing Keytruda®. And they are leading an 84-patient, controlled, multicenter Phase 2 trial of Korlym combined with Xtandi in patients with metastatic castration-resistant prostate cancer ("CRPC"). The Department of Defense and the Prostate Cancer Foundation are funding this trial and Pfizer is providing Xtandi. We are providing Korlym for all of these trials.

We have exclusively licensed patents from the University of Chicago covering the use of cortisol modulators combined with anticancer agents to treat TNBC and CRPC.

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 United States patents covering the use of exicorilant to treat CRPC.

Metabolic Diseases

Antipsychotic-Induced Weight Gain and NASH. In animal models, our proprietary selective cortisol modulator miricorilant potently prevents and reverses the weight gain caused by Eli Lilly and Company's antipsychotic medication Zyprexa® (olanzapine). These findings are similar to the results generated with mifepristone in the same animal models and from placebo-controlled clinical trials in which mifepristone significantly reduced the weight gain and adverse metabolic effects experienced by healthy subjects administered Zyprexa or Johnson & Johnson's antipsychotic medication Risperdal® (risperidone). The results of the clinical trials were published in the journals *Advances in Therapy*, Gross et al (2009) and *Obesity*, Gross et al (2010).

We are conducting a double-blind, placebo-controlled trial testing miricorilant's activity in attenuating antipsychotic-induced weight gain in healthy subjects. Study participants will receive Zyprexa and either miricorilant or placebo for two weeks, with the primary endpoint being change in weight compared to baseline. Markers of metabolic activity, including lipids and glucose are also being measured.

We are planning two Phase 2, double-blind, placebo-controlled trials of miricorilant in patients taking antipsychotic medications – one to study reversal of recent weight gain and the other to study reversal of long-standing weight gain.

Miricorilant is also potent in animal models of fatty liver and liver fibrosis. We conducted these pre-clinical studies in response to data suggesting that cortisol modulation with Korlym plays a role in reversing fatty liver disease in patients with hypercortisolism. Fatty liver disease is a precursor to NASH, a disease that afflicts millions of people in the United States. We plan to conduct a double-blind, placebo-controlled Phase 2 trial evaluating miricorilant as a treatment for NASH.

Our Other Selective Cortisol Modulators

Our portfolio of proprietary selective cortisol modulators are covered by U.S. and foreign patents covering their composition and their methods of use in a wide range of indications. These proprietary compounds potently bind to GR but not the progesterone, estrogen or androgen receptors. Many of them have demonstrated positive results in animal or in vitro models of cortisol modulation. We plan to continue identifying new compounds and advancing the most promising of them towards the clinic.

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 \$72.3 million and \$137.1 million for the three and six months ended June 30, 2019, respectively, compared to \$62.3 million and \$120.0 million for the corresponding periods in 2018, respectively. The increases in net product revenue were primarily due to increased sales volume, as we shipped Korlym to more patients.

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

Cost of sales was \$1.4 million and \$2.6 million for the three and six months ended June 30, 2019, respectively, as compared to \$1.2 million and \$2.3 million for the corresponding periods in 2018, respectively. Cost of sales as a percentage of revenue was 1.9 percent for each of the three and six months ended June 30, 2019 and 2018.

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

Research and development expenses increased to \$21.7 million for the three months ended June 30, 2019 from \$20.5 million for the comparable period in 2018 and increased to \$41.9 million for the six months ended June 30, 2019, from \$37.6 million for the comparable period in 2018. The increases in research and development expenses were primarily due to increased spending on the recruitment and compensation of additional development personnel and on the discovery and pre-clinical advancement of new selective cortisol modulators, partially offset by the completion of drug-drug interaction studies related to relacorilant.

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
	<i>(in thousands)</i>		<i>(in thousands)</i>	
Development programs:				
Oncology	\$ 4,908	\$ 3,306	\$ 10,122	\$ 6,707
Endocrinology	8,726	5,876	15,572	10,021
Pre-clinical and clinical selective cortisol modulators	2,470	7,435	6,029	13,977
Unallocated activities, including pre-clinical, manufacturing and regulatory activities	3,047	1,963	5,693	3,461
Stock-based compensation	2,505	1,963	4,484	3,427
Total research and development expense	\$ 21,656	\$ 20,543	\$ 41,900	\$ 37,593

It is difficult to predict the timing and cost of development activities, which are subject to many uncertainties and risks, including inconclusive or negative results, slow patient enrollment, adverse side effects and difficulties in the formulation or manufacture of study drugs and 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 research and development spending for 2019 to be higher than it was in 2018 as our programs advance and we begin new ones. Research and development expenses for the remainder of 2019 and 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 June 30, 2019 increased to \$24.6 million, from \$20.0 million for the comparable period in 2018, and increased to \$49.0 million for the six months ended June 30, 2019 from \$38.4 million for the comparable period in 2018. The increases in selling, general and administrative expenses were primarily due to increased spending on the recruitment and compensation of additional employees, increased legal and marketing costs, and added distribution expenses arising from increased Korlym sales volumes.

We expect selling, general and administrative expenses to be higher in 2019 than in 2018, due to the commercial and administrative activities work caused by increased sales volumes and more research and development activity. Selling, general and administrative activities for the remainder of 2019 and later years will depend on the cost and extent of our commercial activities and the scope of our research and development programs.

Interest and other income - Interest and other income for the three and six months ended June 30, 2019 was \$1.2 million and \$2.3 million, respectively, compared to \$0.6 million and \$0.9 million, respectively, for the comparable periods in 2018, respectively. The increases in interest and other income were due to growth in our holdings of cash and marketable securities balance and increases in short-term interest rates.

Income tax expense - Income tax expense for the three and six months ended June 30, 2019 was \$5.6 million and \$7.4 million, respectively, compared to \$3.0 million and \$6.8 million for the three and six months ended June 30, 2018, respectively. The increases in income tax expense were primarily due to decreased discrete benefits from the exercise of non-qualified stock options during the six months ended June 30, 2019, as compared to the six months ended June 30, 2018.

Liquidity and Capital Resources

Since 2015, we have relied on revenues from the sale of Korlym to fund our operations. At June 30, 2019, we had an accumulated deficit of \$79.3 million.

Based on our current plans, which include fully funding our Cushing's syndrome commercial operations, conducting Phase 2 and Phase 3 trials of 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.

At June 30, 2019, we had cash, cash equivalents and marketable securities of \$225.7 million, consisting of cash and cash equivalents of \$58.1 million and marketable securities of \$167.6 million, compared to cash and cash equivalents of \$41.6 million and marketable securities of \$165.1 million at December 31, 2018.

The cash in our bank accounts and our marketable securities could be affected if the financial institutions holding them were to fail or be subject to adverse conditions in the financial markets. We have never experienced a loss or lack of access to cash.

Net cash provided by operating activities for the six months ended June 30, 2019 was \$49.2 million, compared to \$49.6 million for the comparable period in 2018. This decrease was primarily due to the receipt of \$12.9 million from our former specialty pharmacy in the first quarter of 2018, partially offset by slightly higher revenue.

Net cash used in investing activities for the six months ended June 30, 2019 was \$1.5 million, compared to \$55.5 million for the comparable period in 2018. This decrease was primarily due to our use of \$31.0 million to repurchase shares of our common stock pursuant to the Stock Repurchase Program.

Net cash used in financing activities for the six months ended June 30, 2019 was \$31.2 million compared to net cash provided by financing activities of \$6.0 million for the comparable period in 2018. Stock option exercises provided \$3.9 million for the six months ended June 30, 2019, compared to \$6.0 million for the comparable period in 2018. Under our Stock Repurchase Program, we acquired 2.8 million shares of our common stock for a total cost of \$31.0 million during the six months ended June 30, 2019. The Stock Repurchase Program expired on June 30, 2019. In total, we repurchased 4.6 million shares of common stock under the program, at a total cost of \$54.6 million. We also acquired 0.4 million shares at a cost of \$4.2 million in satisfaction of cost and withholding requirements for the settlement of a cashless option exercise in March 2019.

Contractual Obligations and Commercial Commitments

Our contractual payment obligations and purchase commitments as of December 31, 2018 are disclosed in our Annual Report on Form 10-K for the year ended December 31, 2018. They have not changed materially during the six months ended June 30, 2019.

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, 2018. During the six months ended June 30, 2019, we implemented internal controls in connection with our adoption of ASC Topic 842 "Leases." There were no other changes in our internal control over financial reporting 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 June 30, 2019 are disclosed in our Annual Report on Form 10-K for the year ended December 31, 2018. They have not changed materially during the six months ended June 30, 2019.

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 June 30, 2019. 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 June 30, 2019 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 1A. LEGAL PROCEEDINGS

Teva ANDA Litigation.

On February 5, 2018, we received a Paragraph IV Notice Letter advising that Teva Pharmaceuticals USA, Inc. (“Teva”) had submitted an Abbreviated New Drug Application (“ANDA”) to the FDA seeking authorization to manufacture, 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 FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations (referred to as 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) 30 months from our February 5, 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”). No new 30-month stay results from the filing of the Amended Complaint or new lawsuit. On February 21, 2019, the District Court consolidated the two lawsuits.

On May 7, 2019, Teva submitted to the U.S. Patent Trial and Appeal Board (“PTAB”) a petition for post-grant review of the ’214 patent. The PTAB has not yet reached a decision as to whether or not it will institute post-grant review.

We will vigorously enforce our intellectual property rights relating to Korlym, but we cannot predict the outcome of our disputes with Teva.

Sun ANDA Litigation

On June 10, 2019, we received a Paragraph IV Notice Letter advising that Sun Pharmaceutical Industries Limited (“Sun Ltd.”), 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.

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 we 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. On February 15, 2019, the PTAB granted institution to the IPR and an oral argument hearing date has been set for November 14, 2019. We plan to vigorously defend the validity of the ’348 patent.

Purported Class Action Complaint

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. Concept Therapeutics Incorporated, et al., Case No. 5:19-cv-01372-LHK). The complaint named the Company and certain of its 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 the company’s 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 May 13, 2019, proposed lead plaintiffs filed motions to be selected as the lead plaintiff. Those motions are still pending.

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, financial position or results of operations.

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 financial statements and related notes. The risks and uncertainties described below are the ones we believe may materially affect us. There may be others of which we are unaware that could materially harm our business or financial condition and cause the price of our stock to decline, in which case you could lose all or part of your investment.

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 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;
- 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.

If generic products that compete with Korlym are approved and launched, our business, financial position or results of operations would be adversely affected.

Although Korlym is protected by patents covering its method of use, potential competitors may attempt to invalidate or design around our patents or assert that they are invalid or otherwise unenforceable. The period of marketing exclusivity provided by Korlym's orphan drug designation expired on February 17, 2019, which means that other companies may seek to introduce generic equivalents of Korlym for the treatment of Cushing's syndrome, provided they receive FDA approval and can show that their products do not infringe our patents or that our patents are invalid or unenforceable. After the introduction of a generic competitor, a significant percentage of the prescriptions written for a product may be filled with the generic version, reducing sales of the branded product and its price, sometimes rapidly.

We have sued Teva and Sun in Federal District Court with respect to their proposed generic versions of Korlym. We cannot predict the outcome of these disputes. Please see "Part II, Item 1, Legal Proceedings."

Litigation to enforce or defend intellectual property rights is complex, costly and involves significant commitments of management time. If our Orange Book patents are successfully challenged and a generic version of Korlym is approved, our sales of Korlym tablets and their price could decline significantly, which would reduce our revenue and 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, Novartis has marketed its somatostatin analogue Signifor® (pasireotide) Injection in both the United States and the EU for adult patients with Cushing’s disease (a subset of Cushing’s syndrome). Novartis is also seeking approval in the United States and EU to market the experimental cortisol synthesis inhibitor osilodrostat to treat patients with Cushing’s syndrome. Osilodrostat has been designated an orphan drug in both jurisdictions for that use. In July 2019, Novartis announced that it has sold worldwide rights to Signifor and osilodrostat to Ricordati S.p.A., an Italian pharmaceutical company.

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 payors, 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 payors 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.

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 payor 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. While the Trump Administration and the Centers for Medicare & Medicaid Services have both stated that the ruling will have no immediate effect, it is unclear how this decision, subsequent appeals and other efforts to repeal the PPACA will affect the law. The Department of Justice has filed a brief supporting repeal. At this time, the full effect that any subsequent legislation regarding the PPACA would have on our business is unclear. 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 payor 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 up to 2 percent per fiscal year, which went into effect on April 1, 2013 and will remain in effect through 2027 unless additional Congressional action is taken, and 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 third parties to manufacture Korlym’s active ingredient, form it into tablets, package it and dispense it to patients. We also depend on third parties to manufacture the API and capsules or tablets for our product candidates. If these suppliers become unable or unwilling to perform these functions and we cannot transfer our business to replacement vendors in a timely manner, our business will be harmed.

A single third-party manufacturer, PCAS, supplies the API in Korlym. Another third-party manufacturer, Alcami, produces and bottles Korlym tablets. Our agreement with Alcami automatically renews and can be terminated by either party, subject to notice provisions. Our agreement with PCAS automatically renews for two one-year terms, unless either party provides 12-months' notice of its intent not to renew. A single specialty pharmacy, Optime Care, Inc. (“Optime”), dispenses the Korlym we sell directly to patients and collects payments from insurers and other payers 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. In addition, we may terminate the agreement for convenience.

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 and are dependent on them for compliance with the regulatory requirements known as good manufacturing practices (“GMPs”). 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 approval for their facilities, which could prohibit us from using the API or drug product they have provided. We have no control over whether our vendors maintain adequate quality control and hire qualified personnel. If the FDA, EMA or other regulatory authorities do not approve the facilities they use or if a necessary approval is withdrawn, 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. In addition, 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.

Although we have product liability insurance with coverage we believe to be appropriate, it may not fully cover our liabilities. Our 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.

We are subject to ongoing regulatory oversight. If we are unable to maintain approval of Korlym for the treatment of patients with Cushing’s syndrome or if we fail to comply with other regulatory requirements, we will be unable to generate revenue or 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,

sales and marketing activities. These requirements include submissions of safety information, annual updates on manufacturing activities and continued compliance with FDA regulations, including GMPs, good laboratory practices (“GLPs”) and good clinical practices (“GCPs”). The FDA enforces these regulations through inspections of us and the laboratories, manufacturers and clinical sites we use. Foreign regulatory authorities have comparable requirements and enforcement mechanisms. Discovery of previously unknown problems with a product or product candidate, such as adverse events of unanticipated severity or frequency or deficiencies in manufacturing processes or management, as well as failure to comply with FDA or other U.S. or foreign regulatory requirements, may subject us to substantial civil and criminal penalties, injunctions, holds on clinical trials, product seizure, refusal to permit the import or export of products, restrictions on product marketing, withdrawal of the product from the market, product recalls, total or partial suspension of production, refusal to approve pending NDAs or supplemental NDAs, and suspension or revocation of product approvals.

We cannot predict how government regulation may change. For example, 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 we market Korlym in a manner that violates FDA regulations or health care fraud and abuse laws.

In the United States, 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 of Korlym, 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 of Korlym, it could ask us to change our training or promotional materials or other activities. 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 be faced with 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. 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 payors 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 prescribers and other health care providers, 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;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 and their respective implementing regulations, which impose obligations on covered healthcare providers, health plans, and healthcare clearinghouses, as well as their business associates that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- 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 payor, 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; 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; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

The risk of our being found in violation of these laws and regulations is increased by the fact that many of them have not been definitively interpreted by the 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 our operations are found to be in violation of any of the laws described above or any other government regulations, we may be subject to civil and criminal penalties, damages, fines, exclusion from governmental health care programs, a corporate integrity agreement or other agreement to resolve allegations of non-compliance, individual imprisonment, and the curtailment or restructuring of our operations, any of which could adversely affect our financial results and ability to operate.

A breakdown or breach of our information technology systems or our failure to protect confidential information concerning patients or others could subject us to liability or interrupt the operation of our business.

We store sensitive data on our computer networks and on the networks of our vendors, including intellectual property and confidential information relating to our business, patients and employees. Despite the implementation of security measures, our internal computer systems and those of our vendors are subject to the risk of cyberattacks, computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. They may also be manipulated by criminals seeking to commit fraud or theft. In addition, system failures could cause the loss or theft of valuable clinical trial data or otherwise disrupt our clinical and commercial activities and be expensive and time-consuming to remedy. 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 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 EU Regulation 2016/679, known as the General Data Protection Regulation (“GDPR”). These and other regulations governing personal and confidential data are evolving rapidly as new rules are enacted and existing ones updated and made more stringent.

The GDPR took effect in Europe on May 25, 2018. It establishes new requirements for the use and safeguarding of personal data in the EU and applies to companies established in the EU as well as companies that collect and use personal data to offer goods or services to, or monitor the behavior of, individuals in the EU (including in clinical trials). Penalties for failure to comply include fines of up to €20 million or four percent of worldwide annual revenue, whichever is greater. Data protection authorities in some of the EU member states have not completed their interpretative guidance and implementing laws and regulations regarding GDPR, which makes compliance difficult. In addition, data protection authorities of the different EU countries may interpret the regulation differently. Once promulgated, national and EU guidance will likely be updated from time to time, which will add complexity and cost to our collection and handling of data.

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, 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 due to uncertainties about their ability to pay their employees could materially harm our business.

The FDA’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, and statutory, regulatory and policy changes. 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 addition, many of our patients pay for Korlym with insurance or other support provided by payers who are funded in whole or in part by the U.S. federal government, such as Medicare, Medicaid, Tricare and the Veterans Administration. If a partial or total shutdown of the federal government prevents these payers from funding their obligations, our revenues could decline.

Recent U.S. tax legislation, the impact of which is still not entirely clear, may adversely affect our results of operations, financial condition and cash flows.

Recently enacted U.S. tax legislation has significantly changed the U.S. federal income taxation of U.S. corporations, including reducing the U.S. corporate income tax rate, limiting interest deductions, permitting immediate expensing of certain capital expenditures, adopting elements of a territorial tax system, revising the rules governing net operating losses and foreign tax credits, and introducing new anti-base erosion provisions. Many of these changes became effective immediately, without transition periods or grandfathering for existing transactions. The legislation is unclear in many respects and could be subject to potential amendments and technical corrections, as well as interpretations and implementing regulations by the Treasury and Internal Revenue Service, which could increase certain adverse impacts of the legislation. In addition, it is unclear how these U.S. federal income tax changes will affect state and local taxation, which often use federal taxable income as a starting point for computing state and local tax liabilities.

A disaster could damage our own or our manufacturers' facilities and equipment, which could require us to cease or curtail operations.

Our business is vulnerable to damage from various types of natural disasters or other disruptive events, including earthquakes, fires, floods, power losses and communications failures. Our headquarters are in the San Francisco Bay Area, which is earthquake-prone. Our specialty pharmacy and tablet manufacturer 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 may not cover or be adequate to cover losses resulting from disasters or other business interruptions.

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.

Clinical development is expensive and lengthy. 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 be too small or otherwise prove inadequate to support regulatory submissions seeking marketing approvals. Even if these trials generate positive results, those results may have to be confirmed in substantially larger, more expensive and lengthier trials before we could realistically seek regulatory approvals.

The commencement and completion of clinical trials may be delayed by many factors, including:

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

We may not be able to select and qualify appropriate clinical sites. If the clinical sites we select do not enroll enough patients in a timely way, we may not complete our trials as planned, which could delay the approval of our product candidates. We could also encounter delays if a clinical trial is suspended or terminated by us, the trial’s data safety monitoring board or the IRBs governing the sites where the trial is being conducted. The FDA or other regulatory authorities may suspend or terminate a trial 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.

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 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 GCPs, or if the quality or accuracy of the data it produces is compromised, affected clinical trials may be extended, delayed or terminated and we may be unable to obtain approval for our product candidates. Similarly, failure of our manufacturers to perform their duties or comply with GMP may require us to repeat clinical trials, which would delay regulatory approval.

If our agreements with any of these third parties terminate, we may not be able to enter into alternative arrangements in a timely manner or on reasonable terms.

We may be unable to obtain or maintain regulatory approvals for our product or product candidates. Failure can occur at any stage of drug development.

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 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 GMPs. Our inability or the inability of our suppliers 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.

Future governmental action or changes in FDA policy or personnel may also result in delays or rejection of an NDA or supplemental NDA. We expect that the label for mifepristone for any indication will include, as Korlym's does, limitations on its use, including a "black-box" warning that it should not be used by pregnant women or women seeking to become pregnant.

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 will specify the uses for which they may be marketed and may also require costly post-marketing studies.

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.

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

The pharmaceutical industry is very competitive and subject to rapid technological change. Our present and potential competitors include large, diversified pharmaceutical companies, specialized pharmaceutical firms, universities and public and private research institutions. These competitors may develop and commercialize medications that are superior to and less expensive than ours. We expect competition to intensify.

Many of our competitors and potential competitors have greater experience, more financial and marketing resources and larger research and development staffs than we do. In addition, many of them, either alone or together with their partners, have significantly greater experience than we do in drug development, obtaining regulatory approvals, manufacturing and commercialization. They may develop drugs that are superior to our product candidates, which could render our product candidates obsolete or uncompetitive.

Our efforts to discover, develop and commercialize product candidates beyond Korlym for the treatment of patients with Cushing's syndrome may not succeed.

To develop additional sources of revenue, we must develop new product candidates or new therapeutic uses for Korlym. Our selective cortisol modulators, including relacorilant, may not be effective to treat any disorder. We may discover that cortisol modulators have unacceptable side effects or are otherwise not safe. We are developing multiple compounds, which will increase our spending, with no assurance of developing drugs that are safe, effective or commercially viable.

We will need to increase the size of our organization and we 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 future financial performance and our ability to compete effectively will depend on our ability to manage growth effectively. To that end, we must:

- manage our sales and marketing efforts, clinical trials, research and development activities and supply chain effectively;
- hire additional management, clinical development, administrative and sales and marketing personnel; and
- develop our administrative, accounting and management information systems and controls.

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

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

Our ability to operate successfully and manage growth depends upon hiring and retaining skilled, experienced 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 can 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, we may need to 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. In any event, equity financing would cause dilution and debt financing, if available, may involve restrictive covenants. If we obtain funds through collaborations with other companies, we may have to relinquish rights to Korlym or our product candidates. If adequate funds are not available, we may have to delay, reduce the scope of, or eliminate one or more of our development programs or even discontinue operations.

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.

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 the subject of costly litigation. The patents issued or licensed to us may be challenged at any time. Similarly, competitors and others may take actions we believe infringe our intellectual property, causing us to take legal action to defend our rights. Litigating with respect to patents and other forms of intellectual property is costly and time-consuming and the outcomes are uncertain. If we do not protect our intellectual property, competitors may erode our competitive advantage.

Our patent applications may not result in issued patents. Any patent issued to us may be challenged, invalidated, held unenforceable or circumvented. Our patent claims may not prevent third parties from producing competing products. The foreign countries in which 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 competing products in those countries based on our technology.

Patent disputes are costly and require a great deal of management's time. Their outcome is uncertain.

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 these licenses, we must make milestone and royalty payments. If we do not comply with our payment and other obligations, 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 provide adequate protection, 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.

The mifepristone patents we own or license cover the use of mifepristone, 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 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 July 29, 2019, our average daily trading volume was approximately 1,190,593 shares and the intra-day sales prices per share of our common stock on The Nasdaq Stock Market ranged from \$9.14 to \$19.48. As of July 29, 2019, 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:

- actual or anticipated variations in our operating results or changes to any public guidance we have provided;

- actual or anticipated timing and results of our clinical trials;
- changes in the expected or actual timing of our competitors' potential development programs, including developments in ANDA litigation and the announcement of ANDA filings seeking approval for generic versions of Korlym;
- 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 biotechnology and pharmaceutical industries, including the market valuations of companies similar to Corcept;
- general market and economic conditions;
- additions or departures of key personnel;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;
- our cash and short-term investment position; and
- additional financing activities.

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

The guidance we provide as to our expected 2019 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. For example, the rate of physician adoption of Korlym and the actions of government and private payors is uncertain. 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 have published revenue and earnings estimates based on their own analyses. 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 July 29, 2019, 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 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 repurchases of our common stock made by us during the three months ended June 30, 2019 (in thousands, except per share data):

Fiscal Period	Total Number of Shares Purchased As Part of a Publicly Announced Program(1)	Average Price Paid Per Share	Approximate Dollar Amount of Shares That May Yet be Purchased Under the Program(2)
April 1, 2019 to April 30, 2019	152	\$ 11.82	\$ 60,996
May 1, 2019 to May 31, 2019	1,030	10.87	49,799
June 1, 2019 to June 30, 2019	430	10.29	45,368
Total	1,612	\$ 10.81	\$ 45,368

(1) No shares were purchased other than as part of a publicly announced program.

(2) On August 9, 2018, our board of directors authorized the repurchase of issued and outstanding shares of our common stock having an aggregate value of up to \$100 million pursuant to the Stock Repurchase Program. The Stock Repurchase Program expired on June 30, 2019 and was not renewed.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

Exhibit Number	Description of Document
3.1	Amended and Restated Certificate of Incorporation, as amended (incorporated by reference to Exhibit 3.1 to the registrant's Quarterly Report on Form 10-Q filed on August 9, 2012).
3.2	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.1 to the registrant's Current Report on Form 8-K filed on February 13, 2017).
31.1	Rule 13a-14(a)/15d-14(a) Certifications of Joseph K. Belanoff, M.D., Chief Executive Officer of the registrant.
31.2	Rule 13a-14(a)/15d-14(a) Certifications of G. Charles Robb, Chief Financial Officer of the registrant.
32.1	18 U.S.C. Section 1350 Certifications of Joseph K. Belanoff, M.D., Chief Executive Officer of the registrant.
32.2	18 U.S.C. Section 1350 Certifications of G. Charles Robb, Chief Financial Officer of the registrant.
101	The following materials from the registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2019, formatted in Extensible Business Reporting Language (XBRL): (i) Unaudited Condensed Consolidated Balance Sheets at June 30, 2019 and December 31, 2018, (ii) Unaudited Condensed Consolidated Statements of Comprehensive Income for the three and six month periods ended June 30, 2019 and 2018, (iii) Unaudited Condensed Consolidated Statements of Cash Flows for the six month periods ended June 30, 2019 and 2018, (iv) Unaudited Condensed Consolidated Statement of Stockholder's Equity and (v) Notes to Unaudited Condensed Consolidated Financial Statements.

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: August 1, 2019

/s/ Joseph K. Belanoff

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

Date: August 1, 2019

/s/ G. Charles Robb

G. 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 June 30, 2019 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

August 1, 2019

CERTIFICATION

I, G. Charles Robb, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the period ended June 30, 2019 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/ G. Charles Robb

G. Charles Robb

Chief Financial Officer and Secretary

August 1, 2019

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 June 30, 2019, 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

August 1, 2019

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 June 30, 2019, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, G. 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/ G. Charles Robb

G. Charles Robb
Chief Financial Officer and Secretary
August 1, 2019

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.