

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended September 30, 2022

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)

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

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

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 October 26, 2022, there were 107,649,854 shares of common stock outstanding at a par value of \$0.001 per share.

TABLE OF CONTENTS

<u>PART I. FINANCIAL INFORMATION</u>	3
<u>ITEM 1. FINANCIAL STATEMENTS</u>	3
<u>CONDENSED CONSOLIDATED BALANCE SHEETS</u>	3
<u>CONDENSED CONSOLIDATED STATEMENTS OF INCOME</u>	4
<u>CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME</u>	5
<u>CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS</u>	6
<u>CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY</u>	7
<u>NOTES TO CONDENSED FINANCIAL STATEMENTS</u>	9
<u>ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS</u>	16
<u>ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK</u>	21
<u>ITEM 4. CONTROLS AND PROCEDURES</u>	21
<u>PART II. OTHER INFORMATION</u>	22
<u>ITEM 1. LEGAL PROCEEDINGS</u>	22
<u>ITEM 1A. RISK FACTORS</u>	24
<u>ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS</u>	38
<u>ITEM 3. DEFAULTS UPON SENIOR SECURITIES</u>	39
<u>ITEM 4. MINE SAFETY DISCLOSURES</u>	39
<u>ITEM 5. OTHER INFORMATION</u>	39
<u>ITEM 6. EXHIBITS</u>	40
<u>SIGNATURES</u>	41

PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

CORCEPT THERAPEUTICS INCORPORATED
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands)

	September 30, 2022	December 31, 2021
	(Unaudited)	(See Note 1)
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 50,243	\$ 77,617
Short-term marketable securities	346,019	145,918
Trade receivables, net of allowances	29,414	27,625
Inventory	6,046	4,988
Prepaid expenses and other current assets	20,680	10,315
Total current assets	452,402	266,463
Strategic inventory	11,027	12,962
Operating lease right-of-use asset	1,707	514
Property and equipment, net of accumulated depreciation and amortization	801	1,002
Long-term marketable securities	4,895	112,277
Other assets	5,081	3,083
Deferred tax assets, net	57,342	27,455
Total assets	<u>\$ 533,255</u>	<u>\$ 423,756</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 8,178	\$ 6,908
Accrued research and development expenses	13,771	12,442
Accrued and other liabilities	29,412	27,665
Short-term operating lease liability	1,707	526
Total current liabilities	53,068	47,541
Long-term accrued income taxes payable	6,823	409
Total liabilities	59,891	47,950
Commitments and contingencies (Note 4)		
Stockholders' equity:		
Preferred stock	—	—
Common stock	130	127
Treasury stock	(453,001)	(410,411)
Additional paid-in capital	648,831	591,349
Accumulated other comprehensive loss	(2,381)	(227)
Retained earnings	279,785	194,968
Total stockholders' equity	473,364	375,806
Total liabilities and stockholders' equity	<u>\$ 533,255</u>	<u>\$ 423,756</u>

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

CORCEPT THERAPEUTICS INCORPORATED

CONDENSED CONSOLIDATED STATEMENTS OF INCOME

(Unaudited)

(In thousands, except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Product revenue, net	\$ 101,728	\$ 96,131	\$ 298,802	\$ 267,156
Operating expenses:				
Cost of sales	1,339	1,275	3,905	3,927
Research and development	33,292	28,091	94,237	85,345
Selling, general and administrative	35,163	30,533	110,525	90,071
Total operating expenses	69,794	59,899	208,667	179,343
Income from operations	31,934	36,232	90,135	87,813
Interest and other income	1,070	72	1,780	457
Income before income taxes	33,004	36,304	91,915	88,270
Income tax benefit (expense)	1,604	(5,833)	(7,098)	(7,811)
Net income	34,608	30,471	84,817	80,459
Net income attributable to common stockholders	34,550	30,471	84,755	80,459
Basic net income per common share	\$ 0.32	\$ 0.26	\$ 0.80	\$ 0.69
Diluted net income per common share	\$ 0.30	\$ 0.24	\$ 0.73	\$ 0.63
Weighted-average shares outstanding used in computing net income per common share				
Basic	107,125	115,791	106,479	116,297
Diluted	116,620	125,136	115,818	127,173

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

CORCEPT THERAPEUTICS INCORPORATED

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME

(Unaudited)

(In thousands)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Net income	34,608	30,471	84,817	80,459
Other comprehensive income (loss):				
Unrealized gain (loss) on available-for-sale investments, net of tax effect of \$(23), \$8, \$449 and \$85, respectively	74	(23)	(1,415)	(265)
Foreign currency translation loss, net of tax	(314)	(77)	(739)	(35)
Total comprehensive income	34,368	30,371	82,663	80,159

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

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

	Nine Months Ended September 30,	
	2022	2021
Cash flows from operating activities:		
Net income	\$ 84,817	\$ 80,459
Adjustments to reconcile net income to net cash provided by operations:		
Stock-based compensation	31,921	32,121
Amortization of interest income	2,121	3,805
Depreciation and amortization of property and equipment	599	783
Deferred income taxes	(29,438)	2,047
Non-cash amortization of right-of-use asset	1,623	1,487
Changes in operating assets and liabilities:		
Trade receivables	(1,789)	(310)
Inventory	1,074	2,655
Prepaid expenses and other current assets	(10,365)	(2,288)
Other assets	(1,998)	894
Accounts payable	515	(3,961)
Accrued research and development expenses	1,329	(860)
Accrued and other liabilities	1,747	3,123
Long-term accrued income taxes	6,414	15
Operating lease liability	(1,635)	(1,505)
Net cash provided by operating activities	<u>86,935</u>	<u>118,465</u>
Cash flows from investing activities:		
Purchases of property and equipment	(382)	(404)
Proceeds from maturities of marketable securities	161,718	308,864
Purchases of marketable securities	(258,422)	(312,805)
Net cash used in investing activities	<u>(97,086)</u>	<u>(4,345)</u>
Cash flows from financing activities:		
Proceeds from issuance of common stock under our incentive award plan, net of issuance costs	3,596	13,182
Repurchase of common stock	—	(88,485)
Cash paid to satisfy statutory withholding requirement for net settlement of cashless option exercises and vesting of restricted stock grants	(20,819)	(20,319)
Net cash used in financing activities	<u>(17,223)</u>	<u>(95,622)</u>
Net (decrease) increase in cash and cash equivalents	(27,374)	18,498
Cash and cash equivalents, at beginning of period	77,617	76,190
Cash and cash equivalents, at end of period	<u>\$ 50,243</u>	<u>\$ 94,688</u>
Supplemental disclosure:		
Exercise cost of shares repurchased for net settlement of cashless option exercises	\$ 21,975	\$ 9,705
Recognition of right-of-use asset and lease liability	\$ 2,816	\$ —

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

CORCEPT THERAPEUTICS INCORPORATED

CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

(Unaudited)
(In thousands)

	Common Stock		Additional Paid-in Capital	Treasury Stock	Accumulated Other Comprehensive Income (Loss)	Retained Earnings	Total Stockholders' Equity
	Shares	Amount					
Balance at December 31, 2020	116,735	\$ 122	\$ 516,140	\$ (75,795)	\$ 415	\$ 82,456	\$ 523,338
Issuance of common stock upon exercise of options	1,832	2	10,081	—	—	—	10,083
Purchases of treasury stock	(1,282)	—	—	(33,540)	—	—	(33,540)
Shares purchased to satisfy cost and statutory withholding requirements for net settlement of cashless option exercises	(808)	—	—	(22,520)	—	—	(22,520)
Stock-based compensation	—	—	10,142	—	—	—	10,142
Other comprehensive loss, net of tax	—	—	—	—	(166)	—	(166)
Net income	—	—	—	—	—	23,465	23,465
Balance at March 31, 2021	116,477	\$ 124	\$ 536,363	\$ (131,855)	\$ 249	\$ 105,921	\$ 510,802
Issuance of common stock upon exercise of options	855	1	6,660	—	—	—	6,661
Purchases of treasury stock	(1,365)	—	—	(29,170)	—	—	(29,170)
Shares purchased to satisfy cost and statutory withholding requirements for net settlement of cashless option exercises	(146)	—	—	(3,238)	—	—	(3,238)
Stock-based compensation	—	—	11,131	—	—	—	11,131
Other comprehensive loss, net of tax	—	—	—	—	(34)	—	(34)
Net income	—	—	—	—	—	26,523	26,523
Balance at June 30, 2021	115,821	\$ 125	\$ 554,154	\$ (164,263)	\$ 215	\$ 132,444	\$ 522,675
Issuance of common stock upon exercise of options	904	1	6,224	—	—	—	6,225
Purchases of treasury stock	(1,220)	—	—	(25,775)	—	—	(25,775)
Shares purchased to satisfy cost and statutory withholding requirements for net settlement of cashless option exercises	(202)	—	—	(4,266)	—	—	(4,266)
Stock-based compensation	—	—	10,999	—	—	—	10,999
Other comprehensive loss, net of tax	—	—	—	—	(100)	—	(100)
Net income	—	—	—	—	—	30,471	30,471
Balance at September 30, 2021	115,303	\$ 126	\$ 571,377	\$ (194,304)	\$ 115	\$ 162,915	\$ 540,229
Balance at December 31, 2021	105,940	\$ 127	\$ 591,349	\$ (410,411)	\$ (227)	\$ 194,968	\$ 375,806
Issuance of common stock upon exercise of options	586	1	6,543	—	—	—	6,544
Shares purchased to satisfy cost and statutory withholding requirements for net settlement of cashless option exercises	(305)	—	—	(7,037)	—	—	(7,037)
Stock-based compensation	—	—	10,825	—	—	—	10,825
Other comprehensive loss, net of tax	—	—	—	—	(1,124)	—	(1,124)
Net income	—	—	—	—	—	22,797	22,797
Balance at March 31, 2022	106,221	\$ 128	\$ 608,717	\$ (417,448)	\$ (1,351)	\$ 217,765	\$ 407,811
Issuance of common stock upon exercise of options and vesting of restricted stock	873	—	6,597	—	—	—	6,597
Shares purchased to satisfy cost and statutory withholding requirements for net settlement of cashless option exercises	(436)	—	—	(9,366)	—	—	(9,366)
Stock-based compensation	—	—	10,662	—	—	—	10,662
Other comprehensive loss, net of tax	—	—	—	—	(790)	—	(790)
Net income	—	—	—	—	—	27,412	27,412
Balance at June 30, 2022	106,658	\$ 128	\$ 625,976	\$ (426,814)	\$ (2,141)	\$ 245,177	\$ 442,326

Issuance of common stock under our incentive award plan	1,934	2	12,224	—	—	—	12,226
Shares purchased to satisfy cost and statutory withholding requirements for net settlement of cashless option exercises	(981)	—	—	(26,187)	—	—	(26,187)
Stock-based compensation	—	—	10,631	—	—	—	10,631
Other comprehensive loss, net of tax	—	—	—	—	(240)	—	(240)
Net income	—	—	—	—	—	34,608	34,608
Balance at September 30, 2022	<u>107,611</u>	<u>\$ 130</u>	<u>\$ 648,831</u>	<u>\$ (453,001)</u>	<u>\$ (2,381)</u>	<u>\$ 279,785</u>	<u>\$ 473,364</u>

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

CORCEPT THERAPEUTICS INCORPORATED

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

1. Basis of Presentation and Summary of Significant Accounting Policies

Description of Business and Basis of Presentation

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

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

Basis of Presentation

We have prepared the following in accordance with U.S. generally accepted accounting principles (“GAAP”) for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X: (i) condensed consolidated balance sheet as of September 30, 2022, (ii) condensed consolidated statements of income, comprehensive income and stockholders’ equity for the three- and nine-month periods ended September 30, 2022 and 2021, and (iii) condensed consolidated statements of cash flows for the nine-month periods ended September 30, 2022 and 2021. These do not include all of the information and footnotes required by GAAP for complete financial statements. In the opinion of management, all adjustments considered necessary for a fair presentation (which in the applicable periods consist only of normal, recurring adjustments) have been included. Operating results for the three- and nine-month periods ended September 30, 2022 are not necessarily indicative of the results for the remainder of 2022 or any other period. These financial statements and notes should be read in conjunction with the financial statements for the year ended December 31, 2021 included in our Annual Report on Form 10-K. The December 31, 2021 balance sheet was derived from audited financial statements at that date.

There have been no material changes to the significant accounting policies described in our Annual Report on Form 10-K for the year ended December 31, 2021.

2. Composition of Certain Balance Sheet Items

Inventory

	September 30, 2022	December 31, 2021
	<i>(in thousands)</i>	
Work in progress	\$ 11,171	\$ 11,450
Finished goods	5,902	6,500
Total inventory	17,073	17,950
Less strategic inventory classified as non-current	(11,027)	(12,962)
Total inventory classified as current	\$ 6,046	\$ 4,988

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

Property and equipment, net of accumulated depreciation and amortization

	September 30, 2022	December 31, 2021
	<i>(in thousands)</i>	
Furniture and equipment	\$ 1,220	\$ 1,157
Software	1,508	1,508
Leasehold improvements	1,597	1,262
Total property and equipment	4,325	3,927
Less accumulated depreciation and amortization	(3,524)	(2,925)
Property and equipment, net of accumulated depreciation and amortization	<u>\$ 801</u>	<u>\$ 1,002</u>

Accrued and other liabilities

	September 30, 2022	December 31, 2021
	<i>(in thousands)</i>	
Accrued compensation	\$ 12,297	\$ 13,339
Government rebates	11,683	11,174
Legal fees	2,058	842
Accrued selling and marketing costs	1,602	1,351
Professional fees	909	150
Other	863	809
Total accrued and other liabilities	<u>\$ 29,412</u>	<u>\$ 27,665</u>

Other assets

As of September 30, 2022 and December 31, 2021, other assets included \$4.9 million and \$2.9 million of deposits for clinical trials, respectively.

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

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

	September 30, 2022	December 31, 2021
	<i>(in thousands)</i>	
Cash equivalents	\$ 24,973	\$ 45,088
Short-term marketable securities	346,019	145,918
Long-term marketable securities	4,895	112,277
Total marketable securities	<u>\$ 375,887</u>	<u>\$ 303,283</u>

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

	Fair Value Hierarchy Level	September 30, 2022				December 31, 2021			
		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	\$ 151,372	\$ —	\$ (1,415)	\$ 149,957	\$ 125,370	\$ 3	\$ (276)	\$ 125,097
Commercial paper	Level 2	118,993	—	—	118,993	30,963	—	—	30,963
Asset-backed securities	Level 2	8,423	—	(10)	8,413	57,801	—	(67)	57,734
U.S. Treasury securities	Level 1	73,952	—	(402)	73,550	44,473	—	(72)	44,401
Money market funds	Level 1	24,974	—	—	24,974	45,088	—	—	45,088
Total marketable securities		<u>\$ 377,714</u>	<u>\$ —</u>	<u>\$ (1,827)</u>	<u>\$ 375,887</u>	<u>\$ 303,695</u>	<u>\$ 3</u>	<u>\$ (415)</u>	<u>\$ 303,283</u>

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

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

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

We classified accrued interest on our marketable securities of \$0.9 million and \$1.4 million as of September 30, 2022 and December 31, 2021, respectively, as prepaid and other current assets on our condensed consolidated balance sheets.

As of September 30, 2022, all our marketable securities had original maturities of less than two years. The weighted-average maturity of our holdings was five months. As of September 30, 2022, our long-term marketable securities had remaining maturities of 18 months. None of our marketable securities changed from one fair value hierarchy to another during the three and nine months ended September 30, 2022.

4. Commitments and Contingencies

There have been no material changes in our obligations under contractual agreements described in our Annual Report on Form 10-K for the year ended December 31, 2021.

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. For further information about our ongoing legal matters, see *Part II, Item 1, Legal Proceedings*.

5. Leases

We lease our office facilities in Menlo Park, California. In March 2022, we amended our lease to extend its term from March 31, 2022 to June 30, 2023. As a result of this amendment, we recognized an additional right-of-use asset and corresponding lease liability of \$2.8 million. The right-of-use asset and lease liability recognized equals the present value of the remaining payments due under our amended lease.

As the operating lease for our facilities does not expressly state an interest rate, we calculated the present value of remaining lease payments using a discount rate equal to the interest rate we would pay on a collateralized loan with monthly

payments and a term equal to the monthly payments and remaining term of our lease. We recognize operating lease payments as expenses using the straight-line method over the term of the lease.

Operating lease expense for the three and nine months ended September 30, 2022 was \$0.6 million and \$1.7 million, respectively, compared to \$0.5 million and \$1.6 million, respectively, for the comparable periods in 2021.

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

	Three months ended September 30,		Nine months ended September 30,	
	2022	2021	2022	2021
Cash paid for operating lease liabilities	\$ 578	\$ 530	\$ 1,687	\$ 1,574
Right-of-use assets obtained in exchange for new operating lease obligations	\$ —	\$ —	\$ 2,816	\$ —
Weighted-average remaining lease term			9 months	6 months
Weighted-average discount rate			4.0 %	4.8 %

As of September 30, 2022, future minimum lease payments under non-cancelable operating leases were as follows (in thousands):

2022 (remainder)	\$ 578
2023	1,157
Total lease payments	1,735
Less imputed interest	(28)
Present value of operating lease liabilities	\$ 1,707

6. Stockholders' Equity

Incentive Award Plan

We have one stock option plan – the Corcept Therapeutics Incorporated 2012 Incentive Award Plan (the “2012 Plan”). In December 2021, our Board of Directors authorized a 4.2 million increase in the shares available for grant under the 2012 Plan.

Stock Options

During the three and nine months ended September 30, 2022, we issued 1.9 million and 3.3 million, respectively, shares of our common stock upon the exercise of stock options. Some option holders exercised their options on a “net exercise” basis, pursuant to which they surrendered to us, and we purchased from them, at the then current market price, shares equal in value to the associated exercise price and tax withholding obligations. During the three and nine months ended September 30, 2022, we purchased 1.0 million and 1.7 million shares in connection with option net exercises and paid \$15.4 million and \$20.6 million, respectively, to satisfy associated tax withholding obligations.

During the three and nine months ended September 30, 2021, we issued 0.9 million and 3.6 million, respectively, shares of our common stock upon the exercise of stock options. During the three and nine months ended September 30, 2021, we purchased 0.2 million and 1.2 million shares in connection with option net exercises and paid \$2.3 million and \$20.3 million, respectively, to satisfy associated tax withholding obligations.

We recorded purchased shares as treasury stock on our condensed consolidated balance sheets at cost. As of September 30, 2022 and December 31, 2021, we had 23.0 million and 21.3 million treasury shares outstanding, respectively.

Restricted Stock Units (“RSUs”)

During the three months ended March 31, 2022, we granted employees 0.2 million RSUs with a weighted-average grant date fair value of \$19.34 per share. No RSUs were granted during the three months ended June 30, 2022 and September 30, 2022.

Restricted Stock Awards (“RSAs”)

During the three and nine months ended September 30, 2022, we granted employees 0.2 million and 0.3 million RSAs with a weighted-average grant date fair value of \$26.19 and \$25.20 per share, respectively. RSAs include voting and dividend

rights and are therefore “participating” shares for the purpose of calculating basic and diluted net income per share. See “Note 7” below.

Employee Stock Purchase Plan (“ESPP”)

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

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

Stock-based Compensation

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

The Company values restricted stock at the closing market price of the Company’s common stock on the date of grant.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
	<i>(in thousands)</i>			
Stock-based compensation capitalized in inventory	\$ 77	\$ 47	\$ 197	\$ 151
Cost of sales	19	12	49	38
Research and development	3,149	3,434	9,706	10,764
Selling, general and administrative	7,386	7,506	22,166	21,319
Total stock-based compensation	\$ 10,631	\$ 10,999	\$ 32,118	\$ 32,272

7. Net Income Per Share

We compute our basic and diluted net income per share in conformity with the two-class method required for companies with participating shares. Under the two-class method, net income is determined by allocating net income between common stock and unvested RSAs. We compute basic net income per share by dividing our net income attributable to common stockholders by the weighted-average number of common shares outstanding during the period. We compute diluted net income per share by dividing our net income attributable to common stockholders by the weighted-average number of common shares outstanding during the period, including potentially dilutive stock options and unvested RSUs, less unvested RSAs. We use the treasury stock method to determine the number of dilutive shares of common stock resulting from stock options and unvested RSUs.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
<i>(in thousands)</i>				
Numerator:				
Net income attributable to common stockholders	\$ 34,550	\$ 30,471	\$ 84,755	\$ 80,459
Denominator:				
Weighted-average shares used to compute basic net income per common share	107,125	115,791	106,479	116,297
Dilutive effect of employee stock options and unvested RSUs	9,495	9,345	9,339	10,876
Weighted-average shares used to compute diluted net income per common share	116,620	125,136	115,818	127,173
Net income per share attributable to common stockholders				
Basic	\$ 0.32	\$ 0.26	\$ 0.80	\$ 0.69
Diluted	\$ 0.30	\$ 0.24	\$ 0.73	\$ 0.63

As of September 30, 2022, we had 23.5 million stock options, 0.2 million RSUs and 0.2 million RSAs outstanding. As of September 30, 2021, we had 25.5 million stock options outstanding and no RSUs or RSAs outstanding.

We excluded from the computation of diluted net income per share, on a weighted-average basis, 7.5 million and 7.2 million stock options and unvested RSUs outstanding during the three and nine months ended September 30, 2022, respectively, and 5.3 million and 4.1 million stock options outstanding during the three and nine months ended September 30, 2021, respectively, because including them would have reduced dilution.

8. Income Taxes

We recorded income tax benefit of \$1.6 million for the three months ended September 30, 2022 and income tax expense of \$7.1 million for the nine months ended September 30, 2022. In the three and nine months ended September 30, 2021, our income tax expense was \$5.8 million and \$7.8 million, respectively. The income tax benefit during the three months ended September 30, 2022 was due to excess tax deductions from stock-based compensation compared to income tax expense in the corresponding period in 2021. The decrease in income tax expense during the nine months ended September 30, 2022 was due to increased tax credits that were generated and utilized in the current year compared to the corresponding period in 2021.

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

During the three and nine months ended September 30, 2022, unrecognized tax benefits increased by \$0.6 million and \$1.6 million, respectively. As of September 30, 2022, the Company had unrecognized tax benefits of \$8.4 million that, if recognized, would reduce the Company's effective tax rate and approximately \$2.4 million of unrecognized tax benefits that would not reduce the effective tax rate, because they would be offset by an increase in the valuation allowance.

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

Beginning in 2022, the Tax Cuts and Jobs Act of 2017 eliminates the right to deduct research and development expenditures for tax purposes in the period the expenses were incurred and instead requires all U.S. and foreign research and development expenditures to be amortized over five and fifteen tax years, respectively. Congress has considered legislation that would defer the amortization requirement to later years, but as of September 30, 2022, the requirement has not been modified.

Accordingly, we have capitalized our research and development expenses for tax purposes, resulting in higher cash paid for taxes as compared to prior years.

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

The following Management's Discussion and Analysis of Financial Condition and Results of Operations ("MD&A") is intended to help the reader understand our results of operations and financial condition and is provided as a supplement to, and should be read in conjunction with our condensed consolidated financial statements and the accompanying notes to financial statements, risk factors and other disclosures included in this Form 10-Q. Our condensed consolidated financial statements have been prepared in accordance with U.S. Generally Accepted Accounting Principles ("U.S. GAAP").

We make statements in this section that are "forward-looking" within the meaning of the federal securities laws. For a complete discussion of such statements and the potential risks and uncertainties that may affect their accuracy, see the "Risk Factors" section of this Form 10-Q and the "Overview" and "Liquidity and Capital Resources" sections of this MD&A.

Overview

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

Cushing's Syndrome

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

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

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

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

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

The United States Food and Drug Administration ("FDA") and the European Commission ("EC") have designated relacorilant as an orphan drug for the treatment of Cushing's syndrome. In the United States, relacorilant's orphan designation

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

Oncology

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

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

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

In March 2022, we announced overall survival (“OS”) data from this trial. OS was assessed after a pre-determined number of patient deaths had occurred. At the time of database cutoff, 128 of the 178 patients who enrolled in the study had died. Patients who received relacorilant intermittently lived longer (median OS: 13.9 months versus 12.2 months, hazard ratio: 0.67; p-value: 0.066) compared to those who received nab-paclitaxel alone.

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

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

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

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

Relacorilant in Patients with Prostate Cancer. Androgen deprivation is the standard treatment for prostate cancer because androgens stimulate prostate tumor growth. Tumors often escape androgen deprivation therapy when cortisol’s activity at the GR stimulates tumor growth. Combining a cortisol modulator with an androgen modulator may block this escape route.

Our collaborators at the University of Chicago plan to initiate a randomized, placebo-controlled Phase 2 trial of relacorilant plus enzalutamide in patients with prostate cancer, pre-prostatectomy. We are providing relacorilant and placebo for the study and have licensed patents covering the use of relacorilant combined with anticancer agents such as enzalutamide in the treatment of patients with this indication.

Metabolic Diseases

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

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

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

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

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

The primary endpoint in both the GRATITUDE and GRATITUDE II trials is the change in body weight from baseline, relative to placebo. We are also measuring other important metabolic endpoints. In both trials, all patients have completed their course of treatment. Data is expected by the end of 2022.

Liver Disease. We are studying miricorilant as a potential treatment for nonalcoholic steatohepatitis (“NASH”). In April 2021, we suspended our Phase 2a trial after observing elevated liver enzymes, as well as large, rapid reductions in liver fat, in four of the five patients who had received miricorilant. Liver enzyme levels in all affected patients returned to baseline or below baseline after miricorilant was withdrawn. We are conducting a Phase 1b dose-finding trial in patients with presumed NASH to see if an alternative miricorilant dosing regimen can reduce liver fat without causing excessive liver irritation.

Amyotrophic Lateral Sclerosis (“ALS”)

We have initiated a Phase 2 trial of our selective cortisol modulator dazucorilant (the “DAZALS” trial) in patients with ALS. DAZALS has a planned enrollment of 198 patients, randomized 1:1:1 to receive either 150 mg or 300 mg of dazucorilant or placebo daily for 24 weeks. The primary endpoint is the difference between dazucorilant and placebo on the ALS Functional Rating Scale-Revised (ALSFRS-R) total score.

COVID-19 Pandemic

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

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

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

Please see the risk factor under Item 1A of this Quarterly Report, “*The COVID-19 pandemic has adversely affected and is continuing to adversely affect our business. Other public health emergencies, natural disasters, terrorism or other catastrophes could disrupt our activities and render our own or our vendors’ facilities and equipment inoperable or inaccessible and require us to curtail or cease operations.*”

Results of Operations

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

Net product revenue was \$101.7 million and \$298.8 million for the three and nine months ended September 30, 2022, respectively, compared to \$96.1 million and \$267.2 million for the comparable periods in 2021. Sales volume accounted for 43.8 percent and 60.7 percent of the increases, respectively. Increases in the average price of Korlym accounted for the remaining growth due to price increases effective January 1, 2022 and March 1, 2021.

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

Cost of sales was \$1.3 million and \$3.9 million for the three and nine months ended September 30, 2022, respectively, compared to \$1.3 million and \$3.9 million for the comparable periods in 2021. Cost of sales as a percentage of revenue was 1.3 percent for each of the three and nine months ended September 30, 2022, compared to 1.3 percent and 1.5 percent for the comparable periods in 2021. The decrease in cost of sales as a percentage of revenue for the nine months ended September 30, 2022 was due to reduced manufacturing costs.

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

Research and development expense was \$33.3 million and \$94.2 million for the three and nine months ended September 30, 2022, respectively, compared to \$28.1 million and \$85.3 million for the comparable periods in 2021. The increases were primarily due to increased spending on employee compensation expenses and the advancement of our development programs.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
	(in thousands)			
Development programs:				
Oncology	\$ 5,370	\$ 4,521	\$ 13,000	\$ 12,549
Cushing’s syndrome	6,891	5,779	23,082	21,893
Metabolic diseases	6,593	5,009	17,734	16,129
Pre-clinical and early-stage selective cortisol modulators	5,938	6,379	17,055	16,736
Unallocated activities, including manufacturing and regulatory activities	5,351	2,969	13,660	7,274
Stock-based compensation	3,149	3,434	9,706	10,764
Total research and development expense	<u>\$ 33,292</u>	<u>\$ 28,091</u>	<u>\$ 94,237</u>	<u>\$ 85,345</u>

It is difficult to predict the timing and cost of development activities, which are subject to many uncertainties and risks, including inconclusive or negative results, slow patient enrollment, adverse side effects and difficulties in the formulation or manufacture of study drugs and lack of drug-candidate efficacy. In addition, clinical development is subject to government oversight and regulations that may change without notice. We expect our research and development expense to be higher in 2022 than in 2021 as our clinical programs advance. Research and development spending in future years will depend on the outcome of our pre-clinical and clinical trials and our development plans.

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

Selling, general and administrative expense was \$35.2 million and \$110.5 million for the three and nine months ended September 30, 2022, respectively, compared to \$30.5 million and \$90.1 million for the comparable periods in 2021. The increases were primarily due to increased employee compensation expenses, sales and marketing activities and legal fees.

We expect our selling, general and administrative expense to be higher in 2022 than in 2021 due to increased commercial and administrative activities, including litigation and administrative support for increased research and development and marketing efforts.

Interest and other income – Interest and other income was \$1.1 million and \$1.8 million for the three and nine months ended September 30, 2022, respectively, compared to \$0.1 million and \$0.5 million for the comparable periods in 2021. The increases were due to a higher cash and investments balance and market-wide increases in interest rates.

Income tax benefit (expense) – Income tax benefit was \$1.6 million for the three months ended September 30, 2022 and income tax expense was \$7.1 million for the nine months ended September 30, 2022 compared to income tax expense of \$5.8 million and \$7.8 million for the comparable periods in 2021. The income tax benefit during the three months ended September 30, 2022 was due to excess tax deductions from stock-based compensation compared to the corresponding period in 2021. The decrease in income tax expense during the nine months ended September 30, 2022 was due to increased tax credits that were generated and utilized in the current year compared to the corresponding period in 2021.

Liquidity and Capital Resources

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

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

As of September 30, 2022, we had cash, cash equivalents and marketable securities of \$401.2 million, consisting of cash and cash equivalents of \$50.2 million and marketable securities of \$350.9 million, compared to cash, cash equivalents and marketable securities of \$335.8 million, consisting of cash and cash equivalents of \$77.6 million and marketable securities of \$258.2 million as of December 31, 2021.

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

Net cash provided by operating activities was \$86.9 million for the nine months ended September 30, 2022, compared to \$118.5 million for the comparable period in 2021. This decrease was primarily due to higher deferred income taxes resulting from the capitalization of research and development costs for tax purposes.

Net cash used by investing activities was \$97.1 million for the nine months ended September 30, 2022, compared to \$4.3 million for the comparable period in 2021. The change was primarily due to allocation of cash generated from our operating activities towards marketable securities rather than share repurchases.

Net cash used in financing activities was \$17.2 million for the nine months ended September 30, 2022, compared to \$95.6 million for the comparable period in 2021. In the nine months ended September 30, 2022, we spent \$20.8 million acquiring shares of our common stock in connection with the net exercise of employee and executive stock options, offset by \$3.6 million received from the issuances of common stock under our incentive award plan. In the comparable period in 2021, we spent \$108.8 million acquiring shares of our common stock (\$88.5 million pursuant to our Stock Purchase Program that expired on September 30, 2021 and \$20.3 million in connection with the net exercise of employee and director stock options), offset by \$13.2 million received from the exercise of stock options.

As of September 30, 2022, we had retained earnings of \$279.8 million.

Contractual Obligations and Commitments

Our contractual payment obligations and purchase commitments are disclosed in our Annual Report on Form 10-K for the year ended December 31, 2021. Our payment obligations and purchase commitments did not change materially during the nine months ended September 30, 2022. See Note 4 to our Unaudited Condensed Consolidated Financial Statements for more information regarding our purchase commitments.

Off-Balance Sheet Arrangements

None.

Critical Accounting Policies and Estimates

Our condensed consolidated financial statements have been prepared in accordance with U.S. GAAP, which requires us to make estimates and judgments that affect the amount of assets, liabilities and expenses we report. We base our estimates on historical experience and on other assumptions we believe to be reasonable. Actual results may differ from our estimates. Our significant accounting policies are discussed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2021. There were no changes that occurred during the fiscal quarter covered by this report that materially affected, or are reasonably likely to materially affect, our critical accounting policies and estimates.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our market risks as of September 30, 2022 are disclosed in our Annual Report on Form 10-K for the year ended December 31, 2021. The market risks associated with our cash, cash equivalents and marketable securities, which consist entirely of debt instruments with original maturities of less than 24 months, did not change materially during the nine months ended September 30, 2022.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of disclosure controls and procedures. As of September 30, 2022, our management conducted an evaluation, under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934 (the “Exchange Act”). Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of September 30, 2022, our disclosure controls and procedures were effective to provide reasonable assurance that the information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms and that such information is accumulated and communicated to the officers who certify our financial reports and to the members of the Company’s senior management and board of directors as appropriate to allow timely decisions regarding required disclosure at the reasonable assurance level.

Changes in internal control over financial reporting. Our Chief Financial Officer and other members of management evaluated the changes in our internal control over financial reporting during the quarter ended September 30, 2022 and concluded that there was no change during the quarter that materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

Teva Litigation

In February 2018, we received a Paragraph IV Notice Letter advising that Teva Pharmaceuticals USA, Inc. (“Teva”) had submitted an Abbreviated New Drug Application (“ANDA”) to the FDA seeking authorization to manufacture and sell a generic version of Korlym prior to the expiration of patents related to Korlym that are listed in the FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations (the “Orange Book”). On March 15, 2018, we filed a lawsuit in the United States District Court for the District of New Jersey against Teva for infringement of our patents. On October 12, 2018, Teva received tentative approval from the FDA for its ANDA. In accordance with the Hatch-Waxman Act, however, FDA final approval of Teva’s ANDA was stayed until August 1, 2020.

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

On May 7, 2019, Teva submitted to the Patent Trial and Appeal Board (“PTAB”) a petition for post-grant review (“PGR”) of the ’214 patent. On November 20, 2019, the PTAB agreed to initiate the PGR, and on November 19, 2020 issued a decision upholding the validity of the ’214 patent in its entirety. Teva appealed its loss to the Federal Circuit Court of Appeals, which on December 7, 2021, ruled in our favor.

The time for Teva to appeal or seek reconsideration of these adverse decisions has passed. This matter is closed.

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

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

Sun ANDA Litigation and Settlement

On June 10, 2019, we received a Paragraph IV Notice Letter advising that Sun Pharma Global FZE, Sun Pharma Global, Inc., Sun Pharmaceutical Industries, Inc. and Sun Ltd. (collectively, “Sun”) had submitted an ANDA to the FDA seeking authorization to manufacture, use or sell a generic version of Korlym in the United States prior to the expiration of certain of our patents related to Korlym listed in the Orange Book.

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

On June 9, 2021, we entered into an agreement with Sun resolving this litigation. Pursuant to the agreement, we have granted Sun the right to sell a generic version of Korlym in the United States beginning October 1, 2034 or earlier under circumstances customary for settlement agreements of this type.

Hikma ANDA Litigation

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

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

On March 12, 2021, we filed a lawsuit in the United States District Court for the District of New Jersey against Hikma for infringement of the ’214 patent, the ’216 patent, U.S. Patent Nos. 10,842,800 and U.S. Patent Nos. 10,842,801. The 30-month stay of FDA approval of Hikma’s ANDA expires on August 1, 2023. Hikma responded to our complaint on May 17, 2021, denying our claims. Discovery is set to close in April 2023. No trial date has been set.

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

Other Matters

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

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

On August 24, 2021, the Court granted our motion in part, but also denied it in part. Certain of plaintiff’s claims have proceeded to discovery. Discovery is currently scheduled to close in March 2023.

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

On September 30, 2019, a purported shareholder derivative complaint was filed in the United States District Court for the District of Delaware by Lauren Williams, captioned *Lauren Williams v. G. Leonard Baker, et al.*, Civil Action No. 1:19-cv-01830. The complaint named our board of directors, Chief Executive Officer and current Chief Business Officer as defendants, and us as nominal defendant. The complaint alleges breach of fiduciary duty, violation of Section 14(a) of the Exchange Act, insider selling, misappropriation of insider information and waste of corporate assets and seeks damages in an amount to be proved at trial. On October 23, 2019, this action was stayed pending a resolution of our motions to dismiss the Melucci litigation. On December 20, 2020, the case was further stayed pending a resolution of our motion to dismiss the third amended complaint in the Melucci litigation. On September 30, 2021, the case was further stayed pending a resolution of the Melucci litigation.

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

On December 19, 2019, a second purported shareholder derivative complaint was filed in the United States District Court for the District of Delaware by Jeweltex Pension Plan, captioned *Jeweltex Pension Plan v. James N. Wilson, et al.*, Civil Action No. 1:19-cv-02308. The complaint named our board of directors, Chief Executive Officer and current Chief Business Officer as defendants, and us as nominal defendant. The complaint alleges causes of action for breach of fiduciary duty, violation of Section 14(a) of the Exchange Act, waste of corporate assets, contribution and indemnification, aiding and abetting and gross mismanagement. The complaint seeks damages in an amount to be proved at trial. On April 6, 2020, this action was stayed pending a resolution of our motions to dismiss the Melucci litigation. On December 20, 2020, the case was further stayed pending a resolution of our motion to dismiss the third amended complaint in the Melucci litigation. On September 30, 2021, the case was further stayed pending a resolution of the Melucci litigation.

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

On January 31, 2022, a purported shareholder derivative complaint was filed in the Delaware Court of Chancery by Joel B. Ritchie, captioned *Joel B. Ritchie v. G. Leonard Baker, et al.*, Case No. 2022-0102-SG. The complaint named our board of directors, Chief Executive Officer, current Chief Business Officer and President of Corcept Endocrinology as defendants, and us as nominal defendant. The complaint alleges a single cause of action for breach of fiduciary duty. The complaint seeks damages in an amount to be proved at trial. On April 20, 2022, the case was further stayed pending a resolution of the Melucci litigation.

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

In November 2021, we received a records subpoena from the United States Attorney’s Office for the District of New Jersey (the “NJ USAO”) pursuant to Section 248 of the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) seeking information relating to the sale and promotion of Korlym, our relationships with and payments to health

care professionals who can prescribe or recommend Korlym and prior authorizations and reimbursement for Korlym. The NJ USAO has informed us that it is investigating whether any criminal or civil violations by us occurred in connection with the matters referenced in the subpoena. It has also informed us that it does not currently consider us a defendant but rather an entity whose conduct is within the scope of the government's investigation.

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

ITEM 1A. RISK FACTORS

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

Summary of Principal Risks

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

Risks Related to our Commercial Activities

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

Risks Related to our Research and Development Activities

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

Risks Relating to our Intellectual Property

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

Risks Related to our Stock

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

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

General Risks

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

Risk Factors - Discussion

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

Risks Related to our Commercial Activities

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

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

Many factors could limit our Korlym revenue, including:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

The commercial success of Korlym depends on the availability of acceptable pricing and adequate insurance coverage and reimbursement. Government payers, including Medicare, Medicaid and the Veterans Administration, as well as private insurers and health maintenance organizations, are increasingly attempting to contain healthcare costs by limiting reimbursement for medicines. If government or private payers cease to provide adequate and timely coverage, pricing and reimbursement for Korlym, physicians may not prescribe the medication and patients may not purchase it, even if it is prescribed, or the price we receive may be reduced, which would reduce our revenue.

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

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

Other legislative and regulatory changes have been adopted in the United States since the ACA was enacted. These changes included an aggregate reduction in Medicare payments to providers of 2 percent per fiscal year, which went into effect on April 1, 2013 and will remain in effect through 2030, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022, and a 1 percent reduction from May 1, 2022 through June 30, 2022, unless additional Congressional action is taken. In addition, the American Taxpayer Relief Act of 2012, further reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. In March 2021, the American Rescue Plan Act of 2021 was also signed into law, which, among other things, eliminated the statutory cap on drug manufacturers' Medicaid Drug Rebate Program rebate liability, effective January 1, 2024. Under current law enacted as part of the ACA, drug manufacturers' Medicaid Drug Rebate Program rebate liability is capped at 100% of the average manufacturer price for a covered outpatient drug. Moreover, the federal government and the individual states in the United States have become increasingly active in developing proposals, passing legislation and implementing regulations designed to control drug pricing, including price or patient reimbursement constraints, discounts, formulary flexibility, marketing cost disclosure and transparency measures.

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

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

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

A single third-party manufacturer, Produits Chimiques Auxiliaires et de Synthèse SA (“PCAS”), supplies the API in Korlym. Two other third-party manufacturers produce and bottle Korlym tablets. Our agreement with PCAS automatically renews for two one-year terms, unless either party provides 12-months’ written notice of its intent not to renew. We use a single specialty pharmacy, Optime, to dispense Korlym and perform related pharmacy operations, patient support and related services, including the collection of payments from insurers representing approximately 99 percent of our revenue. If Optime does not adhere to its agreements with payers, it may not be able to collect some or all of the payments due to us. Our agreement with Optime extends to March 31, 2024, subject to customary termination provisions, including the right of Optime to terminate in the event of a material breach by us that we do not cure in a reasonable period of time after receiving written notice. In addition, we may terminate the agreement for convenience.

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

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

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

The active ingredient in Korlym, mifepristone, is approved by the FDA in another drug for the termination of early pregnancy. On June 24, 2022, the United States Supreme Court published its decision in the case of *Dobbs v. Jackson Women's Health Organization* (“*Dobbs*”), which overturned *Roe v. Wade*, the 1973 Supreme Court decision establishing a woman’s right to terminate her pregnancy, subject to certain limitations. *Dobbs* has stimulated many states to enact laws making abortion illegal in virtually every circumstance, including during early pregnancy. More laws banning or heavily restricting termination of pregnancy may be adopted and existing laws may be made more restrictive. Heightened public perception of mifepristone as an abortifacient may draw the attention of hostile state government officials or political activists to Korlym – even though Korlym is not approved for the termination of pregnancy, we do not promote it for that use and we have taken measures to minimize the chance that it will accidentally be prescribed to a pregnant woman. In addition, physicians and patients may choose not to use Korlym as a treatment for Cushing’s syndrome simply to avoid the risk of terminating a pregnancy.

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

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

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

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

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

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

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

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

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

- the federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal health care programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- federal false claims laws, including, without limitation, the False Claims Act, which prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to get a false claim paid. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;
- the federal Civil Monetary Penalties law, which prohibits, among other things, offering or transferring remuneration to a federal healthcare beneficiary that a person knows or should know is likely to influence the beneficiary’s decision to order or receive items or services reimbursable by the government from a particular provider or supplier;
- HIPAA, which created federal criminal laws that prohibit executing a scheme to defraud any health care benefit program or making false statements relating to health care matters; similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- federal “sunshine” laws, including the federal Physician Payment Sunshine Act, that require transparency regarding financial arrangements with health care providers, such as the reporting and disclosure requirements imposed by the ACA on drug manufacturers regarding any “transfer of value” made or distributed to physicians, certain non-physician practitioners, teaching hospitals and ownership or investment interests held by physicians and their immediate family members;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payer, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; and state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and pricing information.

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

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

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

Risks Related to our Research and Development Activities

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

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

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

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

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

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

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

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

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

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

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

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

- delays in enrolling patients or the loss of enrolled patients due to COVID-19 related restrictions;
- delays in clinical site initiation, including difficulties in recruiting clinical investigators and staff;
- delays in receiving authorizations from local regulatory authorities and internal review boards to initiate clinical trials or amend existing protocols;
- delays in clinical sites receiving necessary supplies and materials due to interruptions in local and global shipping;
- changes in local regulations that require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs or cause us to suspend or discontinue a trial in the affected jurisdiction;
- diversion of healthcare resources, including facilities, supplies and staff, away from the conduct of clinical trials;
- interruption of key clinical trial activities, such as clinical trial site monitoring, patient visits and follow-up, study procedures and data collection, that could affect the integrity of clinical trial data, due to limitations on travel;

- the infection of patients enrolled in our clinical trials with COVID-19, which could affect the results of the clinical trial, including by increasing the number of observed adverse events or by causing patients to drop out of the study;
- patient discontinuations due to fear of infection with COVID-19 or public health restrictions implemented by clinical trial sites which make trial participation more time consuming or difficult;
- interruptions or delays in preclinical studies due to restricted or limited operations at laboratory facilities;
- delays in necessary interactions with local regulators, ethics committees and other third parties and contractors due to limitations in employee resources or the furlough of government employees; and
- limitations caused by the sickness of our employees or their families or the desire of employees to avoid contact with large groups of people.

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

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

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

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

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

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

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

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

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

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

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

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

Any of these events could seriously harm our business.

Risks Related to our Capital Needs and Financial Results

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

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

Risks Relating to our Intellectual Property

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

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

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

Risks Related to our Stock

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

We cannot assure investors that a liquid trading market for our common stock will exist at any particular time. As a result, holders of our common stock may not be able to sell shares quickly or at the current market price. During the 52-week period ended October 26, 2022, our average daily trading volume was approximately 1,011,342 shares and the intra-day sales prices per share of our common stock on The Nasdaq Stock Market ranged from \$15.82 to \$29.93. As of October 26, 2022, our officers, directors and principal stockholders beneficially owned approximately 18 percent of our common stock.

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

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

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

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

The guidance we provide as to our expected 2022 revenue is only an estimate of what we believe is realizable at the time we give such guidance. It is difficult to predict our revenue and our actual results may vary materially from our guidance. The

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

General Risk Factors

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

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

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

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

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

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

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

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

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

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

In addition, certain state laws govern the privacy and security of health information in certain circumstances, some of which are more stringent than HIPAA and many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties and private litigation. For example, the California Confidentiality of Medical

Information Act imposes restrictive requirements regulating the use and disclosure of health information and other personally identifiable information. Further, the California Consumer Privacy Act, or the CCPA, which took effect on January 1, 2020, created individual privacy rights for California consumers and increased the privacy and security obligations of entities handling certain personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. The CCPA may increase our compliance costs and potential liability. Further, the California Privacy Rights Act, or CPRA, will impose additional data protection obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It also created a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. While some provisions of the CPRA were effective immediately, the majority of the provisions will go into effect on January 1, 2023, and additional compliance investment and potential business process changes may be required. In the event that we are subject to or affected by HIPAA, the CCPA, the CPRA or other domestic privacy and data protection laws, any liability from failure to comply with the requirements of these laws could adversely affect our financial condition. Similar laws have been passed in Virginia, Colorado, Connecticut and Utah, and have been proposed at the federal level and in other states, reflecting a trend toward more stringent privacy legislation in the United States.

The GDPR went into effect in 2018 and imposes stringent requirements for controllers and processors of personal data of individuals within the European Economic Area (“EEA”), particularly with respect to clinical trials. The GDPR provides that EEA member states may make their own further laws and regulations limiting the processing of health data, which could limit our ability to use and share personal data or could cause our costs to increase and harm our business and financial condition. In addition, the GDPR increases the scrutiny that clinical trial sites located in the EEA should apply to transfers of personal data from such sites to countries that are considered to lack an adequate level of data protection, such as the United States. Recent legal developments have also created complexity and compliance uncertainty regarding certain transfers of information from the EEA to the United States. For example, on June 16, 2020, the Court of Justice of the European Union, or the CJEU, limited how organizations could lawfully transfer personal data from the EEA to the United States by invalidating the EU-US Privacy Shield Framework for purposes of international transfers and imposing further restrictions on use of the standard contractual clauses, or SCCs. These restrictions include a requirement for companies to carry out a transfer impact assessment which, among other things, assesses the laws governing access to personal data in the recipient country and considers whether supplementary measures that provide privacy protections additional to those provided under SCCs will need to be implemented to ensure an essentially equivalent level of data protection to that afforded in the EEA. The European Commission (“EC”) issued revised SCCs on June 4, 2021 to account for the decision of the CJEU and recommendations made by the European Data Protection Board. The revised SCCs must be used for relevant new data transfers from September 27, 2021; existing standard contractual clauses arrangements must be migrated to the revised clauses by December 27, 2022. There is some uncertainty around whether the revised clauses can be used for all types of data transfers, particularly whether they can be relied on for data transfers to non-EEA entities subject to the GDPR. As supervisory authorities issue further guidance on personal data export mechanisms, including circumstances where the SCCs cannot be used, and/or start taking enforcement action, we could suffer additional costs, complaints and/or regulatory investigations or fines, and/or if we are otherwise unable to transfer personal data between and among countries and regions in which we operate, it could affect the manner in which we provide our services, the geographical location or segregation of our relevant systems and operations, and could adversely affect our financial results. The GDPR imposes substantial fines for breaches of data protection requirements, which can be up to four percent of global revenue for the preceding financial year or €20 million, whichever is greater, and it also confers a private right of action on data subjects for breaches of data protection requirements. Compliance with European data protection laws is a rigorous and time intensive process that may increase our cost of doing business, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation and reputational harm in connection with our European activities. From January 1, 2021, we have had to comply with the GDPR and separately the United Kingdom GDPR, which, together with the amended United Kingdom Data Protection Act 2018, retains the GDPR in United Kingdom national law, each regime having the ability to fine up to the greater of €20 million/ £17.5 million or 4% of global turnover. It is unclear how United Kingdom data protection laws and regulations will develop in the medium to longer term and these changes may lead to additional costs and increase our overall risk exposure. On June 28, 2021, the EC adopted an adequacy decision in favor of the United Kingdom, enabling data transfers from EU member states to the United Kingdom without additional safeguards. However, the United Kingdom adequacy decision will automatically expire in June 2025 unless the EC renews or extends that decision and remains under review by the Commission during this period.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

New laws and regulations, as well as changes to existing laws and regulations, including statutes and regulations concerning taxes and the development, approval, marketing and pricing of medications, the provisions of the ACA requiring the

reporting of aggregate spending related to health care professionals, the provisions of the Sarbanes-Oxley Act of 2002, the Dodd Frank Act of 2010 and rules adopted by the SEC and by The Nasdaq Stock Market have and will likely continue to increase our cost of doing business and divert management's attention from revenue-generating activities.

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

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

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

The federal securities laws and regulations, including the corporate governance and other requirements of the Sarbanes-Oxley Act of 2002 and the governance and other requirements of the Dodd Frank Act of 2010, impose complex and continually changing regulatory requirements on our operations and reporting. These developing requirements will continue to increase our compliance costs. Section 404 of the Sarbanes-Oxley Act of 2002 requires that we evaluate the effectiveness of, and provide a management report with respect to, our internal controls over financial reporting. It also requires that the independent registered public accounting firm auditing our consolidated financial statements must attest to and report on the effectiveness of our internal controls over financial reporting. If we are unable to complete the required assessment and report or if our independent registered public accounting firm is unable to issue an unqualified opinion as to the effectiveness of our internal control over financial reporting, investors could lose confidence in our financial reporting and our stock price would likely decline.

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

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

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

As of October 26, 2022, our officers and directors beneficially owned approximately 18 percent of our common stock. Acting together, these stockholders could significantly influence any matter requiring approval by our stockholders, including the election of directors and the approval of mergers or other business combinations. The interests of this group may not always coincide with our interests or the interests of other stockholders and may prevent or delay a change in control. This significant concentration of share ownership may adversely affect the trading price of our common stock because many investors perceive disadvantages to owning stock in companies with controlling stockholders.

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

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

Issuer Purchases of Equity Securities

The following table contains information relating to the purchases of our common stock in the three months ended September 30, 2022 as part of the cashless net exercises of stock options (in thousands, except average price per share):

Fiscal Period	Total Number of Shares Purchased⁽¹⁾	Average Price Per Share	Total Purchase Price of Shares⁽²⁾
July 1, 2022 to July 31, 2022	563	\$ 26.35	\$ 14,834
August 1, 2022 to August 31, 2022	327	27.51	8,988
September 1, 2022 to September 30, 2022	91	25.87	2,365
Total	981	\$ 26.69	\$ 26,187

(1) In July 2022, we issued 1.0 million shares of common stock as part of a net-share settlement of a cashless option exercise, of which 0.6 million shares were surrendered to us in satisfaction of related exercise cost and tax obligations. In August 2022, we issued 0.7 million shares of common stock as part of a net-share settlement of a cashless option exercise, of which 0.3 million shares were surrendered to us. In September 2022, we issued 0.1 million shares of common stock as part of a net-share settlement of a cashless option exercise, of which 0.1 million shares were surrendered to us.

(2) We paid \$15.4 million to satisfy the tax withholding obligations associated with the net-share settlement of these cashless option exercises.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

Exhibit Number	Description of Document
3.1	<u>Amended and Restated Certificate of Incorporation, as amended (incorporated by reference to Exhibit 3.1 to the registrant's Quarterly Report on Form 10-Q filed on August 9, 2012).</u>
3.2	<u>Amended and Restated Bylaws (incorporated by reference to Exhibit 3.1 to the registrant's Current Report on Form 8-K filed on February 13, 2017).</u>
10.1#	<u>Distribution Services Agreement, dated August 4, 2017, between Corcept Therapeutics Incorporated and Optime Care, Inc.</u>
10.2#	<u>Task Order Number One to Distribution Services Agreement, dated August 4, 2017, between Corcept Therapeutics Incorporated and Optime Care, Inc.</u>
10.3#	<u>Amendment to Distribution Services Agreement by and between Optime Care, Inc. and Corcept Therapeutics Incorporated, made and entered into as of August 1, 2022.</u>
10.4#	<u>Amendment No. 2 to Distribution Services Agreement by and between Optime Care, Inc. and Corcept Therapeutics Incorporated, made and entered into as of September 16, 2022.</u>
31.1	<u>Rule 13a-14(a)/15d-14(a) Certifications of Joseph K. Belanoff, M.D., Chief Executive Officer of the registrant.</u>
31.2	<u>Rule 13a-14(a)/15d-14(a) Certifications of Atabak Mokari, Chief Financial Officer of the registrant.</u>
32.1	<u>18 U.S.C. Section 1350 Certifications of Joseph K. Belanoff, M.D., Chief Executive Officer of the registrant.</u>
32.2	<u>18 U.S.C. Section 1350 Certifications of Atabak Mokari, Chief Financial Officer of the registrant.</u>
101	The following materials from the registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2022, formatted in Extensible Business Reporting Language (XBRL): (i) Unaudited Condensed Consolidated Balance Sheets at September 30, 2022 and December 31, 2021, (ii) Unaudited Condensed Consolidated Statements of Income for the three and nine month periods ended September 30, 2022 and 2021, (iii) Unaudited Condensed Consolidated Statements of Comprehensive Income for the three and nine month periods ended September 30, 2022 and 2021, (iv) Unaudited Condensed Consolidated Statements of Cash Flows for the nine month periods ended September 30, 2022 and 2021, (v) Unaudited Condensed Consolidated Statement of Stockholders' Equity and (vi) Notes to Unaudited Condensed Consolidated Financial Statements.
104	Cover Page Interactive Data File - the cover page XBRL tags are embedded within the Inline XBRL document.
#	Certain identified information has been omitted pursuant to Item 601(b)(10) of Regulation S-K because such information is both (i) not material and (ii) information that the registrant treats as private or confidential. The Registrant hereby undertakes to furnish supplemental copies of the unredacted exhibit upon request by the SEC

SIGNATURES

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

CORCEPT THERAPEUTICS INCORPORATED

Date: November 3, 2022

/s/ Joseph K. Belanoff

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

Date: November 3, 2022

/s/Atabak Mokari

Atabak Mokari
Chief Financial Officer

Date: November 3, 2022

/s/Joseph D. Lyon

Joseph D. Lyon
Chief Accounting Officer

Certain identified information has been excluded from the exhibit because it is both (i) not material and (ii) the type of information that the registrant treats as private or confidential. Double asterisks denote omissions.

DISTRIBUTION SERVICES AGREEMENT

This Distribution Services Agreement (“Agreement”), effective as of August 4, 2017 (the “**Effective Date**”), is made by and between **Corcept Therapeutics Inc.**, having its principal place of business at 149 Commonwealth Drive, Menlo Park, CA 94025 (“**Corcept**”) and Optime Care, Inc., having its principal place of business at 4060 Wedgeway Court, Earth City, MO 63045 (“**Optime**”). Corcept and Optime shall be referred to herein together from time to time as the “**Parties**,” and individually as a “**Party**.”

Whereas, Corcept develops, manufactures, and sells certain proprietary pharmaceutical drugs;

Whereas, Optime is in the business of providing certain clinical and administrative specialty pharmacy services;

Whereas, Corcept wishes Optime to provide certain speciality pharmacy services for certain of Corcept’s pharmaceutical drugs; and

Whereas, Optime desires to provide such services to Corcept pursuant to the terms and conditions contained in this Agreement.

Now, Therefore, in consideration of the premises and mutual covenants set forth herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

1. Definitions.

1.1 “**Adverse Enforcement Action**” shall have the meaning set forth in Section 13.1(i).

1.2 “**Adverse Event**” shall mean any undesirable medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have to have a causal relationship with the treatment, including any variant of an “adverse drug experience” as those terms are defined at either 21 C.F.R. Section 312.32 or 21 C.F.R. Section 314.80 and the relevant non-FDA equivalents, whether arising in or outside of a clinical study.

1.3 “**Agreement**” shall have the meaning set forth in the preamble.

1.4 “**Applicable Laws**” shall mean all applicable federal, state, and local laws and governmental agency regulations and requirements, including without limitation the FDCA; HIPAA; the Federal Anti-Kickback Statute (42 U.S.C. § 1320a-7b et seq.), the U.S. Foreign Corrupt Practices Act of 1977, as amended; the Public Contracts Anti-Kickback Act (41 U.S.C. § 51 et seq.); the Stark Law (42 U.S.C. § 1395nn); the Drug Supply Chain Security Act; patient confidentiality and privacy laws; Medicare and Medicaid laws under Title XVIII and XIX of the Social Security Act; and Missouri Uniform Trade Secret Act.

1.5 “**Claims**” shall have the meaning set forth in Section 15.1.

1.6 “**Co-Pay Organization**” shall have the meaning set forth in Section 3.8(g)(ii).

- 1.7 **“Co-Payment Assistance Program”** shall have the meaning set forth in Section 3.8(g)(ii).
- 1.8 **“Confidential Information”** shall have the meaning set forth in Section 9.1.
- 1.9 **“Corcept”** shall have the meaning set forth in the preamble.
- 1.10 **“Corcept Funds”** means any payments, funds, and/or monies that Optime receives or collects on behalf of Corcept, including without limitation payments from public and private payors, providers, patients, charities, or patient assistance programs on behalf of patients.
- 1.11 **“Corcept Group”** shall have the meaning set forth in Section 15.1.
- 1.12 **“Corcept Pre-Existing Intellectual Property”** shall have the meaning set forth in Section 10.1.
- 1.13 **“Corcept Representative”** shall have the meaning set forth Article 4.
- 1.14 **“Corcept Work Product”** shall mean the Deliverables and all Work Product other than Optime Work Product.
- 1.15 **“Customers”** shall mean Patients and other purchasers of the Product, including, without limitation, hospitals, physicians, pharmacies, and clinics.
- 1.16 **“Deliverables”** shall mean all reports, data, analyses and other information that Optime shall provide Corcept pursuant to each Task Order.
- 1.17 **“Disclosing Party”** shall have the meaning set forth in Section 9.2.
- 1.18 **“Effective Date”** shall have the meaning set forth in the preamble of this Agreement.
- 1.19 **“FDA”** shall mean the U.S. Food and Drug Administration.
- 1.20 **“FDCA”** shall mean the U.S. Federal Food, Drug and Cosmetic Act and the regulations promulgated pursuant thereto.
- 1.21 **“Financial Control”** shall have the meaning set forth in Section 3.2.
- 1.22 **“Financial Statements”** shall have the meaning set forth in Section 13.1(k).
- 1.23 **“Government or Public Official”** shall have the meaning set forth in Section 13.3.
- 1.24 **“HIPAA”** shall mean the Health Insurance Portability and Accountability Act of 1996, Public Law No. 104-191, as amended, including the Health Information Technology for Economic and Clinical Health Act, and the regulations promulgated pursuant thereto, including but not limited to 45 C.F.R. Parts 160 and 164.
- 1.25 **“Losses”** shall have the meaning set forth in Section 15.1.
- 1.26 **“Marks”** shall have the meaning set forth in Section 10.5(b).
- 1.27 **“Material”** shall have the meaning set forth in Section 3.5

- 1.28 **“Optime Group”** shall have the meaning set forth in Section 15.2.
- 1.29 **“Optime Pre-Existing Intellectual Property”** shall have the meaning set forth in Section 10.1.
- 1.30 **“Optime Work Product”** means [**].
- 1.31 **“Organization”** shall have the meaning set forth in Section 3.8(g)(i).
- 1.32 **“Party”** and **“Parties”** shall have the meaning set forth in the preamble.
- 1.33 **“Patient”** shall mean patients purchasing or prescribed the Product.
- 1.34 **“Patient Assistance Program”** shall have the meaning set forth in Section 3.8(g)(i).
- 1.35 **“Payment Schedule”** shall have the meaning set forth in Article 6.
- 1.36 **“Previous Agreements”** shall have the meaning set forth in Section 9.1.
- 1.37 **“Price”** shall have the meaning set forth in Article 6.
- 1.38 **“Product”** shall mean a pharmaceutical product owned or controlled by Corcept, to be further defined in each Task Order.
- 1.39 **“Product Complaint”** shall mean any communication that contains any allegation, written, electronic, or oral, expressing concern, for any reason, regarding the quality of a Product, including foul odor, off taste, illness or injury, disintegration time, color variation, tablet size or size variation, under-filled container, foreign material in a Product container, improper packaging, mislabeling, or Products that are superpotent, subpotent, or containing the wrong ingredient or any contaminant, such as bacteria, pesticide, mycotoxin, glass, or lead.
- 1.40 **“Project”** shall have the meaning set forth in Section 2.1.
- 1.41 **“Project Director”** shall have the meaning set forth in Article 4.
- 1.42 **“Receiving Party”** shall have the meaning set forth in Section 9.2.
- 1.43 **“Records”** shall have the meaning set forth in Section 8.1.
- 1.44 **“Representatives”** shall have the meaning set forth in Section 9.2.
- 1.45 **“Services”** means the activities relating to the Product that shall be performed by Optime under this Agreement.
- 1.46 **“Standard Operating Procedure”** or **“SOP”** shall have the meaning set forth in Section 3.2.
- 1.47 **“Task Order”** shall have the meaning set forth in Section 2.1.
- 1.48 **“Term”** shall have the meaning set forth in Section 18.1.
- 1.49 **“Territory”** shall have the meaning set forth in each Task Order.

1.50 “**Third Party**” shall mean a Party other than Corcept and its affiliates and Optime and its affiliates.

1.51 “**Work Product**” means [**].

2. **Task Orders.**

2.1 **Task Orders.** Optime shall provide the Services in the form of separate defined projects (each, a “**Project**”), which shall each be defined in a separate task order (“**Task Order**”) in the form attached hereto as Exhibit A. Optime shall render the Services as set forth in the applicable Task Order. Each Task Order shall be agreed upon by the Parties on a Project-by-Project basis and shall set forth with respect to each Project the following elements, among others, as applicable:

- (a) Product and Territory;
- (b) Name of Optime Project Director and Corcept Representative;
- (c) Optime personnel, defined by title and role (not named individuals), to be staffed for the Project;
- (d) Description of Services;
- (e) SOPs and Financial Controls applicable to the Project;
- (f) Project schedule and timeline for the performance of the Services;
- (g) Service fees under the Project and payment schedule;
- (h) Product Complaint and Adverse Event contact information; and
- (i) All other matters pertinent to completion of the Project.

In the event of a conflict between the terms of a Task Order and this Agreement, the terms of this Agreement shall govern. Each Task Order shall expressly reference this Agreement and, upon execution by both Parties, shall be attached hereto and incorporated herein as a part of this Agreement.

2.1 **Change Orders.** If Corcept requests any changes to the Services being performed or to be performed under a Project, Optime shall prepare an amended Task Order reflecting such changes, [**]. Upon Corcept’s written approval of the amended Task Order, such Task Order shall amend and restate the original Task Order and shall be incorporated herein, and Optime shall perform the Project in accordance with such amended Task Order. Notwithstanding anything herein to the contrary, to the extent that changes to the Services requested by Corcept consist of a reduction in the Services to be performed for a particular Project, at Corcept’s request and prior to Corcept’s written approval of an amended Task Order, Optime shall immediately perform only such reduced Services and the Parties shall negotiate in good faith a reduction to the compensation schedule and an amended Task Order reflecting such change as soon as practicable.

3. **Project Performance.**

3.1 **Conduct.**

- (a) Optime shall use its [**] to provide facilities, supplies and personnel of appropriate professional qualifications training and experience necessary to perform the Services for each Project as provided in the applicable Task Order. Optime shall conduct each Project in accordance with the applicable Task Order, which may be amended from time to time by written agreement between the Parties pursuant to Section 2.2. Subject to Section 2.2, Optime shall not change or deviate from any Task Order without Corcept's prior written approval. Non-material deviations from a Task Order may be made by Optime if such deviations are required to successfully perform the Services and Optime has obtained Corcept's prior written agreement as to the necessity of such deviations and [**]. Material deviations may only be undertaken pursuant to a signed Change Order.
- (b) Optime shall perform the Services [**] and in accordance with all Applicable Laws and shall cause its personnel to perform all activities under this Agreement [**] and in accordance with all Applicable Laws. In the event of a change in regulatory requirements, Optime shall make [**] to satisfy any new requirements that become effective during the applicable portion of the Task Order.
- (c) Optime shall install appropriate quality controls to ensure compliance with this Agreement and each Task Order, as applicable, and shall comply with, and shall train and cause its personnel associated with each Task Order to comply with, all applicable SOPs and Financial Controls at all times. Optime shall train those personnel associated with the applicable Task Order to assure compliance with the SOPs and Financial Controls.
- (d) Optime shall keep complete and accurate records of the status and progress of each Project and the Services provided thereunder.

3.2 **SOPs and Financial Controls.** In addition to the standard operating procedures and financial controls relating to its ordinary course of business apart from the Services, Optime shall establish and maintain standard operating procedures ("**SOPs**") and financial controls ("**Financial Controls**") that are related to the performance of the Services. As implemented by Optime, the Financial Controls shall be sufficient to permit Corcept to rely on the data provided by Optime to prepare its financial reports according to generally accepted accounting principles ("**GAAP**") and the requirements of the Sarbanes-Oxley Act of 2002. As soon as practicable after the Effective Date, Optime shall [**] and [**]. During the Term, Optime shall also [**] and [**] and whether those [**]. Optime must [**]. Optime shall [**]. For the avoidance of doubt, [**].

3.3 Optime may amend any SOP or the Financial Control [**], provided, however, [**].

3.4 **Subcontractors.** Optime may subcontract its obligations under this Agreement only with Corcept's prior written approval. Any authorized subcontractor shall be subject to all of the terms and conditions applicable to Optime under this Agreement or any Task Order, including Sections 9 (Confidential Information) and 10 (Intellectual Property; Work Product; Storage) and Optime shall be responsible and retain primary liability for the performance of all obligations of subcontractors selected, managed and contracted by Optime. All agreements with subcontractors must be in writing. A copy of any agreement with a subcontractor shall be provided to Corcept upon written request. Optime acknowledges and agrees that a breach by any of its subcontractors under this Agreement shall be treated as a breach by Optime. In such circumstance, Optime expressly waives any requirement that Corcept exhaust any right, power or remedy, or proceed directly against such subcontractor for any obligation or performance under this Agreement. For clarity, vendors that Optime may engage in the ordinary course of business, including without limitation, shredding vendors, answering service vendors, pharmacy and patient management and reporting software platform vendors and other information technology

service vendors, mailing and delivery service vendors, accounting, auditing and management consulting vendors, shall not be deemed subcontractors of Optime for the purposes of this Agreement.

3.5 Marketing and Promotion. During the Term, Corcept or its designee may provide Optime with Corcept-approved information, language and other such materials relating to the Products or any programs or services relating to the Products that are offered to Customers by Corcept to assist Optime in performing the Services, which may include information regarding (a) [**], (b) [**], (c) [**], and (d) [**] (collectively, the “**Materials**”). All Materials and all intellectual property rights therein shall be solely owned by Corcept and shall be presumed to be the Confidential Information of Corcept, unless proven otherwise. All Materials distributed by Optime must be approved in writing by Corcept prior to any communication or provision thereof by Optime to Customers or any other third Parties. Optime shall not produce or include with any such Materials its own materials regarding the Products. In no event shall Optime make any representation, warranty or guarantee to any Third Party about Corcept or the Products, whether orally or in writing, except as may be specifically approved by Corcept in writing.

3.6 Database. Optime shall maintain a secure database to store all Records, Deliverables and Corcept Work Product pursuant to the requirements of the applicable SOPs, Financial Controls and/or Applicable Laws. Before disclosing identifiable Patient information to Corcept, Optime shall provide (or receive from Corcept) an appropriate and valid waiver signed by the applicable Patient permitting Optime to disclose such Patient’s information to Corcept. Patient information for those Patients who have not provided appropriate and/or valid waivers shall be de-identified in a manner mutually agreed by the Parties prior to disclosure by Optime. Upon Corcept’s request, Optime shall provide Corcept with de-identified information related to all Patients.

3.7 Provider and Supplier Agreements. Corcept and Optime shall each obtain and maintain all provider or supplier agreements and numbers necessary for the submission by Optime of claims to Payors. Corcept and Optime shall each make available to the other, upon reasonable request, documentation of all of its applicable federal, state and professional licenses, certificates, and provider or supplier agreement numbers.

3.8 Product Distribution. To the extent Corcept provides Optime with Product inventory under this Agreement, the following shall apply:

- (e) **Title.** Corcept shall provide Products to Optime for dispensing to Customers. Optime shall not take title to any Product. Title to Product shall pass directly from Corcept to Customers at the time the Products are received by such Customer.
- (f) **Compliance.** Optime shall at all times handle, store, and distribute the inventory of the Product in accordance with the specifications for storage and handling of the Products provided to Optime by Corcept, and any deviations from such specifications shall be reported to Corcept immediately. In handling, storing, selling and distributing the Products, Optime shall comply with Applicable Laws, SOPs, Financial Controls, and Corcept’s written instructions, if any. At Corcept’s request, Optime shall provide Corcept with evidence of compliance with Applicable Laws, including but not limited to, copies of state licenses, permits and inspection reports for Optime’s facilities.
- (g) **Inventory Monitoring and Storage.** Optime shall record receipt, inventory levels, and shipments of Products pursuant to each Task Order, including each Task Order’s applicable SOPs and Financial Controls.

- (h) **Inspection and Audit.** Upon reasonable notice, Corcept shall have the right to inspect and/or audit Optime’s inventory of Products. Optime shall cooperate and assist Corcept in connection with any such inspection and/or audit; provided that Corcept shall not unreasonably disrupt Optime’s business operations in the conduct of such inspection and/or audit.
- (i) **Shipment.** Optime shall use [**] to maintain an adequate inventory of Products to respond to Customer demands and ensure that such inventory is provided to Customers in accordance with applicable SOPs and Financial Controls.
- (j) **Product Recalls.** Optime agrees to [**] with Corcept in recalling or returning any Products that Corcept identifies to Optime in writing as being the subject of a recall or withdrawal. Such recall or withdrawal shall be at Corcept’s expense, and Corcept will replace Products recalled or withdrawn, and reimburse Optime for mailing, shipping and all reasonable and documented costs and expenses incurred as a result of such recall or withdrawal; provided, however, that Optime has no right to any replacement Product and shall be responsible for the costs of such recall or withdrawal and replacement Product to the extent that such recall or withdrawal is attributable to the negligence, recklessness or intentional misconduct of Optime or breach of this Section 3.8(f) by Optime. During the Term and for [**] years following the Term, Optime will maintain complete and accurate records of all Products sold to facilitate compliance with this Section 3.8(f). Optime will comply with Corcept’s written instructions concerning communications with the public and the procedures to be observed during a recall or withdrawal of Products.
- (k) **Patient Assistance Programs.**
 - (i) Corcept may contract with or sponsor foundations or organizations (“**Organizations**”) that offer eligibility services for free Products to Patients who have no insurance coverage or financial means to cover all or part of the full cost of the Product (the “**Patient Assistance Program**”). Optime shall [**]. Upon Optime’s receipt of a (A) [**] and (B) [**].
 - (ii) Corcept may contract with such Organization or another foundation or organization (“**Co-Pay Organization**”) to assist Patients who cannot afford Products to obtain financial assistance for out-of-pocket expenses from the Co-Pay Foundations “**Co-Pay Assistance Program**”). Optime shall [**]. Upon Optime’s receipt of a (A) [**] and (B) [**] and the [**] from the [**]. Nothing in this Section 3.8(g)(ii) shall [**].

4. [**]

- (a) Optime shall [**]. In no event shall [**] (i) [**], including without limitation [**], and (ii) [**], including without limitation (A) [**], including without limitation [**], or (B) [**], including without limitation [**].
- (b) Optime shall [**], but [**].
- (c) [**] shall be free and clear of all mortgages, deeds of trust, liens, loans and encumbrances, except for statutory liens for the payment of current taxes that are not yet delinquent at all times during the Term.

- (d) In the event, as of the Effective Date, the [**], Optime agrees to use its [**] to establish [**], as promptly as [**] possible, [**] days of the Effective Date, unless otherwise agreed by the Parties. Optime's breach of this Section 4(d) shall be deemed a material breach by Optime.

5. **Project Director and Personnel.**

Optime shall appoint a project director ("**Project Director**") to be responsible for the completion of each Project by Optime. The Project Director shall coordinate performance of a Project with a representative designated by Corcept ("**Corcept Representative**"), which representative shall have responsibility over all matters relating to performance of such Project on behalf of Corcept. Unless otherwise agreed in the relevant Task Order, all communications between Optime and Corcept regarding the conduct of a Project shall be addressed to or routed directly through the Project Director and Corcept Representative for such Project. Optime and Corcept may, upon written notice to the other Party, substitute Project Directors or Corcept Representatives during the course of a Project. Optime shall arrange for qualified personnel necessary and desirable to meet fully Optime's obligations under this Agreement, whereby the number of such qualified personnel and the title and/or position of each such personnel shall be listed in each applicable Task Order.

6. **Payment and Budget**

Each Task Order shall include the applicable fees for the Services to be performed by Optime with respect to the applicable Project and a schedule for the payment of such fees (the "**Payment Schedule**"). Optime shall provide to Corcept invoices in accordance with the Payment Schedule under the applicable Task Order that summarize the Services performed for the applicable Project during the period of time covered by such invoices. Corcept shall pay the undisputed amounts contained in each invoice within [**] days of receipt of an invoice from Optime, unless otherwise indicated in the Payment Schedule in the applicable Task Order, unless the Parties mutually agree in writing to different payment terms. Corcept shall not be obligated to pay Optime any disputed amounts in any invoice or any amount for the performance of the Services hereunder other than those amounts set forth in the applicable Task Order, unless the Parties otherwise agree in writing. Corcept shall promptly notify Optime of any disputed invoices, and the Parties shall use commercially reasonable efforts to resolve any disputes concerning an invoice in good faith and in a reasonable period.

7. **Compliance with Applicable Law**

Optime shall maintain industry standards of professional conduct in the performance of each Project and in the preparation of all reports. Optime shall adhere to all Applicable Laws in the performance of each Project and in the preparation of all reports. Should such laws change, Optime shall make every reasonable effort to satisfy the new requirements. In the event that compliance with such new Applicable Laws necessitates a change in the Task Order for a Project in any material respect, Optime shall submit to Corcept a written, revised technical and cost proposal for Corcept's written acceptance prior to making any changes in the Task Order for such Project.

8. **Records; Inspections; Regulatory**

8.1 **Maintenance of Records; Inspection of Records.** During the Term and for [**] years thereafter, Optime shall maintain complete, true, and accurate written records relating to the performance of this Agreement, including without limitation orders, invoices, inventory records, accounting and financial records, including internal and external financial audit records, SOPs, Financial Controls, all Customer related records (including Patient data as stored and archived

pursuant to the applicable SOPs, Financial Controls and all Applicable Laws) and correspondence pursuant to this Agreement, Customer sales records, inventory-related transactions for the Products (collectively, the “**Records**”). During such period, upon at least [**] days’ prior written notice, accompanied by a detailed audit scope, and during normal business hours, Corcept or its independent auditor (provided that such auditor is subject to Optime’s approval, which approval shall not be unreasonably withheld, conditioned, or delayed, other than to require that such auditor has executed a confidentiality agreement with Optime), shall be entitled to audit and inspect those books and records of Optime that are maintained in connection with the performance of Optime’s obligations under this Agreement, including the Records for purposes of confirming compliance with this Agreement and Applicable Laws. Subject to Section 3.6 and unless permitted under Applicable Law, no Protected Health Information (as defined under HIPAA) will be included in the scope of any audit. [**]. Any review shall be conducted so as not to unreasonably interfere with Optime’s business. If a review uncovers errors or variations resulting in an underpayment or overpayment of amounts due for the period subject to the review, Optime will be entitled to receive the final written report. Both Parties are obligated to maintain the confidentiality of copies of the final report from the independent expert and may share such reports only with advisors under an obligation of confidentiality. Prompt adjustment will be made to fees paid to compensate for any errors or omissions disclosed by such review. Any such review will be paid for by Corcept unless discrepancies are disclosed that amount to [**] or more of the fees payable by Corcept to Optime, in which case Optime shall bear the reasonable costs of such review.

8.2 Financial Audit. On an annual calendar basis, Optime shall obtain a financial audit from an independent external auditor (the “**External Auditor**”). Optime shall promptly (and in any event within [**] days) provide Corcept with (a) all reports it receives from both the External Auditor regarding Optime’s financial controls, (b) a summary income statement, balance sheet and statement of cash flows and (c) any material audit findings. All such reports shall be deemed Confidential Information of Optime and shall be subject to Article 9 (Confidential Information).

8.3 Regulatory Inspections. Optime shall within [**] notify Corcept in writing in the event Optime receives any notice of inspection from a regulatory agency, including the FDA, regarding facilities, operations or procedures used in the provision of the Services hereunder. If allowed by Applicable Law, Optime shall provide Corcept copies of any such notices and/or communications. To the extent not prohibited by Applicable Law, Optime shall discuss in good faith with Corcept any corrective actions to be implemented by Optime and shall enable representatives of Corcept to participate in (including without limitation by providing reasonable advance notice of) any communications or meetings on this subject with any regulatory authority. In the event Optime does not receive any prior notice of a regulatory inspection, Optime shall immediately notify Corcept after such inspection, and will provide in writing to Corcept, to the extent permitted by Applicable Laws, regulatory guidance or court order, copies of all materials, correspondence, statements, forms, and records related to this Agreement and received or generated pursuant to such inspection. Optime shall take all reasonable actions requested by Corcept to cure deficiencies as noted during any such inspection.

8.4 Other Regulatory Correspondence. Optime shall immediately, but within [**] days, notify Corcept in writing in the event Optime receives any notices or other communications (such as notice of inquiry, notice of loss of licensure, and resulting findings) from a regulatory agency, other than a notice of inspection, regarding any matter related to this Agreement, including any facilities, operations or procedures used in the provision of the Services hereunder. The Parties agree that Corcept shall have the primary responsibility for preparing any responses to any such notices relating to this Agreement that may be required by the regulatory authority; provided, however, that Optime shall have the primary responsibility for preparing any responses relating solely to Optime’s operations and procedures. Optime shall provide any proposed correspondence to Corcept for review and approval before submission.

8.5 **Cooperation.** If Corcept requests records, documents or other information from Optime pertaining to an inquiry from a governmental or regulatory authority or in relation to any third-Party dispute, Optime will promptly comply with such request.

8.6 **Product Complaints.** Optime shall notify Corcept within [**] of becoming aware of any Product Complaints in connection with the use of the Products to Corcept's quality assurance representative as provided in each applicable Task Order. Notifications under this Section 8.6 shall include the following information, if available:

- (a) Reporting individual's full name, address, and telephone number;
- (b) Name of the Product being reported;
- (c) A brief description of the complaint being reported; and
- (d) Any other information reasonably necessary for Corcept to adequately report such Product Complaint to the FDA.

8.7 **Adverse Events.** Optime shall notify Corcept within [**] of becoming aware of any Adverse Event in connection with the use of the Products to Corcept's pharmacovigilance representative as provided in each applicable Task Order. Notifications under this Section 8.7 shall include the following information, if available:

- (e) Reporting individual's full name, address, and telephone number;
- (f) Name of the Product being reported;
- (g) A brief description of each Adverse Event being reported (including date and time that each Adverse Event occurred); and
- (h) Any other information reasonably necessary for Corcept to adequately report such Adverse Event to the FDA.

9. Confidential Information

9.1 **Confidential Information.** During the Term, either Party may receive from the other Party confidential or trade secret information, including information concerning regulatory submissions, preclinical and/or clinical information about compounds; financial, accounting or business related information or business plans and strategies; data, testing and research techniques, inventions, materials, processes, practices, trade secret, patent application (including drawings and claims), prices, idea, process, or formula; any sample, compound, and any procedures and formulations for producing such sample and/or compound; any data or information relating to any research project, work in process, or future development; and any engineering, manufacturing, marketing, servicing, financing or personnel matter relating to the Party, its present or future products, sales, suppliers, clients, customers, employees, investors, or business, whether in oral, written, visual, graphic or electronic form (collectively "**Confidential Information**"). For clarity, all: (a) [**]; (b) [**]; and (c) information disclosed by or on behalf of Corcept to Optime under any nondisclosure or confidentiality agreements and/or other agreements between the Parties executed prior to the Effective Date ("**Previous Agreements**"), shall be deemed Corcept's Confidential Information under this Agreement. All: (i) [**]; and (ii) information disclosed by or on behalf of Optime to Corcept under any Previous Agreements, shall be deemed Optime's Confidential Information under this Agreement. This Agreement and [**] established and maintained for the purposes of providing Services herein shall be deemed Confidential Information of both Corcept and Optime.

9.2 Obligations of Confidentiality and Non-Use. The Party receiving the Confidential Information of the other Party (“**Receiving Party**”) agrees to hold in confidence all Confidential Information and, except as permitted under this Agreement, not to use any Confidential Information or disclose or make any Confidential Information available to any third Parties without the written permission of the Party disclosing the Confidential Information (“**Disclosing Party**”). Notwithstanding the foregoing, the Optime may disclose or make Corcept’s Confidential Information available to Optime’s employees who are bound by written obligations of confidentiality and non-use at least as restrictive as the obligations in this Agreement to the extent necessary to perform the Services. The Receiving Party shall ensure that all of its directors, officers, employees, affiliates, consultants, agents or subcontractors (“**Representatives**”) who receive the Disclosing Party’s Confidential Information comply with the terms of this Article 9, and the Receiving Party shall be liable to the Disclosing Party for any failure of its Representatives to so comply. The obligations of confidentiality and non-use contained in this Article 9 shall not apply with respect to any of the Disclosing Party’s Confidential Information that the Receiving Party can demonstrate by competent written proof: (a) was in the public domain at the time it was disclosed by the Disclosing Party to the Receiving Party or has entered the public domain through no fault of the Receiving Party or its Representatives; (b) was known to the Receiving Party, without restriction, at the time of disclosure by the Disclosing Party to the Receiving Party; (c) was or is independently developed by or for the Receiving Party without any use of Disclosing Party’s Confidential Information; or (d) becomes known to the Receiving Party, without restriction, from a source other than the Disclosing Party without breach of this Agreement by the Receiving Party.

9.3 Exceptions.

- (i) Notwithstanding the foregoing, disclosure by the Receiving Party of the Disclosing Party’s Confidential Information shall not be precluded if such disclosure is pursuant to a valid order or requirement of a court, administrative agency or other governmental body or is otherwise required by law or regulation or rules of a securities exchange; provided, however, that the Receiving Party shall provide prompt notice of such court order or requirement to the Disclosing Party to enable the Disclosing Party to seek a protective order or otherwise prevent or restrict such disclosure, and cooperate with the Disclosing Party’s efforts in this regard.
- (j) Corcept may disclose the Optime’s Confidential Information or jointly owned Confidential Information, as the case may be, to regulatory authorities to the extent such disclosure is required to comply with applicable governmental regulations or is in connection with Corcept’s filings, submissions and communications with regulatory authorities, including the U.S. Securities Exchange Commission.

9.4 Survival. The obligations under this Article 9 shall survive for a period commencing on the Effective Date and terminating [**] years from the date of expiration or termination of this Agreement; provided, however, with respect to all [**] (or for a period of [**] years from the expiration or termination of this Agreement, whichever is longer).

9.5 Remedy. Optime agrees that its obligations hereunder are necessary and reasonable in order to protect the Corcept’s Confidential Information and business, and expressly agree that monetary damages would be inadequate to compensate Corcept for any breach of the terms of this Agreement. Accordingly, Optime agrees and acknowledges that any such violation or threatened violation will cause irreparable injury to Corcept, and that, in addition to any other remedies that may be available, in law, in equity or otherwise, to Corcept, Corcept will be

entitled to seek injunctive relief against the threatened breach of this Agreement or any Task Order or the continuation of any such breach, without the necessity of proving actual damages.

10. Intellectual property; Work Product; Storage

10.1 **Pre-Existing Intellectual Property.** Corcept shall remain the sole owner of all right, title and interest in and to, or licensee of, as applicable, all Confidential Information and all intellectual property rights that are owned or controlled by Corcept as of the Effective Date (“**Pre-Existing Corcept Intellectual Property**”), and no right, title or interest therein is transferred or granted to Optime except solely as provided in Section 10.5. Optime shall remain the sole owner of all right, title and interest in and to, or licensee of, as applicable, all Confidential Information and all intellectual property rights that are owned or controlled by or licensed to Optime as of the Effective Date (“**Pre-Existing Optime Intellectual Property**”), [**] and all intellectual property rights claiming or covering the [**] and no right, title or interest therein is transferred or granted to Corcept except solely as provided in Section 10.6.

10.2 **Corcept.** Corcept shall own all right, title, and interest in and to all Corcept Work Product, Materials and Deliverables. Optime shall assign, and shall cause its Representatives to assign, and hereby assigns to Corcept all right, title, and interest in and to the Corcept Work Product, Deliverables and Materials. Optime shall require that, prior to the performance by its Representatives of any work in connection with this Agreement, all such Representatives are bound by written agreements providing for the assignment to Optime of all inventions, discoveries and improvements that they may conceive or make in connection with Corcept Work Product, Deliverables and Materials. Optime shall deliver and execute any further legal instruments and perform any acts which are or may become reasonably necessary to effectuate the purpose and intent of this Section 10.2.

10.3 **Optime.** Optime shall own all right, title, and interest in and to all [**]. Subject to the terms and conditions of this Agreement, Optime hereby grants to Corcept a non-exclusive, irrevocable, perpetual, worldwide, royalty-free, fully-paid license, with the right to grant sublicenses through multiple tiers, under the [**].

10.4 [**]. Corcept and Optime shall [**] established and maintained for the purposes of providing the Services herein.

10.5 License to Optime.

- (a) Subject to the terms and conditions of this Agreement, including Section 10.5(b), Corcept hereby grants Optime a non-exclusive, non-transferable, royalty-free license to use Pre-Existing Corcept Intellectual Property and Corcept Work Product solely for the purpose of [**].
- (b) During the Term, in the event Optime has the need to use Corcept’s trademarks, service marks, and related trade dress (the “**Marks**”) in the Territory solely in connection with the performance of its obligations under this Agreement and/or to provide the Services hereunder, Optime may display or otherwise use the Marks only with prior written approval by Corcept. This Section 10.5(b) shall not constitute a license to use the Marks or the goodwill associated therewith for any other purpose, and upon expiration or termination of this Agreement for whatever reason, Optime shall immediately cease all use of the Marks and the goodwill associated therewith. Optime shall not alter the Marks and further shall not register, or cause to be registered, any marks similar to the Marks. Optime shall not at any time do or permit any act to be done which may in any way impair the rights of Corcept in the Marks. Optime shall not obtain or assert any claim to any

of the Marks (whether owned by Corcept or licensed to Corcept) in the Territory or otherwise, and Optime shall assign and hereby assigns to Corcept all its right, title and interest in to any rights so obtained.

10.6 License to Corcept. Optime hereby grants to Corcept a worldwide, fully-paid, royalty-free, non-exclusive license, with the right to grant sublicenses through multiple tiers, under all intellectual property rights that are owned or controlled by Optime and that are [**].

10.7 No Implied Rights or Licenses. Neither Party grants to the other Party any rights or licenses in or to any patent or other intellectual property right, whether by implication, estoppel or otherwise, except to the extent expressly provided for under this Agreement.

11. Independent Contractor.

The relationship between the Parties is that of independent contractors and not of partners, joint venturers, employers, employees or any other kind of relationship and neither Party has any equity interest, voting right nor control over the other Party. Optime shall have complete and exclusive control over its employees, subcontractors and agents and shall be solely responsible for expenses and liabilities associated with the employment of its employees, subcontractors and agents.

12. Insurance.

12.1 Insurance by Corcept.

- (a) Corcept shall maintain during the Term, or as otherwise provided in Section 12.3, commercial general liability insurance, including products liability insurance on Products. Such insurance shall cover, among other things, [**]. The limits of such insurance shall not be less than \$[**] per occurrence. Such insurance shall name Optime and its subsidiaries as additional insureds. This insurance shall apply as primary insurance with respect to any other insurance or self-insurance program.
- (b) Upon request, Corcept shall provide Optime with a Certificate of Insurance which shall indicate all insurance coverage required by this provision herein. Corcept shall provide Optime with [**] days' notice prior to substantial modification or cancellation of such policies.

12.2 Insurance by Optime.

- (c) Optime shall maintain during the Term, or as otherwise provided in Section 12.3, the following insurance coverage:
 - (i) Warehouseman's legal liability insurance in the amount of at least \$[**]. Corcept acknowledges that such warehouseman's legal liability insurance also insures [**].
 - (ii) Fire and extended property insurance sufficient to cover [**]. Corcept shall provide Optime at all times with [**] as Optime may [**].
 - (iii) Worker's Compensation insurance as required by Applicable Law.
 - (iv) Commercial general liability' insurance and umbrella insurance having a combined limit of not less than \$[**].

- (v) Professional liability and Errors and Omissions Liability insurance covering liability for loss or damage due to an act, error or negligence having a limit of \$[**].
- (d) Upon request, Optime shall provide Corcept with a Certificate of Insurance which shall indicate all insurance coverage required by this provision herein. Optime shall provide Corcept with [**] days' notice prior to substantial modification or cancellation of such policies.

12.1 All insurance required hereunder shall be with insurance companies rated [**], and shall not have deductibles or self-insured retentions [**]. If any insurance required hereunder is [**], then said insurance shall [**].

13. Representations, Warranties, and Covenants.

13.1 **Representations, Warranties and Covenants of Optime.** Optime represents and warrants as of the Effective Date and during the Term of this Agreement as follows:

- (a) Optime (i) is a corporation duly incorporated, validly existing and in good standing; (ii) has taken all necessary actions on its part to authorize the execution, delivery and performance of the obligations undertaken in this Agreement, and no other corporate actions are necessary with respect thereto, and when executed and delivered by it, this Agreement will constitute a legal, valid and binding obligation of it, enforceable against it in accordance with this Agreement's terms; (iii) is not a party to any agreement or understanding and knows of no law or regulation that would prohibit it from entering into and performing this Agreement; (iv) is duly licensed, authorized or qualified to do business and is in good standing in every jurisdiction in which a license, authorization or qualification is required for it to perform its obligations under this Agreement and possesses all approvals, consents, orders or authorizations and has made all designations, registrations, declarations and filings with any governmental authority that is required to perform its obligations under this Agreement; and (v) will not enter into any other agreements that would interfere or prevent performance of the obligations described herein.
- (b) There is no action, proceeding, or investigation pending that would prohibit Optime from performing its obligations hereunder.
- (c) Optime has, and during the Term shall maintain, all necessary federal and state licenses and permits in accordance with Applicable Laws (as amended from time to time) or other appropriate certifications, if applicable, and has the requisite and necessary experience, equipment, facilities and personnel to perform within the Territory the obligations and services contemplated by this Agreement. Optime shall immediately cease all activity under this Agreement if it becomes the subject of an Adverse Enforcement Action, and shall not permit any Representative who, to its knowledge (after performing reasonable inquiry), becomes the subject of an Adverse Enforcement Action from performing any activities under this Agreement. Optime shall immediately notify Corcept if any of its necessary federal and state licenses, permits or other appropriate certifications lapse, expire or are cancelled.
- (d) Optime and each of its Representatives have complied fully with and have not violated, and shall comply fully with and shall not violate, any and all Applicable Laws during the Term, including without limitation (a) the Social Security Act,

(b) HIPAA, (c) all state drug selection, dispensing, Pharmacy practice, privacy and consumer protection laws, (d) the Federal Anti-Kickback Statute (42 U.S.C. § 1320a-7b), (e) the Public Contracts Anti-Kickback Act (41 U.S.C. § 51 *et seq.*), (f) the Stark Law (42 U.S.C. § 1395nn), (g) all applicable patient confidentiality and privacy laws, rules, regulations and requirements relating to the terms of this Agreement, (h) all rules and regulations of the FDA and the Centers for Medicare and Medicaid Services, and (i) Missouri Uniform Trade Secret Act. Optime shall immediately notify Corcept in writing of any material civil, criminal or administrative action brought, or to Optime's knowledge threatened to be brought, against Optime and/or any of its Representatives, and upon request to promptly provide Corcept with reasonably detailed information regarding Optime's handling and disposition of any such action.

- (e) No consent, approval, order or authorization of, or registration, qualification, designation, declaration or filing with, any federal, state or local governmental authority is required on the part of the Optime and any of its Representatives in connection with this Agreement.
- (f) Optime and its Representatives have not breached, violated or defaulted, are not in breach, violation or default of, and shall not breach, violate or default (i) any provisions of its certificate of incorporation or Bylaws, (ii) of any instrument, judgment, order, writ or decree, (iii) under any note, indenture or mortgage, or (iv) under any lease, agreement, contract or purchase order to which it is a party or by which it is bound.
- (g) There is no claim, action, suit, proceeding, arbitration, complaint, charge or investigation pending or to Optime's knowledge, currently threatened against Optime or any of its Representatives.
- (h) Optime owns or possesses or can acquire on commercially reasonable terms sufficient legal rights to all Optime intellectual property, including Optime Pre-Existing Intellectual Property, without any known conflict with, or infringement of, the rights of others, as necessary or useful to perform its obligations under this Agreement. Except as set forth in Exhibit B hereto, neither Optime nor any of its Representatives (i) by conducting its business (including by performing its obligations under this Agreement) would violate any of the patents, trademarks, service marks, tradenames, copyrights, trade secrets, mask works or other proprietary rights or processes of any Third Party and (ii) have received any communications alleging that it has violated, or do violate, by conducting its business (including by performing its obligations under this Agreement), any of the patents, trademarks, service marks, tradenames, copyrights, trade secrets, mask works or other proprietary rights or processes of any Third Party.
- (i) [**], the property and assets that Optime owns are free and clear of all mortgages, deeds of trust, liens, loans and encumbrances, except for statutory liens for the payment of current taxes that are not yet delinquent and encumbrances and liens that arise in the ordinary course of business and do not materially impair Optime's ownership or use of such property or assets. With respect to the property and assets it leases, Optime is in compliance with such leases and, to its knowledge, holds a valid leasehold interest free of any liens, claims or encumbrances other than those of the lessors of such property or assets.
- (j) Neither Optime nor any of its Representatives performing the Services under this Agreement is debarred, suspended, proposed for debarment, or otherwise

determined to be ineligible to participate in federal health care programs (as that term is defined in 42 U.S.C. 1320a-7b(f)), or convicted of a criminal offense related to the provision of health care items or services (collectively, an “**Adverse Enforcement Action**”). Optime shall immediately notify Corcept if it or any of its Representatives performing Services under this Agreement becomes the subject of an Adverse Enforcement Action. Optime shall immediately cease all activity under this Agreement if it becomes the subject of an Adverse Enforcement Action, and shall not permit any Representative who, to its knowledge (after performing reasonable inquiry), becomes the subject of an Adverse Enforcement Action from performing any activities under this Agreement.

- (k) Optime has delivered to Corcept its unaudited financial statements (including balance sheet, income statement and statement of cash flows) as of May 31, 2017 (collectively, the “**Financial Statements**”). The Financial Statements have been prepared in accordance with GAAP applied on a consistent basis throughout the periods indicated, except that the unaudited Financial Statements may not contain all footnotes required by GAAP. The Financial Statements present fairly the financial condition and position of Optime as of the date of such Financial Statements. Since May 31, 2017, there has not been any material change in the assets, liabilities, financial condition or operations of Optime.
- (l) Optime has no material liabilities or obligations, contingent or otherwise, other than (i) liabilities incurred in the ordinary course of business; (ii) obligations under contracts and commitments incurred in the ordinary course of business; and (iii) liabilities and obligations of a type or nature not required under GAAP to be reflected in the Financial Statements, which, in all such cases, individually and in the aggregate would not have a material adverse effect on (a) the results of operations, assets, business or financial condition of Optime or (b) Optime’s ability to perform its obligations under this Agreement. Optime shall maintain sufficient capital and financial wherewithal to maintain its ability to continue as a going concern and until the first anniversary of the Effective Date, Optime shall, solely for the purposes of this Section 13.1(l), exclude any revenues generated from Optime’s customers, including Corcept, to establish its ability to continue as a going concern. Optime maintains and shall continue to maintain a standard system of accounting established and administered in accordance with GAAP.

13.2 Representations, Warranties and Covenants of Corcept. Corcept (a) is a corporation duly incorporated, validly existing and in good standing; (b) has taken all necessary actions on its part to authorize the execution, delivery and performance of the obligations undertaken in this Agreement, and no other corporate actions are necessary with respect thereto, and when executed and delivered by it, this Agreement will constitute a legal, valid and binding obligation of it, enforceable against it in accordance with this Agreement’s terms; and (c) knows of no law or regulation that would prohibit it from entering into and performing this Agreement.

13.3 In connection with this Agreement, each Party represents, warrants and covenants that it has not given or promised to give, and will not make, offer, agree to make or authorize any payment or transfer anything of value, directly or indirectly, to (a) any Government or Public Official (as defined below); (b) any political party, party official or candidate for public or political office; (c) any person while knowing or having reason to know that all or a portion of the value will be offered, given, or promised, directly or indirectly, to anyone described in items (a) or (b) above; or (d) any owner, director, employee, representative or agent of any actual or potential customer of such party (if any such transfer of value would be a violation of any Applicable Laws). Each Party will make reasonable efforts to comply with requests for

information, including answering questionnaires and narrowly tailored audit inquiries, to enable the other Party to ensure compliance with applicable anti-bribery laws. For purposes of this Agreement, “**Government or Public Official**” means any officer or employee or anyone acting in an official capacity on behalf of: a government or any department or agency thereof; a public international organization (such as the United Nations, the International Monetary Fund, the International Red Cross, and the World Health Organization), or any department, agency or institution thereof; or a government-owned or controlled company, institution, or other entity, including a government-owned hospital or university.

13.4 EXCEPT AS SET FORTH IN THIS ARTICLE 13 (REPRESENTATION, WARRANTIES, AND COVENANTS), NEITHER PARTY MAKES ANY REPRESENTATIONS OR WARRANTIES. EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR FOR NON-INFRINGEMENT OF A PATENT, TRADEMARK OR OTHER INTELLECTUAL PROPERTY RIGHT.

14. **Limitation of Liability.**

EXCEPT FOR A BREACH OF ARTICLE 9 (CONFIDENTIALITY) AND SECTION 13.1(h) AND WITHOUT LIMITING A PARTY’S INDEMNIFICATION OBLIGATIONS UNDER ARTICLE 15 (INDEMNIFICATION), IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER PARTY FOR ANY INDIRECT, PUNITIVE, SPECIAL OR EXEMPLARY, INCIDENTAL, CONSEQUENTIAL OR OTHER SIMILAR DAMAGES ARISING OUT OF OR IN ANY WAY CONNECTED WITH THIS AGREEMENT OR WITH THE EXERCISE BY A PARTY OF ITS RIGHTS OR PERFORMANCE BY A PARTY OF ITS OBLIGATIONS HEREUNDER.

15. **Indemnification.**

15.1 **Indemnification by Optime.** Optime shall indemnify, defend, and hold harmless Corcept and its affiliates and their respective officers, directors and employees (the “**Corcept Group**”) from any loss, cost, damage, liability or expense (including reasonable attorneys’ fees) (collectively, “**Losses**”) resulting from any lawsuit, action, claim, demand or proceeding brought by a Third Party (collectively, “**Claims**”) arising from or associated with: (a) the negligence, gross negligence or intentional misconduct of any member of the Optime Group (defined below), including without limitation any Claim that arises from or is associated with a breach of Section 13.1; (b) a failure by any member of the Optime Group to adhere to the terms of a Task Order, Corcept’s written instructions or the terms and conditions of this Agreement (including a breach of any representations and warranties under this Agreement); or (c) a failure by any member of the Optime Group to comply with Applicable Laws in the performance of a Task Order; except, in each case, to the extent that any such Losses from Claims arise from: (i) a failure by any member of the Corcept Group to adhere to the terms and conditions of this Agreement (including a breach of any representations and warranties under this Agreement); (ii) the negligence, gross negligence or intentional misconduct of any member of the Corcept Group; (iii) the manufacture, use, sale, offer for sale, or importation of Product by any member of the Corcept Group.

15.2 **Indemnification by Corcept.** Corcept shall indemnify, defend, and hold harmless Optime and its affiliates and their respective officers, directors and employees (the “**Optime Group**”) from any Losses resulting from any Claims arising from or associated with:

(a) a failure by any member of the Corcept Group to adhere to the terms and conditions of this Agreement (including a breach of any representations and warranties under this Agreement); (b) the negligence, gross negligence or intentional misconduct of any member of the Corcept

Group; or (c) the manufacture, use, sale, offer for sale, or importation of Product by any member of the Corcept Group; except, in each case, to the extent that any such Losses from Claims arise from: (i) the negligence, gross negligence or intentional misconduct of any member of the Optime Group; (ii) a failure by any member of the Optime Group to adhere to the terms of a Task Order. Corcept's written instructions or the terms and conditions of this Agreement (including a breach of any representations and warranties under this Agreement); or (iii) a failure by any member of the Optime Group to comply with Applicable Laws in the performance of a Task Order

15.3 Indemnification Procedure. In the event that either Party seeks indemnification hereunder, the indemnified shall promptly notify the indemnifying Party of a claim after it receives notice thereof and, shall permit the indemnifying Party, at the indemnifying Party's cost, to assume direction and control of the defense and settlement of the claim, and shall cooperate as reasonably requested (at the expense of the indemnifying Party), in the defense of the claim. Neither Party shall settle or otherwise compromise any claim or suit in any manner that adversely affects that other Party hereunder or imposes obligations on the other Party in addition to those set forth in this Agreement, without prior written consent of the other Party, which consent shall not be unreasonably withheld or delayed.

16. Force Majeure.

A Party shall be excused from performing its obligations under this Agreement if its performance is delayed or prevented by any event beyond such Party's reasonable control, including but not limited to, acts of God, fire, explosion, weather, disease, war, acts of terrorism, insurrection, civil strife, riots, government action, or power failure, provided that such performance shall be excused only to the extent of and during such disability; provided, further, that the affected Party takes reasonable, diligent efforts to remove the condition constituting force majeure or to avoid its affects so as to resume performance as soon as practicable. Any time specified for completion of performance in a Task Order falling due during or subsequent to the occurrence of any of such events shall be automatically extended for a period of time equal to the period of such disability. Optime shall promptly notify Corcept if, by reason of any of the events referred to herein. Optime is unable to meet any such time for performance specified in a Task Order.

17. Use of Names.

Subject to Section 10.5(b), neither Party shall use the other Party's name or the name of any member of that Party's personnel in any advertising, packaging, promotional material, or press release relating to this Agreement, without the prior written approval of the other Party except to the extent such disclosure is reasonably necessary for (a) regulatory' filings, including filings with the U.S. Securities and Exchange Commission or the FDA (or any equivalent oversight body in a country other than the United States), or (b) complying with applicable governmental regulations and legal requirements.

18. Termination.

18.1 Term. This Agreement shall have a term of five (5) years from the Effective Date, unless earlier terminated in accordance with this Article 18 (the "**Term**"). This Agreement may be extended by the written agreement of the Parties. Termination of this Agreement as permitted hereunder shall result in the termination of all Task Orders.

18.2 Termination

- (a) **Material Breach.** Either Party may terminate this Agreement in the event of breach of a material obligation of the other if such breach remains uncured after

[**] days' notice; provided, however, in the event Optime breaches Section 13.1(h) of this Agreement, then Corcept may immediately terminate this Agreement upon written notice to Optime.

- (b) **Termination for Debarment.** Corcept shall have the right to terminate this Agreement immediately upon written notice to Optime if Optime or any of Representatives providing Services hereunder becomes debarred or receives notice of or threat of debarment under the provisions of the Generic Drug Enforcement Act of 1992, as amended or any other federal or state debarment or exclusion list.
- (c) **Termination for Convenience.** Corcept shall have the right to terminate this Agreement in its entirety or any Task Order for a particular Project at any time with or without cause upon [**] days' prior written notice to Optime. In the event a Task Order is terminated without cause, Corcept shall [**], together with [**]. Optime shall [**] and any excess funds held in reserve by Optime shall promptly be returned to Corcept.
- (d) **Bankruptcy or Insolvency.** Either Party may terminate this Agreement immediately upon written notice to the other Party, if such other Party makes an assignment for the benefit of creditors, files a petition in bankruptcy, is adjudicated insolvent or bankrupt, a receiver or trustee is appointed with respect to a substantial part of such other Party's property, or a proceeding is commenced against it which will substantially impair its ability to perform hereunder.

18.3 Effect of Termination

- (e) Upon expiration or termination of this Agreement or any Task Order:
 - (vi) Optime shall immediately return and transfer all Corcept property in Optime's possession and control, including [**] and any other Confidential Information of Corcept, according to Company's instructions. Any return of Product inventory shall be at Corcept's expense;
 - (vii) Optime will use its [**] to transfer any data, including patient data and files, inventory and any other items specified by Corcept, as well as any other items as may [**] by the successor pharmacy or pharmacies designated by Corcept and take such other steps, without delay, as are [**] to assure that Patients continue to receive Products without interruption or delay;
 - (viii) Optime shall use its [**] to collect, or assist a Corcept-designated Third Party to collect, any outstanding Corcept Funds.
- (f) The termination of any Task Order will not terminate this Agreement with respect to other ongoing Task Orders.
- (g) Upon termination of any Task Order, Corcept shall pay to Optime all undisputed amounts due for all Services rendered by Optime under the terms of the Task Order in addition to any non-cancellable obligations or expenditures incurred by Optime in accordance with the Task Order, provided that all such payments have been previously authorized by Corcept. Such payments shall be paid on a pro rata basis up to the effective date of termination of such Services to the extent such

payments were not yet paid under the provisions of the applicable Task Order. Any funds held by Optime, which by contract definition or amendment are deemed unearned shall be immediately returned to Corcept, but not less than [**] days after termination or expiration of any Task Order or this Agreement.

- (h) Article 1, 4, 7, Section 8.1, Article 9, Sections 10.1, 10.2, 10.3, 10.4 and 10.7, Articles 11 through 14 (inclusive), Article 17, Sections 18.2 and 18.3, Article 19, Articles 21 through 28 (inclusive) shall survive termination or expiration of this Agreement.

19. Exclusivity; Preferred Provider

19.1 During the Term, Optime shall not, directly or indirectly, perform distribution services for any third party with respect to a treatment or potential treatment for any disorder treated by a Product.

19.2 Unless expressly stated otherwise in the applicable Task Order, Optime shall be Corcept's exclusive provider of direct-to-patient pharmacy services for any Product covered by a Task Order.

20. Assignment.

Neither Party may assign this Agreement in whole or in part without the prior written consent of the other Party. Notwithstanding the foregoing, each Party may assign this Agreement without such consent to an affiliated company or to an entity who acquires all or substantially all of the business or assets of such Party to which this Agreement pertains (whether by merger, acquisition, consolidation, reorganization, sale or otherwise). Any such permitted assignment shall be effective only if the assignee agrees in writing to be bound by the

terms and conditions of this Agreement. Any attempted assignment of this Agreement not in compliance with this Article 19 shall be null and void.

21. Notice.

All notices required or permitted hereunder shall be given to the appropriate Party at the address specified above or at such other address as the Party shall specify in writing. Such notice shall be deemed given: (i) as of the day of personal delivery; (ii) one (1) day after the date sent by confirmed facsimile or confirmed email; or (iii) on the day of successful delivery to the other Party and confirmed by courier service:

Corcept: Corcept Therapeutics Inc.
149 Commonwealth Drive
Menlo Park, CA 94025
Attention: Sean Maduck, Sr. Vice President, Commercial
JD Lyon, Vice President, Corporate Controller
Email: [**]
[**]

Optime: Optime Care, Inc.
4060 Wedgeway Court
Earth City, MO 63045
Attention: President & CEO; Donovan J. Quill
Email: [**]
Fax: 888 868-3147

22. Choice of Law

The validity and interpretation of this Agreement and the legal relations of the Parties under this Agreement shall be governed by the laws of the State of California, without reference to conflict of laws principles requiring the application of a different governing law.

23. No Implied Rights

No right or license is granted under this Agreement by either Party to the other Party (expressly, impliedly or by estoppel), except as specifically set forth in this Agreement.

24. Amendments; Waiver

No amendments or waivers of this Agreement shall be binding upon either Party unless in writing, signed by the Parties and specifying the provision of this Agreement that is amended or waived. No waiver by either Party of any breach of this Agreement or any Task Order by the other Party shall be effective as to any other breach, whether of the same or any other term or condition and whether occurring before or after the date of such waiver.

25. Entire Agreement

This Agreement sets forth the entire agreement between the Parties hereto with respect to the performance of Projects by Optime for Corcept hereunder and as such, supersedes all prior and contemporaneous negotiations, agreements, representations, understandings, purchase orders, and commitments with respect thereto, including any prior confidentiality or nondisclosure agreement between the Parties, and any confidential information disclosed under such prior agreement shall be governed under the terms of this Agreement.

26. Severability

In the event that any one or more of the provisions contained in this Agreement shall, for any reason, be held to be invalid, illegal or unenforceable in any respect, that invalidity, illegality or unenforceability shall not affect any other provisions of this Agreement, and all other provisions shall remain in full force and effect. The Parties shall make a good faith effort to replace any such provision with a valid and enforceable one such that the objectives contemplated by the Parties when entering this Agreement may be realized.

27. Construction

Except where the context otherwise requires, wherever used, the singular shall include the plural, the plural the singular, the use of any gender shall be applicable to all genders, and the word "or" are used in the inclusive sense. No rule of strict construction shall be applied in the interpretation or construction of this Agreement. The headings are included in this Agreement merely for convenience of reference, and they are not to be considered part of this Agreement or used in the interpretation of this Agreement. When used in this Agreement, "including" means "including without limitation." Except as expressly set forth in this Agreement, whenever a Party's consent or approval is required under this Agreement, that Party may grant or deny its consent or approval in its sole and absolute discretion. Time is "of the essence" in the performance of obligations under this Agreement. This Agreement is in the English language only, which language shall be controlling in all respects, and all versions hereof in any other language shall be for accommodation only and shall not be binding upon the Parties.

28. Counterparts

This Agreement may be executed in two (2) or more counterparts, each of which will be an original and all of which will constitute together the same document. Counterparts may be signed and delivered by facsimile, or electronically in PDF format, each of which will be binding when sent.

Signature page follows.

In Witness Whereof, the Parties hereto have duly executed this Agreement. The Parties acknowledge that the date of signature may not be the Effective Date.

CORCEPT THERAPEUTICS INCORPORATED

By: /s/ Charles Robb

Name: Charles Robb

Title: Chief Financial Officer

Date: August 3, 2017

OPTIME CARE, INC.

By: /s/ Donovan J. Quill

Name: Donovan J. Quill

Title: President and CEO

Date: August 3, 2017

EXHIBIT A

FORM OF TASK ORDER

**Task Order Number [INSERT NUMBER]
to Master Services Agreement Between
Corcept Therapeutics Inc. and Optime Care, Inc.**

This Task Order Number [INSERT NUMBER] (the “**Task Order**”) is effective as of [INSERT DATE] pursuant to, and as a part of, that certain Distribution Services Agreement (the “**Agreement**”) effective [June 1], 2017 between Corcept Therapeutics Inc. (“**Corcept**”) and Optime Care, Inc. (“**Optime**”).

Product	For the purposes of this Task Order, “ Product ” shall mean, Corcept’s product known as [INSERT PRODUCT NAME] and any successor thereto.
Territory:	[INSERT TERRITORY (e.g., United States, European Union, etc.)]
Project Director	[INSERT NAME]
Corcept Representative	[INSERT NAME]
Corcept Personnel	[INSERT THE NUMBER OF PERSONNEL TO BE STAFFED ON THIS PROJECT AND ONLY THE APPLICABLE POSITION TITLE OF THE PERSONNEL.]
SOP(s)and Financial Controls:	[INSERT ALL SOPS AND FINANCIALS CONTROLS APPLICABLE TO THIS PROJECT.]
Services to be Performed:	[INSERT DESCRIPTION OF EACH SERVICE TO BE PERFORMED.]
Project Schedule and Timeline of Services	Target Start Date: [INSERT DATE] Target Completion Date (if applicable): [INSERT DATE, ONLY IF APPLICABLE.]
Services Fees	
Deliverables and Delivery Schedule	Optime shall generate and provide to Corcept the following Deliverables: <ul style="list-style-type: none">• [INSERT DELIVERABLE]: [DELIVERY SCHEDULE; E.G., DAILY/WEEKLY/MONTHLY/ QUARTERLY/ANNUALLY].

Product Complaint Contact Information	[INSERT APPROPRIATE CORCEPT QA PERSONNEL NAME AND CONTRACT INFORMATION]
Adverse Event Contact Information	[INSERT APPROPRIATE CORCEPT PV PERSONNEL NAME AND CONTRACT INFORMATION]
Other Terms, If Any	(INSERT TERMS, IF ANY)

In Witness Whereof, the Parties hereto have duly executed this Agreement. The Parties acknowledge that the date of signature may not be the Effective Date.

Corcept Therapeutics Inc.

By: _____

Print Name: _____

Title: _____

Date: _____

Optime care, inc.

By: _____

Print Name: _____

Title: _____

Date: _____

EXHIBIT B

DISCLOSURE SCHEDULE

1. Section 13.1(h)(ii). Letter to Donovan Quill of Optime Care, Inc. from Aaron H. Kastens of Michael Best & Friedrich LLP, counsel to Dohmen Life Science Services, LLC, dated February 28, 2017.
2. Section 13.1(h)(ii). Letter to Aaron H. Kastens of Michael Best & Friedrich LLP, counsel to Dohmen Life Science Services, LLC, from Jeffrey L. Schultz, counsel to Optime Care, Inc., dated March 6, 2017.

Certain identified information has been excluded from the exhibit because it is both (i) not material and (ii) the type of information that the registrant treats as private or confidential. Double asterisks denote omissions.

**Task Order Number One
to Master Services Agreement Between
Corcept Therapeutics Inc. and Optime Care, Inc.**

This Task Order Number One (the “**Task Order**”) is effective as of August 4, 2017 pursuant to, and as a part of, that certain Distribution Services Agreement (the “**Agreement**”) effective August 4, 2017 between Corcept Therapeutics Inc. (“**Corcept**”) and Optime Care, Inc. (“**Optime**”).

Product	For the purposes of this Task Order, “ Product ” means Korlym® and any other medication sold by Corcept for the treatment of patients with hypcrcortisolism.
Territory	The United States of America
Optime Project Director	[**]
Corcept Representative	[**]
Optime Personnel	Optime will provide a team of skilled professionals sufficient to perform the Services (the “ Optime Team ”), as set forth in Exhibit 1 . Optime may [**], provided it gives Corcept [**].
SOPs and Financial Controls	The SOPs and Financial Controls Optime will implement in connection with the Services are listed in Exhibit 2 . Optime may [**], provided it [**]. Optime shall provide Corcept with full documentation for all SOPs and Financial Controls applicable to the Services.
Services Performed and Key Performance Metrics	Pharmacy and related patient and physician support and financial reporting services (the “Services”). Corcept and Optime understand and agree that the effectiveness of the Services can be measured by reference to the key performance metrics set forth in Exhibit 3 to this Task Order (the “ KPMs ”). Optime will use [**] to meet or exceed the KPMs. Corcept will provide Optime with such data as Optime reasonably requires to gauge its performance with respect to the KPMs and make improvements where appropriate. Corcept may [**], provided it [**].

Project Schedule and Termination Date	Start Date: On or about August 7, 2017. Termination Date: Five years, unless terminated earlier as set forth in the Agreement.
Services Fees	Unless the Parties agree otherwise, Corcept shall pay Optime Fees as set forth in Exhibit 4 to this Task Order and pursuant to the terms in the Agreement.
Product Complaint Contact	Optime: Corcept Team Pharmacist (attn. [**]) [**] Corcept: Director, Quality Assurance (attn. [**]); [**]
Adverse Event Contact	Optime: Corcept Team Pharmacist (attn. [**]) [**] Corcept: Ashfteld Pharmacovigilance [**]

In Witness Whereof, the Parties have caused this Task Order to be executed by their duly authorized representatives. The Parties acknowledge that the date of signature may not be the effective date of this Task Order.

CORCEPT THERAPEUTICS INCORPORATED

OPTIME CARE, INC.

By: /s/ Charles Robb

By: /s/ Donovan J. Quill

Name: Charles Robb

Name: Donovan J. Quill

Title: Chief Financial Officer

Title: President and CEO

Date: August 3, 2017

Date: August 3, 2017

Exhibit 1
Optime Team

Optime will dedicate a team whose sole responsibilities will be performing the Services set forth in the Agreement and Task Order One. The team will consist of personnel filling the following roles:

One Team Vice President. The Team Vice President will manage the day-to-day operations of the team and be responsible for all activities related to the Services. [**] will fill this role.

[**] **Care Coordinators.** Care Coordinators will be the primary points of contact for patients and prescribing physicians, with responsibilities including patient welcoming, all reimbursement activities, and coordination of medication delivery. The Care Coordinator team will consist of [**].

One Team Pharmacist. The Team Pharmacist will fulfill all pharmacy duties related to the Services, including, but not limited to, patient counseling, adverse event reporting, product distribution and clinical education. [**] will be the Team Pharmacist.

As provided in Section 6 of the Agreement and in Task Order One, [**]. The parties agree to amend and restate this Exhibit 1 promptly if there is a change to the Optime Team.

Exhibit 2
Financial Controls

[**]

Exhibit 2
Standing Operating Procedures

[**]

Exhibit 3
Key Performance Metrics

[**]

**Exhibit 4
Service Fees**

[**]

Certain identified information has been excluded from the exhibit because it is both (i) not material and (ii) the type of information that the registrant treats as private or confidential. Double asterisks denote omissions.

AMENDMENT TO DISTRIBUTION SERVICES AGREEMENT

This **Amendment to Distribution Services Agreement** (this “**Amendment**”), effective as of August 1, 2022 (the “**Amendment Effective Date**”), is made by and between **Corcept Therapeutics Incorporated**, having its principal place of business at 149 Commonwealth Drive, Menlo Park, CA 94025 (“**Corcept**”) and **Optime Care, Inc.**, having its principal place of business at 4060 Wedgeway Court, Earth City, MO 63045 (“**Optime**”). Capitalized terms used but not otherwise defined herein shall have the meanings ascribed thereto in the Agreement (as defined below).

WHEREAS, Corcept and Optime are parties to that certain Distribution Services Agreement dated as of August 4, 2017 (the “**Agreement**”);

WHEREAS, Corcept and Optime entered into that certain Task Order Number One dated August 4, 2017, pursuant to Section 2.1 of the Agreement (the “**First Task Order**”); and

WHEREAS, in accordance with Section 24 of the Agreement, each of Corcept and Optime desires to amend the Agreement, on the terms and subject to the conditions set forth herein.

NOW, THEREFORE, in consideration of the foregoing and the covenants and agreements set forth herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, and intending to be legally bound hereby, the Parties agree as follows:

1. **Modifications to the Agreement.**

1.1. **Term.** The Term of the Agreement and the First Task Order is hereby amended to extend to September 30, 2022 (the “**Termination Date**”). The Agreement and all related Task Orders will terminate without further notice or action by either party, at 11:59:59 p.m. CDT on the Termination Date.

1.2. **Task Order.** The Parties hereby agree to the terms and conditions of the Second Task Order, attached hereto as Exhibit A, pursuant to which Optime shall provide certain transition services to Corcept.

1.3. **Transition Period Base Fees.** The Parties hereby agree that during the period from August 1, 2022, through September 30, 2022, the following table regarding the Services Fees payable to Optime shall replace the “Base Fee Per Shipment” table applicable under the First Task Order:

Base Fee Per Shipment*

Shipment Type	Original Fee (Task Order One)	Fee – 8/1/2022 thru 9/30/2022
[**]	[**]	[**]
[**]	[**]	[**]
[**]	[**]	[**]
[**]	[**]	[**]

**Base fees are all-inclusive. (For example, shipping, reporting and other costs are not charged separately.)*

1.4. **Return of Product and Program Material Inventory.** Immediately following the expiration or termination of the Agreement, but no later than October 10, 2022, Optime shall return [**], as [**] directed and instructed by Corcept.

1.5. **Patient and Payor Transition Communications.** In connection with the termination or expiration of the Agreement, Optime will use [**] to execute all [**] communications with payors and patients in order to ensure transition of Korlym dispensing to patients and related coverage and reimbursement through a new pharmacy designated by Corcept without [**] interruption or delay.

1.6. **Extended Indemnification.** The Parties hereby agree that Article 15 of the Agreement regarding Indemnification shall survive termination or expiration of the Agreement and any Task Order for a period of [**] following such termination or expiration.

1.7. **Post-Termination Wind Down Services.** [**], Corcept shall compensate Optime at the rate of [**] for time and effort expended by Optime staff in order to address tasks not contemplated by this Amendment or the Second Task Order but necessary and appropriate to wind down all financial transactions and appropriate accounting for same between the period beginning as of October 1, 2022 and ending not later than March 31, 2023. Such compensation shall be due from Corcept within [**] days following Corcept's receipt of a monthly invoice from Optime detailing the services provided and time spent providing such services.

1.8. **Corcept Termination.** The Parties hereby agree that the effectiveness of the Services should continue to be measured by reference to the KPMs set forth in the First Task Order. In the event that the effectiveness of the Services falls substantially below Optime's average performance on such KPMs during the [**], Corcept shall have the right to terminate the Agreement and all related Task Orders upon [**] days' notice to Optime. In such event, Corcept shall have no obligation to pay the Bonus provided for in the Second Task Order.

2. **Limited Amendment.**

This Amendment is limited by its terms and does not and shall not serve to amend or waive any provision of the Agreement except as expressly provided for in this Amendment. All other terms, conditions, and obligations set forth in the Agreement, including those set forth in Section 18.3 of the Agreement, are hereby reaffirmed by the Parties.

3. **Counterparts.**

This Amendment may be executed in two (2) or more counterparts, each of which will be an original and all of which will constitute together the same document. Counterparts may be signed and delivered by facsimile, or electronically in PDF format, each of which will be binding when sent.

4. **Survival.** All provisions of this Amendment reasonably expected and necessary to survive termination or expiration of this Agreement in order to carry out the parties' intentions shall survive any such expiration or expiration, including sections 1.2, and 1.4 through 1.7.

5. **Choice of Law.** The validity and interpretation of this Amendment and the legal relations of the Parties under this Amendment shall be governed by the laws of the State of Delaware, without reference to conflict of laws principles requiring the application of a different governing law. The Parties shall attempt in good faith to resolve informally and promptly any dispute that arises under this Amendment. Jurisdiction for any legal action arising from this

Amendment shall exclusively reside in state or federal courts located in Delaware, and the parties hereby consent to the jurisdiction of such courts.

6. **Escrow.** The Parties agree to negotiate [**] the terms of an escrow arrangement in an amount of [**] by October 3, 2022, to be utilized for [**].

[Signature Page Follows]

IN WITNESS WHEREOF, the Parties hereto have duly executed this Amendment. The Parties acknowledge that the date of signature may not be the Amendment Effective Date.

CORCEPT THERAPEUTICS INCORPORATED

By: /s/ Sean Maduck

Name: Sean Maduck

Title: President, Corcept Endocrinology

Date: 8/1/2022

OPTIME CARE, INC.

By: /s/ Tiffany Burt

Name: Tiffany Burt

Title: President & COO

Date: 8/1/2022

EXHIBIT A

**Task Order Number Two
to Distribution Services Agreement Between
Corcept Therapeutics Incorporated and Optime Care, Inc.**

This Task Order Number Two (the “**Second Task Order**”) is effective as of August 1, 2022, and is entered into pursuant to, and as part of, that certain Distribution Services Agreement dated as of August 4, 2017 (the “**Agreement**”), between Corcept Therapeutics Incorporated (“**Corcept**”) and Optime Care, Inc. (“**Optime**”). This Second Task Order sets forth terms and conditions for the continued provision by Optime of the Services under the First Task Order dated August 4, 2017, and the provision of additional transition services to Corcept.

Product	As outlined in the First Task Order.
Territory	As outlined in the First Task Order.
Optime Representative	[**]
Corcept Representative	[**]
Optime Personnel	As outlined in the First Task Order.
SOPs and Financial Controls	As outlined in the First Task Order.
Services Performed and Key Performance Metrics	Optime will (i) continue to provide the Services as defined and outlined in the First Task Order in accordance with the KPMs and other requirements set forth in the First Task Order and (ii) provide the additional transition services in accordance with the Requirements set forth in <u>Exhibit 1</u> to this Second Task Order.
Project Schedule and Termination Date	Termination Date: September 30, 2022, at 11:59:59 p.m. CDT.
Service Fees	As outlined in the First Task Order and as further amended by this Second Task Order.
Product Complaint Contact Information	Optime: Lead Pharmacist [**] Corcept: VP, Quality Assurance [**]
Adverse Event Contact Information	Optime: Lead Pharmacist [**] Corcept: [**]
Bonus	Corcept will pay Optime a [**] bonus by October 15, 2022, if Optime has [**] met all of the Requirements set forth in Exhibit 1 in a timely manner.

EXHIBIT 1

[**]

Certain identified information has been excluded from the exhibit because it is both (i) not material and (ii) the type of information that the registrant treats as private or confidential. Double asterisks denote omissions.

AMENDMENT NO. 2 TO DISTRIBUTION SERVICES AGREEMENT

This **Amendment No. 2 to Distribution Services Agreement** (this “**Amendment**”), effective as of September 16, 2022 (the “**Amendment Effective Date**”), is made by and between **Corcept Therapeutics Incorporated**, having its principal place of business at 149 Commonwealth Drive, Menlo Park, CA 94025 (“**Corcept**”) and **Optime Care, Inc.**, having its principal place of business at 4060 Wedgeway Court, Earth City, MO 63045 (“**Optime**”). Capitalized terms used but not otherwise defined herein shall have the meanings ascribed thereto in the Agreement (as defined below).

WHEREAS, Corcept and Optime are parties to that certain Distribution Services Agreement dated as of August 4, 2017 (the “**Agreement**”);

WHEREAS, Corcept and Optime entered into that certain Task Order Number One dated August 4, 2017, pursuant to Section 2.1 of the Agreement (the “**First Task Order**”);

WHEREAS, Corcept and Optime entered into that certain Amendment to Distribution Services Agreement dated as of August 1, 2022 (“**Amendment No. 1**”), which attached Task Order No. 2 to the Agreement (“**Second Task Order**”); and

WHEREAS, in accordance with Section 24 of the Agreement, each of Corcept and Optime desires to amend the Agreement, on the terms and subject to the conditions set forth herein.

NOW, THEREFORE, in consideration of the foregoing and the covenants and agreements set forth herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, and intending to be legally bound hereby, the Parties agree as follows:

1. **Modifications to the Agreement.**

1.1. **Term.** The Term of the Agreement and the First Task Order is hereby amended to extend to March 31, 2024 (the “**Termination Date**”). The Agreement and all related Task Orders will terminate without further notice or action by either party, at 11:59:59 p.m. CDT on the Termination Date.

1.2. **Amendment No. 1 and Second Task Order Termination.** The Parties hereby agree that effective as of October 1, 2022, all terms and conditions of Amendment No. 1 and the Second Task Order are hereby terminated and of no further force or effect, including but not limited to Sections 1.6, 1.7 and 6 of Amendment No.1 and any and all obligations of Corcept to make any Bonus payments pursuant to the Second Task Order.

1.3. **Base Fees.** The Parties hereby agree that during the period from October 1, 2022, through the Termination Date, the following table regarding the Services Fees payable to Optime shall replace the “Base Fee Per Shipment” table applicable under the First Task Order, reflecting a [**] increase to these Base fees beginning January 1, 2023:

Base Fee Per Shipment*

Shipment Type	Fee – Applicable 10/1/2022 thru 12/31/2022	Fee – Applicable 1/1/2023 thru 3/31/2024
[**]	[**]	[**]
[**]	[**]	[**]
[**]	[**]	[**]
[**]	[**]	[**]

*Base fees are all-inclusive. (For example, shipping, reporting and other costs are not charged separately.)

2. Limited Amendment.

This Amendment is limited by its terms and does not and shall not serve to amend or waive any provision of the Agreement except as expressly provided for in this Amendment. All other terms, conditions, and obligations set forth in the Agreement, including those set forth in Section 18.3 of the Agreement, are hereby reaffirmed by the Parties.

3. Counterparts.

This Amendment may be executed in two (2) or more counterparts, each of which will be an original and all of which will constitute together the same document. Counterparts may be signed and delivered by facsimile, or electronically in PDF format, each of which will be binding when sent.

4. Survival. All provisions of this Amendment reasonably expected and necessary to survive termination or expiration of this Agreement in order to carry out the parties’ intentions shall survive any such termination or expiration, including Section 1.2.

5. Choice of Law. The validity and interpretation of this Amendment and the legal relations of the Parties under this Amendment shall be governed by the laws of the State of Delaware, without reference to conflict of laws principles requiring the application of a different governing law. The Parties shall attempt in good faith to resolve informally and promptly any dispute that arises under this Amendment. Jurisdiction for any legal action arising from this Amendment shall exclusively reside in state or federal courts located in Delaware, and the parties hereby consent to the jurisdiction of such courts.

[Signature Page Follows]

IN WITNESS WHEREOF, the Parties hereto have duly executed this Amendment. The Parties acknowledge that the date of signature may not be the Amendment Effective Date.

Corcept Therapeutics Incorporated Optime Care, Inc.

CORCEPT THERAPEUTICS INCORPORATED

By: /s/ Sean Maduck

Name: Sean Maduck

Title: President, Corcept Endocrinology

Date: September 16, 2022

OPTIME CARE, INC.

By: /s/ Dea Belazi

Name: Dea Belazi

Title: Chief Executive Officer

Date: 9/16/2022

CERTIFICATION

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

1. I have reviewed this Quarterly Report on Form 10-Q for the period ended September 30, 2022 of Corcept Therapeutics Incorporated;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Joseph K. Belanoff

Joseph K. Belanoff, M.D.
Chief Executive Officer and President
November 3, 2022

CERTIFICATION

I, Atabak Mokari, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the period ended September 30, 2022 of Corcept Therapeutics Incorporated;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Atabak Mokari

Atabak Mokari
Chief Financial Officer
November 3, 2022

Corcept Therapeutics Incorporated

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

In connection with the Quarterly Report of Corcept Therapeutics Incorporated (the "Company") on Form 10-Q for the period ended September 30, 2022, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Joseph K. Belanoff, M.D., Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

/s/ Joseph K. Belanoff

Joseph K. Belanoff, M.D.
Chief Executive Officer and President
November 3, 2022

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

Corcept Therapeutics Incorporated

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

In connection with the Quarterly Report of Corcept Therapeutics Incorporated (the "Company") on Form 10-Q for the period ended September 30, 2022, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Atabak Mokari, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

/s/ Atabak Mokari

Atabak Mokari
Chief Financial Officer
November 3, 2022

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.