CORCEPT THERAPEUTICS INC
Form 10-Q
August 09, 2018

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended June 30, 2018

or

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from to

Commission File Number:

000-50679

CORCEPT THERAPEUTICS INCORPORATED

(Exact Name of Corporation as Specified in Its Charter)

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

149 Commonwealth Drive

Menlo Park, CA 94025

(Address of principal executive offices, including zip code)

(650) 327-3270

(Registrant's telephone number, including area code)

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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post such files). Yes No

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

| | | |
|---|---|---|
| Large accelerated filer | | Accelerated filer |
| Non-accelerated filer | (Do not check if a small reporting company) | Smaller reporting company |
| Emerging growth company | | |

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

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

On August 3, 2018, there were 116,051,242 shares of common stock outstanding at a par value of $0.001 per share.

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PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS
CORCEPT THERAPEUTICS INCORPORATED

CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands, except per share data)

| | June 30, 2018 (Unaudited) | December 31, 2017 (See Note 1) |
|---|---|---|
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents | $ 31,165 | $ 31,062 |
| Short-term marketable securities | 128,780 | 57,682 |
| Trade receivables, net of allowances | 28,704 | 15,300 |
| Other receivable | — | 12,896 |
| Inventory | 4,947 | 4,576 |
| Prepaid expenses and other current assets | 3,579 | 2,669 |
| Total current assets | 197,175 | 124,185 |
| Strategic inventory | 5,500 | 3,800 |
| Property and equipment, net of accumulated depreciation | 552 | 518 |
| Long-term marketable securities | — | 15,281 |
| Other assets | 53 | 50 |
| Deferred tax assets, net | 71,102 | 76,703 |
| Total assets | $ 274,382 | $ 220,537 |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Current liabilities: | | |
| Accounts payable | $ 6,365 | $ 8,579 |
| Accrued clinical expenses | 5,397 | 2,247 |
| Other accrued liabilities | 19,111 | 18,743 |
| Total current liabilities | 30,873 | 29,569 |
| Commitments and contingencies (Note 5) | | |
| Stockholders’ equity: | | |
| Preferred stock | — | — |
| Common stock | 116 | 115 |
| Additional paid-in capital | 401,011 | 384,074 |
| Accumulated other comprehensive loss | (127) | (75) |
| Accumulated deficit | (157,491) | (193,146) |
| Total stockholders’ equity | 243,509 | 190,968 |
| Total liabilities and stockholders’ equity | $ 274,382 | $ 220,537 |

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

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CORCEPT THERAPEUTICS INCORPORATED

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME

(Unaudited)

(In thousands, except per share data)

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2018 | 2017 | 2018 | 2017 |
| Product revenue, net | $62,312 | $35,559 | $119,971 | $63,158 |
| Operating expenses: | | | | |
| Cost of sales | 1,154 | 775 | 2,328 | 1,421 |
| Research and development | 20,543 | 7,876 | 37,593 | 15,052 |
| Selling, general and administrative | 19,981 | 14,113 | 38,421 | 29,150 |
| Total operating expenses | 41,678 | 22,764 | 78,342 | 45,623 |
| Income from operations | 20,634 | 12,795 | 41,629 | 17,535 |
| Interest and other income (expense) | 562 | (98) | 856 | (323) |
| Income before income taxes | 21,196 | 12,697 | 42,485 | 17,212 |
| Income tax expense | (3,000) | (50) | (6,830) | (177) |
| Net income | $18,196 | $12,647 | $35,655 | $17,035 |
| Other comprehensive loss: | | | | |
| Net unrealized income (loss) on available-for-sale investments, net of tax impact of $(7), $0, $41 and $0, respectively | 25 | (5) | (127) | (17) |
| Total comprehensive income | $18,221 | $12,642 | $35,528 | $17,018 |
| | | | | |
| Basic net income per share | $0.16 | $0.11 | $0.31 | $0.15 |
| | | | | |
| Diluted net income per share | $0.14 | $0.10 | $0.28 | $0.14 |
| | | | | |
| Weighted-average shares outstanding used in computing net income per share | | | | |
| Basic | 115,492 | 113,249 | 115,189 | 113,059 |
| Diluted | 127,515 | 123,011 | 127,610 | 122,171 |

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

CORCEPT THERAPEUTICS INCORPORATED

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

(In thousands)

| | Six Months Ended June 30, | |
|---|---|---|
| | 2018 | 2017 |
| Cash flows from operating activities: | | |
| Net income | $ 35,655 | $ 17,035 |
| Adjustments to reconcile net income to net cash generated from operations: | | |
| Stock-based compensation | 10,971 | 5,906 |
| Deferred income taxes | 5,642 | — |
| Accretion of interest (income) expense | (546) | 419 |
| Amortization of debt financing costs | — | 11 |
| Depreciation and amortization of property and equipment | 105 | 22 |
| Changes in operating assets and liabilities: | | |
| Trade receivables | (13,404) | 356 |
| Other receivable | 12,896 | — |
| Inventory | (2,071) | (1,135) |
| Prepaid expenses and other current assets | (910) | (563) |
| Other assets | (3) | (25) |
| Accounts payable | (2,214) | (216) |
| Accrued clinical expenses | 3,150 | 44 |
| Other accrued liabilities | 370 | 3,273 |
| Net cash provided by operating activities | 49,641 | 25,127 |
| Cash flows from investing activities: | | |
| | (140) | (308) |

| | | |
|---|---|---|
| Purchases of property and equipment | | |
| Proceeds from maturities of marketable securities | 40,300 | 1,800 |
| Purchases of marketable securities | (95,664) | (35,853) |
| Cash used in investing activities | (55,504) | (34,361) |
| Cash flows from financing activities: | | |
| Proceeds from issuance of common stock upon exercise of options, net of issuance costs | 5,966 | 1,842 |
| Payments related to debt obligation | — | (10,521) |
| Net cash provided by (used in) financing activities | 5,966 | (8,679) |
| Net increase (decrease) in cash and cash equivalents | 103 | (17,913) |
| Cash and cash equivalents, at beginning of period | 31,062 | 51,536 |
| Cash and cash equivalents, at end of period | $ 31,165 | $ 33,623 |

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 was incorporated in the State of Delaware in May 1998, and our headquarters are located in Menlo Park, California. We are a pharmaceutical company engaged in the discovery, development and commercialization of medications that treat severe metabolic, oncologic and psychiatric disorders by modulating the effect of the stress hormone cortisol. In 2012, the United States Food and Drug Administration ("FDA") approved our first product, Korlym® ("mifepristone") 300 mg tablets, as a once-daily oral medication for treatment of hyperglycemia secondary to hypercortisolism in adult patients with endogenous Cushing's syndrome who have type 2 diabetes mellitus or glucose intolerance and have failed surgery or are not candidates for surgery. We have discovered and patented three structurally distinct series of selective cortisol modulators, consisting of more than 500 compounds, and are developing compounds from these series to treat a broad range of disorders.

Basis of Presentation

We have prepared the June 30, 2018 balance sheet and statements of comprehensive income and cash flows for the three and six months ended June 30, 2018 and 2017 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. They do not include all of the information and footnotes required by GAAP for complete financial statements. In the opinion of management, all adjustments (consisting only of normal recurring adjustments) considered necessary for a fair presentation have been included. Operating results for the three and six months ended June 30, 2018 are not necessarily indicative of the results to expect for the remainder of 2018 or any other period. These financial statements and notes should be read in conjunction with the financial statements for the year ended December 31, 2017 included in our Annual Report on Form 10-K. The December 31, 2017 balance sheet was derived from audited financial statements at that date.

Principles of Consolidation

Our financial statements include the financial position and results of operations of Corcept Therapeutics UK Limited, our wholly owned subsidiary, which we incorporated in the United Kingdom in March 2017. This entity has entered into no material financial transactions and has no assets or liabilities.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ materially from those estimates.

We reevaluate our estimates and assumptions each quarter, including those related to revenue recognition, recognition and measurement of income tax assets and liabilities, inventory, allowances for doubtful accounts and other accrued liabilities, including our bonus accrual, clinical trial accruals and stock-based compensation.

Fair Value Measurements

We value financial instruments using assumptions we believe third-party market participants would use. When choosing which assumptions to rely upon when determining the value of a financial instrument, we look first for quoted prices in active markets for identical instruments ("Level 1 inputs"). If no Level 1 inputs are available, we consider (i) quoted prices in non-active markets for identical instruments; (ii) active markets for similar instruments; (iii) inputs other than quoted prices for the instrument; and (iv) inputs that are not directly observable, but that are corroborated by observable data ("Level 2 inputs"). In the absence of Level 2 inputs, we rely on unobservable inputs, such as our estimates of the assumptions market participants would use in pricing the instrument ("Level 3 inputs").

Cash and Cash Equivalents and Marketable Securities

We consider highly liquid investments purchased with original maturities of three months or less from the date of purchase to be cash equivalents. Cash equivalents are valued using Level 1 inputs, which approximate our cost.

We invest a portion of our funds in marketable securities, primarily U.S. Treasury securities, commercial paper, corporate notes, asset-backed securities and repurchase agreements. We classify our marketable securities as available-for-sale securities and report them at fair value as "cash equivalents" or "marketable securities" on our balance sheet, with related unrealized gains and losses included in stockholders' equity. Realized gains and losses and permanent declines in value are included in "interest and other income (expense)" on our statement of comprehensive income.

CORCEPT THERAPEUTICS INCORPORATED

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS, continued

Concentration of Credit Risk

We are subject to credit risk from our cash equivalents and marketable securities. We limit our investments to U.S. Treasury obligations and high-grade corporate debt, asset-backed securities and repurchase agreements with less than a 36-month maturity at the time of purchase. These investments are diversified and do not expose us to concentrations of credit risk.

Inventory and Cost of Sales

Regulatory approval of product candidates is uncertain. Because product manufactured prior to regulatory approval may not be sold unless regulatory approval is obtained, we record the cost of manufacturing our product candidates as research and development expenses at the time such costs are incurred. We capitalize to inventory manufacturing costs related to Korlym.

We value inventory at the lower of cost or net realizable value and determine the cost of inventory we sell using the specific identification method, which approximates a first-in, first-out basis. We write down inventory that has become obsolete or has a cost basis in excess of its expected net realizable value. Any expired inventory is destroyed and the related costs are recognized as cost of sales in the statement of comprehensive income in that period.

Cost of sales includes the cost of manufacturing Korlym, including materials, third-party manufacturing costs and indirect personnel and other overhead costs, based on the number of Korlym tablets for which we recognize revenue, as well as costs of stability testing, logistics and distribution.

We classify inventory we do not expect to consume within 12 months of the balance sheet date as strategic inventory, a noncurrent asset.

Debt Obligation

Under our Financing Agreement with Biopharma, we made payments each quarter equal to 20 percent of our Korlym sales in the quarter. Accounting for the Financing Agreement required us to estimate the amount of each future quarterly payment and the accretion of interest expense. We extinguished our obligations under the Financing Agreement in July 2017. No further payments are due.

Revenue

We sell Korlym directly to patients through a single specialty pharmacy. We also sell Korlym to a specialty distributor (“SD”), for which we recognize revenue at the time the SD receives Korlym. SD sales were less than one percent of our net revenue in each of the three and six months ended June 30, 2018.

To determine our revenue from the sale of Korlym, we (i) identify our contract with each customer; (ii) identify the obligations of Corcept and the customer under the contract; (iii) determine the contracted transaction price; (iv) allocate the transaction price to the contract’s performance obligations, which in our case consists of delivering Korlym to the customer; and (v) recognize revenue once Korlym has been delivered, provided we deem it probable that we will collect the payment due to us.

Confirmation of coverage by private or government insurance or by a third-party charity is a prerequisite for selling Korlym to a patient. We donate cash to charities that help patients with financial need pay for the treatment of Cushing's syndrome. We do not include payments from these charities in revenue. We provide Korlym at no cost to patients without insurance who do not qualify for charitable support.

To determine net product revenue, we deduct from sales the cost of our patient co-pay assistance program and our estimates of (a) government chargebacks and rebates, (b) discounts provided to our SD for prompt payment and (c) reserves for expected Korlym returns. We record these estimates at the time we recognize revenue and update them as new information becomes available. Our estimates take into account our understanding, based on our experience, of the range of possible outcomes. If results differ from our estimates, we adjust our estimates, causing a change to our net product revenue and earnings. We report any such changes in the period they become known, even if they concern transactions occurring in prior periods.

Government Rebates: Korlym is eligible for purchase by, or qualifies for reimbursement from, Medicaid and other government programs that are eligible for rebates on the price they pay for Korlym. To determine the appropriate amount to reserve against these rebates, we identify Korlym sold to patients covered by government-funded programs, apply the applicable government discount to these sales, then estimate, based on our experience, the portion of total rebates we expect will be claimed. We then (i) deduct this reserve from revenue in the period to which the rebates relate and (ii) include in accrued expenses on our consolidated balance sheet a current liability of equal amount.

CORCEPT THERAPEUTICS INCORPORATED

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS, continued

Chargebacks. Although we sell Korlym to the SD at full price, some of the government entities to which the SD sells receive a discount. The SD recovers such discounts by reducing its payment to us (this reduction is called a "chargeback"). Chargebacks sometimes relate to Korlym sold to SD in prior periods. We deduct from our revenue in each period chargebacks claimed by the SD for Korlym we sold to the SD that period. We also create a reserve for chargebacks we estimate the SD will claim in future periods against Korlym it purchased in the current period but has not yet resold. We determine the amount of this reserve based on our experience with SD chargebacks and our understanding of the SD's customer base and business practices. We then (i) deduct this reserve from revenue and (ii) include in accrued expenses on our consolidated balance sheet a current liability of equal amount.

Patient Assistance Program: It is our policy that no patient be denied Korlym due to inability to pay. We provide financial assistance to eligible patients whose insurance policies have high deductibles or co-payments and deduct the amount of such assistance from gross revenue. We determine the assistance we provide each patient by applying our program guidelines to that patient's financial position and their insurance policy's co-payment and deductible requirements for the purchase of Korlym.

Sales Returns: Federal law prohibits the return of Korlym sold to patients. Sales to our SD are subject to return. We deduct the amount of Korlym we estimate the SD will return from each period's gross revenue. We base our estimates on quantitative and qualitative information including, but not limited to, historical return rates, the amount of Korlym held by the SD and projected demand. If we cannot reasonably estimate returns with respect to a particular sale, we defer recognition of revenue until we can make a reasonable estimate. To date, returns have been insignificant.

The following table summarizes activity in each of the product revenue allowance and reserve categories for the six months ended June 30, 2018.

| | Chargebacks | Government Rebates | Total |
|---|---|---|---|
| | (in thousands) | | |
| Balance at December 31, 2017: | $927 | $ 7,961 | $8,888 |
| Provision related to current period sales | 1,421 | 14,280 | 15,701 |
| Provision related to prior period sales | — | 181 | 181 |
| Credit or payments made during the period | (1,691) | (10,987) | (12,678) |
| Balance at June 30, 2018: | $657 | $ 11,435 | $12,092 |

Research and Development

Research and development expenses include the direct cost of discovery research, pre-clinical studies, clinical trials, manufacturing development, submissions to regulatory agencies and related overhead costs. We expense nonrefundable payments and the cost of technologies and materials used in research and development as we incur them.

We base our accruals for research, preclinical activities and clinical trials on our estimates of work completed, milestones achieved, patient enrollment and past experience with similar contracts. Our estimates include assessments of information from third-party contract research organizations and the status of our own clinical trials and other development and administrative activities.

Segment Reporting

We determine our operating segments based on the way we organize our business, make decisions and assess performance. We have only one operating segment, which is the discovery, development and commercialization of pharmaceutical products.

Stock-Based Compensation

We account for stock-based compensation under the fair value method, based on the value of the award at the grant date. To date, our stock-based compensation has consisted entirely of option grants, which we value using the Black-Scholes model. We recognize stock-based compensation expense over the requisite vesting period, net of estimated forfeitures. If actual forfeitures differ from our estimates, we adjust stock-based compensation expense accordingly.

We recognize the expense of options granted to non-employees based on their fair value at the time of vesting.

CORCEPT THERAPEUTICS INCORPORATED

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS, continued

Recently Adopted Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2014-09, "Revenue from Contracts with Customers," which changes the way companies recognize revenue. This ASU supersedes the revenue recognition requirements in ASC Topic 605, Revenue Recognition and creates a new Topic 606, "Revenue from Contracts with Customers." Topic 606 applies to all contracts with customers.

We conducted our analysis using the "portfolio of contracts" approach, which permits us to analyze as a group all contracts with similar characteristics. We have two customer groups: patients covered by insurance and the SD. We evaluated the contracts with customers governing our sales and reviewed the related disclosures, policies and controls, which we updated as necessary. Because some of our customer contracts are subject to rebates, chargebacks, discounts, co-pay assistance or other deductions (known as "variable consideration") that affect the price of each transaction, we focused our analysis on the new standard's impact on transaction prices. We estimated the amount of variable consideration using either the most likely amount or expected value method, as applicable.

Topic 606 requires us to estimate the net price of each Korlym sale, including any variable consideration, and recognize the estimated amount as revenue at the time we deliver Korlym to the customer. On January 1, 2018, we adopted Topic 606 using the modified retrospective approach. Adoption of this standard had no impact on our financial statements.

In January 2016, the FASB issued Accounting Standards Update No. 2016-01 "Financial Instruments: Recognition and Measurement of Financial Assets and Financial Liabilities." This update changes accounting for equity investments, financial liabilities under the fair value option, and the presentation and disclosure requirements for financial instruments. In addition, it clarifies guidance regarding recognition of deferred tax assets that result from unrealized losses on available-for-sale debt securities. We adopted this standard on January 1, 2018. It had no impact on our financial statements.

In August 2016, the FASB issued ASU No. 2016-15, "Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments," which is intended to reduce the existing diversity in practice in how certain cash receipts and cash payments are classified in the statement of cash flows. In November 2016, the FASB issued ASU 2016-18, Statement of Cash Flows, Restricted Cash (Topic 230) (ASU 2016-18), which requires the inclusion of restricted cash with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. ASU 2016-15 and ASU 2016-18 are both effective for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years, provided that all of the amendments are adopted in the same period. We adopted this standard on January 1, 2018. It had no impact on our financial statements.

In May 2017, the FASB issued ASU No. 2017-09, Stock Compensation (Topic 718): "Scope of Modification Accounting," which changes the accounting for modifications to the terms and conditions of share-based payment awards. We adopted this standard on January 1, 2018. It did not have a material impact on our financial statements.

Recently Issued Accounting Pronouncements Not Yet Adopted

In February 2016, the FASB issued ASU No. 2016-02, "Leases", which requires lease transactions with terms longer than 12 months to be recognized on the balance sheet as "lease liabilities" and "right-of-use assets." We plan to adopt this

new standard using the modified retrospective approach on January 1, 2019. While we are continuing to assess the potential impact of the standard, we believe the most significant impact will relate to our accounting for lease agreements for our leased office spaces. We expect that adoption will increase our “lease liabilities” and “right-of-use assets” equally.

In June 2016, the FASB issued ASU No. 2016-13, “Financial Instruments—Credit Losses (Topic 326), Measurement of Credit Losses on Financial Instruments,” which changes the methodology for measuring credit losses on financial instruments and when such losses are recorded. This standard is effective for fiscal years, and interim periods within those years, beginning after December 15, 2019. Early adoption is permitted beginning after December 15, 2018. We plan to adopt this standard on January 1, 2020 and are currently evaluating the impact of this new standard on our consolidated financial statements.

CORCEPT THERAPEUTICS INCORPORATED

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS, continued

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

In June 2018, the FASB issued ASU No. 2018-07, "Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting," which expands the scope of ASC 718 to include all share-based payment arrangements related to the acquisition of goods and services from nonemployees. This standard is effective for fiscal years and interim periods within those years, beginning after December 15, 2018. We plan to adopt this new standard on January 1, 2019. Although we have not concluded our evaluation, we do not expect its adoption to have a material impact on our consolidated financial statements.

2. Composition of Certain Balance Sheet Items

Inventory

The composition of inventory was as follows:

| | June 30, 2018 | December 31, 2017 |
|---|---|---|
| | (in thousands) | |
| Raw materials | $4,402 | $ 4,287 |
| Work in progress | 132 | 64 |
| Finished goods | 5,913 | 4,025 |
| Total inventory | 10,447 | 8,376 |
| Less strategic inventory classified as non-current | (5,500 ) | (3,800 ) |
| Total inventory classified as current | $4,947 | $ 4,576 |

In order to be prepared for potential demand for Korlym and because we rely on single-source manufacturers of both the active pharmaceutical ingredient ("API") for Korlym and Korlym tablets, we have purchased significant inventory quantities of these materials. We classify inventory we do not expect to sell within 12 months of the balance sheet date as "Strategic Inventory," a long-term asset.

Other Accrued Liabilities

Other accrued liabilities consisted of the following:

| | June 30, 2018 | December 31, 2017 |
|---|---|---|
| | (in thousands) | |
| Government rebates | $11,435 | $ 7,961 |
| Accrued compensation | 5,270 | 8,574 |
| Income taxes payable | 687 | 66 |
| Legal fees | 387 | 276 |
| Professional fees | 390 | 207 |
| Accrued selling and marketing costs | 301 | 208 |
| Accrued manufacturing costs | 69 | 955 |
| Other | 572 | 496 |
| Total other accrued liabilities | $19,111 | $ 18,743 |

CORCEPT THERAPEUTICS INCORPORATED

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS, continued

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

Our available-for-sale securities included:

| | Fair Value Hierarchy Level | Estimated Fair Value | |
|---|---|---|---|
| | | June 30, 2018 | December 31, 2017 |
| | | (in thousands) | |
| Corporate bonds | Level 2 | $37,309 | $ 26,116 |
| Commercial paper | Level 2 | 66,811 | 32,637 |
| Asset-backed securities | Level 2 | 11,320 | — |
| Repurchase agreements | Level 2 | 10,000 | — |
| U.S. treasury securities | Level 1 | 24,809 | 14,210 |
| Money market funds | Level 1 | 1,097 | 14,979 |
| Total Marketable securities | | $151,346 | $ 87,942 |
| | | | |
| Classified as: | | | |
| Cash equivalents | | $22,566 | $ 14,979 |
| Short-term marketable securities | | 128,780 | 57,682 |
| Long-term marketable securities | | — | 15,281 |
| Total marketable securities | | $151,346 | $ 87,942 |

The estimated fair value of marketable securities is based on quoted market prices for these or similar investments obtained from a commercial pricing service. The fair value of marketable securities classified within Level 2 is based upon inputs that may include benchmark yields, reported trades, broker/dealer quotes and issuer spreads. Our accumulated other comprehensive loss on our balance sheets consisted of net unrealized losses on available-for-sale investments of $0.1 million at June 30, 2018 and December 31, 2017, net of tax impact of $41,000 and $0, respectively.

As of June 30, 2018, all our marketable securities had original maturities of less than two years. The weighted-average maturity of our holdings was four months. None of our marketable securities changed from one fair value hierarchy to another during the three and six months ended June 30, 2018.

4. Debt Obligation

As discussed in Note 1, Basis of Presentation and Summary of Significant Accounting Policies, Debt Obligation, under the Financing Agreement with Biopharma we made quarterly payments to Biopharma equal to 20 percent of Korlym sales in that quarter. To secure our obligation, we granted Biopharma a security interest in our patents, trademarks, trade names, domain names, copyrights, know-how, books, records and regulatory approvals related to Korlym and certain other assets and any proceeds from them. Biopharma's right to receive payments expired once our payments reached a total of $45.0 million, which occurred in July 2017. Our obligations under the Financing Agreement are now fully extinguished.

We recorded no interest expense for the three and six months ended June 30, 2018, compared to $0.1 million and $0.4 million for the three and six months ended June 30, 2017, respectively. Total accreted interest for the full term of the Financing Agreement was $15.0 million.

We capitalized $0.1 million of issuance costs related to the Financing Agreement, which we amortized over the term of the obligation. At June 30, 2018 and December 31, 2017, there were no unamortized issuance costs.

5. Commitments and Contingencies

Leases

In February 2016, we extended the lease for our office space through 2019 and added more space. Effective May 1, 2016, we terminated our lease early and replaced it with a new one effective through March 31, 2019. On March 12, 2018, we amended that lease to add more space. Rent expense for each of the three months ended June 30, 2018 and 2017 was $0.3 million. Rent expense for the six months ended June 30, 2018 and 2017 was $0.6 million and $0.5 million, respectively.

CORCEPT THERAPEUTICS INCORPORATED

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS, continued

As of June 30, 2018, future minimum lease payments under non-cancelable operating leases were as follows:

| | Lease Payments |
|---|---|
| 2018 (remainder) | $ 691 |
| 2019 | 342 |
| Thereafter | — |
| Total | $ 1,033 |

Contingencies

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, assuming various litigation, regulatory and settlement strategies. If we determine a loss is probable and its amount can be reasonably estimated, we accrue an amount equal to the estimated loss.

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

6. Stock Option Plans

We have two stock option plans – the 2004 Equity Incentive Plan (the "2004 Plan") and the 2012 Incentive Award Plan (the "2012 Plan"). On February 7, 2018, our Board of Directors authorized a 4.6 million increase in the shares available for grant under the 2012 Plan pursuant to the annual increase provisions of the 2012 Plan.

During the six months ended June 30, 2018, we issued 1,300,000 shares of our common stock upon the exercise of stock options.

The following table summarizes our stock-based compensation:

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2018 | 2017 | 2018 | 2017 |
| | (in thousands) | | (in thousands) | |

| | | | | |
|---|---|---|---|---|
| Research and development | $1,963 | $850 | $3,427 | $1,503 |
| Selling, general and administrative | 4,054 | 2,355 | 7,544 | 4,403 |
| Total stock-based compensation | $6,017 | $3,205 | $10,971 | $5,906 |

7. Net Income Per Share

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

CORCEPT THERAPEUTICS INCORPORATED

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS, continued

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

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2018 | 2017 | 2018 | 2017 |
| | (in thousands) | | (in thousands) | |
| Numerator: | | | | |
| Net income | $18,196 | $12,647 | $35,655 | $17,035 |
| Denominator: | | | | |
| Weighted-average shares used to compute basic net income per share | 115,492 | 113,249 | 115,189 | 113,059 |
| Dilutive effect of employee stock options | 12,023 | 9,762 | 12,421 | 9,112 |
| Weighted-average shares used to compute diluted net income per share | 127,515 | 123,011 | 127,610 | 122,171 |
| Net income per share attributable to common stockholders | | | | |
| Basic | $0.16 | $0.11 | $0.31 | $0.15 |
| Diluted | $0.14 | $0.10 | $0.28 | $0.14 |

On a weighted-average basis, 5.0 million and 3.9 million stock options outstanding during the three and six months ended June 30, 2018, respectively, compared to 4.1 million and 4.2 million stock options outstanding during the three and six months ended June 30, 2017 were excluded from the computation of diluted net income per share because including them would have reduced dilution.

The following table presents information on securities outstanding as of the end of each period that could potentially dilute the per share data:

| | June 30, | |
|---|---|---|
| | 2018 | 2017 |
| | (in thousands) | |
| Stock options outstanding | 22,983 | 21,306 |

8. Income taxes

We recorded an income tax expense of $3.0 million and $6.8 million for the three and six months ended June 30, 2018, respectively, compared to $0.1 million and $0.2 million for the three and six months ended June 30, 2017.

Income tax expense for the three and six months ended June 30, 2018, was primarily attributed to the reduction of deferred tax assets of $2.5 million and $5.6 million, respectively, caused by our utilization of federal and state net operating losses and income tax expense of $0.5 million and $1.2 million, respectively, incurred in states where we have no net operating loss carryforwards to offset our tax obligations. Income tax expense for the three and six months ended June 30, 2017, reflects the income tax expense incurred in states where we have no net operating loss carryforwards to offset our tax obligations. We continue to maintain a valuation allowance for our California deferred tax assets.

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

Each quarter, we assess our ability to use our deferred tax assets to offset our expected federal and state taxable income. In the fourth quarter of 2017, we determined that it was more likely than not that we would generate sufficient taxable income to utilize our federal and state deferred tax assets in every state except California. We therefore included in our balance sheet the net value of all our deferred tax assets except those applicable to California. All tax years from Corcept's inception remain open to examination by the Internal Revenue Service, the California Franchise Tax Board and other state taxing authorities.

The Tax Cuts and Jobs Act of 2017 ("Tax Act"), which became law on December 22, 2017, significantly changed the federal income tax law. Among other things, effective January 1, 2018, the new law reduced the corporate income tax rate from 35 percent to 21 percent, repealed the corporate alternative minimum tax, limited some business deductions, modified the maximum deduction of future net operating losses generated with no carryback but an indefinite carryforward provision and extended the compensation deduction limit applicable to certain highly-compensated executives of publicly traded companies to cover additional executive roles.

CORCEPT THERAPEUTICS INCORPORATED

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS, continued

Accounting Standards Codification (ASC) 740, Income Taxes, requires companies to recognize the effect of tax law changes, such as those enacted by the Tax Act, in the period such changes take effect. We have adjusted our deferred taxes based on the reduction of the U.S. federal corporate tax rate from 35 percent to 21 percent and assessed the realizability of our deferred tax assets based on our current understanding of the new law. As permitted by SEC Staff Accounting Bulletin 118, at December 31, 2017 our accounting for the impacts of the Tax Act was provisional. At June 30, 2018, there have been no changes in our accounting for provisional amounts. We will continue to assess the Tax Act's impact for the rest of 2018, including its interpretation by regulatory authorities and the courts, and will adjust our disclosures and financial presentation as necessary.

9. Subsequent Events

On August 9, 2018, we announced that our Board of Directors approved a program to repurchase up to $100 million of the Company's common stock (the "Stock Repurchase Program"). Unless it is terminated or suspended prior to its expiration, the Stock Repurchase Program will remain in effect until June 30, 2019. The timing and amount of any repurchases pursuant to it will be determined based on market conditions, stock price and other factors. The Stock Repurchase Program does not require us to acquire any specific number of shares and it may be modified, suspended or discontinued at any time without notice. Repurchases pursuant to the Stock Repurchase Program may be made through a variety of methods, including open market purchases, privately negotiated transactions, block trades, accelerated share repurchase transactions or any combination of such methods.

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

Forward-Looking Statements

This Management's Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with the financial statements and accompanying notes in this report. Statements in this section are "forward-looking" within the meaning of the federal securities laws. Forward-looking statements are subject to known and unknown risks and uncertainties that might cause actual results to differ materially from those the statements express or imply. For a discussion of these risks and uncertainties, see "Forward-Looking Statements" included in "Risk Factors" in Part II, Item 1A of this Form 10-Q and the "Overview" and "Liquidity and Capital Resources" sections of this Management's Discussion and Analysis of Financial Condition and Results of Operations.

Overview

We are engaged in the discovery, development and commercialization of drugs that treat severe metabolic, oncologic and psychiatric disorders by modulating the effects of the hormone cortisol. Elevated levels and abnormal release patterns of cortisol are implicated in a broad range of diseases. Our first approved product, Korlym®, treats patients with Cushing's syndrome, a rare disease that is caused by excess cortisol activity. The active ingredient in Korlym is mifepristone, a compound that modulates cortisol activity by acting as a competitive antagonist at the glucocorticoid receptor ("GR"), one of the body's two cortisol receptors. We first made Korlym available to patients commercially in April 2012.

We have discovered three structurally distinct series of proprietary, selective cortisol modulators, all of which share mifepristone's affinity for GR but, unlike mifepristone, do not bind to the progesterone receptor ("PR") and do not cause effects arising from antagonism of progesterone activity, such as termination of pregnancy, endometrial thickening and vaginal bleeding. We are conducting clinical trials of three of these compounds, including: (i) a Phase 2 trial of relacorilant to treat patients with Cushing's syndrome; (ii) a Phase 1/2 trial of relacorilant combined with Celgene Corporation's drug Abraxane® (nab-paclitaxel) to treat patients with a variety of solid tumors; (iii) a Phase 1/2 trial of CORT125281 combined with Pfizer Inc.'s androgen receptor antagonist Xtandi® (enzalutamide) to treat patients with castration-resistant prostate cancer ("CRPC"); and (iv) a Phase 1 trial in healthy subjects to assess the safety and tolerability of CORT118335, which we plan to develop for the treatment of non-alcoholic steatohepatitis ("NASH") and antipsychotic-induced weight gain.

Cushing's Syndrome

Korlym to Treat Patients with Cushing's Syndrome. Cushing's syndrome is the clinical manifestation of hypercortisolism. It most often affects adults aged 20 to 50. An estimated 10 to 15 of every one million people are newly diagnosed with this syndrome each year, resulting in approximately 3,000 new patients and about 20,000 patients with Cushing's syndrome in the United States, approximately half of whom are cured by surgery.

The United States Food and Drug Administration ("FDA") has approved Korlym 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. The FDA has designated Korlym an "orphan drug" for the treatment of this indication. Orphan drugs receive seven years of marketing exclusivity for the approved indication from the date of drug approval, as well as tax credits for certain clinical trial costs, marketing application filing fee waivers and assistance from the FDA in the drug development process.

Our orphan drug marketing exclusivity for Korlym to treat patients with Cushing's syndrome expires in February 2019. We have four patents listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (known as the "Orange Book") covering the use of Korlym in patients with Cushing's syndrome. One of these patents expires in 2028 and the others in 2036.

We sell Korlym exclusively in the United States, using experienced sales representatives targeting the endocrinologists and other physicians who care for patients with Cushing's syndrome. We also reach patients directly through web-based initiatives and interactions with patient groups. 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 diagnosis of this syndrome and the role cortisol modulators can play in treating the disease. In addition, we 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 cover the cost of all aspects of their Cushing's syndrome care, whether or not their care includes taking Korlym.

Relacorilant to Treat Patients with Cushing's Syndrome. We have completed enrollment in a 35 patient, Phase 2 trial of our proprietary, selective cortisol modulator, relacorilant, to treat patients with Cushing's syndrome. Relacorilant shares Korlym's affinity for GR. Unlike Korlym, it has no affinity for PR and so does not cause the effects associated with PR affinity, including endometrial thickening and vaginal bleeding.

The trial is open label and is being conducted at sites in the United States and Europe. The first seventeen patients to enroll in the trial were assigned to a "low-dose" cohort. Results from the low-dose cohort were positive, including statistically significant improvements in glucose tolerance and serum osteocalcin (a marker of bone growth that is suppressed in Cushing's syndrome). Forty-five percent of the patients with uncontrolled hypertension exhibited a five millimeter or greater reduction in systolic or diastolic blood pressure. As expected, patients in the low-dose cohort experienced no progesterone-related side effects. There were no discontinuations due to drug-related adverse events and no serious adverse events. The final 18 patients receive higher doses of relacorilant. Testing of this "high-dose" cohort is ongoing.

We plan to start a Phase 3 trial this year.

FKBP5 Gene Expression Assay. The blood tests available to physicians to diagnosis patients with hypercortisolism and optimize their treatment are imprecise and often fail to identify patients with less severe manifestations of the disease. We have developed an assay to measure expression of the gene FKBP5, which is stimulated by cortisol activity, and have completed analytical validation pursuant to the Clinical Laboratory Improvement Amendments ("CLIA"). We believe this assay will enable physicians to more easily identify new patients with hypercortisolism and better treat those already in their care.

Oncology

Many types of solid tumors express GR and are potential targets for cortisol modulation therapy, among them pancreatic, ovarian, castration-resistant prostate, triple-negative breast, cervical and vulvar cancers, as well as sarcoma and melanoma.

Relacorilant to Treat Patients with Solid-Tumors. We are conducting a Phase 1/2 open label trial of Abraxane in combination with relacorilant to treat solid tumors. As we identify indications of clinical activity in a particular tumor-type, we will further test the combination's efficacy and safety in expansion cohorts of approximately 20 patients. Based on promising data generated in the initial, dose-finding portion of this trial, we have opened expansion cohorts in patients with pancreatic cancer. We continue to explore opening cohorts in patients with other solid tumors, including triple-negative breast cancer. We may also initiate trials that evaluate relacorilant with other cancer therapies as a treatment for solid tumors, including immunotherapy.

Korlym to Treat Patients with Triple-Negative Breast Cancer ("TNBC"). In December 2016, we announced the results of our Phase 1/2 trial of Korlym in combination with eribulin (Eisai Inc.'s drug, Halaven®) to treat patients with metastatic TNBC. The trial studied 21 patients with GR-positive tumors, one with GR-negative tumors and one with tumors whose GR status was not known. As determined using the Response Evaluation Criteria in Solid Tumors ("RECIST"), efficacy results were as follows: four patients exhibited a partial response, defined as a 30 percent or greater reduction in tumor size; eight had stable disease; and 11 had progressive disease. Six patients achieved progression-free survival ("PFS") longer than the upper bound of the 95% confidence interval for PFS (15 weeks) in patients receiving Halaven® monotherapy in a comparable population (Aogi et al., Annals of Oncology 23: 1441-1448, 2012). Median PFS in the trial was 11.1 weeks – compared to 7.2 weeks in the Halaven monotherapy study reported by Aogi.

We believe the addition of Korlym to chemotherapy warrants further study. University of Chicago investigators are leading a 64-patient double-blind, placebo-controlled, multi-center, Phase 2 trial of Korlym combined with Abraxane to treat patients with TNBC. Celgene is funding the trial. University of Chicago investigators are also conducting a 74-patient, open label trial of Korlym combined with Merck's drug Keytruda® (pembrolizumab) in patients with advanced HER2-negative and triple-negative breast cancer. Merck is funding the trial. We are providing Korlym to both trials.

Cortisol Modulators to Treat Patients with Castration-Resistant Prostate Cancer ("CRPC"). Because androgens stimulate prostate tumor growth, androgen deprivation is a common treatment for metastatic prostate cancer. Tumors eventually escape androgen deprivation therapy through the proliferation of cells for which cortisol's stimulation of GR is the primary growth factor. Combining a cortisol modulator with an androgen modulator such as Xtandi may block this escape route.

We have begun dosing patients at sites in the United States and Europe in an open label, Phase 1/2 trial of our proprietary, selective cortisol modulator CORT125281 combined with Xtandi in patients with metastatic CRPC.

University of Chicago investigators are leading an 84-patient, controlled, multicenter Phase 2 trial of Korlym combined with Xtandi to treat patients with metastatic CRPC. The Department of Defense and the Prostate Cancer Foundation are funding the trial. Pfizer is providing Xtandi. We are providing Korlym.

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

Antipsychotic-Induced Weight Gain and NASH. In animal models, our proprietary selective cortisol modulator CORT118335 potently prevents and reverses the weight gain caused by Eli Lilly and Company's antipsychotic medication Zyprexa® (olanzapine). These findings replicate data from placebo-controlled clinical trials we conducted, in which mifepristone (the active ingredient in Korlym) significantly reduced the weight gain and other adverse metabolic effects in healthy subjects administered Zyprexa® or Johnson & Johnson's antipsychotic medication Risperdal® (risperidone). We published the results of these trials in the journals Advances in Therapy, Gross et al (2009) and Obesity, Gross et al (2010).

CORT118335 also prevents and reverses non-alcoholic fatty liver disease and liver fibrosis in animal models. We conducted these pre-clinical studies in response to data suggesting that cortisol modulation with Korlym played a role in reversing fatty liver disease in patients with Cushing's syndrome. Fatty liver disease is a precursor to NASH.

We are conducting a Phase 1 trial of the safety, tolerability and pharmacokinetics of CORT118335. We plan to advance the compound to Phase 2 as a potential treatment for antipsychotic-induced weight gain and NASH.

Our Other Selective Cortisol Modulators

Our portfolio of proprietary selective cortisol modulators, which includes relacorilant, CORT125281 and CORT118335, consists of more than 500 compounds in three structurally distinct families. All of these compounds potently block GR but not the progesterone, estrogen or androgen receptors. Many of these compounds have demonstrated positive results in animal or in vitro models of cortisol modulation. We plan to continue identifying new compounds and advancing the most promising of them towards the clinic.

The United States Patent & Trademark Office ("USPTO") has issued us nine composition of matter patents covering our selective cortisol modulators and 28 method of use patents covering the use of cortisol modulators to treat a wide range of serious disorders, including Cushing's syndrome. We have exclusively licensed three U.S. method of use patents from Stanford University and five method of use patents from the University of Chicago. We also own an extensive portfolio of patents in countries around the world. We have applied, and will continue to apply, for U.S. and foreign patents covering the composition and method of use of our product candidates.

Results of Operations

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

Net product revenue was $62.3 million and $120.0 million for the three and six months ended June 30, 2018, respectively, as compared to $35.6 million and $63.2 million in the corresponding periods in 2017. These increases were primarily due to the sale of more Korlym tablets. A price increase effective in January 2018 accounted for approximately 14.0 percent and 11.1 percent of the increases in net revenue for the three and six months ended June 30, 2018, respectively.

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

Cost of sales was $1.2 million and $2.3 million for the three and six months ended June 30, 2018, respectively, compared to $0.8 million and $1.4 million for the corresponding periods in 2017. For each of the three and six months

ended June 30, 2018, cost of sales was 1.9 percent of net product revenue, compared to 2.2 percent in each of the corresponding periods of 2017. Cost of sales as a percentage of revenue declined due to lower manufacturing costs and an increase in the price of Korlym. The dollar value of our cost of sales increased in both periods due to greater sales unit volumes.

Research and development expenses – Research and development expenses include the cost of (1) retaining and compensating development personnel, (2) clinical trials, (3) discovery research and pre-clinical studies, (4) drug product for use in clinical trials and to support regulatory submissions, (5) the development of drug formulations and manufacturing processes and (6) regulatory activities.

Research and development expenses increased to $20.5 million for the three months ended June 30, 2018 compared to $7.9 million for the comparable period in 2017. Research and development expenses increased to $37.6 million for the six months ended June 30, 2018 compared to $15.1 million for the comparable period in 2017. These increases were due to the clinical advancement of relacorilant and the pre-clinical and clinical development of CORT118335 and CORT125281.

Below is a summary of our research and development expenses by major project:

| Project | Three Months Ended June 30, 2018 | 2017 | Six Months Ended June 30, 2018 | 2017 |
|---|---|---|---|---|
| | (in thousands) | | (in thousands) | |
| Development programs: | | | | |
| Oncology | $3,306 | $1,238 | $6,707 | $2,579 |
| Cushing's syndrome | 5,876 | 1,933 | 10,021 | 3,384 |
| Pre-clinical selective cortisol modulators | 7,435 | 2,747 | 13,977 | 5,400 |
| Unallocated activities, including pre-clinical, manufacturing and regulatory activities | 1,963 | 1,108 | 3,461 | 2,186 |
| Stock-based compensation | 1,963 | 850 | 3,427 | 1,503 |
| Total research and development expense | $20,543 | $7,876 | $37,593 | $15,052 |

Research and development expenses in 2018 and thereafter will depend on the outcomes of our pre-clinical and clinical trials and our development plans. We expect research and development spending for 2018 to be higher than it was in 2017 as our programs advance and we begin new ones.

It is difficult to predict the timing and cost of development activities, which are subject to many risks and uncertainties, including inconclusive results, slow patient enrollment, adverse side effects and unforeseen difficulties in the formulation or manufacture of study drugs and their real or perceived lack of efficacy or safety. Clinical development is also subject to extensive government oversight and to regulations that may change in ways we cannot anticipate.

Selling, general and administrative expenses – Selling, general and administrative expenses include (1) compensation of employees, consultants and contractors engaged in commercial and administrative activities, (2) the cost of vendors that support commercial activities and (3) legal and accounting fees.

Selling, general and administrative expenses for the three months ended June 30, 2018 increased to $20.0 million, from $14.1 million for the comparable period of 2017. Selling, general and administrative expenses for the six months ended June 30, 2018 increased to $38.4 million, from $29.2 million for the comparable period in 2017. These increases were driven primarily by increased compensation expenses for the expanded sales force as well as volume-related pharmacy and other distribution costs.

We expect that selling, general and administrative expenses will be higher in 2018 than in 2017 due to the increased scope of our commercial and clinical activities. Selling, general and administrative activities in 2018 and future years will depend on the cost and scope of our commercial and clinical development efforts.

Interest and other income (expense) – Interest and other income (expense) for the three and six months ended June 30 2018 was $0.6 million and $0.9 million, respectively, compared to $(0.1) million and $(0.3) million for the comparable periods in 2017. For the three and six months ended June 30, 2018, interest and other income primarily consisted of interest income from marketable securities. For the three and six months ended June 30, 2017, interest and other expense primarily consisted of interest expense arising from the Biopharma Financing Agreement. We

extinguished our obligations under the Financing Agreement in July 2017.

Income tax expense – Income tax expense for the three and six months ended June 30, 2018 was $3.0 million and $6.8 million compared to $0.1 and $0.2 million for the three and six months ended June 30, 2017, respectively, primarily due to reduction of our deferred tax assets through the utilization of net operating loss carryovers during the first half of 2018. For the three and six months ended June 30, 2018, $2.5 million and $5.6 million, respectively, of our income tax expense was offset by a reduction of deferred tax assets. The remaining $0.5 million and $1.2 million, respectively, represents income tax expense in states where we have no net operating loss carryforwards.

Liquidity and Capital Resources

At June 30, 2018, we had an accumulated deficit of $157.5 million. Since 2012, we have relied on revenues from the sale of Korlym and proceeds from the sale of common stock and the now repaid Financing Agreement with Biopharma to fund our operations.

Based on our current plans, which include fully funding our Cushing's syndrome commercial operations, conducting Phase 2 and Phase 3 trials of relacorilant in both Cushing's syndrome and solid tumors, the development of CORT125281 to treat patients with CRPC and CORT118335 to treat patients with antipsychotic-induced weight gain and NASH, we expect to fund our operations without needing to raise additional funds, although we may choose to raise additional funds to finance our strategic priorities or for other reasons. If we were to raise funds, equity financing would be dilutive to stockholders. Debt financing, if available, could involve restrictive covenants. Funds raised through collaborations with other companies may require us to relinquish certain rights in our product candidates.

At June 30, 2018, we had cash, cash equivalents and marketable securities of $160.0 million, consisting of cash and cash equivalents of $31.2 million and marketable securities of $128.8 million, compared to cash and cash equivalents of $31.1 million and marketable securities of $73.0 million at December 31, 2017. Net cash provided by operating activities for the six months ended June 30, 2018 was $49.6 million, compared to $25.1 million for the six months ended June 30, 2017 primarily due to higher sales volumes and receipt of $12.9 million from Dohmen. Net cash used in investing activities for the six months ended June 30, 2018 was $55.5 million, primarily due to net purchases of marketable securities, compared to $34.4 million for the six months ended June 30, 2017. Stock option exercises provided $6.0 million for the six months ended June 30, 2018, compared to $1.8 million for the comparable period of 2017. We made no payments under the Biopharma Financing Agreement during the six months ended June 30, 2018, compared to $10.5 million during the six months ended June 30, 2017. We extinguished our obligations under the Financing Agreement in July 2017. No further payments are due.

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

Contractual Obligations and Commercial Commitments

Our contractual payment obligations and purchase commitments as of December 31, 2017 are disclosed in our Annual Report on Form 10-K for the year ended December 31, 2017, and have not changed materially during the six months ended June 30, 2018.

Off-Balance Sheet Arrangements

None.

Critical Accounting Policies and Estimates

We have prepared our financial statements in accordance with GAAP, which requires us to make estimates regarding our assets, liabilities and expenses. We base our estimates on assumptions we believe to be reasonable. Actual results may differ if our assumptions are incorrect or the conditions in which we do business change in ways we did not anticipate. Our critical accounting policies and estimates are discussed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2017. During the six months ended June 30, 2018, we implemented internal controls in connection with our adoption of ASC Topic 606. There were no other changes in our internal control over financial reporting that occurred during the fiscal quarter covered by this report that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our market risks as of June 30, 2018 are disclosed in our Annual Report on Form 10-K for the year ended December 31, 2017. They have not changed materially during the six months ended June 30, 2018.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of disclosure controls and procedures. Our management, under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated our disclosure controls and procedures, as defined under Rules 13a-15(e) and 15d-15(e) of the Exchange Act as of June 30, 2018. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures provide a reasonable level of assurance that the information required to be disclosed in this Quarterly Report on Form 10-Q was (i) recorded, processed, summarized and reported within the time periods specified in the SEC's rules and (ii) communicated to our management, including our Chief Executive Officer and Chief Financial Officer, so as to allow timely decisions regarding required disclosure. Our disclosure controls and procedures are designed to provide reasonable, not absolute, assurance that our disclosures are accurate and timely.

Changes in internal control over financial reporting. Our Chief Financial Officer and other members of management have evaluated the changes in our internal control over financial reporting during the quarter ended June 30, 2018 and concluded that there was no change during the quarter that materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

Teva ANDA Litigation.

In February 2018, we received a Paragraph IV Notice Letter ("Notice Letter") advising us that Teva Pharmaceuticals USA, Inc. ("Teva") had submitted an Abbreviated New Drug Application ("ANDA") to the FDA seeking authorization to manufacture, use or sell a generic version of Korlym in the United States.

The Notice Letter contains Paragraph IV certifications against two of our patents related to Korlym, U.S. Patent No. 8,921,348 (the "'348 patent") and U.S. Patent No. 9,829,495 (the "495 patent"), which are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (referred to as the "Orange Book"). The Notice Letter alleges that the '348 patent with an expiration date in August 2028 and the '495 patent with an expiration date in August 2036 will not be infringed by Teva's proposed product, are invalid and/or are unenforceable. On March 15, 2018, we filed a lawsuit in the U.S. District Court for the District of New Jersey against Teva for infringement of these patents. On June 15, 2018, Teva moved to dismiss our complaint. On July 6, 2018 we amended our complaint to include, among other things, the alleged infringement of another Orange Book patent related to Korlym, U.S. Patent No. 9,943,526, with an expiration date in April 2036. On July 27, 2018, Teva moved to dismiss our amended complaint. We will oppose Teva's motion.

In accordance with the Hatch-Waxman Act, as a result of having filed a timely lawsuit against Teva, FDA approval of Teva's ANDA will be stayed until the earlier of (i) 30 months from our receipt of Teva's Notice Letter or (ii) the date of a District Court decision finding that both the '348 patent and the '495 patent are invalid, unenforceable or not infringed. We will vigorously enforce our intellectual property rights relating to Korlym, but we cannot predict the outcome of this matter.

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

ITEM 1A. RISK FACTORS

Investing in our common stock involves significant risks. Before investing, carefully consider the risks described below and the other information in this Quarterly Report on Form 10-Q, including our financial statements and related notes. The risks and uncertainties described below are the ones we believe may materially affect us. There may be others of which we are unaware, but which become important and materially harm our business or financial condition and cause the price of our stock to decline, in which case you could lose part or all of your investment.

Risks Related to the Commercial Sale of Korlym®

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

For the foreseeable future, our ability to generate revenue and fund our commercial operations and development programs will be solely dependent on the sale of Korlym. 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 in the care of patients with the illness and it may be difficult to persuade them to prescribe Korlym.

Many factors could limit our Korlym revenue, including:

- the preference of some physicians for long-standing off-label treatments for Cushing's syndrome, such as ketoconazole;
- competition from non-medical treatments, such as surgery and radiation;
- the potential introduction of a generic version of Korlym, including by Teva if it is successful in its ANDA submission;
- negative publicity and political concerns about Korlym, RU-486, Mifeprex® or mifepristone;
- the lack of availability of private and government insurance coverage; and
- rapid technological change that makes Korlym obsolete.

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

Korlym's orphan drug designation does not bar other companies from developing different medications to treat patients with Cushing's syndrome. The availability of competing treatments could limit our revenue from the sale of Korlym for the treatment of Cushing's syndrome or other indications.

Although we have received orphan drug designation and exclusivity for Korlym for the treatment of Cushing's syndrome in the United States, the FDA may approve other drugs for the treatment of patients with Cushing's syndrome.

In 2012, Novartis received approval in both the United States and the European Union ("EU") to market its somatostatin analogue Signifor® (pasireotide) Injection for adult patients with Cushing's disease (a subset of Cushing's syndrome that accounts for approximately 70 percent of all patients with Cushing's syndrome) for whom pituitary surgery is not an option or has not been curative. In addition, Novartis is conducting Phase 3 trials of the experimental cortisol synthesis inhibitor osilodrostat to treat patients with Cushing's syndrome and has received orphan drug designation in the United States and the EU for that use. Novartis has substantially more resources and experience than we do and may provide significant competition.

Strongbridge Biopharma plc ("Strongbridge") has received orphan drug designation in the United States and the EU for the use of the cortisol synthesis inhibitor levoketoconazole to treat Cushing's syndrome and is conducting Phase 3 trials in Europe and the United States for this indication. Levoketoconazole is an enantiomer of the generic anti-fungal medication that is sometimes prescribed off-label to treat patients with Cushing's syndrome.

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

Although Korlym is covered by patents covering its method of use, including its use to treat patients with Cushing's syndrome, we cannot assure you that third parties will not attempt to invalidate or design around the patents, or assert that they are invalid or otherwise unenforceable, and introduce generic equivalents of Korlym or any future products. In February 2018, we received notice that Teva had filed an ANDA requesting approval to market a generic version of Korlym. The Paragraph IV Notice Letter certified that our patents listed in the Orange Book for Korlym at the time Teva filed its ANDA are invalid, unenforceable or will not be infringed by Teva's proposed generic product. Corcept has filed suit against Teva in Federal District Court defending its patents, triggering the statutory automatic 30-month stay of FDA approval, beginning as of the date we received the Notice Letter. Litigation to enforce or defend intellectual property rights is complex, costly and involves significant commitments of management time. If our Orange Book listed patents are successfully challenged by Teva or any other party and a generic version of Korlym is approved, the sale of Korlym tablets and their price could decline materially.

In addition, after orphan drug exclusivity for Korlym in the United States for the treatment of Cushing's syndrome expires in February 2019, other companies could attempt to introduce generic equivalents of these products if they do not infringe our patents or can demonstrate that our patents are invalid or unenforceable. After the introduction of a generic competitor, a significant percentage of the prescriptions written for a product may be filled with the generic version, resulting in a loss in sales of the branded product and reducing its price. Generic competition for Korlym or our future products could have a material adverse effect on our sales, results of operations and financial condition.

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

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

for medicines. If government or private payors cease to provide adequate and timely coverage and reimbursement for Korlym, physicians may not prescribe the medication and patients may not purchase it, even if it is prescribed. In addition, delays in coverage for individual patients may reduce our revenues.

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

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

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the PPACA, and we expect there will be additional challenges and amendments to the PPACA in the future. For example, on January 20, 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the PPACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the PPACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers or manufacturers of pharmaceuticals or medical devices. On October 12, 2017, President Trump signed another Executive Order directing federal agencies to expand access to alternative health plans and health reimbursement arrangements, and the U.S. Department of Health and Human Services announced that it would immediately cease making Cost-Sharing Reduction ("CSR") payments to issuers of qualified health plans. The loss of the CSR payments is expected to increase premiums on certain policies issued by qualified health plans under the PPACA. In addition, CMS has proposed regulations that would give states greater flexibility in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the PPACA for plans sold through such marketplaces. Further, each chamber of Congress has put forth multiple bills designed to repeal or repeal and replace portions of the PPACA. Most recently, the Tax Cuts and Jobs Acts was enacted, which, among other things, removes penalties for not complying with the individual mandate to carry health insurance. At this time, the full effect that the PPACA, the Executive Orders, the halting of CSR payments and any subsequent legislation would have on our business remains unclear. Any new limitations on, changes to, or uncertainty with respect to the ability of individuals to enroll in governmental reimbursement programs or other third-party payor insurance plans could impact demand for Korlym, which in turn could affect our ability to successfully develop and commercialize our products.

Other legislative and regulatory changes have been proposed and adopted in the United States since the PPACA was enacted. These changes included an aggregate reduction in Medicare payments to providers of up to 2 percent per fiscal year, which went into effect on April 1, 2013 and will remain in effect through 2025 unless additional Congressional action is taken. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which further reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. On February 1, 2016, the Centers for Medicare & Medicaid Services, or CMS, published a final rule that revised certain requirements involved in our calculation of prices we report in connection with our participation in government reimbursement programs so that Korlym will be eligible for purchase by, or qualify for partial or full reimbursement from, Medicaid and other government programs. The extent to which this rule may alter our reported prices and estimated rebates and chargebacks under government programs remains unclear. Moreover, individual states in the United States have also become increasingly aggressive in passing legislation and implementing regulations designed to control product pricing, including price or patient reimbursement constraints, discounts, marketing cost disclosure and transparency measures.

These new laws and the regulations and policies implementing them, as well as other healthcare reform measures that may be adopted in the future, could materially reduce our ability to successfully develop and commercialize Korlym and our product candidates.

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

The active ingredient in Korlym, mifepristone, is approved by the FDA in another drug for the termination of early pregnancy. As a result, mifepristone has been and continues to be the subject of considerable ethical and political debate in the United States and elsewhere. Public perception of mifepristone may limit our ability to engage alternative manufacturers and may limit the commercial acceptance of Korlym by patients and physicians. Even though we have taken measures to minimize the likelihood of the prescribing of Korlym to a pregnant woman, physicians may choose not to prescribe Korlym to a woman simply to avoid the risk of unintentionally terminating a pregnancy.

We have no manufacturing or pharmacy capabilities and depend on third party vendors to manufacture Korlym's active ingredient, form it into tablets, package it, and dispense it to patients. We also depend on third-party suppliers to manufacture the API and capsules or tablets for relacorilant, CORT118335, CORT125281 and our other product candidates. If these suppliers become unable or unwilling to perform these functions and we cannot transfer our business to qualified replacement vendors in a timely manner, our business will be harmed.

A single third-party manufacturer, PCAS, supplies the API in Korlym. Another third-party manufacturer, Alcami, produces and bottles our Korlym tablets. Our agreements with PCAS and Alcami automatically renew and can be terminated by either party, subject to notice provisions. We also rely on a single manufacturer of relacorilant's API. Our agreement with this manufacturer has a five-year term, which can be terminated by us, subject to notice provisions. The manufacturer can terminate the agreement upon our bankruptcy or insolvency or uncured material breach, subject to notice provisions. A single specialty pharmacy, Optime Care, Inc. ("Optime"), dispenses the Korlym we sell directly to patients and collects payments from insurers and other third-party payers with respect to those sales, which represent approximately 99 percent of our revenue. If Optime fails to adhere to its agreements with third-party payers, it may not be able to collect some or all of the payments due to us. Our agreement with Optime has a five-year term and renews upon the written consent of both parties subject to the ability of either party to terminate upon material breach by either party or bankruptcy or insolvency. We may terminate the agreement for convenience. If any of these vendors is unable or unwilling to meet our requirements, we may not be able to manufacture or dispense our product in a timely manner. We cannot assure you that our

vendors will manufacture Korlym and our product candidates on a timely basis in the quantities that we require or otherwise maintain their contracts with us. If they fail to do so, we may exhaust our Korlym or product candidate inventory and not be able to generate revenue or advance our clinical development programs in a timely manner. In addition, identifying replacement vendors and transitioning our business to them would be time-consuming, complex and expensive, and failure to do so efficiently and in a timely manner would harm our business.

The facilities used by our vendors to manufacture and package Korlym and our product candidates must be approved by the FDA and, in some cases, the European Medicines Agency ("EMA"). We do not control the manufacturing activities of our contract manufacturing partners and are completely dependent on them for compliance with the regulatory requirements known as current good manufacturing practices ("cGMPs"). If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict requirements of the FDA or others, they will not be able to maintain regulatory approval for their manufacturing facilities. We have no control over whether our contract manufacturers maintain adequate quality control and hire qualified personnel. If the FDA, EMA or other regulatory authority does not approve these facilities for the manufacture of our products or if a necessary approval is withdrawn, we may need to find alternative manufacturing facilities, which would be expensive and could significantly hamper our ability to develop, obtain regulatory approval for and market our products. In addition, sanctions could be imposed on us, including fines, injunctions, civil penalties, failure of regulators to approve our product candidates, delays, suspensions or withdrawals of approvals, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could harm our business.

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

We may be subject to product liability or other claims based on allegations that Korlym or one of our product candidates has caused adverse effects. Such a claim may damage our reputation by raising questions about Korlym or our product candidates' safety and could prevent or interfere with product 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 the medicine in our clinical trials and physicians prescribing the medicine to women must take strict precautions to ensure that the medicine is not administered to pregnant women. Failure to observe these precautions could result in significant product liability claims.

We have product liability insurance with coverage limits we believe to be appropriate for a company marketing a single pharmaceutical product and developing others. However, this insurance may become prohibitively expensive or may not fully cover our potential liabilities. Our inability to obtain adequate insurance coverage at an acceptable cost could prevent or inhibit the commercialization of Korlym or our product candidates or could result in meaningful underinsured or uninsured liability. Defending a lawsuit could be costly and significantly divert management's attention from conducting our business.

We are subject to ongoing and continued regulatory review. If we are unable to maintain regulatory approval of Korlym for the treatment of patients with Cushing's syndrome or if we fail to comply with regulatory requirements, we will be unable to generate revenue or may be subject to penalties and our business would be harmed.

We are subject to ongoing obligations and continued regulatory review by the FDA and other regulatory authorities in the United States and other countries with respect to the research, testing, manufacturing, labeling, distribution, adverse event reporting, storage, selling, advertising, promotion, recordkeeping and marketing of products. These requirements include submissions of safety information, annual updates on manufacturing activities and continued compliance with FDA regulations known as cGMPs, current good laboratory practices ("cGLPs") for any nonclinical studies we conduct and current good clinical practices ("cGCPs") for any clinical studies we conduct. The FDA enforces these regulations through periodic 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, including adverse events of unanticipated severity or frequency or with our third-party manufacturers or manufacturing processes, or failure to comply with FDA and applicable foreign and U.S. regulatory requirements, may subject us to substantial civil and criminal penalties, injunctions, holds on clinical trials, product seizure or detention, refusal to permit the import or export of products, restrictions on product marketing, withdrawal of the product from the market, voluntary or mandatory product recalls, total or partial suspension of production, refusal to approve pending NDAs or supplemental NDAs, and suspension or revocation of product approvals.

In addition, we must comply with requirements concerning the advertising and promotion for our products. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved label.

The FDA's policies may change or new regulations may be enacted that prevent, limit or delay regulatory approval of our product candidates. We cannot predict the nature or scope of future government regulations. For example, the Trump administration has taken several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. It is difficult to predict how these Executive

Orders will be implemented, if at all, and the extent to which they will affect the FDA's ability to exercise its authority. If these executive actions impose restrictions on the FDA's ability to engage in oversight and implementation activities or if we are slow or unable to adapt to sudden changes in existing requirements or the adoption of new requirements or policies, we may not be able to maintain regulatory compliance, and we may lose marketing approval or face other enforcement action.

We may be subject to civil or criminal penalties if we market Korlym in a manner that violates FDA regulations or health care fraud and abuse laws.

In the United States, we are subject to FDA regulations governing the promotion and sale of medications. Although physicians are permitted to prescribe drugs for indications other than those approved by the FDA, manufacturers are prohibited from promoting products for such "off-label" uses. 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 have failed surgery or are not candidates for surgery. We provide promotional materials and training programs to physicians covering the use of Korlym for this indication. Although we believe our marketing materials and training programs do not constitute "off-label" promotion of Korlym, the FDA may disagree. If the FDA determines that our promotional materials, training or other activities by our employees or agents constitute "off-label" promotion of Korlym, it could ask us to change our training or promotional materials or other activities. The FDA could also subject us to regulatory enforcement actions, including issuance of a public "warning letter," injunction, seizure, civil fine or criminal penalties. Other federal or state enforcement authorities might act if they believe that the alleged improper promotion led to the submission and payment of claims for an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. Even if it is determined that we are not in violation of these laws, we may be faced with negative publicity, incur significant expenses and be forced to devote management time to defending our position.

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

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from 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 the Medicare and Medicaid programs;
- federal false claims laws, including, without limitation, the False Claims Act, which prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to get a false claim paid. Pharmaceutical companies have been prosecuted under these laws for a variety of promotional and marketing activities, such as allegedly providing free product to or entering into "sham" consulting arrangements with customers to induce such customers to purchase, order or recommend the company's products in violation of the Anti-Kickback Statute and federal false claims laws and regulations; reporting to pricing services inflated average wholesale prices that were then used by certain governmental programs to set reimbursement rates; engaging in the promotion of "off-label" uses that caused customers to submit claims to and obtain reimbursement from governmental payors for non-covered "off-label" uses; and submitting inflated best price information to the Medicaid Drug Rebate Program;
- the federal Civil Monetary Penalties law, which prohibits, among other things, offering or transferring remuneration to a federal healthcare beneficiary that a person knows or should know is likely to influence the beneficiary's decision to order or receive items or services reimbursable by the government from a particular provider or supplier;
- the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which created federal criminal laws that prohibit executing a scheme to defraud any health care benefit program or making false statements relating to health care matters;
- federal "sunshine" laws, including the federal Physician Payment Sunshine Act, that require transparency regarding financial arrangements with health care providers, such as the reporting and disclosure requirements imposed by the

PPACA on drug manufacturers regarding any "transfer of value" made or distributed to prescribers and other health care providers, and ownership or investment interests held by physicians and their immediate family members. Manufacturers are required to submit reports detailing these financial arrangements by the 90th day of each calendar year;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 and their respective implementing regulations, which impose obligations on covered healthcare providers, health plans, and healthcare clearinghouses, as well as their business associates that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, with respect to safeguarding the privacy, security and transmission of individually identifiable health information; and

- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

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

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

A break-down or breach of our information technology systems or our failure to protect adequately confidential information concerning patients or other third-parties could subject us to liability or interrupt the operation of our business.

We store sensitive data on our computer networks and on the networks of third-party vendors, including intellectual property and confidential information relating to our business, patients and employees. Despite the implementation of security measures, our internal computer systems and those of our vendors are subject to the risk of cyber-attacks, computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. They may also be manipulated by criminals seeking to commit fraud or monetary theft. In addition, system failures could cause the loss of valuable clinical trial data or otherwise disrupt our clinical and commercial activities and be expensive and time-consuming to remedy. If a disruption or security breach resulted in the disclosure of confidential or proprietary information, we could incur liability and our research, development and commercialization efforts could be delayed or otherwise harmed.

We are subject to government regulation and other legal obligations relating to privacy and data protection. Compliance with these requirements could result in additional costs and liabilities to us or inhibit our ability to collect and process data. The failure to comply with such requirements could have a material adverse effect on our business.

As we receive, collect, process, use and store personal and confidential data, we are subject to subject to diverse laws and regulations relating to data privacy and security, including, in the United States, HIPAA, and, in the EU and shortly in the European Economic Area (EEA), Regulation 2016/679, known as the General Data Protection Regulation("GDPR"). Compliance with these privacy and data security requirements is rigorous and may increase our cost of doing business. Despite our best efforts, we may be subject to fines and penalties, litigation and reputational harm, which could materially and adversely affect our business, financial condition and results of operations.

In addition, the regulatory framework for the receipt, collection, processing, use, safeguarding, sharing and transfer of personal and confidential data is rapidly evolving and is likely to remain uncertain for the foreseeable future as new global privacy rules are being enacted and existing ones are being updated and strengthened. For example, on May 25, 2018, the GDPR, took effect in Europe. GDPR mandates new requirements for the use and safeguarding of personal data in the EU and applies to companies established in the EU as well as companies that collect and use personal data to offer goods or services to, or monitor the behavior of, individuals in the EU (including via clinical trials). Penalties for failure to comply with GDPR are significant, including fines of up to €20 million or 4% of total worldwide annual revenue, whichever is higher. Data protection authorities in some of the EU member states have not completed their interpretative guidance and implementing laws regarding GDPR, which makes compliance difficult. In addition, the data protection authorities of the different EU countries may interpret the regulation differently. Both national and EU guidance are likely to be updated from time to time, which will add complexity and cost to our collection and handling of data.

While we have updated our applicable policies and procedures and are working with our vendors to ensure compliance with the new regulation, if we or our vendors or partners fail to comply with GDPR or other applicable data privacy laws, or if the data protection measures and disclosures we or our vendors undertake are not considered adequate, we could be subject to government enforcement actions and substantial penalties and fines, which could harm our business.

Recent U.S. tax legislation may materially adversely affect our results of operations, financial condition and cash flows.

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

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

Our business is vulnerable to damage from various types of natural disasters or other disruptive events, including earthquakes, fires, floods, power losses and communications failures. Our headquarters are located in the San Francisco Bay Area, which is earthquake-prone. Our specialty pharmacy is located in an area that is subject to severe weather conditions. Political considerations relating to mifepristone put us and our manufacturers at increased risk for terrorist attacks, protests or other disruptive events. If a disaster or similar event were to occur, we might not be able to operate our business or our manufacturers might not be able to produce or dispense Korlym or our product candidates. Our insurance may not cover or be adequate to cover losses resulting from disasters or other business interruptions.

Risks Related to the Development of our Product Candidates

Clinical drug development is lengthy, expensive and is often not successful. Results of early studies and trials may not be predictive of later trial results.

Clinical development is expensive and takes a long time. Data obtained from clinical trials are susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. The results from early clinical trials may not be predictive of results in later clinical trials. Product candidates may ultimately 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 advanced clinical trials due to lack of efficacy or the adverse safety profile of a product candidate.

Our current clinical trials are too small to support marketing approvals for the compounds being studied. Even if these trials generate positive results, those results would have to be confirmed in one or more substantially larger, more expensive and lengthier trials before we could seek regulatory approvals.

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

- delays obtaining regulatory permission to start a trial;
- inability to secure acceptable terms with CROs, other required vendors and clinical trial sites;
- delays or inability to obtain institutional review board ("IRB") approval at prospective trial sites;
- slow patient enrollment;
- failure of patients or investigators to comply with the clinical trial protocol;
- negative or inconclusive trial results;
- lack of effectiveness or safety of the product candidate; and
- negative findings of inspections of our clinical or manufacturing operations by us, the FDA or other authorities.

We could encounter delays if a clinical trial is suspended or terminated by us, the trial's data safety monitoring board or the IRBs at the sites where the trial is being conducted. The FDA or other regulatory authorities may suspend or terminate a trial for many reasons, including failure to conduct the trial in accordance with regulatory requirements or our clinical protocols, negative findings in an inspection by the FDA or other authorities of our clinical trial operations or clinical trial sites, unforeseen safety issues, failure to demonstrate a benefit from using a product candidate or changes in government regulations.

During the clinical 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 than we had planned, which could delay or prevent the completion of our development program and increase its cost. Even if we conduct all of the clinical trials and supportive studies that we consider appropriate, we may not receive regulatory approval of a product candidate.

We depend on third-parties to conduct and manage some of our clinical trials and to perform data collection and analysis. Failure of these third-parties to successfully perform their contractual duties or meet expected timelines may prevent or delay approval of our product candidates, which could harm our business.

We rely on clinical investigators and clinical sites to enroll patients and third-parties such as CROs to manage many of our trials and to perform required data collection and analysis. Although we control only certain aspects of these third-parties' activities, we are still responsible for ensuring that every study adheres to its protocol and meets all applicable regulatory and scientific standards. If we or any of the third-parties working with us fail to comply with applicable cGCPs, the clinical data generated in our trials may be unreliable and the FDA or foreign regulatory authorities may require us to perform additional clinical trials before approving a product candidate. In addition, failure of our manufacturers to comply with cGMP may require us to repeat clinical trials, which would delay regulatory approval. We may not be able to select and qualify appropriate sites for our trials. If our clinical sites fail to enroll a sufficient number of patients in a timely way, we may be unable to complete our trials as planned, which could delay or prevent the approval of our product candidates.

Although we have agreements with the CROs and consultants helping to conduct our clinical trials, we may fail to maintain satisfactory relationships with them or with our clinical investigators. If our agreements with any of these third-parties terminates, we may not be able to enter into alternative arrangements in a timely manner or on commercially reasonable terms, or at all. If the third-parties on which we rely do not perform their contractual duties or fail to meet expected deadlines or if the quality or accuracy of the data they produce is compromised, our clinical trials may be extended, delayed or terminated and we may be unable to obtain approval for our product candidates.

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

We cannot promote any products before we receive regulatory approval from the FDA or comparable foreign regulatory authorities. We may not receive regulatory approval for any of our product candidates. Obtaining regulatory approval of a new drug is uncertain, lengthy and expensive. Failure can occur at any stage. In order to receive approval from the FDA for a product candidate, we must demonstrate that the new drug product is safe and effective for its intended use and that our manufacturing processes for the product candidate comply with cGMPs, which govern production processes, quality control and recordkeeping. Our inability or the inability of our suppliers to comply with applicable FDA and other regulatory requirements can result in, among other things, delays in or denials of new product approvals, warning letters, fines, consent decrees restricting or suspending manufacturing operations, injunctions, civil penalties, recall or seizure of products, total or partial suspension of product sales and criminal prosecution. Any of these or other regulatory actions could materially harm our business and our financial condition.

Future governmental action or changes in FDA policy or personnel may also result in delays or rejection of an NDA or supplemental NDA in the United States. In addition, because the only other currently FDA-approved use of mifepristone is the termination of pregnancy, we expect that the label for mifepristone for any indication will include, as Korlym's does, some limitations, including a so-called "black-box" warning that it should not be used by pregnant women or women seeking to become pregnant.

If we receive regulatory approval for our future product candidates, we will be subject to ongoing FDA obligations and continued regulatory oversight and review, such as continued safety reporting requirements; and we may also be subject to additional FDA post-marketing restrictions and obligations. If we are not able to maintain regulatory

compliance, we may not be permitted to market our product candidates and may be subject to product recalls or seizures. Any regulatory approvals that we receive for our future product candidates may limit the indicated uses for which the medicine may be marketed or require costly post-marketing studies.

Failure to obtain regulatory approval in foreign jurisdictions would prevent us from commercializing our product candidates abroad.

We may seek to commercialize our products in international markets on our own or with the help of partners. Outside the United States, we may commercialize a product only if we receive a marketing authorization and, in many cases, pricing approval, from the appropriate regulatory authorities, whose approval processes include all of the risks associated with the FDA's approval process, and, in some cases, additional risks. The approval procedure varies among countries and can involve conducting additional pre-clinical or clinical studies. The time required to obtain approval may differ from that required to obtain FDA approval. Although approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by others, failure or delay in obtaining regulatory approval in one country may have a negative effect on the

regulatory process in others. We may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our product candidates in any foreign market. Although we have received orphan drug designation in the EU of Korlym to treat patients with Cushing's syndrome, we do not plan to seek any foreign approvals for that product.

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

The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. Our present and potential competitors include major pharmaceutical companies, specialized pharmaceutical firms, universities and public and private research institutions. These competitors may develop and commercialize medications that are superior to and less expensive than ours. We expect competition to intensify as technical advances are made.

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

Our efforts to discover, develop and commercialize product candidates beyond Korlym for the treatment of patients with Cushing's syndrome are at an early stage and we may fail to successfully commercialize any of them.

To develop additional sources of revenue, we must develop new product candidates or new therapeutic uses for Korlym. Cortisol modulators may not be effective to treat any other disorders. We could discover that cortisol modulators have unacceptable side effects or are otherwise not safe. Due to the potential for lack of efficacy and side effects inherent in novel compounds and in new uses for existing medications, we are developing multiple compounds, which will increase our rate of spending, with no assurance that we will be successful in developing drugs that are safe and effective.

We only have significant clinical and commercial experience with mifepristone, the active ingredient in Korlym, and we may determine that mifepristone is not desirable for uses other than for the treatment of patients with Cushing's syndrome. The compounds developed pursuant to our early discovery, preclinical and clinical research programs may fail to become approved medications, regardless of how much time and money we spend on their development. After a product candidate is identified, we may abandon further development efforts after expending significant expense and time due to financial constraints, concerns over safety or efficacy, marketing considerations, manufacturing difficulties or other reasons. If we are unable to successfully discover and commercialize new uses for cortisol modulators, we may be unable to generate sufficient revenue to support our operations.

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

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

- manage our sales and marketing efforts, clinical trials, research and development activities and supply chain effectively;

- hire additional management, clinical development, administrative and sales and marketing personnel; and
- develop our administrative, accounting and management information systems and controls.

Our failure to accomplish any of these tasks could harm our business.

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

Our ability to operate successfully and manage growth depends significantly upon retaining key managerial, scientific, sales, marketing, and financial personnel. We face intense competition for qualified personnel. We depend substantially on the principal members of our management and scientific staff. We do not have agreements with any of our executive officers that provide for their continued employment with us or employment insurance covering any of our key personnel. Any officer or employee can terminate his or her relationship with us at any time and work for one of our competitors. The loss of key individuals could delay our research, development and commercialization efforts.

Risks Related to Our Capital Needs and Financial Results

We may need additional capital to fund our operating plans, including our clinical development programs, 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 to fund our development programs. If our Korlym revenues decline or fail to grow, we may need to raise funds to support our operating plans, including our research and development activities, or we may choose to raise funds for strategic or other reasons. We cannot be certain that additional funding will be available on acceptable terms or at all. Equity financing would cause dilution. Debt financing, if available, may involve restrictive covenants. If we obtain funds through collaborations with other companies, those arrangements may be on unfavorable terms or may require us to relinquish certain rights to Korlym or our product candidates. If adequate funds are not available, we may be required to delay, reduce the scope of, or eliminate one or more of our research or development programs or we may be required to discontinue operations.

If we acquire other potential products, we will incur a variety of costs and may never realize the anticipated benefits of the acquisition.

If appropriate opportunities arise, we may attempt to acquire products or product candidates that complement our operating plan. Acquiring rights to another potential product or technology may result in unforeseen difficulties and expenditures and may absorb significant management attention that would be spent developing our existing business. We may fail to realize the anticipated benefits of any acquisition, which could dilute our stockholders' ownership interest or cause us to incur debt, expose us to future liabilities and result in amortization or other expenses related to goodwill and other intangible assets.

Risks Relating to Our Intellectual Property

If Korlym or our other product candidates infringe the patents of others or if we become involved in additional intellectual property disputes, we may have to engage in further costly litigation or obtain a license or may be barred from commercializing our product candidates or Korlym for a new indication.

Our success depends on our ability to obtain and maintain adequate patent protection for the composition of our proprietary, selective cortisol modulators and their methods of use and the use of Korlym to treat Cushing's syndrome, TNBC, CRPC and other disorders. Patents in the pharmaceutical industry are highly uncertain, involve complex legal and factual questions and are the subject of very costly litigation. If we do not adequately protect our intellectual property, competitors may erode our competitive advantage. Our patent applications and patents licensed or issued to us may be challenged by third parties in court and in administrative proceedings. Responding to such challenges is costly, time-consuming and the outcomes are uncertain.

We are currently defending certain of our patents in two separate proceedings. In March 2018, in response to the Teva ANDA submission, we filed a lawsuit in the U.S. District Court for the District of New Jersey against Teva for infringement of our patents covering the use of Korlym. The outcome of this lawsuit is uncertain and is likely to be costly and require substantial commitments of management time. Please see the discussion of this matter under Part II, Item 1. Legal Proceedings above. In addition, on August 2, 2018, Neptune Generics, LLC ("Neptune") submitted a petition for Inter Partes Review ("IPR") at the U.S. Patent Trial and Appeal Board ("PTAB") of U.S. Patent No. 8,921,348 (the "'348 patent"), which covers certain methods of using Korlym. If the PTAB agrees to institute Neptune's IPR, it may find grounds to revoke the '348 patent or some of its claims.

Our products and product candidates may also give rise to claims that our patents or the patents we have licensed infringe the rights of others, which may cause us to engage in costly litigation. If it is determined that our product

candidates infringe others' patent rights, we may be required to obtain licenses to those rights. If we fail to obtain licenses when necessary, we may have to delay commercializing our product candidates while we attempt to design around the infringed patent. We could fail and may be unable to commercialize our product candidates. If we become involved in intellectual property litigation, we are likely to incur considerable costs. We do not believe that we infringe any patents or other proprietary rights. We are not obligated to pay royalties relating to the use of intellectual property except to Stanford University and the University of Chicago. To maintain the exclusive license to these patents, we must make milestone and royalty payments to both universities. If we do not comply with our obligations under our licenses, we may lose the right to commercialize cortisol modulators, including mifepristone, for the treatment of psychotic depression, cocaine-induced psychosis, early dementia, TNBC and CRPC.

In addition, our presently pending and future patent applications may not issue as patents, and any patent issued to us may be challenged, invalidated, held unenforceable or circumvented. Our patent claims may not prevent third parties from producing competing products. The foreign countries in which we may someday operate may not protect our intellectual property to the extent of the laws of the United States. If we fail to obtain adequate patent protection in other countries, our competitors may produce competing products in those countries based on our technology, which would impair our ability to succeed.

If a third party successfully asserted an infringement claim against us, we could be forced to obtain an expensive license or pay damages and be prevented from developing, manufacturing or marketing our potential products. We do not have liability insurance for patent infringement. Patent litigation could consume a substantial portion of our resources and management time. Regardless of a claim's merit, defending a lawsuit is expensive and diverts management's attention from productive business.

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

In addition to patents, we rely on a combination of confidentiality, nondisclosure and other contractual provisions, laws protecting trade secrets and security measures to protect our proprietary information. These measures may not provide adequate protection, in which case third-parties could use our proprietary information to diminish our ability to compete. In addition, employees, consultants and others may breach their agreements with us regarding our proprietary information and we may not have adequate remedies for the breach.

The mifepristone patents that we own or license cover the use of mifepristone, not its composition, which may make it more difficult to prevent patent infringement if physicians prescribe another manufacturer's mifepristone or if patients acquire mifepristone from other sources, such as the internet or underground market.

We own or have exclusively licensed issued U.S. patents covering the use of cortisol modulators to treat a variety of disorders, including TNBC and CRPC. A method of use patent covers only a particular use of a compound, not its composition. Because our patents do not cover the composition of mifepristone, we cannot prevent others from commercializing mifepristone to treat disorders not covered by our method of use patents. The availability of mifepristone for these disorders may enable patients to obtain mifepristone for indications covered by our patents. Although such "off-label" use would violate our patents, effectively monitoring compliance and enforcing our rights may be difficult and costly. Patients may be able to purchase mifepristone through the internet or underground market. Mifepristone is sold in the United States by Danco Laboratories for the termination of pregnancy. Although distribution is limited to a single dose provided in the physician's office and covered by other restrictions, we cannot be certain that patients with Cushing's syndrome will not be able to obtain mifepristone from this or other sources, should another company receive approval to market mifepristone for another indication.

Risks Related to Our Stock

The market price of our common stock has been and is likely to continue to be subject to wide fluctuations in price that are beyond our control. Opportunities for the sale of shares at any given time may be limited.

We cannot assure you that an active trading market for our common stock will exist at any particular time. Holders of our common stock may not be able to sell shares quickly or at the market price if trading in our common stock is not active. During the 52-week period ended August 3, 2018, our average daily trading volume was approximately 1,579,796 shares and the intra-day sales prices per share of our common stock on The Nasdaq Capital Market ranged from $12.50 to $25.96. As of August 3, 2018, our officers, directors and principal stockholders beneficially owned approximately 15 percent of our common stock.

Our stock price, like the stock price of many biotechnology companies, sometimes experiences extreme price and volume fluctuations that are unrelated or disproportionate to our operating performance or prospects. This volatility may significantly reduce the market price of our common stock. Securities class action litigation is often instituted against companies following periods of stock market volatility. If instituted against us, such litigation could result in substantial costs and divert management's attention from more productive efforts.

The price of our common stock can fluctuate rapidly and widely in response to a variety of factors, including:

- actual or anticipated variations in our operating results, or changes to any public guidance we have provided;
- actual or anticipated timing and results of our clinical trials;
- changes in the expected or actual timing of our competitors' potential development programs, including the announcement of ANDA filings seeking approval to market generic versions of Korlym;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- changes in estimates or recommendations by securities analysts or the failure of our performance to meet the published expectations of those analysts or any public guidance we have provided;
- purchases or sales of our common stock by our officers, directors or stockholders;
- actual or anticipated regulatory approvals of our product candidates or of competing products;
- changes in laws or regulations applicable to our product candidates or our competitors' products;

- announcements of technological innovations by us, our collaborators or our competitors;
- our cash and short-term investment position;
- trading volume of our common stock;
- conditions or trends in the biotechnology and pharmaceutical industries, including the market valuations of companies similar to Corcept;
- general market and economic conditions;
- additions or departures of key personnel;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments; and
- additional financing activities.

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

The guidance we provide as to our expected 2018 revenue is only an estimate of what we believe is realizable at the time we give such guidance. Our actual results may vary materially. There are inherent difficulties in predicting the amount of Korlym that will be sold. For example, the rate of physician adoption of Korlym is uncertain. We may not meet our financial guidance or other investor expectations for other reasons, including those arising from the risks and uncertainties described in this report and in our other public filings and public statements. Research analysts have published revenue estimates based on their own analyses. The guidance we provide may be one factor they consider when determining their estimates.

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

The market for our common stock may be affected by the reports financial analysts publish about us. If one of the analysts covering us downgrades our stock, its price could decline rapidly and significantly. Securities analysts covering our common stock may discontinue coverage. A lack of research coverage may adversely affect our stock price.

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

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

As of August 3, 2018, our officers and directors beneficially owned approximately 15 percent of our common stock. Acting together, these stockholders could significantly influence any matter requiring approval by our stockholders, including the election of directors and the approval of mergers or other business combinations. The interests of this group may not always coincide with our interests or the interests of other stockholders and may prevent or delay a change in control. This significant concentration of share ownership may adversely affect the trading price of our common stock because many investors perceive disadvantages to owning stock in companies with controlling stockholders.

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

New laws and regulations, as well as changes to existing laws and regulations, including statutes and regulations concerning the development, approval, and marketing of medications, the provisions of the PPACA requiring the reporting of aggregate spending related to health care professionals, the provisions of the Sarbanes-Oxley Act of 2002 and rules adopted by the SEC and by The NASDAQ Capital Market have and will likely continue to increase our cost of doing business. Complying with these regulations may increase our selling, general and administrative expenses and divert management's time and attention from revenue-generating activities.

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

The federal securities laws and regulations, including the corporate governance and other requirements of the Sarbanes-Oxley Act of 2002, impose complex and continually changing regulatory requirements on our operations and reporting. 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 financial statements must attest to and

report on the effectiveness of our internal controls over financial reporting. These requirements have increased and will continue to increase our compliance costs. Furthermore, if we are unable to complete the required assessment and report as to the adequacy of our internal control over financial reporting 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.

Changes in or interpretations of accounting rules and regulations could result in unfavorable accounting charges or require us to change our accounting policies or operating practices.

Accounting methods and policies for business and marketing practices of pharmaceutical companies are subject to continual review, interpretation and guidance from accounting authorities, including the SEC. Although we believe that our accounting practices are consistent with current requirements, changes to accounting methods or policies may require us to reclassify, restate or otherwise change or revise our financial statements. Such changes could result in changes to the amounts or characterization of our assets, liabilities, revenues, expenses and income, which could harm our financial position and results of operations and could cause the price of our common stock to 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 and result in the market price being lower than it would otherwise be.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS
None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES
Not applicable.

ITEM 4. MINE SAFETY DISCLOSURES
Not applicable.

ITEM 5. OTHER INFORMATION
None.

ITEM 6. EXHIBITS

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

SIGNATURES

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

CORCEPT THERAPEUTICS INCORPORATED

Date: August 9, 2018 /s/ Joseph K. Belanoff
Joseph K. Belanoff, M.D.

Chief Executive Officer

Date: August 9, 2018 /s/ G. Charles Robb
G. Charles Robb
Chief Financial Officer