

PERNIX THERAPEUTICS HOLDINGS, INC.

Form 10-Q

August 09, 2018

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-Q

(Mark
One)

þ

Quarterly report pursuant to section 13 or 15(d) of the Securities Exchange Act of 1934

For the quarterly period ended: **June 30, 2018**

o Transition report pursuant to section 13 or 15(d) of the Securities Exchange Act of 1934

For the transition period from: _____ to _____

001-14494

Commission File Number

PERNIX THERAPEUTICS HOLDINGS, INC.

(Exact name of Registrant as specified in its charter)

Maryland

33-0724736

(State or other jurisdiction of incorporation or organization)

(I.R.S. Employer Identification Number)

Edgar Filing: PERNIX THERAPEUTICS HOLDINGS, INC. - Form 10-Q

10 North Park Place, Suite 201, Morristown, NJ

(Address of principal executive offices)

07960

(Zip Code)

(800) 793-2145

(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 report(s)) and (2) has been subject to such filing requirements for the past 90 days. Yes

☐ No ☐ o.

Indicate by check mark whether the Registrant has submitted electronically every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes

☐ No ☐ o.

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

Large accelerated filer	Accelerated filer	Non-accelerated filer	Smaller reporting company	Emerging growth company
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
		(Do not check if a smaller reporting 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 ☐ p

On August 6, 2018, there were 13,920,264 shares outstanding of the Registrant's common stock, par value \$0.01 per share.

PERNIX THERAPEUTICS HOLDINGS, INC. AND SUBSIDIARIES

Quarterly Report on Form 10-Q
For the Three and Six Months Ended June 30, 2018

INDEX

PART I.

FINANCIAL INFORMATION

Item 1.

Financial Statements (unaudited)

Condensed Consolidated Balance Sheets

3

Condensed Consolidated Statements of Operations and Comprehensive (Loss) Gain

4

3

Condensed Consolidated Statements of Stockholders' Equity (Deficit)

5

Condensed Consolidated Statements of Cash Flows

6

Notes to Condensed Consolidated Financial Statements

7

Item 2.

Management's Discussion and Analysis of Financial Condition and Results of Operations

28

Item 3.

Quantitative and Qualitative Disclosures About Market Risk

4

41

Item 4.

Controls and Procedures

41

PART II.

OTHER INFORMATION

Item 1.

Legal Proceedings

42

Item 1A.

Risk Factors

42

Item 2.

Unregistered Sales of Equity Securities and Use of Proceeds

72

Item 3.

Defaults upon Senior Securities

72

Item 4.

Mine Safety Disclosures

72

Item 5.

Other Information

72

Item 6.

Exhibits

73

Signatures

74

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements.

PERNIX THERAPEUTICS HOLDINGS, INC. AND SUBSIDIARIES
Condensed Consolidated Balance Sheets
(In thousands, except share and per share data)
(Unaudited)

Assets	June 30, 2018	December 31, 2017
Current assets:		
Cash and cash equivalents	\$ 19,925	\$ 32,820
Accounts receivable, net	35,275	45,317
Inventory, net	5,058	5,396
Prepaid expenses and other current assets	6,096	8,628
Income tax receivable	101	123
Total current assets	66,455	92,284
Property and equipment, net	681	752
Goodwill	12,100	12,100
Intangible assets, net	85,424	96,606
Other	1,973	2,263
Total assets	\$ 166,633	\$ 204,005
Liabilities and Stockholders' Deficit		
Current liabilities:		
Accounts payable	\$ 10,797	\$ 7,911
Accrued personnel expenses	3,661	5,748
Accrued allowances	54,020	56,309
Other accrued expenses	3,324	6,909
Interest payable	10,524	10,612
Treximet Secured Notes - current, net	-	3,664
Other liabilities - current	3,765	2,648
Total current liabilities	86,091	93,801
Convertible notes - long-term, net	66,928	65,194
Exchangeable notes - long-term, net	9,016	7,975
Delayed draw term loan - long-term, net	28,183	27,248
Derivative liability	72	93
Contingent consideration	1,501	1,358
Treximet Secured Notes - long-term, net	162,853	163,887
Credit facility	14,185	14,185
Arbitration award	2,000	2,000
Other liabilities - long-term	822	2,521
Total liabilities	371,651	378,262
Commitments and contingencies (note 11)		
Stockholders' deficit:		
Preferred stock, \$0.01 par value, authorized 10,000,000 shares; no shares issued and outstanding	-	-
Common stock, \$0.01 par value, 140,000,000 shares authorized, 12,065,487 and 11,841,173 shares issued and outstanding at June 30, 2018 and December 31, 2017, respectively	121	119
Additional paid-in capital	262,492	261,158
Accumulated other comprehensive loss	-	-
Accumulated deficit	(467,631)	(435,534)
Total stockholders' deficit	(205,018)	(174,257)
Total liabilities and stockholders' deficit	\$ 166,633	\$ 204,005

See accompanying notes to condensed consolidated financial statements.

Edgar Filing: PERNIX THERAPEUTICS HOLDINGS, INC. - Form 10-Q

PERNIX THERAPEUTICS HOLDINGS, INC. AND SUBSIDIARIES
Condensed Consolidated Statements of Operations and Comprehensive (Loss) Gain
(In thousands, except per share data)
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Net revenues	\$ 21,088	\$ 34,316	\$ 49,227	\$ 64,058
Costs and operating expenses:				
Cost of product sales	5,569	10,493	14,530	20,533
Selling, general and administrative expense	18,257	19,018	35,540	39,293
Research and development expense	6	82	10	610
Depreciation and amortization expense	1,430	18,215	11,295	36,762
Change in fair value of contingent consideration	(120)	(886)	143	(540)
Restructuring costs	385	31	1,214	131
Total costs and operating expenses	25,527	46,953	62,732	96,789
Loss from operations	(4,439)	(12,637)	(13,505)	(32,731)
Other income (expense):				
Interest expense	(9,530)	(9,209)	(18,990)	(18,168)
Gain on sale of assets	446	-	446	-
Change in fair value of derivative liability	40	270	21	(84)
Foreign currency transaction (loss) gain	(21)	-	(21)	-
Total other income (expense), net	(9,065)	(8,939)	(18,544)	(18,252)
Loss before income tax expense	(13,504)	(21,576)	(32,049)	(50,983)
Income tax expense	9	40	48	95
Net loss	(13,513)	(21,616)	(32,097)	(51,078)
Other comprehensive loss:				
Unrealized gain during period, net of tax of \$0 and \$0, respectively	-	18	-	24
Comprehensive loss	\$ (13,513)	\$ (21,598)	\$ (32,097)	\$ (51,054)
Net loss per common share:				
Basic	\$ (1.13)	\$ (2.16)	\$ (2.70)	\$ (5.10)
Diluted	\$ (1.13)	\$ (2.16)	\$ (2.70)	\$ (5.10)
Weighted-average common shares outstanding:				
Basic	11,913	10,016	11,907	10,016
Diluted	11,913	10,016	11,907	10,016

See accompanying notes to condensed consolidated financial statements.

PERNIX THERAPEUTICS HOLDINGS, INC. AND SUBSIDIARIES
Condensed Consolidated Statements of Stockholders' Equity (Deficit)
(In thousands)
(Unaudited)

	Preferred Stock		Common Stock		Additional	Treasury	Accumulated	Accumulated	Total
	Shares	Amount	Shares	Amount	Paid-In Capital	Stock	Deficit	Other Comprehensive Loss	Stockholders' Deficit
Balance at December 31, 2016	-	\$ -	10,016	\$ 100	\$ 244,309	\$ -	\$ (358,393)	\$ (79)	\$ (114,063)
Conversion of restricted stock units	-	-	44	1	(113)	-	-	-	(112)
Issuance of Convertible Debt	-	-	1,100	11	12,499	-	-	-	12,510
Compensation expense on share-based awards	-	-	-	-	2,491	-	-	-	2,491
Net proceeds from sale of shares	-	-	681	7	1,972	-	-	-	1,979
Other comprehensive loss	-	-	-	-	-	-	-	79	79
Net loss	-	-	-	-	-	-	(77,141)	-	(77,141)
Balance at December 31, 2017	-	-	11,841	119	261,158	-	(435,534)	-	(174,257)
Conversion of restricted stock units	-	-	33	-	(2)	-	-	-	(2)
Compensation expense on share-based awards	-	-	-	-	885	-	-	-	885
Net proceeds from sale of shares	-	-	191	2	451	-	-	-	453
Other comprehensive loss	-	-	-	-	-	-	-	-	-
Net loss	-	-	-	-	-	-	(32,097)	-	(32,097)
Balance at June 30, 2018	-	\$ -	12,065	\$ 121	\$ 262,492	\$ -	\$ (467,631)	\$ -	\$ (205,018)

See accompanying notes to condensed consolidated financial statements.

PERNIX THERAPEUTICS HOLDINGS, INC. AND SUBSIDIARIES

Condensed Consolidated Statements of Cash Flows

(In thousands)

(Unaudited)

	Six Months Ended June 30,	
	2018	2017
Cash flows from operating activities:		
Net loss	\$ (32,097)	\$ (51,078)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	169	185
Amortization of intangibles	11,182	36,637
Amortization of deferred financing costs	1,910	1,482
Accretion expense	2,468	2,702
PIK interest	972	-
Stock compensation expense	885	1,404
Fair market value change in contingent consideration	143	(540)
Fair market value change in derivative liability	(21)	84
Gain on sale of assets	(446)	-
(Increase) decrease in operating assets:		
Accounts receivable	10,042	5,483
Income tax receivable	22	962
Inventory	338	(707)
Prepaid expenses and other assets	2,532	851
Increase (decrease) in operating liabilities:		
Accounts payable and accrued expenses	(1,739)	892
Accrued allowances	(2,289)	(5,222)
Interest payable	(458)	(595)
Other liabilities	(1,689)	(1,717)
Net cash used in operating activities	(8,076)	(9,177)
Cash flows from investing activities:		
Proceeds from sale of non-core assets	446	-
Purchase of software and equipment	(98)	(3)
Net cash provided by (used in) investing activities	348	(3)
Cash flows from financing activities:		
Payments on Treximet Secured Notes	(5,373)	(12,812)
Payments of financing costs	(221)	-
Payments on mortgages and capital leases	(24)	(42)
Proceeds from issuance of common stock, net of tax and costs	453	-
Shares withheld for the payment of taxes	(2)	-
Net cash used in financing activities	(5,167)	(12,854)
Net decrease in cash and cash equivalents	(12,895)	(22,034)
Cash and cash equivalents, beginning of period	32,820	36,375
Cash and cash equivalents, end of period	\$ 19,925	\$ 14,341

See accompanying notes to condensed consolidated financial statements.

PERNIX THERAPEUTICS HOLDINGS, INC. AND SUBSIDIARIES
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

Note 1. Company Overview

Pernix® Therapeutics Holdings, Inc. and subsidiaries (collectively, Pernix, the Company, we, our and us) is a specialty pharmaceutical company focused on the acquisition, development and commercialization of prescription drugs, primarily for the United States (U.S.) market. The Company is currently focused on the therapeutic areas of pain and neurology and has an interest in expanding into additional specialty segments. The Company promotes its branded products to health care professionals through its Pernix sales force and markets its generic portfolio through its wholly owned subsidiaries, Macoven™ Pharmaceuticals, LLC (Macoven) and Cypress Pharmaceuticals®, Inc. (Cypress).

The Company's branded products include Zohydro® ER with BeadTek®, an extended-release opioid agonist indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate, Treximet® a medication indicated for the acute treatment of migraine attacks with and without aura, and Silenor® a non-controlled substance and approved medication for the treatment of insomnia characterized by difficulty with sleep maintenance.

Subsequent Events

Closing of Transactions Regarding Worldwide Rights to Contrave® (*naltrexone HCl / bupropion HCl*)

On April 17, 2018, a wholly owned subsidiary of the Company, Pernix Ireland Pain Designated Activity Company (PIP DAC) entered into a Commitment Letter (the Commitment Letter) pursuant to which PIP DAC committed to provide Nalpropion™ Pharmaceuticals, Inc. (Nalpropion) with \$7.5 million in debt and/or equity capital to fund Nalpropion's purchase of certain assets of Orexigen® Therapeutics, Inc. (Orexigen) on the terms and conditions contained in the Commitment Letter. Nalpropion is a special purpose corporation jointly owned by PIP DAC and certain other co-investors. Nalpropion submitted a "stalking horse" bid to purchase certain assets of Orexigen, which filed a voluntary petition for relief under Chapter 11 of Title 11 of the United States Code, 11 U.S.C. §§ 101, et seq. in the United States Bankruptcy Court for the District of Delaware.

On April 23, 2018, pursuant to a confidential non-binding term sheet agreement between the Company and its co-investors in Nalpropion (the Term Sheet), Nalpropion entered into a "stalking horse" asset purchase agreement to acquire certain assets of Orexigen, including worldwide rights to Contrave® (*naltrexone HCl / bupropion HCl*), a prescription-only weight-loss medication, for \$75 million in cash.

On June 22, 2018, the Company announced that no other bids for Orexigen's assets were received by the court-approved bid deadline and on July 27, 2018, Nalpropion acquired substantially all the assets and assumed certain liabilities of Orexigen. Concurrent with the closing of the transaction, Orexigen and Nalpropion entered into an amendment to the Asset Purchase Agreement that, among other things, reduced the purchase price to \$73.5 million and provided for \$5.0 million of the purchase price to be held back by Nalpropion to cover potential indemnification claims. On July 27, 2018, the Company funded PIP DAC's contribution of 10% of the capital required to fund the purchase price for Orexigen of \$7.35 million and an incremental \$1.82 million for working capital requirements, via its existing delayed draw term loan facility by and among PIP DAC, the lenders party thereto and Cantor Fitzgerald Securities, as agent (the Term Facility). The Company was also issued two purchase options that will enable it to acquire up to 49.9% and 100% of Nalpropion at specified time periods and purchase prices.

The Company owns 10% of the equity and has one of three seats on the Board of Directors of Nalpropion. Nalpropion qualifies as a Variable Interest Entity (VIE) based on its governance structure and the Company will consolidate

Nalpropion in its consolidated financial statements since the Company has the power to direct activities that most significantly impacts Nalpropion's economic performance. The Company will, for an initial term of two years, manage Nalpropion's operations and product distribution in the United States. As consideration for its efforts, the Company will receive a management fee equal to 5% of net sales derived by Nalpropion as well as reimbursement of certain shared services expenses at cost.

The transaction is being accounted for using the acquisition method of accounting for business combinations in accordance with GAAP. Under this method, the total consideration transferred to consummate the acquisition is being allocated to the identifiable tangible and intangible assets acquired and liabilities assumed based on their respective fair values as of the closing date of the transaction. The acquisition method of accounting requires extensive use of estimates and judgments to allocate the consideration transferred to the identifiable tangible and intangible assets acquired and liabilities assumed. Accordingly, the allocation of the consideration transferred is preliminary and will be adjusted upon completion of the final valuation of the assets acquired and liabilities assumed. The final valuation is expected to be completed as soon as practicable but no later than 12 months after the closing date of the transaction.

The consolidated financial statements for the three and six months ended June 30, 2018 and 2017 do not include the operations of Nalpropion. The results of operations for Nalpropion will be included in the Company's consolidated financial statements beginning on July 27, 2018.

2018 Exchange Transactions

On August 1, 2018, the Company entered into an exchange agreement (2018 Exchange Agreement) with certain holders (Exchange Holders) of the Company's outstanding 12% Senior Secured Notes due 2020 (the Treximet Secured Notes) for newly issued shares of common stock of the Company (Common Stock) and shares of a newly created class of convertible preferred stock of the Company designated as 0% Series C Perpetual Convertible Preferred Stock (Convertible Preferred Stock) (Exchange Transactions).

The Exchange Transactions included the following transactions:

- exchange of approximately \$2.7 million aggregate principal amount of the Treximet Secured Notes for 1,204,586 shares of Common Stock, which included accrued and unpaid interest on the Treximet Secured Notes; and
- exchange of \$8.0 million principal amount of the Treximet Secured Notes plus \$100,000 of accrued and unpaid interest for 81,000 shares of Preferred Stock.

These transactions closed on August 1, 2018. In addition, the 2018 Exchange Agreement affords the Exchange Holders the right to exchange up to an additional \$65.1 million aggregate principal amount of the Treximet Secured Notes plus accrued and unpaid interest, until February 1, 2020.

On August 1, 2018, the Company filed with the State Department of Assessments and Taxation of Maryland an Articles Supplementary (the Articles Supplementary) to the Company's Articles of Incorporation setting out the form and terms of the Convertible Preferred Stock.

Exchange Holders of Convertible Preferred Stock have the right to convert their shares of Convertible Preferred Stock, in whole or in part, into shares of Common Stock at any time on or after August 1, 2018 (the Initial Issue Date). The Company has the right, at its option, to automatically convert all shares of Convertible Preferred Stock into shares of Common Stock, subject to the satisfaction of certain specified conditions. Upon any conversion of an Exchange Holder's Convertible Preferred Stock, the Company will deliver shares of Common Stock, calculated by multiplying the number of shares of Convertible Preferred Stock by 41.841 shares of Common Stock per share of Convertible Preferred Stock (the Conversion Rate). The Conversion Rate is initially equal to the number of shares of Common Stock convertible into Common Stock at a price \$0.01 above the consolidated closing bid price on the Initial Issue Date, or \$2.39 per share.

Subsequent to the Initial Issue Date, an Exchange Holder is not able to convert Convertible Preferred Stock into Common Stock to the extent that the Common Stock held by such Exchange Holder and its affiliates would exceed 4.985% of the Common Stock outstanding immediately after giving effect to the issuance of shares of Common Stock.

Moreover, at any time on or after the Initial Issue Date, the Company has the right to redeem the Convertible Preferred Stock, in whole or in part, at a redemption price equal to 100% of the liquidation preference of the shares to be redeemed, plus any accrued and unpaid dividends. Except as required by law or the Articles Supplementary, the Exchange Holders of Convertible Preferred Stock have no voting rights (other than with respect to certain matters regarding the Convertible Preferred Stock).

In accordance with the Articles Supplementary, the Company will not authorize, declare or pay regular or special dividends or other distributions (whether in the form of cash, shares, indebtedness or any other property or asset, but excluding any purchase, redemption or other acquisition of shares) on the shares of the Common Stock, unless simultaneously with the authorization, declaration or payment, it authorizes, declares or pays, as applicable, dividends or other distributions on the Convertible Preferred Stock.

The Equitization Exchange Agreements

On August 1, 2018, the Company entered into separate Equitization Exchange Agreements (the Equitization Exchange Agreements) by and among Pernix and certain holders (each, an Equitization Holder, and collectively the Equitization Holders) of Pernix's Treximet Secured Notes. Pursuant to the Equitization Exchange Agreements, the Company issued 650,190 shares of its Common Stock in exchange for approximately \$1.5 million aggregate principal amount of Treximet Secured Notes held by such Equitization Holders plus accrued and unpaid interest thereon (Equitization Transaction).

Amended ABL Facility and Term Facility

On August 1, 2018 the Company entered into an amendment of its ABL Facility (as defined below) (together with the Term Facility, the Credit Facilities), as well as an amendment to the Term Facility. These amendments were made to permit the exchange of the Treximet Secured Notes into Common Stock in the Exchange Transactions and Equitization Transaction, and to amend certain terms of the Credit Facilities, including (i) certain changes to the borrowing base calculation under the ABL Facility that are intended to improve the Company's borrowing capacity under the ABL Facility and that will also permit the Company, among other things, to include Contrave inventory owned by the Company in the calculation of the borrowing base, (ii) changes to permit the use of subsequent draws under the Term Facility for working capital or other general corporate purposes, (iii) a reduction in the commitments under the ABL Facility from \$40.0 million to \$32.5 million, and (iv) changes to the interest payment provisions under the Term Facility increasing the minimum percentage of interest that must be paid in cash to 6.00% per annum from 4.50% per annum.

Note 2. Basis of Presentation and Summary of Significant Accounting Policies

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements included herein have been prepared by the Company in accordance with generally accepted accounting principles in the United States (GAAP) and under the rules and regulations of the United States Securities and Exchange Commission (SEC) for interim reporting. In management's opinion, the interim financial data presented includes all adjustments (consisting solely of normal recurring items) necessary for fair presentation. All intercompany accounts and transactions have been eliminated. Certain information required by GAAP has been condensed or omitted in accordance with rules and regulations of the SEC. Operating results for the three and six months ended June 30, 2018 are not necessarily indicative of the results that may be expected for any future period or for the year ending December 31, 2018.

These unaudited condensed consolidated financial statements should be read in conjunction with the Company's audited consolidated financial statements and the notes thereto for the year ended December 31, 2017, included in Pernix's 2017 Annual Report on Form 10-K filed with the SEC.

The preparation of the unaudited condensed consolidated financial statements requires management to make estimates and assumptions relating to reporting of the assets and liabilities and the disclosure of contingent assets and liabilities to prepare these unaudited condensed consolidated financial statements and the reported amounts of revenues and expenses during the reporting period in conformity with GAAP. Significant estimates of the Company include: revenue recognition, sales allowances such as returns on product sales, government program rebates, customer coupon redemptions, wholesaler/pharmacy discounts, product service fees, rebates and chargebacks, sales commissions, amortization, stock-based compensation, the determination of fair values of assets and liabilities in connection with business combinations, and deferred income taxes. Actual results could differ from these estimates.

Certain prior period amounts have been reclassified to conform to the current period presentation including reclassifying capitalized debt issuance costs of approximately \$1.5 million from "Prepaid expenses and other current

assets" to the Company's long-term debt instruments within "Total liabilities" except for those related to revolving credit facilities. This reclassification had no effect on previously reported results of operations, financial position or cash flows.

Principles of Consolidation

The unaudited condensed consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. All significant intercompany balances and transactions have been eliminated in consolidation.

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 (Topic 606)* which supersedes nearly all existing revenue recognition guidance. Effective January 1, 2018, the Company adopted ASU No. 2014-09, *Revenue from Contracts with Customers* (ASC 606) and all the related amendments (new revenue standard) to all contracts using the modified retrospective method. No material differences were identified as compared to the Company's historical revenue recognition accounting and accordingly, the Company did not recognize a cumulative effect of applying the new revenue standard as an adjustment to the opening balance of retained earnings. The comparative information has not been restated and continues to be reported under the accounting standards in effect for those periods. The Company does not expect the adoption of the new revenue standard to have a material impact to the Company's net income on an ongoing basis.

The Company's new revenue recognition policy is as follows:

Revenue is recognized upon transfer of control of promised products or services to customers in an amount that reflects the consideration the Company expects to receive in exchange for those products or services. The Company generally enters into contracts to sell approved branded and generic pharmaceutical drugs.

- Product Sales

Product sales revenue is recognized at the estimated consideration to be received when control has transferred to the customer, which is typically on delivery to the customer or, in the case of products that are subject to consignment agreements, when the customer removes product from the Company's consigned inventory location for shipment directly to a patient. Payment terms vary by customer and the products or services offered and is generally required in a term ranging from 30 to 90 days from date of shipment or satisfaction of the performance obligation.

- Significant Judgments

Product sales contracts provide the customer with the right to return the product and also provide for a variety of discounts and allowances including, specialty distributor fees, wholesaler fees, prompt payment discounts, government rebates, government chargebacks, coupon programs and rebates under managed care plans which are accounted for as variable consideration. Returns are estimated through comparison of historical return data to their related sales on a production lot basis. Historical rates of return are determined for each product and are adjusted for known or expected changes in the marketplace specific to each product, when appropriate.

Judgment is required to estimate the appropriate adjustments for variable consideration which is based on sales or invoice data, contractual terms, historical utilization rates, new information regarding changes in these programs' regulations and guidelines that would impact the amount of the actual rebates, the Company's expectations regarding future utilization rates for these programs and channel inventory data.

- Contract Balances

The timing of customer invoicing generally does not differ from the timing of revenue recognition. The Company records provisions for returns, specialty distributor fees, wholesaler fees, government rebates, coupon programs and rebates under managed care plans are included within current liabilities in the Company's consolidated balance sheets. Provision for prompt payment discounts are generally shown as a reduction in accounts receivable.

In May 2017, the FASB issued ASU 2017-09, *Compensation-Stock Compensation (Topic 718): Scope of Modification Accounting*, (ASU 2017-09). ASU 2017-09 provides clarity and reduces both (1) diversity in practice and (2) cost and complexity when applying the guidance in Topic 718, to a change to the terms or conditions of a share-based payment award. ASU 2017-09 is effective for the interim and annual periods beginning after December 15, 2017. The Company adopted the provisions of ASU 2017-09 as of January 1, 2018. There was no material impact on the Company's condensed consolidated financial statements resulting from the adoption of this guidance.

In January 2017, the FASB issued ASU 2017-01, *Business Combinations (Topic 805): Clarifying the Definition of a Business*, which changes the definition of a business to assist entities with evaluating when a set of transferred assets and activities is deemed to be a business. Determining whether a transferred set constitutes a business is important because the accounting for a business combination differs from that of an asset acquisition. The definition of a business also affects the accounting for dispositions. Under the new standard, when substantially all of the fair value of assets acquired are concentrated in a single asset, or a group of similar assets, the assets acquired would not represent a business and business combination accounting would not be required. The new standard may result in more transactions being accounted for as asset acquisitions rather than business combinations. The standard is effective for interim and annual periods beginning after December 15, 2017 and shall be applied prospectively. The Company adopted ASU 2017-01 as of January 1, 2018, and there was no material impact on the Company's condensed consolidated financial statements resulting from the adoption of this guidance.

In August 2016, the FASB issued ASU 2016-15 *Statement of Cash Flows - Classification of Certain Cash Receipts and Cash Payments*, which provides updated guidance on eight classification issues related to the statement of cash flows: debt prepayments and extinguishment costs, settlement of zero-coupon bonds, contingent consideration payments made after a business combination, proceeds from the settlement of insurance claims, proceeds from the settlement of corporate-owned life insurance policies, distributions received from equity method investees, beneficial interests in securitization transactions and separately identifiable cash flows and application of the predominance principle. ASU 2016-15 is effective for interim and annual periods beginning after December 15, 2017. The Company adopted the provisions of ASU 2016-15 as of January 1, 2018. There was no material impact on the Company's results of operations resulting from the adoption of this guidance.

In January 2016, the FASB issued ASU 2016-01, *Financial Instruments-Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities*. The accounting standard primarily affects the accounting for equity investments, financial liabilities under the fair value option, and the presentation and disclosure requirements for financial instruments. In addition, it includes a clarification related to the valuation allowance assessment when recognizing deferred tax assets resulting from unrealized losses on available-for-sale debt securities. The accounting guidance is effective for annual reporting periods (including interim periods within those periods) beginning after December 15, 2017. The Company adopted ASU 2016-01 as of January 1, 2018, and there was no material impact on the Company's condensed consolidated financial statements resulting from the adoption of this guidance.

Recently Issued Accounting Standards, Not Adopted as of June 30, 2018

In March 2018, the FASB issued ASU No. 2018-05, *Income Taxes (Topic 740): Amendments to SEC Paragraphs Pursuant to SEC Staff Accounting Bulletin No. 118* which allowed SEC registrants to record provisional amounts in earnings for the year ended December 31, 2017 due to the complexities involved in accounting for the enactment of the U.S. Tax Cuts and Jobs Act (TCJA) on December 22, 2017. The Company continues to analyze the TCJA, see Note 10, Income taxes for more information.

Management does not believe that any other recently issued, but not yet effective, accounting standards if currently adopted would have a material effect on the Company's consolidated financial statements.

Significant Customers

The Company's customers consist of drug wholesalers, specialty pharmacies, retail drug stores, mass merchandisers and grocery store pharmacies in the United States. The Company primarily sells its products directly to large national drug wholesalers, which in turn resell the products to smaller or regional wholesalers, retail pharmacies, chain drug stores, and other third parties. The following tables list the Company's customers that individually comprised greater than 10% of total gross product sales for the three and six months ended June 30, 2018 and 2017, or 10% of total accounts receivable as of June 30, 2018 and December 31, 2017.

Gross Product Sales:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
McKesson Corporation	32%	34%	33%	34%
AmerisourceBergen Drug Corporation	27%	33%	27%	31%
Cardinal Health, Inc.	21%	23%	24%	25%
Total	80%	90%	84%	90%

Accounts Receivable, net:

	June 30, 2018	December 31, 2017
Cardinal Health, Inc.	38%	31%
McKesson Corporation	30%	29%
AmerisourceBergen Drug Corporation	23%	27%
Total	91%	87%

Note 3. Earnings per Share

Basic net income (loss) per common share is the amount of net income (loss) for the period divided by the weighted average shares of Common Stock outstanding during the reporting period. Diluted income (loss) per common share is the amount of income (loss) for the period plus interest expense on convertible debt divided by the sum of weighted average shares of Common Stock outstanding during the reporting period and weighted average shares that would have been outstanding assuming the issuance of common shares for all dilutive potential common shares.

The following table sets forth the computation of basic and diluted net loss per share (in thousands except per share data):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Numerator:				
Net loss	\$ (13,513)	\$ (21,616)	\$ (32,097)	\$ (51,078)
Denominator:				
Weighted-average common shares, basic	11,913	10,016	11,907	10,016
Dilutive effect of stock options	-	-	-	-
Weighted-average common shares, diluted	\$ 11,913	\$ 10,016	\$ 11,907	\$ 10,016
Net loss per share, basic and diluted	\$ (1.13)	\$ (2.16)	\$ (2.70)	\$ (5.10)

The following table sets forth the potential common shares that could potentially dilute basic income per share in the future that were not included in the computation of diluted income (loss) per share because to do so would have been anti-dilutive for the periods presented (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
4.25% Convertible Notes	682	1,133	682	1,133
Exchangeable Notes	6,499	-	6,499	-
Stock options and restricted stock units	1,303	615	1,295	581
Warrants	4	33	4	33
Total potential dilutive effect	8,488	1,781	8,480	1,747

Note 4. Fair Value Measurement

The Company's financial assets and liabilities are measured using inputs from the three levels of the fair value hierarchy. The three levels are as follows:

Level 1- Inputs are unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the ability to access at the measurement date.

Level 2- Inputs are other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly. Level 2 inputs include quoted prices for similar assets and liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active, inputs other than quoted prices that are observable for the asset or liability (i.e., interest rates, yield curves, etc.), and inputs that are derived principally from or corroborated by observable market data by correlation or other means (market corroborated inputs).

Level 3- Inputs are unobservable and reflect the Company's assumptions that market participants would use in pricing the asset or liability. The Company develops these inputs based on the best information available.

Summary of Assets Recorded at Fair Value

The Company's cash equivalents are classified within Level 1 of the fair value hierarchy because they are valued using quoted market prices or broker or dealer quotations for similar assets.

The Company had no financial assets that are required to be measured at fair value as of June 30, 2018 and December 31, 2017.

There were no transfers of assets or liabilities between Level 1 and Level 2 during the three and six months ended June 30, 2018 and 2017.

The carrying amounts reflected in the unaudited condensed consolidated balance sheets for certain short-term financial instruments including accounts receivable, accounts payable, accrued expenses, and other liabilities approximate fair value due to their short-term nature.

Summary of Liabilities Recorded at Carrying Value and Fair Value

The 4.25% Convertible Notes, Exchangeable Notes, Delayed Draw Term Loan and the Treximet Secured Notes (each, as defined below in Note 8) are recorded at carrying value. The derivative liability and contingent consideration are recorded at fair value. Within the hierarchy of fair value measurements, the derivative liability and contingent consideration are Level 3 fair values. The fair and carrying value of our debt instruments are detailed as follows (in thousands):

	As of June 30, 2018		As of December 31, 2017	
	Fair Value	Carrying Value	Fair Value	Carrying Value
4.25% Convertible Notes	\$ 37,473	\$ 66,928	\$ 36,208	\$ 65,194
Exchangeable Notes	21,207	9,016	21,375	7,975
Delayed draw term loan	30,601	28,183	30,300	27,248
Derivative liability	72	72	93	93
Contingent consideration	1,501	1,501	1,358	1,358
Treximet Secured Notes	139,395	162,853	139,201	167,551
Total	\$ 230,249	\$ 268,553	\$ 228,535	\$ 269,419

4.25% Convertible Notes, Exchangeable Notes and Delayed Draw Term Loan

The fair values of the 4.25% Convertible Notes, the Exchangeable Notes and the Delayed Draw Term Loan were estimated using the (i) terms of the agreements; (ii) rights, preferences, privileges, and restrictions of the underlying security; (iii) time until any restriction(s) are released; (iv) fundamental financial and other characteristics of the Company; (v) trading characteristics of the underlying security (exchange, volume, price, and volatility); (vi) valuation of derivative liability; and (vii) precedent sale transactions.

Given the nature and the variable interest rates under the ABL Facility (as defined below), the fair value of borrowings under this facility approximated their carrying value as of June 30, 2018.

Derivative Liability

The fair value of the derivative liability was determined using a "with and without" conversion scenario. Under this methodology, valuations are performed on the 4.25% Convertible Notes inclusive of all terms as well as for a convertible note that has identical terms and features but excluding the conversion option. The difference between the two valuations is equal to the fair value of the conversion option. Significant increases or decreases in these inputs would result in a significant change in the fair value of the derivative liability.

Contingent Consideration

The fair value of contingent consideration is based on two components - a regulatory milestone and commercial milestone.

For the regulatory milestone, the expected regulatory earn out payment was discounted taking into account (a) the Company's cost of debt, (b) the expected timing of the payment and (c) subordinate nature of the earn out obligation.

The fair value of the commercial milestone was determined using a Monte Carlo simulation. This simulation assumed a risk-neutral framework, whereby future net revenue was simulated over the earn out period using the Geometric Brownian Motion. For each simulation path, the earn out payments were calculated based on the achievement of the revenue milestone and then were discounted to the valuation date. Significant increases or decreases in these unobservable inputs and/or the probability of achievement of these milestones would result in a significant change in the fair value of the contingent consideration.

Treximet Secured Notes

The fair value of the Company's Treximet Secured Notes was estimated using a discounted cash flow model.

Fair Value Measurements Using Significant Unobservable Inputs (Level 3)

For the Company's assets and liabilities measured at fair value on a recurring basis using significant unobservable inputs (Level 3), the following table provides a reconciliation of the beginning and ending balances for each category therein, and gains or losses recognized during the periods (in thousands).

	As of and for the Six months Ended June 30, 2018	As of and for the Six months Ended June 30, 2017
Derivative liability:		
Balance at beginning of year	\$ 93	\$ 230
Remeasurement adjustments - loss (gains) included in earnings	(21)	84
Ending Balance	\$ 72	\$ 314

Contingent consideration:

Edgar Filing: PERNIX THERAPEUTICS HOLDINGS, INC. - Form 10-Q

Balance at beginning of year	\$	1,358	\$	2,403
Remeasurement adjustments - loss (gains) included in earnings		143		(540)
Ending Balance	\$	1,501	\$	1,863

14

Note 5. Inventory

Inventories are stated at the lower of cost or market. Inventories consist of the following (in thousands):

	June 30, 2018	December 31, 2017
Raw materials	\$ 656	\$ 727
Work-in-process	-	238
Finished goods	5,868	5,889
Inventory, gross	6,524	6,854
Reserve for obsolescence	(1,466)	(1,458)
Inventory, net	\$ 5,058	\$ 5,396

Note 6. Goodwill and Intangible Assets

Goodwill consists of the following (in thousands):

	Amount
Balance at December 31, 2016	\$ 30,600
Goodwill impairment	(18,500)
Balance at December 31, 2017	12,100
Goodwill impairment	-
Balance at June 30, 2018	\$ 12,100

The Company performs an impairment test of goodwill annually in the fourth quarter of each fiscal year unless there are triggering events that would require such analysis during an interim period. There were no triggering events during the six months ended June 30, 2018. For the year ended December 31, 2017, the carrying value of the reporting unit exceeded its fair value by \$18.5 million and accordingly an impairment charge of \$18.5 million was recorded in 2017. The decline in the estimated fair value of the reporting unit resulted from management's review of its then-current forecast. As a result of this review, management lowered its forecast for Zohydro ER. The lower projected operating results reflected changes in assumptions related to revenue, market trends, cost structure, and other expectations about the anticipated short-term and long-term operating results of the business.

Intangible assets consist of the following (dollars in thousands):

	As of June 30, 2018				
	Weighted Average Life Remaining	Gross Carrying Amount	Impairment	Accumulated Amortization	Net Carrying Amount
Unamortized intangible assets:					
In-process research and development	Indefinite	\$ 11,000	\$ -	\$ -	\$ 11,000
Total unamortized intangible assets		11,000	-	-	11,000
Amortized intangible assets:					
Product licenses	5.0 years	2,846	-	(1,756)	1,090
Supplier contracts	2.8 years	583	-	(253)	330
Acquired developed technologies	14.7 years	364,686	-	(291,682)	73,004
Total amortized intangible assets		368,115	-	(293,691)	74,424
Total intangible assets		\$ 379,115	\$ -	\$ (293,691)	\$ 85,424

Edgar Filing: PERNIX THERAPEUTICS HOLDINGS, INC. - Form 10-Q

As of December 31, 2017					
	Weighted Average Life Remaining	Gross Carrying Amount	Impairment	Accumulated Amortization	Net Carrying Amount
Unamortized intangible assets:					
In-process research and development	Indefinite	\$ 11,000	\$ -	\$ -	\$ 11,000
Total unamortized intangible assets		11,000	-	-	11,000
Amortized intangible assets:					
Product licenses	5.4 years	2,846	-	(1,623)	1,223
Supplier contracts	3.3 years	583	-	(194)	389
Acquired developed technologies	13.7 years	364,686	-	(280,692)	83,994
Total amortized intangible assets		368,115	-	(282,509)	85,606
Total intangible assets		\$ 379,115	\$ -	\$ (282,509)	\$ 96,606

As of June 30, 2018, the weighted average remaining life for our definite-lived intangible assets in total was approximately 14.5 years.

In process research and development (IPR&D) will be amortized on a straight-line basis over its useful life once the receipt of regulatory approval is obtained.

Estimated amortization expense related to intangible assets with definite lives for each of the five succeeding years and thereafter is as follows (in thousands):

	Amount
2018 (July - December)	\$ 2,754
2019	5,507
2020	5,420
2021	5,325
2022	5,286
Thereafter	50,132
Total	\$ 74,424

Amortization expense was \$1.4 million and \$11.2 million for the three months and six months ended June 30, 2018, respectively, of which, \$27,000 and \$56,000 are included in cost of product sales in the unaudited condensed consolidated statements of operations for the three and six months ended June 30, 2018, respectively. Amortization expense was \$18.1 million and \$36.6 million for the three and six months ended June 30, 2017, respectively, of which, \$29,000 and \$58,000 are included in cost of product sales in the unaudited condensed consolidated statements of operations for the three and six months ended June 30, 2017, respectively

Note 7. Accrued Allowances

Accrued allowances consist of the following (in thousands):

	June 30, 2018	December 31, 2017
Accrued returns allowance	\$ 25,218	\$ 21,681
Accrued price adjustments	11,450	10,766
Accrued managed care rebates	11,358	17,221
Accrued government program rebates	5,994	6,641
Total	\$ 54,020	\$ 56,309

Note 8. Debt and Lines of Credit

Debt, net of discounts and deferred financing costs, consists of the following (in thousands):

	As of June 30, 2018				As of December 31, 2017			
	Principal	Note Discount	Deferred Financing Costs	Net of Discount and Deferred Financing Costs	Principal	Note Discount	Deferred Financing Costs	Net of Discount and Deferred Financing Costs
4.25% Convertible Notes	\$ 78,225	\$ (9,588)	\$ (1,709)	\$ 66,928	\$ 78,225	\$ (11,060)	\$ (1,971)	\$ 65,194
Exchangeable Notes	35,743	(23,450)	(3,277)	9,016	35,743	(24,363)	(3,405)	7,975
Delayed Draw Term Loan	30,601	-	(2,418)	28,183	30,000	-	(2,752)	27,248
Treximet Secured Notes - Long Term	166,697	-	(3,844)	162,853	166,697	-	(2,810)	163,887
Treximet Secured Notes - Short Term	-	-	-	-	5,373	-	(1,709)	3,664
ABL Credit Agreement	14,185	-	-	14,185	14,185	-	-	14,185
Total outstanding debt	\$ 325,451	\$ (33,038)	\$ (11,248)	\$ 281,165	\$ 330,223	\$ (35,423)	\$ (12,647)	\$ 282,153
Less: Current portion of long-term debt				-				3,664
Long-term debt outstanding, net				\$ 281,165				\$ 278,489

Convertible Notes:

4.25% Convertible Notes

On April 22, 2015, the Company issued \$130.0 million aggregate principal amount 4.25% Convertible Notes. The 4.25% Convertible Notes mature on April 1, 2021, unless earlier converted, redeemed or repurchased. Interest on the 4.25% Convertible Notes is payable on April 1 and October 1 of each year, beginning October 1, 2015.

The 4.25% Convertible Notes are governed by the terms of an indenture, between the Company and Wilmington Trust, National Association, each of which were entered into on April 22, 2015. The Company may not redeem the 4.25% Convertible Notes prior to April 6, 2019. However, the holders may convert their 4.25% Convertible Notes at any time prior to the close of business on the business day immediately preceding January 1, 2021 only under certain circumstances. The effective interest rate on the 4.25% Convertible Notes, including debt issuance costs and bifurcated conversion option derivative (discussed below), is 10.4%.

The Company is required to separate the conversion option in the 4.25% Convertible Notes under Accounting Standards Codification (ASC) 815, *Derivatives and Hedging*. During April 2015, the Company recorded the bifurcated conversion option valued at \$28.5 million as a derivative liability, which created a discount on the debt. The derivative liability is marked to market through the other income (expense) section on the unaudited condensed consolidated statements of operations for each reporting period, while the discount created on the 4.25% Convertible Notes is accreted as interest expense over the life of the debt. The derivative liability is valued at \$72,000 and \$93,000 as of June 30, 2018 and December 31, 2017, respectively.

Interest expense was \$1.7 million and \$3.4 million for the three and six months ended June 30, 2018, respectively, and \$2.5 million and \$5.0 million for the three and six months ended June 30, 2017, respectively, related to the 4.25% Convertible Notes. Interest expense includes amortization of deferred financing costs and accretion of debt discount.

Change in fair value of derivative liability was a benefit of \$40,000 and \$21,000 for the three and six months ended June 30, 2018, respectively, and a benefit of \$270,000 and an expense of \$84,000 for the three and six months ended June 30, 2017, respectively. Accrued interest on the 4.25% Convertible Notes was approximately \$831,000 as of June 30, 2018 and December 31, 2017.

As a result of the Exchangeable Notes transaction during the third quarter of 2017, the Company recorded \$14.7 million as gain from exchange of debt for the three months ended September 30, 2017.

Exchangeable Notes

On July 20, 2017, the Company entered into an exchange agreement (the 2017 Exchange Agreement) with certain holders of its 4.25% Convertible Notes (Holders) pursuant to which \$51.8 million of aggregate principal amount of its 4.25% Convertible Notes held by the Holders were exchanged for (i) \$36.2 million aggregate principal amount of 4.25%/5.25% Exchangeable Senior Notes due 2022 (the Exchangeable Notes), issued by PIP DAC pursuant to an Indenture, dated July 21, 2017 (the Exchangeable Notes Indenture), among PIPL, the guarantors party thereto (the Guarantors), and Wilmington Trust, National Association, as Trustee and (ii) 1,100,498 shares of Common Stock.

The Exchangeable Notes issued under the Exchangeable Notes Indenture are guaranteed by the Company and each other subsidiary thereof. The Exchangeable Notes are senior, unsecured obligations of PIP DAC. Interest on the Exchangeable Notes will be paid in cash or a combination of cash and in-kind interest at PIP DAC's election. Interest paid in cash (the All Cash Method) will accrue at a rate of 4.25% per annum, while interest paid in a combination of cash and in-kind will accrue at a rate of 5.25% per annum, with 2.25% per annum (plus additional interest, if any) capitalized to the principal amount of the Exchangeable Notes, and the balance paid in cash. The maturity date of the Exchangeable Notes Indenture is July 15, 2022. The Exchangeable Notes initially are exchangeable into shares of Common Stock at an exchange price per share of \$5.50 (the Exchange Price).

The 2017 Exchange Agreement allowed the Company to reduce the principal amount of its outstanding indebtedness through the exchange of the Holders' 4.25% Convertible Notes for a smaller principal amount of the Exchangeable Notes. The principal amount of the Exchangeable Notes may be reduced if the Holders thereof exchange their Exchangeable Notes for shares of Common Stock. The Exchangeable Notes Indenture will provide capacity to refinance up to an additional \$25.0 million principal amount of the 4.25% Convertible Notes, which refinancing could also provide an opportunity to further reduce the principal amount of the Company's outstanding indebtedness.

The outstanding borrowings of the Exchangeable Notes were paid down by \$500,000 in November 2017 with a portion of the proceeds from the sale of certain non-core assets. Interest expense was \$1.0 million and \$2.0 million for the three and six months ended June 30, 2018, respectively, and included amortization of deferred financing costs and accretion of debt discount. Accrued interest on the Exchangeable Notes was approximately \$860,000 and \$675,000 as of June 30, 2018 and December 31, 2017, respectively.

Term Facility:

On July 21, 2017 PIP DAC entered into a term loan credit agreement (the Delayed Draw Term Loan, the Term Facility or DDTL) with Cantor Fitzgerald Securities, as agent Securities, as agent, and the lenders party thereto to obtain the DDTL. \$30.0 million under the DDTL was drawn on July 21, 2017 in connection with the closing of several refinancing transactions and the remaining \$15.0 million will be available for subsequent draws for certain specified purposes, including to finance certain acquisitions, subject to conditions set forth in the Term Credit Agreement. The DDTL includes an incremental feature that allows PIP DAC, with the consent of the requisite lenders under the Term Facility, to obtain up to an additional \$20.0 million in term loan commitments. Interest on the loans will accrue either in cash or a combination of cash and in kind interest, at PIP DAC's election. Cash interest will accrue at a rate of 7.50% per annum, while the combination of cash and in-kind interest will accrue at a rate of 8.50% per annum, with up to 4.00% per annum added to the principal amount of loans and the balance paid in cash. The DDTL will mature on July 21, 2022. During the first quarter of 2018, PIP DAC elected the PIK option in lieu of making scheduled interest payments. The election increased the principal due on the DDTL by \$601,000 as of June 30, 2018.

On July 27, 2018, PIP DAC drew \$9.2 million under the DDTL. The proceeds were used to fund the Company's investment in Nalpropion for Nalpropion's purchase of certain assets of Orexigen and for working capital requirements.

PIP DAC also entered into a mortgage debenture with Cantor Fitzgerald Securities as agent, pursuant to which PIP DAC's obligations under the DDTL will be secured by substantially all of the assets of PIP DAC and its future-acquired subsidiaries.

Interest expense was approximately \$816,000 and \$1.6 million for the three and six months ended June 30, 2018 related to the DDTL and includes amortization of deferred financing costs. Accrued interest on the DDTL was approximately \$489,000 and \$484,000 as of June 30, 2018 and December 31, 2017, respectively.

On August 1, 2018 the Company entered into an amendment of its Term Facility. These amendments were made to permit the exchange of the Treximet Secured Notes into Common Stock in the Exchange Transactions and Equitization Transaction, and to amend certain terms of the Credit Facilities, including (i) changes to permit the use of subsequent draws under the Term Facility for working capital or other general corporate purposes, and (ii) changes to the interest payment provisions under the Term Facility increasing the minimum percentage of interest that must be paid in cash to 6.00% per annum from 4.50% per annum.

Secured Notes:

Treximet Note Offering

On August 19, 2014, the Company issued \$220.0 million aggregate principal amount of its Treximet Secured Notes pursuant to an Indenture (the August 2014 Indenture) dated as of August 19, 2014 among the Company, certain of its subsidiaries (the Treximet Guarantors) and U.S. Bank National Association (the August 2014 Trustee), as trustee and collateral agent.

On April 13, 2015, the Company amended the August 2014 Indenture to allow the Company to, among other things, incur up to \$42.2 million of additional debt. On December 29, 2017, the Company and the August 2014 Trustee entered into a third supplemental indenture to amend the August 2014 Indenture to clarify the definition of "Net Sales", as such term is defined in the August 2014 Indenture and resulted in the deferral of \$3.2 million of principal payments until maturity of the notes.

The Treximet Secured Notes mature on August 1, 2020 and bear interest at a rate of 12% per annum, payable in arrears on February 1 and August 1 of each year (each, a Payment Date), beginning on February 1, 2015. On each Payment Date, commencing August 1, 2015, the Company began paying installments of principal of the Treximet Secured Notes in an amount equal to 50% of net sales of Treximet for the two consecutive fiscal quarters immediately preceding such Payment Date (less the amount of interest paid on the Treximet Secured Notes on such Payment Date). At each month-end beginning with January 2015, the net sales of Treximet will be calculated, the monthly interest accrual amount will then be deducted from the net sales and this resulting amount will be recorded as the current portion of the Treximet Secured Notes. If the Treximet net sales less the interest due at the end of each six-month period does not result in any excess over the interest due, no principal payment must be paid at that time. The remaining balance outstanding on the Treximet Secured Notes will be due on the maturity date, which is August 1, 2020. As of December 31, 2017, the Company classified \$5.4 million, of the Treximet Secured Notes as a current liability and \$166.7 million as a non-current liability at both June 30, 2018 and December 31, 2017.

The Treximet Secured Notes are secured by a continuing first-priority security interest in substantially all of the assets of the Company and the Treximet Guarantors related to Treximet other than inventory and certain inventory related assets, including accounts arising from the sale of the inventory.

Interest expense related to the Treximet Secured Notes was \$5.5 million and \$11.0 million for the three and six months ended June 30, 2018, respectively, and was \$5.7 million and \$11.6 million for the three and six months ended June 30, 2017, respectively. Interest expense includes amortization of deferred financing costs. Accrued interest on the Treximet Secured Notes was approximately \$8.3 million and \$8.6 million as of June 30, 2018 and December 31, 2017, respectively.

On August 1, 2018, the Company entered into the 2018 Exchange Agreement with the Exchange Holders for newly issued shares of Common Stock and shares of Convertible Preferred Stock.

The exchange transactions closed on August 1, 2018 and were as follows:

- exchange of approximately \$2.7 million aggregate principal amount of the Treximet Secured Notes for 1,204,586 shares of Common Stock which includes accrued and unpaid interest on the Treximet Secured Notes;
- exchange of \$8.0 million principal amount of the Treximet Secured Notes plus \$100,000 of accrued and unpaid interest for 81,000 shares of Convertible Preferred Stock.

The 2018 Exchange Agreement affords the Exchange Holders the right to exchange up to an additional \$65.1 million aggregate principal amount of the Treximet Secured Notes plus accrued and unpaid interest, until February 1, 2020.

On August 1, 2018, the Company entered into separate Equitization Exchange Agreements by and among Pernix and certain Equitization Holders of Treximet Secured Notes. Pursuant to the Equitization Exchange Agreements, the Company issued 650,190 shares of its Common Stock in exchange for approximately \$1.5 million aggregate principal amount of Treximet Secured Notes held by such Equitization Holders plus accrued and unpaid interest thereon. This transaction closed on August 1, 2018.

Credit Facility

:

Cantor Fitzgerald

On July 21, 2017, Pernix and certain subsidiaries of Pernix as borrowers and guarantors (the ABL Borrowers) and PIP DAC, Pernix Ireland Limited, Pernix Holdco 1, LLC, Pernix Holdco 2, LLC and Pernix Holdco 3, LLC as additional guarantors (the ABL Guarantors), entered into an asset-based revolving credit agreement (the ABL Credit Agreement) with Cantor Fitzgerald Securities, as agent (the ABL Agent) and the lenders party thereto to obtain a five-year \$40 million asset-based revolving credit facility (the ABL Facility). On April 23, 2018, the Company entered into an amendment, effective as of April 12, 2018, to modify the borrowing base formula which determines the Company's capacity to draw on the ABL Facility, which could increase such capacity. The amendment also removed concentration limits for accounts receivable due from individual customers or other account debtors that may be included in the borrowing base.

The ABL Borrowers' obligations under the ABL Credit Agreement are guaranteed by the ABL Borrowers and the ABL Guarantors are secured by, among other things, the ABL Borrowers' cash, inventory and accounts receivable, in each case pursuant to a guaranty and security agreement between the ABL Borrowers, ABL Guarantors and Cantor Fitzgerald Securities as agent. Borrowings under the ABL Credit Agreement bear interest at the rate of LIBOR plus 7.50%, payable monthly, in addition to a commitment fee on any undrawn commitments at a rate per annum of 0.25%, payable monthly. The ABL Credit Agreement contains representations and warranties, affirmative and negative covenants, and events of default applicable to the Company, the other ABL Borrowers, the ABL Guarantors and their respective subsidiaries that are customary for credit facilities of this type. The ABL Credit Agreement will mature on July 21, 2022.

Interest expense was \$499,000 and \$978,000 for the three and six months ended June 30, 2018 related to the ABL Credit Agreement and includes amortization of deferred financing costs. Accrued interest on the ABL Credit Agreement was approximately \$9,000 and \$19,000 as of June 30, 2018 and December 31, 2017, respectively. As of June 30, 2018, unamortized debt issuance costs of \$581,000 and \$1.8 million are recorded on the unaudited consolidated balance sheets in Prepaid expenses and other current assets and Other assets, respectively, and are being amortized to interest expense over the life of the agreement. As of December 31, 2017, \$581,000 and \$2.1 million of unamortized debt issuance costs are recorded on the unaudited consolidated balance sheets in Prepaid expenses and

other current assets and Other assets, respectively.

On August 1, 2018 the Company entered into an amendment of the ABL Facility. The amendment provides for (i) certain changes to the borrowing base calculation under the ABL Facility that are intended to improve the Company's borrowing capacity under the ABL Facility and that will also permit the Company, among other things, to include Contrave inventory owned by the Company in the calculation of the borrowing base, and (ii) a reduction in the commitments under the ABL Facility from \$40.0 million to \$32.5 million.

Wells Fargo

On August 21, 2015, the Company entered into the Credit Agreement with Wells Fargo, as Administrative Agent and the lenders party thereto for a \$50.0 million, three-year senior secured revolving credit facility (the Wells Fargo Credit Facility).

The ABL Facility entered into on July 21, 2017 replaced the Wells Fargo Credit Facility and the Company used the proceeds from the ABL Facility to repay the outstanding obligation of the Wells Fargo Credit Facility.

Interest expense including amortization of deferred financing costs related to the Wells Fargo Credit Facility amounted to \$478,000 and \$606,000, for the three and six months ending June 30, 2017, respectively.

The following table represents the future maturity schedule of the outstanding debt and line of credit at June 30, 2018 (in thousands):

	Amount
2018 (July - December)	\$ -
2019	-
2020	166,697
2021	78,225
2022	80,529
Thereafter	-
Total maturities	325,451
Less:	
Note discount	(33,038)
Deferred financing costs	(11,248)
Total outstanding debt, net	\$ 281,165

Note 9. Stockholders' Equity

Convertible Preferred Stock

In connection with the 2018 Exchange Agreement, the Company reclassified and designated 1,500,000 shares of the authorized but unissued preferred stock of the Company to the Convertible Preferred Stock, see Note 1, Company Overview for more information.

Controlled Equity Offering

On November 7, 2014, the Company entered into a controlled equity offering sales agreement (the Sales Agreement) with Cantor Fitzgerald & Co. (Cantor) pursuant to which the Company could issue and sell shares of its Common Stock having an aggregate offering price of up to one hundred million dollars, pursuant to an effective registration statement on Form S-3 (No. 333-200005), from time to time through Cantor, acting as agent. On November 22, 2017, the Company filed a registration statement on Form S-3 (No. 333-221717) to replace the previously-filed registration statement, which was subsequently declared effective by the SEC on December 18, 2017.. The Company will pay Cantor a commission rate of 3.0% of the gross sales price per share of the Common Stock sold through Cantor as agent under the Sales Agreement.

During the six months ended June 30, 2018, the Company sold 191,170 shares of Common Stock under the Sales Agreement at an average price of approximately \$2.51 per share for gross proceeds of \$480,000 and net proceeds of \$453,000, after deducting commission and fees. The Company did not sell any shares of Common Stock during the six months ended June 30, 2017. As of June 30, 2018, approximately \$77.0 million of Common Stock remained available to be sold under this facility, subject to certain limitation to the extent the Company continues to have a public float of less than \$75.0 million.

Warrants

As of June 30, 2018, the Company has approximately 4,380 outstanding Common Stock warrants in connection with the acquisition of Somaxon Pharmaceuticals, Inc. (Somaxon) in March 2013, with exercise prices ranging from \$83.73 to \$258.21 and expiration dates ranging from August 2021 through December 2021.

Share-Based Compensation Plans

In November 2017, the Company's shareholders approved the 2017 Omnibus Incentive Plan (the 2017 Plan) for future equity awards granted by the Company. Subject to the adjustments described below, the maximum number of shares of Common Stock that will be available for issuance under the 2017 Omnibus Incentive Plan will be equal to the sum of (i) one million (1,000,000) shares of Common Stock plus (ii) the number of shares of our Common Stock available for future awards under the 2015 Omnibus Incentive Plan and the 2009 Stock Incentive Plan as of November 15, 2017, plus (iii) the number of shares of Common Stock related to awards outstanding under such plans as of November 15, 2017 that terminate after such date by expiration or forfeiture, cancellation, or otherwise without the issuance of such shares of Common Stock. On May 22, 2018, the Company's stockholders approved an amendment to the 2017 Plan to increase the number of shares reserved under the 2017 Plan from 642,294 shares of Common Stock to 1,242,294 shares of Common Stock.

Stock-Based Compensation

Stock-based compensation expense is recognized, net of an estimated forfeiture rate, on a straight-line basis over the requisite service period, which is the vesting period.

The Company uses the Black-Scholes option pricing model to determine the fair value of its stock options. The weighted average fair value of stock options granted during the periods and the assumptions used to estimate those values using the Black-Scholes option pricing mode were as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Weighted average expected stock price volatility	86.3%	86.9%	86.4%	85.4%
Estimated dividend yield	-	-	-	-
Risk-free interest rate	3.0%	1.9%	2.7%	2.1%
Expected life of option (in years)	6.3	6.2	6.3	6.2
Weighted average grant date fair value per option	\$ 1.95	\$ 3.09	\$ 1.86	\$ 2.12

The Company measures the grant date fair value of restricted stock units (RSUs) using the Company's closing Common Stock price on the grant date.

The accounting policy with respect to stock options and RSUs is described in the audited consolidated financial statements contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2017.

Stock-based compensation expense was \$0.5 million and \$0.9 million for the three and six months ended June 30, 2018, respectively and was \$0.7 million and \$1.4 million for the three and six months ended June 30, 2017. Stock-based compensation expense for the periods presented is included within the selling, general and administrative expense in the unaudited condensed consolidated statements of operations.

Stock Options

The following table shows the option activity, described above, during the six months ended June 30, 2018 (shares and intrinsic value in thousands):

	Shares	Average Exercise Price	Weighted Average Remaining Contractual Life (years)	Aggregate Intrinsic Value
Options Outstanding at December 31, 2017	1,042	\$ 13.80	8.8	
Granted	440	2.50		
Exercised	-	-		
Cancelled	(199)	11.48		
Expired	-	-		
Options outstanding at June 30, 2018	1,283	\$ 10.29	8.8	\$ 4
Options vested and expected to vest as of June 30, 2018	812	\$ 14.47	8.4	\$ 3
Options vested and exercisable as of June 30, 2018	233	\$ 34.84	7.0	\$ 1

As of June 30, 2018, there was approximately \$1.7 million of total unrecognized compensation cost related to non-vested stock options issued to employees and directors of the Company, which is expected to be recognized ratably over a weighted-average period of 2 years.

The total intrinsic value of options exercised during each of the three and six months ended June 30, 2018 and 2017 was \$0.

Options issued subsequent to January 2014 have a graded vesting schedule over either three or four years. The Company's stock option grants expire ten years from the date of grant.

Restricted Stock

The following table shows the Company's non-vested restricted stock activity during the six months ended June 30, 2018 (shares in thousands):

	Shares	Weighted Average Grant Date Fair Value
Non-vested restricted stock outstanding at December 31, 2017	135	\$ 3.17
Granted	62	2.46
Vested	(2)	2.33
Forfeited	(1)	2.78
Non-vested restricted stock outstanding at June 30, 2018	194	\$ 2.95

The total fair value of RSUs vested in the six months ended 2018 and 2017, were \$6,000 and \$0, respectively. As of June 30, 2018, there was \$0.2 million total unrecognized compensation cost related to non-vested restricted stock issued to employees and directors of the Company which is expected to be recognized ratably over a weighted-average period of 2.1 years.

Note 10. Income Taxes

On December 22, 2017, the TCJA (or Tax Act) was enacted reducing the corporate Federal tax rate from 35% to 21% effective for tax years beginning on or after January 1, 2018. ASC 740, *Income Taxes*, requires the effects of changes in tax laws to be recognized in the period in which the legislation is enacted. However, due to the complexity and significance of the TCJA's provisions and anticipated guidance from the U.S. Treasury and the Internal Revenue Service regarding the TCJA, the SEC staff issued Staff Accounting Bulletin 118, which allows companies to record the tax effects of the TCJA on a provisional basis based on a reasonable estimate, and then, if necessary, subsequently adjust such amounts during a limited measurement period as more information becomes available. The measurement period ends when a company has obtained, prepared, and analyzed the information necessary to finalize its

accounting, but cannot extend beyond one year from enactment of the TCJA.

Under the TCJA, the Corporate Alternative Minimum Tax (AMT) was repealed. The Company's previously recorded AMT credits of approximately \$0.2 million are now refundable subject to budgetary sequestration over a four-year period beginning in 2018, and the previously recorded valuation allowance for these AMT credits was reversed during the year ended December 31, 2017. The Company's Irish subsidiaries have accumulated deficits in earnings and profits and thus the Company will not be subject to the one-time transition tax.

The TCJA creates a new requirement that certain income (i.e., Global intangible low taxed income or GILTI) earned by foreign subsidiaries must be included currently in the gross income of the U.S. shareholder. Due to the complexity of the new GILTI tax rules, the Company is continuing to evaluate this provision of the Tax Act and the application of ASC 740. Under U.S. GAAP, the Company is permitted to make an accounting policy election to either treat taxes due on future inclusions in U.S. taxable income related to GILTI as a current-period expense when incurred or to factor such amounts into the Company's measurement of its deferred taxes. The Company has not yet completed its analysis of the GILTI tax rules and is not yet able to reasonably estimate the effect of this provision of the Tax Act or make an accounting policy election for the ASC 740 treatment of the GILTI tax. Therefore, the Company has not recorded any amounts related to potential GILTI tax in its consolidated financial statements and has not yet made a policy decision regarding whether to record deferred taxes on GILTI.

The Company reported an income tax expense of approximately \$9,000 and \$48,000 for the three and six months ended June 30, 2018, respectively and an income tax expense of approximately \$40,000 and \$95,000 for the three and six months ended June 30, 2017, respectively. The Company's effective tax rate was (0.1%) for the six months ended June 30, 2018, compared to an estimated annual effective rate of (0.2%) for the six months ended June 30, 2017.

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amount of the assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. All deferred tax assets were subject to a full valuation allowance as of June 30, 2018 and December 31, 2017.

The Company evaluates the realizability of its U.S. net deferred tax assets based on all available evidence, both positive and negative, on a quarterly basis. The realization of net deferred tax assets is dependent on the Company's ability to generate sufficient future taxable income during periods prior to the expiration of tax attributes to fully utilize these assets. The Company weighed both positive and negative evidence and determined that due to recent losses there is a continued need for a full valuation allowance against all of the Company's deferred tax assets as of June 30, 2018 and December 31, 2017.

As of June 30, 2018, the Company's gross deferred tax assets are comprised primarily of U.S. Federal net operating losses and accruals, and its gross deferred tax liabilities are comprised primarily of differences in the financial statement and tax bases of intangible assets.

The Company files income tax returns with both federal and state-level taxing authorities in the U.S., and with the taxing authorities of various foreign jurisdictions. The associated tax filings remain subject to examination by applicable tax authorities for a certain length of time following the tax year to which those filings relate. As of June 30, 2018, the Company's 2014 and 2015 Federal tax returns are under examination by the Internal Revenue Service. Other years subject to potential examination include 2016 and 2017.

Note 11. Commitments and Contingencies

Legal Proceedings

Pernix Ireland Pain Limited (n/k/a Pernix Ireland Pain Designated Activity Company) and Pernix Therapeutics, LLC v. Actavis Laboratories FL, Inc. (Actavis),

Edgar Filing: PERNIX THERAPEUTICS HOLDINGS, INC. - Form 10-Q

District of Delaware Case No. 16-138; *Pernix Ireland Pain Limited. and Pernix Therapeutics, LLC v. Alvogen Malta Operations, Ltd. (Alvogen)*, District of Delaware Case No. 16-139.

PIP DAC is the owner of (a) U.S. Patent No. 9,265,760 (the '760 Patent), issued on February 23, 2016, (b) U.S. Patent No. 9,326,982 (the '982 Patent), issued on May 3, 2016, (c) U.S. Patent No. 9,333,201 (the '201 Patent), issued on May 10, 2016, and (d) U.S. Patent No. 9,339,499 (the '499 Patent), issued on May 17, 2016 (collectively, the Pernix Zohydro ER Patents). The Pernix Zohydro ER Patents are listed in the United States Food and Drug Administration's (FDA) Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations (the Orange Book) as covering Zohydro ER. Pernix Therapeutics, LLC (Pernix LLC) is the sole distributor of Zohydro ER in the United States. Pernix LLC and Pernix Ireland Pain Limited n/k/a PIP DAC (collectively for the purpose of this paragraph, Pernix) brought suit against Actavis and Alvogen in the District of Delaware on March 4, 2016, seeking declaratory judgment of infringement of the '760 Patent. The Complaints relating to the '760 Patent were served on March 7, 2016. Pernix filed and served First and Second Amended Complaints on May 13, 2016 and May 31, 2016 against Alvogen and Actavis, respectively, adding allegations of infringement with respect to the '982, '201, and '499 Patents. Actavis and Alvogen filed Motions to Dismiss the Complaints under Rule 12(b)(6), asserting that the claims of the Pernix Zohydro ER Patents are invalid under 35 U.S.C. 101. Briefing regarding the Motion to Dismiss was completed on July 11, 2016. United States Patent Nos. 9,421,200 (the '200 Patent) and 9,433,619 (the '619 Patent) issued on August 23, 2016 and September 5, 2016, respectively. Pernix filed and served Second and Third Amended Complaints, against Alvogen and Actavis respectively, on October 12, 2016, adding allegations of infringement with respect to the '200 and '619 Patents. Actavis and Alvogen filed their respective Answers on November 30, 2016, denying Pernix's infringement allegations, and raising Counterclaims of non-infringement and invalidity as to each of the asserted patents. Pernix and Actavis entered into a settlement agreement on January 29, 2018. Under the terms of the agreement, Pernix will grant Actavis a license to begin selling a generic version of Zohydro ER on March 1, 2029, or earlier under certain circumstances. Other details of the settlement are confidential. The launch of Actavis's generic product is contingent upon Actavis receiving final approval from the FDA of its ANDA for a generic version of Zohydro ER. For the Alvogen case, trial testimony was heard from June 11-13, 2018, post-trial briefing was completed on July 12, 2018, and trial will conclude with the parties' closing arguments, to be heard on July 25, 2018 and the judge's final decision rendered on a date thereafter.

Medicine to Go Pharmacies, Inc. v. Macoven Pharmaceuticals, LLC and Pernix Therapeutics Holdings, Inc., District Court of New Jersey Case No. 2:16-cv-07717.

On October 23, 2016, Medicine to Go Pharmacies, Inc. (Plaintiff) filed an action against Pernix and its subsidiary, Macoven and unidentified individuals seeking redress for sending allegedly unlawful advertisements to facsimile machines in violation of the Telephone Consumer Protection Act, 47 U.S.C. 227. On December 2, 2016, the Company filed its answers in defense of the allegations. The December 2013 fax campaign that is the subject of this litigation was administered by a third party, Odyssey Services, Inc. (Odyssey), which was not initially named as a defendant in this litigation. On June 22, 2017, the Company filed a third-party complaint against Odyssey, seeking indemnity and contribution for any amounts that the Company may be liable to pay to the Plaintiff. Odyssey answered the third-party complaint and, in addition, filed a counterclaim for indemnification against the Company, alleging that the Company, not Odyssey, was responsible for the content of the facsimiles transmitted, and thus is liable to Odyssey for any costs or judgments associated with this action. Odyssey filed a motion for summary judgment, seeking to dismiss the third-party claims against it; the Company has moved for summary judgment to hold Odyssey liable to indemnify the Company. Those motions are currently pending before the Court. The Company therefore may not be able to secure indemnification from Odyssey for costs that it might incur relative to this matter, and insurance defense and indemnity do not appear available to the Company. While in the process of attempting to quantify its potential liability and during the pendency of court decisions relative to the outstanding motions, the Company also entered into discussions with counsel for Plaintiff seeking a reduced settlement demand. A settlement conference was conducted by the Court on July 12, 2018 during which counsel for Plaintiff and the Company agreed in principle that for purposes of settlement the defendants will create a settlement fund and the Company will contribute a total of \$1.2 million to said fund, which amount shall be final and includes any and all costs of the settlement, including payment of claims submitted by class members, class notice, settlement administration, Plaintiff's attorneys' fees and costs, and any incentive award to Plaintiff. Further, the Company will not oppose Plaintiff's request that a Rule 23(b)(3) settlement class consisting of all persons and entities with fax numbers who

received a copy of the December 2013 "Dear Pharmacist" fax be certified by the Court and the Company will agree that any unclaimed amounts of the settlement fund shall be distributed to one or more *cy pres* organizations to be selected by the Parties and subject to the approval of the Court. The parties are in the process of finalizing this settlement and obtaining court approval. Odyssey has not yet agreed to participate in this potential settlement.

Opioids Litigation

Beginning in 2014 and continuing to the present, a number of pharmaceutical companies have been named in numerous lawsuits brought by certain state and local governments related to the marketing of opioid pain medications. The claims are generally based on alleged misrepresentations and/or omissions in connection with the sale and marketing of prescription opioid pain medications and/or an alleged failure to take adequate steps to prevent abuse and diversion. The suits generally seek penalties and/or injunctive and monetary relief. These cases are in early stages of litigation. In May 2018, the Company was notified that the State of Arkansas has named approximately 65 companies and individuals, including the Company, in an ongoing lawsuit relative to the marketing and sale of opioid pain medications. During the second quarter of 2018, the Company was also served with two additional lawsuits in which it was included as a defendant, both of which were filed in Philadelphia County, PA (UFCW Local 23 Health Fund v. Endo Pharmaceuticals, Inc., et al. and Iron Workers Dist. Council of Philadelphia & Vicinity, Benefit Fund v. Abbott Laboratories, Inc., et al.). At this time, the Company is unaware of whether it will be named in any of the other opioid pain medication lawsuits.

The Company intends to vigorously defend against the claims asserted against it in these litigations but is unable to predict probable outcomes at this time.

Other Commitments and Contingencies

In July 2012 and January 2013, Somaxon settled two patent litigation claims with parties seeking to market generic equivalents of Silenor. As of June 30, 2018, remaining payment obligations of the Company owed under these settlement agreements are \$500,000. The balance is payable in equal annual installments of \$250,000 through 2019. The current portion is recorded in other liabilities - current and the non-current portion is recorded in other liabilities - long-term on the Company's unaudited condensed consolidated balance sheets as of June 30, 2018.

During the first quarter of 2014, the Company settled all claims arising from certain actions by Cypress under the Texas Medicaid Fraud Prevention Act prior to its acquisition by the Company. As part of the settlement, the Company agreed to pay \$12.0 million, payable in annual amounts of \$2.0 million until the settlement is paid in full. As of June 30, 2018, the net present value of remaining payment obligations owed under this settlement agreement is \$1.9 million and is recorded within other liabilities - current on the Company's unaudited condensed consolidated balance sheets as of June 30, 2018.

GlaxoSmithKline (GSK) Arbitration

Pursuant to Amendment No. 2, the Company agreed that if on or before September 30, 2019, the Company (x) redeems or repurchases its 4.25% Convertible Notes for greater than 31.00 cents for every one dollar of principal amount outstanding or (y) exchange such notes for new notes or similar instruments that have a face value providing such exchanging holders a recovery that is greater than 31.00 cents for every one dollar of 4.25% Convertible Notes exchanged by such holders, the Company shall, no later than five business days thereafter, distribute to GSK additional cash or notes, as applicable, equal to such excess recovery, but in no event to exceed \$2.0 million. GSK has agreed that for so long as the Company complies with the payment terms set forth in the Amendment No. 2, enforcement of the award will be stayed and GSK shall not seek to enforce or exercise any other remedies in respect of the award, and that the outstanding balance of the Award shall be unconditionally and irrevocably forgiven upon satisfaction of such terms. As of June 30, 2018 and December 31, 2017, the Company has recorded \$2.0 million as contingent consideration for the potential payment due by September 30, 2019 and is recorded in Arbitration Award on the Company's consolidated balance sheets. Also, the Company recorded \$10.5 million as a gain from legal settlement for the year ended December 31, 2017 pursuant to Amendment No. 2 in the consolidated statements of operations and comprehensive loss.

Note 12. Restructuring

On January 4, 2018, the Company committed to and commenced a realignment plan to reduce operating costs and better align our workforce with the needs of our business in anticipation of the expiration of certain patents related to Treximet® (2018 Restructuring). The Company completed the realignment plan on January 5, 2018, resulting in a reduction of our workforce by 41 employees, the majority of which were associated with our sales force and commercial infrastructure. As of June 30, 2018, the Company has incurred \$0.8 million in costs related to the 2018 Restructuring, consisting of \$0.7 million related to employee termination benefits and \$0.1 million related to contract termination costs.

On July 7, 2016, the Company announced a restructuring of its sales force and operations (2016 Restructuring). The 2016 Reorganization included a reduction of 54 sales positions, primarily from the Company's Neurology sales team and reduced its administrative staff by 6 employees. To date, the Company has incurred \$2.8 million in costs related to the 2016 Restructuring, consisting of \$1.4 million related to employee termination benefits and \$1.4 million related to contract termination costs. All associated contract termination cost payments are expected to be made by 2020.

A summary of accrued restructuring costs, included as a component of accounts payable and accrued expenses on the unaudited condensed consolidated balance sheets, is as follows (in thousands):

	December 31, 2017	Charges	Cash	Non-cash	June 30, 2018
2018 Restructuring	\$ -	\$ 774	\$ (774)	\$ -	\$ -
2016 Restructuring	\$ 265	\$ 440	\$ (210)	\$ -	\$ 495

Note 13. Business Combinations/Divestitures

There were no acquisitions during the six months ended June 30, 2018.

Sale of Non-Core Assets

On May 29, 2018, the Company received proceeds of \$446,000 from the sale of certain obsolete equipment and was recorded as a Gain on sale of assets line in the consolidated statement of operations and comprehensive loss for the three months ended June 30, 2018.

On November 6, 2017 the Company announced the sale of a non-core product, Cedax (ceftibuten capsules and ceftibuten for oral suspension), a third-generation cephalosporin antibiotic for the treatment of acute bacterial exacerbations of chronic bronchitis and middle ear infection, to SI Pharmaceuticals, LLC, for \$2.0 million in gross cash proceeds. Cedax was discontinued by Pernix in 2016 and the Company has not generated any sales from this product in 2017. This was recorded on the gain on sale of assets line on the consolidated statement of operations and comprehensive loss for the three months ended September 2017.

Note 14. Supplemental Cash Flow Information

Supplemental cash flow information is as follows (in thousands):

	Six Months Ended June 30,	
	2018	2017
Cash (received) paid for income taxes, net	\$ 26	\$ (878)
Cash paid for interest	14,095	14,415
Supplemental disclosures of Non-cash Investing and Financing Activities:		
Amount added to principal of term loan for Payment-in-kind (PIK) interest	\$ 601	\$ -

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited condensed consolidated financial statements and the related notes included in "Part I-Item 1. Financial Statements" of this Quarterly Report on Form 10-Q and the condensed consolidated financial statements and notes thereto and Management's Discussion and Analysis of Financial Condition and Results of Operations contained in our Annual Report on Form 10-K for the year ended December 31, 2017. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report on Form 10-Q, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties, including, but not limited to, those set forth under "Part I-Item 1A. Risk Factors" of our Annual Report on Form 10-K for the year ended December 31, 2017, and "Part II-Item 1A. Risk Factors" of our Quarterly Report on Form 10-Q for the three months ended March 31, 2018 and this Quarterly Report on Form 10-Q for the three and six months ended June 30, 2018.

The discussion below contains forward-looking statements within the meaning of Private Securities Litigation Reform Act of 1995. For this purpose, any statements contained herein, other than statements of current or historical fact, including statements regarding our current expectations of our future growth, results of operations, financial condition, cash flows, performance and business prospects, and opportunities and any other statements about management's future expectations, beliefs, goals, plans or prospects, constitute forward-looking statements. We have tried to identify forward-looking statements by using words such as "anticipate," "believe," "could," "estimate," "expect," "intend," "may," "plan," "project," "should," "target," "will," "would" or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. Among the factors that could cause actual results to differ materially from those indicated in the forward-looking statements are risks and uncertainties inherent in our business including, without limitation: our ability to comply with the covenants under our indebtedness, including our outstanding note securities, our Credit Facilities; the rate and degree of market acceptance of, and our ability and our distribution and marketing partners' ability to obtain reimbursement for, any approved products; our ability to successfully execute our sales and marketing strategy, including to successfully recruit and retain sales and marketing personnel; our ability to obtain additional financing; our ability to maintain regulatory approvals for and the ability to continue to market our products and Contrave in the United States; our ability to successfully manage Nalpropion; our ability to address any adverse impact on our net revenues caused by our ceasing to distribute the combination product isometheptene mucate, dichlorphenazone (IDA), and acetaminophen in compliance with United States Food and Drug Administration (FDA) requirements; the accuracy of our estimates regarding expenses, future revenues and capital requirements; our ability to manage our anticipated future growth; the ability of our products to compete with generic products as well as new products that may be developed by our competitors; our ability and our distribution and marketing partners' ability to comply with regulatory requirements regarding the sales, marketing and manufacturing of our products, the performance of our manufacturers, over which we have limited control; our ability to obtain and maintain intellectual property protection for our products; our ability to operate our business without infringing the intellectual property rights of others; loss of key scientific or management personnel; regulatory developments in the United States and foreign countries; our ability to either acquire or develop and commercialize other product candidates in addition to our current products; the outcome of any litigation to which we may be subject and other risks detailed above in "Part I-Item 1A. Risk Factors" of our Annual Report on Form 10-K for the year ended December 31, 2017 and "Part II-Item 1A. Risk Factors" of this Quarterly Report on Form 10-Q for the three months ended March 31, 2018 and this Quarterly Report on Form 10-Q for the three and six months ended June 30, 2018, as well as any amendments thereto reflected in subsequent filings with the SEC.

Although we believe that the expectations reflected in our forward-looking statements are reasonable, we cannot guarantee future results, events, levels of activity, performance or achievement. In addition, any forward-looking statements in this Quarterly Report on Form 10-Q represent our views only as of the date of this Quarterly Report on Form 10-Q and should not be relied upon as representing our views as of any subsequent date. We anticipate that subsequent events and developments may cause our views to change. However, while we may elect to update these

forward-looking statements publicly at some point in the future, we specifically disclaim any obligation to do so unless required by law, whether as a result of new information, future events or otherwise. Our forward-looking statements do not reflect the potential impact of any acquisitions, mergers, dispositions, business development transactions, joint ventures or investments we may enter into or make in the future.

Overview

We are a specialty pharmaceutical company focused on improving patients' lives by identifying, developing and commercializing differentiated products that address unmet medical needs. Our strategy is to continue to create shareholder value by:

- growing sales of the existing products in our portfolio in various ways, including identifying new growth opportunities; and
- acquiring additional marketed specialty products or products close to regulatory approval to leverage our existing expertise and infrastructure.

We target underserved segments, such as central nervous system (CNS) indications, including pain and neurology. We promote our core branded products to physicians through our sales forces. We market our generic products through our wholly owned subsidiaries, Macoven and Cypress.

Our branded products include Zohydro ER with BeadTek, an extended-release opioid agonist indicated for the management of pain, Silenor, a non-controlled substance and approved medication indicated for the treatment of insomnia characterized by difficulty with sleep maintenance and Treximet, a medication indicated for the acute treatment of migraine attacks, with or without aura, in adults.

Quarterly Update

2018 Exchange Transactions

On August 1, 2018, we entered into an exchange agreement (2018 Exchange Agreement) with certain holders (Exchange Holders) of our outstanding 12% Senior Secured Notes due 2020 (the Treximet Secured Notes) for newly issued shares of our common stock (Common Stock) and shares of a newly created class of our convertible preferred stock designated as 0% Series C Perpetual Convertible Preferred Stock (Convertible Preferred Stock) (Exchange Transactions).

The Exchange Transactions included the following transactions:

- exchange of approximately \$2.7 million aggregate principal amount of the Treximet Secured Notes for 1,204,586 shares of Common Stock which included accrued and unpaid interest on the Treximet Secured Notes; and
- exchange of \$8.0 million principal amount of the Treximet Secured Notes plus \$100,000 of accrued and unpaid interest for 81,000 shares of Convertible Preferred Stock.

These transactions closed on August 1, 2018. In addition, the 2018 Exchange Agreement affords the Exchange Holders the right to exchange up to an additional \$65.1 million aggregate principal amount of the Treximet Secured Notes plus accrued and unpaid interest, until February 1, 2020.

On August 1, 2018, we filed with the State Department of Assessments and Taxation of Maryland an Articles Supplementary (the Articles Supplementary) to our Articles of Incorporation setting out the form and terms of the Convertible Preferred Stock.

Exchange Holders of Convertible Preferred Stock have the right to convert their shares of Convertible Preferred Stock, in whole or in part, into shares of Common Stock at any time on or after August 1, 2018 (the Initial Issue Date). We have the right, at our option, to automatically convert all shares of Convertible Preferred Stock into shares of

Common Stock, subject to the satisfaction of certain specified conditions. Upon any conversion of an Exchange Holder's Convertible Preferred Stock, we will deliver shares of Common Stock, calculated by multiplying the number of shares of Convertible Preferred Stock by 41.841 shares of Common Stock per share of Convertible Preferred Stock (the Conversion Rate). The Conversion Rate is initially equal to the number of shares of Common Stock, such that the Convertible Preferred Stock shall be convertible into Common Stock at a price \$0.01 above the consolidated closing bid price on the Initial Issue Date, or \$2.39 per share.

Subsequent to the Initial Issue Date, an Exchange Holder is not able to convert Convertible Preferred Stock into Common Stock to the extent that the Common Stock held by such Exchange Holder and its affiliates would exceed 4.985% of the Common Stock outstanding immediately after giving effect to the issuance of shares of Common Stock.

Moreover, at any time on or after the Initial Issue Date, we have the right to redeem the Convertible Preferred Stock, in whole or in part, at a redemption price equal to 100% of the liquidation preference of the shares to be redeemed, plus any accrued and unpaid dividends. Except as required by law or the Articles Supplementary, the Exchange Holders of Convertible Preferred Stock have no voting rights (other than with respect to certain matters regarding the Convertible Preferred Stock).

In accordance with the Articles Supplementary, we will not authorize, declare or pay regular or special dividends or other distributions (whether in the form of cash, shares, indebtedness or any other property or asset, but excluding any purchase, redemption or other acquisition of shares) on the shares of the Common Stock, unless simultaneously with the authorization, declaration or payment, it authorizes, declares or pays, as applicable, dividends or other distributions on the Convertible Preferred Stock.

The Equitization Exchange Agreements

On August 1, 2018, we entered into separate Equitization Exchange Agreements (the Equitization Exchange Agreements) with certain holders (each, an Equitization Holder, and collectively the Equitization Holders) of our Treximet Secured Notes. Pursuant to the Equitization Exchange Agreements, we issued 650,190 shares of our Common Stock in exchange for approximately \$1.5 million aggregate principal amount of Treximet Secured Notes held by such Equitization Holders plus accrued and unpaid interest thereon (Equitization Transaction). This transaction closed on August 1, 2018.

Amended ABL Facility and Term Facility

On August 1, 2018 we entered into an amendment of our revolving asset-based credit facility agreement by and among us, the guarantors and lenders party thereto and Cantor Fitzgerald Securities, as agent (the ABL Facility), as well as an amendment to our existing delayed draw term loan facility by and among PIP DAC, the lenders party thereto and Cantor Fitzgerald Securities, as agent (the Term Facility and together with the ABL Facility, the Credit Facilities). These amendments were made to permit the exchange of the Treximet Secured Notes into Common Stock in the Exchange Transactions and Equitization Transaction, and to amend certain terms of the Credit Facilities, including (i) certain changes to the borrowing base calculation under the ABL Facility that are intended to improve our borrowing capacity under the ABL Facility and that will also permit us, among other things, to include Contrave inventory owned by us in the calculation of the borrowing base, (ii) changes to permit the use of subsequent draws under the Term Facility for working capital or other general corporate purposes, (iii) a reduction in the commitments under the ABL Facility from \$40.0 million to \$32.5 million, and (iv) changes to the interest payment provisions under the Term Facility increasing the minimum percentage of interest that must be paid in cash to 6.00% per annum from 4.50% per annum.

Closing of Transactions Regarding Worldwide Rights to Contrave (naltrexone HCl / bupropion HCl)

On April 17, 2018, we entered into a Commitment Letter pursuant to which we committed to provide Nalpropion Pharmaceuticals, Inc. (Nalpropion) with \$7.5 million in debt and/or equity capital to fund Nalpropion's purchase of certain assets of Orexigen Therapeutics, Inc. (Orexigen). Nalpropion is a special purpose corporation jointly owned by us and certain other co-investors. Nalpropion submitted a "stalking horse" bid to purchase certain assets of Orexigen, which filed a voluntary petition for relief under Chapter 11 of Title 11 of the United States Code, 11 U.S.C. 101, et seq. in the United States Bankruptcy Court for the District of Delaware.

On April 23, 2018, pursuant to a confidential non-binding term sheet agreement between us and the co-investors in Nalpropion, Nalpropion entered into a "stalking horse" asset purchase agreement (Asset Purchase Agreement) to acquire certain assets of Orexigen, including worldwide rights to Contrave[®] (naltrexone HCl / bupropion HCl), a prescription-only weight-loss medication, for \$75 million in cash.

On June 22, 2018, we announced that no other bids for Orexigen's assets were received by the court-approved bid deadline and on July 27, 2018, Nalpropion acquired substantially all the assets and assumed certain liabilities of Orexigen for approximately \$73.5 million in cash. Pursuant to an amendment to the Asset Purchase Agreement that was entered into concurrent with closing of the transaction, the purchase price was reduced to \$73.5 million and \$5.0 million of the purchase price was held back by Nalpropion to cover potential indemnification claims. On July 27, 2018, we funded PIP DAC's contribution of 10% of the capital required to fund the purchase price for Orexigen of \$7.35 million and an incremental \$1.82 million for working capital requirements, via its existing Term Facility.

Return to Market of Zohydro ER

with BeadTek 20MG

On March 28, 2018 we resumed distribution of the 20 mg dosage strength of Zohydro ER (hydrocodone bitartrate) with BeadTek. Prior to the back order, the 20 mg dosage strength was the most utilized dosage strength of Zohydro ER with BeadTek, representing approximately 9 percent of second quarter 2018 total prescriptions.

Launch of Treximet Authorized Generic

On February 14, 2018, four patents covering Treximet expired, enabling up to three generic competitors to enter the market. As of June 30, 2018, one of these competitors has entered the market and we are expecting the other two competitors to enter later in 2018. Concurrent with the launch of generics by third parties, we launched an authorized generic version of Treximet and we will also continue to distribute the branded versions of Treximet. We have one additional patent that covers Treximet which will expire in 2026 that we expect to prevent additional generic competitors from entering the market until that time. We expect that generic competition for Treximet will have a material adverse effect on our net revenues for the fiscal year ending December 31, 2018 as compared to the fiscal year ending December 31, 2017.

Patent Litigation Settlement Agreement with Actavis Concerning Zohydro ER

We announced on January 29, 2018 that we had entered into a settlement agreement with Actavis Laboratories FL (Actavis) resolving patent litigation related to Zohydro ER with BeadTek. The litigation has been pending in the U.S. District Court for the District of Delaware and resulted from Actavis's submission of an ANDA to the FDA seeking approval to market a generic version of Zohydro ER with BeadTek. Under the terms of the agreement, we will grant Actavis a license to begin selling a generic version of Zohydro ER with BeadTek on March 1, 2029, or earlier under certain circumstances. Other details of the settlement are confidential. The launch of Actavis's generic product is contingent upon Actavis receiving final approval from the FDA of its ANDA for a generic version of Zohydro ER with BeadTek. The settlement agreement also resolves a pending appeal related to a patent litigation between Recro Gainesville LLC and Actavis, which also relates to Actavis's proposed generic version of Zohydro ER with BeadTek. As required by law, the parties have submitted the settlement agreement to the U.S. Federal Trade Commission and the U.S. Department of Justice for review. A patent litigation that we previously commenced against Alvogen Malta Operations Ltd. related to Alvogen's proposed generic version of Zohydro with BeadTek remains pending in the U.S. District Court for the District of Delaware.

Sales Force Restructure

On January 4, 2018, we committed to and commenced a realignment plan to reduce operating costs and better align our workforce with the needs of our business in anticipation of the expiration of certain patents related to Treximet®. We completed the realignment plan on January 5, 2018, resulting in a reduction of our workforce by 41 employees, the majority of which were associated with our sales force and commercial infrastructure. In connection with this commercial reorganization, we expect to realize annualized cost savings of \$7.0-\$8.0 million beginning in the first quarter of 2018. We recorded a one-time charge of \$0.8 million during the six months ended June 30, 2018 as a result

of this realignment.

Adoption of New Accounting Guidance

Revenue Recognition

On January 1, 2018, we adopted the new accounting standard ASC 606, *Revenue from Contracts with Customers (ASC 606)* and all the related amendments to all contracts using the modified retrospective method. Upon adoption of ASC 606, we did not initially recognize a cumulative effect of applying the new revenue standard as an adjustment to the opening balance of retained earnings. The comparative information has not been restated and continues to be reported under the accounting standards in effect for those periods. We do not expect the adoption of the new revenue standard to have a material impact on our results of operations for the year ending December 31, 2018. See note 2, *Basis of Presentation and Summary of Significant Accounting Policies* to our Condensed Consolidated Financial Statements for more information.

Results of Operations

Comparison of Three Months Ended June 30, 2018 and 2017

The following table summarizes our results of operations for the three months ended June 30, 2018 and 2017 (in thousands):

	Three Months Ended June 30,			Increase / (Decrease)	Percent
	2018	2017			
Net revenues	\$ 21,088	\$ 34,316	\$	(13,228)	-39%
Costs and operating expenses:					
Cost of product sales	5,569	10,493		(4,924)	-47%
Selling, general and administrative expense	18,257	19,018		(761)	-4%
Research and development expense	6	82		(76)	-93%
Depreciation and amortization expense	1,430	18,215		(16,785)	-92%
Change in fair value of contingent consideration	(120)	(886)		766	-86%
Restructuring costs	385	31		354	*
Other income (expense):					
Interest expense	(9,530)	(9,209)		321	3%
Change in fair value of derivative liability	40	270		(230)	*
Foreign currency transaction gain (loss)	(21)	-		(21)	*
Income tax expense (benefit)	9	40		(31)	*

* Comparison to prior period is not meaningful.

Net Revenues

Net revenues consist of net product sales and revenue from co-promotion and other revenue sharing arrangements or agreements. We recognize product sales net of estimated allowances for product returns, price adjustments (customer rebates, managed care rebates, service fees, chargebacks, coupons and other discounts), government program rebates (Medicaid, Medicare and other government sponsored programs) and prompt pay discounts. The factors that determine our net product sales are the level of demand for our products, unit sales prices, the applicable federal and supplemental government program rebates, contracted rebates, services fees, and chargebacks and other discounts that we may offer such as consumer coupon programs. In addition to our own product portfolio, we have entered into co-promotion agreements and other revenue sharing arrangements with various parties in return for a percentage of sales we generate or on sales they generate.

Edgar Filing: PERNIX THERAPEUTICS HOLDINGS, INC. - Form 10-Q

The following table sets forth a summary of our net revenues for the three months ended June 30, 2018 and 2017 (in thousands):

	Three Months Ended June 30,		Increase / (Decrease)		Percent
	2018	2017			
Treximet	\$ 1,559	\$ 16,840	\$ (15,281)		-91%
Treximet AG	3,035	-	3,035		*
Zohydro ER	8,257	6,454	1,803		28%
Silenor	6,355	5,150	1,205		23%
Other	1,635	5,800	(4,165)		-72%
Net product revenues	20,841	34,244	(13,403)		-39%
Co-promotion and other revenue	247	72	175		243%
Total net revenues	\$ 21,088	\$ 34,316	\$ (13,228)		-39%

* Comparison to prior period is not meaningful.

Net revenues decreased \$13.2 million or 39% during the three months ended June 30, 2018 compared to the three months ended June 30, 2017.

Treximet brand net revenues decreased by \$15.3 million, or 91%, during the three months ended June 30, 2018 compared to the three months ended June 30, 2017 due to the loss of exclusivity of Treximet in February 2018 as we experienced generic competition. We expect that future Treximet brand revenues will continue to decrease year over year due to the loss of exclusivity. On February 15, 2018, we launched an authorized generic version of Treximet (Treximet AG).

Treximet AG net revenues were \$3.0 million during the three months ended June 30, 2018 due to its launch on February 15, 2018. There were no sales of Treximet AG prior to its launch.

Zohydro ER net revenues increased by \$1.8 million, or 28%, during the three months ended June 30, 2018 compared to the three months ended June 30, 2017. The increase was due to an increase in net price of \$1.4 million (primarily related to favorable gross to net accrual rates) and sales volume of \$400,000.

Silenor net revenues increased by \$1.2 million, or 23%, during the three months ended June 30, 2018 compared to the three months ended June 30, 2017. The increase was due to an increase in net price of \$700,000 (primarily related to favorable gross to net accrual rates) and sales volume of \$500,000.

Net product revenues - other decreased by \$4.2 million, or 72%, during the three months ended June 30, 2018 compared to the three months ended June 30, 2017. The decrease was due primarily to discontinuation of products no longer sold of \$2.8 million, including IDA, and increased competitive and pricing pressures on our generics portfolio.

Cost of Product Sales

Cost of product sales decreased by \$4.9 million, or 47%, during the three months ended June 30, 2018 compared to the three months ended June 30, 2017. The decrease in cost of product sales was due primarily to a \$3.7 million decrease as a result of lower Treximet brand sales as a result of generic competition as well as \$2.3 million decrease in our other product revenue (primarily related to discontinued products), partially offset by increased Zohydro ER, Treximet AG and Silenor product costs of \$0.4 million, \$0.3 million and \$0.4 million, respectively due to increased volume.

Selling, General and Administrative Expense

Selling, general and administrative expense decreased by \$0.8 million, or 4%, during the three months ended June 30, 2018 compared to the three months ended June 30, 2017. The decrease was driven primarily by lower sales force related expenses of \$1.9 million due to the restructuring announced in January 2018, lower marketing and selling

expenditures of \$0.8 million related primarily to Treximet due to the loss of exclusivity as well as \$0.2 million of lower spend across numerous areas, partially offset by higher legal fees of \$2.1 million primarily related to patent defense and legal settlements.

Research and Development Expense

Research and development expense decreased by \$76,000 during the three months ended June 30, 2018 compared to the three months ended June 30, 2017, due primarily to the discontinuation of certain Zohydro-related research projects.

Depreciation and Amortization Expense

Depreciation and amortization expense decreased by \$16.8 million, or 92%, during the three months ended June 30, 2018 compared to the three months ended June 30, 2017. The decrease was related primarily to Treximet intangible assets becoming fully amortized upon the expiration of certain underlying patents and the loss of its exclusivity in February 2018.

Change in Fair Value of Contingent Consideration

For the acquisition of Zohydro ER, we initially recorded \$14.2 million of contingent consideration. The fair value of the contingent consideration linked to FDA approval was \$2.7 million and the fair value of the contingent consideration linked to achievement of the net sales target was \$11.5 million. As of June 30, 2018, the current fair value of the contingent consideration was approximately \$1.5 million. We recorded a benefit of \$120,000 and \$886,000 as change in fair value of contingent consideration in the three months ended June 30, 2018 and 2017, respectively.

Restructuring Costs

Restructuring costs were \$385,000 and \$31,000 during the three months ended June 30, 2018 and 2017, respectively, due primarily to the 2018 and 2016 initiatives to restructure our sales force and operations.

Interest Expense

Interest expense increased by \$321,000, or 3%, during the three months ended June 30, 2018 compared to the three months ended June 30, 2017. The increase was due primarily to higher average interest rates related to the borrowings under our Term Facility and ABL Facility. These increases were offset partially by reduced interest expense on our Treximet Secured Notes due to the lower principal balance.

Change in Fair Value of Derivative Liability

We are required to separate the conversion option in the 4.25% Convertible Senior Notes Due 2021 (4.25% Convertible Notes) under ASC 815, *Derivatives and Hedging*. We recorded the bifurcated conversion option valued at \$28.5 million at issuance, as a derivative liability, which creates additional discount on the debt. The derivative liability is marked to market through the other income (expense) section on the unaudited condensed consolidated statements of operations for each reporting period. We recorded a benefit of \$40,000 and \$270,000 as change in fair value of derivative liability in other income (expense) in the three months ended June 30, 2018 and 2017, respectively.

Income Tax Expense

We reported an income tax expense of \$9,000 and \$40,000 for the three months ended June 30, 2018 and 2017, respectively.

Comparison of Six Months Ended June 30, 2018 and 2017

The following table summarizes our results of operations for the six months ended June 30, 2018 and 2017 (in thousands):

	Six Months Ended June 30,			Increase / (Decrease)	Percent
	2018	2017			
Net revenues	\$ 49,227	\$ 64,058	\$	(14,831)	-23%
Costs and operating expenses:					
Cost of product sales	14,530	20,533		(6,003)	-29%
Selling, general and administrative expense	35,540	39,293		(3,753)	-10%
Research and development expense	10	610		(600)	-98%
Depreciation and amortization expense	11,295	36,762		(25,467)	-69%
Change in fair value of contingent consideration	143	(540)		683	*
Restructuring costs	1,214	131		1,083	*
Other income (expense):					
Interest expense	(18,990)	(18,168)		822	5%
Change in fair value of derivative liability	21	(84)		105	*
Foreign currency transaction gain	(21)	-		(21)	*
Income tax expense (benefit)	48	95		47	*

* Comparison to prior period is not meaningful.

The following table sets forth a summary of our net revenues for the six months ended June 30, 2018 and 2017 (in thousands):

	Six Months Ended June 30,			Increase / (Decrease)	Percent
	2018	2017			
Treximet	\$ 13,852	\$ 30,610	\$	(16,758)	-55%
Treximet AG	4,882	-		4,882	*
Zohydro ER	15,282	11,650		3,632	31%
Silenor	11,703	8,699		3,004	35%
Other	3,152	12,963		(9,811)	-76%
Net product revenues	48,871	63,922		(15,051)	-24%
Co-promotion and other revenue	356	136		220	162%
Total net revenues	\$ 49,227	\$ 64,058	\$	(14,831)	-23%

* Comparison to prior period is not meaningful.

Net revenues decreased \$14.8 million or 23% during the six months ended June 30, 2018 compared to the six months ended June 30, 2017.

Treximet brand net revenues decreased by \$16.8 million, or 55%, during the six months ended June 30, 2018 compared to the six months ended June 30, 2017 due to the loss of exclusivity of Treximet in February 2018 as we experienced generic competition. We expect that future Treximet brand revenues will continue to decrease year over year due to the loss of exclusivity. On February 15, 2018, we launched Treximet AG.

Treximet AG net revenues were \$4.9 million during the six months ended June 30, 2018 due to its launch on February 15, 2018. There were no sales of Treximet AG prior to its launch.

Zohydro ER net revenues increased by \$3.6 million, or 31%, during the six months ended June 30, 2018 compared to the six months ended June 30, 2017. The increase was due to an increase in net price of \$1.2 million (primarily related to favorable gross to net accrual rates) and sales volume of \$2.4 million. Sales volume was favorably impacted by the relaunch of the 20mg strength of Zohydro ER during the first quarter of 2018.

Silenor net revenues increased by \$3.0 million, or 35%, during the six months ended June 30, 2018 compared to the six months ended June 30, 2017. The increase was due to an increase in net price of \$1.4 million (primarily related to favorable gross to net accrual rates) and sales volume of \$1.6 million.

Net product revenues - other decreased by \$9.8 million, or 76%, during the six months ended June 30, 2018 compared to the six months ended June 30, 2017. The decrease was due primarily to discontinuation of products no longer sold of \$7.2 million, including IDA, and increased competitive and pricing pressures on our generics portfolio.

Cost of Product Sales

Cost of product sales decreased by \$6.0 million, or 29%, during the six months ended June 30, 2018 compared to the six months ended June 30, 2017. The decrease in cost of product sales was due primarily to a \$3.9 million decrease as a result of lower Treximet brand sales as a result of generic competition as well as \$3.9 million decrease in our other product revenue (primarily related to discontinued products), partially offset by increased Zohydro ER, Treximet AG and Silenor product costs of \$0.9 million, \$0.4 million and \$0.5 million, respectively due to increased volume.

Selling, General and Administrative Expense

Selling, general and administrative expense decreased by \$3.8 million, or 10%, during the six months ended June 30, 2018 compared to the six months ended June 30, 2017. The decrease was driven primarily by lower sales force related expenses of \$4.2 million due to the restructuring announced in January 2018, lower marketing and selling expenditures of \$1.7 million related primarily to Treximet due to the loss of exclusivity, as well as \$0.6 million of lower spend across numerous areas, partially offset by higher legal fees of \$2.7 million related primarily to patent defense and legal settlements.

Research and Development Expense

Research and development expense decreased by \$600,000 during the six months ended June 30, 2018 compared to the six months ended June 30, 2017, due primarily to the discontinuation of certain Zohydro-related research projects.

Depreciation and Amortization Expense

Depreciation and amortization expense decreased by \$25.5 million, or 69%, during the six months ended June 30, 2018 compared to the six months ended June 30, 2017. The decrease was related primarily to Treximet intangible assets becoming fully amortized upon the expiration of certain underlying patents and the loss of its exclusivity in February 2018.

Change in Fair Value of Contingent Consideration

For the acquisition of Zohydro ER, we initially recorded \$14.2 million of contingent consideration. The fair value of the contingent consideration linked to FDA approval was \$2.7 million and the fair value of the contingent consideration linked to achievement of the net sales target was \$11.5 million. As of June 30, 2018, the current fair value of the contingent consideration was approximately \$1.5 million. We recorded expense of \$143,000 and a benefit of \$540,000 as change in fair value of contingent consideration in the six months ended June 30, 2018 and 2017, respectively.

Restructuring Costs

Restructuring costs were \$1.2 million and \$131,000 during the six months ended June 30, 2018 and 2017, respectively, due to the 2018 and 2016 initiatives to restructure our sales force and operations.

Interest Expense

Interest expense increased by \$822,000, or 5%, during the six months ended June 30, 2018 compared to the six months ended June 30, 2017. The increase was due primarily to higher average interest rates related to the borrowings under our Term Facility and our ABL Facility. These increases were offset partially by reduced interest expense on our Treximet Secured Notes due to the lower principal balance.

Change in Fair Value of Derivative Liability

We are required to separate the conversion option in the 4.25% Convertible Notes under ASC 815, *Derivatives and Hedging*. We recorded the bifurcated conversion option valued at \$28.5 million at issuance, as a derivative liability, which creates additional discount on the debt. The derivative liability is marked to market through the other income (expense) section on the unaudited condensed consolidated statements of operations for each reporting period. We recorded a benefit of \$21,000 and an expense of \$84,000 as change in fair value of derivative liability in other income (expense) in the six months ended June 30, 2018 and 2017, respectively.

Income Tax Expense

We reported an income tax expense of \$48,000 and \$95,000 for the six months ended June 30, 2018 and 2017, respectively.

Non-GAAP Financial Measures

To supplement our financial results determined by GAAP, we have disclosed in the table below adjusted earnings before interest, taxes, depreciation and amortization (EBITDA).

Adjusted EBITDA is a non-GAAP financial measure that excludes the impact of certain items and, therefore, has not been calculated in accordance with GAAP. This non-GAAP financial measure excludes from net loss: interest expense; depreciation and amortization; income tax expense; selling, general and administrative adjustments; gain from sale of non-core assets; change in fair value of contingent consideration; change in fair value of derivative liability; restructuring costs; and foreign currency transactions. In addition, from time to time in the future there may be other items that we may exclude for the purposes of our use of adjusted EBITDA; likewise, we may in the future cease to exclude items that we have historically excluded for the purpose of adjusted EBITDA. We believe that adjusted EBITDA provides meaningful supplemental information regarding our operating results because it excludes or adjusts amounts that management and the board of directors do not consider part of core operating results or that are non-recurring when assessing the performance of the organization. We believe that inclusion of adjusted EBITDA provides consistency and comparability with past reports of financial results and provides consistency in calculations by outside analysts reviewing our results. Accordingly, we believe that adjusted EBITDA is useful to investors in allowing for greater transparency of supplemental information used by management.

We believe that these non-GAAP financial measures are helpful in understanding our past financial performance and potential future results, but there are limitations associated with the use of these non-GAAP financial measures. These non-GAAP financial measures are not prepared in accordance with GAAP, do not reflect a comprehensive system of accounting and may not be completely comparable to similarly titled measures of other companies due to potential differences in the exact method of calculation between companies. Adjustment items that are excluded from our non-GAAP financial measures can have a material impact on net earnings. As a result, these non-GAAP financial measures have limitations and should not be considered in isolation from, or as a substitute for, net loss, cash flow from operations or other measures of performance prepared in accordance with GAAP. We compensate for these limitations by using these non-GAAP financial measures as a supplement to GAAP financial measures and by reconciling the non-GAAP financial measure to its most comparable GAAP financial measure. Investors are encouraged to review the reconciliations of the non-GAAP financial measure to its most comparable GAAP financial

measure that is included below in this Quarterly Report on Form 10-Q.

Reconciliation of GAAP reported net loss to adjusted EBITDA is as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
GAAP net loss	\$ (13,513)	\$ (21,616)	\$ (32,097)	\$ (51,078)
Adjustments:				
Interest expense	9,530	9,209	18,990	18,168
Depreciation and amortization	1,457	18,245	11,351	36,822
Income tax expense	9	40	48	95
EBITDA	(2,517)	5,878	(1,708)	4,007
Selling, general and administrative adjustments ⁽¹⁾	2,505	935	3,131	1,733
Gain from sale of non-core asset ⁽²⁾	(446)	-	(446)	-
Change in fair value of contingent consideration ⁽³⁾	(120)	(886)	143	(540)
Change in fair value of derivative liability ⁽⁴⁾	(40)	(270)	(21)	84
Restructuring costs ⁽⁵⁾	385	31	1,214	131
Foreign currency transaction (gain) loss	21	-	21	-
Adjusted EBITDA	\$ (212)	\$ 5,688	\$ 2,334	\$ 5,415

- (1) Excludes deal costs of \$0.8 million and \$0.3 million; stock compensation expense of \$0.5 million and \$0.7 million; severance expense of \$112,000 and \$1,000; and litigation settlement expenses of \$1.1 million and \$15,000 for the three months ended June 30, 2018 and 2017, respectively. Also excludes deal costs of \$0.8 million and \$0.3 million; stock compensation expense of \$0.9 million and \$1.4 million; severance expense of \$131,000 and \$44,000; and arbitration and litigation settlement expenses of \$1.3 million and \$18,000 for the six months ended June 30, 2018 and 2017, respectively.
- (2) Excludes the gain from the sale of certain obsolete equipment.
- (3) Excludes loss from change in fair value of contingent consideration related to the 2015 acquisition of Zohydro ER and is linked to the achievement of certain net sales targets. Any change in fair values between the reporting dates is recognized in the condensed consolidated statements of operations.
- (4) Excludes loss from change in fair value of derivative liability consideration. We are required to separate the conversion option in the 4.25% Convertible Notes under ASC 815, Derivatives and Hedging. We recorded the bifurcated conversion option valued at \$28.5 million at issuance, as a derivative liability, which created additional discount on the debt. The derivative liability is marked to market through the other income (expense) section on the condensed consolidated statements of operations for each reporting period.
- (5) Excludes the cost related to the initiative to restructure our sales force and operations for the three and six months ended June 30, 2018 and 2017.

Liquidity and Capital Resources

The following table summarizes our liquidity and capital resources (amounts in thousands):

	June 30, 2018	December 31, 2017
Cash and cash equivalents	\$ 19,925	\$ 32,820
Total current assets	66,455	92,284
Current debt (1)	-	3,664
Arbitration award (2)	2,000	2,000
Non-current debt (1)	281,165	278,489
Stockholders' deficit	\$ (205,018)	\$ (174,257)

Edgar Filing: PERNIX THERAPEUTICS HOLDINGS, INC. - Form 10-Q

- (1) The table below lists the Total Borrowings, the Note Discount, and the Deferred Financing costs that when combined equal the components of Current and Non-current Book Value of the debt listed on our Condensed Consolidated Balance Sheets at June 30, 2018 and December 31, 2017, respectively. See Note 8, *Debt and Lines of Credit* to our Condensed Consolidated Financial Statements.

As of June 30, 2018

	Total Borrowings	Note Discount	Deferred Financing Costs	Book Value
4.25% Convertible Notes	\$ 78,225	\$ (9,588)	\$ (1,709)	\$ 66,928
Exchangeable Notes	35,743	(23,950)	(3,277)	9,016
Delayed Draw Term Loan	30,601	-	(2,418)	28,183
Treximet Secured Notes - Long Term	166,697	-	(3,844)	162,853
Treximet Secured Notes - Short Term	-	-	-	-
ABL Credit Agreement	14,185	-	-	14,185
Balance at June 30, 2018	\$ 325,451	\$ (33,038)	\$ (11,248)	\$ 281,165

As of December 31, 2017

	Total Borrowings	Note Discount	Deferred Financing Costs ^(a)	Book Value
4.25% Convertible Notes	\$ 78,225	\$ (11,060)	\$ (1,971)	\$ 65,194
Exchangeable Notes	35,743	(24,363)	(3,405)	7,975
Delayed Draw Term Loan	30,000	-	(2,752)	27,248
Treximet Secured Notes - Long Term	166,697	-	(2,810)	163,887
Treximet Secured Notes - Short Term	5,373	-	(1,709)	3,664
ABL Credit Agreement	14,185	-	-	14,185
Balance at December 31, 2017 ^(a)	\$ 330,223	\$ (35,423)	\$ (12,647)	\$ 282,153

- (a) We reclassified capitalized debt issuance costs of approximately \$1.5 million from "Prepaid expenses and other current assets" to our long-term debt instruments within "Total liabilities" except for those related to revolving credit facilities to conform to the current period presentation. This reclassification had no effect on previously reported results of operations, financial position or cash flows.

(2) GlaxoSmithKline (GSK) Arbitration

Relates to obligations associated with our arbitration proceeding with GSK. We had been engaged in an arbitration proceeding with GSK relating to an alleged breach by us of a covenant contained in the Asset Purchase and Sale Agreement, dated May 13, 2014, by and among GSK and its affiliates and us pertaining to a pre-existing customer agreement. The parties entered into an interim settlement agreement (the Interim Settlement Agreement) in July 2015 under which we paid approximately \$10.3 million to GSK and escrowed an additional amount of approximately \$6.2 million. On January 31, 2017, the arbitration tribunal issued opinions in favor of GSK, awarding it damages and fees in the amount of approximately \$35.0 million, plus interest (estimated to be approximately \$2.0 to \$5.0 million). On March 17, 2017, we entered into Amendment No.1 to the Interim Settlement Agreement with GSK whereby we agreed to establish a payment schedule for satisfaction of the current balance of the award.

On July 20, 2017, we and GSK entered into Amendment No. 2 to the Interim Settlement Agreement. Amendment No. 2 superseded Amendment No. 1 and permitted payment by us to GSK of a reduced amount in full satisfaction of the remaining approximately \$21.2 million unpaid portion of the award granted to GSK in the arbitration of certain matters previously disputed by the parties. Pursuant to Amendment No. 2, we were obligated to make two fixed payments to GSK: (i) a payment of \$3.45 million due on or before August 4, 2017 and (ii) a payment of \$3.2 million due on or before December 31, 2017. Both of these payments were made as of December 31, 2017. Also pursuant to Amendment No. 2, we agreed that if on or before September

30, 2019, we (x) redeem or repurchase our 4.25% Convertible Notes for greater than 31.00 cents for every one dollar of principal amount outstanding or (y) exchanges such notes for new notes or similar instruments that have a face value providing such exchanging holders a recovery that is greater than 31.00 cents for every one dollar of 4.25% Convertible Notes exchanged by such holders, we shall,

no later than five business days thereafter, distribute to GSK additional cash or notes, as applicable, equal to such excess recovery, but in no event to exceed \$2.0 million. GSK has agreed that for so long as we comply with the payment terms set forth in the Amendment No. 2, enforcement of the award will be stayed and GSK shall not seek to enforce or exercise any other remedies in respect of the award, and that the outstanding balance of the Award shall be unconditionally and irrevocably forgiven upon satisfaction of such terms. As of June 30, 2018, and December 31, 2017, we recorded \$2.0 million as contingent consideration for the potential payment due by September 30, 2019 and is recorded in other liabilities - long term on our condensed consolidated balance sheets. Also, we recorded \$10.5 million as Gain from legal settlement for the year ended December 31, 2017 pursuant to Amendment No. 2 in the consolidated statements of operations and comprehensive loss.

During the six months ended June 30, 2018 and 2017 we utilized cash from operations of \$8.1 million and \$9.2 million respectively.

As of June 30, 2018, we had cash and cash equivalents of \$19.9 million and borrowing availability of \$7.9 million under our ABL Facility.

We have an effective shelf registration statement on Form S-3 with the SEC, which covers the offering, issuance and sale of up to \$150.0 million of our Common Stock, preferred stock, debt securities, warrants, subscription rights and units. The shelf registration statement includes a sales agreement prospectus covering the offering, issuance and sale of up to \$10.0 million shares of our Common Stock that may be issued and sold under the Controlled Equity Offering Sales Agreement, dated November 7, 2014, between us and Cantor Fitzgerald & Co. as agent. We sold 191,170 and 680,926 shares of Common Stock under this controlled equity program during the six months ended June 30, 2018 and the year ended December 31, 2017, respectively, for net proceeds of \$453,000 and \$2.0 million during the six months ended June 30, 2018 and the year ended December 31, 2017, respectively.

As a result of the Exchange Transactions announced on August 1, 2018, the principal amount of our Treximet Secured Notes outstanding at June 30, 2018 was reduced by \$12.2 million to \$154.5 million, resulting in an annual interest savings of \$1.5 million. The amendment to our Term Facility provides us with access to up to \$5.8 million of the delayed draw feature for working capital purposes, further enhancing our liquidity. In addition, the ABL Facility amendment includes changes to the borrowing base calculation, which provides for, among other revisions, the inclusion of Contrave® inventory owned by us going forward. As such, we believe that this amendment will create additional borrowing capacity under the ABL Facility.

On July 27, 2018, we funded the contribution, which contribution was made PIP DAC, our wholly-owned subsidiary, of 10% of the capital, or \$7.35 million, required to fund Nalpropion's acquisition of Orexigen and an incremental \$1.8 million for working capital requirements, via our existing delayed draw term loan facility. On July 27, 2018, Nalpropion acquired substantially all the assets and assumed certain liabilities of Orexigen for approximately \$73.5 million in cash.

Our future capital requirements will depend on many factors, including:

- the level of product sales of our currently marketed products and any additional products that we may market in the future;
- the extent to which we acquire or invest in products, businesses and technologies;
- the level of inventory purchase commitments under supply, manufacturing, license and/or co-promotion agreements;
- the scope, progress, results and costs of development activities for our current product candidates;

- the costs, timing and outcome of regulatory review of our product candidates;
- the number of, and development requirements for, additional product candidates that we pursue;
- the costs of commercialization activities, including product marketing, sales and distribution;
- the costs and timing of establishing manufacturing and supply arrangements for clinical and commercial supplies of our product candidates and products;
- the extent to which we choose to establish collaboration, co-promotion, distribution or other similar arrangements for our marketed products and product candidates;
- the costs of and any judgments resulting from legal proceedings;

Edgar Filing: PERNIX THERAPEUTICS HOLDINGS, INC. - Form 10-Q

- the principal and interest payments due under the Treximet Secured Notes, 4.25% Convertible Notes and 4.25%/5.25% Exchangeable Senior Notes due 2022 (Exchangeable Notes), as applicable;
- our ability to draw down on our Credit Facilities;
- our obligations to make cash payments under our indebtedness; and
- the costs of preparing, filing and prosecuting patent applications and maintaining, enforcing and defending claims related to intellectual property owned by or licensed to us.

Cash Flows

The following table provides information regarding our cash flows for the six months ended June 30, 2018, and 2017 (in thousands).

	Three Months Ended	
	June 30,	
	2018	2017
Cash provided by (used in)		
Operating activities	\$ (8,076)	\$ (9,177)
Investing activities	348	(3)
Financing activities	(5,167)	(12,854)
Net decrease in cash and cash equivalents	\$ (12,895)	\$ (22,034)

Comparison of the Six Months Ended June 30, 2018 and 2017

Net cash used in operating activities

Net cash used in operating activities during the six months ended June 30, 2018 was \$8.1 million, a decrease of \$1.1 million from cash used in operating activities during the six months ended June 30, 2017 of \$9.2 million. The cash used in operating activities during the six months ended June 30, 2018 was driven by the net loss of \$32.1 million and net changes in operating assets/liabilities of \$6.8 million. This use was partially offset by non-cash expenses totaling \$17.4 million. The \$9.2 million used in operating activities during the six months ended June 30, 2017 was driven primarily by a net loss of \$51.1 million. This use was partially offset by non-cash expenses totaling \$42.0 million.

Net cash provided by (used in) investing activities

Net cash provided by investing activities during the six months ended June 30, 2018 was \$348,000 compared to a use of \$3,000 during the six months ended June 30, 2017 resulting from the sale of a non-core asset.

Net cash used in financing activities

Net cash used in financing activities during the six months ended June 30, 2018 was \$5.2 million. This cash usage was primarily for the principal repayment of our Treximet Secured Notes partially offset by \$453,000 of proceeds from the Controlled Equity Offering Sales Agreement. Net cash used in financing activities during the six months ended June 30, 2017 was \$12.9 million. Cash used in financing activities for the six months ended June 30, 2017 was for principal payments on our Treximet Secured Notes.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

ITEM 4. CONTROLS AND PROCEDURES

We maintain "disclosure controls and procedures" within the meaning of Rule 13a-15(e) of the Securities Exchange Act of 1934, as amended (the Exchange Act). Our disclosure controls and procedures, or Disclosure Controls, are designed to ensure that information required to be disclosed by us in the reports we file under the Exchange Act, such as this Quarterly Report on Form 10-Q, is recorded, processed, summarized and reported within the time periods specified in the

U.S. Securities and Exchange Commission's rules and forms. Our Disclosure Controls are also designed to ensure that such information is accumulated and communicated to our management, including our Chief Executive Officer and Principal Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating our Disclosure Controls, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management necessarily was required to apply its judgment in evaluating and implementing possible controls and procedures.

Evaluation of Disclosure Controls and Procedures.

As of June 30, 2018, we evaluated the effectiveness of the design and operation of the Company's disclosure controls and procedures, which was done under the supervision and with the participation of our management, including our Chief Executive Officer and our Principal Financial Officer. Immediately following the Signatures section of this Quarterly Report on Form 10-Q are certifications of our Chief Executive Officer and Principal Financial Officer, which are required in accordance with Rule 13a-14 of the Exchange Act. This Controls and Procedures section includes the information concerning the controls evaluation referred to in the certifications and it should be read in conjunction with the certifications for a more complete understanding of the topics presented. Based on the controls evaluation, our Chief Executive Officer and Principal Financial Officer concluded that as of the date of their evaluation, our disclosure controls and procedures were effective to provide reasonable assurance that (a) the information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and (b) such information is accumulated and communicated to our management, including our Chief Executive Officer and Principal Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

Change in Internal Control over Financial Reporting

. There were no changes in our internal control over financial reporting (as defined in Rule 13a-15(f) and Rule 15d-15(f) under the Exchange Act) during our most recent fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

Information regarding legal proceedings is incorporated by reference herein from *Legal Proceedings* under Note 11, *Commitments and Contingencies*, to our unaudited condensed consolidated financial statements for the three and six months ended June 30, 2018 and 2017 contained in Part I, Item 1 of this Quarterly Report on Form 10-Q.

ITEM 1A. RISK FACTORS

The risk factors below amend and restate the risk factors contained in Part I, Item 1A. of our Annual Report on Form 10-K for the year ended December 31, 2017, filed with the SEC on March 8, 2018 and Part II, Item 1A. of our Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2018, filed with the SEC on May 10, 2018. The occurrence of any one or more of these risks could materially harm our business, operating results, financial condition and prospects. These risks and uncertainties could also cause actual results to differ materially and adversely from those expressed or implied by forward-looking statements that we make from time to time.

Risks Related to our Business

Our business operations and financial position could be adversely affected as a result of our substantial indebtedness and other payment obligations.

As of August 1, 2018, we had approximately \$323.1 million aggregate principal amount of debt outstanding, consisting of approximately \$36.1 million aggregate principal amount of our Exchangeable Notes, issued pursuant to an indenture, as amended by that certain first supplemental indenture, dated July 27, 2018, under which PIP DAC,

formerly known as PIPL, is the issuer and we and our other subsidiaries are the guarantors with Wilmington Trust, National Association, as trustee, of approximately \$78.2 million aggregate principal amount of our Convertible Notes, approximately \$154.5 million aggregate principal amount of our Treximet Secured Notes, approximately \$14.2 million outstanding under our ABL Facility, and approximately \$40.1 million aggregate principal amount outstanding under the Term Credit

Agreement, and together with the ABL Facility, the Credit Facilities). In addition, we have the ability to borrow up to an additional \$5.8 million under the Term Credit Agreement for certain specified purposes, including future acquisitions, working capital or other general corporate purposes, subject to conditions set forth in the Term Credit Agreement, and up to an additional approximately \$9.3 million under the ABL Facility, subject to borrowing base capacity and the conditions set forth in the ABL Facility. In addition, the Term Credit Agreement includes an incremental feature that allows us, with the consent of the requisite lenders under the Term Credit Agreement, to obtain up to an additional \$20.0 million in term loan commitments from new or existing lenders under the Term Credit Agreement that agree to provide such commitments. Our significant indebtedness and other payment obligations could have important consequences. For example, it could:

- make it difficult for us to satisfy our obligations under our outstanding notes and our other indebtedness and contractual and commercial commitments;
- require us to seek Chapter 11 bankruptcy protection;
- limit our flexibility in planning for, or reacting to, changes in our business and the industry in which we operate;
- require us to dedicate a substantial portion of our cash flow from operations to payments on our indebtedness, thereby reducing the availability of our cash flow to fund working capital, capital expenditures and other general corporate purposes;
- restrict us from making strategic acquisitions, entering new markets or exploiting business opportunities;
- place us at a competitive disadvantage compared to our competitors that have proportionally less debt;
- limit our ability to borrow additional funds and/or leverage our cost of borrowing; and
- decrease our ability to compete effectively or operate successfully under adverse economic and industry conditions.

In the event our capital resources are otherwise insufficient to meet future capital requirements and operating expenses, we may seek to finance our cash needs through public or private equity or debt financings, strategic relationships, including the divestiture of non-core assets, assigning receivables, milestone payments or royalty rights, or other arrangements. Securing additional financing will require a substantial amount of time and attention from our management and may divert a disproportionate amount of its attention away from our day-to-day activities, which may adversely affect our management's ability to conduct our day-to-day operations. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. If we are unable to raise additional capital when required or on acceptable terms, we may be required to:

- sell our business or all or substantially all of our assets to one or more third parties;
- seek Chapter 11 bankruptcy protection;
- significantly delay, scale back or discontinue the development or commercialization of our products and product candidates;
- seek collaborators for one or more of our current or future products or product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available; or
- relinquish or license on unfavorable terms, our rights to technologies or product candidates that we otherwise would seek to develop or commercialize ourselves.

Additional equity or debt financing, or corporate collaboration and licensing arrangements, may not be permissible under the indentures governing our outstanding notes or the covenants in the Credit Facilities, or otherwise available on acceptable terms, if at all. Additional equity financing will be dilutive to stockholders, and debt financing, if available, may involve additional restrictive covenants. In addition, if we raise additional funds through collaborations or other strategic transactions, it may be necessary to relinquish potentially valuable rights to our potential products or proprietary technologies, or grant licenses on terms that are not favorable to us.

We may not be able to grow through acquisitions of businesses and assets, the formation of collaborations or other strategic alliances or the in-licensing of products or product candidates.

We have sought growth largely through acquisitions, including the acquisitions of the Zohydro ER product line in 2015, the rights to Treximet intellectual property in 2014, Pernix Sleep in 2013 and Cypress in 2012. As part of our strategy, we plan to pursue acquisitions of assets, businesses or strategic alliances and collaborations (including the in-licensing of products or product-candidates), to expand our existing technologies and operations, such as the July 2018 services agreement with Nalpropion Pharmaceuticals, Inc. (Nalpropion) pursuant to which we manage Nalpropion and exclusively distribute Contrave in the United States. However, the indentures governing the Exchangeable Notes, the Convertible Notes and the Treximet Secured Notes, and the Credit Facilities contain restrictive covenants, which include, among other things, restrictions on the incurrence of indebtedness, as well as certain consolidations, acquisitions, mergers, purchases or sales of assets and capital expenditures, subject to certain exceptions and permissions limited in scope and dollar value,

among other things. For additional information, see the notes to our audited consolidated financial statements for the years ended December 31, 2017 and 2016 contained in Part II, Item 8 of our Annual Report on Form 10-K for the fiscal year ended December 31, 2017. Moreover, it cannot be assured that acquisitions will be available on terms attractive to us or that such acquisitions will be permissible under the indentures governing our outstanding notes and the covenants in the Credit Facilities or that we will be able to arrange financing on terms acceptable to us or to obtain timely federal and state governmental approvals on terms acceptable to us, or at all.

We may be unable to successfully integrate newly acquired businesses or assets and realize the anticipated benefits of these acquisitions or other collaborations or strategic alliances.

Management has in the past devoted, and will in the future devote, significant attention and resources to integrating newly acquired businesses and assets and/or establishing functioning collaborations that leverage our capabilities in pursuit of developing and commercializing our products and product candidates. Potential difficulties we have or may in the future encounter in the integration process include the following:

- the inability to successfully combine our businesses with any newly acquired business, to integrate any newly acquired assets into our existing product portfolio, and to meet our capital requirements following such acquisition, in a manner that permits us to achieve the cost savings or revenue enhancements anticipated to result from these acquisitions, which would result in the anticipated benefits of the acquisitions not being realized in the time frame currently anticipated or at all;
- lost sales and customers as a result of certain of our customers deciding not to do business with us following the acquisition of a business or asset;
- the additional complexities of integrating newly acquired businesses and assets with different core products and markets;
- potential unknown liabilities and unforeseen increased expenses associated with an acquisition of a business or asset;
- performance shortfalls as a result of the diversion of management's attention caused by integrating the operations of a newly acquired business or a newly acquired asset into the existing product portfolio;
- our collaborative partners may not commit adequate resources to the development, marketing and distribution of any collaboration products, limiting our potential revenues from these products;
- our collaborative partners may experience financial difficulties and may therefore be unable to meet their commitments to us;
- our collaborative partners may pursue a competing product candidate developed either independently or in collaboration with others, including our competitors; and
- our collaborative partners may terminate our relationship.

With respect to potential collaborations or strategic alliances, our ability to reach a definitive agreement for any collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to reduce or delay our development or commercialization programs or initiatives.

For all these reasons, you should be aware that it is possible that integrating a newly acquired business or asset and/or the establishment of collaborations or other strategic alliances could result in the distraction of our management, the disruption of our ongoing business or inconsistencies in our products, standards, controls, procedures and policies, any of which could adversely affect our ability to maintain relationships with customers, vendors and employees or to achieve the anticipated benefits of the acquisitions, or could otherwise adversely affect our business and financial results.

Despite our significant level of indebtedness, we and our subsidiaries may still be able to incur substantially more debt, which could exacerbate the risks associated with our substantial leverage.

We may be able to incur substantial additional indebtedness in the future. Although certain of our agreements, including the Credit Facilities and the indentures governing the Exchangeable Notes, the Convertible Notes and the Treximet Secured Notes, limit our ability and the ability of our subsidiaries to incur additional indebtedness, these restrictions are subject to waiver and a number of qualifications and exceptions and, under certain circumstances, debt incurred following receipt of a waiver or in compliance with these restrictions could be substantial. Among other things, we have the ability to borrow up to an additional \$5.8 million under the Term Credit Agreement for certain specified purposes, including future acquisitions, working capital or other general corporate purposes, subject to certain conditions set forth in the Term Credit Agreement, and approximately \$18.3 million of additional funds under the ABL Facility, subject to borrowing base capacity and certain conditions set forth in the ABL Facility. In addition, the Term Credit Agreement includes an

incremental feature that allows us, with the consent of the requisite lenders under the Term Credit Agreement, to obtain up to an additional \$20 million in term loan commitments from new or existing lenders under the Term Credit Agreement that agree to provide such commitments. To the extent that we incur additional indebtedness, the risks associated with our substantial leverage described herein, including our possible inability to service our debt, would increase.

Our debt service obligations may adversely affect our cash flow.

A high level of indebtedness increases the risk that we may default on our debt obligations. We may not be able to generate sufficient cash flow to pay the interest on our debt, and future working capital, borrowings or equity financing may not be available to pay or refinance such debt. If we are unable to generate sufficient cash flow to pay the interest on our debt, we may have to delay or curtail our operations.

Our ability to generate cash flows from operations and to make scheduled payments on our indebtedness will depend on our future financial performance. Our future financial performance will be affected by a range of economic, competitive and business factors that we cannot control, such as those risks described in this section and in our other filings with the SEC. A significant reduction in operating cash flows resulting from changes in economic conditions, increased competition or other events beyond our control could increase the need for additional or alternative sources of liquidity and could have a material adverse effect on our business, financial condition, results of operations, prospects and our ability to service our debt and other obligations. If we are unable to service our indebtedness we will be forced to adopt an alternative strategy that may include actions such as reducing capital expenditures, selling assets, restructuring or refinancing our indebtedness or seeking additional equity capital, or seeking Chapter 11 Bankruptcy Court protection.

These alternative strategies may not be affected on satisfactory terms, if at all, and they may not yield sufficient funds to make required payments on our indebtedness.

If for any reason we are unable to meet our debt service and repayment obligations, we would be in default under the terms of the agreements governing our debt, which may allow our creditors at that time to declare outstanding indebtedness to be due and payable, which would in turn trigger cross-acceleration or cross-default rights between the relevant agreements.

In addition, the borrowings under our credit facilities bear interest at variable rates and other debt we incur could likewise be variable-rate debt. If interest rates increase, our debt service obligations on the variable rate indebtedness would increase even though the amount borrowed thereunder remains the same, and our net income and cash flows, including cash available for servicing our indebtedness, would correspondingly decrease.

The indentures governing the Exchangeable Notes, the Convertible Notes and the Treximet Secured Notes and the covenants in the Credit Facilities and the articles supplementary authorizing the issuance of the Convertible Preferred Stock impose significant operating and/or financial restrictions on us and our subsidiaries that may prevent us from pursuing certain business opportunities and restrict our ability to operate our business.

The indentures governing the Exchangeable Notes, the Convertible Notes and the Treximet Secured Notes and the Credit Facilities contain covenants that restrict our and our subsidiaries' ability to take various actions, such as:

- incur additional debt;
- pay dividends and make distributions on, or redeem or repurchase, our capital stock;
- make certain investments, purchase certain assets or other restricted payments;

- sell assets, including in connection with sale-leaseback transactions;
- create liens;
- enter into transactions with affiliates;
- make lease payments that exceed a specified amount; and
- merge, consolidate or transfer all or substantially all of their assets.

In addition, the articles supplementary authorizing the issuance of our Convertible Preferred Stock prohibit us from authorizing, declaring or paying regular or special dividends or other distributions (whether in the form of cash, shares, indebtedness or any other property or asset, but excluding any purchase, redemption or other acquisition of shares) on the shares of our Common Stock, unless simultaneously with the authorization, declaration or payment, we authorize, declare or pay, as applicable, dividends or other distributions on the Convertible Preferred Stock.

In addition, the terms of the Treximet Secured Notes require us to maintain a minimum liquidity of \$8.0 million at all times and the terms of the ABL Facility require us to maintain unrestricted minimum liquidity of \$7.5 million at all times. In order to maintain minimum liquidity, we must maintain cash or the availability to borrow cash under the ABL Facility in a combined amount of no less than the minimum liquidity set forth in the Treximet Secured Notes indenture and the ABL Facility.

Upon the occurrence of a fundamental change, as described in the indenture governing the 4.25% Convertible Notes, holders of the 4.25% Convertible Notes may require us to repurchase for cash all or part of their 4.25% Convertible Notes at a repurchase price equal to 100% of the principal amount of the 4.25% Convertible Notes to be repurchased, plus accrued and unpaid interest. If a holder elects to convert its 4.25% Convertible Notes for shares in excess of the conversion cap, as described in the indenture governing the 4.25% Convertible Notes, we will be obligated to deliver cash in lieu of any share that was not delivered on account of such limitation. However, we may not have enough available cash or be able to obtain financing at the time we are required to make repurchases of the 4.25% Convertible Notes surrendered therefor in connection with a fundamental change or payments of cash on 4.25% Convertible Notes converted in excess of the conversion cap. In addition, our ability to repurchase the 4.25% Convertible Notes or to pay cash upon conversions of the 4.25% Convertible Notes may be limited by law, by regulatory authority or by agreements governing our indebtedness. Our failure to repurchase the 4.25% Convertible Notes at a time when the repurchase is required by the indenture or to pay any cash payable on future conversions of the 4.25% Convertible Notes as required by the indenture would constitute a default under the indenture. A default under the indenture could also lead to a default under agreements governing our other outstanding indebtedness. If the repayment of the related indebtedness were to be accelerated after any applicable notice or grace periods, we may not have sufficient funds to repay the indebtedness and repurchase the 4.25% Convertible Notes or make cash payments upon conversions as required by the indenture.

Upon the occurrence of a fundamental change, as described in the indenture governing the Exchangeable Notes, holders of the Exchangeable Notes may require us to repurchase for cash all or part of Exchangeable Notes at a repurchase price equal to 100% of the capitalized principal amount of the Exchangeable Notes to be repurchased, plus accrued and unpaid interest. However, we may not have enough available cash or be able to obtain financing at the time we are required to make repurchases of the Exchangeable Notes surrendered therefor in connection with a fundamental change. In addition, our ability to repurchase the Exchangeable Notes or to pay cash upon conversions of the Exchangeable Notes may be limited by law, by regulatory authority or by agreements governing our indebtedness. Our failure to repurchase the Exchangeable Notes at a time when the repurchase is required by the indenture or to pay any cash payable on future conversions of the Exchangeable Notes as required by the indenture would constitute a default under the indenture. A default under the indenture could also lead to a default under agreements governing our other outstanding indebtedness. If the repayment of the related indebtedness were to be accelerated after any applicable notice or grace periods, we may not have sufficient funds to repay the indebtedness and repurchase the Exchangeable Notes or make cash payments upon conversions as required by the indenture.

Our ability to comply with these covenants will likely be affected by many factors, including events beyond our control, and we may not satisfy those requirements. Our failure to comply with our debt-related obligations could result in an event of default under the particular debt instrument, which could permit acceleration of the indebtedness under that instrument and, in some cases, the acceleration of our other indebtedness, in whole or in part.

These restrictions also limit our ability to plan for or react to market conditions, meet capital needs or otherwise restrict our activities or business plans and adversely affect our ability to finance our operations, enter into acquisitions including transactions, collaborations or other commercial transactions or to engage in other business activities that would be in our interest.

Our ability to borrow under the ABL Facility is limited by the amount of our borrowing base. Any negative impact on the elements of our borrowing base, such as accounts receivable and inventory or an imposition of a reserve against our borrowing base, which Cantor Fitzgerald Securities has the authority to do in its sole discretion, could reduce our

borrowing capacity under the ABL Facility.

If we fail to attract and retain key personnel, we may be unable to successfully develop or commercialize our products.

Our success depends in part on our continued ability to attract, retain and motivate highly qualified managerial personnel. We are highly dependent upon our executive management team. The loss of the services of any members of our executive management team or other key personnel could delay or prevent the successful completion of some of our development and commercialization objectives.

Recruiting and retaining qualified sales and marketing personnel is critical to our success. We may not be able to attract and retain these personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us.

Our management devotes substantial time to comply with public company regulations.

As a public company, we incur significant legal, accounting and other expenses. In addition, the Sarbanes-Oxley Act, as well as rules subsequently implemented by the SEC and the Nasdaq Global Market, imposes various requirements on public companies, including with respect to corporate governance practices. Moreover, these rules and regulations increase legal and financial compliance costs and make some activities more time-consuming and costly.

In addition, the Sarbanes-Oxley Act requires, among other things, that our management maintain adequate disclosure controls and procedures and internal control over financial reporting. In particular, we must perform system and process evaluation and testing of our internal control over financial reporting to allow management and, as applicable, our independent registered public accounting firm to report on the effectiveness of our internal control over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act. Our compliance with Section 404 requires us to incur substantial accounting and related expenses and expend significant management efforts. If we are not able to comply with the requirements of Section 404 or if we or our independent registered public accounting firm identifies deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, our financial reporting could be unreliable and misinformation could be disseminated to the public.

Any failure to develop or maintain effective internal control over financial reporting or difficulties encountered in implementing or improving our internal control over financial reporting could harm our operating results and prevent us from meeting our reporting obligations. Ineffective internal controls also could cause our stockholders and potential investors to lose confidence in our reported financial information, which would likely have a negative effect on the trading price of our Common Stock. In addition, investors relying upon this misinformation could make an uninformed investment decision and we could be subject to sanctions or investigations by the SEC, Nasdaq Global Market or other regulatory authorities, or to stockholder class action securities litigation.

Our July 2018 obtainment of the exclusive distribution rights in the United States to Contrave, the April 2015 acquisition of Zohydro ER and the August 2014 acquisition of the rights to Treximet intellectual property and our strategy of obtaining, through asset acquisitions and in-licenses, rights to other products and product candidates for our development pipeline and to proprietary drug delivery and formulation technologies for our life cycle management of current products may not be successful.

We obtained the rights to the exclusive distribution in the United States of Contrave in July 2018, and acquired the rights to Zohydro ER in April 2015 and Treximet intellectual property in August 2014 and from time to time we may seek to engage in additional strategic transactions with third parties to acquire rights to other pharmaceutical products, pharmaceutical product candidates in the late stages of development and proprietary drug delivery and formulation technologies. Because we do not have discovery and research capabilities, the growth of our business will depend in significant part on our ability to acquire or in-license additional products, product candidates or proprietary drug delivery and formulation technologies that we believe have significant commercial potential and are consistent with our commercial objectives. However, we may be unable to license or acquire suitable products, product candidates or technologies from third parties for a number of reasons.

The licensing and acquisition of pharmaceutical products, product candidates and related technologies is a competitive area. A number of more established companies are also pursuing strategies to license or acquire products, product candidates or drug delivery and formulation technologies, which may mean fewer suitable acquisition opportunities

for us as well as higher acquisition prices. Many of our competitors have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities.

Other factors that may prevent us from licensing or otherwise acquiring suitable products, product candidates or technologies include:

- we may be unable to license or acquire the relevant products, product candidates or technologies on terms that would allow us to make an appropriate return on investment;

- companies that perceive us as a competitor may be unwilling to license or sell their product rights or technologies to us;
- we may be unable to identify suitable products, product candidates or technologies within our areas of expertise;
- we may have inadequate cash resources or may be unable to obtain financing to acquire rights to suitable products, product candidates or technologies from third parties; and
- we may be restricted from licensing or otherwise acquiring suitable products due to restrictions contained in the indentures governing the Exchangeable Notes, the 4.25% Convertible Notes and the Treximet Secured Notes and the restrictions contained in the covenants in the Credit Facilities.

If we are unable to successfully identify and acquire rights to products, product candidates or proprietary drug delivery and formulation technologies and successfully integrate them into our operations, we may not be able to increase our revenues in future periods, which could result in significant harm to our financial condition, results of operations and development prospects.

Our failure to adequately address the financial, operational or legal risks of any acquisitions or in-license arrangements could harm our business. Financial aspects of these transactions that could alter our financial position, reported operating results or stock price include:

- use of cash resources;
- higher than anticipated acquisition costs and expenses;
- potentially dilutive issuances of equity securities;
- the incurrence of debt and contingent liabilities, impairment losses or restructuring charges;
- large write-offs and difficulties in assessing the relative percentages of in-process research and development expense that can be immediately written off as compared to the amount that must be amortized over the appropriate life of the asset; and
- amortization expenses related to other intangible assets.

Operational risks that could harm our existing operations or prevent realization of anticipated benefits from these transactions include:

- challenges associated with managing an increasingly diversified business;
- disruption of our ongoing business;
- difficulty and expense in assimilating the operations, products, technology, information systems or personnel of the acquired company or in-licensed product;
- diversion of management's time and attention from other business concerns;
- entry into a geographic or business market in which we have little or no prior experience;
- inability to maintain uniform standards, controls, procedures and policies;

- the assumption of known and unknown liabilities of the acquired business or asset, including intellectual property claims; and
- subsequent loss of key personnel.

If we are unable to successfully manage our licensing or acquisitions, or distribution rights that we have obtained, our ability to develop and commercialize new products and continue to expand our product pipeline may be limited.

If we are unable to effectively train and equip our sales force to sell newly acquired, in-licensed and existing products, our ability to successfully commercialize our products will be harmed.

We have in the past made, and may in the future continue to make, acquisitions or in-licenses of pharmaceutical products. We have also experienced, and expect to continue to experience, turnover of some of our sales representatives that we hired or will hire, requiring us to train new sales representatives. The members of our sales force may have no prior experience promoting the pharmaceutical products that we own or may acquire or in-license in the future. As a result, we expend significant time and resources to train our sales force to be credible and persuasive in convincing physicians to prescribe and pharmacists to dispense these pharmaceutical products. In addition, we must train our sales force to ensure that a consistent and appropriate message about our products and the products that we distribute is being delivered to our potential customers. Our sales representatives may also experience challenges promoting multiple products when they call on physicians and their office staff. In addition, prior to our obtaining the exclusive distribution rights in the United States to Contrave in July 2018, all of our products or the products we distributed related to underserved segments, such as central nervous system (CNS) indications, including pain, neurology, and psychiatry, as well as other specialty therapeutic areas. If we are unable to effectively train our sales force and equip them with effective materials relating to our

pharmaceutical products, including medical and sales literature to help them inform and educate potential customers about the benefits of such products and their proper administration and label indication, our efforts to successfully market these pharmaceutical products could be put in jeopardy, which could have a material adverse effect on our financial condition, stock price and operations.

Recent reductions in workforce associated with our realignment plan could disrupt the operation of our business, distract our management from focusing on revenue-generating efforts, result in the erosion of employee morale, and impair our ability to respond rapidly to growth opportunities in the future.

We completed a realignment plan in January 2018 that resulted in personnel reduction of approximately 22% of our workforce, primarily through a reduction of sales and commercial infrastructure positions. The employee reductions could result in an erosion of morale and affect the focus and productivity of our remaining employees, including those directly responsible for revenue generation and the management and administration of our finances, which in turn may adversely affect our revenue in the future or cause other administrative deficiencies. Additionally, employees directly affected by the reductions may seek future employment with our business partners, customers or competitors. We may face wrongful termination, discrimination, or other claims from employees affected by the reduction related to their employment and termination. We could incur substantial costs in defending ourselves or our employees against such claims, regardless of the merits of such actions. Furthermore, such matters could divert the attention of our employees, including management, away from our operations, harm productivity, harm our reputation and increase our expenses. We cannot assure you that our realignment plan will be successful, and we may need to take additional realignment efforts, including additional personnel reduction, in the future.

Risks Related to Commercialization

Treximet has become subject to competition from generic competitors, which will have a material adverse impact on our sales of Treximet and our results of operations.

We own, have applied for or hold licenses to patents. Our patent protection for our products extends for varying periods in accordance with the legal life of patents. The protection afforded is limited by the applicable terms of our patents and the availability of legal remedies in the United States. Following expiration of patents covering our products, other entities may be able to obtain approval to manufacture and market generic alternatives, which we expect would result in lower net revenue. For example, in August 2014, through our wholly owned subsidiary, Pernix Ireland Limited (PIL), we acquired the U.S. intellectual property rights to Treximet from GSK. Treximet is covered by five patents in the U.S. Including six months of pediatric exclusivity, four of the patents expired on February 14, 2018, and one expires on April 2, 2026. Six companies filed Abbreviated New Drug Applications, or ANDAs, with the U.S. Food and Drug Administration, or FDA, seeking approval to market a generic version of Treximet. Three of the ANDA filers are enjoined from engaging in the commercial manufacture, use, offer to sell, or sale in or importation into the United States of the proposed ANDA products prior to April 2, 2026. One of the two ANDA filers that were legally able to launch their generic versions of Treximet on February 15, 2018 did enter the market and we are expecting the other two to enter the market later in 2018. While we launched our own generic version of Treximet on February 15, 2018, the entry of generics into the market will have a material adverse impact on our sales of Treximet and our results of operations.

The commercial success of our currently marketed products, products that we distribute and any additional products that we successfully commercialize will depend upon the degree of market acceptance by physicians, patients, healthcare payors and others in the medical community.

Any products that we bring to the market may not gain market acceptance by physicians, patients, healthcare payors and others in the medical community. If our products do not achieve an adequate level of acceptance, we may not generate significant product revenue and may not be profitable. The degree of market acceptance of our products depends on a number of factors, including:

- the prevalence and severity of any side effect;
- the efficacy and potential advantages over the alternative treatments;
- the ability to offer our branded products for sale at competitive prices, including in relation to any generic products;
- substitution of our branded products with generic equivalents at the pharmacy level;
- relative convenience and ease of administration;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support; and
- sufficient third-party coverage or reimbursement.

We face competition, which may result in others discovering, developing or commercializing products before or more successfully than us.

The industry in which we operate is highly competitive. Our competitors include large and small pharmaceutical companies, and other private and public research organizations. We face significant competition for our currently marketed products and products that we distribute, including significant price competition from products for the same therapeutic categories. Some of our currently marketed products and products that we distribute do not have patent protection and face or could face generic competition.

Some or all of our products may face competition from other branded and generic drugs approved for the same therapeutic indications, approved drugs used "off-label" for such indications and novel drugs in clinical development. As a result, our commercial opportunities could be reduced or eliminated if competitors develop and commercialize products that are more effective, safer, have fewer or less severe side effects, are more convenient or are less expensive than our products.

Our patent rights, or the patent rights held by certain of our commercial partners or licensors, may not adequately protect our products or product candidates if competitors develop products that compete with us without legally infringing our or our commercial partners' or licensors' patent rights. Further, our or our commercial partners' or licensors' patent rights may be subject to challenge by branded and generic competition.

The FDCA and FDA regulations and policies provide certain exclusivity incentives to manufacturers to develop generic versions of innovator products and 505(b)(2) New Drug Applications. A generic manufacturer may only be required to show that its proposed generic product has the same active pharmaceutical ingredient, dosage form, strength, route of administration and indication as, and is bioequivalent to, our brand-name product. The development costs for such generic products would be significantly less than those for our or our commercial partners' or licensors' brand-name products and could lead to the emergence of multiple lower-priced competitor products, which would substantially limit our or our commercial partners' or licensors' ability to obtain a return on the investments we have made in our brand-name products. Additionally, other branded competitors may obtain FDA or other regulatory approval for their product candidates more rapidly than we may obtain approval for our product candidates, and they may obtain periods of exclusivity under applicable laws that may delay our own product candidates' approval by the FDA.

Products in our portfolio that do not have patent protection are potentially at risk for generic competition. Additionally, products we sell through our distribution, collaborative or co-promotion arrangements may also face competition in the marketplace. The availability of a large number of branded prescription products, including drugs that are prescribed off-label, generic products and over-the-counter products could limit the demand for, and the revenue that we are able to generate from the sale of our products.

Some of our competitors have significantly greater financial, technical and human resources than we have and superior expertise in marketing and sales, research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products and thus may be better equipped than us to discover, develop, manufacture and commercialize products. These competitors also compete with us in recruiting and retaining qualified management personnel and acquiring technologies. Many of our competitors have collaborative arrangements in our target markets with leading companies and research institutions. In many cases, products that compete with our products have already received regulatory approval or are in late-stage development, have well-known brand names, are distributed by large pharmaceutical companies with substantial resources and have achieved widespread acceptance among physicians and patients. Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

We may face competition based on the safety and effectiveness of our products, the timing and scope of regulatory approvals, the availability and cost of supply, marketing and sales capabilities, reimbursement coverage, price, patent

position and other factors. Our competitors may develop or commercialize more effective, safer or more affordable products, or products with more effective patent protection, than our products. Accordingly, our competitors may commercialize products more rapidly or effectively than we are able to, which would adversely affect our competitive position, our revenue and profit from existing products and anticipated revenue and profit from product candidates. If our products or product candidates are rendered noncompetitive, we may not be able to recover the expenses of developing and commercializing those products or product candidates.

Negative publicity regarding any of our products or product candidates could delay or impair our ability to market any such product, delay or prevent approval of any such product candidate and may require us to spend time and money to address these issues.

If any of our products or any similar products distributed by other companies prove to be, or are asserted to be, harmful to consumers and/or subject to FDA enforcement action, our ability to successfully market and sell our products could be impaired. Because of our dependence on patient and physician perceptions, any adverse publicity associated with illness or other adverse effects resulting from the use or misuse of our products or any similar products distributed by other companies could limit the commercial potential of our products and expose us to potential liabilities.

If we are unable to attract, hire and retain qualified sales and management personnel and successfully manage our sales and marketing programs and resources, or if our commercial partners do not adequately perform, the commercial opportunity for our products may be diminished.

We and any other commercialization partner we engage may not be able to attract, hire, train and retain qualified sales and sales management personnel in the future. If we or they are not successful in maintaining an effective number of qualified sales personnel, our ability to effectively market and promote our products may be impaired. Even if we are able to effectively maintain such sales personnel, their efforts may not be successful in commercializing our products.

In addition, a significant portion of the revenues that we might receive from sales of products that are the subject to commercial partnerships could largely depend upon the efforts our partners. The efforts of partners, in many instances, could likely be outside our control. If we are unable to maintain commercial partnerships or to effectively establish alternative arrangements for our products, our business could be adversely affected. In addition, despite arrangements with other partners, we still may not be able to cover all of the prescribing physicians for our products at the same level of reach and frequency as our competitors, and we ultimately may need to further expand our selling efforts in order to effectively compete.

From time to time, we compliment the efforts of our sales force with on-line and other non-personal promotional initiatives that target both physicians and patients. We also focus upon ensuring broad patient access to our products by negotiating agreements with leading commercial managed care organizations, or MCOs, and with government payors. Although our goal is to achieve sales through the efficient execution of our sales and marketing plans and programs, we may not be able to effectively generate prescriptions and achieve broad market acceptance for our products on a timely basis, or at all.

A failure to maintain optimal inventory levels to meet commercial demand for our products could harm our reputation and subject us to financial losses.

Our product, Zohydro ER with BeadTek, contains a controlled substance that is regulated by the DEA under the Controlled Substances Act. DEA quota requirements applicable to Schedule I and II controlled substances limit the amount of controlled substance drug products a manufacturer can manufacture and the amount of API it can use to manufacture those products. We may experience difficulties obtaining raw materials needed to manufacture such product as a result of DEA regulations or we may experience manufacturing challenges in the future. If we are unsuccessful in obtaining quotas, unable to manufacture and release inventory on a timely and consistent basis, fail to maintain an adequate level of product inventory, or if inventory is destroyed or damaged or reaches its expiration date, patients might not have access to our product, our reputation and our brands could be harmed and physicians may be less likely to prescribe such product in the future, each of which could have a material adverse effect on our business, financial condition, results of operations and cash flows.

In addition, Nalpropion is the exclusive supplier of Contrave to us and we are the exclusive distributor of Contrave in the U.S. Nalpropion is currently party to an agreement with Patheon Pharmaceuticals and Patheon Inc., (collectively,

Patheon), pursuant to which Patheon has agreed to manufacture commercial quantities of Contrave tablet products for Nalpropion. If Patheon, or any alternative manufacturer retained by Nalpropion, fails to deliver the required commercial quantities of Contrave on a timely basis, pursuant to provided specifications and at commercially reasonable prices, Nalpropion may be unable to supply us with adequate inventory to meet distribution demand for Contrave in the United States, which would negatively impact our ability to generate revenue.

We and our contract manufacturers may not be able to obtain the regulatory approvals or clearances that are necessary to manufacture pharmaceutical products.

Before approving a new drug, the FDA requires that the facilities in which the product will be manufactured be in compliance with Good Manufacturing Practices, or cGMP, requirements, which include, among other things, requirements relating to quality control and quality assurance, maintenance of records and documentation and utilization of qualified raw materials. To be successful, our products must be manufactured in compliance with cGMP during development and, following approval, in commercial quantities and at acceptable costs.

We and our contract manufacturers, and the contract manufacturers used by our commercial partners and licensors, must comply with these cGMP requirements. While we believe that we and our and Nalpropion's contract manufacturers currently meet these requirements, we cannot assure that the manufacturing facilities used to manufacture and package our products will continue to meet cGMP requirements or will be sufficient to manufacture all of our needs and/or the needs of our customers for commercial materials.

We and our and Nalpropion's contract manufacturers may also encounter problems with the following:

- production yields;
- possible facility contamination;
- quality control and quality assurance programs;
- shortages of qualified personnel;
- compliance with FDA or other regulatory authorities' regulations, including the demonstration of purity and potency;
- changes in FDA or other regulatory authorities' requirements;
- production costs; and/or
- development of advanced manufacturing techniques and process controls.

In addition, we and our and Nalpropion's contract manufacturers must register our and their manufacturing facilities with the FDA, and such manufacturing facilities are subject to FDA inspections to confirm continuing compliance with cGMP and other regulations. If we or our or Nalpropion's contract manufacturers fail to maintain regulatory compliance, the FDA may impose regulatory sanctions including, among other things, temporary or permanent refusal to permit us, Nalpropion or our or Nalpropion's contract manufacturers to continue manufacturing approved products. As a result, our business, financial condition and results of operations may be materially harmed.

If

we or third-party manufacturers fail to comply with regulatory requirements for Zohydro ER with BeadTek, the DEA may take regulatory actions detrimental to our business, resulting in temporary or permanent interruption of distribution, withdrawal of such product from the market or other penalties.

We, third-party manufacturers and our Zohydro with BeadTek product are subject to the Controlled Substances Act and DEA regulations thereunder. Accordingly, we must adhere to a number of requirements, which can include registration, record-keeping and reporting requirements; labeling and packaging requirements; security controls, procurement and manufacturing quotas; and certain restrictions on refills. Failure to maintain compliance with

applicable requirements can result in enforcement action that could have a material adverse effect on our business, financial condition, results of operations and cash flows. The DEA may seek civil penalties, refuse to renew necessary registrations or initiate proceedings to revoke those registrations. In certain circumstances, violations could result in criminal proceedings.

If the suppliers of Contrave fail to comply with stringent regulations applicable to pharmaceutical drug manufacturers, our partners may face delays in the further development or commercialization of Contrave.

Although naltrexone itself is not addictive, synthesis of naltrexone is a multi-step process with a natural opiate starting material that has the potential for abuse and is therefore regulated as a controlled substance under the federal Controlled Substances Act or applicable foreign equivalents. As such, manufacturers of naltrexone API must be registered with the DEA or applicable foreign equivalents. Manufacturers making naltrexone also must obtain annual quotas from the DEA for the opiate starting material. Because of the DEA- related requirements and modest current demand for naltrexone API, there currently exist a limited number of manufacturers of this API. Therefore, API costs for naltrexone are greater than for the other constituents of our product. Demand for Contrave may require amounts of naltrexone greater than the currently available worldwide supply or our or our partners' current forecasts for the supply to us of Contrave or its components. Any lack of sufficient quantities of naltrexone would limit our ability to continue to distribute Contrave in the United States and would limit our partners' ability to commercialize Contrave outside the United States and Europe.

Changes in laws, regulations and policies applicable to the market for opioid products, litigation and government investigations may adversely affect our business, financial condition and results of operations.

The manufacture, marketing, sale, promotion and distribution of Zohydro ER are subject to comprehensive government regulations. Changes in laws and regulations applicable to the market for opioid products, including Zohydro ER with BeadTek, could potentially affect our business. For instance, federal, state and local governments have recently given increased attention to the public health issue of opioid abuse.

At the federal level, the White House Office of National Drug Control Policy continues to coordinate efforts between the FDA, the DEA, and other agencies to address this issue. In 2017, the FDA requested that Endo International plc, or Endo, withdraw Opana ® ER, one of its opioid pain medications, from the market due to the public health consequences of abuse (even when taken at recommended doses) associated with the use of Endo's product. Endo voluntarily complied with the FDA's removal request. In publicly announcing the request, the FDA noted that it would take similar regulatory action with regard to other opioid products if the risks for abuse outweighed the product's potential benefits. The FDA also recently revised the "black-box" warnings required in the labeling of opioid pain medications, including Zohydro ER with BeadTek, that highlight the risk of misuse, abuse, addiction, overdose and death. The DEA continues its efforts to hold manufacturers, distributors, prescribers and pharmacies accountable through various enforcement actions, as well as the implementation of compliance practices for controlled substances. In addition, the Centers for Disease Control and Prevention (CDC), issued national, non-binding guidelines in 2016 relative to the prescribing of opioids. These guidelines included recommended considerations for primary care provider use when prescribing opioids, including specific considerations and cautionary information about opioid dosage increases and morphine milligram equivalents. Certain payors are, or are considering, adopting these CDC guidelines, as well as putting other restrictions on the prescribing of opioid pain medications. Additionally, the Trump administration and certain members of Congress have called for the DEA to restrict the quantity of opioids that can be manufactured in the United States.

Federal activity includes the issuance of a Presidential commission's final recommendations on combating opioid abuse; the federal Department of Health and Human Services declaring the opioid crisis a national public health emergency; President Trump's establishing a commission to make recommendations regarding new laws and policies to combat opioid addiction and abuse; Mallinckrodt's \$35.0 million settlement with the Justice Department regarding allegations that the company failed to report signs that large quantities of its highly addictive oxycodone pills were diverted to the black market in Florida; and the FDA's announced intention to extend to immediate-release opioids the Risk Evaluation and Mitigation Strategy, or REMS, currently imposed on extended-release opioids, such as Zohydro ER. At the state and local level, a number of states and major cities have brought separate lawsuits against various pharmaceutical companies marketing and selling opioid based pain medications, alleging misleading or otherwise improper promotion of opioid drugs to physicians and consumers. In addition, the attorneys general from several states have announced the launch of a joint investigation into the marketing and sales practices of drug companies that manufacture opioid pain medications.

These initiatives and other changes and potential changes in laws, regulations and policies, including those that have the effect of reducing the overall market for opioids or reducing the prescribing of opioids, could adversely affect our business, financial condition and results of operations.

Our ceasing the distribution of our combination drug product IDA will impact our net revenues. In the future, FDA could also request that we no longer market and distribute certain of our other DESI, OTC, medical foods and dietary supplement products.

Through our Macoven entity, Pernix distributed a combination product called isometheptene mucate, dichlorphenazone, and acetaminophen, or IDA, which was originally approved by the US Food and Drug Administration, or FDA, in 1948 for safety only. The product's efficacy as an adjunct treatment for peptic ulcer disease, as well as other medical conditions, such as migraine headaches, was reviewed under the FDA's Drug

Efficacy Study Implementation process, DESI notice 3265.

On October 20, 2017, we received a letter dated October 19, 2017 from the FDA asserting that IDA was subject to DESI 3265 and that any drug products identified in DESI 3265, including IDA, require an approved NDA or ANDA in order for them to continue to be distributed. Since we have not obtained an NDA or ANDA for IDA, the FDA directed that we should immediately cease distribution of IDA. While IDA has a long history of safe use, we complied with the FDA's request and confirmed with the FDA within the requested time frame that we ceased distribution of the product. For the year ended December 31, 2017, our net revenues from the sale of IDA were \$14.9 million. As we will not have further revenues from the product in 2018, the discontinuance of the product will impact net revenues for the fiscal year ending December 31, 2018.

Additionally, it is possible that the FDA could in the future request that we no longer distribute certain of our DESI, OTC, medical foods and dietary supplement products, which could adversely affect our net revenues.

Product liability lawsuits against us could cause us to incur substantial liabilities and limit commercialization of any products that we may develop.

We face an inherent risk of product liability exposure related to the sale of our currently marketed products and any other products that we successfully develop, commercialize or distribute. For example, at the state and local level, a number of states and major cities have brought separate lawsuits against various pharmaceutical companies marketing and selling opioid based pain medications, alleging misleading or otherwise improper promotion of opioid drugs to physicians and consumers. In addition, the attorneys general from several states have announced the launch of a joint investigation into the marketing and sales practices of drug companies that manufacture opioid pain medications. In May 2018, we were notified that the Company was named in an ongoing lawsuit that has been brought by the State of Arkansas against various pharmaceutical companies that market and sell opioid based pain medications. During the second quarter of 2018, we were also served with two additional lawsuits in which we were included as a defendant, both of which were filed in Philadelphia County, PA. At this time, we are unaware of whether we will be named in any of the other lawsuits brought by other state and local governments or in the various investigations by attorneys general from several states.

If we cannot successfully defend ourselves against claims that our products, product candidates or products that we distribute caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for our products, products that we distribute or any products that we may develop;
- injury to reputation;
- withdrawal of clinical trial participants;
- withdrawal of a product from the market;
- costs to defend the related litigation;
- substantial monetary awards to trial participants or patients;
- diversion of management time and attention;
- loss of revenue; and
- the inability to commercialize any products that we may develop.

The amount of insurance that we currently hold may not be adequate to cover all liabilities that we might incur. Further, there may be instances where our existing insurance coverage will not respond to or cover a claimed liability or where our insurers may dispute whether their insurance contracts must legally respond to such claimed liabilities. In such instances, we may not have insurance funds available to cover such liabilities, as well as the legal defense costs that would have to be incurred, which could have a material adverse effect on our business financial condition and results of operations. Finally, insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost and we may not be able to obtain insurance coverage that will be adequate to satisfy any liability that may arise.

Seasonality may cause fluctuations in our financial results.

We generally experience some effects of seasonality due to patients resetting their deductible amounts in the beginning of the calendar year and reaching their deductible amounts during the year. Accordingly, sales of our products and associated revenue have generally decreased in the first quarter of each year and begin to increase during the remainder of the year. This seasonality may cause fluctuations in our financial results. In addition, other seasonality trends may develop and the existing seasonality that we experience may change.

Risks Related to Our Dependence on Third Parties

We may face delays in the development and commercialization of, or be unable to meet demand for, our products and may lose potential revenues if the manufacturers upon whom we rely fail to properly produce our products or in the volumes that we require on a timely basis, or to comply with stringent regulations applicable to pharmaceutical drug manufacturers.

We do not manufacture our products, and we do not currently plan to develop any capacity to do so. We rely on third parties to manufacture our products. The manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of pharmaceutical products often encounter difficulties in production, particularly in scaling up and validating initial production. These problems include difficulties with production costs and yields, quality control, including stability of the product and quality assurance testing, shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations.

Manufacturers may not perform as agreed or may terminate their agreements. Additionally, manufacturers may experience manufacturing difficulties due to resource constraints or as a result of labor disputes or unstable political environments. If manufacturers were to encounter any of these difficulties, or otherwise fail to comply with their contractual obligations, our ability to sell our products or any other product candidate that we commercialize would be jeopardized. Any delay or interruption in our ability to meet commercial demand for our products will result in the loss of potential revenues.

For example, due to a manufacturing issue with one of our suppliers, the 20 mg. strength of Zohydro ER with BeadTek was on back order until March 2018. During that time, we marketed and distributed other strengths of Zohydro ER with BeadTek, including the 10 mg., 15 mg., 30 mg., 40 mg. and 50 mg. strengths. While utilization of the 10 mg., 15 mg. and 30 mg. strengths increased in order to fulfill patient needs, the temporary stock-out of the 20 mg. strength impacted the overall prescription volume for Zohydro ER with BeadTek, which resulted in a continued loss of revenue. While the manufacturer of the product, Recro Pharma, Inc. (Recro), has been able to reinstate supply of the 20 mg. strength of Zohydro to us, Recro has continued to be confronted with manufacturing challenges with the 20 mg. strength that could cause it to be unable to supply us with the 20 mg strength of Zohydro on a short or long term basis in the future.

In addition, in connection with our acquisition of the rights to Treximet intellectual property in August 2014, we discovered short-term supply constraints for the product. While we believe that we have addressed this issue by securing another manufacturer, our failure to obtain sufficient supply of Treximet to meet anticipated demand in the future may result in a loss of revenue.

Prior to the closing of the acquisition of Orexigen's assets, Orexigen informed us that, due to certain packaging defects caused by manufacturing services provided by its third party manufacturer, Patheon, it has elected to conduct a Class III recall at the retail level with respect to six lots of Contrave. The recall was effected on August 9, 2018. We believe Nalpropion has adequate inventory of the product to prevent any product shortages and the product manufacturer, Patheon, has been placed on legal notice of actual and potential claims against it relative to the six lots noted above, as well as any other damages that might be incurred. Nevertheless, future manufacturing issues with Patheon could cause product shortages that would negatively impact our results of operations.

All manufacturers of pharmaceutical products must comply with the FDA's current cGMP requirements enforced by the FDA through its facilities inspection program. The FDA is also likely to conduct inspections of our and our commercial partners' manufacturing facilities as part of their review of any NDAs we submit to the FDA. These cGMP requirements include, among other things, quality control, quality assurance and the maintenance of records and documentation. Manufacturers of our products may be unable to comply with these cGMP requirements and with other FDA, state and foreign regulatory requirements. Failure to comply with these requirements may result in fines and civil penalties, suspension of production, suspension or delay in product approval, product seizure or recall, or withdrawal of product approval. If the safety, efficacy, or quantities of our products are compromised due to our or our commercial partners' manufacturers' failure to adhere to applicable laws or for other reasons, we may not be able to obtain regulatory approval for or successfully commercialize our products.

Moreover, our or our commercial partners' manufacturers and suppliers may experience difficulties related to their overall businesses and financial stability, which could result in delays or interruptions of our supply of our products.

We do not have alternate manufacturing plans in place at this time. If we need to change to other manufacturers, the FDA must approve these manufacturers' facilities and processes in advance, which would require new testing and compliance inspections. Moreover, new manufacturers may have to be trained in or independently develop the processes necessary for production.

Any of these factors could adversely affect the commercial activities for our products and required approvals for any other product candidate that we develop, or entail higher costs or result in our being unable to effectively commercialize our products. Furthermore, if our or our commercial partners' manufacturers failed to deliver the required commercial quantities of raw materials, including bulk drug substance, or finished product on a timely basis and at commercially reasonable prices, we would likely be unable to meet demand for our products and we would lose potential revenues.

The concentration of our product sales to only a few wholesale distributors increases the risk that we will not be able to effectively distribute our products if we need to replace any of these customers, which would cause our sales to decline.

The majority of our sales are to a small number of pharmaceutical wholesale distributors, which in turn sell our products primarily to retail pharmacies, which ultimately dispense our products to the end consumers. For the year ended December 31, 2017, McKesson Corporation, Cardinal Health and AmerisourceBergen Drug Corporation accounted for 34%, 24% and 30%, respectively, of our total gross sales. For the year ended December 31, 2016, McKesson Corporation, Cardinal Health and AmerisourceBergen Drug Corporation accounted for 36%, 26% and 31%, respectively, of our total gross sales.

If any of these customers cease doing business with us or materially reduce the amount of product they purchase from us and we cannot conclude agreements with replacement wholesale distributors on commercially reasonable terms, we might not be able to effectively distribute our products through retail pharmacies. The possibility of this occurring is exacerbated by the recent significant consolidation in the wholesale drug distribution industry, including through mergers and acquisitions among wholesale distributors and the growth of large retail drugstore chains. As a result, a small number of large wholesale distributors control a significant share of the market.

Any collaboration arrangements that we enter into may not be successful, which could adversely affect our ability to develop and commercialize our product candidates.

We enter into collaboration arrangements from time to time on a selective basis. Our collaborations may not be successful. In the future, we might market certain branded and generic products in the U.S. pursuant to collaboration arrangements. The success of such collaboration arrangements may depend heavily on the efforts and activities of our collaborators. Collaborators generally have significant discretion in determining the efforts and resources that they will apply to these collaborations.

Disagreements between parties to collaboration arrangements regarding clinical development and commercialization matters can lead to delays in the development process or commercialization of applicable product candidates and, in some cases, termination of the collaboration arrangement. These disagreements can be difficult to resolve if neither of the parties has final decision-making authority.

Our business could suffer as a result of a failure to manage and maintain our distribution network with our wholesale customers.

We depend on the distribution abilities of our wholesale customers to ensure that our products are effectively distributed through the supply chain. If there are any interruptions in our customers' ability to distribute products through their distribution centers, our products may not be effectively distributed, which could cause confusion and frustration among pharmacists and lead to product substitution.

To the extent that we conduct clinical trials, we plan to rely on third parties to conduct these trials and such third parties may not perform satisfactorily, including failing to meet established deadlines for the completion of such trials.

We do not plan to independently conduct clinical trials for product candidates that we might acquire in the future and, instead, would rely on third parties, such as contract research organizations, clinical data management organizations, medical institutions and clinical investigators. Reliance on these third parties for clinical development activities would reduce our control over these activities, although we would remain responsible for ensuring that clinical trials performed at our direction are conducted in accordance with approved investigational plans and approved clinical trial protocols. Moreover, the FDA requires compliance with good clinical practices for conducting, recording, and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights and confidentiality of trial participants are protected. Reliance on third parties does not relieve a sponsor of

these responsibilities and requirements. Furthermore, these third parties could also have relationships with other entities, some of which may be our competitors. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we might not be able to obtain, or may be delayed in obtaining, regulatory approvals for future product candidates and may not be able to, or may be delayed in our efforts to, successfully commercialize such product candidates.

We are subject to various legal proceedings and business disputes that could have a material adverse impact on our business, financial condition and results of operations and could cause the market value of our Common Stock to decline.

We are subject to various legal proceedings and business disputes and additional claims may arise in the future. Current legal proceedings and disputes as well as those that may arise in the future may be complex and extended and may occupy the resources of our management and employees. These proceedings may also be costly to prosecute and defend and may involve substantial awards or damages payable by us if not found in our favor some or all of which may not be covered by our existing insurance coverage or might result in the granting of certain rights on unfavorable terms in order to settle such proceedings. Defending against or settling such claims and any unfavorable legal decisions, settlements or orders could have a material adverse effect on our business, financial condition and results of operations and could cause the market value of our Common Stock to decline.

Risks Related to Intellectual Property

If we are unable to obtain and maintain protection for the intellectual property relating to our products, the value of our products will be adversely affected.

Our success will depend in part upon our ability, as well as our partners, to obtain and maintain protection for the intellectual property covering or incorporated into the products that we market, distribute and/or sell. The patent situation in the field of pharmaceuticals is highly uncertain and involves complex legal and scientific questions. We rely upon patents, trademarks, trade secrets and confidentiality agreements to protect the products that we market, distribute and/or sell.

We may not be able to obtain additional patent rights relating to our products and pending patent applications to which we have rights may not issue as patents or may not issue in a form that will be advantageous to us. Further, our patents and the patents of our commercial partners could be challenged, narrowed, invalidated, or held to be unenforceable, the cost of any type of patent proceeding could be substantial and the results of which could limit our ability to stop third party competitors from marketing competing products. Moreover, some physicians may prescribe a competitive or similar product that is not approved by the FDA to treat patients with insomnia or weight-related problems in lieu of prescribing Silenor or Contrave, respectively, and we cannot guarantee that our intellectual property or that the intellectual property of our partners, will prevent or deter such "off-label" use. Our patent rights also may not afford us protection against all competitors.

Our collaborators and licensors may not adequately protect our intellectual property rights. Certain of these third parties may have the first right to maintain or defend our intellectual property rights and, although we may have the right to assume the maintenance and defense of our intellectual property rights if these third parties do not, our ability to maintain and defend our intellectual property rights may be compromised by the acts or omissions of these third parties.

Trademark protection of our products may not provide us with a meaningful competitive advantage.

We use trademarks on our marketed, branded products and believe that having distinctive marks is an important factor in marketing those products and maintaining good will. Distinctive marks may also be important for any additional products that we successfully develop and/or commercially market. However, even though we register, maintain, monitor and defend our trademarks as necessary, we generally do not rely on our marks to provide a meaningful competitive advantage over other products. We believe that efficacy, safety, convenience, price, the level of competition and the availability of reimbursement from government and other third-party payors are likely to continue to be more important factors in the commercial success of our products.

If we fail to comply with our obligations in our intellectual property licenses with third parties, we could lose license rights that are important to our business.

We have acquired rights to products and product candidates under license and co-promotion agreements with third parties and expect to enter into additional licenses and co-promotion agreements in the future. Our existing licenses

impose, and we expect that future licenses will impose, various development and commercialization, purchase commitment, royalty, sublicensing, patent protection and maintenance, insurance and other similar obligations on us.

If we fail to comply with our obligations under a license agreement, the licensor may have the right to terminate the license in whole, terminate the exclusive nature of the license or bring a claim against us for damages. Any such termination or claim could prevent or impede our ability to market any product that is covered by the license agreement. Even if we contest any such termination or claim and are ultimately successful, our business could suffer. In addition, upon any termination of a license agreement, our market position could be impacted if we were legally required to provide a licensor with a license to use any related intellectual property that we developed.

If we are unable to protect the confidentiality of our proprietary information and know-how, the value of our technology and products could be adversely affected.

In addition to patents and trademarks, we rely upon trade secrets, technical know-how and continuing technological innovation to develop and maintain our competitive position. We require our relevant persons, such as employees, consultants and other third parties, including vendors (when appropriate), to execute confidentiality and/or assignment-of-inventions agreements with us.

These agreements may be breached, and in some instances, we may not have an appropriate remedy available for breach of the agreements. Furthermore, our competitors may independently develop substantially equivalent proprietary information and techniques, reverse engineer our information and techniques, or otherwise gain access to our proprietary technology. If we are unable to protect the confidentiality of our proprietary information and know-how, competitors may be able to use this information to develop products that compete with our products, which could adversely impact our business.

If we infringe or are alleged to infringe intellectual property rights of third parties, it may adversely affect our business.

Our development and commercialization activities, as well as any product candidates or products resulting from these activities, may infringe or be claimed to infringe one or more claims of an issued patent or pending patent application which we do not hold a license or other rights. Third parties may own or control these patents or patent applications and could bring claims against us or our collaborators that would cause us to incur substantial expenses and, if successful against us, could cause us to pay substantial damages. Further, if a patent infringement suit were brought against us or our collaborators, we or our collaborators could be forced to stop or delay development, manufacturing or sales of the product or product candidate that is the subject of the suit.

If any relevant claims of third-party patents that we are alleged to infringe are upheld as valid and enforceable in any litigation or administrative proceeding, we or our potential future collaborators could be prevented from commercializing a product, or maybe required to obtain licenses from the patent owners of each such patent, or to redesign our products, and could be liable for damages. There can be no assurance that such licenses would be available or, if available, would be available on acceptable terms, or that we would be successful in any attempt to redesign our products. Even if we or our collaborators were able to obtain a license, the rights may be nonexclusive, which could result in our competitors gaining access to the same intellectual property. Ultimately, we could be prevented from commercializing a product, or be forced to cease some aspect of our business operations. An adverse determination in a judicial or administrative proceeding, failure to redesign, or failure to obtain necessary licenses could prevent us or our future collaborators from manufacturing and selling our products and would have a material adverse effect on our business.

There has been substantial litigation and other proceedings regarding patents and other intellectual property rights in the pharmaceutical and biotechnology industries. The cost to us of any patent litigation or other proceedings, even if resolved in our favor, could be substantial. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. Patent litigation and other proceedings may also absorb significant management time.

Risks Related to Our Financial Position

We may need substantial additional funding and may be unable to raise capital when needed, which would force us to delay, reduce or eliminate our product development programs, commercialization efforts or acquisition strategy.

We make significant investments in our currently-marketed products for sales, marketing, and distribution. We have used, and expect to continue to use, revenue from sales of our marketed products and products we distribute to fund acquisitions (at least partially), for development costs and to establish and expand our sales and marketing infrastructure.

Our future capital requirements will depend on many factors, including:

- our ability to restructure our existing debt;
- our ability to successfully integrate the operations of newly acquired businesses and assets and/or in-licensed products or product candidates into our product portfolio;
- our ability to successfully establish and maintain collaborations or other strategic alliances;
- the level of product sales from our currently marketed or distributed products and any additional products that we may market or distribute in the future;
- the extent to which we acquire or invest in products, businesses and technologies;
- the scope, progress, results and costs of clinical development activities for our product candidates;
- the costs, timing and outcome of regulatory review of our product candidates;
- the number of, and development requirements for, additional product candidates that we pursue;
- the costs of commercialization activities, including product marketing, sales and distribution;
- the extent to which we choose to establish additional collaboration, co-promotion, distribution or other similar arrangements for our products and product candidates; and
- the costs of preparing, filing and prosecuting patent applications and maintaining, enforcing and defending intellectual property related claims.

We intend to obtain any additional funding that we require through public or private equity or debt financings, strategic relationships, including the divestiture of non-core assets, assigning receivables, milestone payments or royalty rights, or other arrangements. We cannot assure such funding will be available on reasonable terms, or at all. Additional equity financing will be dilutive to stockholders, and debt financing, if available, may involve restrictive covenants. In addition, if we raise additional funds through collaborations or other strategic transactions, it may be necessary to relinquish potentially valuable rights to our potential products or proprietary technologies, or we may have to grant licenses on terms that are not favorable to us.

If efforts to raise additional funds are unsuccessful, we may be required to delay, scale-back or eliminate plans or programs relating to our business, relinquish some or all rights to our products or renegotiate less favorable terms with respect to such rights than we would otherwise agree to accept or we may have to cease operating as a going concern. In addition, if we do not meet our payment obligations to third parties as they come due, we may be subject to litigation claims. Even if we were successful in defending against these potential claims, litigation could result in substantial costs and be a distraction to management and might result in unfavorable results that could further adversely impact our financial condition.

If we are unable to continue as a going concern, we may have to liquidate our assets and may receive less than the value at which those assets are carried on our financial statements, and it is likely that investors will lose all or a part of their investments.

If the estimates that we make, or the assumptions upon which we rely, in preparing our financial statements prove inaccurate, our future financial results may vary from expectations.

Our financial statements have been prepared in accordance with GAAP. The preparation of our financial statements requires us to make estimates and judgments that affect the reported amounts of our assets, liabilities, stockholders' equity, revenues and expenses, the amounts of charges accrued by us and related disclosure of contingent assets and liabilities. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. For example, at the same time we recognize revenues for product sales, we also record an adjustment, or decrease, to revenue for estimated charge backs, rebates, discounts, vouchers and returns, which management determines on a product-by-product basis as its best estimate at the time of sale based on each product's historical experience adjusted to reflect known changes in the factors that impact such reserves. For new products, these sales adjustments may be estimated based upon information available on any similar products in the marketplace or specific information provided by business partners or if management is not able to derive a reasonable estimate for the adjustments, gross revenue can be deferred and recognized as the product is prescribed.

Actual sales allowances may vary from our estimates for a variety of reasons, including unanticipated competition, regulatory actions or changes in one or more of our contractual relationships. We cannot assure you, therefore, that there may not be material fluctuations between our estimates and the actual results.

Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited.

As of December 31, 2017, we had net operating losses (NOLs) of approximately \$396.5 million for federal income tax purposes. Subject to applicable limitations, these NOLs may be used to offset future taxable income, to the extent we generate any taxable income, and thereby reduce our future federal income taxes otherwise payable.

Under Section 382 of the Internal Revenue Code (the Code), if a corporation undergoes an "ownership change" as defined in that section, the corporation's ability to use its pre-change NOLs and other pre-change tax attributes to offset its post-change income may become subject to significant limitations. In general terms, an ownership change occurs if there is a greater than 50 percentage point increase in the amount of the corporation's stock owned by certain stockholders during a three year testing period. An ownership change may be triggered by the purchase and sale, redemption, or new issuance of stock. \$366.5 million of our NOLs are already subject to limitation under Section 382 of the Code. We may experience an ownership change in the future as a result of shifts in our stock ownership, which may result from, among other things, issuances of Common Stock, including upon the exercise by the holders of our existing convertible debt securities and any convertible debt securities we may offer in the future of the conversion rights under such instruments, and upon the exercise of stock options and other equity compensation awards. If a future ownership change were to be triggered, our ability to use some or all of our remaining NOLs could be significantly limited. Further, depending on the level of our taxable income, all or a portion of our NOLs may expire unutilized, which could prevent us from offsetting future taxable income by the entire amount of our current and future NOLs.

Additionally, on December 22, 2017, the U.S. government enacted comprehensive tax legislation commonly referred to as the Tax Cuts and Jobs Act (the Tax Act). The Tax Act contains significant changes to corporate taxation and modifies several existing laws around NOLs, including a limitation on the deduction for NOLs to 80 percent of current year taxable income as well as an indefinite carryover period for NOLs. Both provisions are applicable for losses arising in tax years beginning after December 31, 2017. For these reasons, even if we generate taxable income in the future, our ability to utilize our NOLs may be limited, potentially significantly so.

If we fail to meet all applicable continued listing requirements of the Nasdaq Global Market and it determines to delist our Common Stock, the market liquidity and market price of our Common Stock could decline.

If we fail to meet all applicable listing requirements of the Nasdaq Global Market and it determines to delist our Common Stock, trading, if any, in our shares may continue to be conducted on an over-the-counter market, such as the OTCQX, OTCQB or the OTC Pink. Delisting of our shares would result in limited release of the market price of those shares and limited analyst coverage and could restrict investors' interest and confidence in our securities. Also, a delisting could have a material adverse effect on the trading market and prices for our shares and our ability to issue additional securities or to secure additional financing. In addition, if our shares were not listed and the trading price of our shares was less than \$5.00 per share, our shares could be subject to Rule 15g-9 under the Exchange Act which, among other things, requires that broker/dealers satisfy special sales practice requirements, including making individualized written suitability determinations and receiving a purchaser's written consent prior to any transaction. In such case, our securities could also be deemed to be a "penny stock" under the Securities Enforcement and Penny Stock Reform Act of 1990, which would require additional disclosure in connection with trades in those shares, including the delivery of a disclosure schedule explaining the nature and risks of the penny stock market. Such requirements could severely limit the liquidity of our securities and our ability to raise additional capital.

If significant business or product announcements by us or our competitors cause fluctuations in our stock price, an investment in our stock may suffer a decline in value.

The market price of our Common Stock may be subject to substantial volatility as a result of announcements by us or other companies in our industry, including our collaborators. Announcements that may subject the price of our Common Stock to substantial volatility include but are not limited to announcements regarding:

- our operating results, including the amount and timing of sales of our products and our ability to successfully integrate the operations of newly acquired businesses or products;
- the availability and timely delivery of a sufficient supply of our products;
- the safety and quality of our products or those of our competitors;
- our licensing and collaboration agreements and the products or product candidates that are the subject of those agreements;
- the results of discoveries, preclinical studies and clinical trials by us or our competitors;
- the acquisition of technologies, product candidates or products by us or our competitors;
- the development of new technologies, product candidates or products by us or our competitors;

- regulatory actions with respect to our product candidates or products or those of our competitors; and
- significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors.

The holders of our debt obligations and preferred stock, if any, will have priority over our Common Stock with respect to payment in the event of liquidation, dissolution or winding up and with respect to the payment of interest and dividends.

In any liquidation, dissolution or winding up of the Company, our Common Stock would rank below all claims of our note holders and other creditors as well as the claims of the Convertible Preferred Stock and any preferred stock issued subsequent to the date hereof. As of August 1, 2018, we had approximately \$323.1million aggregate principal amount of debt outstanding, consisting of approximately (i) \$36.1 million aggregate principal amount of our Exchangeable Notes, (ii) \$78.2 million aggregate principal amount of our 4.25% Convertible Notes, (iii) \$154.5 million aggregate principal amount of our Treximet Secured Notes, and (iv) approximately \$54.3 million outstanding under our Credit Facilities. In addition, on August 1, 2018 we also issued 81,000 shares of the Convertible Preferred Stock and we are authorized, under our articles of incorporation, to issue up to an additional 1,000,000 shares of our Series B Junior Participating Stock and up to 7,500,000 shares of preferred stock, with designations, rights and preferences as they may determine. Accordingly, our Board has in the past and may in the future, without stockholder approval, issue shares of preferred stock with dividend, liquidation, conversion, voting or other rights that could adversely affect the voting power or other rights of the holders of our Common Stock.

In the event of our liquidation, dissolution or winding up, holders of our Common Stock would not be entitled to receive any payment or other distribution of assets upon our liquidation, dissolution or winding up until after all of our obligations to our note holders and other creditors were satisfied and holders of senior equity securities, including holders of our Convertible Preferred Stock, had received any payment or distribution due to them.

Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain.

We did not make any distributions for the years ended December 31, 2017 and 2016. We are currently investing in our promoted products lines and do not anticipate paying dividends in the foreseeable future. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, the terms of the Credit Facilities, the indentures governing the Exchangeable Notes, the 4.25% Convertible Notes and the Treximet Secured Notes and the articles supplementary authorizing the issuance of the Convertible Preferred Stock prohibit us from paying dividends. As a result, capital appreciation, if any, of our Common Stock will be your sole source of gain for the foreseeable future.

Sales of a substantial number of shares of our Common Stock or equity-linked securities could cause our stock price to fall.

Sales of a substantial number of shares of our Common Stock or equity-linked securities in the public market or the perception that these sales might occur, could depress the market price of our Common Stock and could impair our ability to raise capital through the sale of additional equity or equity-linked securities. We are unable to predict the effect that sales may have on the prevailing market price of our Common Stock.

Exchange of the Exchangeable Notes and conversion of the Convertible Preferred Stock and the 4.25% Convertible Notes may dilute the ownership interest of existing stockholders.

Subject to certain contractual restrictions, holders of the Exchangeable Notes and the Convertibles Notes are entitled to exchange or convert, respectively, the Exchangeable Notes or the 4.25% Convertible Notes for shares of our Common Stock at their option at any time prior to the close of business on the second scheduled trading day

immediately preceding the maturity date of the Exchangeable Notes or the 4.25% Convertible Notes, respectively. In addition, holders of the Convertible Preferred Stock, subject to certain contractual restrictions, have the right to convert their shares of Convertible Preferred Stock for shares of our Common Stock at their option. We also have the right, at our option, to automatically convert all shares of the Convertible Preferred Stock, subject to the satisfaction of certain specified conditions. The exchange of some or all of the Exchangeable Notes or the conversion of some or all of the 4.25% Convertible Notes or shares of the Convertible Preferred Stock will dilute the ownership interests of existing stockholders. If holders of the Exchangeable Notes were to exchange all of the outstanding Exchangeable Notes (not taking into account the potential for capitalization of interest or additional interest or changes to the exchange price), we would need to deliver approximately 6,498,636 shares of our Common Stock to settle the exchange, which would result in significant dilution to existing stockholders. If holders of the 4.25% Convertible Notes were to exchange all of the outstanding 4.25%

Convertible Notes, we would need to deliver approximately 682,413 shares of our Common Stock to settle the conversion, which would result in additional dilution to existing stockholders. If holders of the Convertible Preferred Stock were to convert all of the outstanding shares of Convertible Preferred Stock, and not giving effect to any applicable ownership limitations on such conversions, we would need to deliver approximately 3,389,121 shares of our Common Stock to settle the conversions, which would result in additional dilution to existing stockholders. Any sales in the public market of any shares of our Common Stock issuable upon such exchange or conversions could adversely affect prevailing market prices of our Common Stock.

Future issuances of preferred stock may adversely affect the market price for our Common Stock.

Additional issuances and sales of preferred stock, or the perception that such issuances and sales could occur, may cause prevailing market prices for our Common Stock to decline and may adversely affect our ability to raise additional capital in the financial markets at times and prices favorable to us.

Our operating results are likely to fluctuate from period to period.

We anticipate that there may be fluctuations in our future operating results. Potential causes of future fluctuations in our operating results may include:

- period-to-period fluctuations in financial results due to seasonal demands for certain of our products;
- unanticipated potential product liability or patent infringement claims;
- new or increased competition from generics;
- the introduction of technological innovations or new commercial products by competitors;
- changes in the availability of reimbursement to the patient from third-party payers for our products;
- the entry into, or termination of, key agreements, including key strategic alliance agreements;
- the initiation of litigation to enforce or defend any of our intellectual property rights;
- the loss of key employees;
- the results of pre-clinical testing, IND application, and potential clinical trials of some product candidates;
- regulatory changes;
- the results and timing of regulatory reviews relating to the approval of product candidates;
- the results of clinical trials conducted by others on products that would compete with our products and product candidates;
- failure of any of our products or product candidates to achieve commercial success;
- general and industry-specific economic conditions that may affect research and development expenditures;
- future sales of our Common Stock; and

- changes in the structure of health care payment systems resulting from proposed healthcare legislation or otherwise.

Our stock price is subject to fluctuation, which may cause an investment in our stock to suffer a decline in value.

The market price of our Common Stock may fluctuate significantly in response to factors that are beyond our control. The stock market in general has recently experienced extreme price and volume fluctuations. The market prices of securities of pharmaceutical and biotechnology companies have been extremely volatile and have experienced fluctuations that often have been unrelated or disproportionate to the operating performance of these companies. These broad market fluctuations could result in extreme fluctuations in the price of our Common Stock, which could cause a decline in the value of our Common Stock.

If we become subject to unsolicited public proposals from activist stockholders, we may experience significant uncertainty that would likely be disruptive to our business and increase volatility in our stock price.

Public companies, particularly those in volatile industries such as the pharmaceutical industry, have been the target of unsolicited public proposals from activist stockholders. The unsolicited and often hostile nature of these public proposals can result in significant uncertainty for current and potential licensors, suppliers, patients, physicians and other constituents, and can cause these parties to change or terminate their business relationships with the targeted company. Companies targeted by these unsolicited proposals from activist stockholders may not be able to attract and retain key personnel as a result of the related uncertainty. In addition, unsolicited proposals can result in stockholder class action lawsuits. The review and consideration of an unsolicited proposal as well as any resulting lawsuits can be a significant distraction for management and employees, and may require the expenditure of significant time, costs and other resources.

If we were to receive unsolicited public proposals from activist stockholders, we may encounter all of these risks and, as a result, may be delayed in executing our core strategy. We could be required to spend substantial resources on the evaluation of the proposal as well as the review of other opportunities that never come to fruition. If we were to receive any of these unsolicited public proposals, the future trading price of our Common Stock is likely to be even more volatile than in the past, and could be subject to wide price fluctuations based on many factors, including uncertainty associated with the proposals.

We may become involved in securities or other class action litigation that could divert management's attention and harm our business.

The stock market has from time to time experienced significant price and volume fluctuations that have affected the market prices for the Common Stock of pharmaceutical and biotechnology companies. These broad market fluctuations may cause the market price of our Common Stock to decline. In the past, following periods of volatility in the market price of a particular company's securities, securities class action litigation has often been brought against that company. Any securities or other class action litigation asserted against us could have a material adverse effect on our business.

Risks Related to Regulatory Matters

If we are not able to obtain required regulatory approvals, we will not be able to commercialize our product candidates and our ability to generate increased revenue will be materially impaired.

Product candidates and the activities associated with their development and commercialization, including their testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA, the DEA and other regulatory agencies in the United States. Should we acquire or develop a product candidate, the failure to obtain regulatory approval would prevent us from commercializing the product candidate. Securing FDA approval requires the submission of extensive preclinical and clinical data and supporting information for each therapeutic indication to establish the product candidate's safety and efficacy. Securing FDA approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the FDA. Additionally, it is possible that future product candidates may not be effective, may be only moderately effective, or may have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining regulatory approval or prevent or limit commercial use.

The process of obtaining regulatory approvals is expensive, often takes many years, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved and the nature of the disease or condition to be treated. Changes in regulatory approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in the regulatory review process for a product application may cause delays in the approval of, or rejection of, an application. The FDA has substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional preclinical, clinical or other studies. The FDA may decline to approve one or more of our product candidates for many reasons, including:

- disagreement with the design or implementation of our clinical trials;
- failure to demonstrate that a product candidate is safe and effective for its proposed indication;
- failure of clinical trial results to meet the level of statistical significance required for approval;
- failure to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;

- disagreement with our interpretation of data from preclinical studies or clinical trials;
- insufficiency of data collected from clinical trials of a product candidate to support the submission and filing of an NDA or other submission or to obtain regulatory approval;
- disapproval of the manufacturing processes or facilities of third-party manufacturers with whom we contract for clinical and commercial supplies; and
- changes in approval policies or regulations that render our preclinical and clinical data insufficient for approval.

In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent regulatory approval of a product candidate. Any regulatory approval ultimately obtained may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

Any pharmaceutical product for which we currently have marketing approval could be subject to restrictions or withdrawal from the market and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our products.

Any FDA approved products are subject to continued requirements of and review by the FDA. These requirements include submissions of safety and other post-marketing information and reports, registration requirements, cGMP requirements relating to quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping. Even after a product receives FDA approval, that approval may be subject to limitations on the indicated uses for which the product may be marketed, or to requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product. Later discovery of previously unknown problems with our products, manufacturers, or manufacturing processes or failure to comply with regulatory requirements may result in administrative and judicial actions such as:

- withdrawal of the products from the market;
- restrictions on the marketing or distribution of such products;
- requirements to place additional warnings on the labels for such products;
- requirements to develop a REMS for such products or, if a REMS is already in place, to incorporate additional requirements under the REMS;
- requirements to conduct additional post-market studies;
- restrictions on the manufacturers or manufacturing processes;
- warning letters;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recalls;
- fines;
- suspension or withdrawal of regulatory approvals;
- refusal to permit the import or export of our products;
- product seizure;
- injunctions or the imposition of civil or criminal penalties; or
- private lawsuits alleging harm caused to subjects or patients.

For example, even though U.S. regulatory approval has been obtained for Contrave, which we have the exclusive right to distribute in the United States from Nalpropion, the FDA has imposed restrictions on its indicated uses and marketing and has imposed ongoing requirements for post-marketing studies and other activities. Nalpropion also is required to conduct a number of post-marketing studies, including a series of studies in obese pediatric patients to evaluate the safety and efficacy of Contrave for weight management in pediatric populations and a group of short-term trials, including a single-dose pharmacokinetic study in renal and hepatic impairment and a placebo-controlled cardiovascular outcomes clinical trial (the "CVOT"). We cannot assure you that a new CVOT submitted by

Nalpropion will satisfy the FDA's post-marketing requirements related to cardiovascular outcomes or that the FDA will not require Nalpropion to conduct additional studies during or after the CVOT.

Any issues relating to these restrictions or post-marketing requirements (including any additional studies which the FDA may require or a delay in conducting the post-marketing required studies) for our products, or for Contrave, could have an adverse impact on product market acceptance, as well as our ability to market, sell and/or distribute (as applicable) such potentially impacted product in the United States and to generate revenue.

In addition, the FDA strictly regulates labeling, advertising and promotion of marketed products. A pharmaceutical product that receives FDA approval may only be promoted for FDA-approved indications and in accordance with the FDA-approved labeling. We may be subject to enforcement and other liability if we inappropriately promote our products.

Our sales depend on payment and reimbursement from third-party payors, and a reduction in the payment rate or reimbursement could result in decreased use or sales of our products.

Our sales of currently marketed products and products that we distribute and our ability to commercialize our products effectively depends substantially on the availability of sufficient coverage and reimbursement from third-party payors, including U.S. governmental payors such as the Medicare and Medicaid programs, MCOs and private insurers. All of our promoted products are generally well covered by managed care and private insurance plans. Generally, the status or tier within managed care formularies, which are lists of approved products developed by MCOs, varies but coverage is similar to other products within the same class of drugs. However, the position of any of our branded products that requires a higher patient copayment may make it more difficult to expand the current market share for such product. In some cases,

MCOs may require additional evidence that a patient had previously failed another therapy, additional paperwork or prior authorization from the MCO before approving reimbursement for a branded product. Some Medicare Part D plans also cover some or all of our products, but the amount and level of coverage varies from plan to plan. We also participate in the Medicaid Drug Rebate program with the Centers for Medicare & Medicaid Services (CMS) and submit all of our covered products for inclusion in this program. Coverage of our products under individual state Medicaid plans varies from state to state.

Additionally, our covered products are made available under the 340B Drug Pricing Program, which is codified as Section 340B of the Public Health Service Act. The 340B program requires participating manufacturers to agree to charge statutorily defined covered entities no more than the 340B "ceiling price" for the manufacturer's covered outpatient drugs. Details of the 340B program, our reliance on payment and reimbursement from third-party payors, and a reduction in the payment rate or reimbursement are discussed in the Business section under the heading "*Pharmaceutical Pricing and Reimbursement*" in Part I, Item 1, of our most recent Annual Report on Form 10-K.

There have been, there are, and we expect there will continue to be federal and state legislative and administrative proposals that could limit the amount that government health care programs will pay to reimburse the cost of pharmaceutical and biologic products. For example, the Medicare Prescription Drug Improvement and Modernization Act of 2003, or MMA, created a new Medicare benefit for prescription drugs. The Deficit Reduction Act of 2005 significantly reduced reimbursement for drugs under the Medicaid program. More recently, there have been proposals to impose federal rebates on Medicare Part D drugs, requiring federally-mandated rebates on all drugs dispensed to Medicare Part D enrollees or on only those drugs dispensed to certain groups of lower income beneficiaries. Legislative or administrative acts that reduce reimbursement or result in us owing additional rebates for our products could adversely impact our business.

Details of changes under Health Care Reform, as well as current uncertainties arising as a result of Trump administration and Congressional initiatives, are discussed in the Business section under the heading "*Effects of Legislation on the Pharmaceutical Industry*" in Part I, Item 1, of our most recent Annual Report on Form 10-K.

In addition, private insurers, such as MCOs, may adopt their own reimbursement reductions in response to federal or state legislation. Any reduction in reimbursement for our products could materially harm our results of operations. In addition, we believe that the increasing emphasis on managed care in the United States has and will continue to put pressure on the price and usage of our products, which may adversely impact our product sales. Furthermore, when a new product is approved, governmental and private coverage for that product and the amount for which that product will be reimbursed are uncertain. We cannot predict the availability or amount of reimbursement for our product candidates, and current reimbursement policies for marketed products and products that we distribute may change at any time.

The MMA established a voluntary prescription drug benefit, called Part D, which became effective in 2006 for all Medicare beneficiaries. We cannot be certain that our currently marketed products and products that we distribute will continue to be, or any of our product candidates still in development will be, included in the Medicare prescription drug benefit. Even if our products are included, the private health plans that administer the Medicare drug benefit can limit the number of prescription drugs that are covered on their formularies in each therapeutic category and class. In addition, private managed care plans and other government agencies continue to seek price discounts. Because many of these same private health plans administer the Medicare drug benefit, they have the ability to influence prescription decisions for a larger segment of the population. In addition, certain states have proposed or adopted various programs under their Medicaid programs to control drug prices, including price constraints, restrictions on access to certain products and bulk purchasing of drugs.

With respect to Nalpropion, there is also continued uncertainty outside of the U.S., as to the extent that governmental authorities may establish favorable coverage and reimbursement levels for Contrave. The ability of Nalpropion to secure favorable coverage and reimbursement levels outside of the U.S. is important to its revenue projections and

thus its ability to be successful could impact our results of operations.

If we acquire and market additional products to the market, these products may not be considered cost-effective and reimbursement to the patient may not be available or sufficient to allow us to sell our product candidates on a competitive basis to a sufficient patient population. We may need to conduct expensive pharmacoeconomic trials in order to demonstrate the cost-effectiveness of our products and product candidates.

If we fail to comply with our reporting and payment obligations under the Medicaid Drug Rebate program or other governmental pricing programs, we could be subject to additional reimbursement requirements, penalties, sanctions and fines, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

We participate in and have certain price reporting obligations to the Medicaid Drug Rebate program and other governmental pricing programs.

Under the Medicaid Drug Rebate program, we are required to pay a rebate to each state Medicaid program for our covered outpatient drugs that are dispensed to Medicaid beneficiaries and paid for by a state Medicaid program as a condition of having federal funds being made available to the states for our drugs under Medicaid and Medicare Part B (we currently do not market any Part B drugs). Those rebates are based on pricing data reported by us on a monthly and quarterly basis to the CMS the federal agency that administers the Medicaid Drug Rebate program. These data include the average manufacturer price and, in the case of innovator products, the best price for each drug which, in general, represents the lowest price available from the manufacturer to any entity in the United States in any pricing structure, calculated to include all sales and associated rebates, discounts and other price concessions.

Health Care Reform made significant changes to the Medicaid Drug Rebate program, such as expanding rebate liability from fee-for-service Medicaid utilization to include the utilization of Medicaid MCOs as well and changing the definition of average manufacturer price. Health Care Reform also increased the minimum Medicaid rebate; changed the calculation of the rebate for certain innovator products that qualify as line extensions of existing drugs; and capped the total rebate amount at 100% of the average manufacturer price. Finally, Health Care Reform requires pharmaceutical manufacturers of branded prescription drugs to pay a branded prescription drug fee to the federal government.

On February 1, 2016, CMS issued final regulations to implement the changes to the Medicaid Drug Rebate program under Health Care Reform, which became effective on April 1, 2016. The issuance of regulations and coverage expansion by various governmental agencies relating to the Medicaid Drug Rebate program has and will continue to increase our costs and the complexity of compliance, has been and will be time-consuming to implement, and could have a material adverse effect on our results of operations, particularly if CMS challenges the approach we take in our implementation of the final rule.

Federal law requires that any company that participates in the Medicaid Drug Rebate program also participate in the Public Health Service's 340B drug pricing program in order for federal funds to be available for the manufacturer's drugs under Medicaid and Medicare Part B. The 340B program requires participating manufacturers to agree to charge no more than the 340B "ceiling price" for the manufacturer's covered outpatient drugs to a variety of community health clinics and other entities that receive health services grants from the Public Health Service, as well as hospitals that serve a disproportionate share of low-income patients. Health Care Reform expanded the list of covered entities to include certain free-standing cancer hospitals, critical access hospitals, rural referral centers and sole community hospitals. The 340B ceiling price is calculated using a statutory formula based on the average manufacturer price and rebate amount for the covered outpatient drug as calculated under the Medicaid Drug Rebate program. Changes to the definition of average manufacturer price and the Medicaid rebate amount under Health Care Reform and CMS's final regulations implementing those changes also could affect our 340B ceiling price calculations and negatively impact our results of operations.

Health Care Reform obligates the Secretary of HHS, to create regulations and processes to improve the integrity of the 340B program. On January 5, 2017, HRSA issued a final regulation regarding the calculation of 340B ceiling price and the imposition of civil monetary penalties on manufacturers that knowingly and intentionally overcharge covered entities. The effective date of the regulation has been delayed until July 1, 2018. Implementation of this final rule and the issuance of any other final regulations and guidance could affect our obligations under the 340B program in ways we cannot anticipate. In addition, legislation may be introduced that, if passed, would further expand the 340B

program to additional covered entities or would require participating manufacturers to agree to provide 340B discounted pricing on drugs used in the inpatient setting.

Pricing and rebate calculations vary across products and programs, are complex, and are often subject to interpretation by us, governmental or regulatory agencies and the courts. In the case of our Medicaid pricing data, if we become aware that our reporting for a prior quarter was incorrect, or has changed as a result of recalculation of the pricing data, we are obligated to resubmit the corrected data for up to three years after those data originally were due. Such restatements and recalculations increase our costs for complying with the laws and regulations governing the Medicaid Drug Rebate program and could result in an overage or underage in our rebate liability for past quarters. Price recalculations also may affect the ceiling price at which we are required to offer our products under the 340B drug discount program.

We are liable for errors associated with our submission of pricing data. In addition to retroactive rebates and the potential for 340B program refunds, if we are found to have knowingly submitted any false price information to the government, we may be liable for civil monetary penalties. Our failure to submit the required price data on a timely basis could also result in a civil monetary penalty for each day the information is late beyond the due date. Such failure also could be grounds for CMS to terminate our Medicaid drug rebate agreement, pursuant to which we participate in the Medicaid program. In the event that CMS terminates our rebate agreement, federal payments may not be available under Medicaid or Medicare Part B for our covered outpatient drugs.

CMS and the Office of the Inspector General have pursued manufacturers that were alleged to have failed to report these data to the government in a timely manner. Governmental agencies may also make changes in program interpretations, requirements or conditions of participation, some of which may have implications for amounts previously estimated or paid. We cannot assure you that our submissions will not be found by CMS to be incomplete or incorrect.

Federal law requires that for a company to be eligible to have its products paid for with federal funds under the Medicaid and Medicare Part B programs as well as to be purchased by certain federal agencies and grantees, it also must participate in the Department of Veterans Affairs, (VA), Federal Supply Schedule, (FSS), pricing program. To participate, we are required to enter into an FSS contract with the VA, under which we must make our innovator "covered drugs" available to the "Big Four" federal agencies - the VA, the Department of Defense, or DoD, the Public Health Service (PHS), and the Coast Guard - at pricing that is capped pursuant to a statutory federal ceiling price, (FCP), formula set forth in Section 603 of the Veterans Health Care Act of 1992, or VHCA. The FCP is based on a weighted average non-federal average manufacturer price (Non-FAMP), which manufacturers are required to report on a quarterly and annual basis to the VA. If a company misstates Non-FAMPs or FCPs it must restate these figures. In 2017, the civil monetary penalties for the knowing provision of false information in connection with a Non-FAMP filing was \$181,071 for each item of false information. This penalty amount has not yet been updated for 2018.

FSS contracts are federal procurement contracts that include standard government terms and conditions, separate pricing for each product, and extensive disclosure and certification requirements. All items on FSS contracts are subject to a standard FSS contract clause that requires FSS contract price reductions under certain circumstances where pricing is reduced to an agreed "tracking customer." Further, in addition to the "Big Four" agencies, all other federal agencies and some non-federal entities are authorized to access FSS contracts. FSS contractors are permitted to charge FSS purchasers other than the Big Four agencies "negotiated pricing" for covered drugs that is not capped by the FCP; instead, such pricing is negotiated based on a mandatory disclosure of the contractor's commercial "most favored customer" pricing. We offer the same price to the Big 4 and other government agencies on our FSS contract.

In addition, pursuant to regulations issued by the DoD TRICARE Management Activity, now the Defense Health Agency, to implement Section 703 of the National Defense Authorization Act for Fiscal Year 2008, each of our covered drugs is listed on a Section 703 Agreement under which we have agreed to pay rebates on covered drug prescriptions dispensed to TRICARE beneficiaries by TRICARE network retail pharmacies. Companies are required to list their innovator products on Section 703 Agreements in order for those products to be eligible for DoD formulary inclusion. The formula for determining the rebate is established in the regulations and our Section 703 Agreement and is based on the difference between the annual Non-FAMP and the FCP (as described above, these price points are required to be calculated by us under the VHCA).

Our relationships with customers and payors are subject to applicable fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputation harm, and diminished profits and future earnings.

Healthcare providers, payors and others play a primary role in the recommendation and prescription of our products. Our arrangements with third-party payors and customers exposes us to broadly applicable fraud and abuse and other healthcare laws and regulation that may constrain the business or financial arrangements and relationships through

which we market, sell and distribute our products. Applicable federal and state healthcare laws and regulations, include but are not limited to, the following:

- The federal healthcare anti-kickback statute prohibits, among other things, any person or entity from knowingly and willfully soliciting, offering, receiving or paying remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, lease, order or arranging for or recommendation of, any good or service, for which payment may be made, in whole or in part, under federal healthcare programs such as Medicare and Medicaid. The term "remuneration" has been broadly interpreted to include anything of value. The government can establish a violation of the anti-kickback statute without proving that a person or entity had actual knowledge of the statute or specific intent to violate. Some courts, as well as

certain governmental guidance, have interpreted the scope of the anti-kickback statute to cover any situation where one purpose of the remuneration is to induce referrals of federal health care program business, even if there are other legitimate reasons for the remuneration. In addition, the government may assert that a claim including items or services resulting from a violation of the anti-kickback statute constitutes a false or fraudulent claim for purposes of the False Claims Act. The anti-kickback statute has been applied by government enforcement officials to a number of common business arrangements in the pharmaceutical industry. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution. Those exceptions and safe harbors are drawn narrowly. Failure to meet all of the requirements of the exception or safe harbor does not make the conduct per se illegal, but the legality of the arrangements will be evaluated based on the totality of the facts and circumstances. However, there are no safe harbors for many common practices, such as educational and research grants or product support and patient assistance programs. We seek to comply with the available statutory exceptions and safe harbors whenever possible, but our practices may not in all cases meet all of the criteria for safe harbor protection from anti-kickback liability.

- The federal False Claims Act imposes civil penalties, and provides for whistleblower or qui tam actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented claims for payment of government funds that are false or fraudulent or knowingly making, or using or causing to be made or used a false record or statement material to a false or fraudulent claim to avoid, decrease, or conceal an obligation to pay money to the federal government. In recent years, several pharmaceutical and other health care companies have faced enforcement actions under the False Claims Act for, among other things, allegedly submitting false or misleading pricing information to government health care programs and providing free product to customers with the expectations that the customers will bill federal programs for the product. Federal enforcement agencies have also showed increased interest in pharmaceutical companies' product and patient assistance programs, including reimbursement and co-pay support services. Other companies have faced enforcement actions for causing false claims to be submitted because of the company's marketing the product for unapproved uses. False Claims Act liability is potentially significant because the statute provides for treble damages and mandatory penalties of \$11,181 to \$22,363 per false claim or statement. Because of the potential for large monetary damages and penalties, pharmaceutical manufacturers often resolve allegations without admissions of liability for significant and material amounts. Companies may be required to enter into corporate integrity agreements with the government to avoid exclusion from federal health care programs. Corporate integrity agreements impose substantial costs on companies to ensure compliance. There are also federal criminal statutes that prohibit making or presenting a false or fictitious or fraudulent claim to the federal government.
- The Foreign Corrupt Practices Act and similar anti-bribery laws in countries outside of the U.S., such as the U.K. Bribery Act of 2010, prohibit companies and their intermediaries from making, or offering or promising to make, improper payments for the purpose of obtaining or retaining business or otherwise seeking favorable treatment.
- The Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program. HIPAA also prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement or representation, or making or using any false writing or document knowing the same to contain any materially false, fictitious or fraudulent statement or entry in connection with the delivery of or payment for healthcare benefits, items or services.
- The Open Payments program imposes annual reporting requirements on manufacturers of drugs, devices, or biologics for which payment is available under Medicare, Medicaid or the State Children's Health Insurance Program, of certain payments and other transfers of value to physicians and teaching hospitals made during the preceding calendar year, and any ownership and investment interests held by physicians. Failure to submit

required information may result in civil monetary penalties of up to an aggregate of \$150,000 per year (and up to an aggregate of \$1.0 million per year for "knowing failures") for all payments, transfers of value or ownership or investment interests not appropriately reported. Manufacturers must submit reports by the 90th day of each calendar year.

- Analogous state laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third party payors, including private insurers. Several states require pharmaceutical companies to report expenses relating to the marketing and promotion of pharmaceutical products in those states and to report gifts and payments to individual health care providers in those states. Some states also prohibit certain marketing-related activities, including providing gifts, meals or other items to certain health care providers. Some states restrict the ability of manufacturers to offer co-pay support to patients for certain prescription drugs. Other states and cities

require identification or licensing of state representatives. Some states require pharmaceutical manufacturers to implement compliance programs or marketing codes that are consistent with the May 2003 Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers, and/or the voluntary PhRMA Code.

We, as well as many other pharmaceutical companies, sponsor prescription drug coupons and other product support agreements to help ensure that financial need does not limit a patient's access to our products. Co-pay coupon programs and other product and patient assistance programs have received negative publicity related to their use to promote branded pharmaceutical products over less costly generics and as a strategy to increase drug prices by shielding patients from those price increases. In recent years, other pharmaceutical manufacturers were named in class action lawsuits that challenged co-pay programs under a variety of federal and state laws. The Office of Inspector General for the HHS has issued additional guidance related to co-pay and patient assistance programs, and other government enforcement agencies have initiated investigations into and pursued enforcement actions related to other manufacturers' product and patient support programs. We cannot be certain whether our product and patient support programs will be named in any future similar lawsuits or become subject to government scrutiny.

We attempt to ensure that our business arrangements with third parties comply with applicable healthcare laws and regulations, utilizing the expertise of outside experts. However, it is possible that governmental authorities might conclude that our business practices do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our past or present operations, including activities conducted by our sales team or agents, would be found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, imprisonment, fines, exclusion from federal health care programs such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we do business are found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

Many aspects of these laws have not been definitively interpreted by the regulatory authorities or the courts and their provisions are open to a variety of subjective interpretations and remain subject to change. This increases the risk of potential violations. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses, divert our management's attention from the operation of our business and damage our reputation.

If we fail to comply with data protection laws and regulations, we could be subject to government enforcement actions (which could include civil or criminal penalties), private litigation and/or adverse publicity, which could negatively affect our operating results and business.

We are subject to data protection laws and regulations (i.e., laws and regulations that address privacy and data security). In the United States, numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), govern the collection, use, disclosure, and protection of health-related and other personal information. Failure to comply with data protection laws and regulations could result in government enforcement actions and create liability for us (which could include civil and/or criminal penalties), private litigation and/or adverse publicity that could negatively affect our operating results and business. In addition, we may obtain health information from third parties (e.g., healthcare providers who prescribe our products) that are subject to privacy and security requirements under HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act. Although we are not directly subject to HIPAA-other than potentially with respect to providing certain employee benefits-we could be subject to criminal penalties if we knowingly obtain or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA. HIPAA generally requires that healthcare providers and other covered entities obtain written authorizations from patients prior to disclosing protected health information of the patient (unless an exception to the

authorization requirement applies). If authorization is required and the patient fails to execute an authorization, or the authorization fails to contain all required provisions, then we may not be allowed access to and use of the patient's information and our research efforts could be impaired or delayed. Furthermore, use of protected health information that is provided to us pursuant to a valid patient authorization is subject to the limits set forth in the authorization (e.g., for use in research and in submissions to regulatory authorities for product approvals). In addition, HIPAA does not replace federal, state, international or other laws that may grant individuals even greater privacy protections.

Also, the European Parliament has adopted the General Data Protection Regulation (GDPR), which will become effective on May 25, 2018. This regulation replaces the EU's 1995 data protection directive and shall be the single EU standard across all member states. The GDPR takes a broad view of the types of information that are deemed covered as personal

identification information and contains provisions that require businesses to protect such personal data and the privacy of EU citizens for transactions that occur within EU member states. The GDPR also regulates the exportation of personal data outside of the EU. Non-compliance with the GDPR could result in significant penalties. Many companies, including our company, are assessing the requirements of the GDPR against current business practices and preparing for compliance with this regulation once it becomes effective.

Risks Related to our Management of Nalpropion

We have limited experience managing companies for third parties and our management efforts may not be successful.

We, through our services agreement with Nalpropion, are responsible for distributing Contrave, a weight-loss product, in the United States. We are also responsible, through the services agreement, for overseeing the operations of Nalpropion (including overseeing the legal function and financial operations of Nalpropion), which operates in a therapeutic area that we have not previously serviced. We may be unable to adapt our current operations to appropriately service Nalpropion or this market and we may ultimately be unable to realize the anticipated benefits of Nalpropion's acquisition of Contrave and our agreement with Nalpropion. If we are unable to comply with our obligations under the services agreement with Nalpropion, Nalpropion may terminate the services agreement which may have a material adverse effect on our business. In addition, we may have not yet discovered during the due diligence process all known and unknown factors regarding Contrave that could produce unintended and unexpected consequences for Nalpropion and us. Undiscovered factors could cause us to incur potentially material financial liabilities, and prevent both Nalpropion and us from achieving the expected benefits from the transaction within our desired time frames, if at all. Additionally, Nalpropion is subject to certain restrictive covenants under the agreement governing its credit facilities, which may limit or disrupt its ability to manage or conduct its business.

The non-renewal or termination of our services agreement with Nalpropion would result in us losing rights to distribute Contrave and may adversely affect our financial performance and business.

Under the terms of the service agreement with Nalpropion, we will derive income from providing services to Nalpropion for a management fee and a percentage of the revenue generated by Nalpropion. As a result, we will incorporate into our annual financial guidance certain revenue expectations premised upon Nalpropion using a certain level of our services and generating a certain level of revenue. The initial term of our services agreement with Nalpropion is two years, subject to automatic renewals of consecutive one-year terms unless Nalpropion elects not to renew the services agreement at least 90 days prior to the end of the then current term. In addition, either party may terminate the services agreement for material breach after an opportunity to cure and Nalpropion may terminate the services agreement (i) at any time by providing at least 120 days prior written notice or (ii) no earlier than 120 days after the date on which we replace certain members of our management team without appointing replacements satisfactory to Nalpropion. Pursuant to the terms of the stockholders agreement among us, Nalpropion and the other stockholders named therein, we have the option to acquire up to 49.9% and 100% of the outstanding capital stock of Nalpropion at specified time periods and purchase prices, provided, however, both such purchase options terminate in connection with the non-renewal or termination of our services agreement with Nalpropion.

In the event Nalpropion exercised its non-renewal or termination rights under the services agreement, we would no longer be entitled to the exclusive U.S. distributor rights for Contrave (subject to a non-exclusive right to sell any inventory of Contrave we held at the time of such non-renewal or termination for a period not to exceed six months) and would also lose the option to exercise our option to purchase the capital stock of Nalpropion. Such non-renewal or early termination of the services agreement and the loss of our exclusive distributorship rights to Contrave and our option to purchase, respectively, could adversely affect our financial performance and we may be unable to recoup the transaction or business expenses we have incurred or expect to incur in connection with our transaction with Nalpropion. In addition, early termination of the services agreement may harm our business and results of operations as we may have failed to pursue other beneficial opportunities due to the focus of management on the management of Nalpropion prior to realizing all of the anticipated benefits of our transaction with Nalpropion.

Certain members of our executive management team, including our Chief Executive Officer, Chief Legal & Compliance Officer and Chief Business Officer and Principal Financial Officer, may dedicate inadequate time and attention to our Company.

Pursuant to the services agreement with Nalpropion, John A. Sedor, our

Chairman of the Board and Chief Executive Officer, Kenneth R. Piña, our Senior Vice President, Chief Legal & Compliance Officer and Corporate Secretary, and Angus W. Smith, our Senior Vice President, Chief Business Officer and Principal Financial Officer, will serve as officers

of Nalpropion and will allocate a portion of their time of employment with the Company to performing services for Nalpropion. Each of these individuals will allocate their time between our affairs and the affairs of Nalpropion. This situation presents the potential for conflicts of interest in determining the respective percentages of the time that these individuals devote to our affairs and the affairs of Nalpropion. In addition, if the affairs of Nalpropion require these members of our management team to devote more substantial amounts of their time to those affairs in the future, their ability to devote sufficient time to our affairs may be limited and could negatively impact our business.

A variety of risks associated with operating Nalpropion's business and distributing its product, Contrave, in the United States could have a material adverse impact upon the business and financial condition of Nalpropion and consequently materially adversely affect our business and financial condition.

We, through our services agreement with Nalpropion, are responsible for distributing Contrave in the United States and overseeing the operations of Nalpropion. Our business and financial condition could therefore be materially adversely affected by a variety of risks associated with managing Nalpropion's business and distributing Contrave in the United States, including the following:

- While the constituent drugs that make up Contrave, bupropion and naltrexone, have post-marketing safety records and while these constituent drugs have been tested in combination in the clinical trials of Contrave to date, the safety of the combined use of the constituents of Contrave is not yet fully known, and any future clinical trials may produce side effects not observed to date. Undesirable side effects caused by Contrave could cause regulatory authorities to, among other things, (i) withdraw or limit their approval of Contrave, (ii) require the addition of labeling statements, such as an additional "boxed" warning with Contrave or any additional contraindication; (iii) require Nalpropion to change the way Contrave is distributed or administrated; and/or (iv) require Nalpropion to conduct additional clinical trials. In addition, even though we are only the distributor of Contrave in the United States and are not directly responsible for the marketing of the product, it is possible that we could be named as a defendant in product liability lawsuits that are brought relative to Contrave due to our management of Nalpropion and indirect commercial activities relative to Contrave. While Nalpropion is responsible to defend and indemnify us in such instances and while our liability to Nalpropion for any errors or omissions on the part of our personnel under the services agreement is limited to no more than \$6 million, it is possible that Nalpropion might not have the insurance proceeds or assets to adequately protect us from such liabilities.
- We do not control the actions of Nalpropion's manufacturers and other third-party agents, including third party distributors outside of the United States, although we and Nalpropion may potentially be liable for their actions. Violations of laws by such third parties may result in civil or criminal sanctions, which could include monetary fines, criminal penalties, and disgorgement of past profits, which could have a material adverse impact upon the business and financial condition of Nalpropion and consequently on our business and financial condition.
- Nalpropion's market opportunity for Contrave may be limited by the relatively small number of issued U.S. patents and foreign patents that it owns or in-licenses. Moreover, Contrave may face additional competition outside of the United States as a result of a lack of patent enforcement in foreign countries and off-label use of other dosage forms of the generic components in Contrave which could have a material adverse impact upon the business and financial condition of Nalpropion and consequently on our business and financial condition.

- Nalpropion's market opportunity for Contrave may be limited by challenges to its issued U.S. patents. Further, restrictions on patent rights relating to Contrave may limit Nalpropion's ability to prevent third parties from competing against Contrave. Should Nalpropion be unsuccessful in defending against such legal challenges, it could have a material adverse impact upon the business and financial condition of Nalpropion and consequently on our business and financial condition. For example, in April 2015, Orexigen and Takeda received notification of a Paragraph IV certification for certain patents for Contrave which are listed in the FDA's Orange Book. The certification resulted from the filing by Actavis Laboratories FL, Inc. (Actavis) of an ANDA challenging such patents for Contrave. In June 2015, Orexigen and Takeda filed a lawsuit in the U.S. District Court for the District of Delaware against Actavis on the basis that Actavis' proposed generic products infringe certain patents for Contrave. Takeda held the NDA for Contrave and was a licensee of Orexigen's patents until August 2016, at which point the ownership of the NDA was transferred to Orexigen and Takeda's rights to the Orexigen patents were terminated. A bench trial took place in June 2017 and on October 13, 2017, the court issued an opinion finding that the claims of the three patents at issue (U.S. Patent Nos. 7,462,626, 7,375,111 and 8,916,195, which expire in 2024, 2025 and 2030, respectively) were valid and infringed. Actavis filed an appeal, which is pending in the U.S. Court of Appeals for the Federal Circuit (Federal Circuit Appeal). On July 27, 2018, Nalpropion acquired worldwide rights to Contrave, including the rights to the patents at issue. If Actavis is successful in the Federal Circuit Appeal, a generic version of Contrave could be launched prior to the expiration of one or more of the patents at issue, which would materially impact Nalpropion's and our financial condition and results of operations. Further, if Contrave infringes or is alleged to infringe intellectual property rights of third parties, we may be adversely affected.

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

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6.EXHIBITS

EXHIBIT INDEX

Exhibit
No.

Description

10.1

Amendment Number 1 to Credit Agreement, dated April 23, 2018, by and among Pernix Therapeutics Holdings, Inc. and certain of its subsidiaries as borrowers and guarantors, Pernix Ireland Pain Designated Activity Company, Pernix Ireland Limited, Pernix Holdco 1, LLC, Pernix Holdco 2, LLC and Pernix Holdco 3, LLC as additional guarantors, Cantor Fitzgerald Securities as agent, and the lenders party thereto (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on April 23, 2018).

10.2

Pernix Therapeutics Holdings, Inc 2017 Omnibus Incentive Plan, as amended to the Registrant's Current Report on Form 8-K filed on May 22, 2018).

10.3

Form of Restricted Stock Unit Agreement under Pernix Therapeutics Holdings, Inc. 2017 Omnibus Incentive Plan, as amended (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed on May 22, 2018).

10.4

Form of Nonqualified Stock Option Agreement under Pernix Therapeutics Holdings, Inc. 2017 Omnibus Incentive Plan, as amended (incorporated by reference to Exhibit 10.3 of the Registrant's Current Report on Form 8-K filed on May 22, 2018).

31.1*

Certification of the Registrant's Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

31.2*

Certification of the Registrant's Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

32.1*

Certification of the Registrant's Chief Executive Officer and Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

101*

Attached as Exhibit 101 to this report are the following items formatted in XBRL (Extensible Business Reporting Language):

(i) Condensed Consolidated Balance Sheets as of June 30, 2018 and December 31, 2017;

(ii) Condensed Consolidated Statements of Operations and Comprehensive (Loss) Gain for the Three and Six Months Ended June 30, 2018 and 2017;

(iii) Condensed Consolidated Statements of Stockholders' Equity (Deficit) for the Six Months Ended June 30, 2018 and for the Year Ended December 31, 2017;

(iv) Condensed Consolidated Statements of Cash Flows for the Six Months Ended June 30, 2018 and 2017; and

(v) Notes to Condensed Consolidated Financial Statements.

* Filed herewith.

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.

PERNIX THERAPEUTICS HOLDINGS,
INC.

Date: August 9, 2018

By:

/s/ JOHN SEDOR

John Sedor

Chairman and Chief Executive Officer
(Principal Executive Officer)

Date: August 9, 2018

By:

/s/ ANGUS SMITH

Angus Smith

Senior Vice President and Chief Business Officer and Principal Financial Officer

(Principal Financial Officer)