

Pernix Therapeutics Reports Second Quarter 2016 Financial Results and Business Update

August 11, 2016 4:03 PM ET

Net Revenue Increased 13% Sequentially Over First Quarter 2016

Recently Completed Reorganization of Management Team and Restructuring of Sales Force and Operations

MORRISTOWN, N.J., Aug. 11, 2016 (GLOBE NEWSWIRE) -- Pernix Therapeutics Holdings, Inc. (NASDAQ:PTX) (“Pernix” or the “Company”), a specialty pharmaceutical company, today announced financial results for the three and six months ended June 30, 2016.

Second Quarter 2016 Financial and Product Highlights:

- Net Revenue was \$36.7 million, an increase of 13% over the first quarter and a decrease of 22% over the same period in the prior year.
- Prescription volumes grew sequentially compared to the first quarter of 2016 for all three core brands, Treximet®, Silenor® and Zohydro ER® with BeadTek™.
- Gross Margin was 66.8%, an improvement of 140 basis points over the first quarter 2016 and a decrease of 380 basis points over the same prior year period.
- Net loss was \$31.1 million for the three months ended June 30, 2016 as compared to \$32.2 million for the three months ended June 30, 2015.
- Adjusted EBITDA improved to (\$1.4 million) as compared with (\$4.5 million) in the first quarter 2016 and decreased from \$7.9 million in the prior year period.

Business Update:

- Reorganized senior management team to improve execution and efficiency, drive profitability and position the Company for future growth
 - John Sedor appointed Chairman and Chief Executive Officer on a permanent basis
 - Dr. Graham Miao appointed President and Chief Financial Officer
- Restructured sales force and operations to optimize the Company’s resources and improve the effectiveness of its sales force
 - Reduced full-time work force by approximately 23%
 - Combined with the management reorganization above, expected to result in an estimated annualized cost savings of approximately \$11 million
- Issued three new Orange Book patents for Zohydro ER® with BeadTek™ strengthening intellectual property protection through 2033
- Prioritized research and development programs
 - Focus on the development of a next-generation version of Zohydro ER
 - Discontinued the development of a new formulation of Treximet due to a delay in development timeline which significantly reduced our expected return on investment
- Announced positive final results from a Phase IV Study assessing the effects of nighttime administration of insomnia treatments, including Silenor® 6 mg, on arousability, gait, balance, and cognitive performance, after going to sleep, in healthy male volunteers
 - Study results demonstrated that Silenor 6 mg was statistically superior to zolpidem 10 mg on the measures studied

“We’ve addressed a number of challenges recently, and are making important progress on several fronts,” said John Sedor, Chairman and Chief Executive Officer of Pernix Therapeutics Holdings. “I strongly believe that the restructuring of our sales force and the recent management changes optimally position Pernix for future revenue growth and profitability.

Importantly, our commercial team continues to drive increased usage of our three core products, Treximet, Silenor and Zohydro ER, with each showing strong prescription growth in the second quarter over the first quarter. In addition, our prescription fulfillment program, Pernix Prescriptions Direct, continues to gain increased traction each week as more patients utilize this program. Going forward, we will continue to focus on improving our financial flexibility and strengthening our balance sheet. Our objectives are to improve operating cash flow generation through the optimization of our product portfolio and cost structure, and engage with lenders to proactively restructure existing debt in a constructive manner that we believe will ultimately benefit all stakeholders”

Financial Results – Second Quarter 2016

For the three months ended June 30, 2016, net revenue was \$36.7 million compared to \$32.5 million for the three months ended March 31, 2016, an increase of 13%. A summary of net revenue is outlined below (dollars in millions):

	Three Months Ended		
	June 30,	March 31,	Increase
	2016	2016	(Decrease)
Treximet	\$ 17.8	\$ 16.3	\$ 1.5
Silenor	4.2	3.6	0.6
Zohydro ER	5.9	5.5	0.4
Other products	8.7	7.0	1.7
Net product sales	36.6	32.4	4.2
Co-promotion and other revenue	0.1	0.1	0.0
Total net revenues	\$ 36.7	\$ 32.5	\$ 4.2

Treximet net sales increased by \$1.5 million, or 9%, during the three months ended June 30, 2016 compared to the three months ended March 31, 2016. The increase in Treximet net sales was due primarily to favorable gross to net and increased demand, partially offset by inventory destocking at the wholesaler level. Silenor net sales increased by \$0.6 million, or 17%, during the three months ended June 30, 2016 compared to the three months ended March 31, 2016. The increase in Silenor net sales was due primarily to increased volume. Zohydro ER net sales increased by \$0.4 million, or 7%, during the three months ended June 30, 2016 compared to the three months ended March 31, 2016. The increase in Zohydro ER net sales is due primarily to increased demand and favorable gross to net partially offset by inventory destocking at the wholesaler level. Other product revenue increased by \$1.7 million, or 24%, primarily due to increased volume and favorable gross to net adjustments in the Company’s generic portfolio.

For the second quarter of 2016, net revenue was \$36.7 million compared to \$47.0 million in the second quarter of 2015. A summary of net revenue is outlined below (dollars in millions):

	Three Months Ended		
	June 30,		Increase
	2016	2015	(Decrease)
Treximet	\$ 17.8	\$ 25.5	\$ (7.7)
Silenor	4.2	6.0	(1.8)

Zohydro ER	5.9	4.0	1.9
Other products	8.7	11.3	(2.6)
Net product sales	36.6	46.8	(10.2)
Co-promotion and other revenue	0.1	0.2	(0.1)
Total net revenues	\$ 36.7	\$ 47.0	\$ (10.3)

Treximet net sales decreased by \$7.7 million, or 30%, during the three months ended June 30, 2016 compared to the three months ended June 30, 2015. Silenor net sales decreased by \$1.8 million, or 30%, during the three months ended June 30, 2016 compared to the three months ended June 30, 2015. The decrease in Treximet and Silenor sales were due primarily to inventory destocking at the wholesaler level and higher revenue deductions for managed care rebates. Zohydro ER net sales increased \$1.9 million, or 48%, during the three months ended June 30, 2016 compared to the three months ended June 30, 2015. This increase was due to an increase in demand as well as the impact of a full quarter of sales in the three months ended June 30, 2016 compared to two months of sales in the prior year period when Zohydro ER was acquired.

Other net product sales decreased by \$2.6 million, or 23%, during the three months ended June 30, 2016 compared to the three months ended June 30, 2015. This decrease was due primarily to the discontinuation of certain less profitable products, primarily generics, and certain OTC monograph seasonal cough and cold products.

Gross Margin decreased to 67% in the second quarter of 2016 from 71% in the second quarter 2015. This was primarily due to a contractual minimum royalty incurred for sales of Treximet.

Selling, general and administrative expense increased by \$0.6 million, or 3%, during the three months ended June 30, 2016 compared to the three months ended June 30, 2015. The increase was driven primarily by selling and marketing costs for Zohydro ER with BeadTek, which was acquired in April 2015.

Research and development expense increased by \$1.0 million during the three months ended June 30, 2016 compared to the three months ended June 30, 2015. The increase was related to the timing of on-going work for Treximet and Zohydro ER.

Depreciation and amortization expense decreased by \$1.3 million during the three months ended June 30, 2016 compared to the three months ended June 30, 2015. The decrease was primarily a result of an extension of the estimated useful life of Zohydro ER with BeadTek during the three months ended March 31, 2016 and intangible asset impairments during the six months ended June 30, 2016 and the year ended December 31, 2015. These decreases were partially offset by the amortization of Treximet pediatrics developed technology, which began in May 2015.

Interest expense decreased by \$0.8 million, or 8%, during the three months ended June 30, 2016 compared to the prior year period. The decrease was primarily due to the lower principal balance on the Treximet Secured Notes.

Adjusted EBITDA (earnings before interest, taxes, depreciation and amortization, a non-GAAP measure) was (\$1.4) million for the second quarter of 2016 compared to \$7.9 million in the second quarter of 2015. See the table at the end of this press release for a reconciliation of net loss to Adjusted EBITDA.

Six Months Ended June 30, 2016 vs. Six Months Ended June 30, 2015

For the six months ended June 30, 2016, net revenue was \$69.2 million compared to \$80.9 million for the six months ended June 30, 2015. A summary of net revenue is outlined below (dollars in millions):

Six Months Ended		Increase
June 30,		(Decrease)
2016	2015	

Treximet	\$ 34.1	\$ 46.5	\$ (12.4)
Silenor	7.8	11.0	(3.2)
Zohydro ER	11.4	4.0	7.4
Other products	15.7	18.9	(3.2)
Net product sales	69.0	80.4	(11.4)
Co-promotion and other revenue	0.2	0.5	(0.3)
Total net revenues	\$ 69.2	\$ 80.9	\$ (11.7)

Treximet net sales decreased by \$12.4 million, or 27%, during the six months ended June 30, 2016 compared to the six months ended June 30, 2015. Silenor net sales decreased by \$3.2 million, or 29%, during the six months ended June 30, 2016 compared to the six months ended June 30, 2015. The decrease in sales of Treximet and Silenor was primarily driven by a decrease in sales volume and higher revenue deductions for managed care rebates. Zohydro ER net sales increased \$7.4 million, or 185%. This increase was due to an increase in demand, as well as the impact of a full six months of sales in the period ended June 30, 2016 compared to two months of sales in the prior year period when Zohydro ER was acquired. Sales of Other net product sales decreased by \$3.2 million, or 17%, during the six months ended June 30, 2016 compared to the six months ended June 30, 2015. This decrease was due primarily to the discontinuation of certain less profitable products, primarily generics, and certain OTC monograph seasonal cough and cold products.

Gross Margin decreased to 66% in the six months ended June 30, 2016 from 69% in the six months ended June 30, 2015. This was due primarily to a contractual minimum royalty incurred for sales of Treximet.

Selling, general and administrative expense increased by \$5.6 million, or 12%, during the six months ended June 30, 2016 compared to the six months ended June 30, 2015. The increase was driven primarily by selling and marketing costs for Zohydro ER with BeadTek, which was acquired in April 2015.

Research and development expense increased by \$1.0 million during the six months ended June 30, 2016 compared to the six months ended June 30, 2015. The increase was related to the timing of on-going work for Treximet and Zohydro ER.

Depreciation and amortization expense increased by \$4.0 million during the six months ended June 30, 2016 compared to the six months ended June 30, 2015. The increase was primarily a result of the amortization of Treximet pediatrics developed technology, which began in May 2015, and amortization related to the acquisition of Zohydro ER with BeadTek in April 2015. The increase was partially offset by an extension of the estimated useful life of Zohydro ER with BeadTek during the three months ended March 31, 2016, and intangible asset impairments during the six months ended June 30, 2016 and the year ended December 31, 2015.

Interest expense decreased by \$1.2 million, or 6%, during the six months ended June 30, 2016 compared to the prior year period. The decrease was primarily due to the lower principal balance on our Treximet Secured Notes.

Adjusted EBITDA (earnings before interest, taxes, depreciation and amortization, a non-GAAP measure) was (\$5.9) million for the six month period of 2016 compared to \$12.5 million in the same period of 2015. See the table at the end of this press release for a reconciliation of net loss to Adjusted EBITDA.

Liquidity

As of June 30, 2016, the Company had total liquidity of \$40.8 million, consisting of \$29.2 million of cash and approximately \$11.6 million available to draw under its \$50.0 million revolving credit facility.

Total principal amount of debt outstanding at the end of the quarter was \$339.1 million and net debt was \$309.9 million. The total principal amount of debt consists of \$195.1 million of 12% Senior Secured notes, \$130.0 million of 4.25%

convertible notes and \$14.0 million under our revolving credit facility.

To improve financial flexibility, the Company has retained advisors to explore options to restructure its debt and assess other potential alternatives in order to maximize value for all stakeholders.

During the three months ended June 30, 2016, the Company utilized its Controlled Equity Offering program to access the capital market and raised approximately \$12 million of net proceeds through the issuance of 23,921,343 shares of common stock.

Conference Call

As previously announced, Pernix will hold a conference call to discuss results for the second quarter:

- Date: Thursday, August 11
- Time: 4:30 PM EDT
- Toll free (U.S.): 888-542-0999
- International: 719-457-2698
- Conference ID: 2497144
- Webcast: <http://public.viavid.com/index.php?id=120643>

The webcast of the call will be archived for 30 days via the Investors section of the Company's website.

About Pernix Therapeutics

Pernix Therapeutics is a specialty pharmaceutical business with a focus on acquiring, developing and commercializing prescription drugs primarily for the U.S. market. The Company targets underserved therapeutic areas such as CNS, including neurology and psychiatry, and has an interest in expanding into additional specialty segments. The Company promotes its branded products to physicians through its Pernix sales force, uses contracted sales organizations to market its non-core, cough and cold products, and markets its generic portfolio through its wholly owned subsidiaries, Macoven Pharmaceuticals, LLC and Cypress Pharmaceutical, Inc.

To learn more about Pernix Therapeutics, visit www.pernixtx.com.

Treximet® and Silenor® are registered trademarks of Pernix Therapeutics Holdings, Inc.

Zohydro® ER is a registered trademark of Pernix Therapeutics Holdings, Inc.

BeadTek™ is a trademark used by Pernix under license.

Non-GAAP Financial Measures

Pernix is disclosing non-GAAP financial measures in this press release. We believe that these non-GAAP financial measures provide meaningful supplemental information regarding our operating results because they exclude 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. Primarily due to acquisitions, Pernix believes that an evaluation of its ongoing operations (and comparisons of its current operations with historical and future operations) would be difficult if the disclosure of its financial results were limited to financial measures prepared only in accordance with U.S. generally accepted accounting principles (GAAP). In addition to disclosing its financial results determined in accordance with GAAP, Pernix is disclosing non-GAAP results that exclude items such as amortization expense and certain other expense and revenue items in order to supplement investors' and other readers' understanding and assessment of the Company's financial performance. Whenever Pernix uses a non-GAAP measure, it will provide a reconciliation of non-GAAP financial measures to the most closely applicable GAAP financial measure. Investors and other readers are encouraged to review the related GAAP financial measures and the reconciliation of non-GAAP measures set forth herein and should consider non-GAAP measures only as a supplement to, not as a substitute for or as a superior measure to, measures of financial performance prepared in accordance with GAAP.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Statements including words such as “estimate,” “plan,” “project,” “forecast,” “intend,” “expect,” “anticipate,” “believe,” “seek,” “target” or similar expressions are forward-looking statements. These statements reflect the Company’s current views, expectations and beliefs concerning future events. These forward-looking statements include statements regarding: planned development activities relating to a next-generation version of Zohydro ER, estimated annualized cost savings and potential for future revenue growth and profitability resulting from the restructuring of our salesforce and the recent management changes, increased usage of our three core products, Treximet, Silenor and Zohydro ER, increased usage of our prescription fulfillment program, Pernix Prescriptions Direct, and improved financial flexibility through a possible restructuring of our debt and other potential alternatives. The inclusion of forward-looking statements should not be regarded as a representation by Pernix that any of its plans will be achieved. Investors should note that many factors, including the risks and uncertainties inherent in Pernix’s business, as more fully described in Pernix’s filings with the U.S. Securities and Exchange Commission (SEC), including its Annual Report on Form 10-K for the year ended December 31, 2015 and subsequent filings with the SEC, could affect the Company’s future financial results and could cause actual results to differ materially from those expressed in forward-looking statements contained in this press release. The forward-looking statements in this press release are qualified by these risk factors. These are factors that, individually or in the aggregate, could cause our actual results to differ materially from expected and historical results. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. The Company assumes no obligation to publicly update any forward-looking statements, whether as a result of new information, future developments or otherwise.

PERNIX THERAPEUTICS HOLDINGS, INC. AND SUBSIDIARIES

Condensed Consolidated Balance Sheets

(In thousands, except per share data)

(Unaudited)

Assets	2016	2015
Current assets:		
Cash and cash equivalents	\$ 29,207	\$ 56,135
Restricted cash	-	10,002
Accounts receivable, net	48,447	61,209
Inventory, net	9,693	10,035
Prepaid expenses and other current assets	11,651	11,574
Income tax receivable	7,030	6,735
Total current assets	106,028	155,690
Property and equipment, net	1,288	2,346
Goodwill	54,366	54,865
Intangible assets, net	240,763	285,943
Other	302	347
Total assets	\$ 402,747	\$ 499,191
Liabilities and Stockholders' (Deficit) Equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 25,681	\$ 27,772

Accrued allowances	55,746	62,678
Interest payable	11,173	11,903
Treximet Secured Notes – current	3,789	13,335
Restricted cash payable	-	10,002
Other liabilities	4,507	6,753
Total current liabilities	100,896	132,443
Convertible notes – long-term	101,873	99,776
Derivative liability	2,212	9,165
Contingent consideration	4,581	14,055
Treximet Secured Notes – long-term	184,208	188,715
Credit facilities – long-term	14,000	15,000
Deferred income tax liability - long-term	226	202
Other liabilities	4,461	6,738
Total liabilities	412,457	466,094
Commitments and contingencies		
Stockholders' (deficit) equity:		
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, 87,902,468 and 63,874,549 issued and 85,120,081 and 61,112,527 outstanding at June 30, 2016 and December 31, 2015, respectively	851	611
Additional paid-in capital	240,889	226,837
Treasury stock, at cost, 2,782,387 and 2,762,022 shares held at June 30, 2016 and December 31, 2015, respectively	(5,572)	(5,548)
Accumulated deficit	(245,878)	(188,803)
Total stockholders' (deficit) equity	(9,710)	33,097
Total liabilities and stockholders' (deficit) equity	\$ 402,747	\$ 499,191

PERNIX THERAPEUTICS HOLDINGS, INC. AND SUBSIDIARIES

Condensed Consolidated Statements of Operations

(In thousands, except per share data)

(Unaudited)

	Three Months Ended		Six Months Ended	
	June 30, 2016	2015	June 30, 2016	2015
Net revenues	\$ 36,746	\$ 46,977	\$ 69,215	\$ 80,866

Cost of product sales	12,194	13,794	23,432	24,870
Gross profit	24,552	33,183	45,783	55,996
Operating expenses:				
Selling, general and administrative expense	25,492	24,857	51,442	45,843
Research and development expense	2,499	1,470	3,427	2,464
Depreciation and amortization expense	21,062	22,326	44,726	40,759
Change in fair value of contingent consideration	(3,972)	-	(9,474)	-
Loss from disposal and impairments of assets	1,771	-	1,771	-
Restructuring costs	-	(108)	-	1,197
Total operating expenses	46,852	48,545	91,892	90,263
Loss from operations	(22,300)	(15,362)	(46,109)	(34,267)
Other income (expense):				
Interest income	-	54	-	110
Interest expense	(8,937)	(9,733)	(17,961)	(19,131)
Change in fair value of derivative liability	159	8,703	6,953	8,703
Foreign currency transaction (loss) gain	(71)	-	67	-
Cost of inducement	-	(19,500)	-	(19,500)
Total other expense, net	(8,849)	(20,476)	(10,941)	(29,818)
Loss before income tax expense (benefit)	(31,149)	(35,838)	(57,050)	(64,085)
Income tax (benefit) expense	(10)	(3,603)	25	(8,176)
Net loss	\$ (31,139)	\$ (32,235)	\$ (57,075)	\$ (55,909)
Net loss per common and potential common share				
Basic	\$ (0.47)	\$ (0.62)	\$ (0.89)	\$ (1.23)
Diluted	\$ (0.47)	\$ (0.62)	\$ (0.89)	\$ (1.23)
Weighted-average common and potential common shares outstanding:				
Basic	66,687	52,399	63,904	45,481
Diluted	66,687	52,399	63,904	45,481

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

Three Months Ended		Six Months Ended	
June 30,		June 30,	
2016	2015	2016	2015

GAAP net loss	\$ (31,139)	\$ (32,235)	\$ (57,075)	\$ (55,909)
Adjustments:				
Interest expense, net	8,937	9,679	17,961	19,021
Depreciation and amortization	21,081	22,326	44,745	40,759
Income tax expense (benefit)	(10)	(3,603)	25	(8,176)
EBITDA	(1,131)	(3,833)	5,656	(4,305)
Net revenue adjustments (1)	-	(3,286)	-	(2,983)
Cost of product sales adjustments (2)	-	-	-	97
Selling, general and administrative adjustments (3)	2,014	4,376	3,160	7,734
Change in fair value of contingent consideration	(3,972)	-	(9,474)	-
Loss from disposal and impairments of assets (4)	1,771	-	1,771	-
Cost of inducement	-	19,500	-	19,500
Change in fair value of derivative liability	(159)	(8,703)	(6,953)	(8,703)
Foreign currency transaction loss (gain)	71	-	(67)	-
Restructuring costs (5)	-	(108)	-	1,197
Adjusted EBITDA	\$ (1,406)	\$ 7,946	\$ (5,907)	\$ 12,537

(1) To include impact of change in estimates related to gross to net accruals of \$0 and \$3.3 million for the three months ended June 30, 2016 and 2015, respectively. Also, to include impact of change in estimates related to gross to net accruals of \$0 and \$3.3 million; and to exclude impact on returns from FDA reclass of Hydrocodone products from C3 to C2 classification of \$0 and \$303,000, for the six months ended June 30, 2016 and 2015, respectively.

(2) To exclude amortization of inventory step-up from acquisitions.

(3) To exclude deal costs of (\$123,000) and \$3.2 million; stock compensation expense of \$770,000 and \$1.2 million; severance expense of \$727,000 and \$0; and litigation settlement expenses of \$640,000 and \$0 for the three months ended June 30, 2016 and 2015, respectively. Also, to exclude deal costs of \$18,000 and \$3.9 million; stock compensation expense of \$2.2 million and \$2.4 million; severance expense of \$1.2 million and \$0 and litigation settlement expenses of (\$315,000) million and \$1.4 million, for the six months ended June 30, 2016 and 2015, respectively.

(4) To exclude the impairment of assets related to our cough and cold product line.

(5) To exclude the cost related to the initiative to restructure operations and shut down the Charleston, South Carolina site.

matthew@lifesciadvisors.com



Pernix Therapeutics Holdings, Inc.