

Pernix Therapeutics Reports Third Quarter 2016 Financial Results and Provides Business Update

November 10, 2016 4:03 PM ET

Net Revenue Increased 13% Sequentially Over Second Quarter 2016

Prescription Volumes Grew Sequentially and Year-Over-Year for All Three Core Brands, Treximet[®], Zohydro ER[®] with BeadTek[™] and Silenor[®]

MORRISTOWN, N.J., Nov. 10, 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 nine months ended September 30, 2016.

Third Quarter 2016 Financial and Product Highlights:

- Net Revenues were \$41.5 million, an increase of 13% over the second quarter and a decrease of 15% compared to the same period in the prior year.
- Prescription volumes grew sequentially and year-over-year for all three core brands, Treximet, Zohydro ER with BeadTek, and Silenor.
- Gross Margin was 73.9%, an improvement of 710 basis points over the second quarter 2016 and a decrease of 130 basis points over the same prior year period.
- Net loss was \$26.4 million for the three months ended September 30, 2016, as compared to \$31.1 million for the three months ended June 30, 2016 and \$10.7 million for the prior year period.
- Adjusted EBITDA improved to \$8.4 million as compared with (\$1.4 million) in the second quarter 2016 and decreased \$0.3 million from the prior year period.

Business Update:

- Solid increases in prescription volumes in the third quarter due to continued momentum and focused efforts on highest volume prescribers
 - Treximet TRx up 4% sequentially and 2% year-over-year
 - Zohydro ER TRx up 5% sequentially and 16% year-over-year
 - Silenor TRx up 0.3% sequentially and 7% year-over-year
- Began distributing Treximet pediatric dose for patients age 12 and older
 - Provides important therapeutic option to pediatric migraine sufferers
- Issued two new Orange Book patents for Zohydro ER[®] with BeadTek[™] strengthening intellectual property protection through 2033
 - Company has 6 Orange Book listed patents valid through 2033 broadly directed to methods of dosing patients with mild or moderate hepatic impairment with hydrocodone
- Initiated new clinical development efforts to strengthen abuse-deterrent characteristics of Zohydro ER
 - Focused on the development of a next-generation version of Zohydro ER
- Implemented a 1-for-10 reverse stock split effective on October 14th in order to raise the per share trading price of the Company’s common stock and comply with NASDAQ continued listing requirements
- Announced the appointment of Graham G. Miao, Ph.D. and Dennis H. Langer, M.D., J.D. to the Company’s Board of Directors on November 7, 2016, effective immediately. Accordingly, Pernix regained compliance with NASDAQ Listing Rule 5605(c)(2)(A), which requires Pernix to have at least three independent directors on its Audit Committee for continued listing on The NASDAQ Global Market

“We are encouraged with the progress of our turnaround efforts, especially the reorganization of our salesforce, which we expect will increase the efficiency of our company, drive us toward profitability and position us well for future growth,” said John Sedor, Chairman and Chief Executive Officer of Pernix Therapeutics Holdings. “Importantly, in the face of the

workforce reductions, sales force reorganization and efforts to improve our operating efficiency, we are seeing solid increases in prescription trends across each of our core brands, Treximet, Zohydro ER and Silenor. In addition, our prescription fulfillment program, Pernix Prescriptions Direct, continues to gain increased traction as more patients utilize this program.”

“We are pleased to have returned to positive Adjusted EBITDA for the first time since the fourth quarter of 2015, having delivered Adjusted EBITDA of \$8.4 million in the third quarter, a solid increase over the second quarter of 2016,” said Graham Miao, President and Chief Financial Officer. “We continue to focus on improving our financial flexibility and strengthening our balance sheet. We are actively exploring options to improve operating cash flow generation through the optimization of our product portfolio and cost structure. Along with our financial advisors, we are engaging with lenders to proactively restructure existing debt in a constructive manner that we believe will ultimately benefit all stakeholders.”

Three Months Ended September 30, 2016 vs. Three Months Ended June 30, 2016

For the three months ended September 30, 2016, net revenues were \$41.5 million compared to \$36.7 million for the three months ended June 30, 2016, an increase of 13%. A summary of net revenues is outlined below (US dollars in millions):

	Three Months Ended		
	September 30,	June 30,	Increase
	2016	2016	(Decrease)
Treximet	\$ 24.0	\$ 17.8	\$ 6.2
Silenor	4.6	4.2	0.4
Zohydro ER	6.1	5.9	0.2
Other products	6.7	8.7	(2.0)
Net product sales	41.4	36.6	4.8
Co-promotion and other revenue	0.1	0.1	0.0
Total net revenues	\$ 41.5	\$ 36.7	\$ 4.8

Treximet net sales increased by \$6.2 million, or 35%, during the three months ended September 30, 2016, compared to the three months ended June 30, 2016, due primarily to inventory restocking, higher prescription demand and lower gross-to-net revenue deductions.

Silenor net sales increased \$0.4 million, or 10%, as compared to the second quarter of 2016. This increase is due primarily to inventory restocking, partially offset by higher gross-to-net revenue deductions.

Zohydro ER net sales increased \$0.2 million, or 3%, as compared to the second quarter of 2016. This increase is due to inventory restocking and higher prescription demand, which was partially offset by a lower net selling price.

Three Months Ended September 30, 2016 vs. Three Months Ended September 30, 2015

For the three months ended September 30, 2016, net revenue was \$41.5 million, compared to \$48.6 million for the three months ended September 30, 2015, a decrease of 15%. A summary of net revenue is outlined below (US dollars in millions):

	Three Months Ended		
	September 30,	Increase	
	2016	2015	(Decrease)

Treximet	\$ 24.0	\$ 28.6	\$ (4.6)
Silenor	4.6	5.1	(0.5)
Zohydro ER	6.1	5.4	0.7
Other products	6.7	8.5	(1.8)
Net product sales	41.4	47.6	(6.2)
Co-promotion and other revenue	0.1	1.0	(0.9)
Total net revenues	\$ 41.5	\$ 48.6	\$ (7.1)

Treximet net sales decreased by \$4.6 million, or 16%, during the three months ended September 30, 2016, compared to the three months ended September 30, 2015, due primarily to inventory changes at the wholesaler level and a decrease in net selling price.

Silenor net sales decreased by approximately \$0.5 million, or 10%, during the three months ended September 30, 2016, compared to the three months ended September 30, 2015. The decrease in net sales of Silenor was primarily driven by a lower net selling price.

Zohydro ER was acquired in April 2015 with the first sale occurring on May 4, 2015. Zohydro ER net sales increased by \$0.7 million, or approximately 14%, during the three months ended September 30, 2016, compared to the three months ended September 30, 2015. The increase was primarily due to an increase in demand and an increase in the net selling price. These increases were partially offset by a decrease due to inventory changes at the wholesaler level.

Net product sales – other decreased by \$1.8 million, or approximately 22%, during the three months ended September 30, 2016, compared to the three months ended September 30, 2015. Declining net product sales - other was due to (i) the discontinuation of certain less profitable products, primarily generics, and certain OTC monograph seasonal cough and cold products and (ii) the termination of certain contracts pursuant to which we marketed and distributed products for others and invoiced those sales.

Co-promotion and other revenue decreased by \$0.9 million during the three months ended September 30, 2016, compared to the three months ended September 30, 2015. The decrease in co-promotion and other revenue was primarily attributable to the termination of a co-promotion agreement.

Gross Margin was 74% in the third quarter of 2016 as compared to 75% in the third quarter 2015.

Selling, general and administrative expense decreased by \$5.2 million, or 19%, during the three months ended September 30, 2016, compared to the three months ended September 30, 2015. The decrease was driven primarily by lower selling and marketing costs for Treximet and Silenor, partially offset by higher legal expenses.

Research and development expense decreased by \$1.5 million during the three months ended September 30, 2016, compared to the three months ended September 30, 2015. The decrease was related to the timing of work for Zohydro ER.

Depreciation and amortization expense decreased by \$5.0 million during the three months ended September 30, 2016, compared to the three months ended September 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, due to the additional patents that were issued in February 2016, and intangible asset impairments during the nine months ended September 30, 2016 and the fourth quarter of 2015.

Restructuring costs were \$2.3 million during the three months ended September 30, 2016, which were related to the

initiative to restructure the Company's sales force and operations.

Interest expense decreased by \$0.8 million, or 9%, during the three months ended September 30, 2016, compared to the prior year period. The decrease was primarily due to the lower principal balance on the Treximet Secured Notes.

Net loss was \$26.4 million for the third quarter of 2016, compared to \$10.7 million in the third quarter of 2015.

Adjusted EBITDA was \$8.4 million for the third quarter of 2016 compared to \$8.7 million in the third quarter of 2015. See the table at the end of this press release for a reconciliation of net loss to Adjusted EBITDA.

Nine Months Ended September 30, 2016 vs. Nine Months Ended September 30, 2015

For the nine months ended September 30, 2016, net revenue was \$110.7 million compared to \$129.5 million for the nine months ended September 30, 2015, a decrease of 15%. A summary of net revenue is outlined below (US dollars in millions):

	Nine Months Ended		Increase (Decrease)
	September 30, 2016	2015	
Treximet	\$ 58.1	\$ 75.0	\$ (16.9)
Silenor	12.4	16.2	(3.8)
Zohydro ER	17.5	9.3	8.2
Other products	22.4	27.5	(5.1)
Net product sales	110.4	128.0	(17.6)
Co-promotion and other revenue	0.3	1.5	(1.2)
Total net revenues	\$ 110.7	\$ 129.5	\$ (18.8)

Treximet net sales decreased by \$16.9 million or approximately 22% during the nine months ended September 30, 2016, compared to the nine months ended September 30, 2015, due to inventory changes at the wholesaler level, a decrease in the net selling price and a decrease in demand.

Silenor net sales decreased by \$3.8 million, or 23%, during the nine months ended September 30, 2016, compared to the nine months ended September 30, 2015. The decrease in sales of Silenor was primarily driven by a decrease in the net selling price and inventory changes at the wholesaler level. These decreases were partially offset by an increase in demand.

Zohydro ER was acquired in April 2015 with the first sale occurring on May 4, 2015. Zohydro ER net sales increased by \$8.2 million during the nine months ended September 30, 2016, compared to the prior period, which consisted of five months of sales.

Net product sales – other decreased by \$5.1 million, or approximately 18%, during the nine months ended September 30, 2016, compared to the nine months ended September 30, 2015. This decrease was due the discontinuation of certain cough and cold products.

Co-promotion and other revenue decreased by \$1.2 million during the nine months ended September 30, 2016, compared to the nine months ended September 30, 2015, due to the termination of a co-promotion agreement.

Gross Margin decreased to 69% in the nine months ended September 30, 2016 from 71% in the nine months ended September 30, 2015. This decrease was due primarily to a contractual minimum royalty incurred for sales of Treximet.

Selling, general and administrative expense increased by \$0.4 million for the nine months ended September 30, 2016, compared to the nine months ended September 30, 2015. The increase was driven primarily by selling and marketing costs for Zohydro ER with BeadTek, which was acquired in April 2015 and we began to promote in May 2015.

Research and development expense decreased by \$0.5 million during the nine months ended September 30, 2016, compared to the nine months ended September 30, 2015. The decrease was related to the timing of work for Zohydro ER.

Depreciation and amortization expense decreased by \$1.1 million during the nine months ended September 30, 2016, compared to the nine months ended September 30, 2015. The decrease was primarily related to intangible asset impairments during the nine months ended September 30, 2016 and the fourth quarter of 2015. These decreases were partially offset by the amortization of Treximet pediatrics developed technology, which began in May 2015.

Restructuring costs were \$2.3 million and \$1.2 million during the nine months ended September 30, 2016 and 2015, respectively. Restructuring costs during the nine months ended September 30, 2016 were related to the initiative to restructure the Company's sales force and operations. Restructuring costs during the nine months ended September 30, 2015 were related to the initiative to close the operating site in Charleston, South Carolina, in 2015.

Interest expense decreased by \$2.0 million, or 7%, during the nine months ended September 30, 2016, compared to the nine months ended September 30, 2015. The decrease was primarily due to the lower principal balance on the Treximet Secured Notes.

Net loss was \$83.5 million for the nine months ended September 30, 2016, compared to \$66.6 million in the same period last year.

Adjusted EBITDA was \$2.5 million for the nine-month period of 2016 compared to \$21.2 million in the same period of 2015. This decrease is primarily due to lower net sales and gross profit year-over-year. See the table at the end of this press release for a reconciliation of net loss to Adjusted EBITDA.

Liquidity

As of September 30, 2016, the Company had total liquidity of \$39.9 million, consisting of \$28.5 million of cash and approximately \$11.4 million available to draw under its \$50.0 million revolving credit facility.

Total principal amount of debt outstanding at the end of the third quarter was \$333.6 million and net debt was \$305.1 million. The total principal amount of debt consisted of \$189.6 million of 12% Senior Secured notes, \$130.0 million of 4.25% convertible notes and \$14.0 million under the Company's 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 and nine months ended September 30, 2016, the Company raised \$6.2 million and \$18.3 million in net proceeds through the issuance of 984,148 and 3,376,284 shares of common stock, respectively, under the at-the-market Sales Agreement. As of September 30, 2016, approximately \$81.1 million of common stock remained available under this facility.

Conference Call

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

- Date: Thursday, November 10
- Time: 4:30 PM EST
- Toll free (U.S.): 888-397-5350
- International: 719-325-2408
- Conference ID: 2298617
- Webcast: <http://public.viavid.com/index.php?id=121645>

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 the non-GAAP financial measure, Adjusted EBITDA in this press release. In this release, Adjusted EBITDA is defined as net loss excluding interest expense, net, depreciation and amortization, income tax expense (benefit), net revenue adjustments, cost of product sales adjustments, selling, general and administrative adjustments, research and development adjustments, change in fair value of contingent consideration, loss from disposal and impairment of assets, loss on extinguishment of debt, cost of inducement, change in fair value of derivative liability, foreign currency transaction gain and restructuring costs. We believe that Adjusted EBITDA provides meaningful supplemental information regarding our operating results because it excludes amounts that management and the board of directors do not consider part of the Company's core operating results or that are non-recurring when assessing the performance of the Company. 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)

	September 30,	December 31,
	2016	2015
Assets		
Current assets:		
Cash and cash equivalents	\$ 28,521	\$ 56,135
Restricted cash	-	10,002
Accounts receivable, net	44,772	61,209
Inventory, net	8,282	10,035
Prepaid expenses and other current assets	13,256	11,574
Income tax receivable	3,351	6,735
Total current assets	98,182	155,690
Property and equipment, net	1,199	2,346
Goodwill	54,366	54,865
Intangible assets, net	220,138	285,943
Other	279	347
Total assets	\$ 374,164	\$ 499,191
Liabilities and Stockholders' (Deficit) Equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 23,133	\$ 27,772
Accrued allowances	56,355	62,678
Interest payable	6,618	11,903
Treximet Secured Notes – current	633	13,335
Restricted cash payable	-	10,002
Other liabilities - current	4,387	6,753
Total current liabilities	91,126	132,443
Convertible notes – long-term	102,953	99,776
Derivative liability	2,421	9,165
Contingent consideration	5,097	14,055
Treximet Secured Notes – long-term	184,002	188,715
Credit facilities – long-term	14,000	15,000
Deferred income tax liability - long-term	226	202
Other liabilities - long-term	4,408	6,738
Total liabilities	404,233	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, 9,499,812 and 6,387,455 issued and 9,499,812 and 6,111,253 outstanding at September 30, 2016 and December 31, 2015, respectively	95	61
Additional paid-in capital	242,164	227,387
Treasury stock, at cost, 0 and 2,762,022 shares held at September 30, 2016 and December 31, 2015, respectively	-	(5,548)
Accumulated other comprehensive loss	(12)	-
Accumulated deficit	(272,316)	(188,803)
Total stockholders' (deficit) equity	(30,069)	33,097
Total liabilities and stockholders' (deficit) equity	\$ 374,164	\$ 499,191

PERNIX THERAPEUTICS HOLDINGS, INC. AND SUBSIDIARIES

Condensed Consolidated Statements of Operations

(In thousands, except per share data)

(Unaudited)

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2016	2015	2016	2015
Net revenues	\$ 41,468	\$ 48,615	\$ 110,683	\$ 129,481
Costs and operating expenses:				
Cost of product sales	10,840	12,036	34,272	36,906
Selling, general and administrative expense	22,173	27,419	73,615	73,262
Research and development expense	1,712	3,180	5,139	5,644
Depreciation and amortization expense	20,700	25,733	65,426	66,492
Change in fair value of contingent consideration	516	(3,596)	(8,958)	(3,596)
Loss from disposal and impairments of assets	652	-	2,423	-
Restructuring costs	2,277	(4)	2,277	1,193
Total costs and operating expenses	58,870	64,768	174,194	179,901
Loss from operations	(17,402)	(16,153)	(63,511)	(50,420)
Other income (expense):				
Interest income	-	43	-	153
Interest expense	(8,857)	(9,687)	(26,818)	(28,818)
Change in fair value of derivative liability	(209)	10,527	6,744	19,230

Foreign currency transaction gain	31	-	98	-
Loss on extinguishment of debt	-	(1,112)	-	(1,112)
Cost of inducement	-	-	-	(19,500)
Total other expense, net	(9,035)	(229)	(19,976)	(30,047)
Loss before income tax expense (benefit)	(26,437)	(16,382)	(83,487)	(80,467)
Income tax expense (benefit)	1	(5,642)	26	(13,818)
Net loss	\$ (26,438)	\$ (10,740)	\$ (83,513)	\$ (66,649)
Net loss per common share				
Basic	\$ (2.99)	\$ (1.76)	\$ (11.57)	\$ (13.15)
Diluted	\$ (2.99)	\$ (1.76)	\$ (11.57)	\$ (13.15)
Weighted-average common shares outstanding:				
Basic	8,842	6,097	7,215	5,070
Diluted	8,842	6,097	7,215	5,070

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

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2016	2015	2016	2015
GAAP net loss	\$ (26,438)	\$ (10,740)	\$ (83,513)	\$ (66,649)
Adjustments:				
Interest expense, net	8,857	9,644	26,818	28,665
Depreciation and amortization	20,730	25,733	65,475	66,492
Income tax expense (benefit)	1	(5,642)	26	(13,818)
EBITDA	3,150	18,995	8,806	14,690
Net revenue adjustments (1)	-	644	-	(2,339)
Cost of product sales adjustments (2)	-	-	-	97
Selling, general and administrative adjustments (3)	1,606	1,548	4,766	9,282
Research and development adjustments	-	500	-	500
Change in fair value of contingent consideration	516	(3,596)	(8,958)	(3,596)
Loss from disposal and impairments of assets (4)	652	-	2,423	-
Loss on extinguishment of debt	-	1,112	-	1,112
Cost of inducement	-	-	-	19,500
Change in fair value of derivative liability	209	(10,527)	(6,744)	(19,230)

Foreign currency transaction gain	(31)	-	(98)	-
Restructuring costs (5)	2,277	(4)	2,277	1,193
Adjusted EBITDA	\$ 8,379	\$ 8,672	\$ 2,472	\$ 21,209

(1) To include impact of change in estimates related to gross to net accruals of \$0 and \$644,000 for the three months ended September 30, 2016 and 2015, respectively. Also, to include impact of change in estimates related to gross to net accruals of \$0 and \$2.6 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 nine months ended September 30, 2016 and 2015, respectively.

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

(3) To exclude deal costs of \$0 and \$186,000; stock compensation expense of \$(159,000) and \$1.3 million; severance expense of \$431,000 and \$0; loss on disposal of assets of \$0 and \$19,000; and litigation settlement expenses of \$1.3 million and \$0 for the three months ended September 30, 2016 and 2015, respectively. Also, to exclude deal costs of \$18,000 and \$4.1 million; stock compensation expense of \$2.1 million and \$3.8 million; severance expense of \$1.6 million and \$0; litigation settlement expenses of \$1.0 million and \$1.4 million and loss on disposal of assets of \$0 and \$19,000 for the nine months ended September 30, 2016 and 2015, respectively.

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

(5) To exclude the cost related to the initiative to restructure our sales force and operations in 2016 and the restructure of our operations and closure of the Charleston, South Carolina site in 2015.

CONTACT

Investor Relations

Matthew P. Duffy, 212-915-0685

LifeSci Advisors, LLC

matthew@lifesciadvisors.com



Pernix Therapeutics Holdings, Inc.