August 14, 2017

Acura Pharmaceuticals Announces Second Quarter 2017 Financial Results

PALATINE, Ill., Aug. 14, 2017 (GLOBE NEWSWIRE) -- Acura Pharmaceuticals, Inc. (OTCQB:ACUR), a specialty pharmaceutical company innovating abuse deterrent drugs, announced today financial results for the three and six months ended June 30, 2017.

The Company reported a net loss of $2.15 million or $0.18 per diluted share for quarter ended June 30, 2017 compared to a net loss of $3.3 million or $0.28 per diluted share for the same period in 2016. For the six months ended June 30, 2017 the Company reported net loss of $1.7 million or $0.15 per diluted share, compared to net loss of $6.6 million or $0.56 per diluted share for the same period in 2016.

For the six months ended June 30, 2017, the Company recorded $2.5 million in license fee revenue arising from the NEXAFED® and NEXAFED® SINUS licensing agreement with MainPointe Pharmaceuticals LLC.

Research and development expenses associated with product candidates utilizing the Company's LIMITX™, AVERSION® and IMPEDE® Technologies were $1.0 million in the second quarter 2017 compared to $1.4 million in the same period in 2016. These expenses were $1.7 million for the six months ended 2017 compared to $2.4 million for the same period in 2016.

Selling, marketing, general and administrative expenses were $1.1 million in the second quarter 2017 compared to $1.8 million in the same period in 2016. These expenses were $2.4 million for the six months ended 2017 compared to $4.1 million in the same period in 2016. The decrease in these expenses in 2017 were primarily associated with reductions in NEXAFED product line selling and marketing expenses as well as in patent litigation costs.

At August 1, 2017, the Company had unrestricted cash and cash equivalents totaling $6.6 million and $3.9 million in term debt financing. This cash balance includes net proceeds of $3.9 million from a private placement completed on July 24, 2017.

Conference Call Information
Acura Pharmaceuticals, Inc. will host a conference call on Tuesday, August 15, 2017 at 8:30 a.m. ET to discuss the results.

To participate in the live conference call, please dial 888-378-4398 (U.S. and Canada) five to ten minutes prior to the start of the call. The participant passcode is 167446.

A replay of the call will be available beginning August 16, 2017 and ending on September 15, 2017 on the company's website. The replay participant code is 6001822.

About Acura Pharmaceuticals
Acura Pharmaceuticals is a specialty pharmaceutical company engaged in the research, development and commercialization of product candidates intended to address medication abuse and misuse, utilizing its proprietary LIMITx™, AVERSION® and IMPEDE® Technologies. LIMITx contains ingredients that are intended to reduce or limit the rate or extent of opioid release when multiple tablets are ingested. AVERSION contains polymers that cause the drug to gel when dissolved; it also contains compounds that irritate the nasal passages if the product is snorted. IMPEDE is designed to disrupt the processing of pseudoephedrine from tablets into methamphetamine.

OXAYDO® (oxycodone HCl immediate-release tablets) which incorporates the AVERSION Technology, is FDA approved and marketed in the U.S. by our partner Egalet Corporation.

NEXAFED® and NEXAFED® Sinus, which are pseudoephedrine containing products that utilize the IMPEDE Technology, are marketed in the U.S. by our partner MainPointe Pharmaceuticals LLC.

Forward-Looking Statements

Certain statements in this press release constitute "forward-looking statements" within the meaning of the Private Securities

Litigation Reform Act of 1995. Such forward-looking statements involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any future results, performance, or achievements expressed or implied by such forward-looking statements. Forward-looking statements may include, but are not limited to:

- our ability to fund or obtain funding for our continuing operations, including the development of our products utilizing our LIMITx and Impede® technologies;
- the expected results of clinical studies relating to LTX-04 or any successor product candidate, the date by which such studies will complete and the results available and whether LTX-04 or any successor product candidate will ultimately receive FDA approval;
- whether LIMITx will retard the release of opioid active ingredients as dose levels increase;
- whether we will be able to reformulate LTX-04 or any successor product candidate to provide an efficacious level of drug when one or two tablets are taken;
- whether a reformulated LIMITx formulation that achieves an efficacious level of drug will continue to demonstrate acceptable abuse deterrent performance;
- whether we will be able to reformulate LTX-04 or any successor product candidate to improve its abuse deterrent performance;
- whether the extent to which products formulated with the LIMITx technology deter abuse will be determined sufficient by the FDA to support approval or labelling describing abuse deterrent features;
- our and our licensee's ability to successfully launch and commercialize our products and technologies, including Oxaydo® Tablets and our Nexafed® products;
- our and our licensee's ability to obtain necessary regulatory approvals and commercialize products utilizing our technologies;
- the market acceptance of, timing of commercial launch and competitive environment for any of our products;
- our ability to develop and enter into additional license agreements for our product candidates using our technologies;
- the ability to avoid infringement of patents, trademarks and other proprietary rights of third parties;
- the ability of our patents to protect our products from generic competition and our ability to protect and enforce our patent rights in any paragraph IV patent infringement litigation;
- the adequacy of the development program for our product candidates, including whether additional clinical studies will be required to support FDA approval of our product candidates;
- changes in regulatory requirements;
- adverse safety findings relating to our commercialized products or product candidates in development;
- whether the FDA will agree with our analysis of our clinical and laboratory studies;
- whether further studies of our product candidates will be required to support FDA approval;
- whether or when we are able to obtain FDA approval of labeling for our product candidates for the proposed indications and whether we will be able to promote the features of our abuse discouraging technologies; and
- whether Oxaydo or our Aversion and LIMITx product candidates will ultimately deter abuse in commercial settings and whether our Nexafed products and Impede technology product candidates will disrupt the processing of pseudoephedrine into methamphetamine.

In some cases, you can identify forward- looking statements by terms such as "may," "will," "should," "could," "would," "expects," "plans," "anticipates," "believes," "estimates," "indicates," "projects," "predicts," "potential" and similar expressions intended to identify forward-looking statements. These statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties. Given these uncertainties, you should not place undue reliance on these forward-looking statements. We discuss many of these risks in greater detail in our filings with the Securities and Exchange Commission.

ACURA PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands)

	(unaudited) June 30, 2017	(audited) December 31, 2016
Assets - restricted	$2,500	$2,500
Assets - current	1,692	3,410
Property, plant and equipment, net	720	867
Other assets	1,328	1,431
Total assets	$6,240	$8,208
Liabilities - current	$1,638	$1,111
Debt - current	2,857	2,376

Debt - non-current portion, net of discounts	1,431	2,979
Accrued interest - non-current portion	634	559
Stockholders' (deficit) equity	(320)	1,183
Total liabilities and stockholders' equity	$6,240	$8,208

ACURA PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS (INCOME)
(in thousands, except per share amounts)

	(unaudited) Three Months Ended June 30,		(unaudited) Six Months Ended June 30,	
	2017	2016	2017	2016
Revenues:				
License fee revenue	$-	$-	$2,500	$-
Collaboration revenue	23	133	59	233
Royalty revenue	69	30	143	47
Product sales, net	-	94	107	201
Total revenues, net	92	257	2,809	481
Cost and expenses:				
Cost of sales (excluding inventory provisions)	-	99	128	201
Inventory provisions	-	26	-	26
Research and development	1,020	1,403	1,731	2,417
Selling, marketing, general and administrative	1,063	1,808	2,359	4,054
Total cost and expenses	2,083	3,336	4,218	6,698
Operating loss	(1,991)	(3,079)	(1,409)	(6,217)
Non-operating income (expense):				
Investment income	1	21	2	48
Interest expense, net of interest income	(159)	(233)	(337)	(482)
Other income (expense)	-	3	-	(21)
Total other expense, net	(158)	(209)	(335)	(455)
Loss before provision for income taxes	(2,149)	(3,288)	(1,744)	(6,672)
Provision for income taxes	-	-	-	-
Net loss	$(2,149)	$(3,288)	$(1,744)	$(6,672)
Other comprehensive income:				
Unrealized gains on marketable securities	-	21	-	91
Comprehensive loss	$(2,149)	$(3,267)	$(1,744)	$(6,581)
Loss per share:				
Basic	$ (0.18)	$ (0.28)	$ (0.15)	$ (0.56)
Diluted	$ (0.18)	$ (0.28)	$ (0.15)	$ (0.56)
Weighted average number of shares outstanding:				
Basic	11,966	11,858	11,938	11,847
Diluted	11,966	11,858	11,938	11,847

Contact:

Acura Investor Relations, investors@acurapharm.com, 847-705-7709

Primary Logo

Source: Acura Pharmaceuticals, Inc.