

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D. C. 20549

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FORM 8-K

CURRENT REPORT  
Pursuant to Section 13 or 15(d) of the  
Securities Exchange Act Of 1934

November 14, 2016  
Date of Report (Date of earliest event reported)

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**ACURA PHARMACEUTICALS, INC.**  
(Exact Name of Registrant as Specified in Charter)

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**State of New York**  
(State of Other Jurisdiction  
of Incorporation)

**1-10113**  
(Commission File Number)

**11-0853640**  
(I.R.S. Employer  
Identification Number)

**616 N. North Court, Suite 120**  
**Palatine, Illinois 60067**  
(Address of principal executive offices) (Zip Code)

**(847) 705-7709**  
(Registrant's telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
  - ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
  - ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
  - ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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**Item 2.02 Results of Operations and Financial Condition**

On November 14, 2016 we issued a press release disclosing the financial results for our third quarter ended September 30, 2016. A copy of our press release is being furnished as Exhibit 99.1 hereto.

**Item 9.01 Financial Statements and Exhibits****Exhibit Number****Description**

|      |   |
|------|---|
| 99.1 | Press Release announcing financial results for the third quarter ended September 30, 2016 |
|------|---|

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## 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.

### ACURA PHARMACEUTICALS, INC.

By: /s/ Peter A. Clemens  
Peter A. Clemens  
Senior Vice President & Chief Financial Officer

Palatine, Illinois  
Date: November 14, 2016

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## Exhibit Index

### Exhibit Number

### Description

|      |   |
|------|---|
| 99.1 | Press Release announcing financial results for the third quarter ended September 30, 2016 |
|------|---|

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**Acura Pharmaceuticals Announces  
Third Quarter 2016 Financial Results**

Palatine, IL – (November 14, 2016) Acura Pharmaceuticals, Inc. (NASDAQ: ACUR), a specialty pharmaceutical company innovating abuse deterrent drugs, announced today financial results for the three and nine months ended September 30, 2016.

The Company reported a net loss of \$2.3 million for the third quarter of 2016 or \$0.19 per diluted share, compared to net loss of \$2.6 million or \$0.23 per diluted share for the same period in 2015. Revenues for the quarter were \$218 thousand compared to \$210 thousand in the third quarter of 2015.

Research and development expenses were \$0.8 million in the third quarter of 2016, compared to \$0.4 million for the same period in 2015. Research and development expenses were primarily associated with product candidates utilizing the Company's LIMITX™, and IMPEDE® Technologies. Selling, marketing, general and administrative expenses were \$1.3 million in the third quarter of 2016, versus \$2.0 million in the same period last year. Selling and marketing expenses primarily consist of advertising and marketing activities for NEXAFED® and NEXAFED® SINUS.

The Company reported a net loss of \$8.9 million for the nine months ended September 30, 2016 or \$0.75 per diluted share, compared to net loss of \$4.1 million or \$0.39 per diluted share for the same period in 2015. Revenues for the nine months ended September 30, 2016 were \$0.7 million compared to \$5.9 million in the same period last year. The 2015 results reflect the \$5.0 million payment arising from licensing OXAYDO™ (oxycodone HCl) tablets to Egalet Corporation (NASDAQ: EGLT) entities.

Research and development expenses were \$3.3 million in the nine months ended September 30, 2016, compared to \$1.9 million for the same period in 2015. Research and development expenses were primarily associated with product candidates utilizing the Company's LIMITX™, and IMPEDE® Technologies. Selling, marketing, general and administrative expenses were \$5.4 million in the nine months ended September 30, 2016, versus \$6.4 million in the same period last year. Selling and marketing expenses primarily consisted of advertising and marketing activities for NEXAFED® and NEXAFED® SINUS.

At October 31, 2016, we had unrestricted cash and cash equivalents of \$4.2 million (which includes the \$3.5 million payment received under our License Agreement with KemPharm, Inc., and after deduction of our \$2.5 million compensating balance requirement under our term loan with Oxford Finance LLC), and the outstanding term loan balance with Oxford Finance LLC was \$6.2 million.

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### ***Conference Call Information***

Acura Pharmaceuticals is, Inc. will host a conference call on Tuesday, November 15, 2016 at 8:30 a.m. ET to discuss the results.

To participate in the live conference call, please dial (800) 768-6569 (U.S. and Canada) five to ten minutes prior to the start of the call. The participant passcode is 4115835. A digital replay of the call will be available for 5 days following the call by dialing (800) 768-6569 (U.S. and Canada). The replay participant code is 4115835.

### ***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 directed at minimizing the extraction and conversion of pseudoephedrine 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.

Acura markets NEXAFED® and NEXAFED® SINUS, which are pseudoephedrine containing products that utilize the IMPEDE Technology.

### ***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;
  - our ability to remain in compliance with our obligations under our term loan with Oxford Finance, or to obtain a waiver from Oxford for our failure to comply with our covenants contained in such term loan agreement;
  - the expected results of clinical studies relating to LTX-04, the date by which such study results will be available and whether LTX-04 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 to provide an efficacious level of drug when one or two tablets are taken;
  - whether we will be able to reformulate LTX-04 to improve its abuse deterrent performance;
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- whether the extent to which products formulated with the LIMITX Technology deter abuse will be determined sufficient by the FDA to support approval or labeling describing abuse deterrent features;
  - whether our LIMITX Technology can be expanded into extended-release formulations;
  - our and our licensee's ability to successfully launch and commercialize our products and technologies, including OXAYDO® Tablets and our NEXAFED® products;
  - the pricing and price discounting that may be offered by Egalet for OXAYDO;
  - whether we can successfully develop a product under our agreement with Bayer;
  - the results of our development of our LIMITX Technology;
  - 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;
  - the willingness of pharmacies to stock our NEXAFED products;
  - expectations regarding potential market share for our products;
  - our ability to develop and enter into additional license agreements for our product candidates using our technologies;
  - our exposure to product liability and other lawsuits in connection with the commercialization of our products;
  - the increasing cost of insurance and the availability of product liability insurance coverage;
  - 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 ability to fulfill the FDA requirements for approving our product candidates for commercial manufacturing and distribution in the United States, including, without limitation, the adequacy of the results of the laboratory and clinical studies completed to date, the results of laboratory and clinical studies we may complete in the future to support FDA approval of our product candidates and the sufficiency of our development process to meet over-the-counter ("OTC") Monograph standards, as applicable;
  - 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 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.
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In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “should,” “could,” “would,” “expects,” “plans,” “anticipates,” “believes,” “indicates,” “estimates,” “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. Unless required by law, we undertake no obligation to update or revise any forward-looking statements to reflect new information or future events or developments. Accordingly, you should not assume that our silence over time means that actual events are bearing out as expressed or implied in such forward-looking statements.

Contact:  
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(847) 705-7709

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

|  | (unaudited)<br>September 30,<br>2016 | (audited)<br>December 31,<br>2015 |
|--|--------------------------------------|-----------------------------------|
| Assets, current  | \$ 5,276                             | \$ 14,135                         |
| Property, plant and equipment, net   | 979                                  | 1,013                             |
| Other assets   | 1,483                                | 1,813                             |
| Total assets   | <u>\$ 7,738</u>                      | <u>\$ 16,961</u>                  |
| Liabilities, current   | \$ 1,515                             | \$ 924                            |
| Debt, current  | 2,685                                | 2,320                             |
| Debt, non-current portion - net of discount of \$119 and \$193, and debt issuance costs of \$58 and \$97 | 3,508                                | 5,430                             |
| Accrued interest, non-current portion  | 519                                  | 387                               |
| Stockholders' (deficit) equity   | (489)                                | 7,900                             |
| Total liabilities and stockholders' equity   | <u>\$ 7,738</u>                      | <u>\$ 16,961</u>                  |

**ACURA PHARMACEUTICALS, INC.**  
**CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS**  
(Unaudited; in thousands, except per share amounts)

|  | (unaudited)<br>Three months<br>Ended September 30, |            | (unaudited)<br>Nine months<br>Ended September 30, |            |
|--|--|------------|---|------------|
|  | 2016   | 2015       | 2016  | 2015       |
| <b>Revenues:</b>                                   |  |            |   |            |
| License fee revenue                                | \$ -   | \$ -       | \$ -  | \$ 5,250   |
| Collaboration revenue                              | 74   | 95         | 307   | 95         |
| Royalty revenue                                    | 39   | -          | 86  | -          |
| Product sales, net                                 | 105  | 115        | 306   | 563        |
| Total revenues, net                                | 218  | 210        | 699   | 5,908      |
| <b>Cost and expenses:</b>                          |  |            |   |            |
| Cost of sales (excluding inventory write-downs)    | 108  | 132        | 309   | 554        |
| Inventory write-downs                              | -  | 27         | 26  | 334        |
| Research and development                           | 841  | 432        | 3,258   | 1,907      |
| Selling, marketing, general and administrative     | 1,338  | 2,024      | 5,392   | 6,404      |
| Total costs and expenses                           | 2,287  | 2,615      | 8,985   | 9,199      |
| Operating loss                                     | (2,069)  | (2,405)    | (8,286)   | (3,291)    |
| <b>Non-operating income (expense):</b>             |  |            |   |            |
| Investment income                                  | 11   | 39         | 59  | 110        |
| Interest expense                                   | (215)  | (283)      | (697)   | (892)      |
| Other income                                       | 23   | -          | 2   | -          |
| Total other expense, net                           | (181)  | (244)      | (636)   | (782)      |
| Loss before provision for income taxes             | (2,250)  | (2,649)    | (8,922)   | (4,073)    |
| Provision for income taxes                         | -  | -          | -   | -          |
| Net loss   | \$ (2,250)   | \$ (2,649) | \$ (8,922)  | \$ (4,073) |
| <b>Other comprehensive income (loss):</b>          |  |            |   |            |
| Unrealized gains on securities                     | -  | 2          | -   | 2          |
| Comprehensive loss                                 | \$ (2,250)   | \$ (2,647) | \$ (8,922)  | \$ (4,071) |
| <b>Loss per share of common stock:</b>             |  |            |   |            |
| Basic  | \$ (0.19)  | \$ (0.23)  | \$ (0.75)   | \$ (0.39)  |
| Diluted  | \$ (0.19)  | \$ (0.23)  | \$ (0.75)   | \$ (0.39)  |
| <b>Weighted average common shares outstanding:</b> |  |            |   |            |
| Basic  | 11,880   | 11,677     | 11,858  | 10,446     |
| Diluted  | 11,880   | 11,677     | 11,858  | 10,446     |