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

FORM 8-K

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

June 29, 2018
Date of Report (Date of earliest event reported)

ACURA PHARMACEUTICALS, INC.

(Exact Name of Registrant as Specified in Charter)

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 (17CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17CFR240.14d- 2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17CFR 240.13e- 4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging Growth 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.

Item 2.02 Results of Operations and Financial Condition

On June 29, 2018 we issued a press release disclosing the financial results for our first quarter ended March 31, 2018. A copy of our press release is being furnished as Exhibit 99.1 hereto.

Item 9.01 Financial Statements and Exhibits

| <u>Exhibit Number</u> | <u>Description</u> |
|-----------------------|--------------------|
|-----------------------|--------------------|

| | |
|----------------------|---|
| 99.1 | Press Release announcing financial results for the first quarter ended March 31, 2018 |
|----------------------|---|

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: June 29, 2018

Exhibit Index

| <u>Exhibit Number</u> | <u>Description</u> |
|------------------------------|--|
| <u>99.1</u> | <u>Press Release announcing financial results for the first quarter ended March 31, 2018</u> |



Acura Pharmaceuticals Announces First Quarter 2018 Financial Results

Palatine, IL – (June 29, 2018) - Acura Pharmaceuticals, Inc. (OTC PINK: ACUR), a specialty pharmaceutical company innovating abuse deterrent drugs, announced today financial results for the three months ended March 31, 2018.

The Company reported for the first quarter 2018 a net loss of \$1.5 million or \$0.07 per diluted share compared to net income of \$0.4 million or \$0.03 per diluted share for 2017.

For the three month period ended March 31, 2018, the Company recorded \$0.2 million in royalty revenue compared to \$0.1 million for the same period in 2017. For the three month period ended March 31, 2017, the Company also recorded \$2.5 million in license fee revenue, \$0.1 million in NEXAFED® product line net sales, and \$36 thousand in collaboration revenue. In March 2017, we entered into a license agreement with MainPointe Pharmaceuticals, LLC, whereby we licensed our NEXAFED product line to them.

Research and development expenses on the Company's LIMITX™, and IMPEDE® Technologies were \$0.7 million for each of the three month periods ended March 31, 2018 and 2017.

Selling, marketing, general and administrative expenses were \$0.9 million and \$1.3 million for the three month periods ended March 31, 2018 and 2017, respectively. The decrease in these expenses from 2017 was from a reduction of NEXAFED selling and marketing expenses.

At June 28, 2018, the Company had cash, cash equivalents, and refundable deposits of \$0.7 million, term debt financings of \$3.0 million, and accrued term debt interest of \$0.7 million.

Unless we enter into a licensing agreement or receive funding in the very near future, of which there can be no assurance, we will be required to scale back or terminate operations and/or seek protection under applicable bankruptcy laws. This could result in a complete loss of shareholder value in the Company. Even assuming we are successful in securing additional sources of financing to fund continued operations, there can be no assurance that the proceeds of such financing will be sufficient to fund operations until such time, if at all, that we generate sufficient revenue from our products and product candidates to sustain and grow our operation.

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. We have discovered and developed three proprietary platform technologies which can be used to develop multiple products. Our LIMITX™ Technology is intended to address methods of product tampering associated with opioid abuse by retarding the release of active drug ingredients when too many tablets are accidentally or purposefully ingested. Our AVERSION® Technology is intended to address methods of product tampering associated with opioid abuse by incorporating gelling ingredients and irritants into tablets to discourage abuse by snorting and provide barriers to abuse by injection. Our IMPEDE® Technology 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.

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.

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 comply with our obligations under our term loan with Oxford Finance LLC, or to obtain a waiver from Oxford Finance LLC for our failure to comply with our covenants contained in such term loan agreement;
- the expected results of clinical studies relating to LTX-03 or any successor product candidate, the date by which such studies will be complete and the results will be available and whether LTX-03 will ultimately receive FDA approval;
- whether LIMITX will retard the release of opioid active ingredients as dose levels increase;
- 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;
- 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;
- the results of our development of our LIMITX Technology;
- our or 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;
- 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;
- whether the FDA will agree with or accept the results of our studies for our product candidates;
- 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 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.

Contact:

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

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

| | (unaudited) March 31, 2018 | (audited) December 31, 2017 |
|---|----------------------------------|-----------------------------------|
| Assets - current | \$ 1,082 | \$ 2,566 |
| Property, plant and equipment, net | 659 | 679 |
| Other assets | 1,307 | 1,359 |
| Total assets | \$ 3,048 | \$ 4,604 |
| Liabilities - current | \$ 1,500 | \$ 1,237 |
| Accrued interest - current | 745 | 700 |
| Debt - current, net | 2,228 | 2,694 |
| Stockholders' deficit | (1,425) | (27) |
| Total liabilities and stockholders' deficit | \$ 3,048 | \$ 4,604 |

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

| | (unaudited) | |
|---|------------------------------|----------|
| | Three Months Ended March 31, | |
| | 2018 | 2017 |
| Revenues: | | |
| License fee revenue | \$ - | \$ 2,500 |
| Collaboration revenue | - | 36 |
| Royalty revenue | 198 | 74 |
| Product sales, net | - | 107 |
| Total revenues, net | 198 | 2,717 |
| Cost and expenses: | | |
| Cost of sales | - | 128 |
| Research and development | 650 | 711 |
| Selling, marketing, general and administrative | 943 | 1,296 |
| Total cost and expenses | 1,593 | 2,135 |
| Operating (loss) income | (1,395) | 582 |
| Interest expense, net | (99) | (177) |
| (Loss) income before income taxes | (1,494) | 405 |
| Provision for income taxes | - | - |
| Net (loss) income | \$ (1,494) | \$ 405 |
| Net (loss) income per share: | | |
| Basic | \$ (0.07) | \$ 0.03 |
| Diluted | \$ (0.07) | \$ 0.03 |
| Weighted average number of shares outstanding: | | |
| Basic | 21,034 | 11,907 |
| Diluted | 21,034 | 12,083 |