UK: +44 (0)207 989 0813
NA: +1 646 896 3065
AU +61 2 9222 2832
action@proactiveinvestors.com
uk.proactiveinvestors.com

# AcelRx Pharmaceuticals

November 05 2018

## AcelRx shares pop on FDA approval of opioid pain treatment Dsuvia

Shares of AcelRx Inc (NASDAQ:ACRX) are on the rise following the controversial approval by the US Food and Drug Administration of its opioid pain treatment drug Dsuvia.

In a rare move, US regulators have given the green light for the opioid Dsuvia to be used under strict medical supervision at a time when the US opioid crisis has escalated and health officials are looking to crack down on the addictive drugs.

In response, investors sent AcelRx shares up 3% before the opening bell on Monday to $4.95.

Taken by mouth, the quick-acting Dsuvia, which is a form of the opioid sufentanil, will be be used in hospitals as well as surgical centers and emergency departments as an alternative to injectable opioids.

The drug was a priority medical product for the Pentagon which is intending to use it to treat soldiers on the battlefield.

But the drug's approval has generated considerable controversy as it is far more potent than both morphine and fentanyl.

"An opioid that is a thousand times more powerful than morphine is a thousand times more likely to be abused, and a thousand times more likely to kill," said Senator Edward Markey, a Democrat from Massachussetts in a statement last month.

Leland Gershell, an analyst with Oppenheimer, is also remaining on the sidelines about AcelRx's new drug approval, despite the US military having the option to buy 112,000 units of Dsuvia.

"We are on the sidelines as we expect lackluster revenues for both Dsuvia and Zalviso relative to the large acute pain market," he wrote in a note to investors.

Like all opioids, Dsuvia will carry a warning about the risks of misuse and abuse, which can lead to addiction, overdose and death.

READ: AcelRx Pharmaceuticals shares soar following FDA advisory committee's approval vote for Dsuvia

To address concerns about its potential risks, Dsuvia won't be available in retail pharmacies or for home use. It should also not be used for more than 72 consecutive hours, said FDA Commissioner Scott Gottlieb in a statement.

"Dsuvia, which was previously approved by the European Medicines Agency in July under the brand name Dzuveo, has some unique features in that the drug is delivered in a stable form that makes it ideally suited for certain special circumstances where patients may not be able to swallow oral medication, and where access to intravenous pain relief

| | |
|---|---|
| **Price:** | US$2.51 |
| **Market Cap:** | US$155.39M |

**1 Year Share Price Graph**


### Share Information

| | | |
|---|---|---|
| **Code:** | | ACRX |
| **Listing:** | | NASDAQ |
| **52 week** | **High** | **Low** |
| | **5.05p** | **1.65p** |
| **Sector:** | | **Pharma & Biotech** |
| **Website:** | | **www.acelrx.com** |

**Company Synopsis:**

*AcelRx Pharmaceuticals is a development-stage specialty pharmaceutical company focused on the development and commercialization of therapies for the treatment of acute pain. The Company's lead product candidate, Zalviso, is intended for the management of moderate-to-severe acute pain in hospitalized adult patients.*

**Author:**
**Ellen Kelleher**
**+44(0)1202770386**
**action@proactiveinvestors.com**

is not possible," Gottlieb said.

The drug was rejected by the FDA last year due to concerns about its dosing and usage directions.

Since then, AcelRx has lowered the drug's maximum daily dose from 24 tablets to 12 tablets and provided new safety analysis.

The drug's directions were updated and a study was conducted to address concerns that the small size of the tablets would make them easy to misplace.

Last month, the Anesthetic and Analgesic Drug Products Advisory Committee of the FDA voted 10-3 in favor of approving Dsuvia for managing moderate-to-severe acute pain in medically supervised settings for adults.

Dsuvia's commercial launch is expected in the first quarter of next year.

Contact Ellen Kelleher at ellen@proactiveinvestors.com

specific person. You further understand that none of the information providers or their affiliates will advise you personally concerning the nature, potential, advisability, value or suitability of any particular security, portfolio of securities, transaction, investment strategy, or other matter.

You understand that the Site may contain opinions from time to time with regard to securities mentioned in other products, including company related products, and that those opinions may be different from those obtained by using another product related to the Company. You understand and agree that contributors may write about securities in which they or their firms have a position, and that they may trade such securities for their own account. In cases where the position is held at the time of publication and such position is known to the Company, appropriate disclosure is made. However, you understand and agree that at the time of any transaction that you make, one or more contributors may have a position in the securities written about. You understand that price and other data is supplied by sources believed to be reliable, that the calculations herein are made using such data, and that neither such data nor such calculations are guaranteed by these sources, the Company, the information providers or any other person or entity, and may not be complete or accurate.

From time to time, reference may be made in our marketing materials to prior articles and opinions we have published. These references may be selective, may reference only a portion of an article or recommendation, and are likely not to be current. As markets change continuously, previously published information and data may not be current and should not be relied upon.