**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**

**Date of Report (Date of earliest event reported): March 10, 2022**

# ACELRX PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

| **Delaware** | **001-35068** | **41-2193603** |
|---|---|---|
| (State of incorporation) | (Commission File No.) | (IRS Employer Identification No.) |

**25821 Industrial Boulevard, Suite 400**
**Hayward, CA 94545**
(Address of principal executive offices and zip code)

Registrant's telephone number, including area code: **(650) 216-3500**

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))

Securities registered pursuant to Section 12(b) of the Act

| **Title of each class** | **Trading Symbol(s)** | **Name of each exchange on which registered** |
|---|---|---|
| Common Stock, $0.001 par value | ACRX | The Nasdaq Global Market |

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 March 10, 2022, AcelRx Pharmaceuticals, Inc. (the "Company") issued a press release announcing its financial results for the three and twelve months ended December 31, 2021 (the "Release"). A copy of the Release is furnished herewith as Exhibit 99.1.

*The information contained in this Item 2.02 and in Exhibit 99.1 shall be deemed to be "furnished" and shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that Section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended (the "Securities Act"). The information contained in this Item 2.02 and in Exhibit 99.1 shall not be incorporated by reference into any filing under the Securities Act or the Exchange Act made by the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing, except as shall be expressly set forth by specific reference in such filing.*

**Item 9.01 Financial Statements and Exhibits**

| **Exhibit No.** | **Description** |
|---|---|
| 99.1 | Press Release dated March 10, 2022 |
| 104 | Cover Page Interactive Data File (embedded within the Inline XBRL document) |

**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 hereunto duly authorized.

Date: March 10, 2022

ACELRX PHARMACEUTICALS, INC.
By: /s/ Raffi Asadorian
Raffi Asadorian
Chief Financial Officer

# AcelRx Pharmaceuticals Reports Fourth Quarter and Full Year 2021 Financial Results

*AcelRx expanded late-stage pipeline with Niyad™ (nafamostat), which has received Breakthrough Designation status from the FDA and an ICD-10 procedural code from CMS*

*Q4 2021 DSUVIA unit sales growth of 142% compared to Q3 2021*

*AcelRx had $51.6 million of cash and short-term investments as of December 31, 2021*

HAYWARD, Calif., March 10, 2022 – AcelRx Pharmaceuticals, Inc. (Nasdaq: ACRX), (AcelRx), a specialty pharmaceutical company focused on the development and commercialization of innovative therapies for use in medically supervised settings, today reported its fourth quarter and full year 2021 financial results.

“We are executing on our strategy to expand and diversify our product portfolio by acquiring commercial-ready, or late-stage development-ready assets that address what we consider as unmet market needs for medically supervised settings. In particular, we are currently focused on the development and ultimate approval of our newly secured pre-filled syringes and Niyad (nafamostat) product candidates which could potentially provide multiple value creating catalysts for our shareholders in the near-term,” said Vince Angotti, Chief Executive Officer of AcelRx. Mr. Angotti continued, “In addition, we have taken deliberate actions to adapt to the evolving healthcare environment as many medical procedures resulting in moderate-to-severe pain that were previously performed in surgical centers or hospitals have now been shifted to procedural suites, allowing us the opportunity to introduce DSUVIA into these settings. We have thus shifted our commercial resources, beginning in the third quarter, to focus on this new customer base, resulting in solid growth in DSUVIA unit sales in the fourth quarter 2021.”

**FY 2021 and Recent Highlights**

- AcelRx entered into a license agreement with Laboratoire Aguettant (Aguettant) providing AcelRx with two innovative pre-filled syringe product candidates for the U.S. The expected market opportunity for these two product candidates exceeds $100 million, and AcelRx currently plans to file New Drug Applications for both in 2022.

- A second license transaction with Aguettant was completed establishing Aguettant as the commercial partner for DZUVEO in Europe with an expected launch in the third quarter of 2022. AcelRx is entitled to receive up to approximately $55 million in combined up-front and sales-based milestone payments.

- AcelRx announced the closing of its acquisition of Lowell Therapeutics, Inc. (Lowell) in January 2022 in a transaction for consideration of approximately $32.5 million plus net cash acquired and certain other adjustments, and which includes up to approximately $26.0 million of contingent consideration payable in cash or stock at AcelRx’s option, upon the achievement of regulatory and sales-based milestones. Niyad™ (nafamostat) is the lead product, with a targeted indication of anticoagulation of the extracorporeal circuit, and which has received Breakthrough Device Designation from the FDA, as well as an ICD-10 procedural code from CMS which allows for reimbursement. Annual peak sales potential for Niyad is expected to exceed $200 million.

- Since January 2021, six articles on DSUVIA were published reporting the benefits of administering DSUVIA in place of IV opioids, including reducing perioperative opioid use, rapid recovery times, efficacy and safety among a wide range of demographics and the overall advantages of sublingual delivery. Of note, one of these articles was a commentary published in *Military Medicine*, identifying DSUVIA as the next evolution in battlefield pain management. An additional study of DSUVIA for painful cosmetic procedures has been accepted for publication by the *American Journal of Cosmetic Surgery* and another study on the use of DSUVIA during general anesthesia for lengthy plastic surgery procedures has been submitted for publication.

- As of December 31, 2021, AcelRx has achieved 725 approvals compared to our initial target of 615. As of February 28, 2022, AcelRx has achieved 813 formulary approvals for DSUVIA.

- In February 2022, AcelRx was notified that it had met all requirements set by the U.S. Food and Drug Administration (FDA) with regards to the FDA Warning Letter regarding certain DSUVIA promotional materials, dated February 11, 2021, and a Closeout Letter is expected in Q1 2022.

**Financial Information**

- The cash, cash equivalents and short-term investments balance was $51.6 million as of December 31, 2021.

- 8,960 units of DSUVIA were sold in the fourth quarter of 2021, compared to 3,710 units in the third quarter of 2021; however, the Company has recognized only $2 thousand in net revenues in the fourth quarter 2021 as a result of a $0.3 million reserve for potential returns related to a certain wholesale customer that purchased product for the Department of Defense (DoD) in 2020. The DoD has purchased exclusively from a secondary wholesale customer instead of their primary wholesaler, and therefore the Company has recorded a reserve in the event this product is not ultimately sold to the DoD.

- Unit sales growth in the first two months of Q1 2022, compared to the first two months of Q4 2021 is 63%.

- Combined R&D and SG&A expenses for the fourth quarter of 2021 totaled $6.9 million compared to $8.7 million for the fourth quarter of 2020. Excluding non-cash depreciation and stock-based compensation expense, these amounts were $5.6 million for the fourth quarter of 2021, compared to $7.5 million for the fourth quarter of 2020. R&D and SG&A expenses for the year ended December 31, 2021 totaled $35.0 million compared $40.3 million for the year ended December 31, 2020. Excluding non-cash depreciation and stock-based compensation expense, these figures were $29.7 million for the year ended December 31, 2021, compared to $35.4 million for the year ended December 31, 2020. The decrease in combined R&D and SG&A expenses in the fourth quarter and year ended 2021 was primarily due to reductions in personnel-related costs, including travel expense, partially offset by increased Catalent manufacturing-related DSUVIA development expenses.

- Net loss for the fourth quarter of 2021 was $7.9 million, or $0.06 per basic and diluted share, compared to $8.9 million, or $0.10 per basic and diluted share, for the fourth quarter of 2020. Net loss for the year ended December 31, 2021 was $35.1 million, or $0.29 per basic and diluted share, compared to $40.4 million, or $0.47 per basic and diluted share, for the year ended December 31, 2020.

**2022 Guidance**

The Company’s 2022 year-end goals include the submission of two NDAs for its pre-filled syringe product candidates, pending outcome of FDA feedback that is expected in the second quarter, and the manufacturing of initial lots of nafamostat. Quarterly combined R&D and SG&A expense is expected to be approximately $9-$10 million (and $8-$9 million excluding stock compensation and depreciation). Annual debt service is expected to approximate $10 million as the Company continues to pay down amounts outstanding under its senior debt facility that matures in June 2023. Annual capital expenditures are expected to approximate $2 million attributed mainly to the final validation of the automated packaging line at AcelRx’s contract manufacturer.

2022 financial guidance is based on the Company's current expectations and are forward-looking statements. Actual results could differ materially depending on market conditions and the factors set forth under Forward-Looking Statements below.

**Webcast and Conference Call Information**
As previously announced, AcelRx will host a live webcast Thursday, March 10th at 4:30 p.m. Eastern Time (1:30 p.m. Pacific Time) to discuss these financial results and provide other corporate updates. The webcast is accessible by visiting the Investors page of AcelRx's website at http://ir.acelrx.com/ and clicking on the webcast link. The webcast will be accompanied by a slide presentation. Investors who wish to participate in the conference call may do so by dialing (866) 361-2335 for domestic callers, (855) 669-9657 for Canadian callers or (412) 902-4204 for international callers. A webcast replay will be available on the AcelRx website for 90 days following the call by visiting the Investor page of AcelRx’s website at http://ir.acelrx.com/.

**About DSUVIA (sufentanil sublingual tablet), 30 mcg**
DSUVIA®, to be marketed as DZUVEO® in Europe, is indicated for use in adults in certified medically supervised healthcare settings, such as hospitals, surgical centers, and emergency departments, for the management of acute pain severe enough to require an opioid analgesic, and for which alternative treatments are inadequate. DSUVIA was designed to provide rapid analgesia via a non-invasive route of administration and to eliminate dosing errors associated with intravenous (IV) administration of opioid analgesics. DSUVIA is a single-strength solid dosage form administered sublingually via a single-dose applicator (SDA) by healthcare professionals. Sufentanil is an opioid analgesic previously only marketed for IV and epidural anesthesia and analgesia. The sufentanil pharmacokinetic profile when delivered sublingually avoids the high peak plasma levels and short duration of action observed with IV administration. The European Commission approved DZUVEO for marketing in Europe and it will be commercialized by AcelRx's European partner, Aguettant.

For more information, including important safety information and black box warning for DSUVIA, please visit www.DSUVIA.com.

**About nafamostat**
Nafamostat is a broad spectrum, synthetic serine protease inhibitor with anticoagulant, anti-inflammatory and potential anti-viral activities. Niyad™ is a lyophilized formulation of nafamostat and is currently being studied under an investigational device exemption, or IDE, as an anticoagulant for the extracorporeal circuit. Niyad has received Breakthrough Device Designation Status from the FDA. LTX-608 is a proprietary nafamostat formulation for direct IV infusion that we plan to potentially develop as a COVID anti-viral treatment, as well as for the treatment of disseminated intravascular coagulation (DIC), acute respiratory distress syndrome (ARDS), and acute pancreatitis.

**About AcelRx Pharmaceuticals, Inc.**
AcelRx Pharmaceuticals, Inc. is a specialty pharmaceutical company focused on the development and commercialization of innovative therapies for use in medically supervised settings. AcelRx's proprietary, non-invasive sublingual formulation technology delivers sufentanil with consistent pharmacokinetic profiles. The Company has one approved product in the U.S., DSUVIA® (sufentanil sublingual tablet, 30 mcg), known as DZUVEO® in Europe, indicated for the management of acute pain severe enough to require an opioid analgesic for adult patients in certified medically supervised healthcare settings, and has several product candidates in its portfolio. These product candidates include Zalviso® (sufentanil sublingual tablet system, SST system, 15 mcg), an investigational product in the U.S. being developed as an innovatively designed patient-controlled analgesia (PCA) system for reduction of moderate-to-severe acute pain in medically supervised settings, two pre-filled, ready-to-use syringes of ephedrine and phenylephrine licensed for the U.S. market from Aguettant, Niyad™, a regional anticoagulant for the extracorporeal circuit, and LTX-608, for the potential treatment of COVID-19, disseminated intravascular coagulation, acute respiratory distress syndrome and acute pancreatitis. DZUVEO and Zalviso are both approved products in Europe.

This release is intended for investors only. For additional information about AcelRx, please visit www.acelrx.com.

**Non-GAAP Financial Measures**
*To supplement AcelRx's financial results and guidance presented in accordance with U.S. generally accepted accounting principles (GAAP), AcelRx uses certain non-GAAP financial measures in this press release, in particular, excluding non-cash depreciation and stock-based compensation expense from its operating expenses. AcelRx believes that these non-GAAP financial measures provide useful supplementary information to, and facilitate additional analysis by, investors and analysts. In particular, AcelRx believes that these non-GAAP financial measures, when considered together with AcelRx's financial information prepared in accordance with GAAP, can enhance investors' and analysts' ability to meaningfully compare AcelRx's results from period to period and to its forward-looking guidance. In addition, these types of non-GAAP financial measures are regularly used by investors and analysts to model and track AcelRx's financial performance. AcelRx's management also regularly uses these non-GAAP financial measures internally to understand, manage and evaluate AcelRx's business and to make operating decisions. Non-GAAP financial measures are not meant to be considered in isolation or as a substitute for comparable GAAP measures and should be read in conjunction with AcelRx's consolidated financial statements prepared in accordance with GAAP. The non-GAAP financial measures in this press release and the accompanying tables have limits in their usefulness to investors and may be calculated differently from, and therefore may not be directly comparable to, similarly titled measures used by other companies.*

**Forward-Looking Statements**

*This press release contains forward-looking statements, including, but not limited to, statements related to the expected benefits arising from our recent acquisition of Lowell, expected areas of growth for DSUVIA, the expected launch of DZUVEO in Europe by Aguettant and the expected license consideration arising from such commercialization activities, the expected market opportunity for our new product candidates in-licensed from Aguettant and/or acquired through the Lowell acquisition, our plans to file NDAs for our new product candidates and the timing of such filings. These and any other forward-looking statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These statements may be identified by the use of forward-looking terminology such as "believes," "expects," "anticipates," "may," "will," "should," "seeks," "approximately," "intends," "plans," "estimates," or the negative of these words or other comparable terminology. The discussion of financial trends, strategy, plans or intentions may also include forward-looking statements, which are predictions, projections and other statements about future events that are based on current expectations and assumptions. These forward-looking statements involve risks and uncertainties that could cause actual results to differ materially from those projected, anticipated or implied by such statements, including: (i) the risk that the acquisition of Lowell disrupts the current plans and operations of AcelRx and could adversely affect its business and the price of AcelRx's common stock; (ii) risks relating to our ability to successfully market DSUVIA in existing and in new and untested markets; (iii) risks relating to the ability of Aguettant to successfully launch and commercialize DZUVEO in the European marketplace and our attendant ability to realize licensing revenues that are contingent on such success; (iv) risks relating to our ability to obtain regulatory approvals for the pre-filled syringe product candidates in-licensed from Aguettant; (v) risks relating to our ability to successfully commercialize the pre-filled syringe product candidates in-licensed from Aguettant should we obtain regulatory approvals; (vi) risks relating to our ability to obtain regulatory approvals for the nafamostat product candidates acquired from Lowell; (vii) risks relating to our ability to successfully commercialize the nafamostat product candidates acquired from Lowell should we obtain regulatory approvals; (viii) risks relating to AcelRx's product development activities diverting AcelRx management's attention from ongoing commercial business operations; (ix) risks related to the ability of AcelRx to implement its plans, forecasts and other business expectations; (x) risks related to obtaining final validation and regulatory approval of our fully automated packaging line; and (xi) risks related to unexpected variations in market growth and demand for AcelRx's commercial and developmental products and technologies. Although it is not possible to predict or identify all such risks and uncertainties, they may include, but are not limited to, those described under the caption "Risk Factors" and elsewhere in AcelRx's annual, quarterly and current reports (i.e., Form 10-K, Form 10-Q and Form 8-K) as filed or furnished with the Securities and Exchange Commission (SEC) and any subsequent public filings. You are cautioned not to place undue reliance on any such forward-looking statements, which speak only as of the date such statements were first made. To the degree financial information is included in this press release, it is in summary form only and must be considered in the context of the full details provided in AcelRx's most recent annual, quarterly or current report as filed or furnished with the SEC. AcelRx's SEC reports are available at www.acelrx.com under the "Investors" tab. Except to the extent required by law, AcelRx undertakes no obligation to publicly release the result of any revisions to these forward-looking statements to reflect new information, events or circumstances after the date hereof, or to reflect the occurrence of unanticipated events.*

***Investor Contacts***
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**Selected Financial Data**
(in thousands, except per share data)
(unaudited)

| | Three Months Ended December 31 | | Twelve Months Ended December 31 | |
|---|---|---|---|---|
| | 2021 | 2020 | 2021 | 2020 |
| **Statement of Comprehensive Loss Data** | | | | |
| Revenue: | | | | |
| Product sales | $ 2 | $ 657 | $ 1,005 | $ 2,521 |
| Contract and other collaboration | - | 81 | 1,813 | 2,895 |
| Total revenue | 2 | 738 | 2,818 | 5,416 |
| Operating costs and expenses: | | | | |
| Cost of goods sold (1) | 1,234 | 1,300 | 3,753 | 6,032 |
| Research and development (1) | 986 | 836 | 4,095 | 4,017 |
| Selling, general and administrative (1) | 5,957 | 7,846 | 30,935 | 36,330 |
| Total operating costs and expenses | 8,177 | 9,982 | 38,783 | 46,379 |
| Loss from operations | (8,175) | (9,244) | (35,965) | (40,963) |
| Other income (expense): | | | | |
| Interest expense | (467) | (754) | (2,291) | (3,305) |
| Interest income and other income (expense), net | 32 | 272 | 124 | 583 |
| Non-cash interest income on liability related to sale of future royalties | 693 | 808 | 3,038 | 3,310 |
| Total other income (expense) | 258 | 326 | 871 | 588 |
| Provision for income taxes | - | - | (5) | (4) |
| Net loss | $ (7,917) | $ (8,918) | $ (35,099) | $ (40,379) |
| Basic and diluted net loss per common share | $ (0.06) | $ (0.10) | $ (0.29) | $ (0.47) |
| Shares used in computing basic and diluted net loss per common share | 127,688 | 92,290 | 119,860 | 85,257 |
| (1) Includes the following non-cash depreciation and stock-based compensation expense: | | | | |
| Cost of goods sold | $ 73 | $ 104 | $ 294 | $ 514 |
| Research and development | 302 | 192 | 1,072 | 764 |
| Selling, general and administrative | 1,018 | 1,029 | 4,305 | 4,221 |
| Total | $ 1,393 | $ 1,325 | $ 5,671 | $ 5,499 |

| | December 31, 2021 | December 31, 2020 |
|---|---|---|
| **Selected Balance Sheet Data** | | |
| Cash, cash equivalents and investments | $ 51,630 | $ 42,886 |
| Total assets | 77,893 | 66,295 |
| Total liabilities | 113,786 | 122,045 |
| Total stockholders' deficit | (35,893) | (55,750) |

***Reconciliation of Non-GAAP Financial Measures***
***(Operating Expenses less associated stock-based compensation expense)***

| | Three Months Ended December 31 | | Twelve Months Ended December 31 | |
|---|---|---|---|---|
| | **2021** | **2020** | **2021** | **2020** |
| Operating expenses (GAAP): | | | | |
| Research and development | $ 986 | $ 836 | $ 4,095 | $ 4,017 |
| Selling, general and administrative | 5,957 | 7,846 | 30,935 | 36,330 |
| Total operating expenses | 6,943 | 8,682 | 35,030 | 40,347 |
| *Less depreciation and stock-based compensation expense* | 1,320 | 1,221 | 5,377 | 4,985 |
| *Operating expenses (non-GAAP)* | $ 5,623 | $ 7,461 | $ 29,653 | $ 35,362 |