
**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): December 7, 2021

PACIRA BIOSCIENCES, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of
incorporation)

001-35060

(Commission File Number)

51-0619477

(IRS Employer Identification No.)

**5401 West Kennedy Boulevard, Suite 890
Tampa, Florida 33609**

(Address and Zip Code of Principal Executive Offices)

(813) 553-6680

(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:

- 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:

<u>Title of each class</u>	<u>Trading symbol</u>	<u>Name of each exchange on which registered</u>
Common Stock, par value \$0.001 per share	PCRX	Nasdaq Global Select 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 December 7, 2021, Pacira BioSciences, Inc. issued a press release announcing its preliminary unaudited revenue for the month ended November 30, 2021. The full text of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Item 2.02 and Exhibit 99.1 attached hereto shall not be deemed “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, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

Exhibit Number	Description
99.1	Press Release dated December 7, 2021.
104	Cover Page Interactive Data File (Formatted as Inline XBRL)



FOR IMMEDIATE RELEASE

NEWS RELEASE

Pacira BioSciences Reports Preliminary Net Product Sales for EXPAREL® and iovera° of \$48.0 Million for November 2021

-- EXPAREL average daily sales for November 2021 - 122% of November 2020 --

TAMPA, FL, DECEMBER 7, 2021 - Pacira BioSciences, Inc. (Nasdaq: PCRX), the industry leader in its commitment to non-opioid pain management and regenerative health solutions, today reported preliminary unaudited net product sales for EXPAREL® (bupivacaine liposome injectable suspension) and iovera° for the month of November 2021. EXPAREL net product sales were \$46.5 million, compared with \$38.1 million for November 2020. EXPAREL average daily sales for the month of November 2021 were 122 percent of November 2020. The company reports average daily growth rates for EXPAREL to account for differences in the number of selling days per reporting period. The number of EXPAREL selling days were 20 in both November 2021 and November 2020. Net product sales of iovera° were \$1.5 million for the month of November 2021, compared with \$0.8 million for November 2020.

“We are encouraged by EXPAREL’s robust growth in November with product utilization continuing to significantly outpace the recovery of the elective surgery market,” said Dave Stack, chairman and chief executive officer of Pacira BioSciences. “Our team is driving strong results while at the same time advancing integration activities from the Flexion acquisition. We look forward to the significant opportunity and synergies we believe ZILRETTA will add to our commercial offering in 2022 and beyond. As we close out 2021, we look forward to delivering strong top- and bottom-line growth as we build upon our mounting momentum and leadership in non-opioid pain management to improve patient care along the neural pain pathway.”

On November 19, 2021, Pacira completed its acquisition of Flexion Therapeutics, which added ZILRETTA® (triamcinolone acetonide extended-release injectable suspension) to its commercial offering. Pacira is currently not reporting preliminary monthly ZILRETTA net product sales as the required adjustments for certain product rebate programs are calculated after the end of the quarter and, as a result, ZILRETTA net product sales for the months of November 2021 and 2020 are not included in the amounts above. In addition to pandemic-related challenges, Flexion previously reported that its sales were negatively impacted in the third quarter of 2021 by rebate program modifications and several unanticipated manufacturing batch failures that led to short-dated ZILRETTA inventory resulting in smaller order sizes and product returns. Pacira expects to exit 2021 with ZILRETTA quarterly sales tracking more in line with ZILRETTA second quarter of 2021 sales with sales trends improving thereafter as Pacira extends inventory dating, simplifies the rebate program, and completes integration activities in 2022.

The company's net product sales were negatively impacted by the COVID-19 pandemic in 2020 due to the significant postponement or suspension in the scheduling of elective surgical procedures resulting from public health guidance and government directives. Elective surgery restrictions began to lift on a state-by-state basis in April 2020, allowing EXPAREL sales to return to year-over-year growth in June 2020. However, while many restrictions have since eased and COVID-19 vaccines have become more widely available and administered to the general public, it is still unclear how long it will take the elective surgery market to normalize, or if restrictions on elective procedures will recur due to COVID-19 variant strains or otherwise.

The company has not provided 2021 financial guidance given the continued uncertainty around COVID-19 and the pace of recovery for the elective surgery market. To provide greater transparency, Pacira is reporting monthly intra-quarter unaudited net product sales for EXPAREL and iovera^o and will continue to do so until it has gained enough visibility around the impacts of COVID-19. The company is also providing weekly EXPAREL utilization and elective surgery data within its investor presentation, which is accessible at investor.pacira.com.

The financial information included in this press release is preliminary, unaudited, and subject to adjustment. It does not present all information necessary for an understanding of the company's financial results for the fourth quarter or full year 2021.

About Pacira BioSciences

Pacira BioSciences, Inc. (Nasdaq: PCRX) is committed to providing a non-opioid option to as many patients as possible to redefine the role of opioids as rescue therapy only. The company is also developing innovative interventions to address debilitating conditions involving the sympathetic nervous system, such as cardiac electrical storm, chronic pain, and spasticity. Pacira has three commercial-stage non-opioid treatments: EXPAREL[®] (bupivacaine liposome injectable suspension), a long-acting, local analgesia currently approved for postsurgical pain management; ZILRETTA[®] (triamcinolone acetonide extended-release injectable suspension), an extended-release, intra-articular, injection indicated for the management of osteoarthritis knee pain; and iovera^o, a novel, handheld device for delivering immediate, long-acting, drug-free pain control using precise, controlled doses of cold temperature to a targeted nerve. To learn more about Pacira, including the corporate mission to reduce overreliance on opioids, visit www.pacira.com.

About EXPAREL[®]

EXPAREL (bupivacaine liposome injectable suspension) is indicated in patients 6 years of age and older for single-dose infiltration to produce postsurgical local analgesia, and in adults as an interscalene brachial plexus nerve block to produce postsurgical regional analgesia. Safety and efficacy have not been established in other nerve blocks. Since its launch, EXPAREL has been used in over nine million patients. EXPAREL utilizes the company's proprietary multivesicular liposomal drug delivery technology composed of a honeycomb of numerous, non-concentric, internal aqueous chambers containing bupivacaine. After injection, bupivacaine is released over time, as the lipid membranes are absorbed, prolonging the duration of action. EXPAREL is the first and only multivesicular liposome local anesthetic that can be utilized in the peri- or postsurgical setting. A single dose of EXPAREL provides significant reductions in cumulative pain scores with up to a 78 percent decrease in opioid

consumption; the clinical benefit of the opioid reduction was not demonstrated. Additional information is available at www.EXPAREL.com.

Important Safety Information about EXPAREL for Patients

EXPAREL should not be used in obstetrical paracervical block anesthesia. In studies in adults where EXPAREL was injected into a wound, the most common side effects were nausea, constipation, and vomiting. In studies in adults where EXPAREL was injected near a nerve, the most common side effects were nausea, fever, and constipation. In the study where EXPAREL was given to children, the most common side effects were nausea, vomiting, constipation, low blood pressure, low number of red blood cells, muscle twitching, blurred vision, itching, and rapid heartbeat. EXPAREL can cause a temporary loss of feeling and/or loss of muscle movement. How much and how long the loss of feeling and/or muscle movement depends on where and how much of EXPAREL was injected and may last for up to 5 days. EXPAREL is not recommended to be used in patients younger than 6 years old for injection into the wound, for patients younger than 18 years old for injection near a nerve, and/or in pregnant women. Tell your health care provider if you or your child has liver disease, since this may affect how the active ingredient (bupivacaine) in EXPAREL is eliminated from the body. EXPAREL should not be injected into the spine, joints, or veins. The active ingredient in EXPAREL can affect the nervous system and the cardiovascular system; may cause an allergic reaction; may cause damage if injected into the joints; and can cause a rare blood disorder.

About ZILRETTA®

On October 6, 2017, ZILRETTA (triamcinolone acetonide extended-release injectable suspension) was approved by the U.S. Food and Drug Administration as the first and only extended-release intra-articular therapy for patients confronting osteoarthritis (OA)- related knee pain. ZILRETTA employs proprietary microsphere technology combining triamcinolone acetonide—a commonly administered, short-acting corticosteroid—with a poly lactic-co-glycolic acid (PLGA) matrix to provide extended pain relief. The pivotal Phase 3 trial on which the approval of ZILRETTA was based showed that ZILRETTA significantly reduced OA knee pain for 12 weeks, with some people experiencing pain relief through Week 16. Learn more at www.zilretta.com.

Indication and Select Important Safety Information for ZILRETTA

Indication: ZILRETTA is indicated as an intra-articular injection for the management of OA pain of the knee. **Limitation of Use:** The efficacy and safety of repeat administration of ZILRETTA have not been demonstrated.

Contraindication: ZILRETTA is contraindicated in patients who are hypersensitive to triamcinolone acetonide, corticosteroids or any components of the product.

Warnings and Precautions:

- **Intra-articular Use Only:** ZILRETTA has not been evaluated and should not be administered by epidural, intrathecal, intravenous, intraocular, intramuscular, intradermal, or subcutaneous routes. ZILRETTA should not be considered safe for epidural or intrathecal administration.

- **Serious Neurologic Adverse Reactions with Epidural and Intrathecal Administration:** Serious neurologic events have been reported following epidural or intrathecal corticosteroid administration. Corticosteroids are not approved for this use.
- **Hypersensitivity reactions:** Serious reactions have been reported with triamcinolone acetonide injection. Institute appropriate care if an anaphylactic reaction occurs.
- **Joint infection and damage:** A marked increase in joint pain, joint swelling, restricted motion, fever and malaise may suggest septic arthritis. If this occurs, conduct appropriate evaluation and if confirmed, institute appropriate antimicrobial treatment.

Adverse Reactions: The most commonly reported adverse reactions (incidence $\geq 1\%$) in clinical studies included sinusitis, cough, and contusions.

Please see ZILRETTALabel.com for full Prescribing Information.

About iovera[®]

The iovera[®] system is used to destroy tissue during surgical procedures by applying freezing cold. It can also be used to produce lesions in peripheral nervous tissue by the application of cold to the selected site for the blocking of pain. It is also indicated for the relief of pain and symptoms associated with osteoarthritis of the knee for up to 90 days. In one study, the majority of the patients suffering from osteoarthritis of the knee experienced pain and system relief beyond 150 days. The iovera[®] system's "1x90" Smart Tip configuration (indicating one needle which is 90 mm long) can also facilitate target nerve location by conducting electrical nerve stimulation from a separate nerve stimulator. The iovera[®] system is not indicated for treatment of central nervous system tissue. Additional information is available at www.iovera.com.

Important Safety Information for iovera[®]

The iovera[®] system is contraindicated for use in patients with the following: Cryoglobulinemia; Paroxysmal cold hemoglobinuria; cold urticaria; Raynaud's disease; open and/or infected wounds at or near the treatment line. Potential complications: As with any surgical treatment that uses needle-based therapy, there is potential for temporary site-specific reactions, including but not limited to: bruising (ecchymosis); swelling (edema); inflammation and/or redness (erythema); pain and/or tenderness; altered sensation (localized dysesthesia). Typically, these reactions resolve with no physician intervention. Patients may help the healing process by applying ice packs to the affected sites, and by taking over-the-counter analgesics.

Forward-Looking Statements

Any statements in this press release about Pacira's future expectations, plans, trends, outlook, projections and prospects, and other statements containing the words "believes," "anticipates," "plans," "estimates," "expects," "intends," "may," "will," "would," "could," "can" and similar expressions, constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements include, without limitation, statements related to the acquisition of Flexion and the benefits thereof, Pacira's ability to extend inventory dating, simplify Flexion's rebate program, and complete integration activities in 2022, Pacira's strategy, plans,

objectives, expectations (financial or otherwise) and intentions, future financial results and growth potential, anticipated product portfolio, development programs, patent terms and other statements that are not historical facts. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including risks relating to, among others: risks associated with acquisitions, such as the risk that the businesses will not be integrated successfully, that such integration may be more difficult, time-consuming or costly than expected or that the expected benefits of the transaction will not occur; risks related to future opportunities and plans for Flexion and its products, including uncertainty of the expected financial performance of Flexion and its products; the possibility that if Pacira does not achieve the perceived benefits of the Flexion acquisition as rapidly or to the extent anticipated by financial analysts or investors, the market price of Pacira's shares could decline; the impact of the worldwide COVID-19 (Coronavirus) pandemic and related global economic conditions on Pacira's business and results of operations; the success of Pacira's sales and manufacturing efforts in support of the commercialization of EXPAREL, iovera^o and ZILRETTA; the rate and degree of market acceptance of EXPAREL, iovera^o and ZILRETTA; the size and growth of the potential markets for EXPAREL, iovera^o and ZILRETTA and Pacira's ability to serve those markets; Pacira's plans to expand the use of EXPAREL, iovera^o and ZILRETTA to additional indications and opportunities, and the timing and success of any related clinical trials for EXPAREL, iovera^o and ZILRETTA; the ability to successfully integrate any future acquisitions into Pacira's existing business, including Flexion; and the recoverability of Pacira's deferred tax assets and factors discussed in the "Risk Factors" of Pacira's most recent Annual Report on Form 10-K and in other filings that Pacira periodically makes with the Securities and Exchange Commission. In addition, the forward-looking statements included in this press release represent Pacira's views as of the date of this press release. Important factors could cause actual results to differ materially from those indicated or implied by forward-looking statements, and as such Pacira anticipates that subsequent events and developments will cause its views to change. However, while Pacira may elect to update these forward-looking statements at some point in the future, Pacira specifically disclaims any obligation to do so, except as required by law. These forward-looking statements should not be relied upon as representing Pacira's views as of any date subsequent to the date of this press release.

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