



## Pacira BioSciences to Acquire Flexion Therapeutics Further Expanding Leadership Position in Non-Opioid Pain Management

October 11, 2021

*-- Adds highly complementary ZILRETTA® to Pacira commercial offering --*

*-- Combined portfolio offers end-to-end non-opioid solutions along the pain pathway --*

*-- Further enhances topline revenue growth; provides attractive potential synergies and expected to be accretive to full-year 2022 earnings and significantly accretive thereafter --*

*-- Pacira to host conference call today at 8:30 AM ET --*

TAMPA, Fla. and BURLINGTON, Mass., Oct. 11, 2021 (GLOBE NEWSWIRE) -- [Pacira BioSciences, Inc.](https://www.pacira.com) (Nasdaq: PCRX), the industry leader in its commitment to non-opioid pain management and regenerative health solutions, and Flexion Therapeutics, Inc. (Nasdaq: FLXN) today announced a definitive agreement pursuant to which Pacira will acquire Flexion for \$8.50 per share in cash, plus one non-tradeable contingent value right (CVR) worth up to \$8.00 per share in cash. The CVR is payable (subject to certain terms and conditions) in the event certain sales and/or regulatory milestones are achieved, as set forth in more detail below. The transaction was unanimously approved by the board of directors of each of Pacira and Flexion.

Flexion is a commercial-stage biopharmaceutical company focused on the development and commercialization of novel, local non-opioid therapies for the treatment of patients with musculoskeletal conditions, including osteoarthritis (OA), postsurgical pain and low back pain. Approved in 2017, Flexion's lead product, ZILRETTA<sup>®</sup> (triamcinolone acetonide extended-release injectable suspension) is the first and only FDA-approved treatment for OA knee pain utilizing extended-release microsphere technology.

"This acquisition is a major milestone in our strategy to build a robust offering of novel, non-opioid treatments to improve patient care along the neural pain pathway while simultaneously providing us with a complementary commercial asset in ZILRETTA for the treatment of OA knee pain," said Dave Stack, chairman and chief executive officer of Pacira. "We believe the Flexion portfolio further solidifies Pacira as a leader in opioid-sparing pain management as we continue to redefine the role of opioids as a last resort rescue medication. Importantly, this acquisition creates diversification and growth to our topline while providing what we would expect to be meaningful synergies that should result in substantial near- and long-term accretion to our cash flows and earnings."

"Pacira shares our commitment to advancing non-opioid pain control and we believe it is ideally positioned to drive continued clinical and commercial success of ZILRETTA, FX201, and FX301," said Michael Clayman, M.D., chief executive officer and co-founder of Flexion. "This combination with Pacira offers Flexion stakeholders excellent prospects for value creation, particularly as the contingent value rights provide the opportunity to continue to benefit from the ongoing success of Flexion's products and programs."

"I'd like to thank all of our employees – past and present -- for their extraordinary commitment and superb contributions that have translated into ZILRETTA, a medicine that matters, getting to increasing numbers of patients in need and to a pipeline of potentially transformative medicines," continued Dr. Clayman.

### Pacira Transaction Rationale

- Innovative non-opioid portfolio directly aligns with the Pacira mission to provide an opioid alternative to as many patients as possible and address medical needs along the neural pain pathway.
- Flexion's ZILRETTA is a non-opioid injection that will allow Pacira to offer a treatment to manage OA pain of the knee at an earlier stage of the patient's journey along the neural pain pathway
- Complementary sales call points and clinical-stage pipeline offer significant cost synergies across research and development and commercial activities.
- Adds multiple clinical milestones, including the initiation of a Phase 3 registration trial of ZILRETTA in shoulder osteoarthritis and the advancement of Phase 1 studies of FX201 for musculoskeletal pain, including OA, and FX301 as a lower extremity nerve block for postsurgical pain.
- Immediately revenue generating and expected to be accretive to full-year 2022 earnings and significantly accretive thereafter.

### Transaction Details

Under the terms of the definitive agreement, Pacira will commence a tender offer to acquire all outstanding shares of Flexion for a purchase price of \$8.50 per share in cash, plus one non-tradeable CVR. The CVR will entitle Flexion stockholders to up to an additional \$8.00 per share in cash payable (subject to certain terms and conditions) upon achievement of the following milestones:

- \$1.00 per share if total calendar year ZILRETTA net sales achieve \$250 million;
- \$2.00 per share if total calendar year ZILRETTA net sales achieve \$375 million;
- \$3.00 per share if total calendar year ZILRETTA net sales achieve \$500 million;

- \$1.00 per share upon U.S. FDA approval of FX201; and
- \$1.00 per share upon U.S. FDA approval of FX301.

The milestones associated with each contingent cash payment must be achieved, if at all, on or before December 31, 2030. There can be no assurance any payments will be made with respect to the CVR. The transaction is not subject to any financing condition and Pacira will fund the transaction from its existing cash resources.

Flexion's board of directors unanimously recommends that Flexion's stockholders tender their shares in the tender offer. Additionally, Flexion's directors and executive officers, or their affiliates, have (subject to certain terms and conditions) agreed to tender their shares in the tender offer.

### Timing to Close

The transaction is anticipated to close during the fourth quarter of 2021, subject to customary closing conditions, including receipt of required regulatory approvals and the tender of a majority of the outstanding shares of Flexion's common stock. Following the successful closing of the tender offer, Pacira will acquire any shares of Flexion that are not tendered in the tender offer through a second-step merger at the same consideration as paid in the tender offer.

### Third Quarter Performance and Guidance Update

Today Pacira and Flexion are providing the following preliminary unaudited results and updates for the third quarter of 2021. 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 either company's financial results for the third quarter or full year 2021.

- EXPAREL net product sales of \$121.9 million for the third quarter and \$39.7 million for the month of September 2021, compared with \$113.7 million and \$39.5 million in the prior year, respectively. The number of EXPAREL selling days for the month of September was 21 in both 2021 and 2020. The elective surgery market faced additional pandemic-related challenges in August and September due to regional surges in COVID-19 delta variant cases, staffing shortages, and surgical fatigue from care teams addressing significant procedure backlogs. These variables began to subside in the latter part of September and Pacira expects the fourth quarter to reflect improving market dynamics.
- iovera<sup>®</sup> net product sales of \$4.2 million for the third quarter and \$2.3 million for the month of September 2021, compared with \$2.7 million and \$1.1 million in the prior year, respectively.
- Flexion expects that ZILRETTA net sales were in the range of \$21 million to \$23 million for the third quarter of 2021. Third quarter 2021 sales were negatively impacted, particularly in the second half of the quarter, by the following primary factors: (a) temporary disruptions from rebate program modifications, (b) pandemic-related challenges, and (c) several unanticipated manufacturing batch failures that led to short-dated ZILRETTA inventory resulting in smaller order sizes by physician practices and product returns from specialty distributors.
- Consistent with Pacira practices, Flexion is withdrawing its ZILRETTA sales guidance for 2021.

### Advisors

J.P. Morgan Securities LLC acted as financial advisor to Pacira and Perkins Coie LLP is serving as its legal advisor. Lazard acted as lead financial advisor and Goldman Sachs also acted as financial advisor to Flexion. Cooley LLP is serving as Flexion's legal advisor.

### Conference Call and Webcast

The Pacira management team will host a conference call today at 8:30 AM ET to discuss the proposed transaction. To participate in the conference call, dial 1-877-845-0779 and provide the passcode 9675803. International callers may dial 1-720-545-0035 and use the same passcode. In addition, a live audio of the conference call will be available as a webcast. Interested parties can access the event through the "Events" page on the Pacira website at [investor.pacira.com](http://investor.pacira.com).

For those unable to participate in the live call, a replay will be available at 1-855-859-2056 (domestic) or 1-404-537-3406 (international) using the passcode 9675803. The replay of the call will be available for two weeks from the date of the live call. The webcast will be available on the Pacira website for approximately two weeks following the call.

### About Pacira BioSciences

Pacira BioSciences, Inc. (Nasdaq: PCRX) is the industry leader in its commitment to non-opioid pain management and regenerative health solutions to improve patients' journeys along the neural pain pathway. The company's long-acting local analgesic, EXPAREL<sup>®</sup> (bupivacaine liposome injectable suspension) was commercially launched in the United States in April 2012. EXPAREL utilizes DepoFoam<sup>®</sup>, a unique and proprietary product delivery technology that encapsulates drugs without altering their molecular structure and releases them over a desired period of time. In April 2019, Pacira acquired the iovera<sup>®</sup> system, a handheld cryoanalgesia device used to deliver precise, controlled doses of cold temperature only to targeted nerves. To learn more about Pacira, including the corporate mission to reduce overreliance on opioids, visit [www.pacira.com](http://www.pacira.com).

### About Flexion Therapeutics

Flexion Therapeutics (Nasdaq: FLXN) is a biopharmaceutical company focused on the development and commercialization of novel, local therapies for the treatment of patients with musculoskeletal conditions, beginning with osteoarthritis (OA), the most common form of arthritis. The company's approved product, ZILRETTA<sup>®</sup>, is the first and only extended-release, intra-articular, or IA (meaning in the joint), injection indicated for the management of OA knee pain. ZILRETTA is a non-opioid therapy that employs a proprietary microsphere technology to provide effective pain relief. To learn more about Flexion, please visit [flexiontherapeutics.com](http://flexiontherapeutics.com).

### About EXPAREL<sup>®</sup>

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. The product combines bupivacaine with DepoFoam<sup>®</sup>, a proven product delivery technology that delivers medication over a desired time period. EXPAREL represents the first and only multivesicular liposome local anesthetic that can be utilized in the peri- or postsurgical setting. By utilizing the DepoFoam platform, a single dose of EXPAREL delivers bupivacaine over time, providing 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](http://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 iovera<sup>®</sup>**

The iovera<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> system is not indicated for treatment of central nervous system tissue.

### **Important Safety Information for iovera<sup>®</sup>**

The iovera<sup>®</sup> 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.

### **About ZILRETTA (triamcinolone acetonide extended-release injectable suspension)**

On October 6, 2017, ZILRETTA was approved by the U.S. FDA as the first and only extended-release intra-articular therapy for patients confronting 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](http://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](http://ZILRETTALabel.com) for full Prescribing Information.

**About FX201 (*humantakinogene hadenovec*)**

FX201 is a novel, intra-articular gene therapy product candidate that utilizes a helper-dependent adenovirus (HDAd) vector based on human serotype 5 (Ad5) that is designed to transfer a gene to cells in the joint to produce an anti-inflammatory protein, interleukin-1 receptor antagonist (IL-1Ra), under the control of an inflammation-sensitive promoter. Inflammation is a known cause of pain, and chronic inflammation is thought to play a major role in the progression of OA. By persistently suppressing inflammation, Flexion believes FX201 holds the potential to provide long-term pain relief and functional improvement, and to modify disease progression. A Phase 1b study in patients with moderate to severe OA knee pain is currently being conducted. Flexion expects initial results by year end.

#### **About FX301 (funapide formulated in a proprietary thermosensitive hydrogel)**

FX301 is a locally administered Nav1.7 inhibitor product candidate, known as funapide, formulated for extended release in a thermosensitive hydrogel. The initial development of FX301 is intended to support administration as a peripheral nerve block for control of post-operative pain. Flexion believes FX301 has the potential to provide effective and durable pain relief while preserving motor function. A Phase 1b study in patients undergoing bunionectomy surgery is currently being conducted. Flexion expects results by year end.

#### **About Osteoarthritis of the Knee**

OA, also known as degenerative joint disease, affects more than 30 million Americans and accounts for more than \$185 billion in annual expenditures. In 2017, approximately 15 million Americans were diagnosed with OA of the knee and the average age of physician-diagnosed knee OA has fallen by 16 years, from 72 in the 1990s to 56 in the 2010s. The prevalence of OA is expected to continue to increase as a result of aging, obesity and sports injuries. Each year, approximately five million OA patients receive either a corticosteroid (immediate-release or extended-release) or hyaluronic acid intra-articular injection to manage their knee pain.

#### **Forward-Looking Statements**

*Any statements in this press release about Pacira's or Flexion'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 anticipated consummation of the acquisition of Flexion and the timing and benefits thereof, 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 related to Pacira's ability to complete the transaction on the proposed terms and schedule or at all; whether the tender offer conditions will be satisfied; whether sufficient stockholders of Flexion tender their shares in the transaction; the outcome of legal proceedings that may be instituted against Flexion and/or others relating to the transaction; the failure (or delay) to receive the required regulatory approvals relating to the transaction; the possibility that competing offers will be made; 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, including whether the milestones will ever be achieved; disruption from the proposed transaction, making it more difficult to conduct business as usual or maintain relationships with customers, employees or suppliers; the occurrence of any event, change or other circumstance that could give rise to the termination of the acquisition agreement; the possibility that if Pacira does not achieve the perceived benefits of the proposed transaction 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 and/or Flexion's business and results of operations; the success of Pacira's sales and manufacturing efforts in support of the commercialization of EXPAREL and iovera<sup>®</sup>; the rate and degree of market acceptance of EXPAREL and iovera<sup>®</sup>; the size and growth of the potential markets for EXPAREL and iovera<sup>®</sup> and Pacira's ability to serve those markets; Pacira's plans to expand the use of EXPAREL and iovera<sup>®</sup> to additional indications and opportunities, and the timing and success of any related clinical trials for EXPAREL and iovera<sup>®</sup>; 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 each of Pacira's and Flexion's most recent Annual Report on Form 10-K and in other filings that Pacira and Flexion periodically make with the Securities and Exchange Commission (SEC). In addition, the forward-looking statements included in this press release represent Pacira's and/or Flexion's views, as applicable, 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 each of Pacira and Flexion anticipates that subsequent events and developments will cause its respective views to change. However, while Pacira or Flexion may elect to update these forward-looking statements at some point in the future, each of Pacira or Flexion specifically disclaims any obligation to do so, except as required by law. These forward-looking statements should not be relied upon as representing either Pacira's or Flexion's views as of any date subsequent to the date of this press release.*

#### **Additional Information about the Transaction and Where to Find It**

The tender offer (the "Offer") described in this press release has not yet commenced, and this release is neither a recommendation, nor an offer to purchase nor a solicitation of an offer to sell any shares of the common stock of Flexion or any other securities. On the commencement date of the Offer, a tender offer statement on Schedule TO, including an offer to purchase, a letter of transmittal and related documents, will be filed with the SEC by Pacira and its acquisition subsidiary, and a Solicitation/Recommendation Statement on Schedule 14D-9 will be filed with the SEC by Flexion. The Offer to purchase the outstanding shares of Flexion will only be made pursuant to the offer to purchase, the letter of transmittal and related documents filed as a part of the Schedule TO. **INVESTORS AND SECURITY HOLDERS ARE URGED TO READ THE TENDER OFFER MATERIALS (INCLUDING AN OFFER TO PURCHASE, A LETTER OF TRANSMITTAL AND RELATED DOCUMENTS) AND THE SOLICITATION/RECOMMENDATION STATEMENT ON SCHEDULE 14D-9 REGARDING THE OFFER, AS THEY MAY BE AMENDED OR SUPPLEMENTED FROM TIME TO TIME, WHEN THEY BECOME AVAILABLE BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION THAT INVESTORS AND SECURITY HOLDERS SHOULD CONSIDER BEFORE MAKING ANY DECISION REGARDING TENDERING THEIR SHARES, INCLUDING THE TERMS AND CONDITIONS OF THE OFFER.** Investors and security holders may obtain a free copy of these statements (when available) and other documents filed with the SEC at the website maintained by the SEC at [www.sec.gov](http://www.sec.gov) or by directing such requests to the information agent for the Offer, which will be named in the tender offer statement. Investors and security holders may also obtain, at no charge, the documents filed or furnished to the SEC by Flexion under the "Investors" section of Flexion's website at [ir.flexiontherapeutics.com](http://ir.flexiontherapeutics.com). Investors and security holders may also obtain, at no charge, the documents filed or furnished to the SEC by Pacira under the "Investors" section of Pacira's website at [investor.pacira.com](http://investor.pacira.com).

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