



Pacira BioSciences Notified of Abbreviated New Drug Application Filing from The WhiteOak Group for EXPAREL®

October 21, 2025

BRISBANE, Calif., Oct. 21, 2025 (GLOBE NEWSWIRE) -- Pacira BioSciences, Inc. (Nasdaq: PCRX), the industry leader in its commitment to deliver innovative, non-opioid pain therapies to transform the lives of patients today reported it has received a Paragraph IV Certification Notice Letter (PIV Notice) from The WhiteOak Group, a subsidiary of a small private Chinese company. WhiteOak has filed an Abbreviated New Drug Application, or ANDA, with the FDA for a product claiming to be a generic of EXPAREL. Neither WhiteOak nor its parent company have any commercialized products. The parent company is Zhejiang Haichang Biotechnology Co Ltd.

In the PIV Notice, WhiteOak alleges that the claims of 19 EXPAREL patents listed in the FDA's Orange Book (U.S. Patent Nos. 11,033,495, 11,179,336, 11,278,494, 11,304,904, 11,311,486, 11,357,727, 11,426,348, 11,452,691, 11,819,574, 11,819,575, 11,925,706, 12,144,890, 12,151,024, 12,156,940, 12,226,610, 12,251,468, 12,296,047, 12,318,483, 12,370,142) are invalid, unenforceable and/or will not be infringed by WhiteOak's manufacture, use or sale of the product described in its ANDA submission.

The company's contested Orange Book listed patents are primarily from two distinct patent families with the first family expiring on January 22, 2041, and the second family expiring on July 2, 2044.

Pacira intends to vigorously assert and enforce its intellectual property rights and has 45 days from receipt of the PIV Notice to file a lawsuit if it deems the ANDA filer is infringing its intellectual property. The lawsuit will trigger an automatic 30-month stay of FDA approval of White Oak's ANDA submission pursuant to the Hatch Waxman statute.

About Pacira

Pacira delivers innovative, non-opioid pain therapies to transform the lives of patients. Pacira has three commercial-stage non-opioid treatments: EXPAREL® (bupivacaine liposome injectable suspension), a long-acting local analgesic currently approved for infiltration, fascial plane block, and as an interscalene brachial plexus nerve block, an adductor canal nerve block, and a sciatic nerve block in the popliteal fossa 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. The company is also advancing the development of PCRX-201 (enekinragene inzadenovec), a novel locally administered gene therapy with the potential to treat large prevalent diseases like osteoarthritis. To learn more about Pacira, visit www.pacira.com.

About EXPAREL® (bupivacaine liposome injectable suspension)

EXPAREL is indicated to produce postsurgical local analgesia via infiltration in patients aged 6 years and older, and postsurgical regional analgesia via an interscalene brachial plexus block in adults, a sciatic nerve block in the popliteal fossa in adults, and an adductor canal block in adults. The safety and effectiveness of EXPAREL have not been established to produce postsurgical regional analgesia via other nerve blocks besides an interscalene brachial plexus nerve block, a sciatic nerve block in the popliteal fossa, or an adductor canal block. The product combines bupivacaine with multivesicular liposomes, 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 multivesicular liposome 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.

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.

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 "anticipate," "believe," "can," "could," "estimate," "expect," "intend," "may," "plan," "project," "should," "will," "would," and similar expressions, constitute forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and the Private Securities Litigation Reform Act of 1995, including, without limitation, statements related to: '5x30', our growth and business strategy, our future outlook, the strength and efficacy of our intellectual property protection and patent terms, our future growth potential and future financial and operating results and trends, our plans, objectives, expectations (financial or otherwise) and intentions, including our plans with respect to the repayment of our indebtedness, anticipated product portfolio and product development programs, strategic alliances, plans with respect to the Non-Opioids Prevent Addiction in the Nation ("NOPAIN") Act, the expected cost savings and benefits of a July 2025 reduction in force and any other statements that are not historical facts. For this purpose, any statement that is not a statement of historical fact should be considered a forward-looking statement. We cannot assure you that our estimates, assumptions and expectations will prove to have been correct. 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: the failure to realize the anticipated benefits and synergies from the acquisition of GQ Bio Therapeutics GmbH; 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; our manufacturing and supply chain, global and United States economic conditions (including tariffs, inflation and rising interest rates), and our business, including our revenues, financial condition, cash flows and results of operations; the success of our sales and manufacturing efforts in support of the commercialization of EXPAREL, ZILRETTA and iovera°; the rate and degree of market acceptance of EXPAREL, ZILRETTA and iovera°; the size and growth of the potential markets for EXPAREL, ZILRETTA and iovera° and our ability to serve those markets; our plans to expand the use of EXPAREL, ZILRETTA and iovera° to additional indications and opportunities, and the timing and success of any related clinical trials for EXPAREL, ZILRETTA, iovera° and any of our other product candidates, including PCRX-201; the commercial success of EXPAREL, ZILRETTA and iovera°; the related timing and success of United States Food and Drug Administration supplemental New Drug Applications and premarket notification 510(k)s; the related timing and success of European Medicines Agency Marketing Authorization Applications; our plans to evaluate, develop and pursue additional product candidates utilizing our proprietary multivesicular liposome ("pMVL") drug delivery technology; the approval of the commercialization of our products in other jurisdictions; clinical trials in support of an existing or potential pMVL-based product; our commercialization and marketing capabilities; our ability to successfully complete capital projects; the outcome of any litigation; the recoverability of our deferred tax assets; assumptions associated with contingent consideration payments; assumptions used for estimated future cash flows associated with determining the fair value of the Company and the anticipated funding or benefits of our share repurchase program. and factors discussed in the "Risk Factors" of our most recent Annual Report on Form 10-K and in other filings that we periodically make with the Securities and Exchange Commission. In addition, the forward-looking statements included in this press release represent our 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 we anticipate that subsequent events and developments will cause our views to change. Except as required by applicable law, we undertake no intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, and readers should not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this press release.

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