

# **PACIRA (NASDAQ: PCRX) FDA RESOLUTION OVERVIEW**

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December 15, 2015



# Forward-Looking Statements

This presentation contains forward-looking statements, within the meaning of Section 21E of the Securities Exchange Act of 1934 (collectively, forward-looking statements), about our business, including statements about our plans and expectations regarding EXPAREL® (bupivacaine liposome injectable suspension), our future expectations, plans, outlook and prospects. Actual results or developments may differ materially from those projected or implied in these forward-looking statements. Factors that may cause such a difference include: the success of our sales and marketing efforts in support of the commercialization of EXPAREL; the rate and degree of market acceptance of EXPAREL; the size and growth of the potential markets for EXPAREL and our ability to serve those markets; potential indications and expanded uses for our product candidates and the timing and likelihood of future development and commercialization of these opportunities and products; future financial results and guidance; results and timing of clinical trials; the outcome of the U.S. Department of Justice inquiry; our and Patheon's ability to successfully construct dedicated EXPAREL manufacturing suites according to current projections; our timelines and plans for the DepoFoam® spray manufacturing process; and other factors discussed in the "Risk Factors" section of our most recent Annual Report on Form 10-K for the fiscal year ended December 31, 2014 and in other filings that we periodically make with the SEC. In addition, the forward-looking statements included in this presentation represent our views as of the date of this presentation. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we specifically disclaim any obligation to do so. These forward-looking statements should not be relied upon as representing our views as of any date subsequent to the date of this presentation.

# AGENDA

**Jim Scibetta**

President and Chief Financial Officer

Pacira Pharmaceuticals, Inc.

# Today's Agenda

TOPIC	PRESENTER
Overview of Resolution	<b>Dave Stack</b> Chief Executive Officer and Chairman
Overview of Legal Process	<b>Kristen Williams, JD</b> Chief Administrative Officer, General Counsel and Secretary
Resolution Highlights	<b>Dave Stack</b>
Business Ramifications of Resolution	<b>Jim Scibetta</b>
Q&A	<b>Jim Scibetta</b>
Summary Remarks	<b>Dave Stack</b>

# OVERVIEW OF RESOLUTION

**Dave Stack**

Chief Executive Officer and Chairman

Pacira Pharmaceuticals, Inc.

# Overview of Resolution: Three Key Outcomes

- Reaffirmation of the broad indication for EXPAREL granted at approval in 2011
- Increased opportunity to uphold Pacira mission
- Successful collaboration with FDA to advance a common goal of addressing the critical need for opioid alternatives

# OVERVIEW OF RELATED LEGAL PROCESS

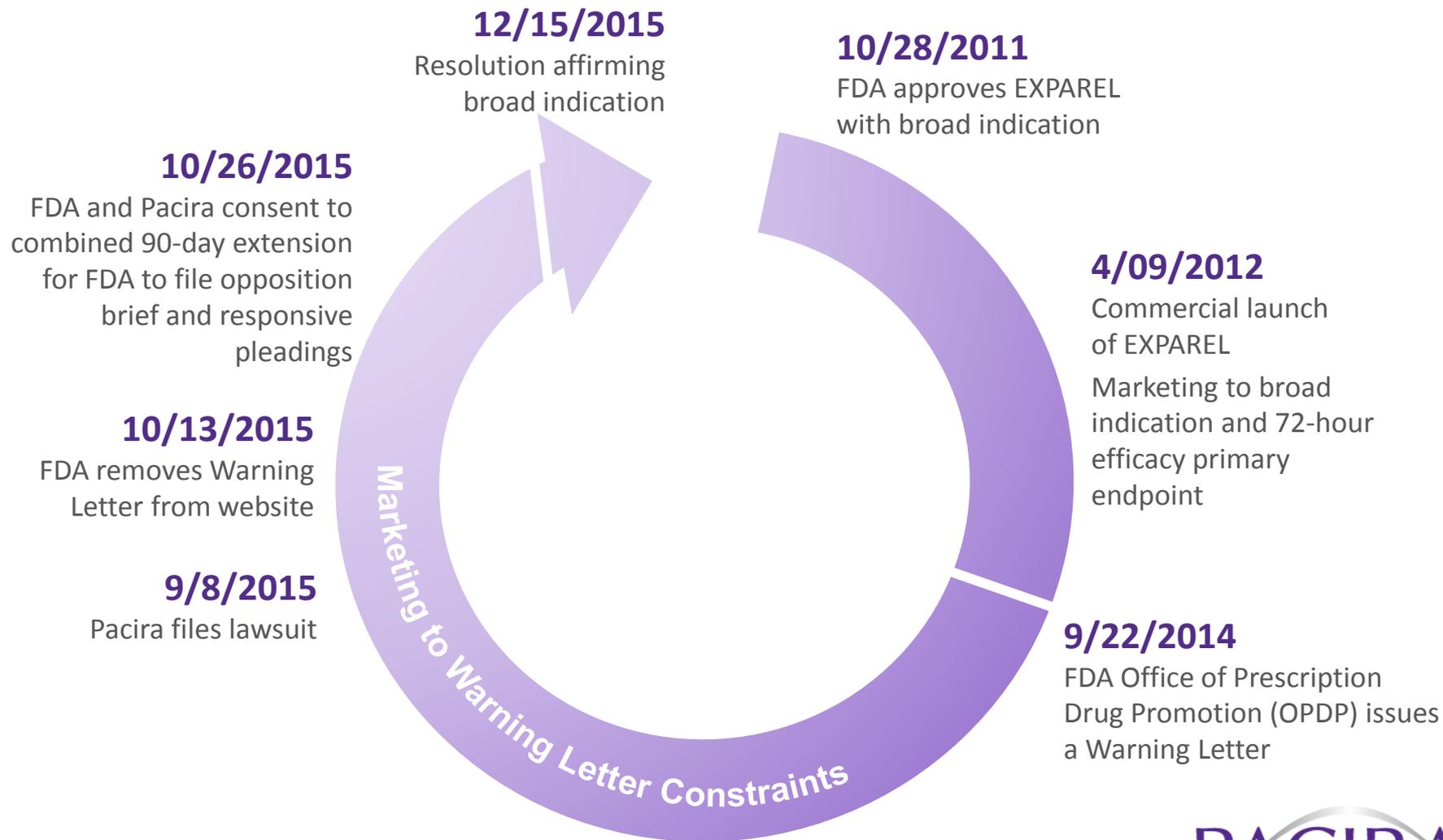
**Kristen Williams**

Chief Administrative Officer, General Counsel and Secretary

Pacira Pharmaceuticals, Inc.

# Legal Process

## Recap of Events



# Legal Process

## *Resolution Encompassed in 3 Documents*

<b>Settlement Agreement</b>	<b>Revised Package Insert (Label)</b>	<b>Rescission Letter</b>
<p>FDA approves new EXPAREL Package Insert (PI) and issues Rescission Letter nullifying Warning Letter concurrent with entering into Settlement Agreement</p> <p>Broad indication affirmed for EXPAREL, not limited to those surgeries studied in its pivotal trials</p> <p>Non-retaliation section</p> <p>Dismissal of action and claims sections</p>	<p>Highlights</p> <ul style="list-style-type: none"><li>• Broad indication</li><li>• Dosing clarity</li><li>• Admixing</li><li>• Nursing mothers/pregnancy information</li><li>• Duration of efficacy</li></ul>	<p>Letter to Dave Stack from Janet Woodcock, MD, Director of the Center for Drug Evaluation and Research (CDER) at the FDA</p> <p>Nullifies Warning Letter</p> <p>Asserts transversus abdominis plane (TAP) is an infiltration covered by the EXPAREL PI</p> <p>Affirms oral surgery as infiltration is covered by the EXPAREL PI</p>

# Legal Process

## *FDA & Pacira Collaborative Efforts*

- FDA plays a vital role in regulating the pharmaceutical industry
  - Our lawsuit was solely focused on rectifying the issues emanating from the Warning Letter
- The new Package Insert was reviewed and approved by the Division of Analgesia, Anesthesia and Addiction Products (DAAAP)
- Pacira and FDA collaborated effectively and efficiently to the benefit of patients and the medical community

# RESOLUTION HIGHLIGHTS

**Dave Stack**

Chief Executive Officer and Chairman

Pacira Pharmaceuticals, Inc.

# Broad Indication

**“The United States confirms that EXPAREL has, since October 28, 2011, been approved for ‘administration into the surgical site to produce postsurgical analgesia’ for use in a variety of surgeries not limited to those studied in its pivotal trials.”**

*- Settlement Agreement, Section III*

- Clarifications made to the EXPAREL Prescribing Information
  - Section 1: Indications and Usage
  - Section 2: Dosage and Administration
  - Section 14: Clinical Studies
- Formal rescission of Warning Letter issued in 2014

# Broad Indication

## Section 1. Indications and Usage

### 1. INDICATIONS AND USAGE

EXPAREL is a liposome injection of bupivacaine, an amide type local anesthetic, indicated for administration into the surgical site to produce postsurgical analgesia.

EXPAREL has not been studied for use in patients younger than 18 years of age.

- The **Indications and Usage** section, by law, dictates the FDA's "intended use" of a product "for which it has been determined to be safe and effective"
- No significant alterations to indication language, as original approval in 2011 was for EXPAREL use in a variety of surgical settings

FULL PRESCRIBING INFORMATION

### 1. INDICATIONS AND USAGE

EXPAREL is indicated for administration into the surgical site to produce postsurgical analgesia. EXPAREL has not been studied for use in patients younger than 18 years of age.

### 2. DOSAGE AND ADMINISTRATION

EXPAREL is intended for single-dose administration only.

The recommended dose of EXPAREL is based on the following factors:

- Size of the surgical site
- Volume required to cover the area
- Individual patient factors that may impact the safety of an amide local anesthetic
- Maximum dose of 266 mg (20 mL)

As general guidance in selecting the proper dosing for the planned surgical site, two examples of dosing are provided. One example of the recommended dose comes from a study in patients undergoing bunionectomy. A total of 8 mL (106 mg) was administered as 7 mL of EXPAREL infiltrated into the tissues surrounding the osteotomy, and 1 mL infiltrated into the subcutaneous tissue.

Another example comes from a study of patients undergoing hemorrhoidectomy. A total of 20 mL (266 mg) of EXPAREL was diluted with 10 mL of saline, for a total of 30 mL, divided into six 5 mL aliquots, injected by visualizing the anal sphincter as a clock face and slowly infiltrating one aliquot to each of the even numbers to produce a field block.

#### 2.1 Injection Instructions

EXPAREL should be injected slowly into soft tissues of the surgical site with frequent aspiration to check for blood and minimize the risk of intravascular injection.

- EXPAREL is intended for single-dose administration only.
- Different formulations of bupivacaine are not bioequivalent even if the milligram strength is the same. Therefore, it is not possible to convert dosing from any other formulations of bupivacaine to EXPAREL.
- EXPAREL should be administered with a 25 gauge or larger bore needle.
- The maximum dosage of EXPAREL should not exceed 266 mg (20 mL, 1.3% of undiluted drug).
- EXPAREL can be administered undiluted or diluted to increase volume up to a final concentration of 0.89 mg/mL (i.e. 1:14 dilution by volume) with normal (0.9%) saline or lactated Ringer's solution.

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# Broad Indication

## Section 2. Dosage and Administration

- Replaced procedure-specific dosing table with guidance around dose selection based on various patient and procedure-specific factors
- Two specific examples of dosing (bunionectomy and hemorrhoidectomy) provided as “general guidance in selecting the proper dosing for the planned surgical site”

FULL PRESCRIBING INFORMATION

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Surgery	Dose of EXPAREL	Volume of EXPAREL
Bunionectomy <sup>1</sup>	266 mg	8 mL
Hemorrhoidectomy <sup>2</sup>	266 mg	20 mL

<sup>1</sup>Infiltrate 7 mL of EXPAREL into the tissues surrounding the osteotomy and 1 mL into the subcutaneous tissue.

<sup>2</sup>Dilute 20 mL of EXPAREL with 10 mL of saline, for a total of 30 mL, and divide the mixture into six 5 mL aliquots. Perform the anal block by visualizing the anal sphincter as a clock face and slowly infiltrating one aliquot to each of the even numbers.

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# Broad Indication

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Hemorrhoidectomy <sup>2</sup>	266 mg	20 mL

1. Infiltrate 7 mL of EXPAREL into the tissues surrounding the osteotomy and 1 mL into the subcutaneous tissue.

2. Dilute 20 mL of EXPAREL with 10 mL of saline, for a total of 30 mL, and divide the mixture into six 5 mL aliquots. Perform the anal block by visualizing the anal sphincter as a clock face and slowly infiltrating one aliquot to each of the even numbers.

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# Broad Indication

## Section 14. Clinical Studies

### 14. CLINICAL STUDIES

The efficacy of EXPAREL was compared to placebo in two multicenter, randomized, double-blinded clinical trials. One trial evaluated the treatments in patients undergoing bunionectomy; the other trial evaluated the treatments in patients undergoing hemorrhoidectomy. ~~EXPAREL has not been demonstrated to be safe and effective in other procedures~~

- Removed to eliminate any ambiguity or confusion about the broad scope of the approved indication for EXPAREL

### 14. CLINICAL STUDIES

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#### 14.1 Bunionectomy

A multicenter, randomized, double-blind, placebo-controlled, parallel-group study evaluated the safety and efficacy of 106 mg EXPAREL in 193 patients undergoing bunionectomy. The mean age was 43 years (range 18 to 72). Study medication was administered directly into the wound at the conclusion of the surgery, prior to wound closure. Pain intensity was rated by the patients on a 0 to 10 numeric rating scale (NRS) out to 72 hours. Postoperatively, patients were allowed rescue medication (5 mg oxycodone/325 mg acetaminophen orally every 4 to 6 hours as needed) or, if that was insufficient within the first 24 hours, ketorolac (15 to 30 mg IV). The primary outcome measure was the area under the curve (AUC) of the NRS pain intensity scores (cumulative pain scores) collected over the first 24 hour period. There was a significant treatment effect for EXPAREL compared to placebo.

In this clinical study, EXPAREL demonstrated a significant reduction in pain intensity compared to placebo for up to 24 hours. The difference in mean pain intensity between treatment groups occurred only during the first 24 hours following study drug administration. Between 24 and 72 hours after study drug administration, there was minimal to no difference between EXPAREL and placebo treatments on mean pain intensity.

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# Broad Indication

## *Clarity Related to TAP Infiltration*

**“A TAP block is a regional anesthetic technique used for post-surgical analgesia of the anterolateral abdomen...the end result is a field block... a field block is consistent with the procedure described in your hemorrhoidectomy trial submitted in support of EXPAREL’s approval... Therefore, TAP blocks are covered by EXPAREL’s labeling.”**

*- FDA Rescission Letter; Dec. 14, 2015*

- FDA clarification validates the Company’s long-standing position that TAP infiltration is an on-label administration technique consistent with creating a field block applicable for various abdominal procedures

# Broad Indication

## *Clarity Related to Infiltration in Oral Surgery*

**“EXPAREL’s indication does not include its use as a nerve block prior to dental restorative procedures or oral surgical procedures...however, EXPAREL’s indication does encompass use for postoperative analgesia when administered as local infiltration at the site of oral surgical procedures, including tooth extractions.”**

*- FDA Rescission Letter; Dec. 14, 2015*

- FDA clarification goes on to describe that EXPAREL deposited near a terminal branch of the maxillary or mandibular branch of the trigeminal nerve (often referred to as *periapical injections*) is also an approved use, consistent with the broad indication granted at approval in 2011

# Broad Indication

## *Rescission Letter Nullifying Warning Letter*

**“Based on the plain language of the Indications and Usage section of the full Prescribing Information, as well as the clinical trials submitted in support of that approval, FDA determined that the indication approved in 2011 was not limited to bunionectomy and hemorrhoidectomy procedures. In light of this determination, on October 13, 2015, the Agency rescinded the Warning Letter issued to Pacira.”**

*- FDA Rescission Letter; Dec. 14, 2015*

- FDA clarification that Warning Letter issued September 22, 2014 is null and void

# Duration of Efficacy

- Label states that the primary outcome measure for the study looked at pain intensity scores over 72 hours and that there was a significant treatment effect for EXPAREL compared to placebo
- Elimination of language stating there was “minimal to no difference between EXPAREL and placebo on pain intensity scores between 24 and 72 hours”; replaced with Figure 1 and specific information related to opioid use
  - % of opioid-free patients at 72 hours (**28% vs 10%**)
  - Median time to first rescue (15 hours vs 1 hour)

## 14.2 Hemorrhoidectomy Study 2

A multicenter, randomized, double-blind, placebo-controlled, parallel-group study clinical trial evaluated the safety and efficacy of 266 mg (20 mL) EXPAREL in 189 patients undergoing hemorrhoidectomy. The mean age was 48 years (range 18 to 86).

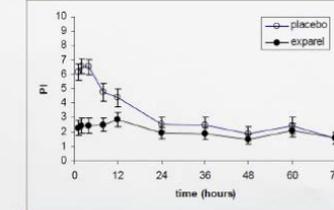
Study medication was administered directly into the situs verus (greater than or equal to 3 cm) at the conclusion of the surgery. Dilution of 20 mL of EXPAREL with 10 mL of saline, for a total of 30 mL, was divided into six 5 mL aliquots. A field block was performed by visualizing the anal sphincter as a clock face and slowly infiltrating one aliquot to each of the even numbers.

Pain intensity was rated by the patients on a 0 to 10 NRS at multiple time points up to 72 hours. Postoperatively, patients were allowed rescue medication (morphine sulfate 10 mg intramuscular every 4 hours as needed).

The primary outcome measure was the AUC of the NRS pain intensity scores (cumulative pain scores) collected over the first 72 hour period.

There was a significant treatment effect for EXPAREL compared to placebo. See Figure 1 for the mean pain intensity over time for the EXPAREL and placebo treatment groups for the 72-hour efficacy period.

Figure 1. Mean Pain Intensity versus Time plot for hemorrhoidectomy study (C-315)



This resulted in a decrease in opioid consumption, the clinical benefit of which was not demonstrated.

Twenty-eight percent of patients treated with EXPAREL required no rescue medication at 72 hours compared to 10% treated with placebo. For those patients who did require rescue medication, the mean amount of morphine sulfate intramuscular injections used over 72 hours was 22 mg for patients treated with EXPAREL and 29 mg for patients treated with placebo.

The median time to rescue analgesic use was for 15 hours for patients treated with EXPAREL and one hour for patients treated with placebo.

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# Co-administration with Bupivacaine HCl

## *New Information on Admixing*

Bupivacaine HCl administered together with EXPAREL may impact the pharmacokinetic and/or physicochemical properties of EXPAREL, and this effect is concentration dependent. Therefore, bupivacaine HCl and EXPAREL may be administered simultaneously in the same syringe, and bupivacaine HCl may be injected immediately before EXPAREL as long as the ratio of the milligram dose of bupivacaine HCl solution to EXPAREL does not exceed 1:2.

- New information permitting admixing (i.e., simultaneous administration in the same syringe) of bupivacaine HCl and EXPAREL, provided certain ratios are observed
- Revision provides beneficial information to many physicians who administer EXPAREL through admixing

### 2.2 Administration-Precautions-Compatibility Considerations

Some physicochemical incompatibilities exist between EXPAREL and certain other drugs. Direct contact of EXPAREL with these drugs results in a rapid increase in free (unencapsulated) bupivacaine, altering EXPAREL characteristics and potentially affecting the safety and efficacy of EXPAREL. Therefore, admixing EXPAREL with other drugs prior to administration is not recommended [See Drug Interactions (7)].

- Non-bupivacaine based local anesthetics, including lidocaine, may cause an immediate release of bupivacaine from EXPAREL if administered together locally. The administration of EXPAREL may follow the administration of lidocaine after a delay of 20 minutes or more.
- Bupivacaine HCl administered together with EXPAREL may impact the pharmacokinetic and/or physicochemical properties of EXPAREL, and this effect is concentration dependent. Therefore, bupivacaine HCl and EXPAREL may be administered simultaneously in the same syringe, and bupivacaine HCl may be injected immediately before EXPAREL as long as the ratio of the milligram dose of bupivacaine HCl solution to EXPAREL does not exceed 1:2.

~~Bupivacaine HCl when injected immediately before EXPAREL may impact the pharmacokinetic and/or physicochemical properties of the drug if the milligram dose of bupivacaine HCl solution exceeds 50% of the EXPAREL dose.~~ The toxic effects of these drugs are additive and their administration should be used with caution including monitoring for neurologic and cardiovascular effects related to toxicity [See Warnings and Precautions (3.1) and Overdosage (10)].

- When a topical antiseptic such as povidone iodine (e.g., Betadine<sup>®</sup>) is applied, the site should be allowed to dry before EXPAREL is administered into the surgical site. EXPAREL should not be allowed to come into contact with antiseptics such as povidone iodine in solution.

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# Use in Nursing Mothers

- Removal of restriction on use of EXPAREL in nursing mothers
- Revision allows physicians to utilize EXPAREL in this patient population at their discretion

## 5.2 Warnings and Precautions Specific for EXPAREL

As there is a potential risk of severe life-threatening adverse effects associated with the administration of bupivacaine, EXPAREL should be administered in a setting where trained personnel and equipment are available to promptly treat patients who show evidence of neurological or cardiac toxicity [See *Overdosage* (10)].

Caution should be taken to avoid accidental intravascular injection of EXPAREL. Convulsions and cardiac arrest have occurred following accidental intravascular injection of bupivacaine and other amide-containing products.

Using EXPAREL followed by other bupivacaine formulations has not been studied in clinical trials. Formulations of bupivacaine other than EXPAREL should not be administered within 96 hours following administration of EXPAREL [See *Dosage and Administration* (2.2) and *Clinical Pharmacology* (12.3)].

EXPAREL has not been evaluated for the following uses and, therefore, is not recommended for these types of analgesia or routes of administration.

- epidural
- intrathecal
- regional nerve blocks
- intravascular or intra-articular use

EXPAREL has not been evaluated for use in the following patient population and, therefore, it is not recommended for administration to these groups.

- patients younger than 18 years old
- pregnant patients

• nursing patients

The ability of EXPAREL to achieve effective anesthesia has not been studied. Therefore, EXPAREL is not indicated for pre-incisional or pre-procedural loco-regional anesthetic techniques that require deep and complete sensory block in the area of administration.

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# BUSINESS RAMIFICATIONS OF RESOLUTION

**Jim Scibetta**

President and Chief Financial Officer

Pacira Pharmaceuticals, Inc.

# Business Ramifications of Resolution

## *Communication Plan*

- Goal is to proactively communicate resolution to customers, potential customers and scientific community
- Written communications
  - Broad communication to all recipients (~16K HCPs) of the initial corrective letter
  - Targeted personal communication to customers impacted by the Warning Letter
  - Communication shipped with product to all ordering customers
  - Letters sent to major anesthesia societies and journals related to FDA position on TAP
- Media strategy
  - Integrated print and digital media buy across high-traffic HCP outlets [Q1 2016]
- Pacira field teams, speakers, and consultant preparation for inquiries
  - Detailed outreach plan to ensure consistent, accurate communication related to the resolution, and where to go for more information

# Business Ramifications of Resolution

## *Marketing & Training*

- Opportunity for Surgical Account Specialists (sales representatives) to engage directly with surgeons and anesthesiologists across a broad range of surgical models
- Significant investment required to train field force [Q1-Q2 2016]
  - Training on the new EXPAREL label
  - (Re)training of targeted surgical models beyond bunions and hemorrhoids
    - Knees, hips, spine, abdominal/colorectal procedures via surgeon infiltration or anesthesia TAPs, and surgical oncology

# Business Ramifications of Resolution

## *2016 Outlook*

- Standardization of established best practice and learnings since launch from customers' experience utilizing EXPAREL
  - Dose, volume and technique are important considerations
  - TKA randomized control study (RCT) [targeted initiation Q1 2016, expected topline data Q4 2016]
  - Spine RCT [targeted initiation H2 2016]
- Oral surgery launch targeted to coincide with the annual meeting of American Association of Oral and Maxillofacial Surgeons (AAOMS) during September 18-23, 2016
  - Exploring regulatory options for incorporating specific dosing information for oral surgeries on the label
  - RCT study in third molar extraction [expected topline data Q1 2016]

# Business Ramifications of Resolution

## *2016 Outlook*

- Growth prospects heightened in intermediate and long term
  - Training efforts in support of new EXPAREL label, oral surgery launch, and investment in RCT studies are expected to result in payoff beginning in H2 2016
  - Economic pressure on customers remains a dominant factor

# Q&A

**Jim Scibetta**

President and Chief Financial Officer

Pacira Pharmaceuticals, Inc.

# SUMMARY REMARKS

**Dave Stack**

Chief Executive Officer and Chairman

Pacira Pharmaceuticals, Inc.