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# DIPEX~~IUM~~

Pharmaceuticals, Inc.

*May 2016*

**LOCILEX<sup>®</sup>**   
(pexiganan cream 0.8%)

*Commercializing a Low-Risk, Late-Stage Compound*

# Cautionary Note Regarding Forward-Looking Statements

This presentation includes or incorporates by reference statements that constitute forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These statements relate to future events or to our future financial performance, and involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance, or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. These statements include, but are not limited to, information or assumptions about expenses, capital and other expenditures, financing plans, capital structure, cash flow, liquidity, management's plans, goals and objectives for future operations and growth. In some cases, you can identify forward-looking statements by the use of words such as "may," "could," "expect," "intend," "plan," "seek," "anticipate," "believe," "estimate," "predict," "potential," "continue," or the negative of these terms or other comparable terminology. You should not place undue reliance on forward-looking statements since they involve known and unknown risks, uncertainties and other factors which are, in some cases, beyond our control and which could cause actual performance or results to differ materially from those expressed in or suggested by forward-looking statements.

Important factors that could cause such differences include, but are not limited to (i) risks and uncertainties associated with our research and development activities, including our clinical trials; (ii) our dependence on Locilex<sup>®</sup> as our only product; (iii) our ability to raise capital when needed; (iv) the timing of and our ability to achieve US or international regulatory approvals for Locilex<sup>®</sup> or any other product candidates we may develop; (v) our dependence on others to conduct clinical research of, and to manufacture and market, Locilex<sup>®</sup>; (vi) the terms of future licensing arrangements, and whether we can enter into such arrangements at all; (vii) risks associated with the timing and receipt of licensing and milestone revenues, if any; (viii) our ability to gain market acceptance for Locilex<sup>®</sup> or any other product candidates we may develop; (ix) our ability to maintain or protect the validity of our patents and other intellectual property, including in connection with pending or future litigation against us; (x) our ability to secure registration for our current and future patent applications; (xi) our expectations regarding minimizing our development risk; (xii) our ability to establish new relationships and maintain current relationships; and (xiii) our ability to attract and retain key personnel.

Should one or more of these risks or uncertainties materialize, or should any of our assumptions prove incorrect, actual results may vary in material respects from those projected in these forward-looking statements. We do not undertake any obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required under applicable securities laws.

# Introduction

- 1H 2010: Company inception and acquisition of WW rights to Locilex<sup>®</sup>
- Locilex<sup>®</sup> is a topical antibiotic cream that has demonstrated efficacy at treating the pathogens that cause skin infections in superficial wounds in both clinical and microbiology studies
- Dipexium completed one of two Pivotal Phase 3 Clinical Trials in May 2016 and completion of enrollment in the 2<sup>nd</sup> Pivotal Phase 3 Clinical Trial is pending. Trial Design: Double Blind Placebo Controlled Superiority Studies to treat mild infections of diabetic foot ulcers or “Mild DFI”
- SPA Agreement with FDA on clinical program
- No additional clinical trials anticipated for EU approval
- **Locilex<sup>®</sup> could become the first antibiotic FDA-approved specifically for mild infections of diabetic foot ulcers**

# Investment Highlights

## Unmet Medical Need

- No FDA approved antibiotics for Mild Infections of Diabetic Foot Ulcers (Mild DFI)
- Current antibiotics used off-label to treat Mild DFI generate systemic antibiotic resistance, exhibit poor safety, narrow spectrum of activity

## Significant Market Opportunity

- \$1.46B worldwide market for Diabetic Foot Infections (DFI); > 30 mm diabetics in U.S.
- Multiple other skin and skin structure infection opportunities
- Dipexium owns 100% of the worldwide rights to Locilex®

## Locilex® Differentiation

- Novel, bactericidal mechanism of action
- No antibiotic induced systemic resistance
- Broad spectrum of activity
- Excellent safety and tolerability profile

## Strong Clinical Results to Date

- Two prior Phase 3 trials completed in patients with Mild/Moderate DFI
  - **Only topical to demonstrate non-inferiority to systemic antibiotic in Mild/Moderate DFI**

## Clear Pathway to FDA/EMA Approval

- Reached agreement with the FDA on Special Protocol Assessment (SPA) for our Phase 3 program
- Based on EMA formal advice, no additional trials required to file MAA in Europe
- **Data from Pivotal Phase 3 placebo controlled superiority studies anticipated for 2H 2016**

## Strong Intellectual Property

- US Formulation/Method of Use Patent: valid through June 2032
- Japan, Australia and New Zealand Formulation Patents valid through June 2033

# Unmet Medical Need

- No FDA approved antibiotics for Mild Infections of Diabetic Foot Ulcers (Mild DFI)
- Off-label oral antibiotics lack clinical data in the Mild DFI clinical indication
- Current **oral antibiotics** used off-label to treat Mild DFI have drawbacks:
  - generate systemic antibiotic resistance
  - exhibit poor safety and tolerability profile; and
  - Have a narrow spectrum of activity
- Current **topical antibiotics** lack clinical efficacy to treat Mild DFI and generally have a narrow spectrum of activity
- 2012 Infectious Disease Society of America (IDSA) treatment guidelines classify DFI severity into three categories:
  - Mild (47%), Moderate (34%), and Severe (18%)
- Amputation risk is low in Mild DFI patients (2-3%)
- However, Mild DFI can progress to Moderate or Severe DFI, where amputation rates are 45% and 75%, respectively

# Topical Locilex® for Mild DFI – Objectives

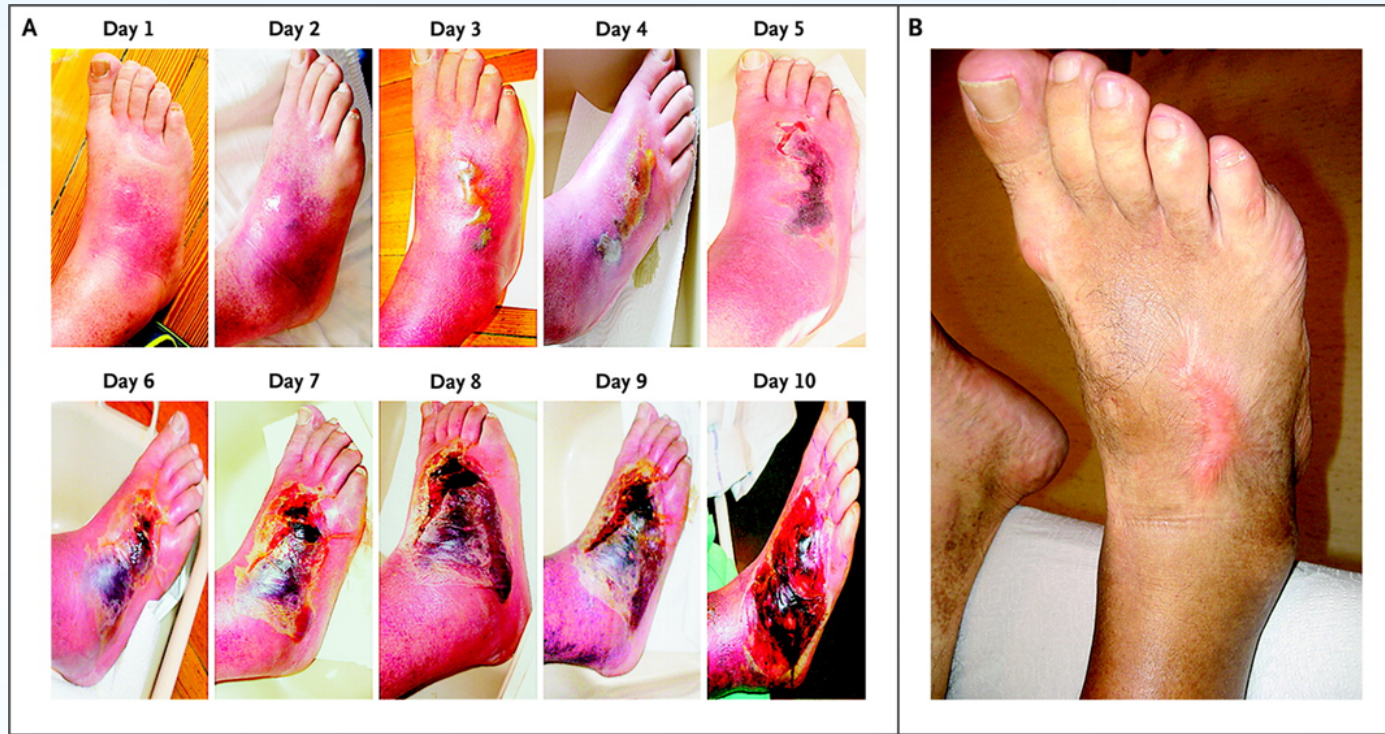
■ To recap, all classes of oral antibiotics are associated with one or more significant drawbacks:

- Generate systemic antibiotic resistance
- Limited spectrums of activity
- Poor safety/tolerability
- Drug-drug interactions with diabetes medications or impact blood glucose

## ■ Objectives of topical Locilex®:

- Achieve equivalent or improved infection control relative to systemic agents, while sparing patients from exposure to:
  - Systemic antibiotic resistance
  - Systemic toxicity, and
  - Drug-drug interactions with diabetes medications
- According to the International Working Group on the Diabetic Foot (2012), topical antibiotic therapy is appealing, although available data do not support the use of any currently marketed topical antibiotic for the treatment of DFI

# Evolution of a Diabetic Foot Infection - NEJM Case Study



An obese 50-year-old man with no known medical history presented with a necrotizing infection of his right foot that had begun 10 days previously with lesions that he attributed to wearing new shoes. He was found to have diabetes (glycated hemoglobin level, 10.5%) with peripheral neuropathy; he was afebrile, without leukocytosis or radiographic evidence of bone involvement in his right foot. The patient had photographed the lesion twice daily, thinking it would heal spontaneously (Panel A). The preoperative photographs show erythema (day 1), blisters (day 3), a necrotizing abscess (day 6), and wound infection requiring surgery (day 10). The patient underwent operative débridement; tissue cultures grew *Enterobacter cloacae* and *Streptococcus agalactiae*. He was treated with antibiotic agents for 3 weeks. The infection resolved, with no recurrence or sequelae during 3 years of follow-up (Panel B); during this period, the infection-related swelling disappeared and the patient lost a considerable amount of weight. **Diabetic foot infection may evolve rapidly, especially in patients with neuropathy.**

Tobalem M, Uçkay I. New England Journal of Medicine 2013;369:2252-2252.

# Significant Market Opportunity

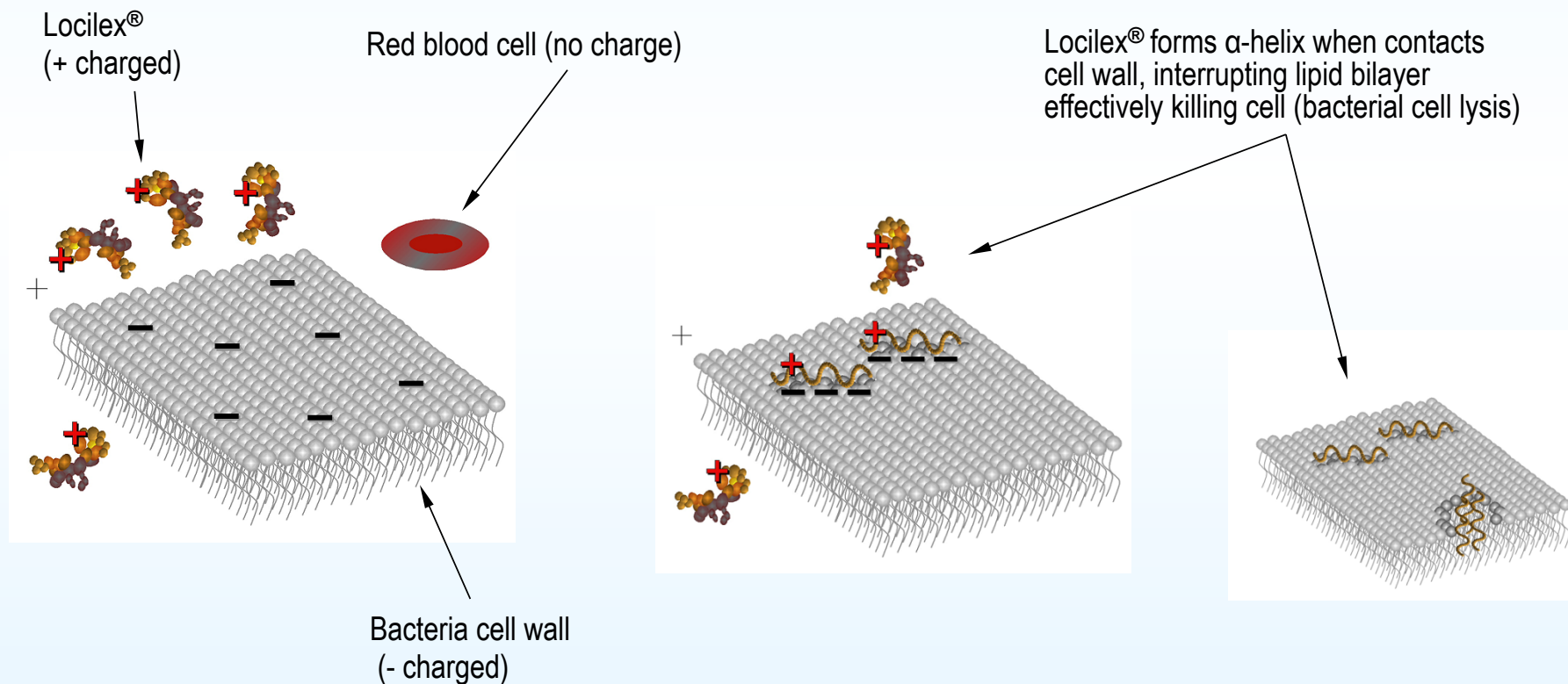
- Diabetics commonly develop foot ulcers (DFU) for many reasons, including lack of sensation in their extremities – AMA update suggests 12-14% of US population has diabetes
- An estimated 6% of diabetics develop DFUs each year in the U.S.
- 61% of DFUs will become a DFI
  - ***Before a wound can be treated, the infection must be eradicated***
  - DFI is the leading cause of diabetes-related hospitalizations and lower limb amputations
- Estimated annual DFI incidence : 1,350,000 patients in US / 2,700,000 patients in the EU
- Market for DFI antibiotics: WW: \$1.46B / US: \$1.01B (Global Data: 2011)



# Locilex<sup>®</sup> Differentiation

## New Chemical Entity, Novel Mechanism of Action

- NCE, novel 22-amino acid peptide isolated from skin of African Clawed Frog (chemically synthesized)
- Novel mechanism of action – kills microbial targets through disruption of bacterial cell membrane permeability



# Locilex® in Diabetic Foot Infections – Results to Date

## ■ Investigated in two prior Phase 3 trials in Mild/Moderate DFI vs. a systemic antibiotic control

- Study “304” achieved statistical non-inferiority (Primary endpoint: clinical cure or improved); Study 303 did not
  - Locilex® is the only topical to demonstrate non-inferiority vs. a systemic antibiotic in late-stage DFI trials
- Combined analysis of two trials demonstrated clinical and microbiological statistical non-inferiority

### Clinical outcome (% cure or improved)

Study	Locilex®		ofloxacin		Treatment Difference
	n/N	%	n/N	%	(95% Confidence Interval)
303	186/243	76.5	201/240	83.8	-7.21 (-14.29 to -0.12)
304	134/163	82.2	137/163	84.0	-1.84 (-9.97 to 6.29)
<b>Combined</b>	<b>320/406</b>	<b>78.8</b>	<b>338/403</b>	<b>83.9</b>	<b>-5.05 (-10.41 to 0.31)</b>

### Microbiological outcome (% responders)

Study	Locilex®		ofloxacin		Treatment Difference
	n/N	%	n/N	%	(95% Confidence Interval)
303	78/185	42.2	90/194	46.4	-4.23 (-14.23 to 5.77)
304	55/130	42.3	62/134	46.3	-3.96 (-15.94 to 8.02)
<b>Combined</b>	<b>133/315</b>	<b>42.2</b>	<b>152/328</b>	<b>46.3</b>	<b>-4.12 (-11.80 to 3.56)</b>

# Locilex® in Diabetic Foot Infections – FDA History

## ■ FDA Anti-Infectives Advisory Committee Meeting – Key Takeaways

- Safety Vote: 9 – 0 in favor *UNANIMOUS*
- Efficacy Vote: 5 – 4 against
- Recommendation to conduct small-scale placebo-controlled trial to confirm appropriateness of statistical plan used to establish non-inferiority in studies 303 and 304

## ■ FDA Non-Approvable Letter – Key Takeaways

- Sole focus on two manufacturing issues:
  - Physical Instability: Water separation in cream formulation
  - Unacceptable Impurity Profile in Active Pharmaceutical Ingredient (API): >5%
  - These manufacturing issues have been addressed

# Locilex<sup>®</sup> – New Manufacturing Process

- **Dipexium team adjusted ratio of emulsifiers and oil/water ratio which resulted in complete fix to prior manufacturing issues**
  - Water Separation Issue Resolved
    - Novel manufacturing process resulted in confirmed physical stability of cGMP batch at 18-months
    - Trended physical stability analysis supports a shelf life > 24 months for Locilex<sup>®</sup>
  - API Impurity Issue Resolved
    - Novel manufacturing method resulted in API impurity profile of 0.6% in cGMP batch
- **Manufactured Non-cGMP material**
  - Scale-up to 30 kg commercial scale batches with no issues noted with physical or chemical stability
  - Achieved 18-month stability data and filed with FDA's CMC Division in October 2013
  - Type C Meeting with FDA CMC Division in December 2013
- **Manufactured cGMP material**
  - Produced 3 batches of cGMP drug supply at commercial scale – 30 kg
  - Required stability data needed for NDA submission is in hand (2 year shelf life anticipated)
  - Successfully achieved scale up to 140 kg commercial lots in Q3 2015

**As a result of these changes, we believe we have resolved the stability and purity concerns previously articulated by the FDA's Drug Advisory Committee**

# Locilex® – New Approval Pathway for Mild DFI

## ■ Phase 3 Clinical Trials

- Reached agreement with the FDA on a Special Protocol Assessment (SPA) for our Phase 3 program
- Commenced patient enrollment in Q3 2014; enrollment expected to be completed in 1H 2016
- Design for pivotal DPX-305 and DPX-306 clinical trials:
  - 180 patients per trial (1:1 randomized, placebo-controlled), up to 37 sites per trial in the U.S.
  - Twice-daily dosing for 14 days of treatment → follow-up on day 28 → no follow-up required thereafter
  - Primary endpoint: Infection resolved in judgment of treating physician using DFI Treatment Guidelines (2012)
  - Statistical plan: 90% power,  $P \leq 0.05$
  - **100% enrolled as of May 10, 2016 (combined)**
  - **Top-line data anticipated Q3 2016**

# Locilex<sup>®</sup> – New Approval Pathway for Mild DFI

## ■ Regulatory – U.S.

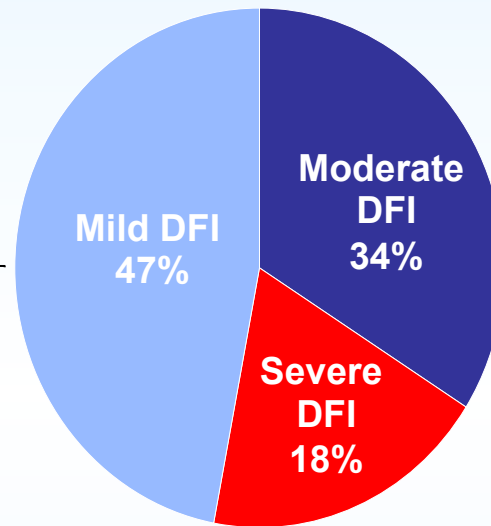
- NDA filing expected in 1H 2017
- Anticipated FDA Approval by end of 2017
- FDA agrees safety database can be supported by clinical data in 509 patients treated with Locilex<sup>®</sup> from prior sponsor's clinical studies

## ■ Regulatory – E.U.

- Received formal advice from EMA on planned MAA submission – no additional clinical trials required
- MAA filing expected in 1H 2017; anticipated approval in 1H 2018

# Addressable Market for Mild/Moderate DFI in the US and EU

- *The chart below is a breakdown of the DFI Market based upon patients' first presentation to a treating physician:*



## Mild DFI

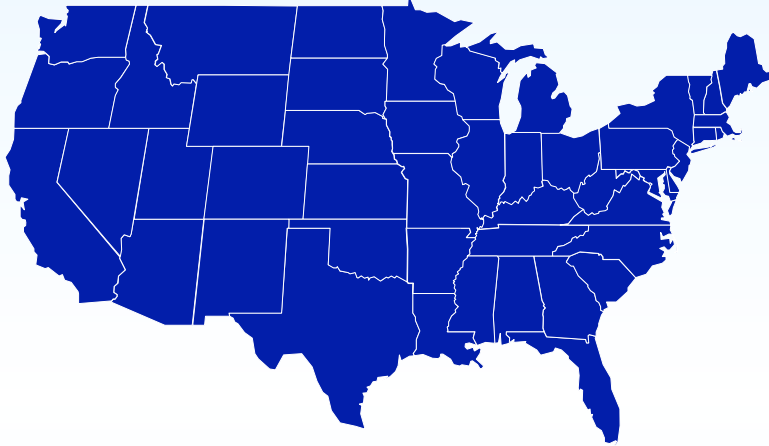
- Currently no FDA approved product
- Incidence: Approximately 650,000 patients/year (US)
- Incidence Approximately 630,000 patients/year (EU)
- Pricing: \$600 per full treatment (US) and \$280 per full treatment (EU)
- Locilex® could become the standard of care

## Moderate DFI

- Currently only systemic antibiotics are used
- Incidence: Approximately 470,000 patients/year (US)
- Incidence Approximately 455,000 patients/year (EU)
- Same pricing as Mild DFI (see box to left)
- Combination therapy with Locilex® anticipated

# Commercialization Strategy

Dipexium owns 100% of the worldwide rights to Locilex®



## U.S. Market

- Plan to hire two senior executives, in Marketing and in Sales in 2016
  - Plan to work with commercial team to build out sales staff
  - Preliminary plan is to appoint fully dedicated CSO sales staff
  - Start with 40 sales representatives, increasing to 100-125

## EU Market – *Strategic Decision To Be Determined*

- Create wholly-owned EU subsidiary run by a senior executive based in the NY office, in order to commercialize Locilex® independently
  - Plan to hire one EU Commercial Director in 2016
  - Preliminary plan is to appoint fully dedicated EU CSO sales staff
  - Start with 10 medical science liaisons, increasing to 25-50



# Locilex® Growth Strategy

## Value Drivers

## Opportunity

### Clinical Indications

- Expand label to include skin and soft tissue infections (SSTI's) including
  - infected surgical wounds
  - infected burns
  - infected decubitus ulcers
- Potential to include wound closures in initial indication

### Geographic Growth Targets

- Europe: CHMP clinical and regulatory advice received May 2015
- Anticipate filing for approval in Europe without conducting any European clinical studies
- EU MAA submission targeted for 1H 2017
- Japan development activities commence Q2 2016

# Locilex® Growth Strategy: Clinical Justification for Use in SSTIs

- **Antibacterial spectrum of pexiganan shows activity against virtually all SSTI pathogens, including strains resistant to other antibiotics**
- **Benefits to using Locilex® to treat SSTIs:**
  - Efficacy against relevant pathogens
  - Mechanism of action
  - Ability to treat bacteria with known resistance mechanisms
  - Topical route of administration with low absorption potential
  - Significant improvement of the adverse event profile, compared to systemic antibiotics

# Most Common Pathogens in Infected DFUs Overlap SSTI Pathogens

- Infected DFUs can be considered a more complicated subset of SSTIs with comparable pathogenic species; therefore, existing pexiganan DFU data directly translate to SSTI
  - **Infected DFUs**
    - *Staphylococcus aureus* (including MRSA, methicillin-sensitive *Staphylococcus aureus* [MSSA]), *Streptococcus* and *Enterococcus* species
    - In moderate infections of DFUs *Enterobacteriaceae*, obligate anaerobes and *Pseudomonas aeruginosa* may also be present
  - **SSTIs**
    - Endogenous *Staphylococcus aureus* (including MRSA, MSSA), and *Streptococcus* species (particularly groups A, B, C and G)

Organism	No. of pathogens at baseline in ITT (n = 659 patients)
<b>Staphylococcus aureus</b>	303
<b>Enterococcus faecalis</b>	210
<b>Streptococcus agalactiae</b>	125
<b>Pseudomonas aeruginosa</b>	58
<b>Staphylococcus epidermidis</b>	47
<b>Proteus mirabilis</b>	41
<b>Enterococcus species</b>	38
<b>Escherichia coli</b>	35

# Strong Intellectual Property

## United States

- New formulation/method-of-use patent issued in September 2013 by USPTO extends US protection to June 2032 and may provide worldwide patent protection through June 2032 (Patent No. 8,530,409)
- US composition-of-matter patent extends to June 2021, assuming additional 5-year Hatch-Waxman extension

## European Union

- Rolling 10-year regulatory exclusivity available in EU for New Chemical Entities (NCEs)

## Rest of World

- New formulation/method of use patent issued in September 2013 may extend patent protection worldwide through June 2032
  - **Australia:** Patent extends through June 2033
  - **New Zealand:** Patent extends through June 2033
  - **Japan:** Patent extends through June 2033

# Recent & Upcoming Milestones – Met Targets since IPO

<input type="checkbox"/> Initiate Phase 1 skin irritation and skin sensitization studies DPX-110 and DPX-120	✓	Q1 2014
<input type="checkbox"/> Initiate pivotal Phase 3 Mild DFI studies DPX-305 and DPX-306	✓	Q2 2014
<input type="checkbox"/> Complete Phase 1 skin irritation study DPX-110	✓	Q2 2014
<input type="checkbox"/> Complete Phase 1 skin sensitization study DPX-120	✓	Q4 2014
<input type="checkbox"/> Finalize European Drug Development Strategy	✓	1H 2015
<input type="checkbox"/> Obtain EMA Clinical and Regulatory Advice	✓	1H 2015
<input type="checkbox"/> <b>Complete enrollment in pivotal Phase 3 Mild DFI studies</b>		<b>1H 2016</b>
<input type="checkbox"/> <b>File NDA Amendment (FDA)</b>		<b>1H 2017</b>
<input type="checkbox"/> <b>File MAA (EMA)</b>		<b>1H 2017</b>

**Locilex® could be approved by the FDA in 2H 2017 and by EMA in 1H 2018**

# Financial Highlights

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<b>Cash On Hand</b>	\$27.2 million (as of March 31, 2016)
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<b>Shares Outstanding</b>	10,351,613 shares of common stock
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<b>Insider Equity</b>	~ 40% primary; ~45% fully diluted (as of December 31, 2015)
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<b>Fully Diluted Equity</b>	11,516,400 shares of common stock (includes 24,500 warrants and 1,112,287 employee options)
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<b>Market Cap</b>	~ \$125 million (as of May 4, 2016)
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<b>Exchange: Ticker</b>	NASDAQ: DPRX
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<b>Other Financial Factors</b>	<ul style="list-style-type: none"><li>▪ No milestones or royalties due to any third parties</li><li>▪ Zero long-term debt or preferred stock; and almost no warrants</li><li>▪ Monthly Burn (2016 annualized): Approx \$1.3 mm per month</li></ul>
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# Investment Thesis in Detail

## Unmet Medical Need

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## Significant Market Opportunity

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*Commercializing a Low-Risk, Late-Stage Compound*

# Management Team and Advisors

## Key Management and Directors

### David Luci (Co-Founder)

- President & CEO
- 20 years experience consummating public offerings, private placements, M&A and licensing transactions strategically in the pharmaceutical industry
- Previously served as a member of the Board of Directors and President of MacroChem Corporation and member of the Board of Directors of Access Pharmaceuticals, Inc.
- Previously served as CFO, General Counsel and Corporate Secretary of Bioenvision Inc.

### Robert DeLuccia (Co-Founder)

- Executive Chairman
- Over 40 years of pharmaceutical industry experience with global pharmaceutical and development stage biopharmaceutical companies
- Former Chairman & CEO of MacroChem Corporation
- Also served as President & CEO of Immunomedics, Inc.

### David Garrett

- Vice President, Finance & Corporate Development
- Previously served as Director, Healthcare Equity Sales and Capital Markets at Canaccord Genuity and as an equity analyst covering the biotechnology and pharmaceuticals industries at Scudder Kemper, Wachovia, UBS and Fortis
- Assisted over 45 emerging biotechnology and medical technology companies in IPO's, secondary public offerings and PIPEs raising over \$2.9 billion

## Scientific Advisors

### Jonathan Wilkin, MD

*Founding Director (retired) of the Division of Dermatology and Dental Products at the FDA*

### Benjamin Lipsky, MD, FACP, FIDSA, FRCP

*Head of the International Working Group on the Diabetic Foot (IWGDF) and lead author of the Diabetic Foot Infection Treatment Guidelines, published in June 2012*

### David Armstrong, MD, DPM, PhD

*Professor of Surgery and Director, Southern Arizona Limb Salvage Alliance (SALSA), University of Arizona College of Medicine*

### Warren Joseph, DPM, FIDSA

*Managing Editor of the Journal of the American Podiatric Medical Association*

### Michael Zasloff, MD, Ph.D.

*Original inventor of the "magainin peptides", including pexiganan, as a research scientist at the NIH*