Developing Well-Differentiated Antibiotics

June 2016

PRABHAVATHI FERNANDES, PhD
President and CEO
Forward Looking Statement

This presentation contains forward-looking statements regarding future events. These statements are just predictions and are subject to risks and uncertainties that could cause the actual events or results to differ materially. These risks and uncertainties include, among others: our and our strategic partners’ ability to obtain FDA and foreign regulatory approval of our product candidates; risks related to the costs, sources of funding, timing, regulatory review and results of our studies and clinical trials and those of our strategic partners; our need to obtain additional funding and our ability to obtain future funding on acceptable terms; our ability to commercialize and launch whether on our own or with a strategic partner any product that receives regulatory approval; our anticipated capital expenditures and our estimates regarding our capital requirements; our dependence on the success of solithromycin and TAKSTA; the unpredictability of the size of the markets for, and market acceptance of, any of our products, including solithromycin and TAKSTA; our ability to produce and sell any approved products and the price we are able to realize for those products; our ability to retain and hire necessary employees and to staff our operations appropriately; the possible impairment of, or inability to obtain, intellectual property rights and the costs of obtaining such rights from third parties; our ability to compete in our industry; innovation by our competitors; and our ability to stay abreast of and comply with new or modified laws and regulations that currently apply or become applicable to our business. Please refer to the documents that we file from time to time with the Securities and Exchange Commission.
Highlights – Cempra, a Differentiated and Growing Company

• Cempra has consistently executed on plan – the leading antibacterial biotech

• Cempra has submitted NDAs for solithromycin and expects to launch product Q1 2017–large market potential for CABP
  - New macrolide is urgently needed - resistance to azithromycin and serious adverse event labeling of levofloxacin. Little generic competition, no branded competition
  - Additional indications near term- *product within a product* – Pediatrics, COPD, Gonorrhea
  - Validated by license for Japan, partnerships with BARDA and NIAID

• Cempra has a second antibiotic in Taksta in Phase 3 - ABSSSI and refractory BJI
  - Only oral antibiotic for long term use with large market potential

• Cempra owns macrolide platform technology and discovery programs for non-anti-inflammatories and motilin agonists

• Cempra has hired experienced staff in Commercialization, Medical Affairs, Regulatory, Clinical, Chemistry, Finance, IT – to support readiness for launch

• Well financed and ROW (except Japan) licensing potential is still open
# Proven Management Team

<table>
<thead>
<tr>
<th>Name</th>
<th>Position</th>
<th>Achievements and Responsibilities</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Prabhavathi Fernandes, PhD</strong>&lt;br&gt;President &amp; CEO</td>
<td></td>
<td>- Azactam (Aztreonam)&lt;br&gt;- Biaxin (Clarithromycin)&lt;br&gt;- Dificid (Fidaxomicin)</td>
</tr>
<tr>
<td><strong>Mark Hahn, CPA</strong>&lt;br&gt;CFO</td>
<td></td>
<td>- IPO and M&amp;A&lt;br&gt;- Athenix-Bayer CropScience&lt;br&gt;- Charles &amp; Colvard (CTHR)&lt;br&gt;- E&amp;Y</td>
</tr>
<tr>
<td><strong>David Moore, MBA</strong>&lt;br&gt;CCO</td>
<td></td>
<td>- Levaquin (Levofloxacin)&lt;br&gt;- Topamax (Topiramate)&lt;br&gt;- Ultram (Tramadol)&lt;br&gt;- Nucynta (Tapentadol)</td>
</tr>
<tr>
<td><strong>Munir Abdullah, PhD</strong>&lt;br&gt;EVP Regulatory</td>
<td></td>
<td>- Flonase (Fluticasone Propionate)&lt;br&gt;- Veramyst (Fluticasone Furoate)&lt;br&gt;- Avodart (Dutasteride)&lt;br&gt;- Tykerb (Lapatinib)</td>
</tr>
<tr>
<td><strong>Gary Horwith, MD</strong>&lt;br&gt;EVP Pharmacovigilance &amp; QA</td>
<td></td>
<td>- <em>S. aureus</em> vaccine&lt;br&gt;- Abelcet (Amphotericin B)</td>
</tr>
<tr>
<td><strong>David Oldach, MD</strong>&lt;br&gt;Chief Medical Officer</td>
<td></td>
<td>- Viread (Tenofovir)&lt;br&gt;- Combinations Against HCV</td>
</tr>
<tr>
<td><strong>David Pereira, PhD</strong>&lt;br&gt;EVP Chemistry</td>
<td></td>
<td>- Injectable Penicillins&lt;br&gt;- Dobutamine HCI Injection&lt;br&gt;- Ranitidine Injection</td>
</tr>
</tbody>
</table>
# Cempra’s Late Stage Portfolio

<table>
<thead>
<tr>
<th>PRODUCT CANDIDATE</th>
<th>INDICATION</th>
<th>FORMULATION</th>
<th>PRECLINICAL</th>
<th>PHASE 1</th>
<th>PHASE 2</th>
<th>PHASE 3</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>SOLITHROMYCIN</strong></td>
<td>Community Acquired Bacterial Pneumonia (CABP)</td>
<td>Oral Completed</td>
<td>NDA submitted 4/28/2016</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Pediatric: Capsule/Suspension/IV</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Biodefense Use</td>
<td>Oral/Suspension</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Urethritis/Gonorrhea</td>
<td>Oral</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Anti-Inflammatory/NASH</td>
<td>Oral</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Anti-Inflammatory/COPD</td>
<td>Oral</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>TAKSTA FUSIDIC ACID</strong></td>
<td>Chronic Bone and Joint Infections</td>
<td>Oral</td>
<td></td>
<td>[green]</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>ABSSSI</td>
<td>Oral</td>
<td></td>
<td>[green]</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>NON-ANTIBIOTIC MACROLIDE</strong></td>
<td>Diabetic Gastroparesis and GERD</td>
<td>Oral</td>
<td>[purple]</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
NDAs Submitted - with Potential To Be a Successful Antibiotic

• Solithromycin has completed 2 pivotal Phase 3 trials
• Positive clinical data from both trials — safe and effective
• Fast Track and Priority review (QIDPs) designations received from the FDA
• NDA (rolling NDA) submitted 28 April, 2016. EU submission documents preparation on track
Expected Time-Lines

• June 30, 2016: Submission of MAA to EMA
• 3Q 2016: Acceptance of NDAs by FDA
• EOY 2016: PDUFA date
• EOY 2016: NDA approval expected
• Launch Q1 2017

Qualified Infectious Disease Program (QIDP): Two QIDPs for Oral capsules and IV for CABP
Provides 8 Month Priority Review
Fast Track Designation – Rolling NDA
Community Acquired Bacterial Pneumonia: Prevalent, Deadly and Growing

Prevalent and Deadly

- 5-10M Cases Annually
  - 1.1M Patients Hospitalized
- #1 Cause of Death from an Infection ¹
  - More Deaths from Pneumococcal Infections in US than Breast or Prostate Cancer ²
- Affects Young Children and the Old Disproportionately

Growing

HOSPITAL DISCHARGES FOR PNEUMONIA ³

Appropriate Empiric Therapy Critical for Positive Outcomes

Multiple Pathogens (Pneumocococcus Most Frequent)

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¹ Freeman, MK. CABP: A Primer for Pharmacists: US Pharmacist July 1, 2013
³ Source: 2011 HCUP, ARHQ.gov
Resistance Has Created a Large Macrolide Market Opportunity

US COMMUNITY ANTIBIOTIC RXs
Total = 264 M in 2013\(^a\)

- Macrolides (62M)
- Other Antibacterials (28M)
- Tetracyclines/ Aminoglycosides (21M)
- Cephalosporins (39M)
- Fluoroquinolones (36M)
- Beta-lactams (79M)

Source:  
\(^a\) IMS Health (Retail) AMR Hospital Data (Inpatient)

Macrolide Antibiotics - Used Traditionally by Physicians to Treat Respiratory Tract Infections

- Targeted Spectrum of Activity
- Good Safety
- Excellent Tissue / Intracellular Distribution
- Anti-Inflammatory Activity

Azithromycin

- Leading Macrolide
- 51M Rx’s in US in 2013\(^b\)
- Most Widely Prescribed Treatment for CABP / RTIs (Respiratory Tract Infections)
- Resistance Driving Need for a New Macrolide

>60% OF RTI MARKET

Source:  
\(^b\) 2013 IMS New Prescription Audit
# Pneumococcal Resistance Drives Need for New Macrolide

## % Resistance

<table>
<thead>
<tr>
<th>Region</th>
<th>AZITHROMYCIN</th>
<th>SOLITHROMYCIN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Europe</td>
<td>28.0%*</td>
<td>0%</td>
</tr>
<tr>
<td>North America</td>
<td>48.0%***</td>
<td>0%</td>
</tr>
<tr>
<td>Asia</td>
<td>70.5%*</td>
<td>0%</td>
</tr>
</tbody>
</table>

### MIC 90% (µg/mL)

<table>
<thead>
<tr>
<th>Region</th>
<th>AZITHROMYCIN</th>
<th>SOLITHROMYCIN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Europe</td>
<td>&gt;1</td>
<td>0.06</td>
</tr>
<tr>
<td>North America</td>
<td>&gt;1</td>
<td>0.25</td>
</tr>
<tr>
<td>Asia</td>
<td>&gt;1</td>
<td>0.5</td>
</tr>
</tbody>
</table>

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** Kim, SH, AAC, 2012; 56: 1418-1426
*** Jones, RN. DMID 2013; 75:107-109
Solithromycin: 4th Generation Macrolide - The First Fluoroketolide

Currently Approved Macrolides

ERYTHROMYCIN

CLARITHROMYCIN

AZITHROMYCIN

SOLITHROMYCIN

Interacts with Bacterial Ribosome at Three Sites – Resistance Rare and Could Only Occur If Mutations Occur at Three Distinct Sites
What do these three celebrities have in common?

Merle Haggard
Michael Moore
Yoko Ono

Hospitalized in the winter of 2015-2016

...but why did they have to be hospitalized?
<table>
<thead>
<tr>
<th>Healthy Outpatient</th>
<th>Outpatient at Risk of DRSP*</th>
<th>Inpatient Non-ICU</th>
<th>Inpatient ICU†</th>
</tr>
</thead>
<tbody>
<tr>
<td>Macrolide Or Doxycycline</td>
<td>Respiratory Fluoroquinolone Or Beta-lactam plus Macrolide</td>
<td>Beta-lactam‡ plus Macrolide Or Respiratory Fluoroquinolone Or Tigecycline</td>
<td>Beta-lactam plus Azithromycin Or Beta-lactam plus Fluoroquinolone</td>
</tr>
</tbody>
</table>

* **Drug Resistant S. pneumoniae** - Recent antimicrobials; comorbidities; Includes healthy patients in regions with high rates of macrolide resistance

† Treatment of *Pseudomonas* or MRSA is the main reason to modify standard therapy for ICU

‡ Ceftriaxone, cefotaxime, amp/sulbactam, ertapenem, ceftaroline (from CMS list)

Current CABP Therapies Have Use-Limiting Formulations and Safety Issues

2 Primary Options

1. Cephalosporin (e.g. Ceftriaxone) + Macrolide (e.g. Azithromycin)

2. Fluoroquinolone (e.g., Levofloxacin, Moxifloxacin)

IDSA / ATS Recommends Broad Spectrum, Empiric Coverage

Issues

NO ORAL OPTION

- Requires IV Ceftriaxone AND Hospitalization
- No Oral Switch Therapy Replacement

Hospitalization Issues

- Hospitalized CABP High Mortality Rate
- Hospital-Acquired Infections Costs and Hazards

SAFETY CONCERNS

- Focus of FDA Advisory Committee, Nov. 5, 2015. Label changes May 2016
- Kill Bowel Flora – Increased frequency of C. difficile Colitis
- Tendonitis, Achilles Tendon Rupture, Hepatotoxicity and Peripheral Neuritis, Retinal Detachment
- Treatment Failures from Resistant Strain Selection
- Not Approved for Use in Pediatrics
- No Longer Used for CABP in Several Countries

1 Freeman, MK. US Pharmacist. July 1, 2013
2 Magill, SS. And CDC and Emory Authors. NEJM 2014. 1198-1208, 2014
Solithromycin – Spectrum of Activity That Addresses CABP Pathogens

**Solithromycin Has Class-Leading Potency Against CABP Pathogens**

Overcomes macrolide resistance that limits existing macrolides

<table>
<thead>
<tr>
<th>GRAM</th>
<th>ORGANISMS</th>
<th>SOLITHROMYCIN</th>
<th>AZITHROMYCIN</th>
<th>CEFTRIAXONE</th>
<th>LEVOFLOXACIN or MOXIFLOXACIN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive</td>
<td><em>Streptococcus pneumoniae</em></td>
<td>✔️</td>
<td>❌</td>
<td>✔️</td>
<td>✔️</td>
</tr>
<tr>
<td>Negative</td>
<td><em>Haemophilus influenzae</em></td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
</tr>
<tr>
<td>Positive</td>
<td><em>Staphylococcus aureus</em></td>
<td>✔️</td>
<td>❌</td>
<td>✔️</td>
<td>✔️</td>
</tr>
<tr>
<td>Atypical</td>
<td><em>Legionella pneumophila</em></td>
<td>✔️</td>
<td>✔️</td>
<td>❌</td>
<td>✔️</td>
</tr>
<tr>
<td>Atypical</td>
<td><em>Mycoplasma pneumoniae</em></td>
<td>✔️</td>
<td>✔️/ ❌</td>
<td>❌</td>
<td>✔️</td>
</tr>
<tr>
<td>Atypical</td>
<td><em>Chlamyphilia pneumoniae</em></td>
<td>✔️</td>
<td>✔️</td>
<td>❌</td>
<td>✔️</td>
</tr>
</tbody>
</table>

Azithromycin Monotherapy not used to Treat Moderate to Severe Pneumonia – Potency, Spectrum and Resistance Allow Use Only in Simpler Infections or Add-On To Ceftriaxone
CABP Antibiotic Usage

AZ and Levo comprise majority of Retail CABP Rx

<table>
<thead>
<tr>
<th></th>
<th>2010</th>
<th>2011</th>
<th>2012</th>
<th>2013</th>
<th>2014</th>
</tr>
</thead>
<tbody>
<tr>
<td>Retail Scripts (MM)</td>
<td>8.7</td>
<td>8.5</td>
<td>9.5</td>
<td>9.5</td>
<td>9.7</td>
</tr>
</tbody>
</table>

Retail Levofoxacin Use increasing for CABP and Bronchitis

<table>
<thead>
<tr>
<th></th>
<th>2010</th>
<th>2011</th>
<th>2012</th>
<th>2013</th>
<th>2014</th>
</tr>
</thead>
<tbody>
<tr>
<td>CABP</td>
<td>18.5%</td>
<td>21.7%</td>
<td>25%</td>
<td>25.1%</td>
<td>25%</td>
</tr>
<tr>
<td>Bronchitis</td>
<td>16.7%</td>
<td>15.5%</td>
<td>17.2%</td>
<td>21.2%</td>
<td>23%</td>
</tr>
</tbody>
</table>

Source: 2014 IMS NPA and NDTI

Ceftriaxone/Azi, Levo and Zosyn ~65-70% of hospital days of therapy

Source: AMR Days of Therapy, 2014
**Oral Phase 2 Trial - Toyama**

*Solithromycin safety and efficacy further validated by Toyama (FUJIFILM)*

All efficacy outcome measures favored solithromycin

<table>
<thead>
<tr>
<th>Population</th>
<th>SOLITHROMYCIN</th>
<th>LEVOFLOXACIN</th>
<th>Favors Levofloxacin</th>
<th>Favors Solithromycin</th>
<th>Delta (CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Success Rate%</td>
<td>Success Rate%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>modified-ITT</td>
<td>77.3</td>
<td>61.7</td>
<td></td>
<td></td>
<td>+15.57 (-5.2, 36.4)</td>
</tr>
<tr>
<td>(34/44)</td>
<td></td>
<td>(29/47)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Per Protocol</td>
<td>85.0</td>
<td>67.4</td>
<td></td>
<td></td>
<td>+17.56 (-2.7, 37.8)</td>
</tr>
<tr>
<td>(34/40)</td>
<td></td>
<td>(29/43)</td>
<td></td>
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</tbody>
</table>

-24 -20 -16 -12 -8 -4 0 4 8 12 16 20 24

Treatment difference
Partnership Provides Validation and Adds Value

**GEOGRAPHY**
- Japan – Exclusive License
- (2nd Largest Antibiotic Market)

**DEVELOPMENT / REGULATORY**
- Global Development Program

**VALUE**
- $30M Upfront / Milestones Rec’d
- Up to $40M Additional Milestones
- Double Digit Tiered Royalties, Subject to Reaching Sales/Contract Levels

ROW (Europe, China/Asia, South America etc.) is expected to be licensed
Growing resistance, exceeding 80% in Asia
Large market potential for a macrolide
Solithromycin May Have Potential In a Broad Range of Indications

**RESPIRATORY TRACT INFECTIONS (RTI)**
- Hospital-Acquired Pneumonia, Simple RTIs such as Pharyngitis, Acute Exacerbation of Chronic Bronchitis (AECB)

**ANTIBACTERIAL AND ANTI-INFLAMMATORY**
- COPD, Cystic Fibrosis, NASH

**PEDIATRICS AND PREGNANCY**
- No Pediatric Drug with Broad Potential in Development
- Infections in Pregnancy – Neonatal Sepsis
- Infections in Utero – Premature, Cerebral Palsy, Autism

**MULTIPLE UNIDENTIFIED PATHOGENS**
- Anthrax, Tularemia

**GENITAL INFECTIONS (GONORRHEA AND CHLAMYDIA)**
- Major Public Health Crisis – Multi Drug Resistance, No Oral Therapy

**OTHER INFECTIONS**
- Helicobacter Gastritis, Tick and Insect Borne Diseases
- Ophthalmic drops – eye infections and blepharitis
Solithromycin Phase 3 Trial: Gonorrhea

BACKGROUND / RATIONALE

- **Gonorrhea:** 2nd Most Common Communicable Disease: 800K US; 500M Globally/Year
- **Drug Resistant Gonorrhea:** CDC “Emergency Need”
- **Current Intramuscular-Only Treatment Precludes “Brown Bag” Treatment of Partners**

**Solithromycin Was 100% Effective in All Culture-Proven Cases of Gonorrhea in a Phase 2 Trial**

<table>
<thead>
<tr>
<th>INDICATION</th>
<th>FORMULATION</th>
<th>PRECLINICAL</th>
<th>PHASE 1</th>
<th>PHASE 2</th>
<th>PHASE 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Urethritis / Gonorrhea</td>
<td>Oral</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**TRIAL DESIGN**

- Single Dose of Solithromycin (1000 mg Oral)

**COMPARATOR**

- Ceftriaxone 500 mg Intramuscular Injection + Azithromycin 1000 mg Oral

**PATIENTS (n)**

- 300 Patients with Gonorrhea (with or without Chlamydia)

**PRIMARY ENDPOINT**

- Culture Negative at 7 Days (TOC)

**STATUS**

- Study being expanded for women and children with NIAID - NDA expected to be submitted after CABP

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Clinical Development for Pediatric Use

First antibiotic in over 2 decades being developed for use intravenously/oral capsules or as a suspension formulation – dosing flexibility

FDA has granted QIDP for suspension formulation

Phase 1a completed
Enrollment in Phase 1b is proceeding well. Ages 0-17 being enrolled
Phase 2/3 – pivotal trial is expected initiated 1H 2016 – Mostly funded by BARDA

~ 55MM pediatric antibiotic prescriptions annually in the US for all indications*
~ 23% were for azithromycin*

Source: http://pediatrics.aappublications.org/content/130/1/23.full.pdf+html
## Solithromycin - Differentiated from Other Recently Approved Antibiotics

<table>
<thead>
<tr>
<th>Category</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Community and Hospital</strong></td>
<td>• Oral and IV product expected to capture the large need in the ER, Urgent care and hospital</td>
</tr>
<tr>
<td><strong>Generic Competition</strong></td>
<td>• Alternatives to avoid treatment failures and hospitalization</td>
</tr>
<tr>
<td></td>
<td>• No branded competition — 100% share of voice</td>
</tr>
<tr>
<td><strong>Pricing</strong></td>
<td>• Pricing expected to be in the hundreds of dollars per prescription</td>
</tr>
<tr>
<td><strong>Pediatrics</strong></td>
<td>• Oral suspension for pediatrics in addition to capsules and intravenous formulations</td>
</tr>
<tr>
<td><strong>Pulmonologists, ER, Urgent Care MDs</strong></td>
<td>• Respiratory product - 80% of use in pulmonary infections</td>
</tr>
</tbody>
</table>

Source: 2013 IMS NPA, NDTI
Results from recent quantitative Market Research PULM, ID, PCP

• **What is your current level of satisfaction with current CABP treatments?**
  - 66% Somewhat Satisfied, 17% Very Satisfied

• **If you were told that macrolide resistance to pneumococcus has reached 50%, would you seek an alternative treatment?**
  - 96% Yes

• **Are you concerned with safety of fluoroquinolones (levofloxacin/moxifloxacin)?**
  - 65% Yes

What is needed is a new antibiotic that has the efficacy of a fluoroquinolone but the safety of the macrolide class

Source: Instar Market Research, N = 120
Cempra Believes It Can Successfully Launch Solithromycin

- There is a recognized urgent need for a new macrolide
- IV/PO formulations allow in-patient and outpatient dosing
- A select group of providers write a disproportionate share of AZ and LEVO CABP prescriptions
- Acute CABP prescriptions are not actively managed by 3rd party payors
- Cempra has a unique opportunity to own 100% share of voice of the branded antibiotic CABP market
- We expect the price to be in the hundreds of dollars and not in the thousands - we expect to be a favorable formulary tier with reasonable patient co-pays
A very small group (4%) writes a disproportionate share of AZ and LEVO CABP prescriptions (40%).

4% of Prescribers (34,927) Out of a total of 803,717

40% of AZ/LEVO CABP TRxs

SOURCE: IMS Deciler Prescriber Level Data, Time Period: Moving Annual Total (MAT) FEB 2015.
~80,000 Prescribers are Responsible for 60% of TRx volume

~43,000 HCPs*
Targeted thru non-personal
24 Rx’s per year

~35,000 HCPs*
Targeted thru personal and non-personal
62 Rx’s per year

*SOURCE: IMS Deciler Prescriber Level Data, Time Period: Moving Annual Total (MAT) FEB 2015
Launch Preparation Underway

Pre-launch Activities

1st Half 2016
- Launch API
- Disease Awareness
- Commercial Leads
- MSLs
- KOL Development
- Physician Targeting

2nd Half 2016
- Finished Goods
- Digital Tactics
- Infrastructure
- Pricing & Reimbursement
- Coming Soon Ads

Launch
- Inventory / AR
- Branded Campaign
- Sales Force
- Medical Education
- Payer Contracting
Taksta™ (Fusidic Acid)

An ORAL Antibiotic for MRSA Infections Being Developed for ABSSSI and for CHRONIC Use in Bone and Joint Infections in the U.S.

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<tbody>
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<td>Chronic Bone and Joint Infections</td>
<td>Oral</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ABSSSI Initiated Dec 2015</td>
<td>Oral</td>
<td></td>
<td></td>
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</tbody>
</table>
Taksta Highlights

**Fusidic Acid**

- 40 Years of Safety and Efficacy in Acute and Chronic Oral Use in Staph Infections (Including MRSA) Ex-U.S.
- Unique Structure, No Known Cross Resistance
- **No Other Antibiotic Available For Long Term Oral Treatment of Staph Infections**

**CLINICAL TRIALS**
- Well Tolerated in ABSSSI Phase 2 Study; No Resistance Observed
- Phase 2 PJI Study Data Reported
- Phase 3 study for ABSSSI and exploratory refractory BJI study enrolling

**REGULATORY**
- QIDP granted for ABSSSI – Exclusivity and priority review
- Orphan Drug Designation for PJI Granted by FDA (Oct. 2013)
  - Request pending for Orphan Designation for refractory BJI
Strong IP Protection with Long Patent Runway

- **Loading Dose Patent to 2029** (Plus Patent Term Extensions)
- **12 Years** of Statutory Protections Possible (7 yrs Orphan Drug + 5 yrs GAIN)

**CEMPRA’S LOADING DOSE**
Concentration (mg/L)

**European Dosing**
- EU Dose 500 mg dose
- Cempra dose 1200 mg Q12h Day followed by 600 mg Q12h
Projected 2016 Milestones

4.28.16: Completed NDA submissions to FDA for Solithromycin Oral capsules and IV formulation

1H 16: Complete MAA submissions to EMA for Solithromycin Oral capsules and IV formulation

7.1.16: Acceptance of NDAs

12.30.16: NDAs Approved

1H 16: Solithromycin: Initiate global Phase 2/3 Pediatrics pivotal trial (BARDA)

EOY 16: Solithromycin: Complete Phase 1b - Pediatrics. All formulations

EOY 16: Solithromycin: Complete enrollment in Phase 2 NASH Trial

EOY 16: Solithromycin: Complete enrollment in Phase 2 COPD Trial
Finance - Strong Balance Sheet

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