



# **Investor Presentation**

**Updated March 2, 2009**

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# Corporate Highlights

## ■ SPECIALTY PHARMACEUTICAL COMPANY

- Leverage novel proprietary patent-protected drug delivery technologies to rapidly advance the commercialization of new applications of proven therapeutics to address unmet market needs

## ■ HIGH ROI DRUG DEVELOPMENT PLATFORM

- Utilize the 505 (b)(2) regulatory process to bring products to market faster, with less risk, and at lower costs resulting in higher return on investment

## ■ FOCUSED COMMERCIAL APPROACH

- Commercial focus on products targeting conditions common to surgical and oncology patients such as pain and infections

## ■ COMPELLING BILLION DOLLAR PORTFOLIO PROJECTED

- **Near-term product opportunity:** ONSOLIS™ (BEMA™ Fentanyl), 1H 2009 approval anticipated; Strong marketing partner – MEDA AB
- **Medium-term product portfolio:** BEMA™ Buprenorphine, Bioral™ Amphotericin B Phase 2 in 2009

## ■ STRONG FINANCIALS

- No Debt; Near-term revenue opportunities - \$30 million plus royalties upon ONSOLIS™ approval and commercial launch.



# Capital Efficient Business Model

Lead product ONSOLIS™ – Early and significant return on investment

Product Development		Product Return	
Timeline to NDA	3 Years	Received – Deal Closing	\$30M
		Upon NDA Approval	\$30M
Total Costs	<\$25M	Upon Sales Milestones	\$30M
		Sales Royalty*	<i>Double-digit</i>

\* Approval anticipated 1H09

# Key Value Driver: 1H 2009 Approval of ONSOLIS™ Anticipated For Breakthrough Cancer Pain

- August 28, 2008: BDSI received a *Complete Response Letter* from FDA
- ONSOLIS™ Complete Response Content:
  - Conversion of risk minimization action plan (“RiskMAP”) to a risk evaluation mitigation strategy (“REMS”)
  - No other deficiencies noted, including chemistry, manufacturing and controls, nonclinical, or clinical efficacy/safety.
- Resubmission completed December 12, 2008
  - Anticipate 1<sup>st</sup> half 2009 approval

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# ONSOLIS™ Market Opportunity

# Significant Market Opportunity – Breakthrough Cancer Pain

## Current/Future Market Size:

- US cancer breakthrough pain market:  
Branded Drugs - sales estimated to grow from \$400 mln → ~\$1.3 bln by 2017<sup>1</sup>

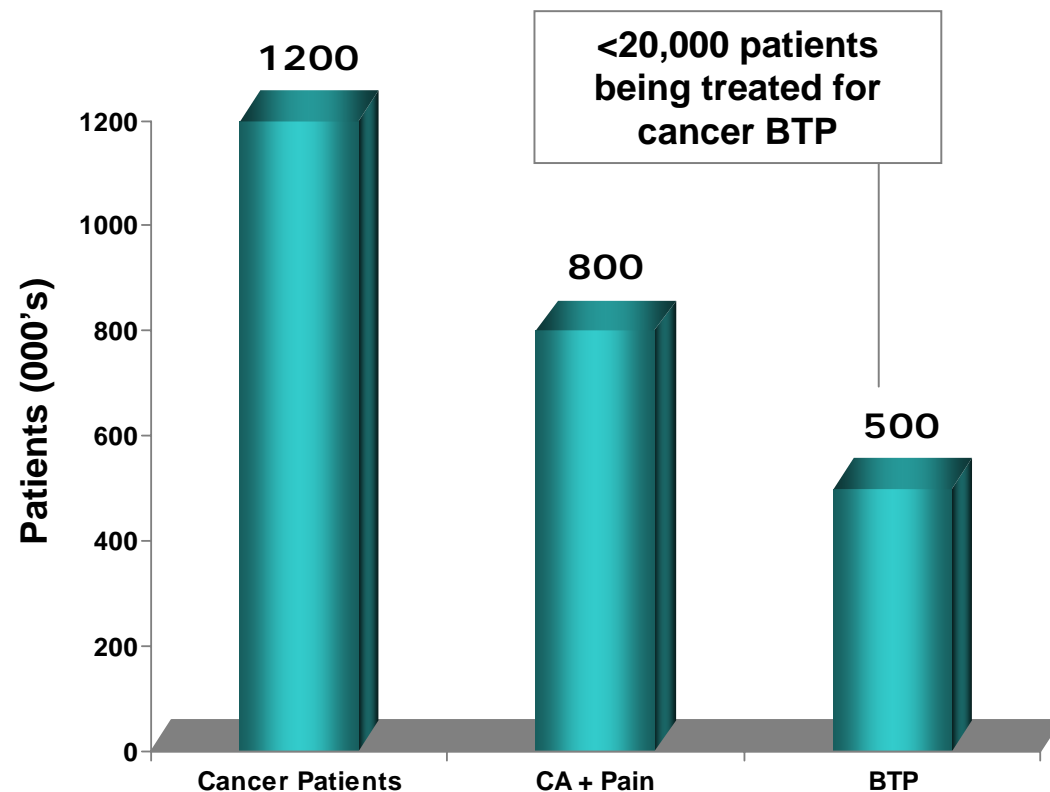
## Current Market Leaders<sup>2</sup> :

- Fentora™: \$182 million
- Actiq®/Generics: \$562 million

Source:

<sup>1</sup> Datamonitor, Commercial & Pipeline Insights – Opioids; March 2008

<sup>2</sup> Wolters Kluwer, 2008 sales



Source: Data Monitor

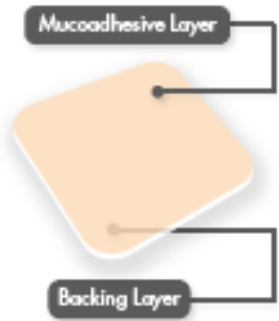
(US Data Only-calculations based on one year incidence, actual numbers will be higher due to survival beyond one year)

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# BEMA™ Drug Delivery Technology

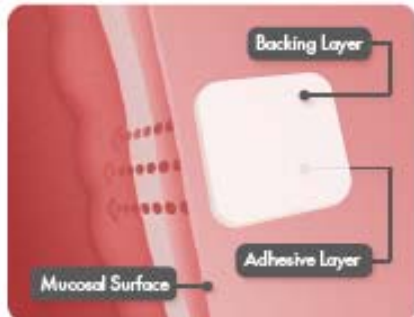
# BEMA™ (BioErodible MucoAdhesive) Film Technology



- ⇒ Bi-layered film technology
- ⇒ Active drug in the muco-adhesive layer
- ⇒ Backing layer facilitates unidirectional flow of drug



- ⇒ Adheres to oral mucosa in < 5 seconds
- ⇒ Dissolves within 15-30 minutes



- ⇒ Designed to optimize delivery across the mucosa

## ***BEMA attributes:***

- ***Convenient***
- ***Easy to use***
- ***Good oral tolerability in clinical studies***
- ***Cannot be crushed or snorted***

# ***Near-Term Product Opportunity:***

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**ONSOLIS™ under review at FDA**

**Commercial partnership with MEDA**

# Transmucosal Fentanyl Delivery Systems

Actiq®  
(1996)



**Formulation:** Oral transmucosal lozenge

**Administration:** Place between cheeks and gums and actively suck while moving around the mouth.

Fentora®  
(2006)



**Formulation:** Buccal tablet

**Administration:** Place between cheek and gums above a molar. Allow to dissolve. After 30 minutes, if remnants still remain, swallow with a glass of water.

ONSOLIS™



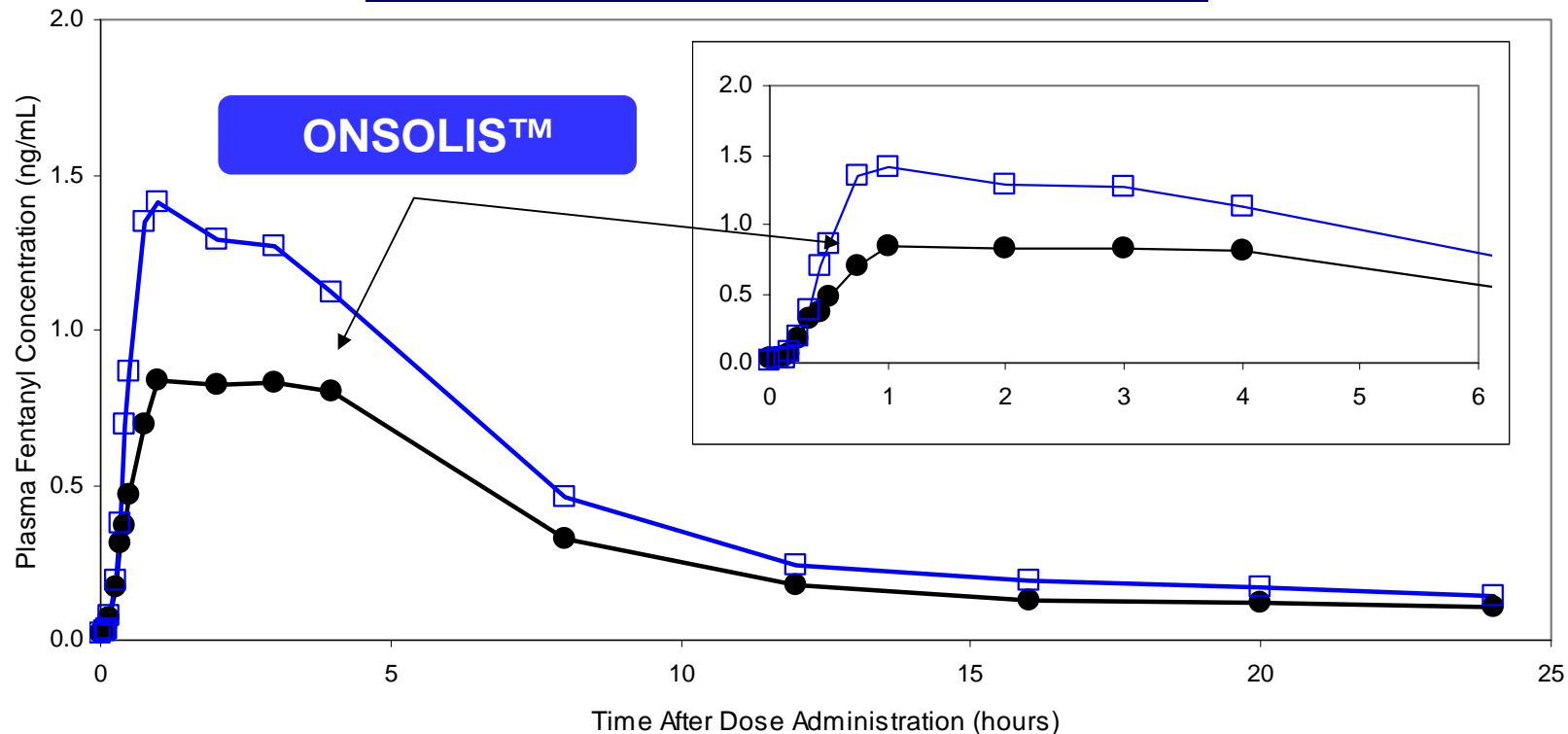
**Formulation:** Buccal soluble film

**Administration:** Place inside mouth on inner cheek. Hold for 5 seconds. Dissolves within 15-30 minutes.

# Greater and More Rapid Absorption of Fentanyl Compared to Actiq® in this PK Study

Plasma Concentrations – 800 mcg doses\*

40% Greater Absorption versus Actiq®

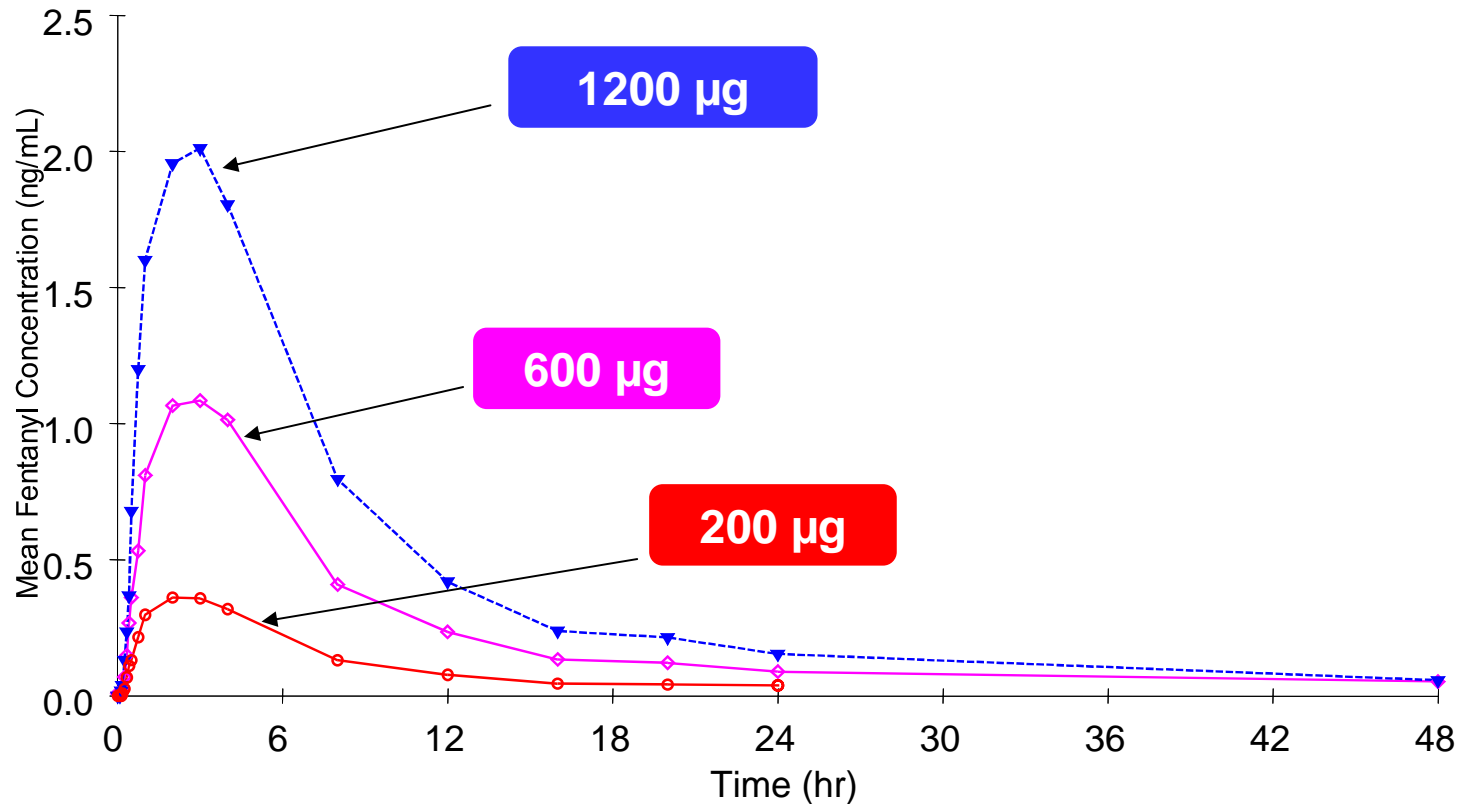


- The mean peak concentration was higher after ONSOLIS™ than Actiq®
- The median Tmax was shorter on ONSOLIS™ (1 hour) than Actiq® (2 hours)

# ONSOLIS™: Dose Proportionality Across Dose Range

## ONSOLIS Plasma Fentanyl Concentrations

### Dose Proportionality Demonstrated Based on Linear Pharmacokinetics



# Pivotal Trial: Results

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- **Primary Endpoint:**
  - **SPID 30 ( P=0.004)**
- Secondary Endpoints (statistically significant difference):
  - SPID 15
  - Global analysis of product (overall patient satisfaction)
- Efficacy and safety established with over 82,000 doses administered in the clinical development program

# ONSOLIS™ Attributes

<b>Convenient, Easy to use</b> <i>“Adheres – Delivers - Dissolves”</i>	<b>Thin Film</b> <b>(simple placement)</b>
<b>Provides linear pharmacokinetics across full dose range</b> <ul style="list-style-type: none"><li>- Dose range</li><li>- Effective dose not found</li></ul>	<b>200 – 1200 mcgs</b> <b>3%*</b>
<b>Good Oral Tolerability</b> <ul style="list-style-type: none"><li>- Incidence of drug-related application site AEs</li><li>- Discontinued due to application site AEs</li></ul>	<b>2.0%*</b> <b>0%*</b>

\* % patients in FEN-201 and FEN-202 Phase 3 clinical studies

# ONSOLIS™ Represents a Significant Financial Opportunity for BDSI

## Financial Benefits to BDSI

- \$30 million upon NDA approval and commercial launch
- \$30 million for achievement of specified sales milestones
- Significant double digit royalty
- Meda covers all future development costs for ONSOLIS including REMS program; Phase IIIB-IV and Non-Cancer Breakthrough Pain program

## Peak Forecast Sales in excess of \$200 million\*

- Anders Lonner, CEO of Meda AB, stated “*BEMA Fentanyl represents a huge opportunity for us in the U.S. Our ambition with this product within the breakthrough cancer pain in opioid tolerant patients indication is to reach well over \$200 million in yearly sales.*”

\* BDSI estimate

# ONSOLIS™ Global Commercialization Partner\*: MEDA AB

- *Intl specialty pharma based in Sweden*
- *2,500 employees/1,650 com ops*
- *Sales: 2001 - 2007: \$30M → \$1.3B*
- *Significant US presence via MedPointe (Carter Wallace) acquisition in 2007*
- *Therapeutic expertise includes pain/inflammation (Soma®, tramadol, NSAIDs) and respiratory (Astellin®)*



***Global partner – pain experience***

***ONSOLIS™ #1 priority worldwide***

***Primary detailing position - 2 yrs***

***Over 400 US sales reps; coverage of pain specialists***

\* Licensing agreement does not include Taiwan and South Korea

# Medium-Term Product Portfolio – Phase 2 in 2009

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**BEMA™ Buprenorphine**

*- Entry into the broader pain market*

**Bioral™ Amphotericin B**

*- Oral fungicidal; Potential to be first to market*

# BEMA™ Buprenorphine: Schedule III Narcotic

## BDSI's Entry Into Broader Pain Market

### *Market Need*

- Rapidly escalating problem of opioid abuse and addiction in the US
- Short and long-term side effect issues with opioids
- Safety issues with COX-2 inhibitors and NSAIDS

### *Available Formulations*

- IV: Moderate to severe acute pain; e.g. post-op (US)
- SL & Transdermal: Acute and chronic pain (EU)

### *Potential Attributes*

- Lower abuse and addiction potential
- Lower incidence of opioid side effects
- Once daily dosing

### *Development Goals*

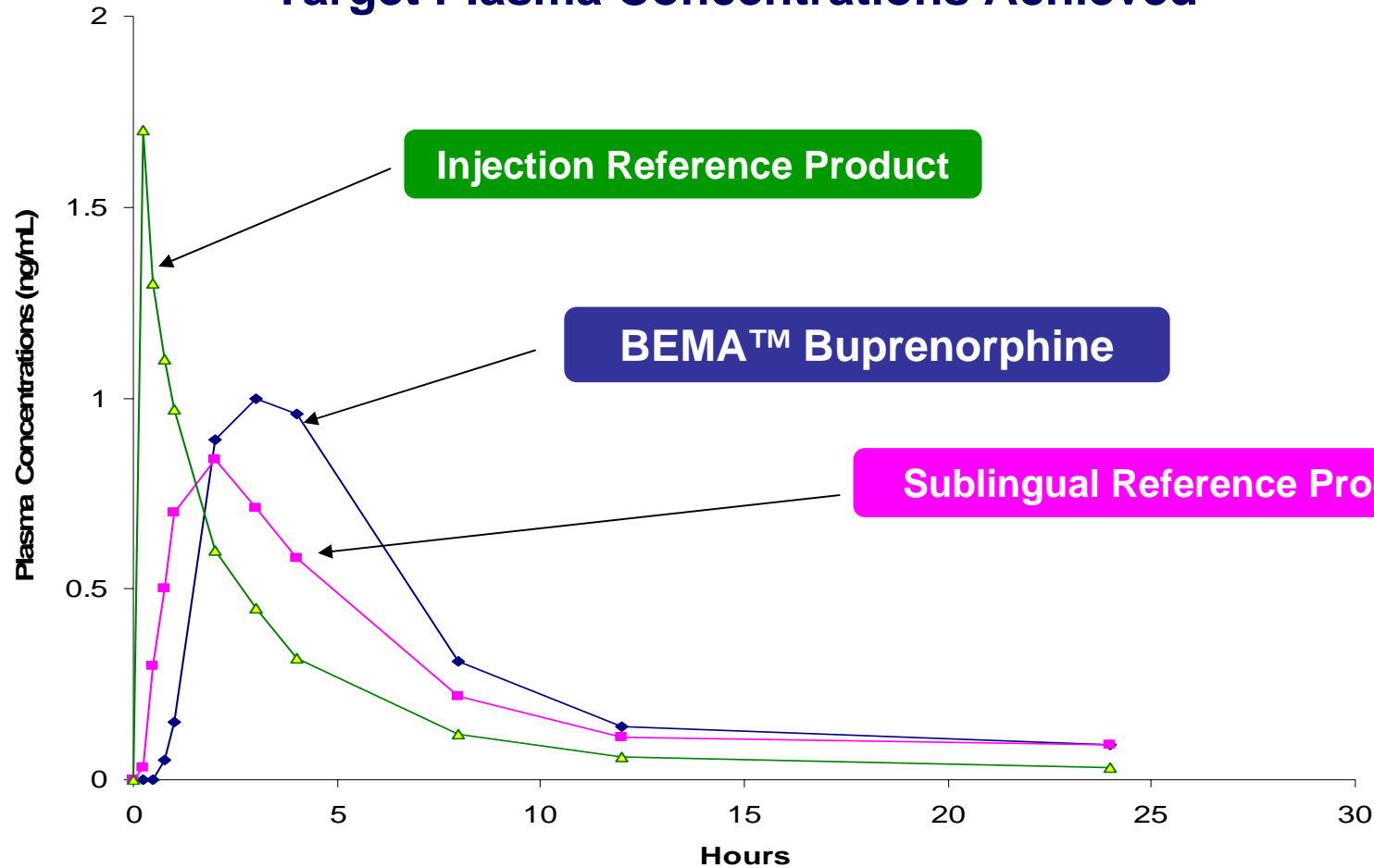
- Initial indication: Moderate to severe post-op pain
- Follow-on indications: Chronic pain (back Pain, osteoarthritis)

### *Market Opportunity*

- Peak Forecast Sales Potential >\$500 million \*

# BEMA™ Buprenorphine Initial PK Study

## Target Plasma Concentrations Achieved



\*Data from BUP-101; mean plasma concentrations in normal volunteers

# Buprenorphine – Insight from European Prescribers<sup>1</sup>

- Potential for abuse is “considerably less” than for other opioid products
  - Consequence of the absence of euphoria (due to partial agonist activity)
- Does not usually cause opioid side effects that patients often dislike, including:
  - Constipation
  - Respiratory depression
  - Cognitive confusion and memory loss
- Best suited for moderate to severe pain, including:
  - Lower back pain that has not responded to other medications such as NSAIDS
  - Non-tumor, chronic pain
  - Neuropathic pain (including post-herpetic)
  - Post-op: including thoracic, abdominal, hip replacement, joint replacement
  - Post-trauma pain

<sup>1</sup> Mattson Jack Group, Research conducted February 2008

# BEMA™ Buprenorphine Development Plan

## Buprenorphine:

- Currently approved for:
  - I.V.: Moderate to severe acute pain; e.g. post-operative (US)
  - SL & Transdermal: Management of acute and chronic pain (outside US)

## BEMA™ Buprenorphine Development:

- Initial indication: Moderate to severe post-operative pain, 505(b)(2)
- Potential follow-on indications: Chronic Pain (e.g., Low Back Pain & Osteoarthritis)

***Overall goal is to fulfill an unmet need between NSAIDs and CII drugs (e.g., OxyContin®, Vicodin®, etc.)***

# BEMA™ Buprenorphine: Market Opportunity

- Initial market research - (May '06; 75 Pain specialists and 75 PCPs)<sup>1</sup>
  - 25-33% of their pain patients would be switched to BEMA™ Buprenorphine
- Follow up research - (May '08; 42 Pain specialists and PCPs)<sup>2</sup>
  - Most physicians of either specialty expressed considerable receptivity to the description of the new buprenorphine product.
  - Physicians estimated that they would prescribe this in about one-quarter of their chronic and one-quarter of their acute pain patients.

## Minimum Peak Forecast Sales: \$500 million\*

- Represents approximately <2% of the total pain market

<sup>1</sup> Medical Marketing Research, Research conducted May 2006

<sup>2</sup> Mattson Jack Group, Research conducted May 2008

\*BDSI Estimate

# BEMA™ Buprenorphine Development Timeline

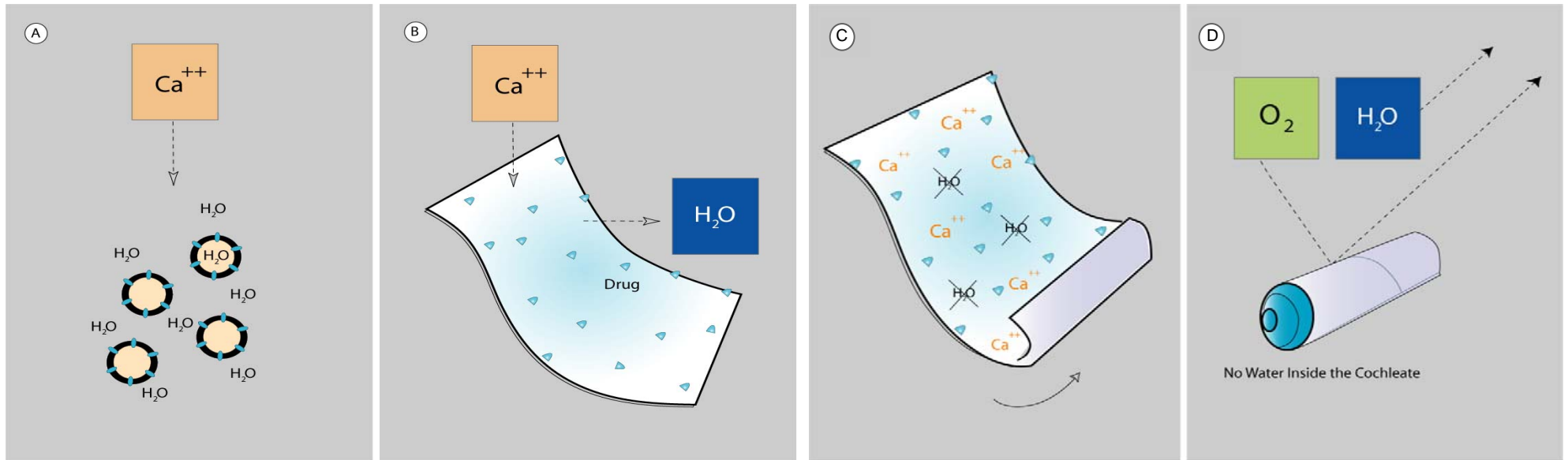
<b>Phase 1</b>	Complete 1Q 2009
<b>Phase 2</b>	Dental pain study 2Q 2009 Osteoarthritis study 3Q 2009
<b>Phase 3</b>	Planned for 1Q 2010
<b>Commercial Partner</b>	Anticipated 1Q 2010
<b>NDA Submission</b>	Anticipated 1H 2011

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# Bioral™ Technology

# Bioral™ Technology: IV → Oral Delivery

## How Cochleates Encapsulate and Protect Drugs



**Calcium Interaction with Negatively Charged Lipid**

**Formation of Stable Drug-Cochleate Nano Crystal**

# Bioral™ Amphotericin B: Potential First Oral Fungicidal

## *Market Need*

- Drug resistance to existing oral “fungistatic” agents leads to hospitalization and IV amphotericin B treatment
- No orally available agents

## *Development Goals*

- First oral fungicidal agent; Potential to prevent hospitalizations and/or facilitate earlier patient discharge
- Treatment of esophageal candidiasis
- Improved tolerability

## *Development Support*

- Cooperative R&D agreement (CRADA) with Walter Reed Army Institute for Research (WRAIR): Leishmaniasis
- Drugs for Neglected Disease initiative (DND<sup>i</sup>) –clinical program for neglected parasitic diseases

## *Market Opportunity*

- Peak Forecast Sales >\$400 million \*

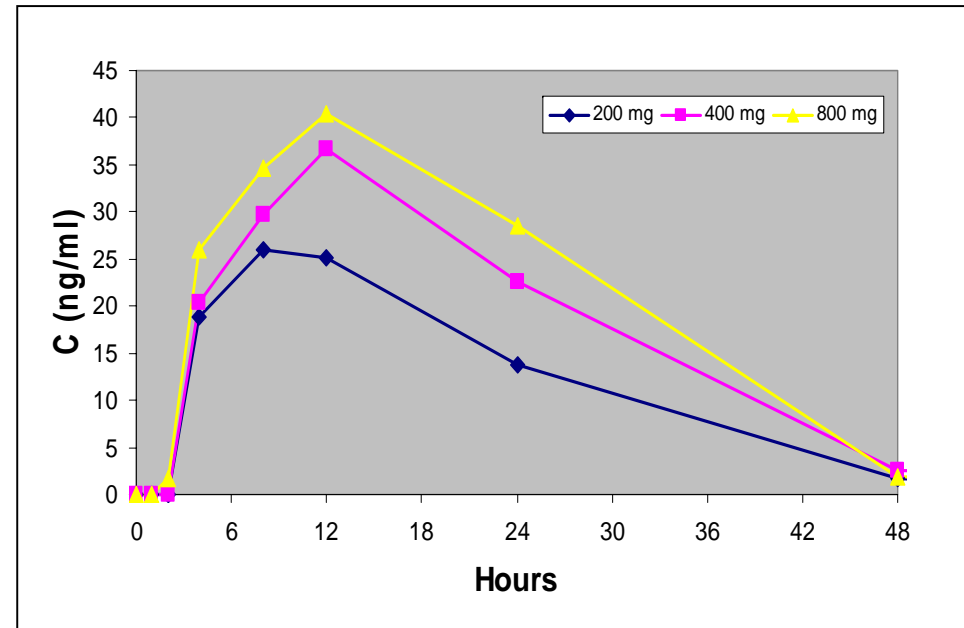
\* BDSI estimate

# Phase 1 Study Results Show Tolerability and Plasma Concentrations of Amphotericin B

## *Oral Administration of Bioral Amphotericin B in Humans: A Phase 1 Study of Tolerability and Pharmacokinetics\**

### Study Conclusions:

- Bioral Amphotericin B was well-tolerated at single oral doses of 200 and 400 mg
- Plasma concentrations of Ampho are comparable to prior results from animal studies
- Adverse events were primarily GI related and mild in all cases with the 200 and 400 mg dose.
- No abnormalities in lab values or other safety testing, including those associated with renal function.



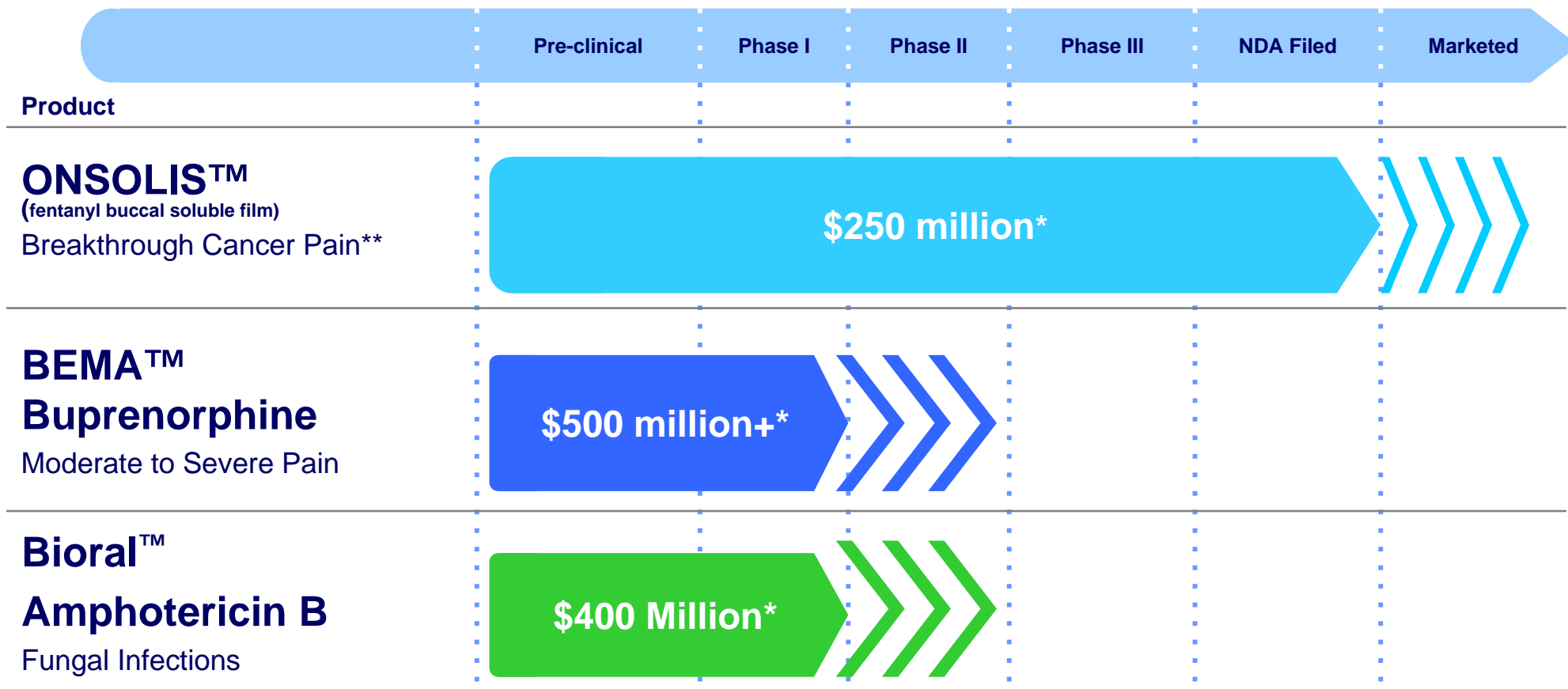
\* Abstract presented at the Focus on Fungal Infections Meeting, March 2009

# Bioral™ Amphotericin B Development Timeline\*

<b>Phase 1</b>	Single dose study of safety, tolerability and pharmacokinetics completed 4Q 2008 Multi-dose pharmacokinetic study 2Q 2009
<b>Phase 2</b>	Leishmaniasis 2010
<b>Phase 3</b>	Esophageal Candidiasis: Planned for 2011
<b>Commercial Partner</b>	Anticipated 1Q 2010

\* Research and development partnership with Drugs for Neglected Diseases initiative (DNDi) and Walter Reed Army Institute for Research.

# Product Portfolio Summary



\* peak sales potential, BDSI estimate

\*\* Opioid tolerant patients

Anticipated in 2009

# 2009 Revenue Opportunities

- ONSOLIS™ ROW License/Milestone Advance (1/09) \$6.0 Million
- ONSOLIS™ NDA Approval & Launch \$30.0 Million\*
- ONSOLIS™ EU Approval & Launch \$5.0 Million
- Royalty on Sales of ONSOLIS™ Double-digit

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**> \$40 Million Potential**

Includes \$3.0 million advance received January 2009

# Investor Highlights: BDSI

- **2 Novel, Patented Drug Delivery Platforms** (BEMA™, Bioral™)
- **Near-Term Product Opportunity:** ONSOLIS™ (BEMA™ Fentanyl) approval anticipated in 1H 2009, Strong Commercial Partner making ONSOLIS™ #1 Global Priority
- **Medium-Term Product Portfolio** (BEMA™ Buprenorphine, Bioral™ Amphotericin B) = Revenue Growth Potential
- **Strong Financials:**
  - Debt free
  - > \$40 Million Revenue Potential in 2009
  - Anticipated cash flow positive from operations

\* Market cap (02/27/09): \$61 million based on 19.2 million shares outstanding at \$3.18