



**Cowen & Company 29th
Annual Health Care Conference**

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**Dr. Mark A. Sirgo
President & Chief Executive Officer**

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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.



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 1st half 2009 approval

Transmucosal Fentanyl Drug Delivery Technologies

Competitive Landscape

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.

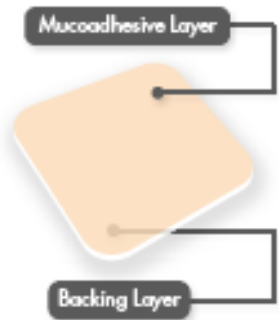
ONSOLIS™



Formulation: Buccal soluble film

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

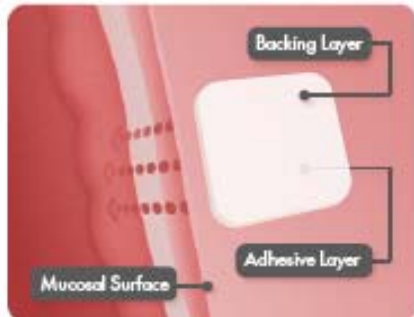
BEMA™ (BioErodible MucoAdhesive) Film Technology



- ⇒ 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:

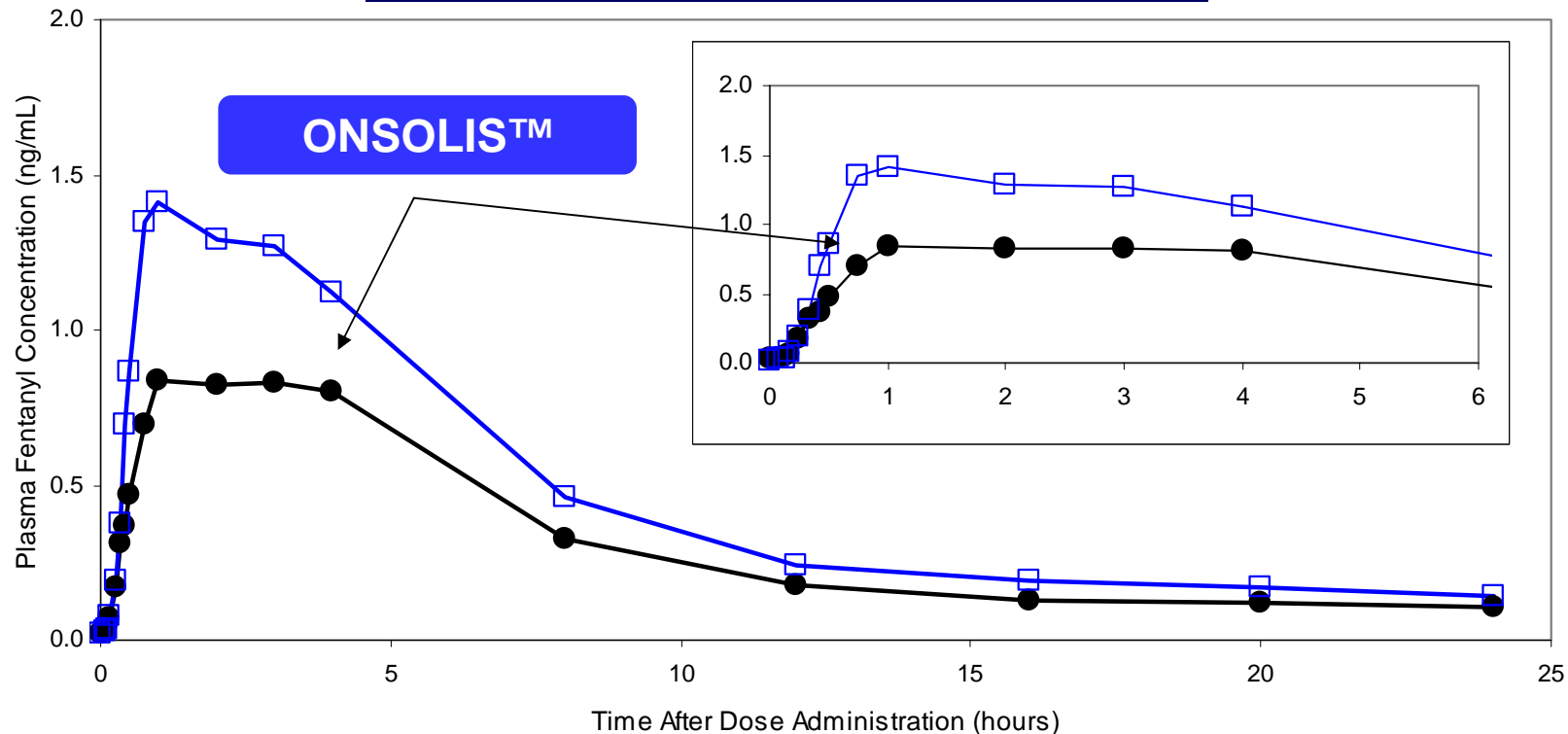
- ***Convenient***
- ***Easy to use***
- ***Good oral tolerability in clinical studies***
- ***Cannot be crushed or snorted***

ONSOLIS™ - Profile and Attributes

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

Plasma Concentrations – 800 mcg doses*

40% Greater Absorption versus Actiq®

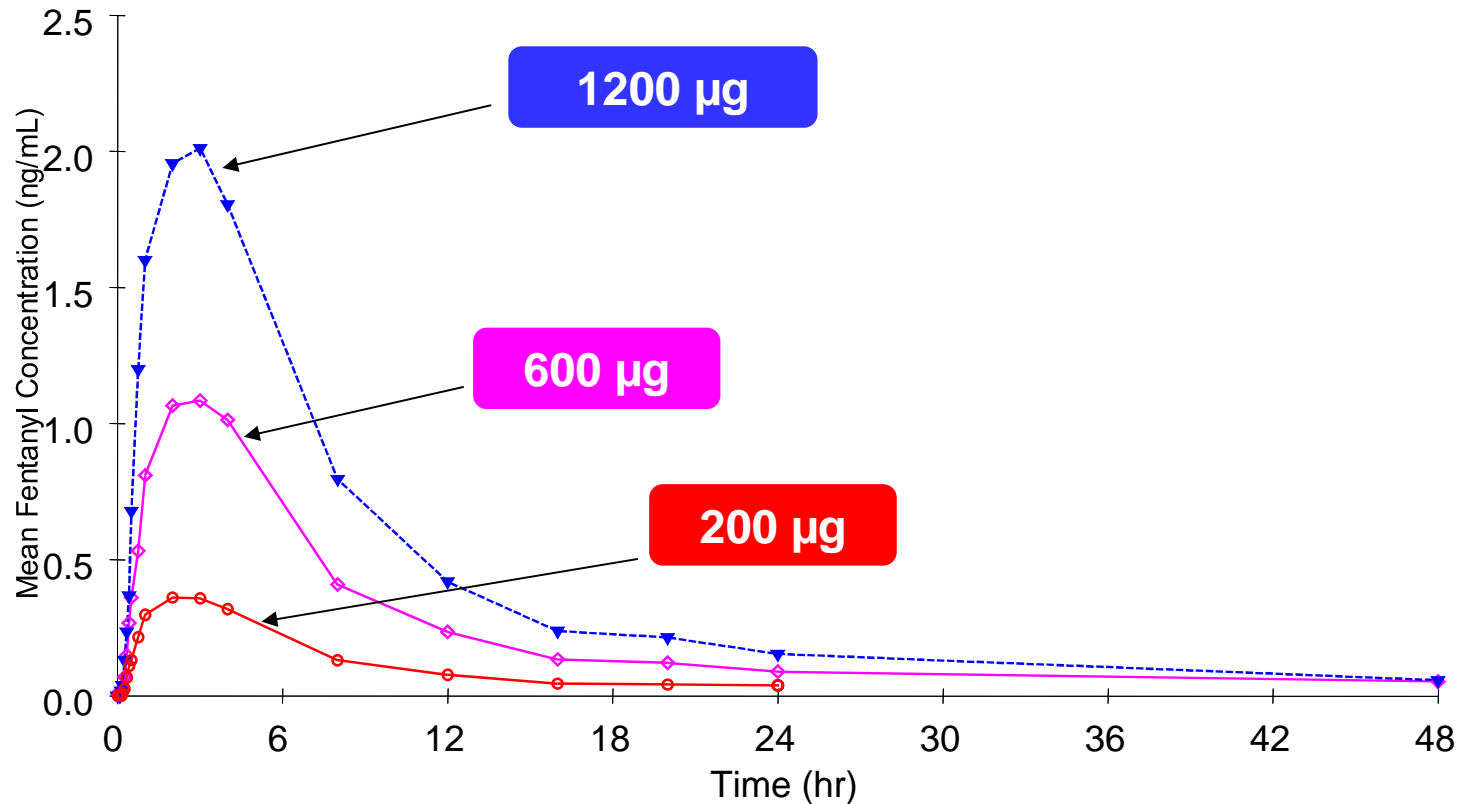


- The mean peak concentration was higher after ONSOLIS™ than Actiq®
- The median Tmax was shorter on ONSOLIS™ (1 hour) than Actiq® (2 hours)

ONSOLIS™: Dose Proportionality Across Dose Range

ONSOLIS Plasma Fentanyl Concentrations

Dose Proportionality Demonstrated Based on Linear Pharmacokinetics



ONSOLIS™ Attributes

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

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

ONSOLIS™ Market Opportunity

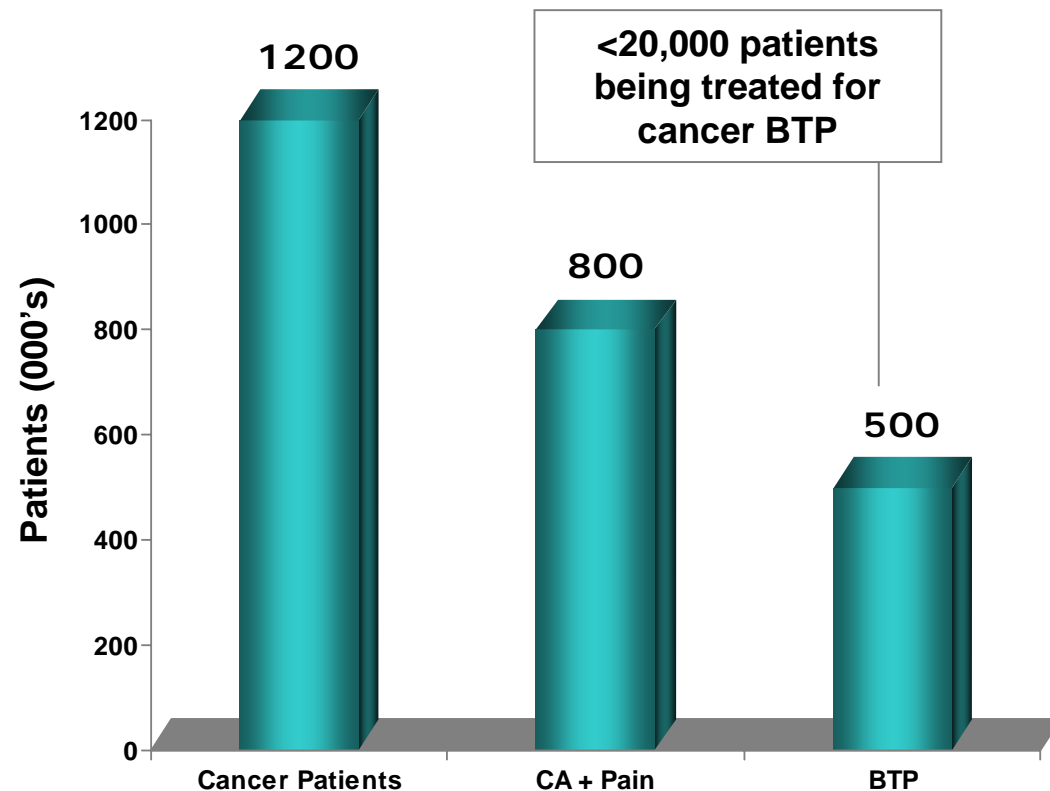
Significant Market Opportunity – Breakthrough Cancer Pain

Current/Future Market Size:

- US cancer breakthrough pain market:
Branded Drugs - sales estimated to grow from \$400 mln ➔ ~\$1.3 bln by 2017¹

Current Market Leaders² :

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



Source:

¹ Datamonitor, Commercial & Pipeline Insights – Opioids; March 2008

² 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)

ONSOLIS™ Commercial Partner

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

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



Capital Efficient Business Model

ONSOLIS™ – Early and significant return on investment

Product Development	
Timeline to NDA	3 Years
Total Costs	<\$25M

* Approval anticipated 1H09

Medium-Term Product Portfolio

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

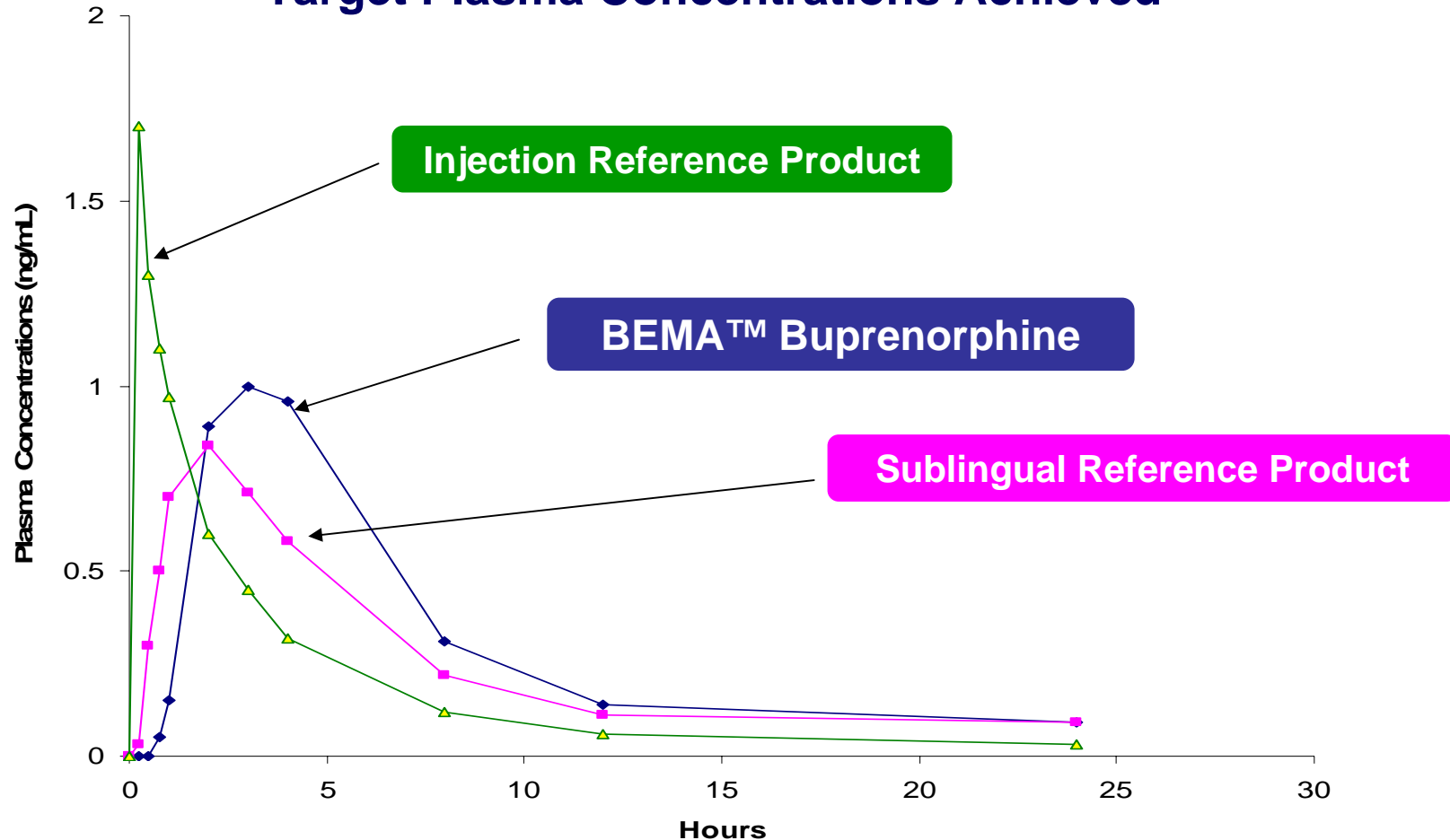
- Initial indication: Moderate to severe post-op pain
- Follow-on indications: Chronic pain (back Pain, osteoarthritis)

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

BEMA™ Buprenorphine Development Timeline

Phase 1	Complete 1Q 2009
Phase 2	Dental pain study 2Q 2009 Osteoarthritis study 3Q 2009
Phase 3	Planned for 1Q 2010
Commercial Partner	Anticipated 1Q 2010

Bioral™ Drug Delivery Technology

IV → Oral Delivery

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 (DNDⁱ) –clinical program for neglected parasitic diseases

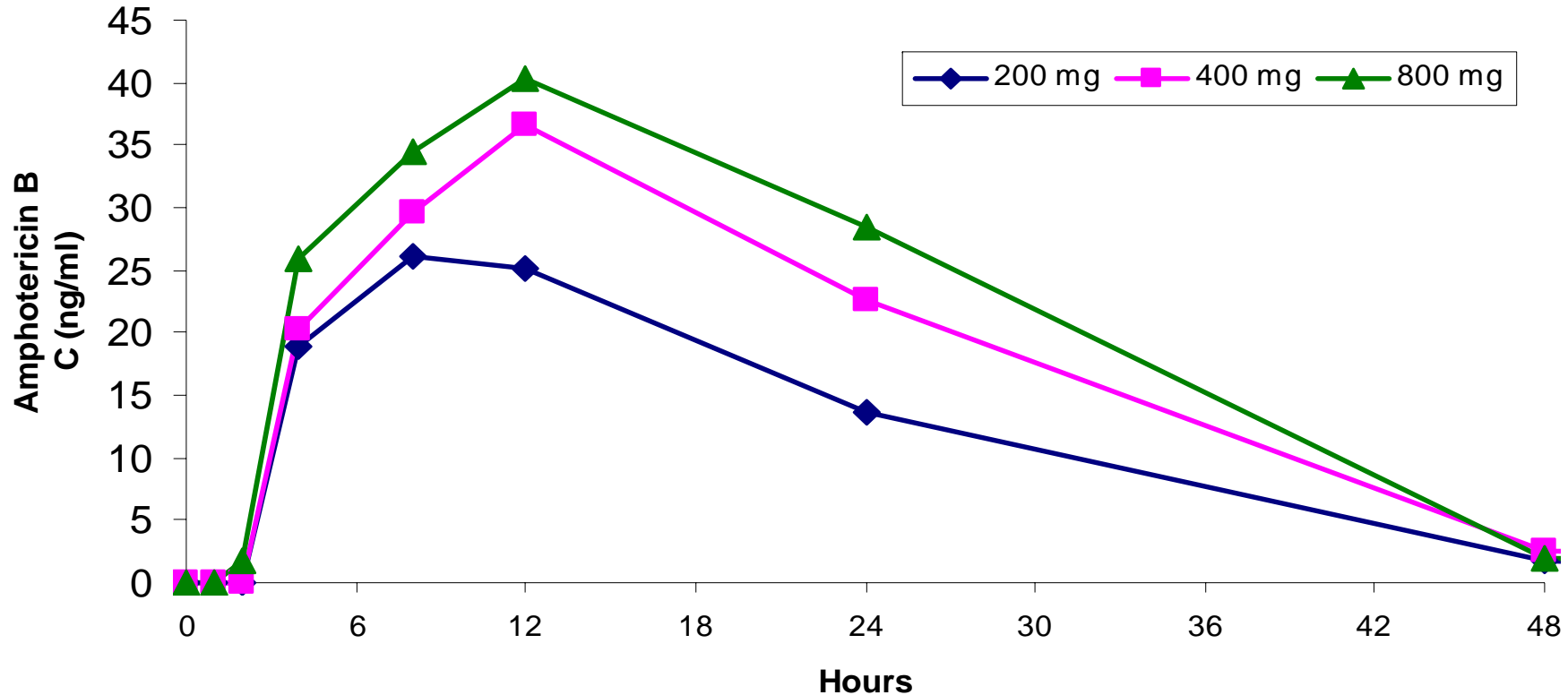
Market Opportunity

- Peak Forecast Sales >\$400 million *

* BDSI estimate



Phase 1 Study Results - Bioral™ Amphotericin B



- Bioral™ Amphotericin B was well-tolerated at single oral doses of 200 & 400 mg
- Plasma concentrations of Amphotericin are comparable to prior results from animal studies

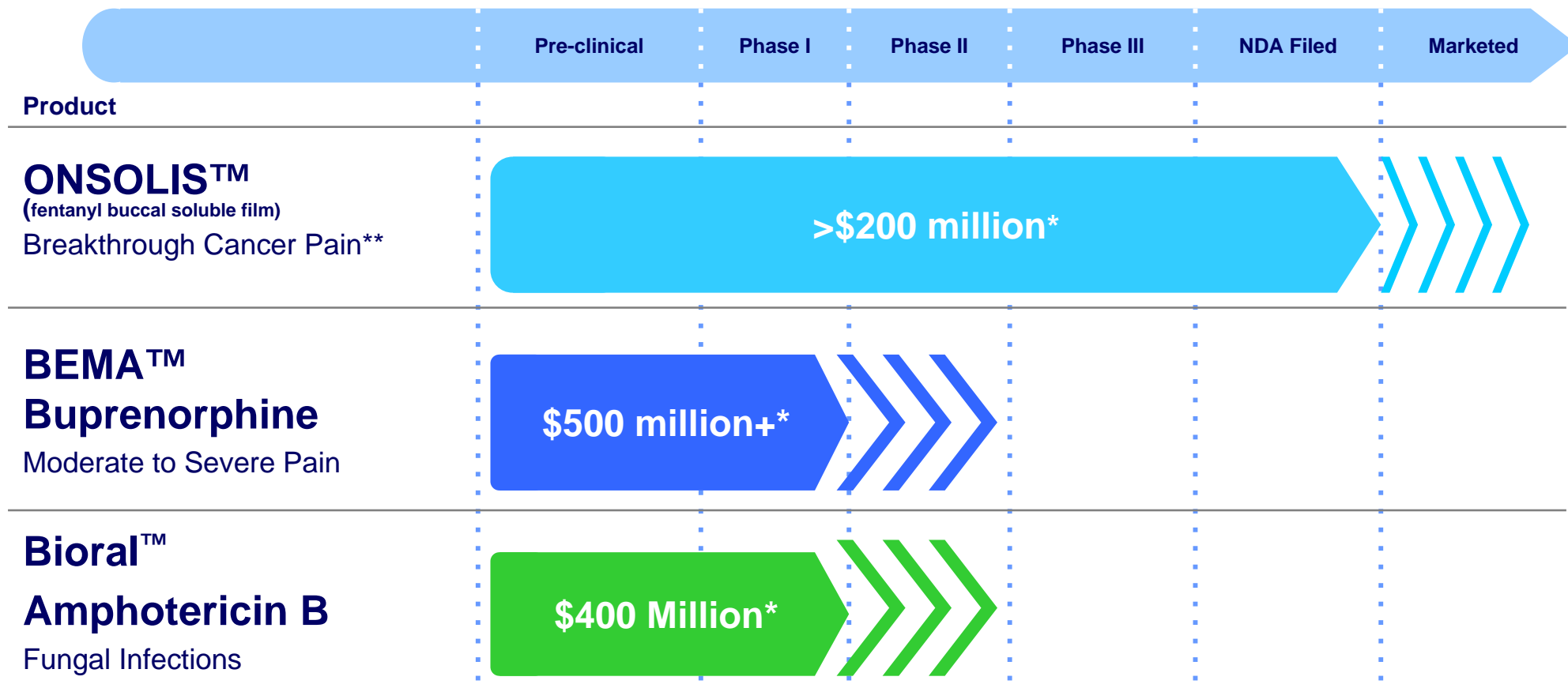
* Abstract presented at the Focus on Fungal Infections Meeting, March 2009

Bioral™ Amphotericin B Development Timeline*

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

> \$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 Potential** (BEMA™ Buprenorphine, Bioral™ Amphotericin B) = Revenue Growth Potential
- **2009 Key Financials:**
 - Debt free
 - > \$40 Million Revenue Potential and cash flow positive 2009

* Market cap (03/10/09): \$56 million based on 19.2 million shares outstanding at \$2.92

