BDSI – Fully Integrated Specialty Pharmaceutical Company with a Focus in Pain and Addiction Medicine

Leveraging novel drug delivery technologies to develop and commercialize new applications of proven therapeutics

- Use FDA 505(b)(2) regulatory process
- Ability to bring products to market faster, with less risk and cost

2016 – Key Value Drivers

- **BELBUCA™ (buprenorphine HCl) buccal film (CIII) – Chronic Pain**
  - Launched by Endo Pharmaceuticals; mid to upper teen royalty on net sales

- **BUNAVAIL® (bup/naloxone) buccal film (CIII) – Opioid Dependence**
  - 41% increase in net revenue in Q1 2016 versus the prior quarter
  - Reduced cost structure and growth opportunities allow BUNAVAIL to reach profitability by end of 2017

- **ONSOLIS® (fentanyl buccal soluble film)(CII) – Cancer BTP**
  - Licensed to Collegium Pharmaceutical; anticipated return to market mid-2017

- **Continued progression of pipeline**
  - Clonidine Topical Gel Phase 2B study enrolling; last patient out by end of year
  - Buprenorphine 30 day injection IND submission 3Q
# BDSI Product Portfolio: Commercialization Strategy

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<tr>
<th></th>
<th>Formulation Development</th>
<th>Phase I</th>
<th>Phase II</th>
<th>Phase III</th>
<th>NDA</th>
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<td><strong>ONSOLIS®/BREAKYL™</strong></td>
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<td><strong>Clonidine Topical Gel</strong></td>
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<td><strong>Buprenorphine Depot Injection</strong></td>
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*Licensed to Endo Pharmaceuticals for all territories worldwide.
**Licensed to Meda for all territories outside North America except Taiwan (TTY BioPharm). North American rights licensed to Collegium Pharmaceutical.
BEMA® (BioErodible MucoAdhesive) Film Technology

Commercial Foundation of Portfolio
BEMA® (BioErodible MucoAdhesive) Technology

Bi-Layered, Dissolvable Film

Muco-adhesive layer with active drug

Paper thin

Backing layer designed to facilitate unidirectional flow of medicine
BEMA® (BioErodible MucoAdhesive) Advantages

- Bi-layered film technology
- Muco-adhesive layer adheres to oral mucosa in seconds
- Backing layer facilitates unidirectional flow across the oral mucosa, resulting in high bioavailability
- Drug absorbed within minutes
- Patient is free to talk while the film completely dissolves
- Pleasant taste
Opioid Dependence
Opioid Dependence Remains Under Diagnosed & Undertreated

Widespread opioid use – lack of alternatives

Most users unaware of their own dependence, do not seek treatment or are not diagnosed.

Poor treatment compliance, complex patient population and lack of prescribing physicians

1) National Institute on Drug Abuse (NIDA)
2) NSDUH, NIDA website
3) 2012 National Survey on Drug Use and Health, US Dept of Health and Human Services
4) Symphony Health Solutions, January 2014
Increased Focus on the Epidemic of Drug Addiction in the U.S.

Obama Administration Announces Additional Actions to Address the Prescription Opioid Abuse and Heroin Epidemic

White House, Office of the Press Secretary
March 29, 2016

Includes:

- Department of Health and Human Services (HHS) proposed rule to increase the current patient limit from 100 to 200
  - 60 day comment period ended May 31
  - Expected to add tens of thousands of new patients into treatment in first year
  - Proposal includes requirements for diversion control planning

- Doubling the number of buprenorphine prescribers in the next three years (2,200 committed to date)

- Funding to increase substance use disorder treatment services

First and only bi-layered buccal film for the maintenance treatment of opioid dependence
Efficient delivery: 2X bioavailability of buprenorphine vs Suboxone tablet
- May limit potential for misuse/diversion; potentially lessen incidence of certain side effects

Easy and convenient for patients to use
- Adheres in seconds; patients free to speak and go about normal activities
- > 8 out of 10 patients – rated use as very easy, easy or neutral

Effective and well tolerated over the course of 12 week study
- Only 8% of patients had a positive urine test for non-prescribed opioids
- 68% experiencing constipation on Suboxone saw resolution when switched to BUNAVAIL

BUNAVAIL is indicated for the maintenance treatment of opioid dependence. BUNAVAIL should be used as part of a complete treatment plan to include counseling and psychosocial support. BUNAVAIL is contraindicated in patients with hypersensitivity to buprenorphine or naloxone. Adverse events commonly observed with administration of BUNAVAIL during clinical trials are headache, nausea, vomiting, hyperhidrosis, constipation, signs and symptoms of withdrawal, insomnia and pain. See www.Bunavail.com for more information including full prescribing information.

Data from a self-administered symptom check list (n=186) in BNX-201 reported the incidence of constipation in patients discontinuing treatment with Suboxone decreased after 12 weeks of treatment with BUNAVAIL.
Launch Progress
BUNAVAIL® Launch Progress

BUNAVAIL quarterly prescription growth

- Over 100,000 prescriptions for BUNAVAIL dispensed since launch

Source: Symphony Health, Monthly Rx sales. April based on weekly Rx's.
Growing BUNAVAIL® Prescriber Base

Source: Symphony monthly prescriber volume
# Opioid Dependence Market Challenges and Solutions

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<th>Challenges</th>
<th>Progress Made</th>
<th>Opportunities</th>
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<tr>
<td>Physician resistance to change</td>
<td>&gt;3,000 prescribers</td>
<td>Education on benefits of BUNAVAIL</td>
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<td>&gt;3,000 prescribers</td>
<td>Cap lift provides “new” patients</td>
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<td>Tennessee Medicaid exclusive</td>
<td>Contracting</td>
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<td>Peer influence programs</td>
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<td>Patient influence on product selection</td>
<td>&gt;110,000 Rx’s</td>
<td>Direct to patient initiative</td>
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<td>Diversion, Misuse and Abuse</td>
<td>Tennessee Medicaid experience</td>
<td>Increased focus on diversion control</td>
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<td>Contracting platform</td>
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Managed Markets Update
## Improved Managed Care Positioning and Additional Opportunities in 2016

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<thead>
<tr>
<th>Payer</th>
<th>Status</th>
<th>2016 Focus</th>
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<tr>
<td>Commercial Insurance</td>
<td>~180 million covered lives including:</td>
<td>Focus on top 40 plans that drive 90% of covered lives</td>
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<td>CVS/Caremark</td>
<td>Maintain Tier 3 focus and improve non-formulary positions with key accounts</td>
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<td>ESI/Medco</td>
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<td>Tricare</td>
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<td>Medicaid/Medicare</td>
<td>Added in 26 states</td>
<td>Continued focus on remainder of top 34 states</td>
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<td>1 exclusive (TN)</td>
<td>Leverage Tennessee Medicaid impact</td>
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<td>19 at parity</td>
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<td>7 non-preferred</td>
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<tr>
<td>Managed Medicaid</td>
<td>Limited focus to date</td>
<td>Target top 3 managed Medicaid plans (representing &gt;100,000 Rx’s/Year)</td>
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**Payer Mix**

- Commercial: 57%
- Medicare: 11%
- Medicaid: 10%
- Cash: 15%
- Managed Medicaid: 7%
Utilization of Tennessee Medicaid Data
Impact of Tennessee Medicaid on Prescriber Base

BUNAVAIL Prescribers by Month - Tennessee

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Tennessee Medicaid: Growth Among Commercial and Cash Paying Segments

Source: Symphony Health
Tennessee Medicaid: Near Full Conversion to BUNAVAIL® with Decline in Overall Rx Volume

Tennessee Medicaid Rx’s

Symphony Weekly PHAST Rx Data
Reduced Buprenorphine/Naloxone Prescriptions Dispensed in a State Medicaid Population Following Formulary Conversion from Suboxone® to Bunavail®: Implications for Potential Diversion
Richard Soper, MD, JD, MS, FASAM, DABAM

Data Presented at International Conference on Opioids (ICOO June 5-7, 2016, Boston, MA)

- During the measurement period, a 63% reduction of the market was seen from 10/1/2015 to present.

- A survey of physicians participating in the Medicaid program indicated*:
  
  • 77% of patients remain on BBF. Of the 23% who discontinued BBF therapy, 64% of patients opted to pay for SSF out-of-pocket, rather than continue use of BBF – a surprising percentage.

  • Bunavail® buccal film appeared more difficult to abuse or misuse (67% vs. 40%) when compared to Suboxone® sublingual film.

*Data on file BDSI
BUNAVAIL Commercial Changes – Focus on Profitability in 2017
BUNAVAIL® Focus – Profitability by End of 2017

Bring expenses in line with revenue while key initiatives take hold:

Actions Taken (May 2016):

- Consolidation of sales force to focus on the most productive territories (95% of current business; 85% of overall Rx’s)
- Top performing representatives transitioned from contract sales arrangement to BDSI employees
- Reduction in marketing budget to focus on initiatives that have demonstrated a favorable impact

Savings of ~$20 million over next 6 quarters
BUNAVAIL® Focus – Profitability by End of 2017

➢ Drive BUNAVAIL prescription sales growth:

- Focused effort by sales team in areas with greatest growth potential

- Utilize Tennessee Medicaid diversion data to drive new managed care contracts

- Enhanced patient focus- Address patient lack of awareness of BUNAVAIL and resistance to switch through a targeted, digital direct to patient initiative

- Drive patients to BUNAVAIL following lifting of patient cap (100 to 200)
BUNAVAIL® Focus – Profitability by End of 2017

➤ Improve operating margins:

▪ Improve gross to net
  - Managed care contracting
  - Grow business in commercial and cash pay segments

▪ Continue to decrease COGS
  - High speed packaging equipment (online May 2016)
  - Manufacturing efficiencies and yield improvements
BUNAVAIL 2016 Activity Timeline

- **MAY**
  - TN Diversion Data Published

- **JUN**
  - Potential New State Medicaid Decisions/Implementation
  - >25,000 Rx’s

- **JUL**
  - Direct to Patient Initiative Pilot

- **AUG**
  - Induction Indication

- **SEP**
  - DTP Pilot Results
  - Potential Additional Rx’s

- **OCT**
  - Potential New State Medicaid Decisions/Implementation
  - >115,000 Rx’s

- **NOV**
  - HHS Cap Lift Potential Impact Yr 1
  - >500,000 Rx’s*

- **DEC**
  - Potential New State Medicaid Decisions/Implementation
  - >115,000 Rx’s

*Estimate based on data from HHS proposal. Up to 72,000 patient in year 1, with average of 7-10 Rx’s
Commercial Opportunity
Market Sales Exceeded $2 Billion in 2015

Market Dynamics:

- Suboxone film generated $1.4 billion in sales in 2015
- Market showing continued growth in prescriptions from 2014 to 2015 (up 6%)

Symphony Health; integrated sales of buprenorphine products for opioid dependence through 2015. US Sales only.
BUNAVAIL® - Opportunity to Achieve Meaningful Share of Branded Market

Estimated Market Sales (2018)

Total Rx’s - Bup/Naloxone¹

- Branded 75%
- Generic 25%

>$2 Billion

¹ Branded market assumed to consists of Suboxone film, Zubsolv and BUNAVAIL.
BELBUCA™ (buprenorphine) buccal film

Treatment of Chronic Pain
BELBUCA™ (buprenorphine) buccal film

Marketed by commercial partner – Endo Pharmaceuticals

- **Indication**: BELBUCA is indicated for the management of pain serious enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.

**CONTRAINDICATIONS**
BELBUCA™ is contraindicated in patients with: significant respiratory depression, acute or severe bronchial asthma in an unmonitored setting or in the absence of resuscitative equipment, known or suspected gastrointestinal obstruction, including paralytic ileus and hypersensitivity (eg, anaphylaxis) to buprenorphine. See [www.Belbuca.com](http://www.Belbuca.com) for more information including full prescribing information.

BELBUCA is licensed worldwide to Endo Pharmaceuticals.
Why BELBUCA™ (buprenorphine) buccal film?

Unique Set of Value Drivers

- **Efficacy** – Strong and durable efficacy in naïve and experienced patients (naïve to 160 mg MSE)

- **Tolerability** – Rates of adverse events comparable to placebo in pivotal studies

- **Convenience**
  - Schedule III for prescribing and dispensing convenience
  - Flexible dosing options (7 strengths)
  - Buccal administration optimizes buprenorphine delivery

The most common adverse reactions (>5%) reported by patients treated with BELBUCA in the clinical trials were nausea, constipation, headache, vomiting, fatigue, dizziness, somnolence, diarrhea, dry mouth, and upper respiratory tract infections. See [www.Belbuca.com](http://www.Belbuca.com) for more information including full prescribing information.

BELBUCA is licensed worldwide to Endo Pharmaceuticals.
BELBUCA™ Early Launch Progress by Endo

- **HCP Receptivity:**
  - Schedule III message resonating
  - Early feedback that pain control needs being met
  - Conversion from short acting opioids (SAO) therapy promising

- **Access:**
  - 2/3rds commercial patient lives covered with at least default coverage
  - Co-pay assistance program
  - Pharmacy stocking not a barrier

- **Patient Experience:**
  - Positive patient experience
  - Schedule III allows for greater Rx convenience

- **Opportunities:**
  - Education around tapering
  - Formulary negotiations
  - Building awareness of a new option for chronic pain

Endo projects sales of BELBUCA to be >$250 million in 2019

Source: IMS
Endo Partnership and Licensing Agreement
Endo Pharmaceuticals Partnership and Licensing Agreement

**Milestones:**
- $50 Million: Received following NDA approval October 23, 2015
- Up to $55 million in potential sales milestones

**Royalty:**
- Net sales - tiered, mid to upper teen in U.S.
ONSOLIS®
(fentanyl buccal soluble film)

Breakthrough Cancer Pain in Opioid Tolerant Patients
Collegium Pharmaceutical Licensing Agreement for ONSOLIS – Allows for Potential Return to Market by Mid-2017

Key Financial Terms*:

- $2.5 million upfront payment
- Reimbursement for pre-determined amount of remaining expenses for ongoing transfer of manufacturing
- $4 million upon first commercial sale
- Up to $17 million in potential payments based on performance and sales milestones
- 18-20% royalty based on net sales thresholds

*ONSOLIS continues to be marketed by Meda outside the U.S., except for Korea and Taiwan (TTY Biopharm), under the trade name BREAKYL. Financial terms established enable Meda to share in the proceeds of any new North American partnership for ONSOLIS.
Clonidine Topical Gel
Clonidine Gel Study (CLO-291) - >70% of Needed Subjects Randomized

Double-blind, placebo controlled, Phase 2b study in Painful Diabetic Neuropathy patients

Key Design Changes to Reduce Placebo Response and Improve Assay Sensitivity:

- Patient Selection and Enrichment
  - Subjects required to have PDN diagnosis for ≥6 months; restricted to up to 1 background medication to exclude treatment refractory patients
  - Exclusion of patients with highly variable pain scores during baseline period: Use of a Proprietary Inclusion Algorithm
  - Exclude patients with disorders masquerading as PDN

- Improve assay sensitivity: Accurate pain reporting training and placebo response reduction training

- Efficient longitudinal statistical analysis methodology: Mixed Model Repeated Measures (MMRM)

Randomized sample size = ~50 patients per arm
Clonidine Gel Study (CLO-291) – Anticipated Timeline

Timeline dependent on study recruitment rate
Buprenorphine Depot Injection
Buprenorphine Depot Injection

- Licensed from Evonik Corporation in October 2014
- Uses proprietary FormEZE® microparticle technology to produce a formulation of buprenorphine potentially capable of providing 30 days of continuous opioid therapy
- Rights secured for the treatment of opioid dependence and chronic pain
- Formulation selected; pre-clinical studies underway
- Pre-IND meeting in November
- IND submission in 3Q 2016 followed by single dose PK study in 4Q 2016
Buprenorphine Depot Injection Formulation Meets Desired Profile – 30 Day, Low Burst Effect

Non-GLP and GLP Plasma Buprenorphine Concentration vs. Time Profile Following Single Doses Buprenorphine Depot in Gottingen Minipigs
BDSI Projected Milestones - 2016
BDSI 2016 Milestones

Quarterly Calendar

1Q16
- BELBUCA™ Launch by Endo

2Q16
- Buprenorphine Injectable Depot IND Submission
- Clonidine Topical Gel Study Begins

3Q16
- Buprenorphine Injectable Depot Single Dose PK Study
- BUNAVAIL® Induction claim approval anticipated

4Q16
- Clonidine Topical Gel Study Completed (LPO)
Reasons to Invest in BDSI

- Reduced cost structure and growth opportunities allow BUNAVAIL to reach profitability by end of 2017

- BELBUCA is a top priority for Endo; Schedule III opioid; significant royalties on net sales

- ONSOLIS partnership secured; return to market in mid-2017

- Promising pipeline to support future growth with upcoming Buprenorphine 30 day injection IND filing and Clonidine Topical Gel study completion/data

- <$100 million enterprise value with cash of $69 million
Balance Sheet Highlights

Cash position
- $69.4 million – as of March 31, 2016

BDSI: 53,594,979 million shares outstanding\(^1\)

\(^1\) June 2016
\(^2\) Market close March 8, 2016