Our vision is that all patients around the world will have unrestricted access to high-quality treatment services for the chronic relapsing conditions and co-morbidities of addiction.
FORWARD-LOOKING STATEMENTS

This presentation contains certain statements that are forward-looking and which should be considered, amongst other statutory provisions, in light of the safe harbour provisions of the United States Private Securities Litigation Reform Act of 1995. By their nature, forward-looking statements involve risk and uncertainty as they relate to events or circumstances that will or may occur in the future. Actual results may differ materially from those expressed or implied in such statements because they relate to future events. Forward-looking statements include, among other things, statements regarding our financial guidance for 2016 and our medium- and long-term growth outlook, our operational goals, our product development pipeline and statements regarding ongoing litigation.

Various factors may cause differences between Indivior’s expectations and actual results, including: factors affecting sales of Indivior products and any future products; the outcome of research and development activities; decisions by regulatory authorities regarding the Indivior Group’s drug applications; the speed with which regulatory authorizations, pricing approvals and product launches may be achieved; the outcome of post-approval clinical trials; competitive developments; difficulties or delays in manufacturing; the impact of existing and future legislation and regulatory provisions on product exclusivity; trends toward managed care and healthcare cost containment; legislation or regulatory action affecting pharmaceutical product pricing, reimbursement or access; claims and concerns that may arise regarding the safety or efficacy of the Indivior Group’s products and product candidates; risks related to legal proceedings; the Indivior Group’s ability to protect its patents and other intellectual property; the outcome of patent litigation relating to the ongoing ANDA lawsuits; changes in governmental laws and regulations; issues related to the outsourcing of certain operational and staff functions to third parties; uncertainties related to general economic, political, business, industry, regulatory and market conditions; and the impact of acquisitions, divestitures, restructurings, internal reorganizations, product recalls and withdrawals and other unusual items.

This presentation does not constitute an offer to sell, or the solicitation of an offer to subscribe for or otherwise acquire or dispose of shares in the Company to any person in any jurisdiction to whom it is unlawful to make such offer or solicitation.

Statements about an investigational product in development are for discussion and planning purposes only.
Our vision is that all patients around the world will have unrestricted access to high-quality treatment services for the chronic relapsing conditions and co-morbidities of addiction.
## Indivior R&D Day: Agenda & Outline

<table>
<thead>
<tr>
<th>Time (EST)</th>
<th>Topic</th>
<th>Presenter</th>
</tr>
</thead>
<tbody>
<tr>
<td>7:30 AM - 8:00 AM</td>
<td>Outline of the day</td>
<td>Coffee – Get Together</td>
</tr>
<tr>
<td>8:00 AM - 9:00 AM</td>
<td>Outline of the day</td>
<td>Christian Heidbreder, Chief Scientific Officer</td>
</tr>
<tr>
<td></td>
<td>R&amp;D Strategic Drivers</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Welcome &amp; Agenda</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Architecture; People; Strategic Pipeline; Processes</td>
<td></td>
</tr>
<tr>
<td>9:00 AM - 10:30 AM</td>
<td>RBP-6000: Once Monthly Buprenorphine</td>
<td>Glenn Tyson, VP Global Therapy Areas</td>
</tr>
<tr>
<td></td>
<td>- Vision for RBP-6000: Part I</td>
<td>Susan Learned, SVP Global Clinical Development</td>
</tr>
<tr>
<td></td>
<td>- Clinical Development</td>
<td>Barbara Haight, Medicine Development Leader &amp; Brent Boyett,</td>
</tr>
<tr>
<td></td>
<td>- RBP-6000 through the lens of a clinician</td>
<td>Boyett Health Services, Hamilton, AL</td>
</tr>
<tr>
<td></td>
<td>- Vision for RBP-6000: Part II</td>
<td>Glenn Tyson, VP Global Therapy Areas</td>
</tr>
<tr>
<td>10:30 AM - 10:45 AM</td>
<td>Break</td>
<td></td>
</tr>
<tr>
<td>10:45 AM - 12:00 PM</td>
<td>RBP-7000: Once Monthly Risperidone</td>
<td>Anne Andorn, Head, Late Stage Clinical Development</td>
</tr>
<tr>
<td></td>
<td>- Schizophrenia through the lens of a psychiatrist</td>
<td>Susan Learned, SVP Global Clinical Development &amp; Jay Graham,</td>
</tr>
<tr>
<td></td>
<td>- Clinical Development</td>
<td>Medicine Development Leader</td>
</tr>
<tr>
<td></td>
<td>- Vision for RBP-7000</td>
<td>Glenn Tyson, VP Global Therapy Areas</td>
</tr>
<tr>
<td>12:00 PM - 12:20 PM</td>
<td>Strengthening our global leadership in treatment of addiction</td>
<td>Shaun Thaxter, Chief Executive Officer</td>
</tr>
<tr>
<td>12:20 PM - 1:00 PM</td>
<td>Q&amp;A</td>
<td></td>
</tr>
</tbody>
</table>
Our vision is that all patients around the world will have unrestricted access to high-quality treatment services for the chronic relapsing conditions and co-morbidities of addiction.
Focus on patient needs to drive decisions
Seek the wisdom of the team
Believe that people’s actions are well intended
Care enough to coach
See it, own it, make it happen
Demonstrate honesty and integrity at all times
A Vision to Enable Indivior’s Future

Leadership:
- Set and lead access to quality treatment options

R&D Center of Excellence:
- Pioneer breakthrough life-transforming treatments

Core values:
- Unmatched patient focus
- Treatment leadership
- Increase patient access to care
- Seeking the wisdom of KOLs and patient advocacy groups

Patient Needs

Create differentiated treatment approaches
- Stream of sustained innovations
- Contribute to help shape public policies

Indivior’s Current Position:
- Expand access to treatment in opioid use disorder
- Open access to rescue medications
- Address unmet needs in alcohol use disorder
- Address unmet needs in stimulant use disorder
- Focus on psychiatric co-morbidities of addiction

Indivior’s Future Position
- Expand core capabilities into new geographies
- Expand access to treatment in alcohol use disorder and stimulant use disorder
- Address unmet needs in cannabis use disorder
- Focus on co-morbidities of addiction
- Explore new opportunities
R&D Strategic Drivers 2016

Architecture
New state-of-the-art R&D facilities

People
Attract, develop and retain talents & build internal capabilities to enable future growth

Portfolio
12 clinical studies, the most in the history of Indivior
Many significant clinical milestones in 2016-2017
3 NDA preparations
21 evaluation processes in Addiction Medicine

Processes
Best-in-class processes to meet milestones, deliver on commitments based on GO-NO GO stage gates along development plans

Indivior R&D Day | December 9th 2016
R&D Strategic Drivers 2016: ARCHITECTURE

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BUILDING A NEW R&D CENTRE OF EXCELLENCE IN HULL, UK
OUR VISION BACK IN DECEMBER 2015

Source: Boulting Environmental Services (BES), Manchester, UK
Delivering on Our Vision: December 2016

- New building (5,000m²/54,000Ft²) to be handed over to Indivior within Q2-2017.
- On track for completion by end of Q4-2017.
R&D STRATEGIC DRIVERS 2016: PEOPLE

Architecture
New state-of-the-art R&D facilities

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EXPERIENCED & TALENTED TEAM

Christian Heidbreder
Chief Scientific Officer

Susan Learned
SVP Clinical Development

Graham Cairns
Sr Director CMC

Eddie Li
SVP Regulatory Affairs

Ju Yang
VP R&D China

Dan Hutcheson
R&D Liaison Officer

Bill Dewey
Director R&D Training

Barbara Haight
Medicine Dvlpt Leader

Anne Andorn
Head Late Stage Clin Dvlpt

Jay Graham
Medicine Dvlpt Leader

Vijay Nadipelli
Director HEOR

Glenn Tyson
VP Global Therapy Areas

Indivior R&D Day | December 9th 2016

Presenting today
**Current R&D Organization (N=155 in December 2016)**

- **CMC** (40%)
  - Regulatory Strategy
  - Regulatory Operations
  - Regulatory Affairs (RA) NA
  - RA EU
  - RA Australasia

- **Clinical** (25%)
  - Clinical Operations
  - Clinical Pharmacology & TM
  - Late Clinical Development
  - Ex-US Clinical Development
  - Data and Statistical Sciences
  - HEOR
  - Preclinical Sciences
  - Epidemiology

- **Regulatory** (32%)
  - Clinical Operations
  - Clinical Pharmacology & TM
  - Late Clinical Development
  - Ex-US Clinical Development
  - Data and Statistical Sciences
  - HEOR
  - Preclinical Sciences
  - Epidemiology

- **Other** (3%)
  - R&D China
  - R&D Training
  - R&D Liaison

- **Formulation Development**
- **Analytical Development**
- **Chemical Development**
- **Process Development**
- **Technology Transfer**
R&D STRATEGIC DRIVERS 2016: PORTFOLIO

Architecture
New state-of-the-art R&D facilities

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OPIOID USE DISORDER

<table>
<thead>
<tr>
<th>Product</th>
<th>Geography</th>
<th>Milestone</th>
</tr>
</thead>
<tbody>
<tr>
<td>SUBOXONE® Tablet</td>
<td>![Map]</td>
<td>Additional Dosage Strengths 12mg/3 mg and 16 mg/4 mg: sNDS submitted to Health Canada (HC) Dec 6th, 2016.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>NDA preparation: Plan to submit NDA to CFDA by end of Q4-2016</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- REMission from Chronic Opioid Use: Studying EnVironmental and socioEconomic factors on Recovery (RECOVER®) study: Logo USPTO-approved registered TM in Jul 2016; &gt;400 subjects achieving baseline survey; Baseline interim analysis report in Q4-2016.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Regulatory: Fast Track Designation May 23rd; REMS meeting Sep 28th; Pre-NDA meeting Dec 14th; NDA submission (pending outcome of pre-NDA meeting): Q2-2017.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Meeting with Regulatory Agencies Q4-2016: TGA; HC; ANSM; MHRA; MPA; BfArM</td>
</tr>
</tbody>
</table>

# Psychiatric Co-Morbidities

<table>
<thead>
<tr>
<th>Product</th>
<th>Geography</th>
<th>Milestone</th>
</tr>
</thead>
<tbody>
<tr>
<td>RBP-7000 in ATRIGEL®</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- **Phase 3 efficacy and safety trial (RB-US-09-0010):**
  - Positive top line results released May 5\(^{th}\), 2015.

- **Phase 3 long-term safety extension trial (RB-US-13-0005):**
  - Database Lock achieved Oct 21\(^{st}\), 2016.

- **US Health Economics & Outcomes Research (HEOR) studies:**

- **Pre-NDA meeting held August 4\(^{th}\), 2016:**
  - FDA agreement with proposed stability testing timelines & NDA submission strategy (Target: Q4-2017).
ALCOHOL USE DISORDER

<table>
<thead>
<tr>
<th>Product</th>
<th>Geography</th>
<th>Milestone</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td> Arbaclofen Placarbil appears to be safe &amp; well tolerated up to a dose of 240mg in controlled abstinence setting.</td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>However:</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td> Significant inter-individual variability in pharmacokinetics profile as doses increased.</td>
</tr>
<tr>
<td></td>
<td></td>
<td> <em>In vitro</em> and potential <em>in vivo</em> alcohol interactions require:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>— new formulation development.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>— additional clinical studies (regional absorption and alcohol interaction) to mediate safety risk prior to further outpatient studies in AUD patients.</td>
</tr>
</tbody>
</table>
# Rescue Medications for Drug Overdose/Intoxication

<table>
<thead>
<tr>
<th>Product</th>
<th>Geography</th>
<th>Milestone</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intranasal Naloxone for Opioid Overdose</td>
<td></td>
<td>▪ <strong>Temporary Authorization for Use (ATU):</strong> Approved by French ANSM on Nov 5\textsuperscript{th}, 2015.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>▪ ANSM approved <strong>ATU launch</strong> on Jul 26\textsuperscript{th}, 2016 with NALSCUE\textsuperscript{®} launch in France on Jul 27\textsuperscript{th}, 2016.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>▪ <strong>MAA submitted Nov 28\textsuperscript{th}, 2016.</strong></td>
</tr>
<tr>
<td>RBP-8000: Cocaine Esterase for Cocaine Intoxication</td>
<td></td>
<td>▪ <strong>Breakthrough Therapy Designation:</strong> Granted Oct 17\textsuperscript{th}, 2014.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>▪ <strong>Second Type B meeting with the FDA:</strong> Mar 16\textsuperscript{th}, 2016.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>▪ Per agreement with FDA, work has continued with the development of a lyophilized product and first test batch has been manufactured in October 2016.</td>
</tr>
</tbody>
</table>

*ANSM: Agence Nationale de Sécurité du Médicament et des Produits de Santé; MAA: Marketing Authorisation Application*
**EARLY STAGE ASSET DEVELOPMENT**

Unmet Need

- **Efficacy**
- **Side effects**
- **Delivery**
- **Cost**

Maturity

- **Efficacy**
- **Side effects**
- **Delivery**
- **Cost**

Stimulant Use Disorder (SUD)
Impulse Control Disorder (ICD)
Cannabis Use Disorder (CUD)

Alcohol Use Disorder (AUD)

Opioid Use Disorder (OUD)
### Early Stage Asset Development Opportunity Mapping

#### Timing to Maturity (Potential Market Entry)

<table>
<thead>
<tr>
<th>Asset Product Profile Score</th>
<th>2014-2016</th>
<th>2016-2022</th>
<th>2022+</th>
</tr>
</thead>
<tbody>
<tr>
<td>High (7)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Absence of transformational addiction targets</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Med (4 – 6)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Few near-term accretive opportunities</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low (1 – 3)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- Opioid Use Disorder (OUD)
- Alcohol Use Disorder (AUD)
- Stimulant Use Disorder (SUD)
- Impulse Control Disorder (ICD)/Cannabis Use Disorder (CUD)
R&D Strategic Drivers 2016: PROCESSES

Architecture
New state-of-the-art R&D facilities

People
Attract, develop and retain talents & build internal capabilities to enable future growth

Portfolio
12 clinical studies, the most in the history of Indivior
Many significant clinical milestones in 2016-2017
3 NDA preparations
21 due diligence processes in Addiction Medicine

Processes
Best-in-class processes to meet milestones, deliver on commitments based on GO-NO GO stage gates along development plans
Effective Decision Making Processes

Science & Policy Committee
Composition: Subset of Board Members with scientific background & expertise
Responsibility: Reviews all scientific matters related to R&D and pipeline progress

R&D Leadership Committee
Composition: R&D Function Heads
Responsibility: Manages all matters related to pipeline progression and makes recommendations to Portfolio Review Committee

Portfolio Review Committee
Composition: Key stakeholders beyond R&D
Responsibility: Makes recommendations to the Executive Committee and Board on R&D strategy, priorities and all major pipeline-related decisions
INDIVIOR R&D DAY DECEMBER 9TH, 2016

RBP-6000: ONCE MONTHLY BUPRENORPHINE

Glenn Tyson, VP Global Therapy Areas, Indivior Inc.
Susan Learned, SVP Global Clinical Development, Indivior Inc.
Barbara Haight, Medicine Development Leader, Indivior Inc.
Brent Boyett, Boyett Health Services, Hamilton, AL.

Our vision is that all patients around the world will have unrestricted access to high-quality treatment services for the chronic relapsing conditions and co-morbidities of addiction.
INDIVIOR R&D DAY

RBP-6000: VISION FOR THE TREATMENT OF OPIOID USE DISORDER

Glenn Tyson
Vice-President, Global Therapy Areas, Indivior Inc.

Our vision is that all patients around the world will have unrestricted access to high-quality treatment services for the chronic relapsing conditions and co-morbidities of addiction.
>3 people in the US die of opioid overdose every hour of every day\(^1\)

Images like this one from the shocking Ohio overdose story in September are becoming all too common

The daily rate of overdose deaths in the US is the equivalent of an 80-passenger plane crashing every day with no survivors.¹

**RBP-6000 GOALS**

**Improving treatment access**

- >2.5m patients diagnosed with OUD in the US\(^1\)
- <50% of diagnosed patients receive any BMAT\(^2\)

**Improving treatment retention**

- 52% of BMAT patients leave treatment within 2 months\(^2\)
- 69% of patients who leave treatment are asked to leave by their physician as assessed in quantitative market research\(^3\)

---

\(^1\)SAMHSA, Results from the 2014 National Survey on Drug Use and Health. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2016.

\(^2\)NSDUH survey 2014 and INDV analytics, \(^3\)INDV quantitative market research, 2015, \(n=123\)

MAT: Medication-Assisted Treatment; BMAT: Buprenorphine Medication-Assisted Treatment
A STUDY SHOWS LONG-TERM MAINTENANCE LEADS TO GREATER TREATMENT RETENTION AND BETTER OUTCOMES

Study Design

- **Maintenance arm**: subjects were induced and stabilized at 16 mg, then maintained there for duration
- **Taper arm**: patients were inducted, stabilized at 16 mg for 4 weeks, then tapered by 2 mg decrease every 3 days for 3 weeks

Results

- Buprenorphine short term treatment/taper resulted in poorer retention in treatment
- 28% of patients in the taper arm required re-initiation of buprenorphine therapy due to relapse after the taper

---

American Society of Addiction Medicine (ASAM) and the World Health Organization (WHO), consider Medication-Assisted Treatment [MAT, maintenance] an evidence-based best practice for treating opioid use disorder (OUD).1

“Although MAT [maintenance] has significant evidence to support it as an effective treatment, it remains highly underutilized.” 3

- Health and Human Services Secretary Sylvia M. Burwell

1SAMHSA Advisory, Winter 2016 • Volume 15 • Issue 1 American Society of Addiction Medicine
2INDV quantitative market research, 2016, n=150
3DHHS, Opioid Abuse in the U.S. and HHS Actions to Address Opioid-Drug Related Overdoses and Deaths, March 26, 2015
PHYSICIANS IN MARKET RESEARCH ARE MOTIVATED & CONFIDENT THEY CAN ACHIEVE SUCCESS

But a disconnect still exists between waivered physicians and patient perceptions of success

**PHYSICIAN MOTIVATION**

- 5% Not at all motivated
- 36% Slightly motivated
- 41% Moderately motivated
- 18% Very motivated
- 0% Extremely motivated

**PHYSICIAN CONFIDENCE**

- 11% Not at all confident
- 43% Slightly confident
- 32% Moderately confident
- 12% Very confident
- 0% Extremely confident

**ONGOING USE OF ILLICIT OPIOIDS**

- Only 1 in 8 (12%) physicians perceive that the patient described is still using illicit opioids
- But, nearly half (41%) of patients receiving BMAT claim to use illicit opioids

---

1INDV quantitative market research, July 2016, n=376
BMAT: Buprenorphine Medication-Assisted Treatment
ON HOW TO ADDRESS CURRENT UNMET MEDICAL NEEDS?

- Sustained plasma levels of buprenorphine that translate into high µ-opioid receptor occupancy to suppress withdrawal symptoms and block the subjective and objective effects of opioid agonists.
- Once-monthly buprenorphine delivery that is consistent across the entire 1-month period.
- Reduce risk of diversion and misuse.
- Enhance compliance/adherence to treatment.
- Monthly decisions (12/year) rather than daily decisions (365/year).
Our vision is that all patients around the world will have unrestricted access to high-quality treatment services for the chronic relapsing conditions and co-morbidities of addiction.
THEORETICAL ORDERING OF μ-OPIOID RECEPTOR REQUIREMENTS FROM WITHDRAWAL SUPPRESSION TO BLOCKADE OF OPIOID SUBJECTIVE EFFECTS

- Reinforcing effect
- Analgesic effect
- Withdrawal suppression
- Opioid blockade

Criterion difference

Increasing receptor occupancy (RO) -> (or decreasing receptor availability)

50-60% RO

>70% RO
(Buprenorphine, 2-3 ng/mL)

Buprenorphine Dose-Effect on μ-Opioid Receptor Availability


Indivior R&D Day | December 9th 2016
PK/PD/RO RELATIONSHIP & BLOCKADE OF OPIOID SUBJECTIVE EFFECTS WITH RBP-6000

An average buprenorphine plasma level of 2-3 ng/mL is expected to produce ~70% µ-opioid receptor occupancy. The “opioid blockade” hypothesis was tested clinically. The outcome of the “opioid blockade” study was used to support the design of the pivotal Phase 3 trial.

MODELED PK/PD/RO TO DEFINE PHASE 3 RBP-6000 DOSING REGIMENS

Dose regimen #1: 6 x 300 mg

Dose regimen #2: 2 x 300 mg + 4 x 100 mg
### RBP-6000: Phase 3 Study (RB-US-13-0001)

#### Comparative Inclusion/Exclusion Criteria

<table>
<thead>
<tr>
<th>RBP-6000</th>
<th>CAM2038</th>
<th>PROBUPHINE*</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Key Inclusion:</strong></td>
<td><strong>Key Inclusion:</strong></td>
<td><strong>Key Inclusion:</strong></td>
</tr>
<tr>
<td>- Moderate-severe OUD</td>
<td>- Moderate-severe OUD</td>
<td>- Clinically stable OUD: Treated with sublingual (SL) Buprenorphine X 6 months and abstinent on stable doses of SL Buprenorphine ≤ 8mg/day X 3 months</td>
</tr>
<tr>
<td>- Seeking treatment for OUD</td>
<td>- Seeking treatment for OUD</td>
<td></td>
</tr>
<tr>
<td>- No MAT for OUD within 90 days</td>
<td>- No MAT for OUD within 60 days</td>
<td></td>
</tr>
<tr>
<td><strong>Key Exclusion:</strong></td>
<td><strong>Key Exclusion:</strong></td>
<td><strong>Key Exclusion:</strong></td>
</tr>
<tr>
<td>- Other current diagnosis requiring opioids</td>
<td>- Current diagnosis of pain requiring opioids</td>
<td>- Current diagnosis of pain requiring opioids</td>
</tr>
<tr>
<td>- Other SUD (other than: mild cocaine or cannabis SUD if UDS negative at screening; mild alcohol UD, caffeine or nicotine UD)</td>
<td>- Other Moderate-Severe SUD (other than opioids, caffeine or nicotine)</td>
<td>- Other SUD (other than opioids or nicotine)</td>
</tr>
<tr>
<td>- Recent history of suicidality</td>
<td>- Recent history of suicidality</td>
<td>- Significant medical problems</td>
</tr>
<tr>
<td>- Significant medical problems</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*OUD: Opioid Use Disorder; SUD: Substance Use Disorder; MAT: Medication-Assisted Treatment*

*Source: [www.ClinicalTrials.gov](http://www.ClinicalTrials.gov)*
## RBP-6000: COMPARATIVE PRIMARY & SECONDARY ENDPOINTS

<table>
<thead>
<tr>
<th>Key differentiators</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Primary endpoints</strong></td>
</tr>
<tr>
<td>Superiority to placebo is a higher efficacy bar for RBP-6000 trial</td>
</tr>
<tr>
<td><strong>Definition of primary endpoint</strong></td>
</tr>
<tr>
<td>RBP-6000 trials set higher bar for primary efficacy endpoints:</td>
</tr>
<tr>
<td>1) More rigid definitions of no illicit opioid use</td>
</tr>
<tr>
<td>2) RBP-6000 abstinence endpoint was regulatory authority agreed</td>
</tr>
<tr>
<td><strong>Definition of Responder</strong></td>
</tr>
<tr>
<td>▪ RBP-6000 higher order responder rate definition</td>
</tr>
<tr>
<td><strong>FDA Definition of Responder</strong></td>
</tr>
<tr>
<td>▪ The primary endpoint for RBP-6000 was the regulatory-agreed primary endpoint of the study, with dosing designed to achieve opioid blockade</td>
</tr>
<tr>
<td><strong>Craving and withdrawal measures</strong></td>
</tr>
<tr>
<td>▪ Clear measures for craving for treatment-duration</td>
</tr>
<tr>
<td>▪ Prescribed supplemental treatment not allowable</td>
</tr>
<tr>
<td><strong>Prospective HEOR</strong></td>
</tr>
<tr>
<td>HEOR endpoints embedded into pivotal Phase 3 trials and dedicated RECOVER® study</td>
</tr>
</tbody>
</table>

1 Based on Phase 3 trial RB-US-13-0001 vs. ClinicalTrials.gov information on CAM2038 and Probuphine
**RBP-6000: Phase 3 Study (RB-US-13-0001) Design**

**Randomization**
- (n= 489)

- **Induction**
  - 3 days
  - 2-24mg SL

- **Stabilization**
  - 4 – 11 days
  - 8-24mg SL

**Treatment**
- Randomization
- Induction
- Stabilization
- 6 double-blind injections; and weekly urine visits with individualized counseling (IDC) (Weeks 1-21)
- RBP-6000 300 mg x 2 months/
  - 100mg x 4 months + IDC (194 subjects)
- RBP-6000 300mg + IDC x 6 months
  - (196 subjects)
- Placebo + IDC x 6 months
  - (99 subjects, volume matched equivalent)

**Follow Up**
- (option to roll into safety extension)

**Primary endpoint:**
The CDF (Cumulative Distribution Function) of the percentage of urine samples negative for opioids combined with self-reports negative for illicit opioid use collected from Week 5 through Week 24.

**Key Secondary Endpoint:**
Treatment success, defined as any subject with ≥80% of urine samples negative for opioids combined with self-reports negative for illicit opioid use between Week 5-24.
## RB-US-13-0001: Subject Demographics

<table>
<thead>
<tr>
<th></th>
<th>RBP-6000 300mg/100mg + IDC %</th>
<th>RBP-6000 300mg/300mg + IDC %</th>
<th>Placebo + IDC %</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mean Age (years)</strong></td>
<td>40</td>
<td>39</td>
<td>39</td>
</tr>
<tr>
<td><strong>Male</strong></td>
<td>66</td>
<td>67</td>
<td>65</td>
</tr>
<tr>
<td><strong>Race</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>68</td>
<td>71</td>
<td>78</td>
</tr>
<tr>
<td>Black or African American</td>
<td>29</td>
<td>28</td>
<td>20</td>
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<tr>
<td>American Indian or Alaska Native</td>
<td>2</td>
<td>&lt;1</td>
<td>1</td>
</tr>
<tr>
<td>Multiple</td>
<td>1</td>
<td>&lt;1</td>
<td>1</td>
</tr>
<tr>
<td><strong>Ethnicity</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hispanic or Latino</td>
<td>6</td>
<td>9</td>
<td>10</td>
</tr>
</tbody>
</table>

*Topline results Phase 3 study (RB-US-13-0001); IDC: Individualized Counseling*
### RB-US-13-0001: Baseline Clinical Characteristics

<table>
<thead>
<tr>
<th>Substance Use At Screening</th>
<th>RBP-6000 300mg/100mg + IDC (%)</th>
<th>RBP-6000 300mg/300mg + IDC (%)</th>
<th>Placebo + IDC (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-injectable opioid user</td>
<td>71</td>
<td>69</td>
<td>58</td>
</tr>
<tr>
<td>Injectable opioid user</td>
<td>43</td>
<td>41</td>
<td>51</td>
</tr>
<tr>
<td>Tobacco</td>
<td>92</td>
<td>92</td>
<td>93</td>
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<td>Alcohol</td>
<td>78</td>
<td>79</td>
<td>81</td>
</tr>
<tr>
<td>Caffeine</td>
<td>92</td>
<td>92</td>
<td>95</td>
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<tr>
<td>Drug Use History</td>
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<td>Cannabinoids</td>
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<td>47</td>
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<tr>
<td>Cocaine</td>
<td>47</td>
<td>40</td>
<td>42</td>
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<tr>
<td>Amph/Methamph</td>
<td>25</td>
<td>15</td>
<td>19</td>
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<tr>
<td>Psychiatric Disorders History</td>
<td></td>
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</tr>
<tr>
<td>Depression</td>
<td>14</td>
<td>11</td>
<td>13</td>
</tr>
<tr>
<td>Anxiety</td>
<td>9</td>
<td>10</td>
<td>10</td>
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<tr>
<td>Medical History</td>
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<tr>
<td>Hepatitis C</td>
<td>16</td>
<td>12</td>
<td>10</td>
</tr>
</tbody>
</table>

*Topline results Phase 3 study (RB-US-13-0001); IDC: Individualized Counseling*
RBP-6000 in both dosing regimens significantly superior to placebo ($P<0.0001$) on the primary endpoint (abstinence rate weeks 5-24)
RBP-6000 in both dosing regimens statistically superior to placebo \((P<0.0001)\) on the key secondary endpoint of treatment success*.

* Defined as \(\geq 80\%\) of urine samples negative for opioids combined with self-reports negative for illicit opioid use (Weeks 5-24)

Topline results Phase 3 study (RB-US-13-0001)
SIGNIFICANTLY MORE RBP-6000 SUBJECTS IN BOTH GROUPS COMPLETED THE STUDY COMPARED WITH PLACEBO ($P<0.0001$)

![Bar chart showing % completers for different groups](image-url)

- **300 mg/300 mg**: 64.3%
- **300 mg/100 mg**: 61.3%
- **Placebo**: 33.3%

*Topline results Phase 3 study (RB-US-13-0001)*
RBP-6000 reduced withdrawal symptoms relative to baseline as measured by the investigator.

Placebo group experienced an increase in withdrawal symptoms vs. baseline despite more than twice the rate of illicit opiate use in Placebo subjects as early as week 2.
### Subjective Opiate Withdrawal Scale (SOWS)

- RBP-6000 reduced withdrawal symptoms relative to baseline as rated by the subject.
- Placebo group experienced an increase in withdrawal symptoms vs. baseline despite more than twice the rate of illicit opiate use among Placebo subjects as early as week 2.
OPIOID CRAVING BY VAS

Increase in craving in the Placebo group, relative to baseline and compared with active groups, despite more than twice the rate of illicit opiate use among Placebo subjects as early as week 2.
SAFETY RESULTS - NO NEW OR UNEXPECTED SAFETY FINDINGS
GENERALLY WELL TOLERATED

% Occurrence

- Any TEAE
- Related TEAEs
- Serious TEAEs
- Related Serious TEAEs
- Severe TEAEs
- TEAEs leading to discontinuation

RBP-6000 (300/100) %
RBP-6000 (300/300) %
Placebo %

Topline results Phase 3 study (RB-US-13-0001); TEAE’s: Treatment Emergent Adverse Events
**SAFETY RESULTS - TEAEs occurring in ≥ 5% in any treatment group and more frequently in RBP-6000 group than in Placebo group**

<table>
<thead>
<tr>
<th>Condition</th>
<th>Placebo</th>
<th>RBP-6000 (300mg/100mg)</th>
<th>RBP-6000 (300mg/300mg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood CPK increased</td>
<td>1</td>
<td>5.4</td>
<td>2.5</td>
</tr>
<tr>
<td>Headache</td>
<td>6</td>
<td>9.4</td>
<td>8.5</td>
</tr>
<tr>
<td>Nasopharyngitis</td>
<td>1</td>
<td>5.4</td>
<td>5</td>
</tr>
<tr>
<td>URT Infection</td>
<td>1</td>
<td>7.4</td>
<td>6</td>
</tr>
<tr>
<td>Vomiting</td>
<td>4</td>
<td>9.4</td>
<td>5.5</td>
</tr>
<tr>
<td>Constipation</td>
<td>0</td>
<td>9.4</td>
<td>8</td>
</tr>
<tr>
<td>Nausea</td>
<td>5</td>
<td>8.9</td>
<td>8</td>
</tr>
<tr>
<td>Fatigue</td>
<td>3</td>
<td>3.9</td>
<td>6</td>
</tr>
<tr>
<td>Injection site pain</td>
<td>3</td>
<td>4.9</td>
<td>6</td>
</tr>
<tr>
<td>Injection site pruritus</td>
<td>4</td>
<td>6.4</td>
<td>9.5</td>
</tr>
</tbody>
</table>

*Topline results Phase 3 study (RB-US-13-0001); TEAE’s: Treatment Emergent Adverse Events*
RBP-6000 Value Dossier Contents

- Disease Overview & Epidemiology
- Burden of Disease
- Treatment Patterns, Costs & Unmet Needs
- Clinical Evidence
- Economic Evidence
- Humanistic /Quality of Life/ Patient Reported Outcomes Evidence
- Product Value Proposition (Evidence-based)
- References & Appendices

Retrospective HEOR Research

Prospective HEOR Research

AMCP: Academy of Managed Care Pharmacy
RETROSPECTIVE HEOR STUDIES: MARKETSCAN® & AETNA HEALTHCARE CLAIMS

Characteristics and Treatment Patterns of OUD Patients

How is relapse measured in claims data?

What are the dosing patterns of patients on BMAT?

What are the determinants of BMAT adherence?

What are the concomitant meds used before & after BMAT?

What are the effects of BMAT dosing and adherence on relapse and healthcare utilization and costs?

What are the incidence and costs of relapse?

OUD: Opioid Use Disorder; BMAT: Buprenorphine Medication-Assisted Treatment
PROSPECTIVE HEOR STUDIES

RB-US-13-0001 Efficacy Trial Analysis

Quality of life
Treatment satisfaction
Resource use
Employment status & health insurance

Targeted HEOR Trial Analysis of 0001/0003

Comparison of outcomes in 0001/0003 by: Retention;
Opioid use, withdrawal, cravings

RB-US-13-0003 Long-Term Safety Trial Analysis

Quality of life
Treatment satisfaction
Impact of opioid dependence on daily living

RECOVER® Study

Characterize the periods of abstinence over a 12-month observational window, such as # days abstinent, time to relapse, # relapses, and time to return to abstinence after relapse -- Economic impact of compliance such as adherence & persistence to MAT

MAT: Medication-Assisted Treatment
## RBP-6000: Planned Phase 3 & HEOR Data Rollout

<table>
<thead>
<tr>
<th>Conferences</th>
<th>Date</th>
<th>Presentation</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPDD</td>
<td>June 2017</td>
<td>Phase 3 Efficacy &amp; Safety</td>
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<td></td>
<td></td>
<td>Phase 3 HEOR</td>
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<tr>
<td>ACoP</td>
<td>October 2017</td>
<td>Phase 3 Exposure/Response</td>
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<tr>
<td>AATOD</td>
<td>March 2018</td>
<td>Phase 3 Efficacy Safety</td>
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<tr>
<td></td>
<td></td>
<td>Phase 3 HEOR</td>
</tr>
<tr>
<td>ASCPT</td>
<td>March 2018</td>
<td>Phase 3 Exposure/Response</td>
</tr>
<tr>
<td>ASAM</td>
<td>April 2018</td>
<td>Phase 3 Long-term Safety</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Peer-Reviewed Publications</th>
<th>Target Submission Date</th>
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<td>Phase 3 Efficacy &amp; Safety</td>
<td>3Q2017</td>
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<tr>
<td>Phase 3 HEOR</td>
<td>3Q2017</td>
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<tr>
<td>Phase 3 Exposure/Response</td>
<td>1Q2018</td>
</tr>
<tr>
<td>Phase 3 Long-term Safety</td>
<td>1Q2018</td>
</tr>
</tbody>
</table>

INDIVIOR R&D DAY

RBP-6000 THROUGH THE LENS OF A CLINICIAN

Brent Boyett, D.M.D., D.O.
Boyett Health Services, Hamilton, AL

Barbara Haight, Pharm.D.
Medicine Development Leader, Indivior Inc.

Our vision is that all patients around the world will have unrestricted access to high-quality treatment services for the chronic relapsing conditions and co-morbidities of addiction
DR. BRENT BOYETT, D.M.D., D.O.

- Trained and practices both Family Medicine and Family Dentistry (Diplomat of the *American Academy of Family Practice* & the *American Dental Society of Anesthesiology*).
  - Completed his undergraduate education at Birmingham-Southern College then graduated from the University of Alabama at Birmingham in 1994 with a D.M.D. degree.
  - Went on to medical school at the University of Health Sciences College of Osteopathic Medicine and graduated in 1998.
  - Started a three-year Family Medicine Residency (internal medicine, anesthesia and oral surgery) with the University of Mississippi in Tupelo, which he completed in 2001.
- Board certified in addiction through the *American Board of Addiction Medicine (ABAM)*.
  - Implemented an addiction program for the treatment of opioid dependence in 2009.
INDIVIOR R&D DAY

RBP-6000: VISION FOR THE TREATMENT OF OPIOID USE DISORDER

Glenn Tyson
Vice-President, Global Therapy Areas, Indivior Inc.

Our vision is that all patients around the world will have unrestricted access to high-quality treatment services for the chronic relapsing conditions and co-morbidities of addiction.
EDUCATING PHYSICIANS ON PK/PD/RO RELATIONSHIP TO EFFICACY & SAFETY VARIABLES IS A KEY LAUNCH OBJECTIVE FOR RBP-6000

Clearly articulate RBP-6000 PK/PD/RO relationship to efficacy & safety

Sustained Opioid Blockade (> 70% RO; > 3 ng/mL)

Withdrawal Suppression

Craving Suppression

Sustained Abstinence

Physicians connect these attributes with patient success in recovery
MOST COMPELLING DIFFERENTIATOR RELEVANT TO THIS POPULATION

Core segment of patients with moderate to severe OUD with multiple relapses

Patients new to OUD treatment and naïve to BMAT, and OUD patients relapsing but not currently on MAT

Defined OUD patient population with multiple relapses and/or adherence challenges, i.e. patients in need of treatment

Total OUD potential patient population

Delivers once-monthly buprenorphine with stable plasma concentrations of buprenorphine

Therapeutically-relevant plasma concentrations of buprenorphine for entire dosing interval, reduces withdrawal, craving, and protects against illicit use

Delivers Long-Acting Injectable (LAI) benefits that may include better long-term outcomes, help prevent relapse, lower risk of misuse and diversion

Provides potentially transformative treatment to patients who are struggling in the grip of addiction
INDIVIOR R&D DAY DECEMBER 9TH, 2016

RBP-7000: ONCE MONTHLY RISPERIDONE

Anne Andorn, Head Late Stage Clinical Development
Glenn Tyson, VP Global Therapy Areas
Susan Learned, SVP Global Clinical Development
Jay Graham, Medicine Development Leader

Our vision is that all patients around the world will have unrestricted access to high-quality treatment services for the chronic relapsing conditions and co-morbidities of addiction
INDIVIOR R&D DAY

SCHIZOPHRENIA THROUGH THE LENS OF A PSYCHIATRIST

Anne Andorn, M.D.
Head Late Stage Clinical Development, Indivior Inc.

Our vision is that all patients around the world will have unrestricted access to high-quality treatment services for the chronic relapsing conditions and co-morbidities of addiction.
INTRODUCTION

- Schizophrenia is a devastating chronic relapsing illness characterized by:
  - Adolescent onset
  - Abnormalities of perception, thought, volition, cognition
- Affecting around 5 million people world-wide
- Due to complex genetic/environmental interaction as yet unidentified
- A top 10 cause of disability (and health care cost) in Western world
- No known cure but effective treatments to control symptoms are available

Long acting treatments have been shown to reduce disability

### What are the Symptoms of Schizophrenia?

<table>
<thead>
<tr>
<th>Positive Symptoms</th>
<th>Negative Symptoms</th>
<th>Cognitive Defects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Multiple defects in perception (hallucinations, delusions)</td>
<td>Loss of ability to engage socially (flat affect or diminished emotional expression, amotivational, anhedonic [inability to derive pleasure])</td>
<td>Leading to impairment of executive function and other functions</td>
</tr>
<tr>
<td>Defects in reality testing, loss of tight reality based associations</td>
<td></td>
<td>impaired insight</td>
</tr>
<tr>
<td>Abnormal ideation (paranoia, grandiosity, bizarre ideation)</td>
<td></td>
<td>impaired abstraction/planning ahead</td>
</tr>
<tr>
<td></td>
<td></td>
<td>rapid cognitive disintegration (dementia praecox)</td>
</tr>
</tbody>
</table>

**References**

CASE VIGNETTE

- Ph.D. from prestigious university, male aged 29
- Gradual onset of suspiciousness developing into frank paranoia
- Became agitated and convinced his team was out to harm him
- Hallucinating but denying both auditory and visual hallucinations
- Did not recognize his abnormal behavior
- Only first generation antipsychotics (e.g. haloperidol) were available at the time
- Rapidly lost cognitive function even though paranoia resolved to a manageable level
- Severe Extrapyramidal Syndrome (EPS) which could not be well managed
THE SECOND GENERATION OF ANTIPSYCHOTICS (SGAs)

- **Clozapine**
  - Significant effect on negative symptoms

- **Risperidone**
  - Janssen molecule risperidone then shown to benefit negative symptoms
  - Clinicians talk about it as a typical atypical because predominantly dopamine antagonist

- **SGAs**
  - For the most part SGAs affect many neurotransmitter systems with differing potencies

---

CASE VIGNETTES

- 24-year old male college student with 2-year history of social withdrawal, delusions, and auditory hallucinations, with prominent negative symptoms
- First generation antipsychotics had no effect on negative symptoms which were disabling – no motivation, no insight into illness, no social engagement, blunted affect
- Started an investigational second generation antipsychotic and within weeks recognized he had something wrong, after months went back to school, completed an MA, and had insight into his persistent difficulty with social cues and sought group treatment for that
- Another patient with similar trajectory in the same clinical trial stopped the medication because of fear of a side effect and reverted to disability level which left him unable to care for himself and disabled son
NON-COMPLIANCE REMAINS A SIGNIFICANT CHALLENGE

- Adverse Events
- Not curative – auditory hallucinations just not as clear - more annoying
- Impaired insight into illness is a major cause of non-compliance
- Anosognosia (deficit of self-awareness)
- Lack of motivation to address disease – and lack of motivation is a symptom
- Behavior improves enough for family/friends so they stop monitoring

It takes a care team

Hospital stays are reduced (recidivism decreases)
Disability is reduced and functional ability is improved

Recidivism is high – 3-5 hospitalizations
Disability increases – longer psychosis
Primary cause of relapse

LONG ACTING ANTIPSYCHOTICS (LAI) HELP WITH COMPLIANCE BUT THERE ARE CURRENTLY CLINICAL LIMITATIONS

We believe that the following characteristics are potential differentiating attributes for future LAIs¹:

- Rapid onset
- Extended treatment duration
- Manageable tolerability
- No oral co-medication
- Measurable quality of life benefits

¹ Based on prescribing Information for RISPERDAL® CONSTA®, INVEGA SUSTENNA®, and ARISTADA®, Section 2 Dosage and Administration
INDIVIOR R&D DAY

RBP-7000: CLINICAL DEVELOPMENT

Susan Learned, M.D., Pharm.D., Ph.D.
Senior Vice-President, Global Clinical Development, Indivior Inc.

Jay Graham, Pharm.D.
Medicine Development Leader, Indivior Inc.

Our vision is that all patients around the world will have unrestricted access to high-quality treatment services for the chronic relapsing conditions and co-morbidities of addiction.
# Clinical Development: Phase 1 and Phase 2A

<table>
<thead>
<tr>
<th>Phase</th>
<th>Title</th>
<th>Description</th>
<th>Population</th>
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</thead>
<tbody>
<tr>
<td>Phase 1</td>
<td>RB-US-09-0007</td>
<td>First-in-man, OL study to assess the safety, tolerability &amp; PK of a single dose (60 mg)</td>
<td>Clinically stable schizophrenics (N=11)</td>
</tr>
<tr>
<td>Phase 1</td>
<td>RB-US-09-0008</td>
<td>Single ascending dose (SAD), open-label study to assess the safety, tolerability, and PK of RBP-7000 (60 mg, 90 mg, 120 mg)</td>
<td>Clinically stable schizophrenics (N=43)</td>
</tr>
<tr>
<td>Phase 2A</td>
<td>RB-US-09-0009</td>
<td>Multiple ascending dose (MAD), open-label study to assess the safety, tolerability, PK and switchability of 60 mg, 90 mg and 120 mg RBP-7000</td>
<td>Clinically stable schizophrenics (N=45)</td>
</tr>
<tr>
<td>Phase 3</td>
<td>RB-US-09-0010</td>
<td>Randomized, double-blind, placebo-controlled study to evaluate the efficacy, safety and tolerability of RBP-7000 (90 mg, 120 mg)</td>
<td>Subjects with acute schizophrenia (N=354)</td>
</tr>
<tr>
<td>Phase 3</td>
<td>RB-US-13-0005</td>
<td>Open-label, long-term safety and tolerability study of RBP-7000 in the treatment of subjects with schizophrenia</td>
<td>Clinically stable schizophrenics (N=500)</td>
</tr>
</tbody>
</table>
PK/PD MODEL: DOPAMINE (DA) D₂ RECEPTOR OCCUPANCY

- Data from Gefvert et al. (2005), where 13 schizophrenic patients received injections of Risperdal Consta (25, 50 or 75 mg) every 2 weeks

- Brain DA D₂ receptor occupancy assessed with [¹¹C]Raclopride under steady-state conditions for active moiety plasma concentrations

RBP-7000 provides therapeutically-relevant plasma concentrations of risperidone immediately after the first injection.

**Predicted Receptor Occupancy (RO) in Phase 2a Multiple Dose Study**

- 9 of 15 subjects exceeded 80% DA $D_2$ RO under oral risperidone 4 mg
- 2 of 15 subjects exceeded 80% DA $D_2$ RO under RBP-7000 120 mg

**ACTIVE MOIETY EXPOSURE: COMPARING RBP-7000 VS. RISPERDAL CONSTA® (RLAI) 25MG**

- The blue line represents the median predicted active moiety concentrations, the yellow region represents the 5th and 95th percentiles predicted for the active moiety after the SC RBP-7000 injections.
- The red line represents the median predicted active moiety concentrations, the gray region represents the 5th and 95th percentiles predicted for the active moiety after RLAI.

**Predicted DA D_{2} Receptor Occupancy: Comparing RBP-7000 vs. Risperdal CONSTA® (RLAI) 25mg**

- The **blue line** represents the median predicted D2 receptor occupancy, the yellow region represents the 5th and 95th percentiles predicted for D2 receptor occupancy after the SC RBP-7000 injections.
- The **red line** represents the median predicted D2 receptor occupancy, the gray region represents the 5th and 95th percentiles predicted for D2 receptor occupancy after RLAI.

---

**Source:**
CONCLUSIONS PHASE 1 & PHASE 2A

- The PK/PD modeling strategy was successful in supporting dose selection for Phase 2A and Phase 3
- Biomarker (DA D₂ RO) increased the probability of targeting the right therapeutic window in confirmatory Phase 3 trials
- Modeling & simulation accelerated decision making by bringing together PK, biomarker, and other PD data from various sources (internal data & peer-reviewed literature)
### Clinical Development: Pivotal Phase 3

<table>
<thead>
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</tr>
</tbody>
</table>
RB-US-09-0010: OBJECTIVES OF PHASE III EFFICACY & SAFETY TRIAL

- Randomized, double-blind, Placebo (PBO)-controlled, multicenter trial to evaluate the efficacy, safety and tolerability of RBP-7000 (90 mg and 120 mg) in subjects with acute schizophrenia over 8 weeks.
  - **Primary objective**: Assess the efficacy of RBP-7000 compared with PBO using the change from baseline to end of treatment in total *Positive and Negative Syndrome Scale* (PANSS) score and *Clinical Global Impression Severity of Illness* (CGI-S) scale.
  - **Secondary objective**: Establish a PK/PD/RO model.
  - **Tertiary objective**: Assess health-related quality of life, subjective well-being, subject satisfaction with medication, and subject and caregiver medication preference.
**RB-US-09-0010: Design of Phase 3 Efficacy & Safety Trial**

---

### Entry Criteria:
- Each subject who met entry criteria at Visit 1 was placed in an in-patient facility.
- Positive and Negative Syndrome Scale (PANSS) total score between 80 and 120 at Visit 1, and a score of > 4 on at least two of the following 4 items: hallucinatory behavior, delusions, conceptual disorganization, or suspiciousness/persecution.

### Diagnosis:
- Diagnosis of acute exacerbation of schizophrenia and PANSS total score were confirmed by an experienced State, Assessability, Face, Ecological, and Rule (SAFER) rater of Massachusetts General Hospital’s (MGH) Clinical Trials Network & Institute (CTNI).
- Subjects were excluded if improvement in their PANSS total score was ≥ 20% between the initial screening visit (Visit 1) and first injection (Visit 3; Day 1).
- At Visit 3, subjects were randomized to one of the three treatment arms: RBP-7000 (90 mg), RBP-7000 (120 mg) or placebo.

---

**Visit 1 (Day-8 to Day-3)**

**Visit 2 (Day-1)**

**Randomization Visit 3 Day 1 (n= 337)**

**Double-blind treatment (Weeks 1 - 8)**

- **RBP-7000 90mg x 2 months**
  - (111 subjects)

- **RBP-7000 120mg x 2 months**
  - (114 subjects)

- **Placebo x 2 months**
  - (112 subjects)

---

**Follow Up (option to roll into safety extension)**

Day 64

V10

---

**Source:** Nasser et al. (2016) J Clin Psychopharmacology, 36(2) 130-140

---
## RB-US-09-0010: SUBJECT DEMOGRAPHICS

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Placebo (n=112)</th>
<th>90 mg RBP-7000 (n=111)</th>
<th>120 mg RBP-7000 (n=114)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>%</td>
<td>n</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>81</td>
<td>72.3</td>
<td>93</td>
</tr>
<tr>
<td>Female</td>
<td>31</td>
<td>27.7</td>
<td>18</td>
</tr>
<tr>
<td>Race</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>25</td>
<td>22.3</td>
<td>28</td>
</tr>
<tr>
<td>Black</td>
<td>84</td>
<td>75.0</td>
<td>79</td>
</tr>
<tr>
<td>Asian</td>
<td>1</td>
<td>0.9</td>
<td>1</td>
</tr>
<tr>
<td>Native Hawaiian or Pacific Islander</td>
<td>1</td>
<td>0.9</td>
<td>1</td>
</tr>
<tr>
<td>Other</td>
<td>1</td>
<td>0.9</td>
<td>2</td>
</tr>
<tr>
<td>Ethnicity</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hispanic/Latino</td>
<td>10</td>
<td>8.9</td>
<td>7</td>
</tr>
<tr>
<td>Not Hispanic or Latino</td>
<td>101</td>
<td>90.2</td>
<td>104</td>
</tr>
<tr>
<td>Unknown</td>
<td>1</td>
<td>0.9</td>
<td>0</td>
</tr>
</tbody>
</table>

### RB-US-09-0010: Baseline Clinical Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Placebo (n=112)</th>
<th>90 mg RBP-7000 (n=111)</th>
<th>120 mg RBP-7000 (n=114)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>SD</td>
<td>Mean</td>
</tr>
<tr>
<td>Age at First Schizophrenia Diagnosis (years)</td>
<td>26.6</td>
<td>9.25</td>
<td>25.5</td>
</tr>
<tr>
<td>PANSS</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total Score</td>
<td>94.1</td>
<td>8.89</td>
<td>95.5</td>
</tr>
<tr>
<td>Positive symptom subscale</td>
<td>25.4</td>
<td>3.31</td>
<td>26.0</td>
</tr>
<tr>
<td>Negative symptom subscale</td>
<td>22.6</td>
<td>3.79</td>
<td>23.5</td>
</tr>
<tr>
<td>General psychopathology subscale</td>
<td>46.2</td>
<td>5.49</td>
<td>45.9</td>
</tr>
<tr>
<td>CGI-S</td>
<td>4.8</td>
<td>0.59</td>
<td>4.8</td>
</tr>
<tr>
<td>C-SSRS</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Suicidal ideation and behavior</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Suicidal ideation score</td>
<td>*</td>
<td>*</td>
<td>1</td>
</tr>
<tr>
<td>Suicidal intensity rating</td>
<td>10.9</td>
<td>2.10</td>
<td>3</td>
</tr>
<tr>
<td>SAS</td>
<td>0.3</td>
<td>0.70</td>
<td>0.4</td>
</tr>
<tr>
<td>AIMS</td>
<td>0.1</td>
<td>0.43</td>
<td>0.2</td>
</tr>
<tr>
<td>BARS</td>
<td>0.2</td>
<td>0.62</td>
<td>0.2</td>
</tr>
</tbody>
</table>

AIMS, Abnormal Involuntary Movement Scale; BARS, Barnes Akathisia Rating Scale; SAS, Simpson-Angus Scale; SD: standard deviation

RB-US-09-0010: Efficacy & Safety Study Results

<table>
<thead>
<tr>
<th>Endpoints</th>
<th>Treatment</th>
<th>LS Means</th>
<th>Difference vs. Placebo (95% CI)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Primary: PANSS Score</strong></td>
<td>90 mg (N=111)</td>
<td>-15.367</td>
<td>-6.15 (-9.98; -2.31)</td>
<td>0.0004</td>
</tr>
<tr>
<td></td>
<td>120 mg (N=114)</td>
<td>-16.456</td>
<td>-7.24 (-11.05; -3.43)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td></td>
<td>Placebo (N=112)</td>
<td>-9.219</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Secondary: CGI-S Scale</strong></td>
<td>90 mg (N=111)</td>
<td>-0.868</td>
<td>-0.35 (-0.56; -0.14)</td>
<td>0.0002</td>
</tr>
<tr>
<td></td>
<td>120 mg (N=114)</td>
<td>-0.914</td>
<td>-0.39 (-0.60; -0.19)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td></td>
<td>Placebo (N=112)</td>
<td>-0.518</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- **PANNS Total Score**
- **CGI-S Total Score**

Subjects With 1+ TEAE
- 90 mg (N = 115): 81 (70.4%)
- 120 mg (N = 117): 91 (77.8%)
- Placebo (N = 118): 81 (68.8%)

Subjects With 1+ Serious TEAE
- 90 mg (N = 115): 0 (0.0%)
- 120 mg (N = 117): 1 (0.9%) - Chest Pain
- Placebo (N = 118): 1 (0.8%) - GI

TEAE: Treatment Emergent Adverse Events
RB-US-09-0010: Efficacy & Safety Study Results

Data on file - Baseline was the last measurement on or before the date of randomization
# RB-US-09-0010: HEOR ENDPOINTS & MEASURES

<table>
<thead>
<tr>
<th>Subjective well-being</th>
<th>SWN-S Under Neuroleptic Scale: Mental functioning; Self-control; Physical functioning; Emotional regulation; Social integration; Total score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health-related quality of life</td>
<td>EuroQol EQ-5D-5L: Mobility; Self-care; Usual activities; Pain/discomfort; Anxiety/depression</td>
</tr>
<tr>
<td>Patient and caregiver preference</td>
<td>Preference of Medicine Questionnaire (POM): Subjects’ preference for the current antipsychotic compared with their most recent pre-study antipsychotic</td>
</tr>
<tr>
<td>Patient satisfaction</td>
<td>Medication Satisfaction Questionnaire (MSQ): Satisfaction with patients antipsychotic medication</td>
</tr>
</tbody>
</table>

RB-US-09-0010: QUALITY OF LIFE (EQ-5D-5L SCORES)

Change From Baseline (LS mean +/- SE)

<table>
<thead>
<tr>
<th>Treatment</th>
<th>LS Mean (+/- SE)</th>
</tr>
</thead>
<tbody>
<tr>
<td>RBP-7000 120mg</td>
<td>8.184 (+/- 3.295)</td>
</tr>
<tr>
<td>RBP-7000 90mg</td>
<td>5.156 (+/- 3.295)</td>
</tr>
<tr>
<td>Placebo</td>
<td>3.295 (+/- 3.295)</td>
</tr>
</tbody>
</table>

* P<0.05 vs. Placebo

RB-US-09-0010: Medication Satisfaction


* P<0.05; ** P<0.01 vs. Placebo
RB-US-13-0005: ONGOING PHASE 3 LONG-TERM SAFETY TRIAL

- Open label, long-term safety and tolerability study of RBP-7000 for the treatment of subjects with schizophrenia
  - **Primary objective:** Assess the long-term safety and tolerability of RBP-7000 (90 mg, 120 mg).
  - **Secondary objective:** Continue collecting clinical outcome data with RBP-7000 (90 mg, 120 mg) using the PANSS and CGI-S scales.
  - **Tertiary objective:** Continue collecting health economics and subject-reported outcome data with RBP-7000.
Phase 3 & HEOR Data Summary: RBP-7000

- Once a month dosing
- Rapid onset of action
- No loading dose with initiation of treatment
- No supplemental dosing during treatment
- Demonstrated clinical efficacy & safety in schizophrenia
- Overall well tolerated
- Measurable quality of life and medication satisfaction benefits
INDIVIOR R&D DAY

RBP-7000: Vision for the Treatment of Schizophrenia

Glenn Tyson
Vice-President, Global Therapy Areas, Indivior Inc.

Our vision is that all patients around the world will have unrestricted access to high-quality treatment services for the chronic relapsing conditions and co-morbidities of addiction.
Physicians see RBP-7000 as having the potential to increase compliance

1. Well known molecule, in addition to having a better dosing regimen

2. Perceived as convenient. Its dosing schedule and lack of concomitant oral dosing may lead to better compliance, especially in those who are struggling

3. Perceived as providing more stability and reliability for patients with schizophrenia, due to its better dosing schedule and convenience

Source: INDV quantitative market research, Jan 2016, n=121
Any statements about RBP-7000 are for discussion and planning purposes only.
Risperidone remains the most commonly used antipsychotic to treat schizophrenia

Source: IMS and Source Healthcare, MAT April 2016
LONG-ACTING INJECTABLE SCHIZOPHRENIA MARKET GROWING BY BOTH VOLUME AND VALUE YEAR-OVER-YEAR

Source: IMS sales, factored for schizophrenia, MAT April 2016
Market research reflecting psychiatrists’ perception of RBP-7000

Potential Advantage or Disadvantage Over Current Treatments (% of respondents)

- Major Advantage: 22%
- Modest Advantage: 43%
- Similar to Current Options: 33%
- Modest Disadvantage: 0%
- Major Disadvantage: 2%

Source: INDV quantitative market research study, Dec 2015 – N=122
Any statements about RBP-7000 are for discussion and planning purposes only.
Market research reflecting likelihood to prescribe RBP-7000

**Likelihood to Prescribe (% of respondents)**

- **Definitely Would Prescribe**: 36%
- **Probably Would Prescribe**: 44%
- **Might Or Might Not Prescribe**: 16%
- **Probably Would Not Prescribe**: 2%
- **Definitely Would Not Prescribe**: 2%

Source: INDV quantitative market research, Dec 2015 – N=122
Any statements about RBP-7000 are for discussion and planning purposes only.
RBP-7000 POTENTIAL PATIENT BUILD

POPULATION DESCRIPTION

- Patients with schizophrenia new to LAIs for whom a risperidone-containing LAI is physician target
- Patients with schizophrenia currently on risperidone-containing LAI with bi-weekly dosing

MOST COMPELLING DIFFERENTIATOR RELEVANT TO THIS POPULATION

Delivers once-monthly risperidone with a pharmacokinetic (PK) profile that may help patients achieve stability and potentially reduce relapse and hospitalizations

Patients with schizophrenia taking oral or injectable risperidone with multiple relapses and/or adherence challenges

Novel method of delivery for the most common and preferred molecule for treatment of schizophrenia

Schizophrenia patients with multiple relapses and/or adherence challenges, i.e. patients in need of an LAI

Delivers known LAI benefits of lower relapse/hospitalization costs in schizophrenia patients\(^1\)

Schizophrenia patients seeking maintenance treatment

Provides potential benefit to a population for whom relapse is highly debilitating

\(^1\)INDV analysis of Truven Health Marketscan\(^\circledR\) Commercial and Medicare Supplemental Databases and The Multi-state Medicaid Database Time Period: July 1, 2009 - April 30, 2015

Any statements about RBP-7000 are for discussion and planning purposes only.
INDIVIOR R&D DAY DECEMBER 9TH, 2016

STRENGTHENING OUR GLOBAL LEADERSHIP IN TREATMENT OF ADDICTION

Shaun Thaxter, Chief Executive Officer

Our vision is that all patients around the world will have unrestricted access to high-quality treatment services for the chronic relapsing conditions and co-morbidities of addiction.
Our vision is that all patients around the world will have unrestricted access to high-quality treatment services for the chronic relapsing conditions and co-morbidities of addiction.
OUR VISION

That all patients around the world will have unrestricted access to high-quality treatment services for the chronic relapsing conditions and co-morbidities of addiction
**Drivers of Growth for Indivior**

- Market Growth & Resilient Share
- New Pipeline Products
- Geographical Expansion
- Inorganic Opportunity
**Role of R&D in Generating Drivers of Growth for Indivior**

1. Market Growth & Resilient Share → Commercial Operations
2. New Pipeline Products → R&D
3. Geographical Expansion → R&D & Commercial
4. Inorganic Opportunity → Corporate

Indivior R&D Day | December 9th 2016
Preserve leadership position in USA against 5 (now 7) generic and 3 branded competitors

1. SUBOXONE® Film Resilience

- New treatment areas of addiction and related morbidities
- Expand treatment access in USA
- Opioid painkiller dependence in Europe
- File NDA in China

2. Develop the pipeline

- Transformational lifecycle products for Buprenorphine
- Treatments for other addictions and addiction rescue

3. Finance ready for BD / M&A

- Expand business
- Diversify risk through targeted business development

US Listing process

BD/M&A and US listing on hold until litigation/investigation is clarified / resolved

4. Expand Global treatment

- New treatment areas of addiction and related morbidities
- Expand treatment access in USA
- Opioid painkiller dependence in Europe
- File NDA in China

Resolve litigation & investigations and secure long-term certainty for Company
EXISTING BUSINESS

2016 a strong year – resumption of growth implicit in raised guidance

- Market growth is picking up helped by public focus on opioid epidemic.
- Implementation of CARA Act and other regulatory change should create new growth opportunities
- SUBOXONE® Film share has been very resilient
  - Multiple generic tablet entries and sliding generic pricing
  - Branded competition not making headway
- Net pricing has been more resilient in 2016
  - Price increase in January has held (first since 2012)
  - Formulary access has been maintained
R&D PIPELINE DELIVERY

Success with the major projects

• RBP-6000: Phase 3 efficacy & safety trials concluded
  ✓ Efficacy achieved all endpoints
• RBP-7000: Phase 3 efficacy & safety trials concluded
  ✓ Efficacy achieved all endpoints
• Arbaclofen Placarbil: Reformulating and plan for next steps in 2017

Scale of Market Opportunity as indicated on demerger ¹

<table>
<thead>
<tr>
<th>Product</th>
<th>Potential Peak NR**</th>
</tr>
</thead>
<tbody>
<tr>
<td>RBP-6000</td>
<td>$400m - $700m</td>
</tr>
<tr>
<td>RBP-7000</td>
<td>$100m - $200m</td>
</tr>
<tr>
<td>Arbaclofen Placarbil</td>
<td>$500m - $900m</td>
</tr>
</tbody>
</table>

• 2014 estimates – markets have grown since then and our knowledge base has increased
• Will revisit peak NR estimates in 2017

¹ Indivior PLC investor day November 21, 2014, slide 184
**First priority is always to invest in organic growth**
Lower risk, investing in what we know

---

**Pre-commercialisation for RBP-6000**

Medical education
Healthcare professional & patient preparation
Development of distribution channels
Salesforce training

---

**SUBOXONE® Tablet in China**

NDA preparation ongoing
Investing in pre-commercial infrastructure

---

**Accelerating growth in treatment USA**

Significant investment in driving patients into treatment opportunities arising from legislative and regulatory change
- Nurse practitioners and physician assistants
- Patient cap raised for certain qualified, waived doctors

---

**RBP-7000 strategy**

Still open minded on route forward – internal or external – and there is no rush to resolve this, NDA not filed until H2-2017
However, time to start education, marketing and medical affairs investment is 2017 whichever route is taken
## Business Development — So What Have We Done?

<table>
<thead>
<tr>
<th>Reviewed all assets in addiction</th>
<th>Looked at sensible adjacencies</th>
<th>Rejected most</th>
<th>Short list of interesting assets</th>
</tr>
</thead>
<tbody>
<tr>
<td>Most are competing products with what we already have</td>
<td>Reviewed dozens of potential add-on opportunities</td>
<td>Most make no strategic sense — we would not necessarily add value to them</td>
<td>There are several early stage opportunities</td>
</tr>
<tr>
<td>There are one or two complimentary products but embedded in other companies</td>
<td>Across several different CNS disease spaces</td>
<td>Or they make no financial sense — they just compound our profile</td>
<td>But no BD is executable at this time</td>
</tr>
<tr>
<td></td>
<td></td>
<td>We have maintained strong capital discipline despite encouragement to diversify fast</td>
<td>So we continue to monitor these opportunities and will be prepared to move when opportunity arises.</td>
</tr>
</tbody>
</table>
**IMPLICATIONS FOR 2017**

- We have already increased our investment by <$35m in 2016 in pre-commercialisation activities primarily for RBP-6000.

- We will likely be looking to step up pre-launch investment in RBP-6000, in China and in driving more access to treatment in US in 2017. The quantum of additional investment for 2017 will be confirmed in February.

- To help offset this increasing P&L cost of the business
  - Indirect cost project in 2016 (Project Jumpstart) has baked in savings of $8m (some in 2016)
  - Looking to other aspects of the cost optimisation project to help contain inflation in base business costs.

- Will give detailed guidance on this as part of the 2017 guidance in February.
SUMMARY

We face the future with renewed confidence

We face the future with renewed confidence

We are making progress in managing the risks to the business

We look forward to continuing our progress
Our vision is that all patients around the world will have unrestricted access to high-quality treatment services for the chronic relapsing conditions and co-morbidities of addiction.
ADDENDA
INDIVIOR R&D DAY DECEMBER 9TH, 2016

CLINICAL TRIALS 2016

Our vision is that all patients around the world will have unrestricted access to high-quality treatment services for the chronic relapsing conditions and co-morbidities of addiction.
Single Ascending Dose (RB-CN-10-0012)
Multiple Ascending Dose (RB-CN-10-0013)
Efficacy & Safety (RB-CN-10-0015)
# Single Ascending Dose (RB-CN-10-0012)

<table>
<thead>
<tr>
<th>Title</th>
<th>A single ascending dose, open-label study to examine the pharmacokinetic profile of SUBOXONE® sublingual tablets 2mg/0.5mg, 4mg/1mg, 8mg/2mg, 12mg/3mg 16mg/4mg and 24mg/6mg in healthy Chinese subjects under a naltrexone block.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study Phase</td>
<td>Phase 1</td>
</tr>
<tr>
<td>Design</td>
<td>Single-dose escalation, open-label PK study</td>
</tr>
<tr>
<td># of patients</td>
<td>82</td>
</tr>
<tr>
<td>Primary endpoints</td>
<td>PK profiles of buprenorphine, norbuprenorphine and naloxone</td>
</tr>
<tr>
<td>Status</td>
<td>Completed</td>
</tr>
<tr>
<td>NCT ref.</td>
<td>N/A</td>
</tr>
</tbody>
</table>
# MULTIPLE ASCENDING DOSE (RB-CN-10-0015)

<table>
<thead>
<tr>
<th><strong>Title</strong></th>
<th>An open-label, parallel-group, multiple-dose, steady-state pharmacokinetic study of SUBOXONE® 16 mg/4 mg and 24mg/6 mg administered to patients who are in withdrawal treatment of opioid dependence</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Study Phase</strong></td>
<td>Phase 1</td>
</tr>
<tr>
<td><strong>Design</strong></td>
<td>Open-label, multiple-dose study</td>
</tr>
<tr>
<td><strong># of patients</strong></td>
<td>32</td>
</tr>
<tr>
<td><strong>Primary endpoints</strong></td>
<td>PK profiles of buprenorphine, norbuprenorphine and naloxone at steady state</td>
</tr>
<tr>
<td><strong>Status</strong></td>
<td>Completed</td>
</tr>
<tr>
<td><strong>NCT ref.</strong></td>
<td>N/A</td>
</tr>
</tbody>
</table>
# Efficacy & Safety (RB-CN-10-0013)

A randomized, double-blind, placebo-controlled multi-center outpatient maintenance study comparing buprenorphine HCl/naloxone HCl dihydrate (SUBOXONE®) versus placebo for treatment of opioid dependence in Chinese subjects stabilized on sublingual buprenorphine hydrochloride/naloxone hydrochloride dihydrate (SUBOXONE®)

<table>
<thead>
<tr>
<th>Title</th>
<th>A randomized, double-blind, placebo-controlled multi-center outpatient maintenance study comparing buprenorphine HCl/naloxone HCl dihydrate (SUBOXONE®) versus placebo for treatment of opioid dependence in Chinese subjects stabilized on sublingual buprenorphine hydrochloride/naloxone hydrochloride dihydrate (SUBOXONE®)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study Phase</td>
<td>Phase 3</td>
</tr>
<tr>
<td>Design</td>
<td>Randomized, double blind, placebo controlled</td>
</tr>
<tr>
<td># of patients</td>
<td>260</td>
</tr>
<tr>
<td>Primary endpoints</td>
<td>Treatment retention time: Defined as time from randomization to treatment completion or treatment failure</td>
</tr>
<tr>
<td>Status</td>
<td>Completed</td>
</tr>
<tr>
<td>NCT ref.</td>
<td>N/A</td>
</tr>
</tbody>
</table>
Our vision is that all patients around the world will have unrestricted access to high-quality treatment services for the chronic relapsing conditions and co-morbidities of addiction.
**Efficacy & Safety (RB-US-13-0001)**

<table>
<thead>
<tr>
<th>Title</th>
<th>A Randomized, Double-blind, Placebo-Controlled, Multicenter Study to Assess the Efficacy, Safety, and Tolerability of Multiple Subcutaneous Injections of RBP-6000 [100 mg and 300 mg] Over 24 Weeks in Treatment-Seeking Subjects with Opioid Use Disorder</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study Phase</td>
<td>Phase 3</td>
</tr>
<tr>
<td>Design</td>
<td>Multi-center, Multi-dose, Randomized, Double-blind, Placebo-controlled, 24-week efficacy, safety, and tolerability study</td>
</tr>
<tr>
<td># of patients</td>
<td>N = 489</td>
</tr>
<tr>
<td>Primary endpoints</td>
<td>Abstinence Rate (CDF of the percentage of urine samples combined with self-reports negative for illicit opioid use collected from Week 5 through Week 24). Key Secondary: Responder analysis (defined as ≥80% abstinent rate)</td>
</tr>
<tr>
<td>Status</td>
<td>Complete</td>
</tr>
<tr>
<td>NCT ref.</td>
<td><a href="https://clinicaltrials.gov/ct2/results?term=NCT02357901">NCT02357901</a></td>
</tr>
</tbody>
</table>
# RBP-6000: Comparative Primary & Secondary Endpoints

<table>
<thead>
<tr>
<th>RBP-6000</th>
<th>CAM2038</th>
<th>Probuphine</th>
<th>Key differentiators</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Primary endpoints</strong></td>
<td>Superiority to placebo on abstinence rate (from illicit opioids)</td>
<td>Non-inferiority to SL BUP on responder rate</td>
<td>Superiority to placebo is a higher efficacy bar for RBP-6000 trial</td>
</tr>
</tbody>
</table>
| **Definition of primary endpoint** | ▪ Abstinence rate week 5-24  
▪ Urines measured weekly.  
▪ Missing urines assumed positive.  
▪ Supplemental buprenorphine use not allowed.  | ▪ A responder is defined as a subject with at least: 33% abstinence from illicit opioids during the 12-week induction phase and 67% abstinence during the 12-week treatment phase.  
▪ Urines measured weekly during induction phase and twice monthly during treatment phase.  | ▪ Responder rate (≥ 4 of 6 months -abstinence from illicit opioids ).  
▪ Urines measured monthly + 4 random measures  
▪ Missing urines not counted (20% penalty applied in analysis).  
▪ Supplemental buprenorphine use allowed.  
▪ RBP-6000 trials set higher bar for primary efficacy endpoints:  
  1) More rigid definitions of no illicit opioid use  
  2) RBP-6000 abstinence endpoint was regulatory authority agreed |
| **Definition of Responder** | ▪ Responder rate (80% abstinence week 5-24) (Key secondary)  | ▪ A subject with at least: 33% abstinence from illicit opioids during the 12-week induction phase and 67% abstinence during the 12-week treatment phase.  | ▪ Responder rate (≥ 4 of 6 months -abstinence from illicit opioids ).  
▪ RBP-6000 higher order responder rate definition |
| **FDA Definition of Responder** | ▪ Abstinence rate week 5-24  | ▪ 75% abstinent rate weeks 9-12 and 83% abstinent rate weeks 13-24.  | ▪ No illicit opioid use over 6 months with ≤ 2 episodes of rescue medication  
▪ The primary endpoint for RBP-6000 was the regulatory-agreed primary endpoint of the study, with dosing designed to achieve opioid blockade |
| **Craving and withdrawal measures** | ▪ Opioid craving VAS\(^1\)  
▪ COWS\(^1\) & SOWS\(^1\)  | ▪ Unknown  | ▪ Opioid craving* VAS\(^1\)  
▪ COWS\(^1\) & SOWS\(^1\)  
▪ Supplemental use of sublingual buprenorphine  
▪ Clear measures for craving for treatment-duration  
▪ Prescribed supplemental treatment not allowable |

*Described as “desire and need to use” in protocol.

\(^1\)VAS: Visual Analog Scale; COWS: Clinical Opiate Withdrawal Scale; SOWS: Subjective Opiate Withdrawal Scale; \(^2\)(RB-US-13-0001)
LONG-TERM SAFETY EXTENSION (RB-US-13-0003)

<table>
<thead>
<tr>
<th>Title</th>
<th>Open-Label, Long-Term Safety and Tolerability Study of RBP-6000 in Treatment-Seeking Subjects With Opioid Use Disorder</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study Phase</td>
<td>Phase 3</td>
</tr>
<tr>
<td>Design</td>
<td>Multi-center, Multi-dose, Open-label, long-term safety and tolerability study (extension of RB-US-13-0001)</td>
</tr>
<tr>
<td># of patients</td>
<td>N = 672 (415 de novo, 257 rollover)</td>
</tr>
<tr>
<td>Primary endpoints</td>
<td>Adverse events, local injection site tolerability, injection site pain, suicidality, changes in laboratory results, vital signs, ECGs.</td>
</tr>
<tr>
<td>Status</td>
<td>Ongoing; interim analysis ongoing for the 500 exposed for 6 months and 100 for 12 months</td>
</tr>
<tr>
<td>NCT ref.</td>
<td>NCT02510014</td>
</tr>
</tbody>
</table>
**Open Label Extension (INDV-6000-301)**

<table>
<thead>
<tr>
<th>Title</th>
<th>An Open-Label RBP-6000 Treatment Extension Study in Subjects With Opioid Use Disorder</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study Phase</td>
<td>Phase 3</td>
</tr>
<tr>
<td>Design</td>
<td>Multi-center, Multi-dose, Open-label, long-term safety (extension of RB US 13-0003)</td>
</tr>
<tr>
<td># of patients</td>
<td>N = 600 (planned)</td>
</tr>
<tr>
<td>Primary endpoints</td>
<td>Safety assessments including AEs, local injection site tolerability, injection site pain, suicidality, changes in clinical laboratory results, vital signs</td>
</tr>
<tr>
<td>Status</td>
<td>Ongoing</td>
</tr>
<tr>
<td>NCT ref.</td>
<td>NCT02896296</td>
</tr>
</tbody>
</table>
# MOLECULAR WEIGHT (RB-US-13-0006)

<table>
<thead>
<tr>
<th>Title</th>
<th>Pharmacokinetics, Safety, and Tolerability of RBP-6000 at Three Different Molecular Weights in Treatment-Seeking Subjects With Opioid Use Disorder</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study Phase</td>
<td>Phase 1</td>
</tr>
<tr>
<td>Design</td>
<td>Randomized, Single-dose, Open-label, PK study using PLGH Polymer of 2 Different Molecular Weights (Low and High) in Comparison to Intermediate Molecular Weight (Reference Treatment)</td>
</tr>
<tr>
<td># of patients</td>
<td>N= 47</td>
</tr>
<tr>
<td>Primary endpoints</td>
<td>Bioavailability</td>
</tr>
<tr>
<td>Status</td>
<td>Completed</td>
</tr>
<tr>
<td>NCT ref.</td>
<td>NCT02559973</td>
</tr>
<tr>
<td>Title</td>
<td>REmission from Chronic Opioid Use: Studying EnVironmental and socioEconomic factors on Recovery</td>
</tr>
<tr>
<td>----------------------------------------------------------------------</td>
<td>-------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Study Phase</td>
<td>Observational study</td>
</tr>
<tr>
<td>Design</td>
<td>12-month multicenter, observational study of subjects either discontinuing or completing RB-US-13-0001 and/or RB-US-13-0003 studies</td>
</tr>
<tr>
<td># of patients</td>
<td>475 (planned)</td>
</tr>
</tbody>
</table>
| Primary endpoints                                                   | • Periods of abstinence over a 12-month observational window, i.e., # days abstinent, time to relapse, # relapses, and time to return to abstinence after relapse  
|                                                                      | • Biological, psychosocial and environmental factors associated with periods of abstinence and relapse  
|                                                                      | • Health economics impact of treatments for opioid use disorder                                  |
| Status                                                              | Ongoing                                                                                         |
| NCT ref.                                                            | NA                                                                                              |
INDIVIOR R&D DAY

RBP-7000 MONTHLY RISPERIDONE

Long-term safety extension (RB-US-13-0005)
Molecular Weight (RB-US-13-0006)

Our vision is that all patients around the world will have unrestricted access to high-quality treatment services for the chronic relapsing conditions and co-morbidities of addiction.
**LONG-TERM SAFETY EXTENSION (RB-US-13-0005)**

<table>
<thead>
<tr>
<th>Title</th>
<th>An Open-Label, Long-Term Safety and Tolerability Study of RBP-7000 in the Treatment of Subjects With Schizophrenia</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study Phase</td>
<td>Phase 3</td>
</tr>
<tr>
<td>Design</td>
<td>An open-label study to assess the long-term safety and tolerability of 120 mg of RBP-7000 subcutaneous (SC) injections administered monthly for up to one year in subjects with schizophrenia. Subjects included rollover subjects from RB-US-09-0010 and <em>de novo</em> subjects stabilized on 3 or 4 mg of risperidone prior to treatment. This study also continued collecting clinical outcome data (PANSS &amp; CGI-S) and HEOR data</td>
</tr>
<tr>
<td># of patients</td>
<td>500</td>
</tr>
<tr>
<td>Primary endpoints</td>
<td>Evaluation of treatment emergent adverse events (TEAE)</td>
</tr>
<tr>
<td>Status</td>
<td>Completed</td>
</tr>
<tr>
<td>NCT ref.</td>
<td><a href="https://clinicaltrials.gov/show/NCT02203838">NCT02203838</a></td>
</tr>
</tbody>
</table>
# MOLECULAR WEIGHT (RB-US-15-0001)

<table>
<thead>
<tr>
<th>Title</th>
<th>A Multicenter, Randomized, Open-Label, Single-Dose Study to Evaluate the Pharmacokinetics, Safety, and Tolerability of RBP-7000 Using Poly (DL-lactide-co-glycolide) Polymer of Two Different Molecular Weights (MW) (Low and High MW as Test Treatments) Compared to Intermediate MW (Reference Treatment) Polymer in clinically stable Subjects with schizophrenia not currently taking risperidone</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study Phase</td>
<td>Phase 1</td>
</tr>
<tr>
<td>Design</td>
<td>44 subjects (~14 per group) were randomized to receive a single SC injection of RBP-7000 120 mg formulated with PLGH polymer of either 21 kilodaltons (kDa) (low MW group), 29 kDa of PLGH polymer (high MW group), or 26 kDa of PLGH polymer (intermediate MW group).</td>
</tr>
<tr>
<td># of patients</td>
<td>44</td>
</tr>
<tr>
<td>Primary endpoints</td>
<td>PK endpoints of AUC and Cmax for initial burst parameters, secondary peak parameters, and overall PK parameters</td>
</tr>
<tr>
<td>Status</td>
<td>Completed</td>
</tr>
<tr>
<td>NCT ref.</td>
<td>NCT02687984</td>
</tr>
</tbody>
</table>
Dose-escalation (RB-US-14-0001)
Bioavailability (INDV-AP-102)
## Dose Escalation (RB-US-14-0001)

<table>
<thead>
<tr>
<th>Title</th>
<th>A Randomized, Double-Blind, Placebo Controlled, Dose Escalation Study to Determine the Maximum Tolerated Dose of Arbaclofen Placarbil (AP) in Subjects with Alcohol Use Disorder (AUD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study</td>
<td>Phase 2A</td>
</tr>
<tr>
<td>Design</td>
<td>Randomized Double Blind AP:Placebo 2:1</td>
</tr>
<tr>
<td># of subjects</td>
<td>18</td>
</tr>
<tr>
<td>Primary endpoints</td>
<td>To determine the maximum tolerated dose (MTD) of arbaclofen placarbil (AP) in the treatment of subjects with AUD confirmed by Diagnostic and Statistical Manual of Mental Disorders-5 (DSM-5) criteria. To assess the pharmacokinetics (PK) of AP and R-baclofen in subjects with AUD confirmed by DSM-5 criteria, following AP administration</td>
</tr>
<tr>
<td>Status</td>
<td>Completed</td>
</tr>
<tr>
<td>NCT ref.</td>
<td><a href="https://clinicaltrials.gov/ct2/show/NCT02511886">NCT02511886</a></td>
</tr>
</tbody>
</table>

**Title:** A Randomized, Double-Blind, Placebo Controlled, Dose Escalation Study to Determine the Maximum Tolerated Dose of Arbaclofen Placarbil (AP) in Subjects with Alcohol Use Disorder (AUD)

**Study Phase:** 2A

**Design:** Randomized Double Blind AP:Placebo 2:1

**# of subjects:** 18

**Primary endpoints:**
- To determine the maximum tolerated dose (MTD) of arbaclofen placarbil (AP) in the treatment of subjects with AUD confirmed by Diagnostic and Statistical Manual of Mental Disorders-5 (DSM-5) criteria.
- To assess the pharmacokinetics (PK) of AP and R-baclofen in subjects with AUD confirmed by DSM-5 criteria, following AP administration.

**Status:** Completed

**NCT ref.:** [NCT02511886](https://clinicaltrials.gov/ct2/show/NCT02511886)
# Bioavailability (INDV-AP-102)

<table>
<thead>
<tr>
<th>Title</th>
<th>Phase 1 Bioavailability Study of Arbaclofen Placarbil Modified Release Formulations in Healthy Volunteers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study Phase</td>
<td>1B</td>
</tr>
<tr>
<td>Design</td>
<td>Open Label</td>
</tr>
<tr>
<td># of subjects</td>
<td>12 to 36 depending on success of first formulation</td>
</tr>
<tr>
<td>Primary endpoints</td>
<td>To evaluate PK and safety/tolerability of arbaclofen in 2-4 different formulations in HV and its bioavailability with food and alcohol</td>
</tr>
<tr>
<td>Status</td>
<td>Planned first dosing 1Q2017</td>
</tr>
<tr>
<td>NCT ref.</td>
<td>N/A yet</td>
</tr>
</tbody>
</table>
Our vision is that all patients around the world will have unrestricted access to high-quality treatment services for the chronic relapsing conditions and co-morbidities of addiction.
Our vision is that all patients around the world will have unrestricted access to high-quality treatment services for the chronic relapsing conditions and co-morbidities of addiction.
Method Development - I


- A simple, sensitive and rapid liquid chromatography/electrospray ionization tandem mass spectrometry (LC-ESI-MS/MS) method for simultaneous quantification of naloxone, buprenorphine and norbuprenorphine in human plasma.
A rapid and sensitive LC-MS/MS method for the simultaneous determination of buprenorphine and its three metabolites (buprenorphine glucuronide, norbuprenorphine and norbuprenorphine glucuronide) as well as naloxone and its metabolite naloxone glucuronide in the rat plasma.
Method Development - III


- Improve the oral bioavailability of buprenorphine (BUP) by inhibiting presystemic metabolism via the oral co-administration of generally recognized as safe (GRAS) compounds, thus providing an orally administered drug product with less variability and comparable or higher exposure compared to the sublingual route.
Our vision is that all patients around the world will have unrestricted access to high-quality treatment services for the chronic relapsing conditions and co-morbidities of addiction.

- Demonstrate that RBP-6000 blocks the subjective effects and reinforcing efficacy of hydromorphone in subjects with moderate or severe opioid use disorder (OUD).
- RBP-6000 at a 300 mg dose provides durable and potent blockade of the subjective effects and reinforcing efficacy of hydromorphone in subjects with moderate or severe OUD.
A population pharmacokinetic (PK) model associated with predicted levels of $\mu$-opioid receptor occupancy described the time course of buprenorphine plasma concentrations after repeated SC injections of RBP-6000 at 50 mg, 100 mg, 200 mg, or 300 mg in treatment-seeking opioid-dependent subjects previously on SUBUTEX® treatment.

The model provided quantitative criteria for clinical dose selection of RBP-6000 with a dosage strength of 300 mg every 28 days immediately achieving effective exposure after the first SC injection and maintaining effective levels of exposure during chronic treatment.
Our vision is that all patients around the world will have unrestricted access to high-quality treatment services for the chronic relapsing conditions and co-morbidities of addiction.
RBP-7000 - I

Assess the **efficacy, safety, and tolerability of RBP-7000** (90, 120 mg) compared to placebo in subjects with acute exacerbation of schizophrenia over an 8-week period.

- Efficacy was evaluated as a change from baseline to EOS in Positive and Negative Syndrome Scale (PANSS) total score (**primary endpoint**) and Clinical Global Impression – Severity (CGI-S) score (**secondary endpoint**).
- RBP-7000 significantly reduced PANSS total scores and significantly improved CGI-S scores. Both RBP-7000 dosages were well tolerated.


- **Health-Related Quality of Life data** derived from pivotal Phase 3 trial.
- Significantly greater improvements in HRQoL and overall well-being were demonstrated in patients randomized to RBP-7000 vs. placebo.
- Patient satisfaction improved significantly and patient preference for their medicine favored RBP-7000 90 mg and 120 mg vs. Placebo.
Our vision is that all patients around the world will have unrestricted access to high-quality treatment services for the chronic relapsing conditions and co-morbidities of addiction.
Early Stage Asset Development - I


- Selective DA D3 receptor antagonists have been shown to reduce or block drug-induced incentive motivation, attenuate drug's rewarding efficacy, and reduce reinstatement of drug-seeking behavior.
- A joint computational-medicinal chemistry “scaffold hopping” strategy resulted in the discovery of novel, selective and developable DA D3 receptor antagonists.
- The lead optimization of this new class is currently ongoing.

- A detailed structure activity relationship (SAR) and pharmacokinetic (PK) in vitro and in vivo strategy was described to characterize this new series of highly potent and selective DA D3 receptor antagonists.
- The lead optimization of this new class is currently ongoing.
ARLY STAGE ASSET DEVELOPMENT - III


- A novel series of 1,2,4-Triazolyl 5-Azaspiro[2.4]heptanes with high affinity and selectivity at the DA D3 receptor was described.
- A few derivatives with overall favorable developability characteristics were selected for further late lead optimization studies.
Our vision is that all patients around the world will have unrestricted access to high-quality treatment services for the chronic relapsing conditions and co-morbidities of addiction
The Company has recorded a charge of $220m in the third quarter of 2016 for the investigative and antitrust litigation matters noted below. Because these matters are in various stages, the Company cannot predict with any certainty the ultimate resolution or cost of all of the matters. The final amount might be materially different from this reserve.
A federal criminal grand jury investigation of Indivior initiated in December 2013 is continuing, and includes marketing and promotion practices, pediatric safety claims, and overprescribing of medication by certain physicians. The U.S. Attorney’s Office for the Western District of Virginia has served a number of subpoenas relating to SUBOXONE® Film, SUBOXONE® Tablet, SUBUTEX® Tablet, buprenorphine and our competitors, among other issues. We are in the process of responding by producing documents and other information in connection with this on-going investigation, and in preliminary discussion about a possible resolution of the investigation. It is not possible at this time to predict with any certainty the potential impact of this investigation on us or to quantify the ultimate cost of a resolution. We are cooperating fully with the relevant agencies and prosecutors and will continue to do so.

On October 12, 2016, the Company was served with a subpoena for records from the state of Connecticut Office of the Attorney General under its Connecticut civil false claims act authority. The subpoena requests documents related to the Company’s marketing and promotion of SUBOXONE® products and its interactions with a non-profit third party organization. On November 16, 2016, the Company was served with a subpoena for records from the state of California Department of Insurance under its California insurance code authority. The subpoena requests documents related to SUBOXONE® Film, SUBOXONE® Tablet, and SUBUTEX® Tablet. The Company is cooperating in these investigations.
The Judge overseeing the legal privilege dispute in the FTC investigation has appointed a Special Master (an independent external lawyer) to investigate the claims of legal privilege and provide a recommendation to the Court on how the documents at issue should be treated. An initial report and recommendation relating to the first tranche of privileged documents reviewed by the Special Master was finalized in April 2016 and adopted by the Court on August 1st, 2016. Pursuant to this report and the Court’s order, Indivior produced certain additional documents. A second tranche of documents remains under review. Following that review, the Court’s decision then may be subject to appeal by either party.

Amneal Pharmaceuticals LLC, a manufacturer of generic buprenorphine / naloxone tablets, filed a complaint against the Company in December 2015. This case has been coordinated with the Class Action litigation. Amneal’s complaint contains antitrust allegations similar in nature to those set out in the class action complaints, and Amneal has also alleged violations of the Lanham Act.

On September 22, 2016, 35 states and the District of Columbia filed a complaint against the Company in the same district where the Class Action and Amneal litigation is pending. The States' complaint is similar to the other pending complaints, and alleges violations of state and federal antitrust and consumer protection laws.

On November 16, 2016 the States served an amended complaint, adding six additional states as plaintiffs. This lawsuit relates to the investigation conducted by various states, as discussed in previous filings.

Fact discovery is continuing in the antitrust class action litigation described on our Annual Report (“Class Action Litigation”). Plaintiffs allege, among other things, that Indivior violated federal and state antitrust laws in attempting to delay generic entry of alternatives to SUBOXONE®® tablets, and plaintiffs further allege that Indivior unlawfully acted to lower the market share of these products.
The ruling after trial against Actavis and Par in the lawsuit involving the Orange Book-listed patents for SUBOXONESUBOXONE® Film issued on June 3rd, 2016. Ruling found the asserted claims of the ‘514 patent valid and infringed; the asserted claims of the ‘150 patent valid but not infringed; and the asserted claims of the ‘832 patent invalid, but found that certain claims would be infringed if they were valid.

Based on the ruling as to the ‘514 patent, Actavis and Par are currently enjoined from launching a generic product. Par has appealed and Actavis is expected to appeal this ruling. The generics have also moved to reopen the judgment based on a more stringent claim construction in the Dr Reddy’s case. In light of the motions to reopen, Par’s appeal has been deactivated until the District Court rules on the motions, and the deadline for Actavis to file a notice of appeal has been postponed.

Trial against Dr. Reddy’s, Actavis and Par in the lawsuits involving the process patent (US Patent No. 8,900,497) took place on November 16th and 21st-23rd, 2016.

Trial against Dr. Reddy’s in the lawsuit involving the Orange Book-listed patents for SUBOXONESUBOXONE® Film took place on November 7th, 16th, and 21st-23rd, 2016, with Dr. Reddy’s 30-month stay of FDA approval on ANDA No. 20-5806 expiring April 17th, 2017. Indivior believes Dr. Reddy’s 30-month stay of FDA approval on ANDA No. 20-5299 also expires on April 17th, 2017, however, Dr Reddy’s disputes the applicability of the stay to this ANDA.

Trial against Alvogen in the lawsuit involving the Orange Book-listed patents and the ‘497 process patent for SUBOXONESUBOXONE® Film has been postponed and is presently expected to take place in September 2017, with Alvogen’s 30-month stay of FDA approval expiring October 29th, 2017.

By a Court order dated August 22nd, 2016, Indivior’s SUBOXONE® Film patent litigation against Sandoz has been dismissed without prejudice because Sandoz is no longer pursuing Paragraph IV certifications for its proposed generic formulations of SUBOXONE® film.

Trial against Mylan in the lawsuit involving the Orange Book-listed patents and the ‘497 process patent for Suboxone® Film is scheduled for September 25th, 2017, with Mylan’s stay expiring March 24, 2018.

Indivior received a Paragraph IV notification from Teva, dated February 8, 2016, indicating that Teva had filed a 505(b)(2) New Drug Application (NDA) for a 16mg/4mg strength of Buprenorphine/naloxone sublingual film. The Indivior Group and Teva agreed that infringement by Teva’s 16 mg/4 mg dosage strength will be governed by the infringement ruling on the accused 8 mg/2 mg dosage strength in its ANDA currently scheduled for trial in November 2016.
The USPTO declined to institute Teva’s petitions for inter partes review of the three Orange Book-listed patents on procedural grounds.

Dr. Reddy’s has filed an inter partes review petition on each of the three Orange Book Patents. These petitions are substantively similar to those filed by Teva. The USPTO denied the petitions, finding Dr. Reddy’s had failed to establish a reasonable likelihood of showing the challenged claims are unpatentable as obvious.

Certain claims of the ‘832 patent were found invalid in an IPR proceeding brought by BioDelivery Sciences International (BDSI), a decision that has been affirmed by the Court of Appeals for the Federal Circuit.