

# Indivior PLC

Q2 / H1 2021 Results  
July 29, 2021



# AGENDA

**Overview & Strategic Priorities**

Mark Crossley

**Q2 / H1 Performance & FY 2021 Guidance**

Ryan Preblich

**R&D Update**

Christian Heidbreder

**Conclusion**

Mark Crossley

**Q & A**

---



Mark Crossley

Chief Executive Officer



## Forward-looking statements

This announcement contains certain statements that are forward-looking. By their nature, forward-looking statements involve risks and uncertainties as they relate to events or circumstances that may or may not 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 the Indivior Group's financial guidance for 2021 and its medium- and long-term growth outlook, its operational goals, its product development pipeline and statements regarding ongoing litigation and other statements containing the words "subject to", "believe", "anticipate", "plan", "expect", "intend", "estimate", "project", "may", "will", "should", "would", "could", "can", the negatives thereof, variations thereon and similar expressions.

Various factors may cause differences between Indivior's expectations and actual results, including, among others (including those described in the risk factors described in the most recent Indivior PLC Annual Report and in subsequent releases): factors affecting sales of Indivior Group's products and financial position; the outcome of research and development activities; decisions by regulatory authorities regarding the Indivior Group's drug applications or authorizations; the speed with which regulatory authorizations, pricing approvals and product launches may be achieved, if at all; the outcome of post-approval clinical trials; competitive developments; difficulties or delays in manufacturing and in the supply chain; disruptions in or failure of information technology systems; 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; challenges in the commercial execution; 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, including compliance with the Indivior Group's agreements with the U.S. Department of Justice and with the Office of Inspector General of the Department of Health and Human Services, non-compliance with which could result in potential exclusion from participating in U.S. Federal health care programs; the ongoing investigative and antitrust litigation matters; the opioid national multi-district litigation and securities class action litigation; the Indivior Group's ability to protect its patents and other intellectual property; the outcome of patent infringement litigation relating to Indivior Group's products, including the ongoing ANDA lawsuits; changes in governmental laws and regulations; issues related to the outsourcing of certain operational and staff functions to third parties; risks related to the evolving COVID-19 pandemic and the potential impact of COVID-19 on the Indivior Group's operations and financial condition, which cannot be predicted with confidence; 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.

Consequently, forward-looking statements speak only as of the date that they are made and should be regarded solely as our current plans, estimates and beliefs. You should not place undue reliance on forward-looking statements. We cannot guarantee future results, events, levels of activity, performance or achievements. Except as required by law, we do not undertake and specifically decline any obligation to update, republish or revise forward-looking statements to reflect future events or circumstances or to reflect the occurrences of unanticipated events.



## Q2 2021 key takeaways

- Good execution across all Strategic Priorities
- Organized Health System (OHS) focus for SUBLOCADE® delivering
- Moving forward with confidence – initiating \$100m share repurchase program



# Strategic Priorities report card: Q2 2021

1

## Grow SUBLOCADE® >\$1 bil.

- **Q2 21 NR:** \$61m  
+42% vs. Q1 21;  
+110% vs. Q2 20
- **Q2 21 US dispenses:** 43.0k\*  
+20% vs. Q1 21;  
+60% vs. Q2 20
- **Q2 21 SUBLOCADE patients\*\*:** 36.9k  
+15% vs. Q1 21;  
+60% vs. Q2 20
- **Q2 21 OHS activation:**  
>49%\* of NR now from OHS channel;  
approx. 250 OHS activated (targeting 500+)

ONCE-MONTHLY  
**Sublocade**<sup>®</sup>  
(buprenorphine extended-release)  
injection for subcutaneous use  
100mg-300mg

2

## Diversify Revenue

- **SUBUTEX® Prolonged Release (ROW):**  
Q2 21 NR: \$4m  
+33% vs. Q1 21  
available in Australia, Canada and Israel; recently approved in Germany and Italy
- **PERSERIS Q2 21 NR:** \$4m  
+33% vs. Q1 21 and Q1 20
- **SUBOXONE® Film (ROW):** now available in Canada, Germany, the Nordics and the UK



3

## Build Our Pipeline

- **SUBLOCADE® Post Marketing Commitments:** All approved by FDA and considered closed
- **SUBLOCADE® label:** updated to include relevant fentanyl pharmacodynamic study (FDA approved)
- **Aelis Farma (AEF 0117):** entered exclusive option for leading mid-stage asset targeting cannabis-related disorders
- **INDV-2000 & INDV-1000:** Respective development studies and plans on-track



4

## Optimize Operating Model

- **Cash:** \$1bn  
+\$142m vs. FYE 2020
- **Net Cash:** \$750m  
+\$127m vs. FYE 2020
- **Completed Term Loan Refinancing**
- **Sold TEMGESIC® / BUPREX® / BUPREXX® (buprenorphine) analgesic business for ~\$21m of cash\*\*\***



\* Excludes units related to CJS order

\*\* Rolling 12-month patients estimate using both Specialty Pharmacy and Specialty Distributor proxy data

\*\*\* Closed in early July 2021; cash proceeds not included in H1 / Q2 2021 financials



Ryan Preblich

Chief Financial Officer



# Profit & Loss Account\*

	Q2			H1		
	2021 Adjusted	2020 Adjusted	% change	2021 Adjusted	2020 Adjusted	% change
(\$ in mil. at actual FX)						
<b>Net Revenues</b>	<b>201</b>	<b>150</b>	<b>34%</b>	<b>381</b>	<b>303</b>	<b>26%</b>
Cost of Sales	(30)	(19)		(62)	(35)	
<b>Gross Profit</b>	<b>171</b>	<b>131</b>	<b>31%</b>	<b>319</b>	<b>268</b>	<b>19%</b>
<i>Gross Margin (%)</i>	85%	87%	-200bps	84%	88%	-400bps
Selling, General and Administration Expenses	(92)	(99)		(180)	(223)	
Research & Development Expenses	(13)	(8)		(22)	(19)	
<b>Operating Profit</b>	<b>66</b>	<b>24</b>	<b>NM</b>	<b>117</b>	<b>26</b>	<b>NM</b>
<i>Operating Margin (%)</i>	33%	16%	NM	31%	9%	NM
Net interest	(6)	(5)		(10)	(6)	
Taxation	(11)	(2)		(20)	(6)	
<i>Effective Tax Rate (%)</i>	18%	10%		19%	27%	
<b>Net Income</b>	<b>49</b>	<b>17</b>	<b>NM</b>	<b>87</b>	<b>14</b>	<b>NM</b>

\* Please see Appendix for full reconciliation for periods indicated.





## Cash & borrowing position

(\$ in mil.)	H1 2021	FY 2020
Cash & Cash Equivalents	\$1,000	\$858
Current Borrowings	(3)	(4)
Long-term Borrowings	(239)	(230)
Loan issuance costs	(8)	(1)
Net cash	\$750	\$623

- Net cash growth to \$750m (vs. \$623m at FY 2020):
  - ✓ Better H1 2021 operating performance
  - ✓ Stable government payables
- Maintaining disciplined & balanced cash stance:
  - ✓ Deliver against SUBLOCADE® net rev. goal of >\$1 billion
  - ✓ Organically diversify revenue base (PERSERIS®, Ex.-US launches)
  - ✓ Deliver on existing early-stage assets; small early-stage acqs. possible (low double-digit \$millions)
  - ✓ Returning capital to shareholders via \$100m share repurchase program



## Term Loan Replacement

Debt maturity extension to June 2026

Balloon payment deferred from December 2022

Leverage covenant threshold removed

Lower annual mandatory principal prepayments

Liquidity covenant added (greater of \$100M or 50% of loan balance)

Pricing – LIBOR (0.75% min.) +5.25

**Greater flexibility to utilize the Company's cash enabled by extending maturity and removing leverage covenant**



# Upgraded FY 2021 guidance reiterated

FY 21 Guidance (\$ in mil.)	
<b>Total NR</b> <ul style="list-style-type: none"><li>• SUBLOCADE NR</li><li>• PERSERIS NR</li></ul>	<b>\$705m to \$740m</b> <ul style="list-style-type: none"><li>• \$210m to \$230m</li><li>• \$17m to \$20m</li></ul>
<b>Adj. gross margin</b>	<b>Low 80% range</b>
<b>Adj. OPEX (SG&amp;A + R&amp;D)</b>	<b>\$470m to \$480m</b>
<b>Adj. pre-tax income</b>	<b>Positive</b>

## Additional top-line items:

- Continued strong underlying BMAT market growth
- F/X translation benefits of ~\$10m
- SUBOXONE® Film
  - ✓ More modest share erosion in FY21
  - ✓ The Group continues to expect that SUBOXONE® Film share loss will ultimately revert to observed industry analogues<sup>(1)</sup>
- Rest of World
  - ✓ Availability of new products (SUBUTEX PR, SUBOXONE Film) offset by continued austerity measures in legacy Western European markets resulting in relatively unchanged NR versus FY 2020

## Margin & Expense detail:

- Mid single digit decline in FY 2021 adj. gross margin primarily due to current product and regional mix; adj. GM expected to return to mid-80's in 2022 as more profitable SUBLOCADE is expected to grow as a proportion of total NR.
- Adj. OPEX (combined SG&A and R&D) of \$470m to \$480m reflects:
  - ✓ Benefits from completed strategic alignment in 2020;
  - ✓ More than offset by incremental investments for US LAI technologies of up to \$25m fueled by the relative share resilience of SUBOXONE Film in the US; and,
  - ✓ COVID-delayed LAI capacity expansion projects.



(1) IMS Institute Report, January 2016: "Price Declines after Branded Medicines Lose Exclusivity in the U.S."

# Christian Heidbreder

Chief Scientific Officer



# TODAY'S UPDATE

- Disease State
- Pipeline Update
- Peer-Reviewed Publications & Conferences

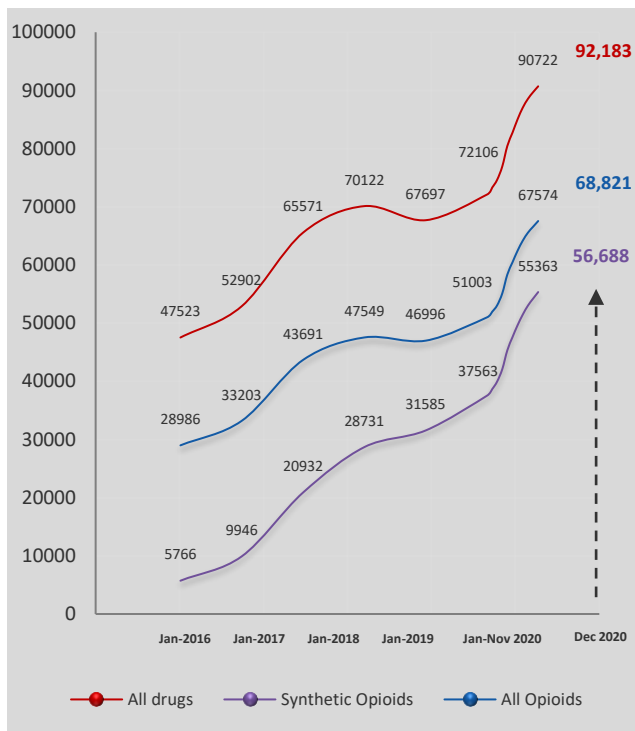




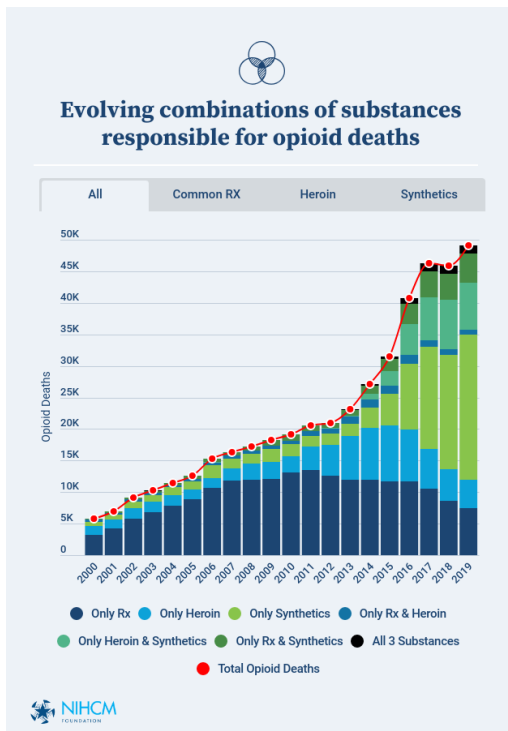
Disease State

# UNPRECEDENTED NUMBER OF REPORTED DRUG OVERDOSE DEATHS IN THE US

## → GROWING IMPACT OF SYNTHETIC OPIOIDS

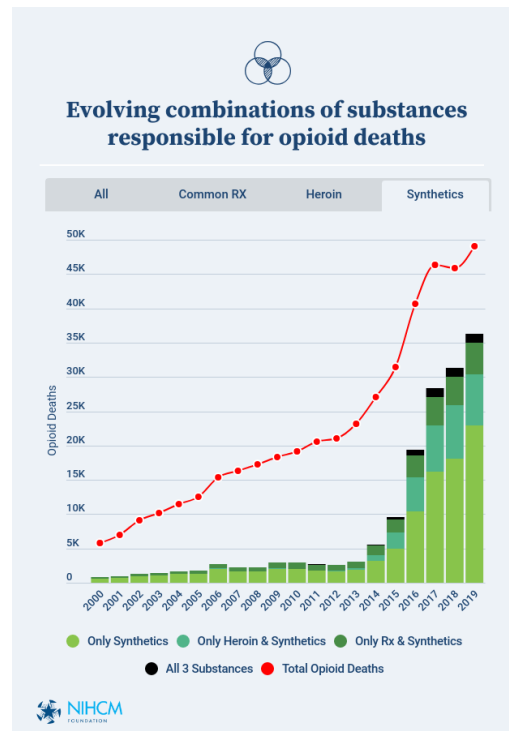


Source (updated 7/4/2021: [Products - Vital Statistics Rapid Release - Provisional Drug Overdose Data \(cdc.gov\)](https://www.cdc.gov/drugoverdose/data))

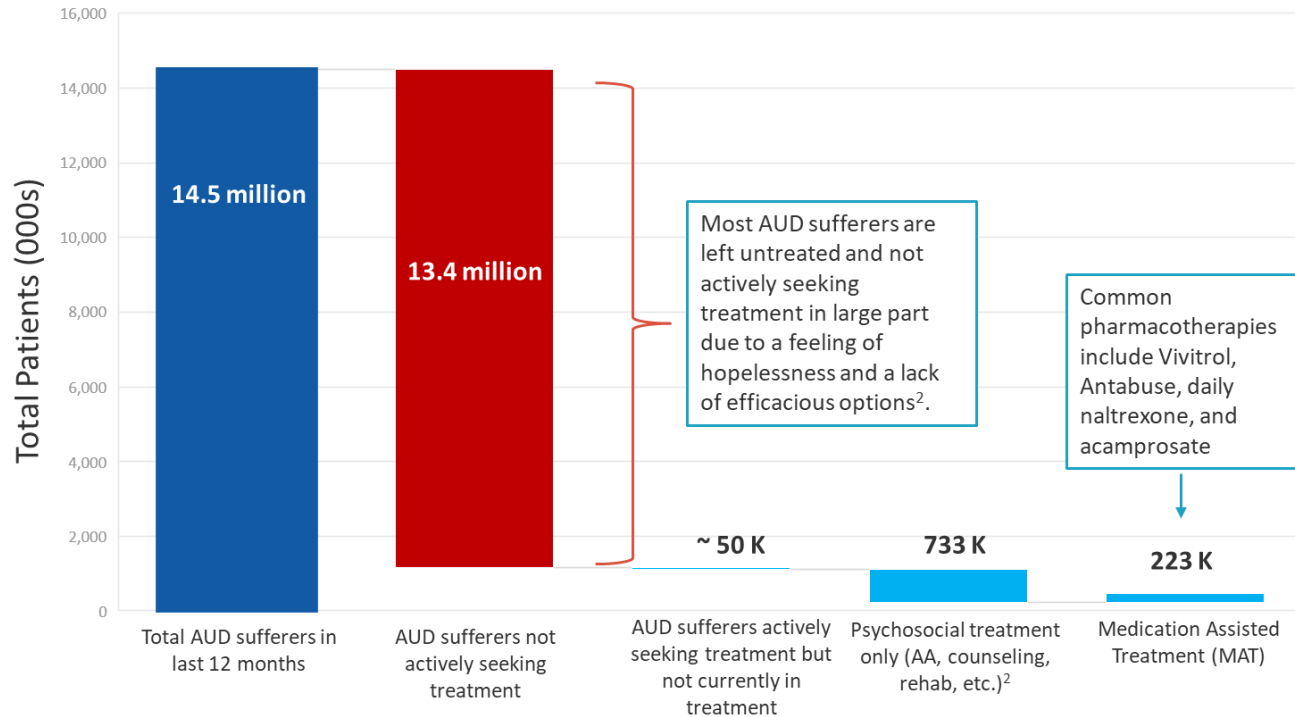


Source: CDC Health Alert Network December 17, 2020

[https://emergency.cdc.gov/han/2020/han00438.asp?ACSTrackingID=USCDC\\_511-DM44961&ACSTrackingLabel=HAN%20438%20-%20General%20Public&deliveryName=USCDC\\_511-DM44961](https://emergency.cdc.gov/han/2020/han00438.asp?ACSTrackingID=USCDC_511-DM44961&ACSTrackingLabel=HAN%20438%20-%20General%20Public&deliveryName=USCDC_511-DM44961)



# ALCOHOL USE DISORDER (AUD): IN THE US, 14.5M PEOPLE AGED 12> HAD AUD IN THE PAST YEAR



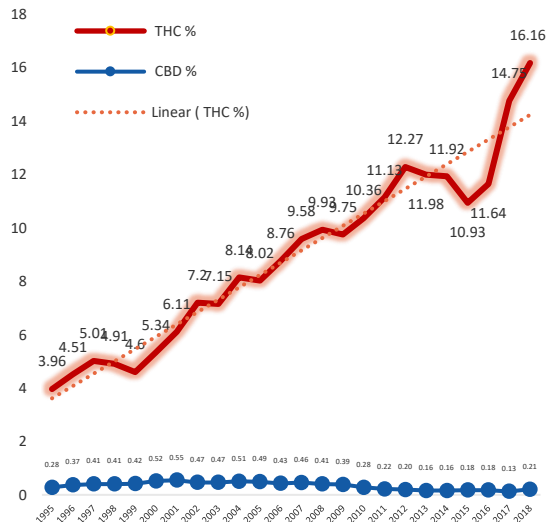
*Source:* Substance Abuse and Mental Health Services Administration. (2020). Key substance use and mental health indicators in the United States: Results from the 2019 National Survey on Drug Use and Health (HHS Publication No. PEP20-07-01-001, NSDUH Series H-55). Rockville, MD: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration. Retrieved from <https://www.samhsa.gov/data/>





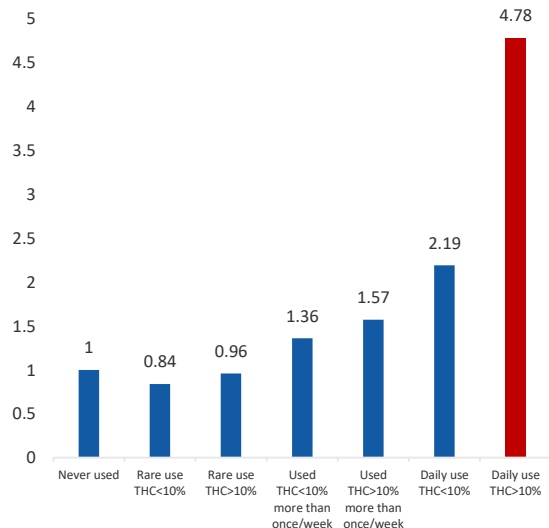
# CANNABIS-RELATED DISORDERS ARE ON THE RISE: 4.8 MIL. PEOPLE HAD A PAST-YEAR CANNABIS USE DISORDER (CUD) IN THE US\*

Cannabis potency (% Δ-9 THC) quadrupled in past 20 years



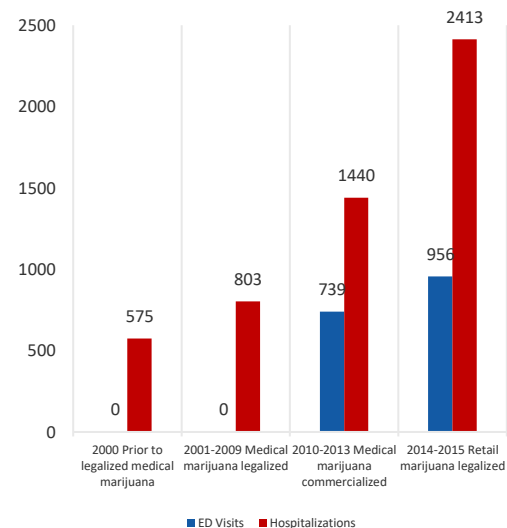
Source: Potency Monitoring Program, Quarterly report Number 139, NIDA Contract Number: N01DA-15-7793

Adjusted odds ratio of psychotic disorders for combined frequency & type of cannabis use



Source: The Lancet Psychiatry 2019 6, 427-436. DOI: (10.1016/S2215-0366(19)30048-3)

Rates of hospitalizations (HD) and emergency department (ED) visits per 100,000 per year in CO



Source: Reproduced from Marijuana Legalization in Colorado: Early Findings. A Report Pursuant to Senate Bill 13-283. Colorado Department of Public Safety. 2016. Available at: <http://cdpsdocs.state.co.us/ors/docs/reports/2016-SB13-283-Rpt.pdf>. Accessed March 2018.

\*Source: Substance Abuse and Mental Health Services Administration. (2020). Key substance use and mental health indicators in the United States: Results from the 2019 National Survey on Drug Use and Health (HHS Publication No. PEP20-07-01-001, NSDUH Series H-55). Rockville, MD: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration. Retrieved from <https://www.samhsa.gov/data/>





## Pipeline Update

# SUBLOCADE<sup>®</sup>, SUBOXONE<sup>®</sup> FILM & PERSERIS<sup>®</sup>



## SUBLOCADE<sup>®</sup> in the US

- US Label updates: FDA approvals
  - Transition to SUBLOCADE from SL buprenorphine: May 11, 2021
  - Buprenorphine-Fentanyl interaction: May 17, 2021
- Post Marketing Requirement study: Rapid induction of OUD treatment with SUBLOCADE and characterization of patients who may benefit from the 300 mg dose scheduled to start in Q4-2021

## PERSERIS<sup>®</sup> in the US

- PMC 3451-1 (clinical efficacy & safety of PERSERIS<sup>®</sup> 180 mg (2 x 90 mg) and alternate injection site): Submission February 12, 2021 with PDUFA date of December 12, 2021

Region		SUBLOCADE <sup>®</sup> Approvals
Canada	✓	November 21, 2018
Australia	✓	July 17, 2019
Israel	✓	February 13, 2020
Sweden	✓	April 15, 2020
Finland	✓	July 10, 2020
New Zealand	✓	November 05, 2020
Denmark	✓	December 21, 2020
Germany	✓	April 29, 2021
Italy	✓	May 17, 2021
Norway		Under review Jul-Sep 2021
UK		Under review Sep-Nov 2021

*The trademark of SUBLOCADE<sup>®</sup> in Europe is SUBUTEX<sup>®</sup> prolonged-release (PR) solution for injection*

Region		SUBOXONE <sup>®</sup> Film Approvals
Israel	✓	April 07, 2020
EU (Centralized) * #	✓	July 03, 2020
Canada	✓	July 17, 2020
United Arab Emirates	✓	Review completed
New Zealand		Under review
Qatar; Kuwait		Under review
Kingdom of Saudi Arabia		Planned submission

*\* Valid for all European Union (EU) Member States as well as the United Kingdom, Iceland, Norway and Liechtenstein*

*# Submission to EMA to extend shelf-life from 18 to 24 months submitted December 17, 2020, and approved January 29, 2021. The shelf-life extension also implemented in US (to be included in AR 2021), Canada and application submitted in Israel (post-approval in EU)*



# INDIVIOR CURRENT PIPELINE



## Opioid Use Disorder (OUD)

INDV-2000 (Selective Orexin-1 Receptor Antagonist)

- **Phase 1 Single Ascending Dose (SAD) study** has completed and shows encouraging safety and pharmacokinetics in healthy volunteers. The final Clinical Study Report is expected by the end of Q4-2021.
- **Phase 1 Multiple Ascending Dose (MAD) study** currently planned with the first subject anticipated to be dosed in Q3-2021.



## Alcohol Use Disorder (AUD)

INDV-1000 (Selective GABA<sub>B</sub> Positive Allosteric Modulator)

- New **lead identification and optimization** program is ongoing in partnership with Addex Therapeutics.
- Identification of lead molecules to enter the **late lead optimization phase** in Q3-2021.



## Cannabis-Related Disorders (CrD)

AEF0117 (Synthetic CB1 Specific Signaling Inhibitor)

- Strategic collaboration with Aelis Farma announced June 8, 2021.
- First Indivior-Aelis **Joint Steering Committee (JSC)** held July 19, 2021.
- Preparation for readiness of **clinical Phase 2B study**.



# Conclusion

## SUBOXONE® (BUPRENORPHINE AND NALOXONE) SUBLINGUAL FILM (CIII)

### INDICATION AND USAGE

SUBOXONE® Film is indicated for treatment of opioid dependence. SUBOXONE Film should be used as part of a complete treatment plan that includes counseling and psychosocial support

### HIGHLIGHTED SAFETY INFORMATION

Prescription use of this product is limited under the Drug Addiction Treatment Act.

### CONTRAINDICATIONS

SUBOXONE Film is contraindicated in patients with a history of hypersensitivity to buprenorphine or naloxone.

### WARNINGS AND PRECAUTIONS

**Addiction, Abuse, and Misuse:** Buprenorphine can be abused in a manner similar to other opioids and is subject to criminal diversion. Monitor patients for conditions indicative of diversion or progression of opioid dependence and addictive behaviors. Multiple refills should not be prescribed early in treatment or without appropriate patient follow-up visits.

**Respiratory Depression:** Life-threatening respiratory depression and death have occurred in association with buprenorphine use. Warn patients of the potential danger of self-administration of benzodiazepines or other CNS depressants while under treatment with SUBOXONE Film. Strongly consider prescribing naloxone at the time SUBOXONE Film is initiated or renewed because patients being treated for opioid use disorder have the potential for relapse, putting them at risk for opioid overdose. Educate patients and caregivers on how to recognize respiratory depression and, if naloxone is prescribed, how to treat with naloxone.

**Unintentional Pediatric Exposure:** Store SUBOXONE Film safely out of the sight and reach of children. Buprenorphine can cause severe, possibly fatal, respiratory depression in children.

**Neonatal Opioid Withdrawal Syndrome:** Neonatal opioid withdrawal syndrome (NOWS) is an expected and treatable outcome of prolonged use of opioids during pregnancy.

**Adrenal Insufficiency:** If diagnosed, treat with physiologic replacement of corticosteroids, and wean patient off of the opioid.

**Risk of Opioid Withdrawal with Abrupt discontinuation:** If treatment is temporarily interrupted or discontinued, monitor patients for withdrawal and treat appropriately.

**Risk of Hepatitis, Hepatic Events:** Monitor liver function tests prior to initiation and during treatment and evaluate suspected hepatic events.

**Precipitation of Opioid Withdrawal Sign and Symptoms:** An opioid withdrawal syndrome is likely to occur with parenteral misuse of SUBOXONE Film by individuals physically dependent on full opioid agonists, or by sublingual or buccal administration before the agonist effects of other opioids have subsided.

**Risk of Overdose in Opioid Naïve Patients:** SUBOXONE Film is not appropriate as an analgesic. There have been reported deaths of opioid naïve individuals who received a 2 mg sublingual dose

### ADVERSE REACTIONS

Adverse events commonly observed with the sublingual/buccal administration of the SUBOXONE Film are oral hypoesthesia, glossodynia, oral mucosal erythema, headache, nausea, vomiting, hyperhidrosis, constipation, signs and symptoms of withdrawal, insomnia, pain, and peripheral edema.

### DRUG INTERACTIONS

**Benzodiazepines:** Use caution in prescribing SUBOXONE Film for patients receiving benzodiazepines or other CNS depressants and warn patients against concomitant self-administration/misuse.

**CYP3A4 Inhibitors and Inducers:** Monitor patients starting or ending CYP3A4 inhibitors or inducers for potential over- or under- dosing.

**Antiretrovirals:** Patients who are on chronic buprenorphine treatment should have their dose monitored if NNRTIs are added to their treatment regimen. Monitor patients taking buprenorphine and atazanavir with and without ritonavir. Dose reduction of buprenorphine may be warranted.

**Serotonergic Drugs:** Concomitant use may result in serotonin syndrome. Discontinue SUBOXONE Film if serotonin syndrome is suspected.

### USE IN SPECIFIC POPULATIONS

**Lactation:** Buprenorphine passes into the mother's milk.

**Geriatric Patients:** Monitor geriatric patients receiving SUBOXONE Film for sedation or respiratory depression.

**Moderate or Severe Hepatic Impairment:** Buprenorphine/naloxone products are not recommended in patients with severe hepatic impairment and may not be appropriate for patients with moderate hepatic impairment.

To report pregnancy or side effects associated with taking SUBOXONE Film, please call 1-877-782-6966.

For more information about SUBOXONE Film, the full Prescribing Information, and Medication Guide visit [www.suboxone.com](http://www.suboxone.com). For REMS information visit [www.suboxoneREMS.com](http://www.suboxoneREMS.com).



## SUBLOCADE (buprenorphine extended-release) injection, for subcutaneous use (CIII)

### INDICATION

SUBLOCADE is indicated for the treatment of moderate to severe opioid use disorder in patients who have initiated treatment with a transmucosal buprenorphine-containing product, followed by dose adjustment for a minimum of 7 days.

SUBLOCADE should be used as part of a complete treatment plan that includes counseling and psychosocial support.

### HIGHLIGHTED SAFETY INFORMATION

#### WARNING: RISK OF SERIOUS HARM OR DEATH WITH INTRAVENOUS ADMINISTRATION; SUBLOCADE RISK EVALUATION AND MITIGATION STRATEGY

- Serious harm or death could result if administered intravenously. SUBLOCADE forms a solid mass upon contact with body fluids and may cause occlusion, local tissue damage, and thrombo-embolic events, including life threatening pulmonary emboli, if administered intravenously.
- Because of the risk of serious harm or death that could result from intravenous self-administration, SUBLOCADE is only available through a restricted program called the SUBLOCADE REMS Program. Healthcare settings and pharmacies that order and dispense SUBLOCADE must be certified in this program and comply with the REMS requirements.

Prescription use of this product is limited under the Drug Addiction Treatment Act.

### CONTRAINDICATIONS

SUBLOCADE should not be administered to patients who have been shown to be hypersensitive to buprenorphine or any component of the ATRIGEL® delivery system

### WARNINGS AND PRECAUTIONS

**Addiction, Abuse, and Misuse:** SUBLOCADE contains buprenorphine, a Schedule III controlled substance that can be abused in a manner similar to other opioids. Monitor patients for conditions indicative of diversion or progression of opioid dependence and addictive behaviors.

**Respiratory Depression:** Life threatening respiratory depression and death have occurred in association with buprenorphine. Warn patients of the potential danger of self-administration of benzodiazepines or other CNS depressants while under treatment with SUBLOCADE.

Opioids can cause sleep-related breathing disorders e.g., central sleep apnea (CSA), sleep-related hypoxemia. Opioid use increases the risk of CSA in a dose-dependent fashion. Consider decreasing the opioid using best practices for opioid taper if CSA occurs.

Strongly consider prescribing naloxone at SUBLOCADE initiation or renewal because patients being treated for opioid use disorder have the potential for relapse, putting them at risk for opioid overdose. Educate patients and caregivers on how to recognize respiratory depression and how to treat with naloxone if prescribed.

**Risk of Serious Injection Site Reactions:** The most common injection site reactions are pain, erythema and pruritis with some involving abscess, ulceration, and necrosis. The likelihood of serious injection site reactions may increase with inadvertent intramuscular or intradermal administration.

**Neonatal Opioid Withdrawal Syndrome:** Neonatal opioid withdrawal syndrome is an expected and treatable outcome of prolonged use of opioids during pregnancy.

**Adrenal Insufficiency:** If diagnosed, treat with physiologic replacement of corticosteroids, and wean patient off the opioid.

**Risk of Opioid Withdrawal With Abrupt Discontinuation:** If treatment with SUBLOCADE is discontinued, monitor patients for several months for withdrawal and treat appropriately.

**Risk of Hepatitis, Hepatic Events:** Monitor liver function tests prior to and during treatment.

**Risk of Withdrawal in Patients Dependent on Full Agonist Opioids:** Verify that patient is clinically stable on transmucosal buprenorphine before injecting SUBLOCADE.

**Treatment of Emergent Acute Pain:** Treat pain with a non-opioid analgesic whenever possible. If opioid therapy is required, monitor patients closely because higher doses may be required for analgesic effect.

### ADVERSE REACTIONS

Adverse reactions commonly associated with SUBLOCADE (in ≥5% of subjects) were constipation, headache, nausea, injection site pruritus, vomiting, increased hepatic enzymes, fatigue, and injection site pain.

For more information about SUBLOCADE, the full Prescribing Information including BOXED WARNING, and Medication Guide, visit [www.sublocade.com](http://www.sublocade.com).



## ABOUT PERSERIS® (risperidone) for extended-release injectable suspension

### INDICATION

PERSERIS® (risperidone) is indicated for the treatment of schizophrenia in adults.

#### **WARNING: INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS**

*See full prescribing information for complete boxed warning.*

- \* Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death.
- \* PERSERIS is not approved for use in patients with dementia-related psychosis.

### CONTRAINDICATIONS

PERSERIS should not be administered to patients with known hypersensitivity to risperidone, paliperidone, or other components of PERSERIS.

### WARNINGS AND PRECAUTIONS

Cerebrovascular Adverse Reactions, Including Stroke in Elderly Patients with Dementia-Related Psychosis: Increased risk of cerebrovascular adverse reactions (e.g., stroke, transient ischemic attack), including fatalities. PERSERIS is not approved for use in patients with dementia-related psychosis.

Neuroleptic Malignant Syndrome (NMS): Manage with immediate discontinuation and close monitoring.

Tardive Dyskinesia: Discontinue treatment if clinically appropriate.

Metabolic Changes: Monitor for hyperglycemia, dyslipidemia and weight gain.

Hyperprolactinemia: Prolactin elevations occur and persist during chronic administration. Long-standing hyperprolactinemia, when associated with hypogonadism, may lead to decreased bone density in females and males.

Orthostatic Hypotension: Monitor heart rate and blood pressure and warn patients with known cardiovascular disease or cerebrovascular disease, and risk of dehydration or syncope.

Leukopenia, Neutropenia, and Agranulocytosis: Perform complete blood counts (CBC) in patients with a history of a clinically significant low white blood cell count (WBC) or history of leukopenia or neutropenia. Consider discontinuing PERSERIS if a clinically significant decline in WBC occurs in absence of other causative factors.

Potential for Cognitive and Motor Impairment: Use caution when operating machinery.

Seizures: Use caution in patients with a history of seizures or with conditions that lower the seizure threshold.

### ADVERSE REACTIONS

The most common adverse reactions in clinical trials ( $\geq 5\%$  and greater than twice placebo) were increased weight, sedation/somnolence and musculoskeletal pain. The most common injection site reactions ( $\geq 5\%$ ) were injection site pain and erythema (reddening of the skin).

For more information about PERSERIS™, the full prescribing information, including BOXED Warning, visit <https://www.perseris.com>.





# Appendix



# Q2 Profit & Loss Account Reconciliation

	Q2 2021			Q2 2020		
	Q2 2021 Actual	Adjustments	Q2 2021 Adjusted	Q2 2020 Actual	Adjustments	Q2 2020 Adjusted
(\$ in mil.)						
<b>Net Revenues</b>	<b>201</b>		<b>201</b>	<b>150</b>		<b>150</b>
Cost of Sales	(30)		(30)	(18)	(1) <sup>(1)</sup>	(19)
<b>Gross Profit</b>	<b>171</b>		<b>171</b>	<b>132</b>		<b>131</b>
Selling, General and Administration Expenses	(85)	(7) <sup>(1)</sup>	(92)	(99)		(99)
Research & Development Expenses	(13)		(13)	(8)		(8)
<b>Operating Profit</b>	<b>73</b>		<b>66</b>	<b>25</b>		<b>24</b>
Net interest	(7)	1 <sup>(2)</sup>	(6)	(5)		(5)
Taxation	(4)	(7) <sup>(3)</sup>	(11)	(2)		(2)
<b>Net Income</b>	<b>62</b>		<b>49</b>	<b>18</b>		<b>17</b>

(1) Excludes \$7m of exceptional items – \$8m benefit related to a legal provision release and \$1m costs related to debt refinancing

(2) Excludes \$1m write-off of historical deferred financing costs

(3) Adjusted taxation excludes the effects of exceptional items

(1) Exceptional item related to favorable inventory provision



# H1 Profit & Loss Account Reconciliation

	H1 2021			H1 2020		
	H1 2021 Actual	Adjustments	H1 2021 Adjusted	H1 2020 Actual	Adjustments	H1 2020 Adjusted
(\$ in mil.)						
<b>Net Revenues</b>	<b>381</b>		<b>381</b>	<b>303</b>		<b>303</b>
Cost of Sales	(62)		(62)	(41)	6 <sup>(1)</sup>	(35)
<b>Gross Profit</b>	<b>319</b>		<b>319</b>	<b>262</b>		<b>268</b>
Selling, General and Administration Expenses	(167)	(13) <sup>(1)</sup>	(180)	(408)	185 <sup>(2)</sup>	(223)
Research & Development Expenses	(22)		(22)	(19)		(19)
<b>Operating (Loss) / Profit</b>	<b>130</b>		<b>117</b>	<b>(165)</b>		<b>26</b>
Net interest	(11)	1 <sup>(2)</sup>	(10)	(6)		(6)
Taxation	23	(43) <sup>(3)</sup>	(20)	26	(32) <sup>(3)</sup>	(6)
<b>Net (Loss) / Income</b>	<b>142</b>		<b>87</b>	<b>(145)</b>		<b>14</b>

(1) Excludes \$13m of exceptional items – \$13m benefit related to a legal provision release, \$1m related to proceeds from out-licensing of nasal naloxone patents and \$1m costs related to debt refinancing

(2) Excludes \$1m write-off of historical deferred financing costs

(3) Excludes tax benefit related to development credits for SUBLOCADE and impact of settlement costs with RB

(1) H1 2020 adjusted cost of sales excludes \$6m related to the adverse impact of COVID-19 on inventory

(2) H1 2020 adjusted results exclude \$183m increase of legal provision related to the DOJ matter and \$2m primarily of lease disposal cost

(3) H1 2020 adjusted taxation exclude the effects of exceptional items



# H2 21 Capital Markets Calendar

September 2021						
S	M	T	W	T	F	S
			1	2	3	4
5	6	7	8	9	10	11
12	13	14	15	16	17	18
19	20	21	22	23	24	25
26	27	28	29	30		

October 2021						
S	M	T	W	T	F	S
					1	2
3	4	5	6	7	8	9
10	11	12	13	14	15	16
17	18	19	20	21	22	23
24	25	26	27	28	29	30
31						

November 2021						
S	M	T	W	T	F	S
	1	2	3	4	5	6
7	8	9	10	11	12	13
14	15	16	17	18	19	20
21	22	23	24	25	26	27
28	29	30	31			

- Market Holiday
- Key IR Date

Date	Key Event
September 13th	<b>Morgan Stanley NYC HCare Conference (Registered)</b> <ul style="list-style-type: none"> <li>• 1:1's (Virtual)</li> </ul>
September 15th	<b>Bank of America European HCare Conference (Registered)</b> <ul style="list-style-type: none"> <li>• 1:1's (Virtual)</li> </ul>
October 28th	<b>Q3 / 9 Mos. Results</b> <ul style="list-style-type: none"> <li>• Release</li> <li>• Call materials</li> </ul>
October 28th to Nov 5th	<b>Post Q3 / 9 Mos. Results Roadshow</b>
November 15th	<b>Stifel NYC HCare Conference</b> <ul style="list-style-type: none"> <li>• 1:1's (Virtual)</li> </ul>
November 16th	<b>JEFCO London Healthcare Conference (Registered)</b> <ul style="list-style-type: none"> <li>• Presentation and 1:1's (In-person planned)</li> </ul>



## PEER-REVIEWED PUBLICATIONS 2021



Le Moigne A et al. (2021) Reanalysis of a phase 3 trial of a monthly extended-release risperidone injection for the treatment of acute schizophrenia. *J Clin Psychopharmacol*, 41(1): 76-77.

<https://doi.org/10.1097/JCP.0000000000001319>



Kranzler HR et al. (2021) Moderation by a Delta-Opioid Receptor Gene Polymorphism of the Therapeutic Effect of Extended-Release Buprenorphine in Opioid Use Disorder. *Int. J. Neuropsychopharm.*, 24(2): 89-96.

<https://doi.org/10.1093/ijnp/pyaa069>



Monico LB et al. (2021) Exploring non-prescribed use of buprenorphine in the criminal justice system through qualitative interviews among individuals recently released from incarceration. *J. Subst. Abuse Treat.*, 123:108267.

<https://doi.org/10.1016/j.jsat.2020.108267>



Allsop G et al. (2021) Process Development Towards a Pro-Drug of R-Baclofen. *Org. Process Res. Dev.*, 25(1): 136–147.

<https://pubs.acs.org/doi/10.1021/acs.oprd.0c00491>



Kharidia J et al. (2021) Quantitative Prediction of the Systemic Exposure to Buprenorphine Extended-Release Monthly Injection Following Co-administration of Strong CYP3A4 Inhibitors/Inducers. *Clin. Pharmacol. Drug Dev.*, Epub ahead of print <http://doi.org/10.1002/cpdd.934>



Jones AK et al. (2021) Population Pharmacokinetics of a Monthly Buprenorphine Depot Injection for the Treatment of Opioid Use Disorder: A Combined Analysis of Phase II and Phase III Trials. *Clin Pharmacokinetics*, 60(4):527-540.

<http://doi.org/10.1007/s40262-020-00957-0>



Algera MH et al. (2021) Tolerance to opioid-induced respiratory depression in chronic high-dose opioid users: a model-based comparison with opioid-naïve individuals. *Clin. Pharmacol. Ther.* 109(3):637-645.

<https://doi.org/10.1002/cpt.2027>



Wiest K et al. (2020) RBP-6000: a rationally designed prolonged-release buprenorphine formulation. *Heroin Addiction and Related Clinical Problems (HARCP)*. Published Ahead of Print, January 18, 2021.



Lintzeris N et al. (2021) Strategies for transfer between buprenorphine and methadone for medication-assisted treatment for opioid use disorders and associated outcomes: a systematic review. *J Addict Med*, e-published

[https://journals.lww.com/journaladdictionmedicine/Abstract/9000/Strategies\\_for\\_Transfer\\_From\\_Methadone\\_to.99047.aspx](https://journals.lww.com/journaladdictionmedicine/Abstract/9000/Strategies_for_Transfer_From_Methadone_to.99047.aspx)



Hill D et al. (2021) Clinical Case Conference: Strategies for Transferring from Methadone to Buprenorphine. *J Addict Med*, e-published ahead of print: *J Addict Med*. Apr 14. <http://doi.org/10.1097/ADM.0000000000000854>






Gryczynski J et al. (2021) Use of non-prescribed buprenorphine in the criminal justice system: Perspectives of individuals recently released from incarceration. *J. Subst. Abuse Treat.*, e-published

[https://www.journalofsubstanceabusetreatment.com/article/S0740-5472\(21\)00075-1/fulltext](https://www.journalofsubstanceabusetreatment.com/article/S0740-5472(21)00075-1/fulltext)



# CONFERENCES 2021

-  Poster/ Podium presentation
-  Booth/Table
-  Symposium

