Indivior PLC

FY 2020 Results
February 18, 2021

Mark Crossley

Chief Executive Officer

INDIVIOR

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 2020, if any, 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.

AGENDA

FY 2020 Overview & Strategic Update	Mark Crossley
R&D Update	Christian Heidbreder
FY 2020 Financials & FY 2021 Guidance	Ryan Preblick
Conclusion	Mark Crossley

Q & A

CEO perspective: FY 20

Looking past COVID-19 & legacy issues; focused on realizing our potential

Performance

- Results were good considering ongoing COVID-19 challenges
  - ✓ Positive adj. net income* in Q4 and FY
  - ✓ SUBLOCADE® FY 20 NR was better than expected at $130m (+81% vs. FY 19); FY 20 PERSERIS® NR was $14m (+133% vs. FY 19)
  - ✓ Cash of $858m; net cash of $623m
- Completed cost actions to protect against COVID-19 impacts and provide for long-term growth
  - ✓ $60m to $70m in pre-tax savings in FY 2021 versus expected FY 2020 OPEX base (see FY 20 Guidance pg. 26)
- Resolved Department of Justice (DOJ) matter

Outlook

- Assume COVID-19 challenges persist until vaccinations achieve critical mass
  - ✓ HCPs continuing to restrict in-person interactions
- FY 21 guidance introduced; meaningful SUBLOCADE® growth expected

Priorities

- 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)
- Maintain operational excellence and financial flexibility
- Uphold compliance commitments and protect our people

* On an Adjusted basis. See Appendix for reconciliations.

SUBLOCADE®: Why we are confident

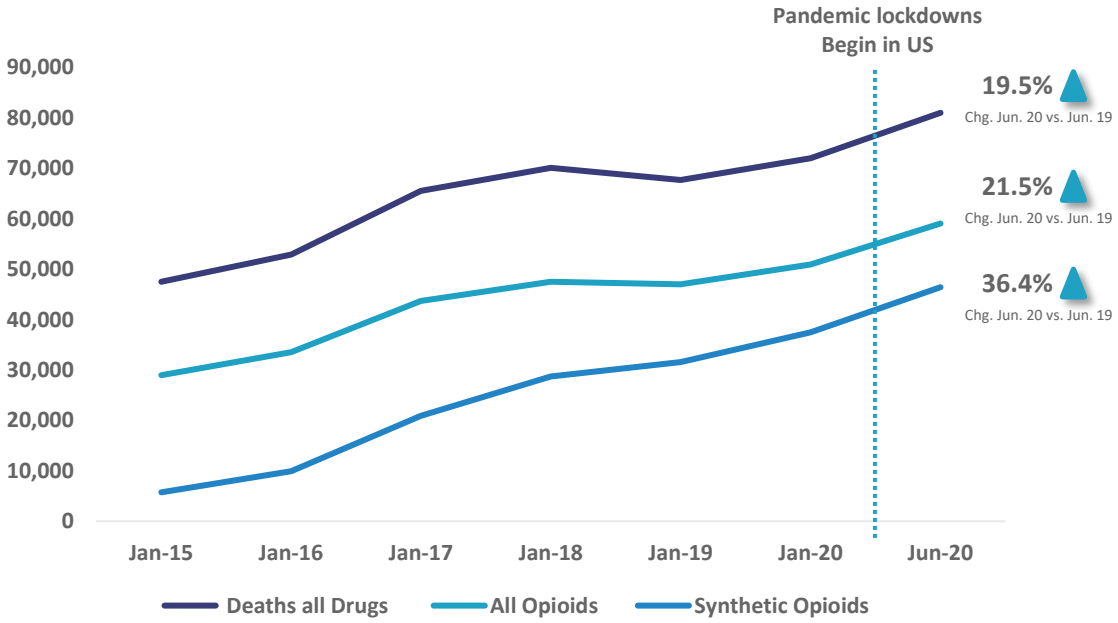
1. Tremendous unmet need
2. Novel treatment paradigm
3. Right strategy

INDIVIOR

ONCE-MONTHLY
Sublocade®
(buprenorphine extended-release)
injection for subcutaneous use ℞
100mg·300mg

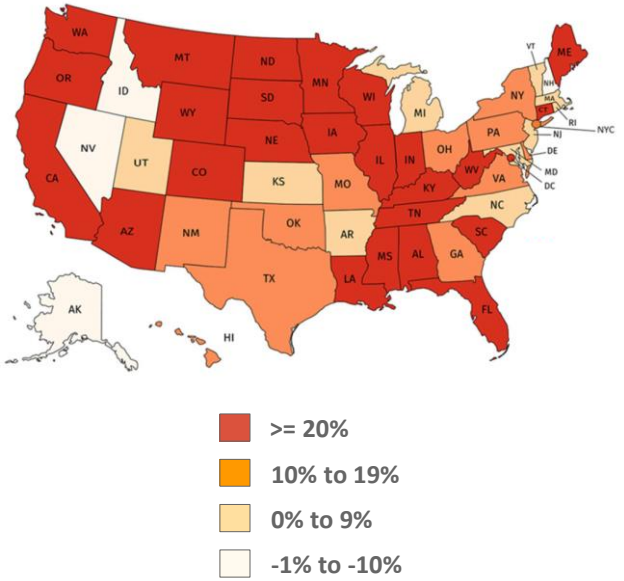
There is a tremendous urgent & unmet need

12 MONTH-ENDING *PROVISIONAL* NUMBER OF US DRUG OVERDOSE DEATHS BY DRUG OR DRUG CLASS (*AS OF JUNE 2020*)



CHANGE ALL FATAL DRUG OVERDOSES JUNE 2019 - MAY 2020

(Data collected from 50 states, the District of Columbia, and New York City)



Source: https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm

Buprenorphine is a cornerstone of medically assisted treatment

- World Health Organization list of essential medications
- Tightly binds to the mu-opioid receptor due to particularly high receptor affinity
  - ✓ preventing other opioids with lower affinity (e.g. heroin) from binding
- Buprenorphine is a safe medication
  - ✓ stabilizes physical needs associated with OUD
  - ✓ ceiling effect – once reaching a moderate dose, its effects no longer increase, leading to blunting of:
    - euphoria/rewarding effects of opioids
    - respiratory depression
- Buprenorphine is known to:
  - ✓ reduce cravings
  - ✓ reduce withdrawals
  - ✓ block rewarding effects of illicit opioids

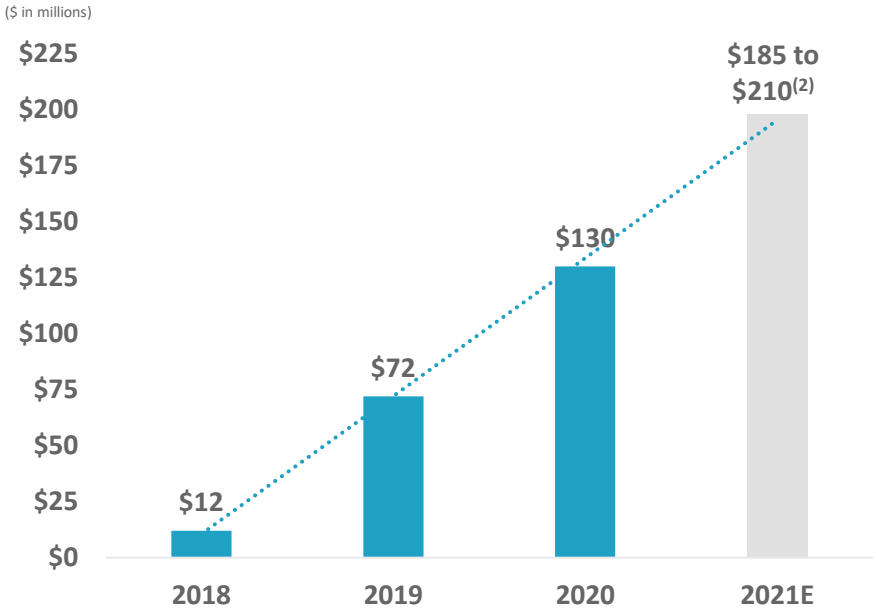
SAMSHA, TIP 63: Medication of OUD. 2020

SUBLOCADE®(1) is a paradigm shift in treatment

SUBLOCADE® Attributes

- **SUBLOCADE®** is the **first buprenorphine-based long-acting injectable** approved by U.S. FDA **for the treatment of moderate to severe OUD**
- Rationally designed to deliver **therapeutic levels of buprenorphine of ≥2 ng/mL over the entire monthly dosing period resulting in >70% mu-receptor occupancy**
  - Consistent and sustained levels
  - No daily ups and downs
  - No supplemental or booster dosing
- **Blocks** the subjective and rewarding effects of opioids
- **1 treatment decision, 1 time per month**
- **Potential to help millions** of patients based on FDA-approved indication

SUBLOCADE® Total Net Revenue



(1) Please refer to full Prescribing Information for important safety information, including boxed warning: www.SUBLOCADE.com SUBLOCADE™ (buprenorphine extended-release) is indicated for the treatment of moderate to severe opioid use disorder in adults after initiation with transmucosal buprenorphine. SUBLOCADE™ should be used as part of a complete treatment program that includes counseling and psychosocial support.

(2) Base case FY 2021 NR range. See FY 2021 Guidance discussion on slide 26.

Ensuring SUBLOCADE is accessible to all patients by penetrating Organized Health Systems

Core Prescribers
(Single HCP & Clinics)

Organized Health Systems

Integrated Delivery Networks
(Consolidated hospital groups)

Federal Health Systems
(VA, DOD, Justice System)

Organized Customers
(Multi-site and multi-state clinics)

Less resources available

- Remain valuable to SUBLOCADE®'s long-term success
- Can be resource constrained, limiting ability to grow patients per HCP near-term for specialty products

Increased infrastructure and resources

- OHS have 20k+ (est.) waivered HCP's and approximately half of all BMAT patients
- Greater resources and support systems to manage specialty products enabling accelerated patients per HCP
- Expanded dedicated OHS access team recruited Q4 2020
- Activation in place with 200+ organizations at FYE 2020 with an overall goal to activate 500+ priority organizations

** Note: Targets and results based on datasets for OHS entities validated thus far. This is an ongoing process due to continued integration of community offices & OHS entities, coupled with COVID19 induced alternative fulfillment models. Based on the continued review, we expect the associations to increase which is also broadly reflective of the market trend.

Indivior has the right strategy

Path to $1bn+ goal is clear and achievable

>10 mil.
Misuse opioids in US(1)

>3.0 mil.
OUD diagnosed in US (2)

~180,000
Target SUBLOCADE® patients

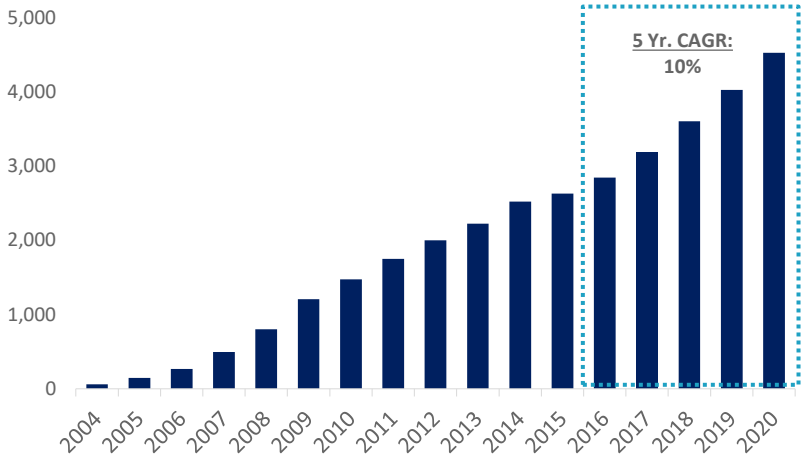
Market growth	>	• Sustained U.S. market growth: high single to low double-digits
HCPs & patients	>	• Penetrating OHS (including criminal justice system)
Relevance & Evidence	>	• Pursuing effectiveness against fentanyl • Evidence from RECOVER Study™ demonstrates improved recovery outcomes

(1) National Inst. Of Health – HEAL Initiative; Integrative Management of Chronic Pain and OUD for Whole Recovery (IMPOWR)
(2) Symphony Health Analytica and Indivior analytics

BMAT treatment continues to grow in response to the opioid epidemic

Strong, consistent market expansion…

Total buprenorphine market in mg[1,2] (millions)

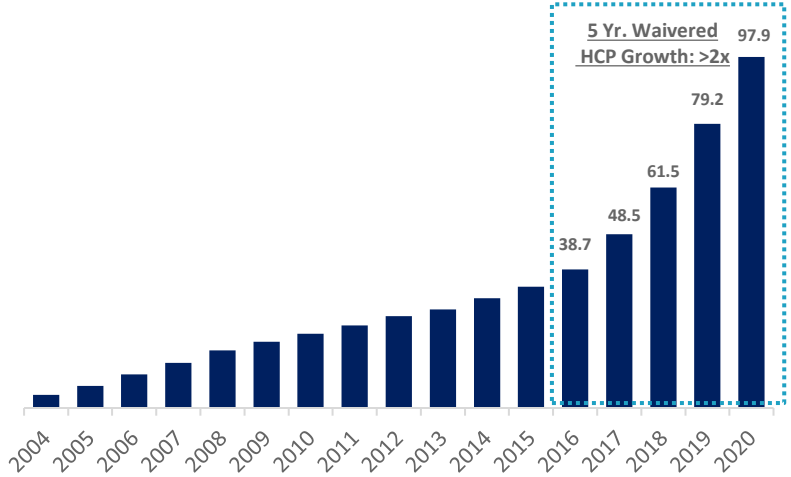


(1) Market MG volume in 2015 - 2020 derived from New IDV
(2) Non-Retail TRx MG volume projected for 2019 & 2020

Source: Symphony Health Retail & Non-Retail TRx MG (IDV)

Driven by growing treatment capacity

No. of HCP certifications (cumulative certifications in thousands)

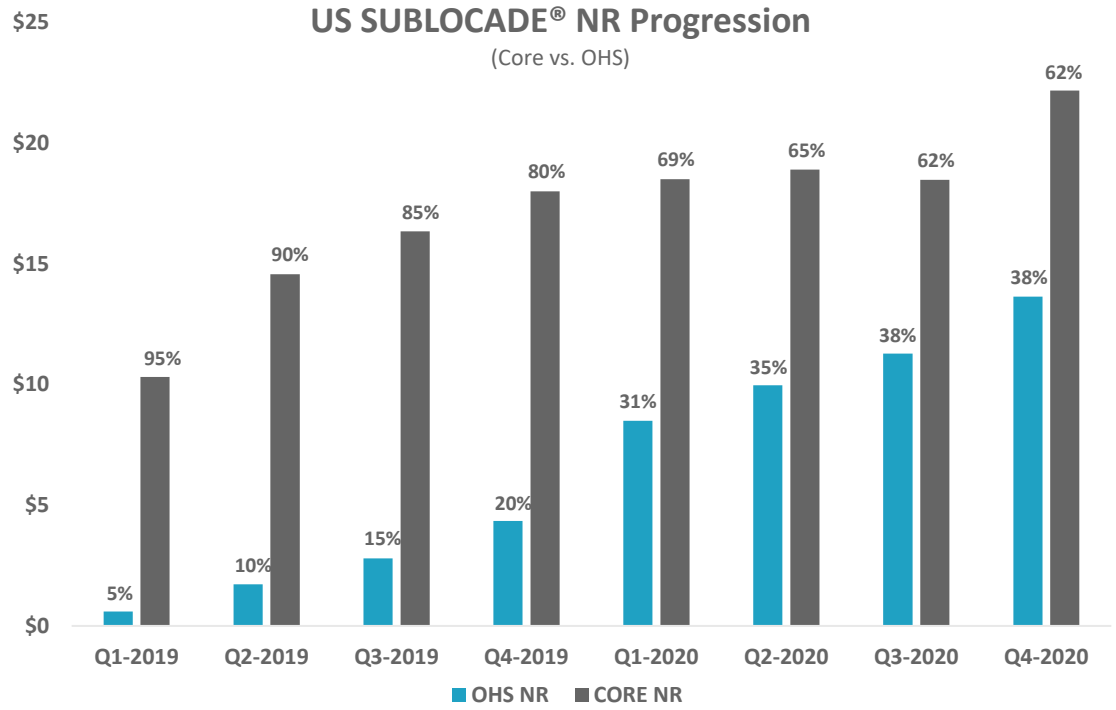


* 2017 includes 4,571 newly waivered NP/PAs
** 2018 includes 5,510 newly waivered NP/PAs
*** 2019 includes 6,598 newly waivered NP/PAs
**** 2020 includes 8,256 newly waivered NP/PAs

Source: NTIS DEA Certifications; Internal estimates

OHS strategy is working

($ in millions)



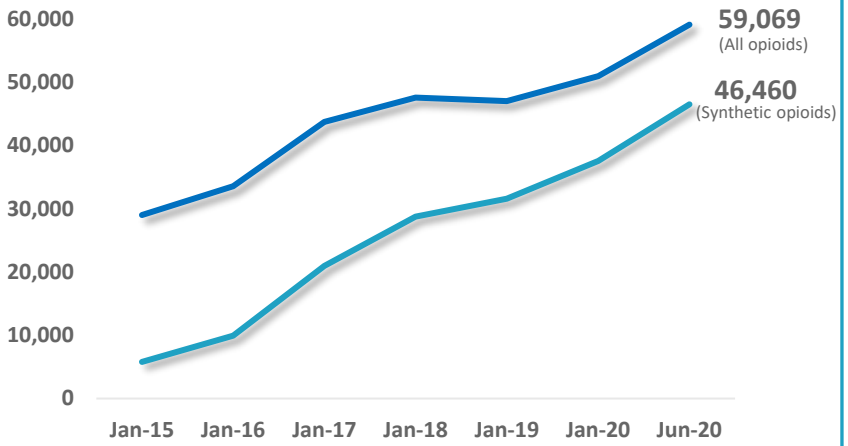
>70%

of SUBLOCADE® growth coming from OHS channel exiting FY 2020

Increasing relevance and generating evidence to support OUD treatment

Relevance

Buprenorphine plasma concentrations (approximately 2 ng/mL and 6 ng/mL) were effective in reducing the frequency and magnitude of respiratory depression induced by fentanyl at doses that caused apnea.

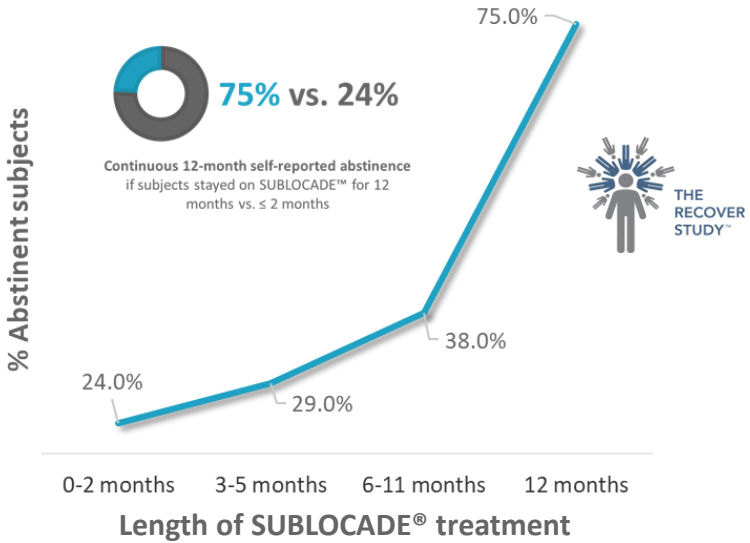


Opioids & Synthetic Opioids (mainly Fentanyl) Overdose Deaths, 2015-June 2020 (provisional)

Source: https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm

Evidence

The likelihood of continuous 12-month abstinence after cessation of SUBLOCADE® treatment increases with length of SUBLOCADE® treatment



Length of SUBLOCADE® treatment

Source: Ling W, Nadipelli VR, Ronquest N, Aldridge A, Solem C, Chilcoat H, Albright V, Johnson C, Learned SM, Mehra V, **Heidbreder C** (2020) Recovery from OUD post-monthly buprenorphine-XR treatment: 12-month longitudinal outcomes J. Addict. Med., March 13, 2020 Publication ahead of print. https://doi.org/10.1097/ADM.0000000000000647

Diversify Revenue

1. PERSERIS®
2. Ex.-US
3. Pipeline

PERSERIS®: 2020 accomplishments

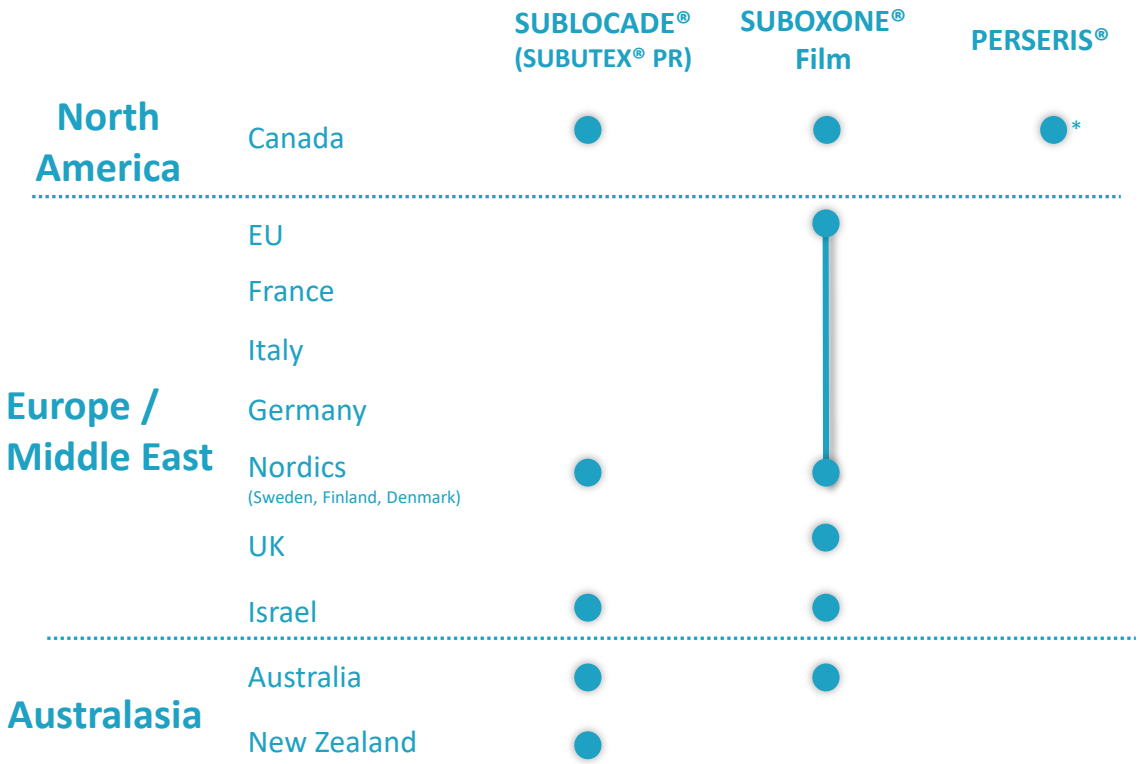
Notable accomplishments in the face of significant COVID impact

- Increasing hybrid selling effectiveness to adapt to the COVID environment
- Monthly sequential growth in the number of HCPs prescribing
- Average share of 13% amongst HCPs actively prescribing, demonstrating the utility and performance of PERSERIS for the schizophrenia patient population
- Refill retention through the COVID period

once-monthly
PERSERIS®
(risperidone) for extended-release injectable suspension
90 mg · 120 mg

Ex.-US NR trajectory returning to growth

Current major ex.-US drug approvals (Feb. 2021)



Availability

- **SUBLOCADE® (SUBUTEX® PR)**
  - Available in Australia, Canada, Israel
  - Nordics in 2021
  - Awaiting approvals in other key EU geographies and UK
- **SUBOXONE® Film**
  - Israel
  - Canada and EU in 2021

* In exclusive partnership with HLS Therapeutics

FY 2020 SCIENCE UPDATE

Christian Heidbreder, Chief Scientific Officer

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Focus on you.

SUBLOCADE® US: EVIDENCE GENERATION

12-month treatment with **SUBLOCADE® is clinically safe and effective** for patients with moderate or severe OUD

ORIGINAL CONTRIBUTION

OPEN

Treating Opioid Use Disorder With a Monthly Subcutaneous Buprenorphine Depot Injection: 12-Month Safety, Tolerability, and Efficacy Analysis

Anne C. Andorn, MD, Barbara R. Haight, PharmD,* Sunita Shinde, MD,* Paul J. Fudala, PhD,* Yue Zhao, DrPH,* Christian Heidbreder, PhD,* Susan M. Learned, MD,* Norma Lynn Fox, PhD,* Vijay R. Nadipelli, MS,* David Hassman, DO,† and Daniel Rutrick, MD‡*

12-month treatment with **SUBLOCADE® improves patient-reported outcomes** including health status, health-related quality of life, employment and insurance status, healthcare resource utilization, medication satisfaction, treatment effectiveness and addiction severity

Effects of monthly buprenorphine extended-release injections on patient-centered outcomes: A long-term study

Walter Ling[a], Vijay R. Nadipelli[b], Caitlyn T. Solem[b,c], Naoko A. Ronquest[b,1], Yu-Chen Yeh[d], Susan M. Learned[d], Vishaal Mehra[e], Christian Heidbreder[f]

The likelihood of continuous 12-month abstinence increases with **length of SUBLOCADE® treatment**

THE RECOVER STUDY™

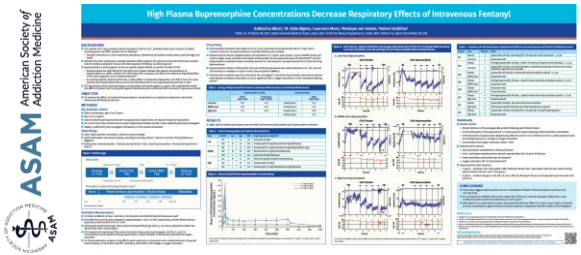
ORIGINAL RESEARCH

OPEN

Recovery From Opioid Use Disorder (OUD) After Monthly Long-acting Buprenorphine Treatment: 12-Month Longitudinal Outcomes from RECOVER, an Observational Study

Walter Ling, MD, Vijay R. Nadipelli, MS, Arnie P. Aldridge, PhD, Naoko A. Ronquest, PhD, Caitlyn T. Solem, PhD, Howard Chilcoat, ScD, Victoria Albright, MA, Courtney Johnson, MPH, Susan M. Learned, PhD, Mshaal Mehra, MD, and Christian Heidbreder, PhD

Sustained buprenorphine plasma concentrations of 2 ng/mL and 6 ng/mL were shown to be effective in reducing the frequency and magnitude of **fentanyl-induced respiratory depression**



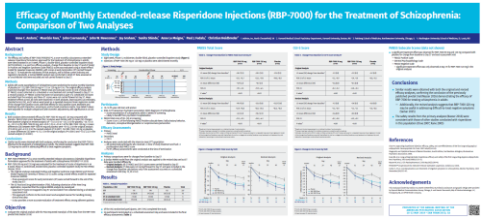
Studies to support SUBLOCADE® label changes:

- Rapid induction
- Patient subpopulations benefiting from SUBLOCADE® high maintenance dose
- Transition from transmucosal buprenorphine to SUBLOCADE® in clinically stable OUD patients
- Formulation safety
- Fentanyl study

PERSERIS® US: EVIDENCE GENERATION

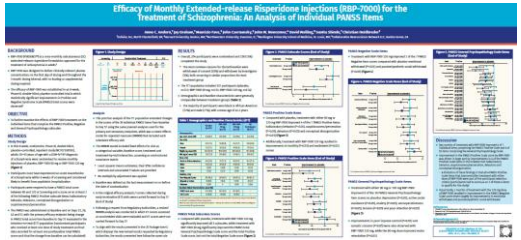
A new analysis of Phase 3 data revealed that **PERSERIS® 120 mg** may be useful in **addressing difficult-to-treat negative symptoms**

AMERICAN PSYCHIATRIC ASSOCIATION



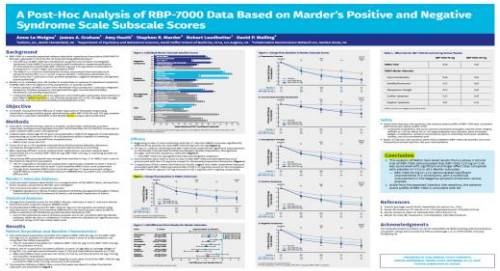
- 2-month treatment with **PERSERIS® (90 and 120 mg) improved individual items of the PANSS Positive** and **General Psychopathology Scales**
- 2-month treatment with **PERSERIS® (120 mg) improved the PANSS Negative Scale score**.

SIRS Schizophrenia International Research Society



Psych Congress

PERSERIS® (120 mg) significantly improved all 5 Marder subscales vs. Placebo: Positive and Negative symptoms, Disorganized thought, Uncontrolled hostility/Excitement and Anxiety/Depression



Long-term treatment with PERSERIS® is **clinically safe and effective** for patients with moderate or severe OUD

Studies to support PERSERIS® label changes:

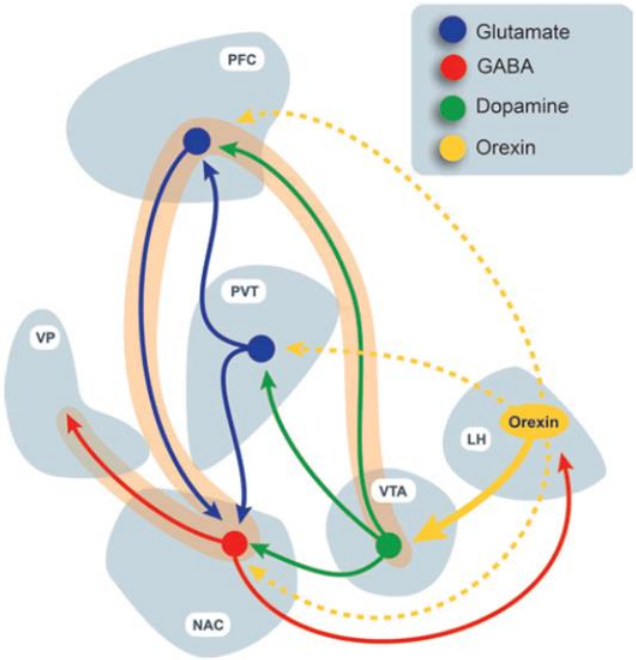
- Safety, tolerability, PK, and efficacy of 180 mg (2x90 mg) PERSERIS® following transition from 6 mg oral risperidone in patients with clinically stable schizophrenia
- Alternate injection site

November 19, 2020:

Approval of PERSERIS® in Canada

Partnership with HLS Therapeutics

EARLY-STAGE ASSET DEVELOPMENT (ESAD)



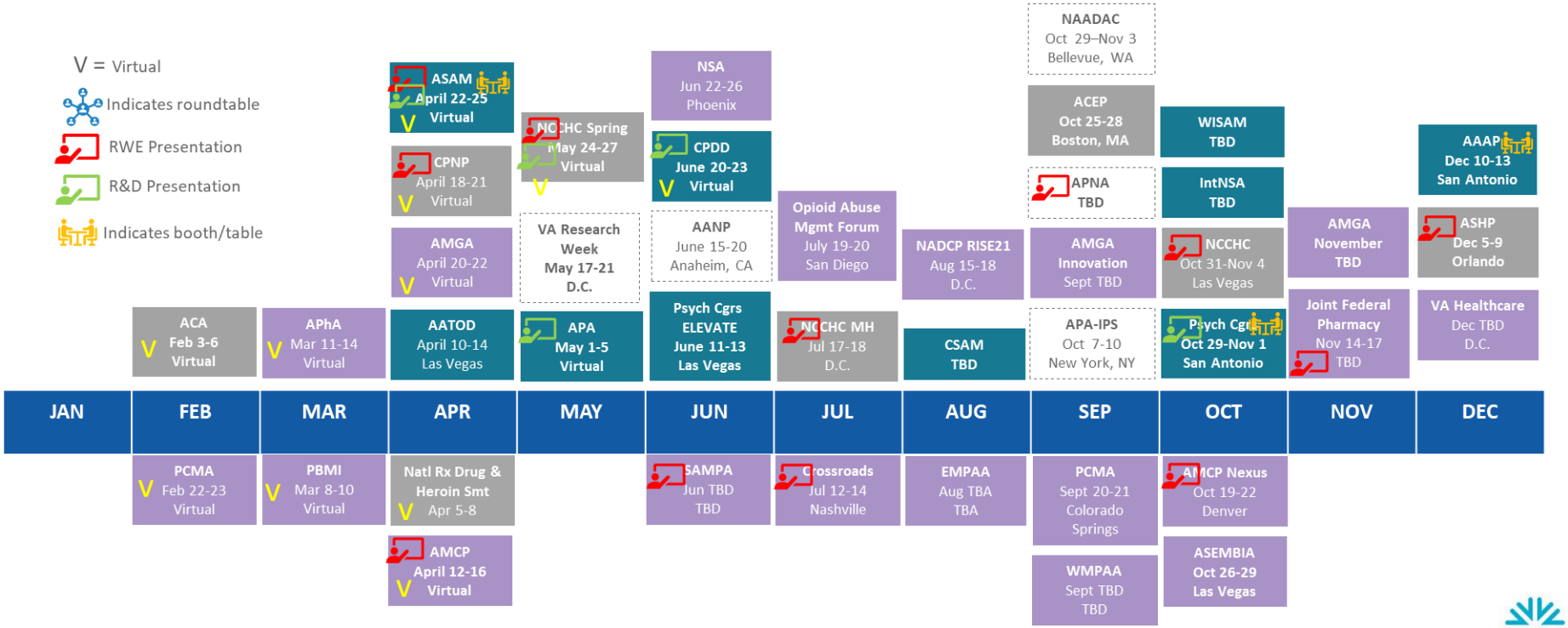
INDV-2000 (selective OX1 receptor antagonist): A non-opioid strategy for OUD treatment

- NIH HEAL Grant enables clinical, nonclinical and pharmaceutical development activities
- FDA approval of IND in February 2020
- Phase 1 Single Ascending Dose (SAD) started July 28, 2020: 7 cohorts successfully dosed as of January 2021; Cohort #8 ongoing. Results estimated Q3-2021
- Year 2 NIH grant awarded in September 2020 with clear plan & deliverables for 2021.

INDV-1000 (selective $GABA_B$ Positive Allosteric Modulator): A new mechanism for the treatment of Alcohol Use Disorder (AUD)

- Significant progress on lead optimization program with the identification of new chemical series leading to optimized leads ready for Late Lead Optimization (LLO).
- Clear LLO plan & deliverables for 2021.
- Completion of LLO program by Q4-2021 with the identification of lead molecules to move toward candidate selection and IND readiness

2021 Key Congress Calendar



Ryan Preblick

Chief Financial Officer

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Income statement*

($ in mil.)	FY 2020 Adjusted	FY 2019 Adjusted	FY % change	Q4 2020 Adjusted	Q4 2019 Adjusted	Q4 % change
Net Revenues	**$647**	**$785**	**-18%**	**$185**	**$133**	**+39%**
Cost of Sales	(92)	(140)		(29)	(43)	
Gross Profit	**$555**	**$645**	**-14%**	**$156**	**$90**	**+73%**
Gross Margin %	*86%*	*82%*	*+4 pp*	*84%*	*68%*	*+16 pp*
Selling, General and Administration Expenses	(427)	(390)	+9%	(111)	(119)	-7%
Research & Development Expenses	(40)	(53)	-25%	(13)	(17)	-24%
Profit on Ordinary Activities (before interest & taxation)	**$88**	**$202**	**-56%**	**$32**	**($46)**	**NM**
Operating Margin %	*14%*	*26%*	*-12 pp*	*17%*	*NM*	*NM*
Net Finance Income / (Expense)	(17)	2		(5)	0	
Taxation	(12)	(28)		(1)	9	
Effective Tax Rate %	*17%*	*14%*		*4%*	*20%*	
Net Income	**$59**	**$176**	**-66%**	**$26**	**($37)**	**NM**

*Please see Appendix for full reconciliation of Actual to Adjusted for periods indicated; may not add due to rounding.
NM: Not meaningful
pp: percentage points

Cash & borrowing position

($ in mil.)	FY 2020	FY 2019
Cash & Cash Equivalents	$858	$1,060
Current Borrowings	(4)	(4)
Long-term Borrowings	(230)	(233)
Loan issuance costs	(1)	(2)
Net cash	$623	$821

- Net cash of $623m at end of FY20 reflects:
  - ✓ $103m payment to DOJ required by resolution
  - ✓ Change in net working capital
- Maintaining prudent and 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)
  - ✓ Uphold compliance commitments and protect our people

FY 21 guidance introduced

FY 21 Guidance[1] ($ in mil.)	
Total Base Case NR • SUBLOCADE NR base case • PERSERIS NR base case	**Up to $625m** • $185m to $210m • $17m to $20m
Adj. gross margin	**Mid- to high-single digit % point decline**
Adj. OPEX (SG&A + R&D)	**$420m to $440m**
Adj. pre-tax income	**Positive**

FY 2021 NR Assumptions

- **Base case NR:** Currently assumes the operating backdrop will improve in H2 2021, as COVID-19 pandemic restrictions impacting in-person healthcare practitioner access subside and healthcare systems approach normality.
  - Downside case if COVID-19 pandemic restrictions impacting in-person healthcare practitioner access persist in H2 2021: Total NR of $565m; SUBLOCADE NR of $170m; PERSERIS NR of $15m

Additional top-line items:

- Double-digit underlying BMAT market growth
- SUBOXONE® Film
  - ✓ Flat to modest share erosion in Q1 with potential accelerated share erosion thereafter from any formulary actions
  - ✓ The Group continues to expect that SUBOXONE® Film share loss will ultimately revert to observed industry analogues[2]
- 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

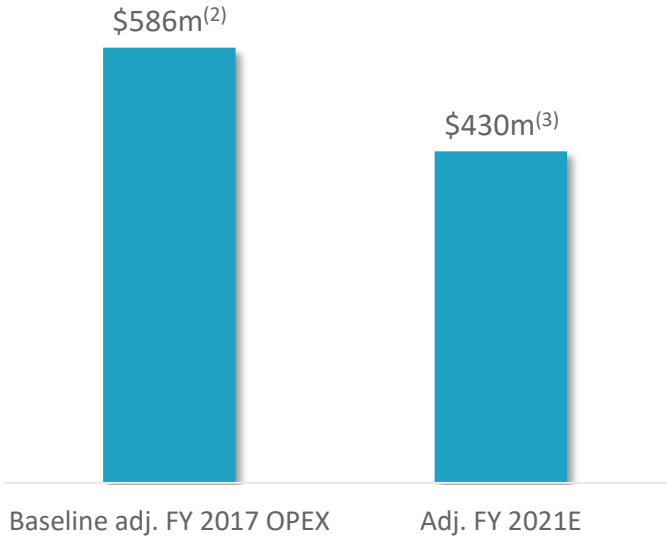
Margin & Expense detail:

- Mid- to high-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 $420m to $440m reflects:
  - ✓ Benefits from completed strategic alignment in 2020;
  - ✓ Partially offset by incremental investments for US LAI technologies fueled by the recent strength in US SUBOXONE Film (the Group may make further LAI growth investments based on continued relative US Film strength); and,
  - ✓ COVID-delayed supply-related projects.

(1) Before F/X and exceptional costs
(2) IMS Institute Report, January 2016: "Price Declines after Branded Medicines Lose Exclusivity in the U.S."

Capturing significant OPEX[(1)] savings

Over $155m of adj. OPEX savings achieved vs. FY 2017



- Captures actions completed from FY18 to FY20
  - ✓ Reduced headcount by 20%+
  - ✓ Realigned and reinvested in US business, with primary focus on OHS channel
  - ✓ Refocused R&D on supporting LAI technologies and early-stage asset progression
  - ✓ Streamlined corporate functions
- Actions have not impacted ability to deliver our treatments

(1) OPEX = combined SG&A and R&D expenses
(2) FY 2017 Adj. OPEX excludes $185 mil. provision for investigative and antitrust matters, the release of a legacy provision and $25 mil. related to the settlement of Amneal antitrust matter
(3) Reflects the midpoint of FY 2021 adj. OPEX range of $420m to $440m (see slide 26)

Concluding Remarks

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

INDICATION AND HIGHLIGHTED SAFETY INFORMATION

INDICATION
SUBOXONE® Film is indicated for the 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 should not be used by patients who have been shown to be hypersensitive to buprenorphine or naloxone.

WARNINGS AND PRECAUTIONS
Addiction, Abuse, and Misuse: SUBOXONE Film 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. 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.

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 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 Signs 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.

For more information about SUBOXONE Film, please see the full Prescribing Information and Medication Guide at www.suboxone.com.

SUBLOCADE® (BUPRENORPHINE EXTENDED-RELEASE) INJECTION FOR SUBCUTANEOUS USE (CIII)

INDICATION AND HIGHLIGHTED SAFETY INFORMATION

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.

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.**

HIGHLIGHTED SAFETY INFORMATION

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.

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 of 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.

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

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

WARNING: INCREASED MORTALITY IN ELDERY 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 (≥ 5% and greater than twice placebo) were increased weight, sedation/somnolence and musculoskeletal pain. The most common injection site reactions (≥ 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

Income Statement: Q4 2020 vs. Q4 2019

	Q4 2020				Q4 2019		
	Q4 2020 Actual	Adjustments	Q4 2020 Adjusted	Δ Y-o-Y (adjusted)	Q4 2019 Actual	Adjustments	Q4 2019 Adjusted
($ in mil. at Actual FX)							
Net Revenues	**185**		**185**	**+39%**	**133**		**133**
Cost of Sales	(23)	(6) [1]	(29)		(43)		(43)
Gross Profit	**162**		**156**	**+73%**	**90**		**90**
Gross Margin (%)	*88%*		*84%*		*68%*		*68%*
Selling, General and Administration Expenses	(158)	47 [2]	(111)		(115)	4 [1]	(119)
Research & Development Expenses	(13)		(13)		(17)		(17)
Profit / (Loss) on Ordinary Activities before interest & taxation	**(9)**		**32**	**NM**	**(42)**		**(46)**
Operating Margin (%)	*NM*		*17%*		*NM*		*NM*
Net interest	(5)		(5)		(0)		(0)
Taxation	1	(2) [3]	(1)		(13)	(22) [2]	9
Effective Tax Rate (%)	*7%*		*4%*		*31%*		*20%*
Net Income/ (Loss)	**(13)**		**26**	**NM**	**(55)**		**(37)**

NM: Not Meaningful

Q4 2020 Notes:

(1) Excludes $6m of exceptional gain related to inventory provisions due to COVID-19
(2) Excludes $47m of exceptional costs related RB settlement $50m partially offset by DOJ reduction in accrual of ($5m) and restructuring costs of $2m
(3) Excludes $2m of exceptional pre-tax and taxation items

Q4 2019 Notes:

(1) Excludes $4m of exceptional gain related to out-licensing of patents related to intranasal naloxone
(2) Excludes $22m of exceptional pre-tax and taxation items

Income Statement: FY 2020 vs. FY 2019

	FY 2020				FY 2019		
	2020 Actual	Adjustments	2020 Adjusted	Δ Y-o-Y (adjusted)	2019 Actual	Adjustments	2019 Adjusted
($ in mil. at Actual FX)							
Net Revenues	**647**		**647**	**-18%**	**785**		**785**
Cost of Sales	(97)	5 (1)	(92)		(140)		(140)
Gross Profit	**550**		**555**	**-14%**	**645**		**645**
Gross Margin (%)	*85%*		*86%*		*82%*		*82%*
Selling, General and Administration Expenses	(666)	239 (2)	(427)		(414)	24 (1)	(390)
Research & Development Expenses	(40)		(40)		(53)		(53)
Profit on Ordinary Activities before interest & taxation	**(156)**		**88**	**-56%**	**178**		**202**
Operating Margin (%)	*NM*		*14%*		*23%*		*26%*
Net interest	(17)		(17)		2		2
Taxation	25	(37) (3)	(12)		(46)	18 (2)	(28)
Effective Tax Rate (%)	*14%*		*17%*		*26%*		*14%*
Net Income	**(148)**		**59**	**-66%**	**134**		**176**

FY 2020 Notes:

(1) Excludes $5m of exceptional costs related to inventory provisions due to adverse impact of COVID-19 on business
(2) Excludes $239m of exceptional costs related DOJ resolution of $178m, RB settlement of $50m and restructuring costs of $11m
(3) Excludes $37m of exceptional pre-tax and taxation items

FY 2019 Notes:

(1) Excludes net $24m of exceptional items – $20m costs related to restructuring; $8m cost related to potential redress, offset by $4m gain related to out-licensing of patents related to intranasal naloxone
(2) Excludes net $18m related to exceptional pre-tax and taxation items -- $5m benefit related to exceptional items; $23m charge related to S267(a) reserve and Orphan Drug Credit release