Indivior PLC

Q2 2022 Results
July 28, 2022

AGENDA

Overview & Strategic Priorities Update	Mark Crossley
Q2 / H1 Performance & FY 2022 Guidance	Ryan Preblick
R&D Update	Christian Heidbreder
Conclusion	Mark Crossley
Q&A	All

INDIVIOR

Mark Crossley

Chief Executive Officer

INDIVIOR

Forward-looking statements

This presentation contains certain statements that are forward-looking. Forward-looking statements include, among other things, statements regarding the Indivior Group's financial guidance for 2022 and its medium- and long-term growth outlook, the potential for an additional U.S. stock exchange listing, expected market growth rates, expected changes in market share, future exchange rates, its operational goals, its product development pipeline, ongoing litigation and other statements containing the words "subject to", "believe", "anticipate", "plan", "expect", "intend", "estimate", "potential", "project", "strategic priorities," "may", "will", "should", "would", "could", "can", the negatives thereof, variations thereon and similar expressions.

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 speak only as of the date that they are made and should be regarded solely as our current plans, estimates and beliefs. 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. Various factors may cause differences between Indivior's expectations and actual results, including, among others, the risk factors described in the most recent Indivior PLC Annual Report and in subsequent releases, and: 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 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 the Indivior Group's compliance with its 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, future levels of inflation and foreign exchange rates, and other unusual items.

Q2 2022 key messages

Strong overall performance led by SUBLOCADE® growth; execution on Strategic Priorities continues

Raising FY 2022 net revenue guidance for SUBLOCADE®; total Group net revenue and adj. operating income expectations maintained

>$1 bil. gross cash and investments[1]; disciplined approach to capital allocation

Pursuing shareholder approval for additional US listing

[1]See discussion of obligations in Note 9 and 10 from Q2/H1 2022 Results press release dated July 28, 2022

Strategic Priorities update: Q2 2022

Grow SUBLOCADE® >$1 bil.

Q2 22 NR: $98m
+15% vs. Q1 22
+81%[1] vs. Q2 21

Q2 22 US dispenses: 75.5k
+18% vs. Q1 22
+76%[1] vs. Q2 21

Ending Q2 22 patients[2]: 65k
+14% vs. Q1 22
+76% vs. Q2 21

OHS[3] Accessed: 500+

[1] Excludes $7m CJS bulk order in Q2 21
[2] Rolling 12-month patients estimate using both Specialty Pharmacy and Specialty Distributor proxy data
[3] Organized Health Systems

Diversify Revenue

PERSERIS®
Q2 22 NR: **$7m**
+40% vs. Q1 22
+75% vs. Q2 21
Expanded national sales force in field since Q1 22

SUBUTEX® Prolonged Release (ROW):
Q2 22 NR: **$6m**
unch. vs. Q1 22
+50% vs. Q2 21

Build Our Pipeline

Aelis Farma (AEF 0117) Cannabis Use Disorder: Phase 2b study initiated Q2 22; other workstreams progressing

INDV-1000 (w/ ADDEX) Alcohol Use Disorder: Two lead molecules chosen for optimization with one candidate selection targeted for Q1 23

INDV-2000 (w/ C4X) Opioid Use Disorder:
Completed Phase 1 study with no events of clinical concern; re-initiate MAD[1] study in Q3 22 upon FDA clearance

A complete R&D update may be found here.

[1] Multiple Ascending Dose

Optimize Operating Model

Q2 22 Adj. Operating Profit[1]: $60m
(vs. adj. $66m Q2 21)

Gross cash & Investments[2]: $1,015m Q2 22
(vs. $1,102m FY 2021)

Settled legacy patent litigation (DRL)

7.6m shares repurchased during Q2 2022

[1] Adjusted reconciliations in appendix
[2] See discussion of obligations in Note 9 and 10 from Q2/H1 2022 Results press release dated July 28, 2022

OHS Strategy focused on SUBLOCADE prescribing depth

Early OHS cohorts show steady **increases** in HCPs prescribing for 5+ patients

Achieved access to 500+ priority OHS parents

Hospital Systems | Veterans Administration | Criminal Justice System (CJS)

Driving deeper prescribing in OHS accounts

OHS Facilities (not incl. CJS)
- Drive access to OHS children

Prescribing OHS HCPs
- Majority of prescribing HCPs

OUD Diagnosed OHS Patients[1]
- Large patient base of ~ 2.3m

OHS accounts for ~70% of SUBLOCADE net revenue growth and overall SUBLOCADE net revenue in H1 22

[1] Opioid Use Disorder (OUD) patient population amongst OHS HCPs writing based on internal Indivior analysis

Ryan Preblick

Chief Financial Officer

INDIVIOR

Q2 2022 financial highlights

Takeaways

- Double-digit top-line growth
- SUBLOCADE NR up 81% YOY[1]
- PERSERIS traction with NR up 75% YOY
- Expected SG&A increase from growth investments behind SUBLOCADE and PERSERIS
- Maintained strong financial flexibility
- SUBLOCADE FY 2022 NR guidance increased

Profit & Loss ($ in mil. actual F/X)

	Q2 22	Q2 21	Change
US Net Revenue	$179	$154	16%
ROW Net Revenue	$42	$47	-11%
Total Net Revenue	**$221**	**$201**	**10%**
Key product NR			
SUBLOCADE NR	$98	$54[1]	81%
PERSERIS NR	$7	$4	75%
Adj. Gross Profit[2]	**$183** 83%	**$171** 85%	**7%**
Adj. Op Exp[2]	($121)	($105)	15%
SG&A	($107)	($92)	16%
R&D	($14)	($13)	8%
Adj. Other Operating Income/(Expense)	**(2)**	**0**	**NM**
Adj. Operating Income[2]	**$60**	**$66**	**-9%**
Gross cash & Investments[3]	**$1,015**	$1,000	+ $15m

[1] Excludes $7m CJS bulk order in Q2 21
[2] See Appendix for reconciliation
[3] See discussion of obligations in Note 9 and 10 from Q2/H1 2022 Results press release dated July 28, 2022

Cash & Borrowing position

Cash & Borrowing table

($ in mil.)	Q2 22	FY 21
Cash & Cash Equivalents	$857	$1,102
ST & LT Investments	$158	NM
Total Cash & Investments	$1,015	$1,102
Current Borrowings	(3)	(3)
Long-term Borrowings	(237)	(239)
Loan issuance costs	(8)	(7)

Takeaways

Total gross cash & investments of $1,015m[1]:

- Strong cash generation from operations (excluding litigation settlement payments in H1)
- ANDA litigation payment in Q2 with July'22 return of cash collateral
- Cash optimization strategy with portion of cash invested in short-term, investment-grade fixed-income securities

Maintaining disciplined & consistent capital allocation:

- Deliver against SUBLOCADE NR goal of >$1 billion
- Organically diversify revenue base (PERSERIS®, Ex.-US new products)
- Deliver on existing early-stage assets
- $100m share repurchase program underway
- Potential inorganic growth opportunities

[1] See discussion of obligations in Note 9 and 10 from Q2/H1 2022 Results press release dated July 28, 2022

FY 22 guidance – SUBLOCADE NR expectations raised; total Group guidance maintained

FY 22 Guidance[1] ($ in mil.)

Total Net Revenue	**$840m to $900m** (unchanged)
Key LAI products:	
• SUBLOCADE NR	• $390m to $420m (+66% at mid-point vs. FY21)
• PERSERIS NR	• $27m to $32m (unchanged)
Adj. gross margin %	**Low to mid 80% range** (unchanged)
Total OPEX (SG&A + R&D)	**$520m to $540m** (unchanged)
• SG&A	• $440m to $455m
• R&D	• $80m to $85m
Adj. op. income	**Similar to FY21 levels** (unchanged)

FY 22 Assumptions

- Continued easing of COVID constraints to US healthcare system
- Further update with Q3 results in late October at the latest

Additional top-line items

- **Underlying BMAT market growth of mid- to high-single digits**
- **US SUBOXONE® Film**
  - Potential market impact to the US sublingual film market in H2 from launch of 4th generic[2]; guidance assumes entry at the start of Q4 2022 with SUBOXONE film subject to an accelerated rate of share erosion
- **ROW**
  - Traction for new products (SUBUTEX PR, SUBOXONE Film) more than offset by volume and pricing pressure on legacy products
  - Unfavorable F/X translation impact due to strength of US dollar

Margin & Expense detail

- **Expected adj. gross margin: low- to mid-80% range mainly due to expected relative strength of SUBOXONE Film & higher cost inflation**
- **Total Adj. OPEX (SG&A + R&D) of $520m to $540m reflects:**
  - SG&A range of $440m to $455m
    - ✓ Annualization of investments to grow SUBLOCADE and PERSERIS®
    - ✓ Incremental costs associated with additional US listing
  - R&D range of $80m to $85m
    - ✓ Further SUBLOCADE Lifecycle Management studies
    - ✓ Manufacturing capacity expansion
    - ✓ Early-stage asset advancement

[1] Before exceptional items.
[2] Apotex generic buprenorphine/naloxone sublingual film approved by FDA on 2 June 2022.

Christian Heidbreder

Chief Scientific Officer

INDIVIOR

Pipeline progress

Phase 2

AELIS FARMA

Cannabis Use Disorders (CUD)

AEF0117 (Synthetic CB1 Specific Signaling Inhibitor)

- **Phase 2b**, randomized, double-blind, placebo-controlled, 4-arm, parallel-group, prospective, multicenter study in treatment-seeking subjects with moderate to severe cannabis use disorder (CUD), according to DSM-5 criteria: First Subject First Visit achieved on May 23, 2022.
- Other CMC, nonclinical toxicology and clinical workstreams progressing as planned

Phase 1

C4X Discovery

Opioid Use Disorder (OUD)

INDV-2000 (Selective Orexin-1 Receptor Antagonist)

- Completion of clinical **Phase 1 Single Ascending Dose (SAD)** study with 8 doses (1, 5, 20, 50, 120, 180, 360, 720 mg): No events of clinical concern
- **Phase 1 Multiple Ascending Dose (MAD) study** currently planned and scheduled to start Q3-2022 following completion of additional nonclinical toxicology study required by the FDA and subsequent FDA clearance.
- Major progress on the formulation and chemical development fronts.

Pre-clinical

addex therapeutics

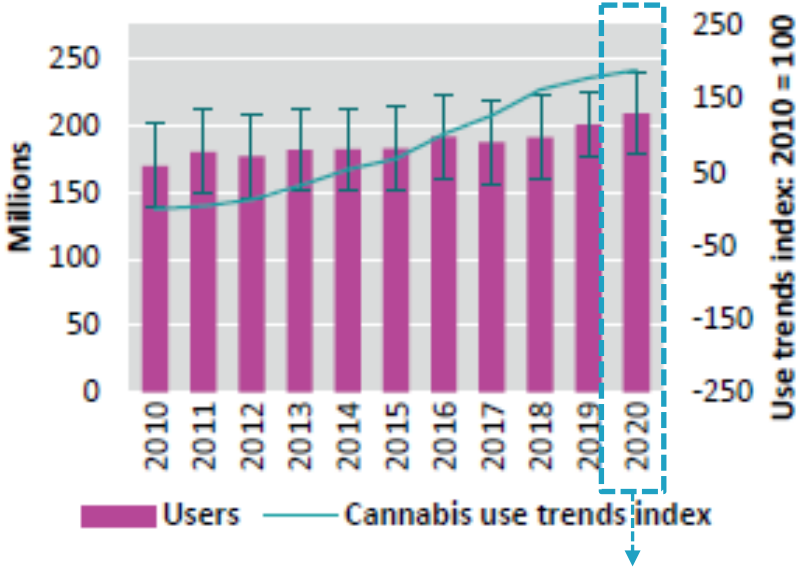
Alcohol Use Disorder (AUD)

INDV-1000 (Selective GABAb Positive Allosteric Modulator)

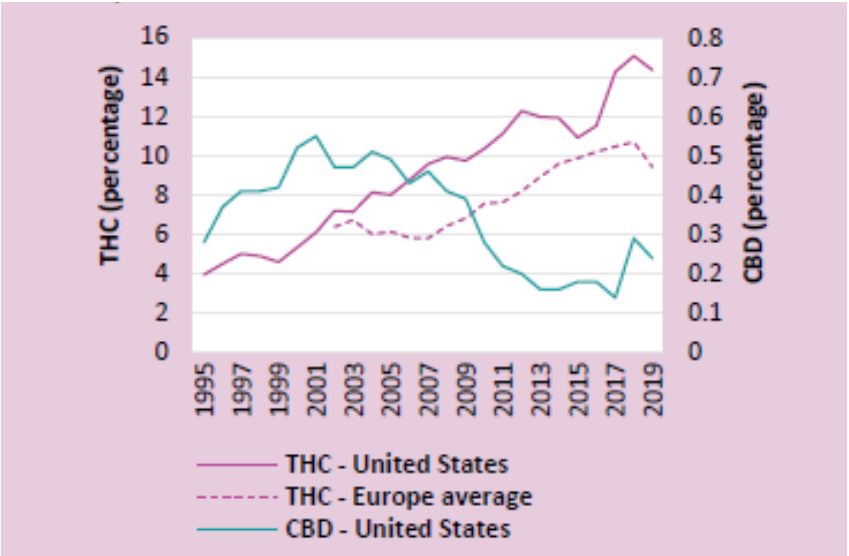
- Two **lead molecules chosen** for late optimization work i.e., Potency – Selectivity – ADME – Physico-chemical properties
- **Candidate selection**: Q1-2023.

Global cannabis use

The number of cannabis users aged 15–64 has increased by 23% over the past decade - Rising Δ^9-THC & falling CBD levels amplify health risks



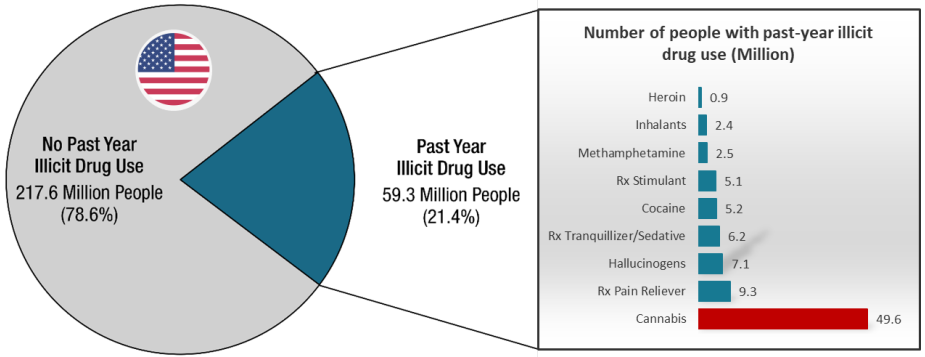
209 million or 4% of the global population



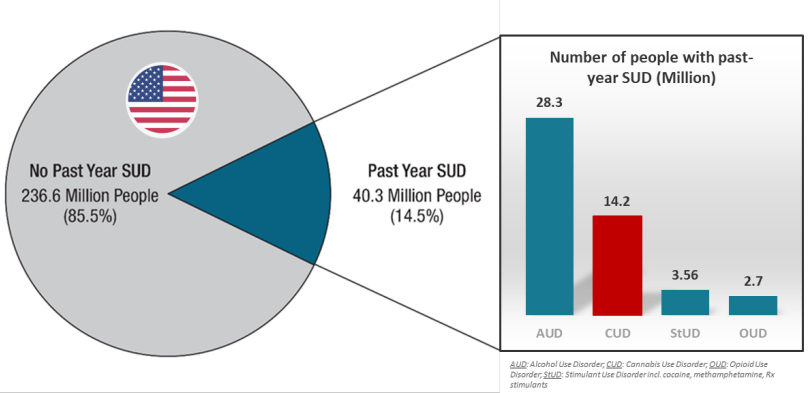
Source: UNODC, World Drug Report 2022 (United Nations publication, 2022)

Cannabis users and Cannabis Use Disorder (CUD) in US people Aged 12> (2020)

49.6 million used cannabis over the past year



14.2 million had CUD over the past year



Source: Substance Abuse and Mental Health Services Administration. (2021). Key substance use and mental health indicators in the United States: Results from the 2020 National Survey on Drug Use and Health (HHS Publication No. PEP21-07-01-003, NSDUH Series H-56). Rockville, MD: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration.

Long-term consequences of persistent cannabis use

Research

JAMA Psychiatry | Original Investigation

Association of Cannabis Use During Adolescence With Neurodevelopment

Matthew D. Albaugh, PhD; Jonatan Ottino-Gonzalez, PhD; Amanda Sidwell, BS; Claude Lepage, PhD; Anthony Juliano, PsyD; Max M. Owens, PhD; Bader Chaarani, PhD; Philip Spechler, PhD; Nicholas Fontaine, BS; Pierre Rioux, MSc; Lindsay Lewis, PhD; Seun Jeon, PhD; Alan Evans, PhD; Deepak D'Souza, MD; Rajiv Radhakrishnan, MD; Tobias Banaschewski, MD, PhD; Arun L. W. Bokde, PhD; Erin Burke Quinlan, PhD; Patricia Conrod, PhD; Sylvane Desrivières, PhD; Herta Flor, PhD; Antoine Grigis, PhD; Penny Gowland, PhD; Andreas Heinz, MD, PhD; Bernd Ittermann, PhD; Jean-Luc Martinot, MD, PhD; Marie-Laure Paillère Martinot, MD, PhD; Frauke Nees, PhD; Dimitri Papadopoulos Orfanos, PhD; Tomáš Paus, MD, PhD; Luise Poustka, MD; Sabina Millenet, PhD; Juliane H. Fröhner, MSc; Michael N. Smolka, MD; Henrik Walter, MD, PhD; Robert Whelan, PhD; Gunter Schumann, MD; Alexandra Potter, PhD; Hugh Garavan, PhD; for the IMAGEN Consortium

PNAS

Persistent cannabis users show neuropsychological decline from childhood to midlife

Madeline H. Meier[a,b,1], Avshalom Caspi[a,b,c,d,e], Antony Ambler[a,f], HonaLee Harrington[b,c,d], Richard S. E. Keefe[g], Kay McDonald[f], Aimee Ward[f], Richie Poulton[f], and Terrie E. Moffitt[a,b,c,d,e]

[a]Duke Transdisciplinary Prevention Research Center, Center for Child and Family Policy, [b]Department of Psychology and Neuroscience, and [c]Institute for Genome Sciences and Policy, Duke University, Durham, NC 27708; [d]Department of Psychiatry and Behavioral Sciences, Duke University Medical Center, Durham, NC 27710; [e]Social, Genetic, and Developmental Psychiatry Centre, Institute of Psychiatry, King's College London, London SE5 8AF, United Kingdom; and [f]Dunedin Multidisciplinary Health and Development Research Unit, Department of Preventive and Social Medicine, School of Medicine, University of Otago, Dunedin 9054, New Zealand

Edited by Michael I. Posner, University of Oregon, Eugene, OR, and approved July 30, 2012 (received for review April 23, 2012)

CelPress Cell

Article

Cannabinoid receptor 1 antagonist genistein attenuates marijuana-induced vascular inflammation

Tzu-Tang Wei,[1,2,3,6,7,17] Mark Chandy,[1,2,3,14,17] Masataka Nishiga,[1,2,3,17] Angela Zhang,[1,2,3] Kaavya Krishna Kumar,[4] Dilip Thomas,[1,2,3] Amit Manhas,[1,2,3] Siyeon Rhee,[1,2,3,14] Johanne Marie Justesen,[1,2,3] Ian Y. Chen,[1,2,3] Hung-Ta Wo,[1,2,3,16] Saereh Khanamiri,[1,2,3] Johnson Y. Yang,[1,2,3] Frederick J. Seidl,[5] Noah Z. Burns,[5] Chun Liu,[1,2,3] Nazish Sayed,[1,2,3] Jiun-Jie Shie,[10] Chih-Fan Yeh,[6,11] Kai-Chien Yang,[6,11] Edward Lau,[12] Kara L. Lynch,[13] Manuel Rivas,[5] Brian K. Kobilka,[4,15] and Joseph C. Wu[1,2,3,14,16,*]

[1]Stanford Cardiovascular Institute, Stanford University School of Medicine, Stanford, CA 94305, USA
[2]Department of Medicine, Division of Cardiovascular Medicine, Stanford University School of Medicine, Stanford, CA 94305, USA
[3]Department of Radiology, Molecular Imaging Program at Stanford, Stanford University, Stanford, CA 94305, USA
[4]Department of Molecular and Cellular Physiology, Stanford University School of Medicine, Stanford, CA 94305, USA
[5]Department of Biomedical Data Science, Stanford University School of Medicine, Stanford, CA 94305, USA
[6]Department and Graduate Institute of Pharmacology, College of Medicine, National Taiwan University, Taipei, Taiwan
[7]Chemical Biology and Molecular Biophysics, Taiwan International Graduate Program in Chemical Biology and Molecular Biophysics (TIGP-CBMB), Academia Sinica, Taipei, Taiwan
[8]Novo Nordisk Foundation Center for Basic Metabolic Research, University of Copenhagen, Copenhagen, Denmark
[9]Department of Chemistry, Stanford University, Stanford, CA, USA
[10]Institute of Chemistry, Academia Sinica, Taipei, Taiwan
[11]Division of Cardiology, Department of Internal Medicine, National Taiwan University Hospital, Taipei, Taiwan
[12]Department of Medicine, Division of Cardiology, University of Colorado School of Medicine, Aurora, CO, USA
[13]Department of Laboratory Medicine, University of California, San Francisco, San Francisco, CA, USA
[14]Greenstone Biosciences, Palo Alto, CA 94304, USA
[15]Department of Chemical and Systems Biology, Stanford University School of Medicine, Stanford, CA 94305, USA
[16]Division of Cardiology, Department of Internal Medicine, Chang Gung Memorial Hospital, Linkou Branch, Taoyuan, Taiwan
[17]These authors contributed equally
[18]Lead contact
*Correspondence: joewu@stanford.edu
https://doi.org/10.1016/j.cell.2022.04.005

The contribution of cannabis use to variation in the incidence of psychotic disorder across Europe (EU-GEI): a multicentre case-control study

*Marta Di Forti, Diego Quattrone, Tom P Freeman, Giada Tripoli, Charlotte Gayer-Anderson, Harriet Quigley, Victoria Rodriguez, Hannah E Jongsma, Laura Ferraro, Caterina La Cascia, Daniele La Barbera, Ilaria Tarricone, Domenico Berardi, Andrei Szöke, Celso Arango, Andrea Tortelli, Eva Velthorst, Miguel Bernardo, Cristina Marta Del-Ben, Paulo Rossi Menezes, Jean-Paul Selten, Peter B Jones, James B Kirkbride, Bart PF Rutten, Lieuwe de Haan, Pak C Sham, Jim van Os, Cathryn M Lewis, Michael Lynskey, Craig Morgan, Robin M Murray, and the EU-GEI WP2 Group**

BCPT Basic & Clinical Pharmacology & Toxicology

Basic & Clinical Pharmacology & Toxicology, 2018, **122**, 660–662 Doi: 10.1111/bcpt.12962

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

"Zombie" Outbreak Caused by the Synthetic Cannabinoid AMB-FUBINACA in New York

Axel J. Adams, B.S., Samuel D. Banister, Ph.D., Lisandro Irizarry, M.D., Jordan Trecki, Ph.D., Michael Schwartz, M.D., M.P.H., and Roy Gerona, Ph.D.

The Prevalence of Cannabinoid Hyperemesis Syndrome Among Regular Marijuana Smokers in an Urban Public Hospital

Joseph Habboushe[1], Ada Rubin[1], Haoming Liu[1] and Robert S. Hoffman[1,2]

[1]Ronald O. Perelman Department of Emergency Medicine, New York University School of Medicine, New York, NY, USA and [2]Division of Medical Toxicology, New York University School of Medicine, New York, NY, USA

(Received 8 October 2017; Accepted 3 January 2018)

Research Article

"*Spice Was Made, by the Devil Himself*": A Thematic Analysis of the Experience of an Addiction to Synthetic Cannabinoids

Blessing N. Marandure, Samson Mhizha & Amanda Wilson

Received 06 Dec 2021, Accepted 29 Mar 2022, Published online: 31 May 2022

Download citation https://doi.org/10.1080/02791072.2022.2083534 Check for updates

Appendix

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. For REMS information visit www.btodrems.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.

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.

Income statement: Q2 2022 vs. Q2 2021

	Q2 2022				Q2 2021		
	Q2 2022 Actual	Adjustments	Q2 2022 Adjusted	Δ Y-o-Y (adjusted basis)	Q2 2021 Actual	Adjustments	Q2 2021 Adjusted
($ in mil. at Actual FX)							
Net Revenues	**221**		**221**		**201**		**201**
Cost of Sales	(38)		(38)		(30)		(30)
Gross Profit	**183**		**183**		**171**		**171**
Gross Margin (%)	*83%*		*83%*		*85%*		*85%*
Selling, General and Administration Expenses	(109)	2(1)	(107)		(85)	(7)(1)	(92)
Research & Development Expenses	(14)		(14)		(13)		(13)
Other Operating Income	3	(5)(2)	(2)		0		0
Profit (Loss) on Ordinary Activities before interest & taxation	**63**		**60**		**73**		**66**
Operating Margin (%)	*29%*		*27%*		*36%*		*33%*
Net interest (expense) / income	(5)		(5)		(7)	1(2)	(6)
Taxation	(10)		(10)		(4)	(7)(3)	(11)
Effective Tax Rate (%)	*(17%)*		*(18%)*		*(6%)*		*(18%)*
Net Income / (loss)	**48**		**45**		**62**		**49**

Q2 2022 Notes:

(1) Excludes exceptional consulting costs in preparation for a potential additional listing of Indivior shares on a major US exchange
(2) Excludes exceptional benefits related to proceeds received from a Director's & Officers' insurance reimbursement claim

Q2 2021 Notes:

(1) Excludes $7m of exceptional items - $8m benefit related to a legal provision release and $1m cost related to debt refinancing
(2) Excludes $1m write-off of historical deferred financing cost
(3) Adjusted taxation excludes the effects of exceptional items

Income statement: H1 2022 vs. H1 2021

($ in mil. at Actual FX)	H1 2022 Q2 2022 Actual	H1 2022 Adjustments	H1 2022 Q2 2022 Adjusted	Δ Y-o-Y (adjusted basis)	H1 2021 Q2 2021 Actual	H1 2021 Adjustments	H1 2021 Q2 2021 Adjusted
Net Revenues	**428**		**428**		**381**		**381**
Cost of Sales	(75)		(75)		(62)		(62)
Gross Profit	**353**		**353**		**319**		**319**
Gross Margin (%)	*82%*		*82%*		*84%*		*84%*
Selling, General and Administration Expenses	(217)	2[(1)]	(215)		(168)	(13)[(1)]	(181)
Research & Development Expenses	(23)		(23)		(22)		(22)
Other Operating Income	4	(5)[(2)]	(1)		1		1
Profit (Loss) on Ordinary Activities before interest & taxation	**117**		**114**		**130**		**117**
Operating Margin (%)	*27%*		*27%*		*37%*		*34%*
Net interest (expense) / income	(11)		(11)		(11)	1[(2)]	(10)
Taxation	(17)		(17)		23	(43)[(3)]	(20)
Effective Tax Rate (%)	*(16%)*		*(17%)*		*(19%)*		*19%*
Net Income / (loss)	**89**		**86**		**142**		**87**

Q1 2022 Notes:

H1 2022 Notes:
(1) Excludes exceptional consulting costs in preparation for a potential additional listing of Indivior shares on a major US exchange
(2) Excludes exceptional benefits related to proceeds received from a Director's & Officers' insurance reimbursement claim

H1 2021 Notes:
(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 cost 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

H2 2022 Capital Markets Calendar

Date	Key Event
Sept 12th – 13th	**Morgan Stanley Healthcare Conference New York** • Fireside chat • 1:1s
Sept 15th – 16th	**Bank of America Healthcare Conference London** • Presentation & 1:1s
Oct 27th – Nov 2nd	**Q3 22 Results Earnings Call & Investor Roadshow**
Nov 15th – 16th	**Stifel Healthcare Conference New York** • Presentation & 1:1s
Nov 15th – 17th	**Jefferies Healthcare Conference London** • Presentations & 1:1
Dec 7th	**Indivior Capital Markets Day – New York City**

Indivior Capital Markets Day – Save the date

Indivior senior executives will present a detailed outlook and execution path for delivering the Group's strategic priorities. The meeting will include live question and answer sessions.

When: Wednesday, December 7th

Where: New York City (Webcast will be available for those unable to attend in-person)

Additional details will be forthcoming

Peer-reviewed publications H1-2022

PLOS ONE

OPEN ACCESS PEER-REVIEWED

RESEARCH ARTICLE https://doi.org/10.1371/journal.pone.0256752

Effect of sustained high buprenorphine plasma concentrations on fentanyl-induced respiratory depression: A placebo-controlled crossover study in healthy volunteers and opioid-tolerant patients

Laurence M. Moss, Marijke Hyke Algera, Robert Dobbins, Frank Gray, Stephanie Strafford, Amy Heath, Monique van Velzen, Jules A. A. C. Heuberger, Marieke Niesters, Erik Olofsen, Celine M. Laffont, Albert Dahan, Geert Jan Groeneveld

Published: January 27, 2022 • https://doi.org/10.1371/journal.pone.0256752

83 news stories from 46 news outlets

https://doi.org/10.1172/jci.insight.156973

Clinical trials | Neuroscience | Open Access | 10.1172/jci.insight.156973

Modelling buprenorphine reduction of fentanyl-induced respiratory depression

Erik Olofsen,[1] Marijke Hyke Algera,[1] Laurence Moss,[1] Robert L. Dobbins,[2] Geert J. Groeneveld,[1] Monique van Velzen,[1] Marieke Niesters,[1] Albert Dahan,[1] and Celine M. Laffont[3]

Published March 22, 2022 - More info

Recovery from opioid use disorder: A 4-year post-clinical trial outcomes study

William H. Craft [a,b], Allison N. Tegge [b,c], Diana R. Keith [b], Hwasoo Shin [c], Jacob Williams [c], Liqa N. Athamneh [b], Jeffrey S. Stein [b], Howard D. Chilcoat [d,e], Anne Le Moigne [d], Angela DeVeaugh-Geiss [d], Warren K. Bickel [b,*]

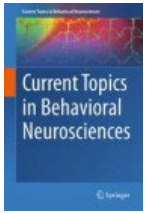
https://doi.org/10.1016/j.drugalcdep.2022.109389

Research paper

Outcomes of a single-arm implementation trial of extended-release subcutaneous buprenorphine depot injections in people with opioid dependence

Michael Farrell [a,*], Jeyran Shahbazi [a], Marianne Byrne [a,b], Jason Grebely [b], Nicholas Lintzeris [c,d], Mark Chambers [e], Briony Larance [a,c,f], Robert Ali [a,g], Suzanne Nielsen [a,h], Adrian Dunlop [i], Gregory J. Dore [b], Michael McDonough [b], Mark Montebello [j,l], Thomas Nicholas [e], Rob Weiss [m], Craig Rodgers [n], Jon Cook [o], Louisa Degenhardt [a], on behalf of the CoLAB study team

https://doi.org/10.1016/j.drugpo.2021.103492



Current Perspectives on Selective Dopamine D_3 Receptor Antagonists/Partial Agonists as Pharmacotherapeutics for Opioid and Psychostimulant Use Disorders

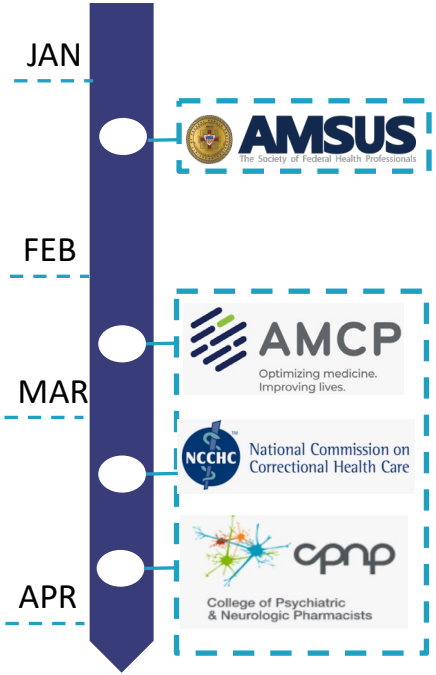
Amy Hauck Newman, Zheng-Xiong Xi & Christian Heidbreder

https://doi.org/10.1007/7854_2022_347

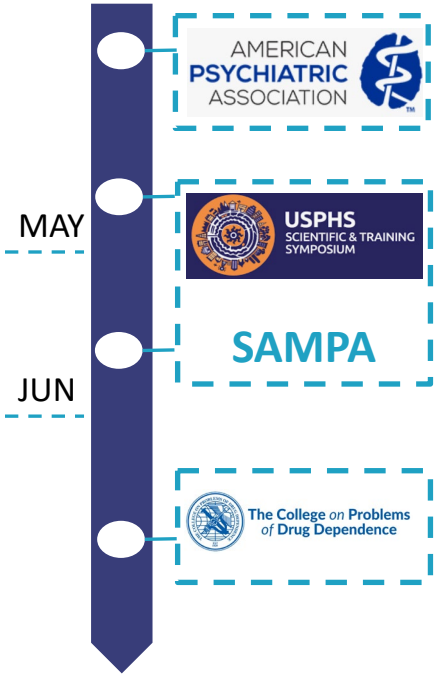
Chapter | First Online: 12 May 2022

Part of the Current Topics in Behavioral Neurosciences book series

Conferences H1-2022



- ✓ Providers and payers perceive that patients with OUD experienced worse outcomes in 2020 due to the COVID-19 pandemic because of difficulties in accessing care and the underlying complexities of managing OUD
- ✓ Regions that have high poverty, high unemployment or low education rate have a trend of lower distribution of waivered providers utilizing buprenorphine than the regions that do not. Top 5 states with the lower socioeconomic factors are MS, LA, AZ, KY and WV.



- ✓ Poor mental health is associated with higher levels of poverty, poor physical health, low education, lack of internet access., use of food stamps, and incarceration. Areas of highest need lack access to substance abuse treatment centers.
- ✓ UMPs designed to improve access to MOUD appear to have a positive impact on MOUD utilization and HCRU.
- ✓ INDV-2000 in Healthy Volunteers
- ✓ Buprenorphine-fentanyl interactions
- ✓ Buprenorphine misuse in OUD
- ✓ Transition from SL buprenorphine to monthly buprenorphine injection.
- ✓ Pain in recovery from OUD.
- ✓ Long-term recovery from OUD.
- ✓ OUD and treatment for opioid problems among OUD symptom subtypes.

THANK YOU