

Indivior PLC

FY 2018 Results
February 14, 2019



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 2019 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 this release): factors affecting sales of Indivior Group's products; the outcome of research and development activities; decisions by regulatory authorities regarding the Indivior Group's drug applications; the speed with which regulatory authorizations, pricing approvals and product launches may be achieved, if at all; the outcome of post-approval clinical trials; competitive developments; difficulties or delays in manufacturing; the impact of existing and future legislation and regulatory provisions on product exclusivity; trends toward managed care and healthcare cost containment; legislation or regulatory action affecting pharmaceutical product pricing, reimbursement or access; claims and concerns that may arise regarding the safety or efficacy of the Indivior Group's products and product candidates; risks related to legal proceedings, including the ongoing investigative and antitrust litigation matters; 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; 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

Shaun Thaxter

Business Overview

Mark Crossley

Financial Review

Javier Rodriguez

Litigation Update

Christian Heidbreder

R&D Update

Shaun Thaxter

Conclusion

Q & A



FY 2018 snapshot & FY 2019 guidance

FY 2018 Performance

(on an adjusted basis* vs. FY 2017)

Net Rev.:	\$1,005m	-8%
Op. Profit:	\$332m	-18%
Net Inc.:	\$272m	+1%
Cash:	\$924m	+\$61m
Net Cash:	\$681m	+\$305m

FY 2019 Guidance:

- Indivior intends to provide total company guidance once the U.S. SUBOXONE® Film market dynamics are clearer; anticipated with Q1 2019 results
- SUBLOCADE™ NR of \$50m to \$70m
- OPEX⁽¹⁾ of \$440m to \$460m

Operational Overview

Double-digit U.S. market growth continues to be mainly driven by Government channels

FY 2018 NR: U.S. market growth more than offset by SUBOXONE® Film market share decline, unfavorable mix and further rebating vs. generic tablet price

FY 2018 SUBLOCADE™ (buprenorphine extended - release) Injection NR of \$12m; Q4 18 NR of \$7m; KPIs continue to progress

FY 2018 op. profit decline primarily reflects lower NR and planned launch investments in SUBLOCADE™ and PERSERIS™, partially offset by OPEX savings

Voluntarily repaid \$235m of outstanding Term Loan principal; \$243m remains outstanding

Pipeline Progress

SUBLOCADE™ new drug submissions made in Australia and Europe

SUBLOCADE™ HEOR studies (12 and 24 mos.), all post market requirement (PMR) and post-marketing commitment (PMC) studies are on track; key LEGO studies also on track

PERSERIS™ (risperidone) for extended release injectable suspension launching the week of February 18th

Reached agreement to divest rights related to SUBOXONE® Sublingual Tablets in China for total potential consideration of up to \$122.5m (subject to closing conditions)

Termination of Arbaclofen Placarbil and ADDEX lead compound development; pursuing back-up GABAB compounds with ADDEX

* See Appendix for reconciliation
(1) OPEX = SG&A and R&D combined



2018 takeaways: meeting generic challenges & preparing for our future

Challenge

Response

Growth



- ✓ Conserve cash generated by SUBOXONE® Film franchise to fuel growth of new depot technologies with long-lived IP — SUBLOCADE™ and PERSERIS™
- ✓ Focus on driving success of SUBLOCADE™ and PERSERIS™ in most attractive markets; U.S. is main focus near-term
- ✓ ROW focus is on maximizing cash flow generation near-term

Generic “at-risk” Launch



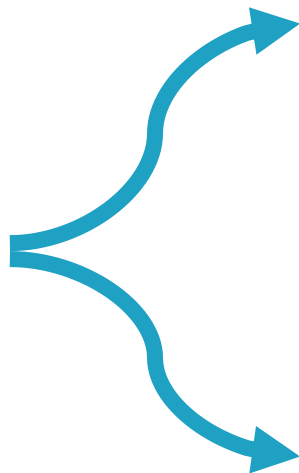
- ✓ Voluntarily repaid \$235m of Term Loans; \$243m remains outstanding
- ✓ Significant operating expense reduction – targeting \$440m to \$460m of OPEX⁽¹⁾ in FY 2019
- ✓ Ready to launch authorized generic of buprenorphine/naloxone sublingual film
- ✓ Continue to assert intellectual property against ANDA filers

(1) OPEX = Combined SG&A and R&D expenses, excluding exceptional items



Creating a strong growth platform targeting addiction and schizophrenia

2018



Adding Behavioral Health to established leadership position in OUD provides **diversification** and **additional revenue growth** as well as **a broader scope** for long-term business development



Driving the full commercial potential in the highest value markets

U.S.

- ✓ Remains most compelling growth opportunity
- ✓ Drive SUBLOCADE™ success
- ✓ Diversify with PERSERIS™

ROW

- ✓ Maintain SUBOXONE® Film and SUBOXONE® Tablet positions
- ✓ Maximize cash flow
- ✓ Potentially register and launch SUBLOCADE™ and PERSERIS™ on case-by-case basis

China

- ✓ Agreement to divest rights to SUBOXONE® tablet to Pukang
- ✓ Potentially worth up to \$122.5m*; \$17.5m* of near-term payments



*Based on the achievement of certain development and commercial milestones; Subject to various closing conditions. See Feb. 4, 2019 announcement.

Driving long-term value with innovative depot technologies in the U.S.

Innovative Depot Technologies

ONCE-MONTHLY
Sublocade™
(buprenorphine extended-release)
injection for subcutaneous use ©
100mg-300mg

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



Targeting Unmet Patient Needs

Now:

- ☀ U.S. (core market)
- ☀ Ex-U.S. (selective)

Later:

- ☀ Business development
- ☀ Early stage assets



Indivior Future State

- ☀ Renewed profitable growth post transition phase
- ☀ More balanced mix (product/geographic)
- ☀ Scalable organization
- ☀ Long-dated IP assets



Positive fundamentals underpin our strategy

- > Recognized leader in global addiction treatment
- > Core U.S. addiction treatment market volume continues to grow at double-digit rates⁽¹⁾
- > Favorable U.S. legislation — additional funding; permanent treatment capacity expansions; favorable to long-acting injectable (LAI) market development for OUD treatments
- > Expand to behavioral health — almost half of schizophrenia patients have a co-morbid substance use disorder⁽²⁾; schizophrenia LAIs projected⁽²⁾ to grow at 20%+ CAGR to >\$3 billion net revenue⁽³⁾
- > Scalable operating structure and tightened strategic focus to maximize cash through transition phase
- > Patient-inspired culture; high level of organizational agility and resilience

(1) IQUVIA / INDV Business Analytics

(2) Swofford CD, Scheller-Gilkey G, Miller AH, Woolwine B, Mance R. Double jeopardy: schizophrenia and substance use. Am J Drug Alcohol Abuse. 2000;26:343–353. and Brady, Kathleen T. and Sinha, Rajita. Co-Occurring Mental and Substance Use Disorders: The Neurobiological Effects of Chronic Stress. Am J Psychiatry 162:8, August 2005

(3) Johnson & Johnson, Otsuka, Lundbeck and Alkermes Quarterly reports & investor presentations, INDV internal analysis



SUBLOCADE™

(buprenorphine extended-release) Injection



ONCE-MONTHLY

Sublocade™
(buprenorphine extended-release)
injection for subcutaneous use Ⓒ

SUBLOCADE™ focus

- Only once-monthly buprenorphine subcutaneous injection
- Sustained plasma concentrations of buprenorphine for a month
- Blocks the subjective effects of opioids
- Opportunity to fully engage with counseling and psychosocial support

Please refer to full Prescribing Information for important safety information, including boxed warning: www.SUBLOCADE.com

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

ONCE-MONTHLY
Sublocade™
*(buprenorphine extended-release)
injection for subcutaneous use ©*



2019 SUBLOCADE™ baseline

Objectives Achieved



- Positive treatment experience among patients⁽¹⁾
- Payor access – 83% exiting FY 2018
- Prescription journey – sustained at 15 to 22 days

Work in Progress



- Dispensing yield – improving, but not yet at target
- HCP* prescribing base – target greater adoption
- Increase awareness – create greater patient request for information about SUBLOCADE™

(1) Based on anecdotal patient feedback

* HCP = Healthcare professional



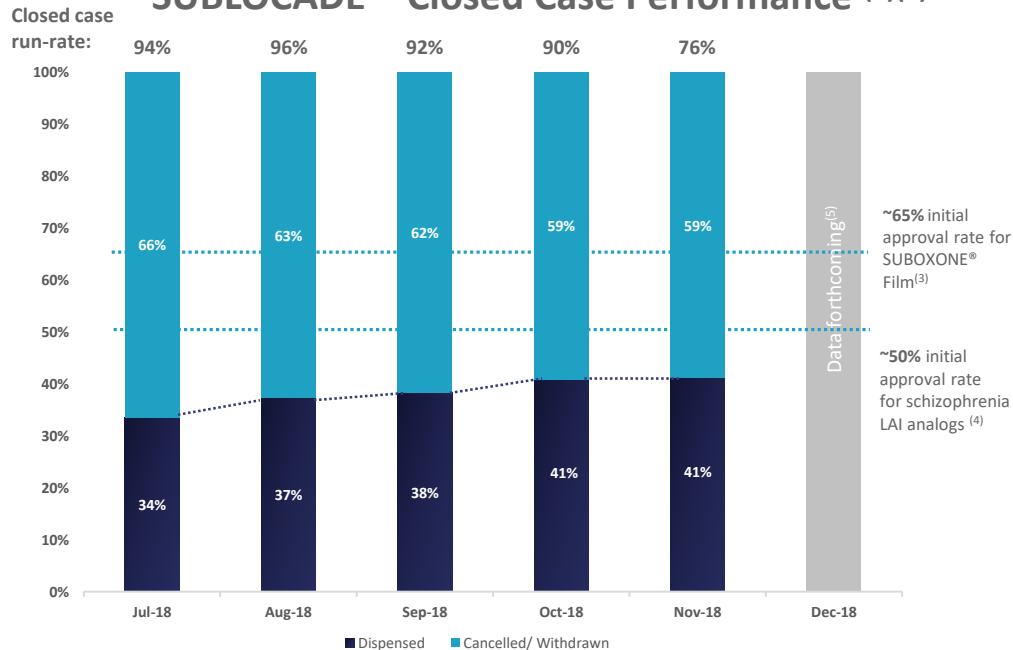
Unique SUBLOCADE™ patients increasing month over month; dispensing yield progressing toward target

Cumulative Launch to 12/31/18 ⁽¹⁾

16,275 Unique prescriptions initiated

4,709 Unique patients injected

SUBLOCADE™ Closed Case Performance ⁽¹⁾⁽²⁾



(1) Proprietary Indivior SUBLOCADE™ data – Nov and Dec. 2018 dispensing rate will change based on data refresh

(2) Closed cases unique to the month of enrollment. Tracking closed cases unique to the month of enrollment aligns with all other metrics (unique prescriptions and unique injections) and allows us to track developments over time

(3) Proprietary Indivior SUBOXONE® data

(4) Amundsen Consulting Analysis

(5) Data is measured 45 days after the quarter

(1) Total includes estimate for patients with HCPs using Specialty Distributors (Buy and Bill)



SUBLOCADE™ KPIs – HCP data & patient repeat injections

Cumulative Launch to 12/31/18

2,430

HCPs initiated prescription journeys

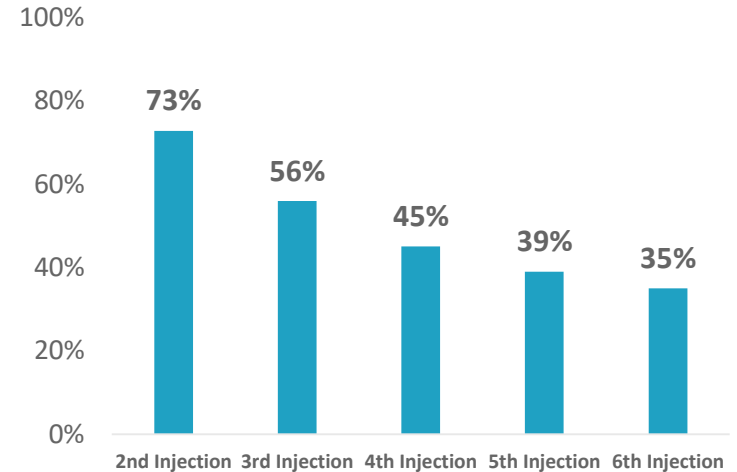
1,325

HCPs administered SUBLOCADE™

232

HCPs administered ≥ 5 patients

Repeat Injections
(All patients with initial injection during March to Oct.)



2019 SUBLOCADE™ priorities

Payor access quality – simpler coverage & expand to IDNs*

Continued progress in improving dispense yield %

Improve commercial effectiveness

Expand HCP prescriber base

Increase patient awareness & request



Simplify the treatment journey



Increase HCP base and adoption

* IDN = Integrated Delivery Network



PERSERIS™

(risperidone) for extended-release injectable suspension



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

PERSERIS™ concept: clear and focused approach

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



- 1 First and only once-monthly risperidone LAI
- 2 Supplemental oral risperidone or loading dose not recommended
- 3 Initial peak plasma concentrations achieved in 4 to 6 hours
- 4 Just one subcutaneous injection monthly

Please refer to full Prescribing Information for important safety information, including boxed warning: www.PERSERIS.com



PERSERIS™ priorities for 2019

- Payor access currently at 38%; targeting quality of access comparable with peers
- Promotional launch February 18th with a field force of 50 salespeople
- Targeting appropriate HCPs with high volume LAI practices
- Focus on key differentiating product specific attributes



Mark Crossley

Chief Financial Officer



Income Statement*

	FY			Q4		
	2018 Adjusted	2017 Adjusted	% change	2018 Adjusted	2017 Adjusted	% change
(\$ in mil.)						
Net Revenues	1,005	1,093	-8	236	265	-11
Cost of Sales	(128)	(104)		(35)	(32)	
Gross Profit	877	989	-11	201	233	-14
<i>Gross Margin (%)</i>	87%	90%	-300 bps	85%	88%	-300 bps
Selling, General and Administration Expenses	(478)	(497)	-4	(106)	(141)	-25
Research & Development Expenses	(67)	(89)	-25	(17)	(22)	-23
Profit on Ordinary Activities (before interest & taxation)	332	403	-18	78	70	+11
<i>Operating Margin (%)</i>	33%	37%	-400 bps	33%	26%	-138 bps
EBITDA	348	416	-16	83	74	+12
Net Finance Expense	(14)	(42)		0	(8)	
Taxation	(46)	(91)		(11)	(8)	
<i>Effective Tax Rate (%)</i>	15%	25%		14%	13%	
Net Income	272	270	+1	67	54	+24

*Please see Appendix for full reconciliation of Actual to Adjusted for periods indicated; may not add due to rounding.



Cash & Borrowing Position

(\$ in mil.)	FY 2018	FY 2017
Cash & Cash Equivalents	924	863
Current Borrowings	(4)	(5)
Long-term Borrowings	(237)	(477)
Other	(2)	(5)
Net cash	681	376

- Net cash of \$681m at end of FY 18, improvement of \$305m in the period
- Long-term borrowings significantly reduced by \$235m of voluntary Term Loan principal repayments
- Retaining cash on balance sheet at present:
 - ✓ Protect against “at-risk” generic buprenorphine/naloxone film launch
 - ✓ Flexibility until resolution of legal matters



Cash Conversion

Twelve months ended
December 31st:

Cash Flows from Operating Activities

(\$ in mil.)

	<u>FY 18</u>	<u>FY 17</u>
Operating Profit	292	193
Depreciation, amortization and impairment	40	13
Reversal of other non-cash items	(34)	22
Changes in assets and liabilities	(6)	(60)
Provisions	35	201
Cash generated from Operations	327	369
Loan expenses and taxes paid	(24)	(74)
Net cash inflow from operating activities	303	295
Net Cash Flow as % of Adj. Operating Profit	90%	73%

Net cash flow improvement of \$8 million driven by lower interest and tax paid; conversion improved to 90% of adj. operating profit



FY 2019 Total Company Guidance

Given the continued uncertainties surrounding how the U.S. market for both SUBOXONE® Film and generic alternatives will ultimately develop, Indivior is unable to provide FY 2019 total company net revenue and net income guidance at this time.

Indivior has executed key elements of its contingency plan. The overriding objective of the contingency plan is to ensure a minimum cash balance of \$250m to remain in compliance with its debt covenants and to help provide resources to cover the transition period of expected material and rapid loss of SUBOXONE® film net revenue in the U.S. until combined net revenue from SUBLOCADE™ and PERSERIS™, along with continued net revenue from rest of world (ROW), is able to return the Group to profitable growth.

Indivior is providing FY 2019 guidance on SUBLOCADE™ net revenue and operating expenses, and intends to provide FY 2019 Group net revenue and net income guidance (before exceptionals and currency) once the total U.S. buprenorphine/naloxone sublingual film market dynamics are clearer, which is anticipated to be at its Q1 2019 results release scheduled for May 2, 2019.

Top-line:

- Rapidly changing U.S. buprenorphine/naloxone sublingual film competitive conditions, therefore currently not predictable
- Intensifying competitive and generic pressures in Europe and Canada; Australasia remains steady
- Net revenue expectation for SUBLOCADE™
 - ✓ Expected to be \$50m to \$70m

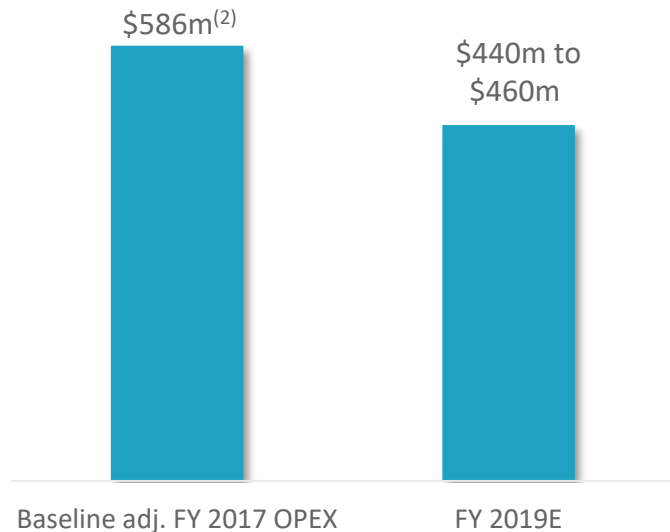
Expenses:

- Operating expenses (SG&A and R&D combined) of approximately \$440m to \$460m, excluding exceptional items.
- Continued investments to drive the commercial success of SUBLOCADE™ and PERSERIS™ and to support continued regulatory and compliance enhancements
- Before F/X and exceptional costs



Operating Expense Savings

~\$140m of actual adj. OPEX⁽¹⁾ savings by end of FY 2019 vs. FY 2017 baseline



Takeaways:

- Captures actions completed to date
 - ✓ Reduced headcount by ~30%; savings partially reinvested in PERSERIS™ launch
 - ✓ Reprioritized R&D
 - ✓ Reduced third-party expenditures
- Includes maintaining investments in SUBLOCADE™ and PERSERIS™ to achieve commercial success
- Cost of actions is expected to be approximately \$15m; will be considered exceptional

(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



Javier Rodriguez

Chief Legal Officer



Legal Proceedings Update

Litigation Matters

- DOJ Investigation / State Subpeonas
- Opioid Class Action Litigation

ANDA Litigation

- Dr. Reddy's Laboratories (DRL) Preliminary Injunction (PI)
- Motion for Temporary Restraining Order (TRO) / PI against Alvogen
- Authorized Generic
- CAFC Appeals
- District Court Cases



Key ANDA Litigation Milestones

<u>Event</u>	<u>Estimated Date</u>
Supreme Court ruling on application to stay mandate pending <i>Certiorari</i> petition outcome	Q1 2019
Federal Circuit ruling in expedited appeal of '514 patent non-infringement decision	Q2 - Q3 2019
Supreme Court ruling on <i>Certiorari</i> petition	Q2 - Q4 2019
District Court trial against Actavis on the '305 and '454 patents	December 2019
District Court trial against Teva/DRL/Alvogen on the '305 and '454 patents	Q4 2019 - Q1 2020



Christian Heidbreder

Chief Scientific Officer

EARLY STAGE ASSET DEVELOPMENT

▪ Arbaclofen Placarbil (AP):

- ✓ Overall profile of Arbaclofen Placarbil (AP) significantly improved as a result of our clinical development and reformulation plans
- ✓ Risks related to variability in absorption and enzyme polymorphism still remain and would have to be addressed unequivocally before committing to further development
- ✓ Development of AP for alcoholic liver disease + cirrhosis faces additional development hurdles
- ✓ The final recommendation in light of this overall risk profile is to stop any further development of AP and rather focus on the development of the GABA_B positive allosteric modulator family of molecules through our partnership with Addex Therapeutics.

▪ ADX71441 (GABA_B PAM – ADDEX):

- ✓ New seizure risk with lead molecule ADX71441 identified in dogs. NOAEL dose without aberrant EEG findings in dogs currently set at low dose, which is below therapeutic range.
- ✓ The final recommendation is to stop the development of the lead molecule ADX71441.
- ✓ Plans in place to accelerate our backup program (new lead identification & optimization) in partnership with ADDEX.

▪ C4X3256 (OX1 receptor antagonist):

- ✓ Finalization of all preclinical study reports. Formulation development and stability work to support First time in Human (FTIH) studies.

▪ APV202701A (D3 receptor antagonist):

- ✓ Finalization of target validation of lead molecule APV202701A and initiation of IND preparation.



SUBLOCADE™

SUBLOCADE™ U.S.:

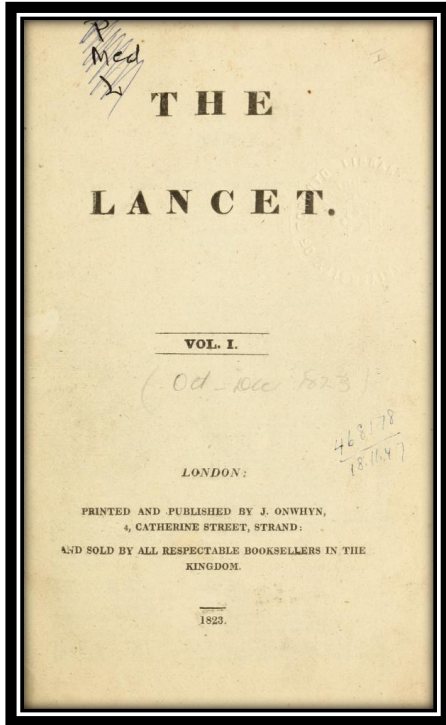
- ✓ **PMRs and PMCs:** All on track
- ✓ **LEGO studies:** All on track with a focus on (1) Epidemiology of Buprenorphine Abuse, Misuse & Diversion; (2) VOTIVE; (3) Fentanyl blockade study, and (4) Global Real-World HEOR study
- ✓ **Patient-Reported Outcomes studies:** (1) SUBLOCADE™ 12-month Phase III trial; (2) RECOVER baseline and 12-month data points; (3) RECOVER 24-month on track for final report in December 2019.

SUBLOCADE™ ex-U.S.:

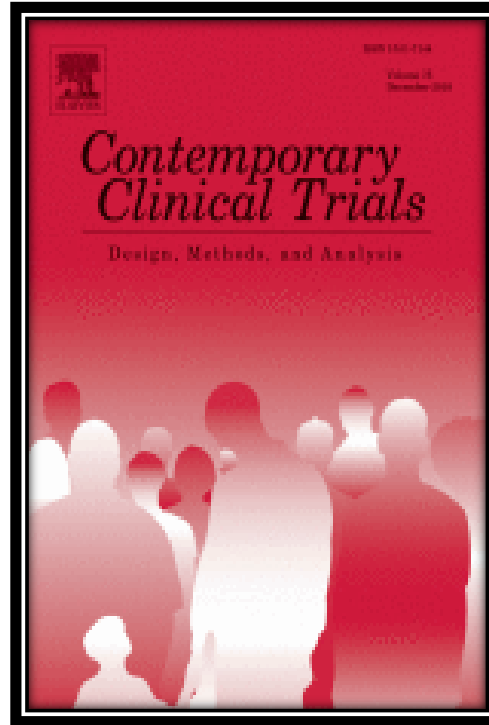
- ✓ Canada approval November 21, 2018
- ✓ Regulatory filings in Australia, New Zealand, Israel, and Europe (decentralized procedure) all completed by November 2018



SUBLOCADE™ PEER-REVIEWED PUBLICATIONS: PIVOTAL PHASE III DATA & RECOVER®



Haight BR, Learned SM, Laffont CM, Fudala PJ, Zhao Y, Garofalo AS, Greenwald MK, Nadipelli VR, Ling W, Heidbreder C (2018) *Efficacy and safety of a monthly buprenorphine depot injection for opioid use disorder: a multicentre, randomised, double-blind, placebo-controlled trial. The Lancet.* Available online February 19th, 2019.



Ling W, Nadipelli V, Ronquest N, Albright V, Aldridge A, Learned S, Mehra V, Heidbreder C (2018) *Remission from Chronic Opioid Use—Studying Environmental and Socio-economic Factors on Recovery (RECOVER): study design and participant characteristics. Contemporary Clinical Trials, 76: 93-103.* <https://doi.org/10.1016/j.cct.2018.11.015>





THE RECOVER STUDY™

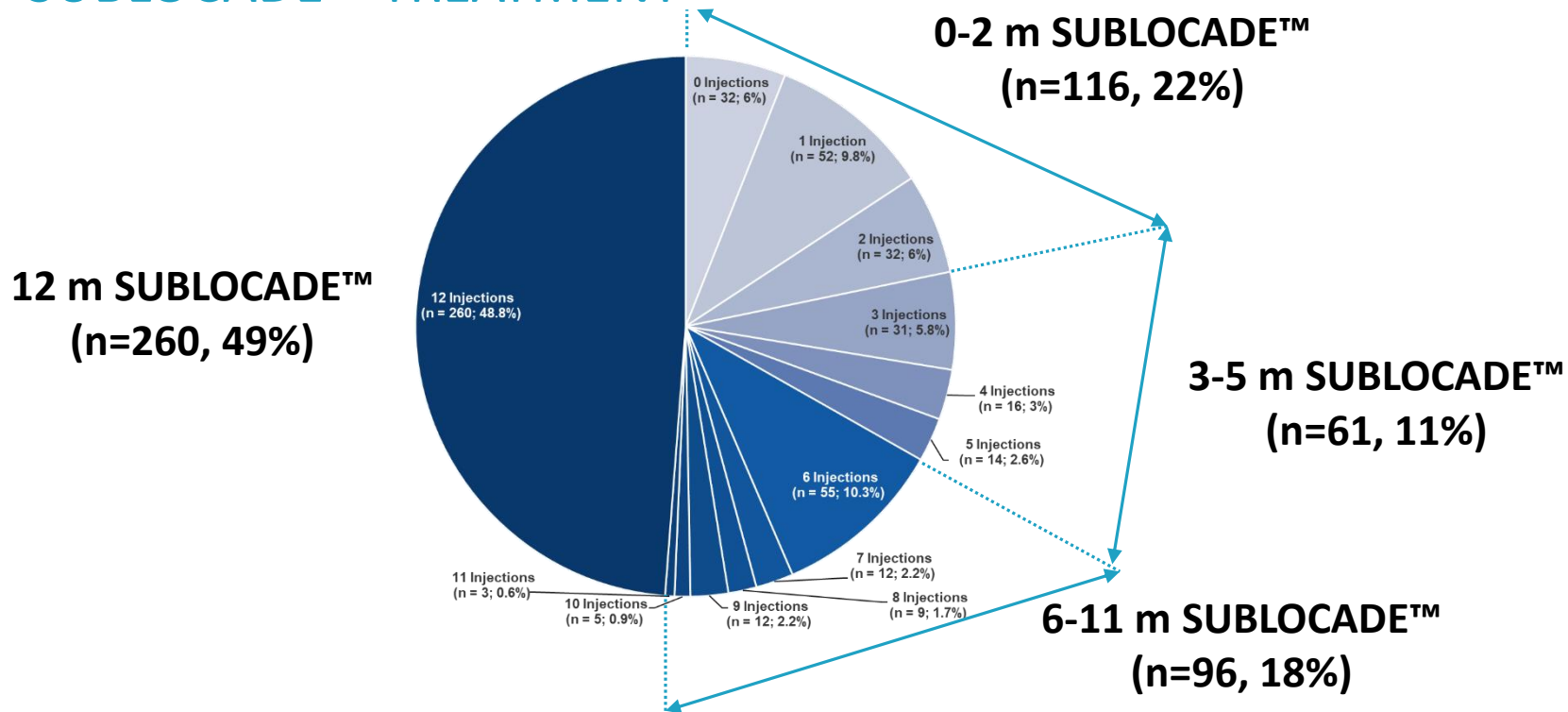
*Remission from Chronic Opioid Use – Studying Environmental
and Socio-Economic Factors on Recovery*



Source: Ling W, Nadipelli V, Ronquest N, Albright V, Aldridge A, Learned S, Mehra V, Heidbreder C (2018) Remission from Chronic Opioid Use—Studying Environmental and Socio-economic Factors on Recovery (RECOVER): study design and participant characteristics. *Contemporary Clinical Trials*, 76: 93-103. <https://doi.org/10.1016/j.cct.2018.11.015>, Mehra V, Heidbreder C (2018) Remission from Chronic Opioid Use—Studying Environmental and Socio-economic Factors on Recovery (RECOVER): study design and participant characteristics. Submitted



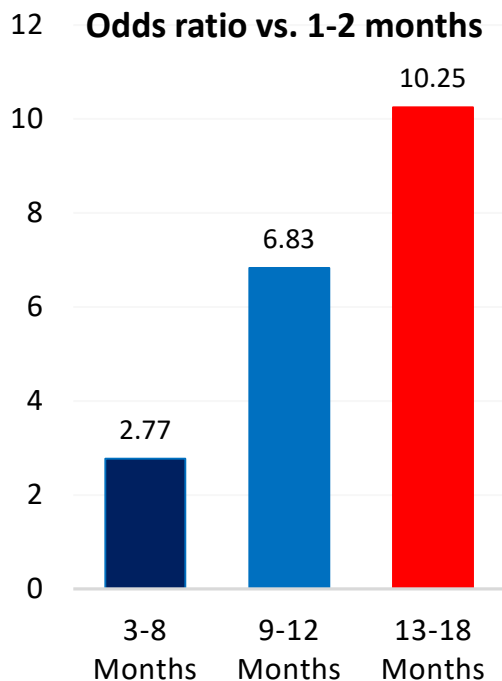
THE RECOVER STUDY™: PARTICIPANTS BY LENGTH OF SUBLOCADE™ TREATMENT



Source: Ling W, Nadipelli V, Ronquest N, Albright V, Aldridge A, Learned S, Mehra V, Heidbreder C (2018) Remission from Chronic Opioid Use—Studying Environmental and Socio-economic Factors on Recovery (RECOVER): study design and participant characteristics. *Contemporary Clinical Trials*, 76: 93-103. <https://doi.org/10.1016/j.cct.2018.11.015>



BASELINE PAST-MONTH SELF-REPORTED OPIOID ABSTINENCE BY LENGTH OF SUBLOCADE™ TREATMENT



Compared to subjects who received SUBLOCADE™ ≤ 2 months, the odds of achieving past-month abstinence were estimated to be about

3x higher

For those staying on SUBLOCADE™ for **3-8 months**

7x higher

For those staying on SUBLOCADE™ for **9-12 months**

10x higher

For those staying on SUBLOCADE™ for **13-18 months**



PEER-REVIEWED PUBLICATIONS – PRIORITIES 2019



- ✓ SUBLOCADE™ Patient-Reported Outcomes
- ✓ SUBLOCADE™ Long-term safety, tolerability & efficacy
- ✓ SUBLOCADE™ Exposure-Response analysis
- ✓ SUBLOCADE™ RECOVER 12-month datapoints
- ✓ PERSERIS™ Long-term safety, tolerability & efficacy
- ✓ PERSERIS™ Health-related quality of life in schizophrenia patients



CONFERENCE PRESENTATIONS – PRIORITIES 2019

March 25-28

San Diego, CA

AMCP Managed Care & Specialty Pharmacy Annual Meeting

- SUBLOCADE™ PRO Phase 3
- SUBLOCADE™ Injectors
- PERSERIS™ Budget Impact Model (BIM)
- PERSERIS™ Cost-Effectiveness Analysis (CEA)

April 4-7

Orlando, FL

50th Annual Meeting of the American Society of Addiction Medicine (ASAM)

- SUBLOCADE™ RECOVER 12-month data points
- SUBLOCADE™ long-term safety
- Fentanyl blockade

May 18-22

San Francisco, CA

172nd Annual Meeting of the American Psychiatric Association (APA)

- PERSERIS™ efficacy PANSS analysis

June 15-19

San Antonio, TX

81st Annual Scientific Meeting of the College on Problems of Drug Dependence (CPDD)

- SUBLOCADE™ RECOVER 12-month data points
- SUBLOCADE™ Injectors



Shaun Thaxter

Chief Executive Officer



Execution on strategic priorities is creating a clear path for future success

1

Building the resilience of our franchise

SUBOXONE®/ OUD leadership has created a strong foundation for renewed growth with SUBLOCADE™

2

Developing our innovative pipeline

PERSERIS™ launch enabled by the creation of the Behavioral Health commercial team

3

Expanding global treatment

Strong presence in key geographies creates future opportunities for SUBLOCADE™ and PERSERIS™

4

Developing and fortifying the business

Strong financial discipline across cost base, cash flow and capital structure helping ensure investment for growth



Appendix



Income Statement: FY 2018 vs. FY 2017

	FY 2018			Δ Y-o-Y (adjusted)	FY 2017		
	2018 Actual	Adjustments	2018 Adjusted		2017 Actual	Adjustments	2017 Adjusted
(\$ in mil. at Actual FX)							
Net Revenues	1,005		1,005	-8%	1,093		1,093
Cost of Sales	(128)		(128)		(104)		(104)
Gross Profit	877		877	-11%	989		989
<i>Gross Margin (%)</i>	<i>87%</i>		<i>87%</i>		<i>90%</i>		<i>90%</i>
Selling, General and Administration Expenses	(494)	(16) ⁽¹⁾	(478)		(707)	(210) ⁽¹⁾	(497)
Research & Development Expenses	(91)	(24) ⁽²⁾	(67)		(89)		(89)
Profit on Ordinary Activities before interest & taxation	292		332	-18%	193		403
<i>Operating Margin (%)</i>	<i>30%</i>		<i>33%</i>		<i>18%</i>		<i>37%</i>
EBITDA	308		348	-16%	206		416
Net interest	(14)		(14)		(56)	(14) ⁽²⁾	(42)
Taxation	(3)	43 ⁽³⁾	(46)		(79)	12 ⁽³⁾	(91)
<i>Effective Tax Rate (%)</i>	<i>(1%)</i>		<i>15%</i>		<i>58%</i>		<i>25%</i>
Net Income	275		272	+1%	58		270

FY2018 Notes:

- (1) Excludes \$11m of exceptional items – \$13m costs related to restructuring; \$40m cost related to potential redress, offset by \$37m gain related to out-licensing of patents related to intranasal naloxone
- (2) Excludes \$24m of exceptional impairment of the Arbaclofen Placarbil and ADDEX assets
- (3) Excludes \$43m related to exceptional pre-tax and taxation items

FY2017 Notes:

- (1) Excludes \$185 mil. provision for investigative and antitrust matters and the release of a legacy provision and \$25 mil. related to the settlement of Amneal antitrust matter
- (2) Excludes \$14 mil. of exception costs related to the replacement of the Term Loan facilities
- (3) Excludes \$12 mil. benefit related to exceptional pre-tax and taxation items



Income Statement: Q4 2018 vs. Q4 2017

	Q4 2018			Δ Y-o-Y (adjusted)	Q4 2017		
	Q4 2018 Actual	Adjustments	Q4 2018 Adjusted		Q4 2017 Actual	Adjustments	Q4 2017 Adjusted
(\$ in mil. at Actual FX)							
Net Revenues	236		236	-11%	265		265
Cost of Sales	(35)		(35)		(32)		(32)
Gross Profit	201		201	-14%	233		233
<i>Gross Margin (%)</i>	85%		85%		88%		88%
Selling, General and Administration Expenses	(140)	(34) ⁽¹⁾	(106)		(326)	(185) ⁽¹⁾	(141)
Research & Development Expenses	(41)	(24) ⁽²⁾	(17)		(22)		(22)
Profit on Ordinary Activities before interest & taxation	20		78	+11%	(115)		70
<i>Operating Margin (%)</i>	11%		33%		NA		26%
EBITDA	30		83	+12%	NA		74
Net interest	(0)		(0)		(22)	(14) ⁽²⁾	(8)
Taxation	4	(15) ⁽³⁾	(11)		(8)		(8)
<i>Effective Tax Rate (%)</i>	(20%)		14%		6%		13%
Net Income	24		67	24%	(145)		54

Q4 2018 Notes:

- (1) Excludes \$34m of exceptional items – \$13m costs related to restructuring; \$40m cost related to potential redress, offset by \$19m gain related to out-licensing of patents related to intranasal naloxone
- (2) Excludes \$24m of exceptional impairment of the Arbaclofen Placabil and ADDEX assets
- (3) Excludes \$15m related to exceptional pre-tax and taxation items

Q4 2017 Notes:

- (1) Excludes \$185 mil. provision for investigative and antitrust matters and release of legacy provision.
- (2) Excludes \$14 mil. of exception costs related to the replacement of the Term Loan facilities



Capital Markets Agenda 2019*

Date	Event
Feb. 14 th & 15 th	FY 2018 Results (London Presentation) & Investor Meetings
May 2 nd	Q1 2019 Results (Conference Call)
June 4 th to 6 th	Jefferies US Healthcare Conference (New York City)
July 31 st to Aug. 2 nd	H1 2019 Results (London) & Investor Meetings
September 11 th & 12 th	Morgan Stanley Healthcare Conference (New York City)
October 31 st	Q3 2019 Results (Conference Call)
November (TBD)	Jefferies London Healthcare Conf. (London)
November 18 th & 19 th	Stifel Healthcare Conference (New York City)
December (TBD)	CITI Global Healthcare Conference (New York City)

* Subject to updates and changes



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 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>.

