

Indivior PLC

Q1 2021 Results
April 29, 2021



Mark Crossley

Chief Executive Officer



Forward-looking statements

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

Various factors may cause differences between Indivior's expectations and actual results, including, among others (including those described in the risk factors described in the most recent Indivior PLC Annual Report and in subsequent releases): factors affecting sales of Indivior Group's products and financial position; the outcome of research and development activities; decisions by regulatory authorities regarding the Indivior Group's drug applications or authorizations; the speed with which regulatory authorizations, pricing approvals and product launches may be achieved, if at all; the outcome of post-approval clinical trials; competitive developments; difficulties or delays in manufacturing and in the supply chain; disruptions in or failure of information technology systems; the impact of existing and future legislation and regulatory provisions on product exclusivity; trends toward managed care and healthcare cost containment; legislation or regulatory action affecting pharmaceutical product pricing, reimbursement or access; challenges in the commercial execution; claims and concerns that may arise regarding the safety or efficacy of the Indivior Group's products and product candidates; risks related to legal proceedings, including compliance with the Indivior Group's agreements with the U.S. Department of Justice and with the Office of Inspector General of the Department of Health and Human Services, non-compliance with which could result in potential exclusion from participating in U.S. Federal health care programs; the ongoing investigative and antitrust litigation matters; the opioid national multi-district litigation and securities class action litigation; the Indivior Group's ability to protect its patents and other intellectual property; the outcome of patent infringement litigation relating to Indivior Group's products, including the ongoing ANDA lawsuits; changes in governmental laws and regulations; issues related to the outsourcing of certain operational and staff functions to third parties; risks related to the evolving COVID-19 pandemic and the potential impact of COVID-19 on the Indivior Group's operations and financial condition, which cannot be predicted with confidence; uncertainties related to general economic, political, business, industry, regulatory and market conditions; and the impact of acquisitions, divestitures, restructurings, internal reorganizations, product recalls and withdrawals and other unusual items.

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



Q1 2021 key messages

Executing on our Strategic Priorities

- Good start to FY 2021 – continued SUBLOCADE® progression; overall net revenue and profit* improvement
- Strong financial position maintained – grew cash balance to \$945m
- FY 2021 “Base Case” guidance reconfirmed

* On an Adjusted basis. See Appendix for reconciliations.



Strategic Priorities report card: Q1 2021

1

Grow SUBLOCADE® >\$1 bil.

- **Q1 21 NR:** \$43m (+10% vs. Q4 20; +48% vs. Q1 20)
- **Q1 21 US dispenses:** 35.7k (+11% vs. Q4 20; +51% vs. Q1 20)
- **Q1 21 SUBLOCADE patients*:** 32.1k (+11% vs. Q4 20; +55% vs. Q1 20)
- **Q1 21 OHS activation:** >40% of NR now from OHS channel

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

2

Diversify Revenue

- **SUBUTEX® Prolonged Release (ROW):** Q1 21 NR: \$3m (available in Australia, Canada and Israel); reviews ongoing in Norway, Germany, UK, and Italy
- **PERSERIS Q1 21 NR:** \$3m (-25% vs. Q4 20; unchanged vs. Q1 20)
- **SUBOXONE® Film (ROW):** now available in Canada, Sweden, Germany, Denmark, UK and Finland



3

Build Our Pipeline

- **SUBLOCADE® US Labeling:** All additional label submissions (fentanyl, safety, and transition from long-term transmucosal bupe to SUBLOCADE) are submitted / under FDA review
- **INDV-2000:** Phase 1 Single Ascending Dose (SAD) study completed; shows encouraging safety and pharmacokinetics in healthy volunteers
- **INDV-1000:** Rapid progress in the identification of new chemical series leading to optimized lead molecules
- **Peer-Reviewed Pubs. (4/21):** n=10
- **Accepted Conf. Abstracts & Presentations 2021 (4/21):** n=13



4

Optimize Operating Model

- **Cash:** \$945m (+\$87m vs. FYE 2020)
- **Net Cash:** \$711m (+88m vs. FYE 2020)
- **Strategic Realignment completed:**
 - ✓ OHS acceleration – 90%+ of US commercial platform now allocated to OHS HCPs
 - ✓ Refined R&D model (Connect & Develop) functioning and focused on defined early-stage assets and real-world evidence generation



Current US environment: significant support and funding for treatment

- **\$3 bil. in new funding** for Substance Use Disorders (SUD) and mental health treatment from American Rescue Plan Act
- **\$10.7 bil. requested in Biden HHS budget** to combat opioid epidemic (+\$3.9 bil. vs. 2021)
- **Biden-Harris drug policy for year one** prioritizes access to treatment and racial equity, includes language for eliminating barriers to buprenorphine treatment for OUD
- **Hearing in key House subcommittee** focuses on SUD as “epidemic within a pandemic” – one of the very few bipartisan issues in Washington
- **Active Federal legislation seeking to breakdown treatment barriers** (eliminating waiver requirement, non-waivered injector, retaining telehealth)

The
Washington
Post

Opinion: The U.S. is facing its
worst addiction crisis ever.

(4/14/21)

The
New York
Times

**Overdose Deaths Have Surged
During the Pandemic, C.D.C.
Data Shows** (4/14/21)

THE
WALL STREET
JOURNAL

**Fentanyl Has Spread West and Overdoses
Are Surging**

More than twice as many people died from drug overdoses
as from Covid-19 in San Francisco last year (4/15/21)



Ryan Preblich

Chief Financial Officer



Income statement*

	Q1		
	2021 Adjusted	2020 Adjusted	% change
(\$ in mil.)			
Net Revenue	\$180	\$153	+18%
Cost of Sales	(32)	(16)	
Gross Profit	\$148	\$137	+8%
<i>Gross Margin %</i>	82%	90%	-8 pp
Selling, General and Administration Expenses	(88)	(124)	-29%
Research & Development Expenses	(9)	(10)	-10%
Profit on Ordinary Activities (before interest & taxation)	\$51	\$3	NM
<i>Operating Margin %</i>	28%	2%	NM
Net Finance Expense	(4)	(2)	
Taxation	(9)	(4)	
<i>Effective Tax Rate %</i>	19%	NM	
Net Income / (loss)	\$38	\$(3)	NM

Highlights

Net Rev.: Reflects strong SUBLOCADE® growth, underlying US BMAT market growth along with relatively stable SUBOXONE® Film share in US; ROW net rev. up modestly on favorable currency translation

Gross Margin: Expected decline primarily due to continued strength of SUBOXONE® Film in US Government channels

Op. Income: Increase due to higher overall NR and a decline in SG&A expense from lower marketing (DTC in Q1 20) and legal expenses

Net Income: Due to higher overall net rev. and lower OPEX (SG&A and R&D combined)

*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.)	Q1 2021	FY 2020
Cash & Cash Equivalents	\$945	\$858
Current Borrowings	(4)	(4)
Long-term Borrowings	(229)	(230)
Loan issuance costs	(1)	(1)
Net cash	\$711	\$623

- Net cash growth to \$711m at end of Q1 21 reflects:
 - ✓ Timing of government rebate payables
 - ✓ \$26m of returned collateral from surety bond provider
- 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)



FY 2021 guidance reiterated

FY 21 Guidance ⁽¹⁾ (\$ in mil.)	
Total Base Case NR	Up to \$625m
<ul style="list-style-type: none"> SUBLOCADE NR base case PERSERIS NR base case 	<ul style="list-style-type: none"> \$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."



Appendix



Income statement: Q1 2021 vs. Q1 2020

	Q1 2021			Δ Y-o-Y (adjusted basis)	Q1 2020		
	Q1 2021 Actual	Adjustments	Q1 2021 Adjusted		Q1 2020 Actual	Adjustments	Q1 2020 Adjusted
(\$ in mil. at Actual FX)							
Net Revenues	180		180	+18%	153		153
Cost of Sales	(32)		(32)		(23)	7 ⁽¹⁾	(16)
Gross Profit	148		148	+8%	130		137
<i>Gross Margin (%)</i>	82%		82%	-800 bps	85%		90%
Selling, General and Administration Expenses	(82)	(6) ⁽¹⁾	(88)	-29%	(309)	185 ⁽²⁾	(124)
Research & Development Expenses	(9)		(9)	-10%	(10)		(10)
Profit (Loss) on Ordinary Activities before interest & taxation	57		51	NM	(189)		3
<i>Operating Margin (%)</i>	32%		28%	NM	NM		2%
Net interest (expense) / income	(4)		(4)		(2)		(2)
Taxation	27	(36) ⁽²⁾	(9)		28	(32) ⁽³⁾	(4)
<i>Effective Tax Rate (%)</i>	51%		(19%)		15%		NM
Net Income / (loss)	80		38	NM	(163)		(3)

NM= Not meaningful

Q1 2021 Notes:

- (1) Excludes \$6m of exceptional items – \$5m benefit related to a legal provision release and \$1m related to proceeds from out-licensing of nasal naloxone patents
- (2) Excludes \$36m benefit related to development credits for SUBLOCADE

Q1 2020 Notes:

- (1) Excludes \$7m of exceptional items related to inventory provisions due to adverse impact from Covid-19
- (2) Excludes \$183m of legal expenses/ provisions related to the DOJ matter and \$2m of restructuring costs primarily related to lease impairments
- (3) Excludes \$32m benefit related to exceptional pre-tax items

