

Investor Presentation

June 2025

For Investor Relations Purposes Only

Important Cautionary Statement Regarding Forward-looking Statements

This presentation contains certain statements that are forward-looking. Forward-looking statements include, among other things, express and implied statements regarding expected future cash flows; the Company's financial guidance including operating and profit margins for 2025 and its medium- and long-term growth outlook; expected future savings; expected future growth and expectations for sales levels for particular products; expected future product launches in particular markets; expected growth in LAI usage, the prescriber base, payor access, and the number of patients treated with our products; our product development pipeline and potential future products, the timing of clinical trials, expectations regarding regulatory approval of such product candidates, the timing of such approvals, and the timing of commercial launch of such products or product candidates, and eventual annual revenues of such future products; patent applications the potential future issuance of patents; and other statements containing the words "believe," "anticipate," "plan," "expect," "intend," "estimate," "forecast," "strategy," "target," "guidance," "outlook," "potential," "project," "priority," "may," "will," "should," "would," "could," "guidance," the negatives thereof, and 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 these forward-looking statements due to a number of factors, including: lower than expected future sales of our products; greater than expected impacts from competition; failure to achieve market acceptance of OPVEE; unanticipated costs including the effects of potential tariffs and potential retaliatory tariffs; whether we are able to identify efficiencies and fund additional investments that we expect to generate increased revenues, and the timing of such actions; and other unanticipated events. For additional information about some of the risks and important factors that could affect our future results and financial condition, see "Risk Factors" in Indivior's Annual Report on Form 10-K for the fiscal year 2024 filed March 3, 2025 and its other filings with the U.S. Securities and Exchange Commission.

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 or revise forward-looking statements to reflect future events or circumstances or to reflect the occurrences of unanticipated events.



Founded to Help Address the Opioid Crisis

Leading with Science

- Leading in discovery and commercialization of buprenorphine evidence-based medicines for opioid dependence for over 30 years
- 10-year company history of bringing science-based, life-transforming treatments to tackle the opioid crisis, one of the largest and most urgent U.S. public health emergencies of our time
- SUBLOCADE® is a **first-in-class** monthly subcutaneous long-acting injectable (LAI) medication for the treatment of moderate to severe opioid use disorder (OUD)

Financial Strength

- \$1,188m total net revenue (NR) (FY2024)
- \$320m Non-GAAP operating income (FY2024)⁴
- Ability to leverage revenue growth and create durable cash generation
- \$400m in cash and investments (as of Q1 2025)
- ~1.0x adjusted leverage ratio⁵ (excluding legal settlements)

SUBLOCADE Positioned to be a Durable Growth Driver

- No. 1 prescribed LAI in the U.S., with over 350k lives treated, supporting OUD recovery
- Formulated to deliver sustained buprenorphine concentrations of ≥2ng/mL throughout dosing intervals to block opioid-rewarding effects^{1,2,3}
- The only once monthly LAI with rapid initiation on day 1
- Strong IP management with patents to 2031-2038

U.S. Commercial Portfolio

Recovery



(buprenorphine extended-release) injection for subcutaneous use ® 100mg-300mg

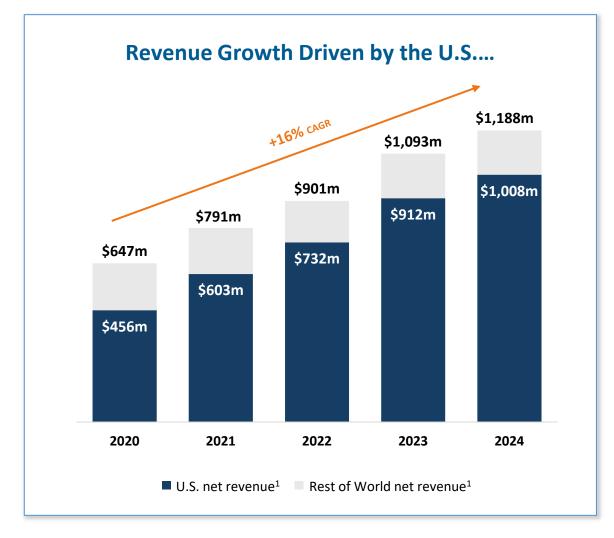


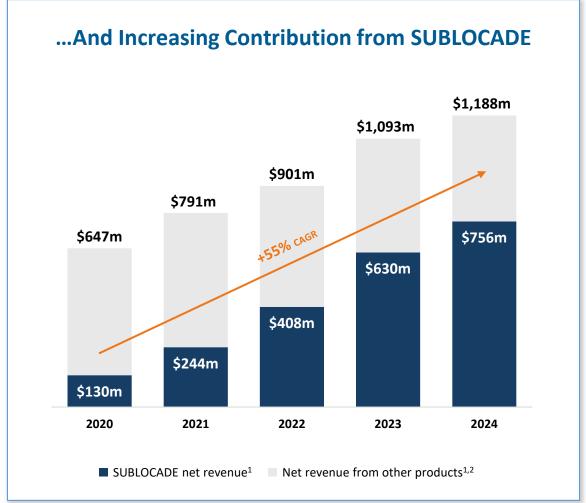
Rescue





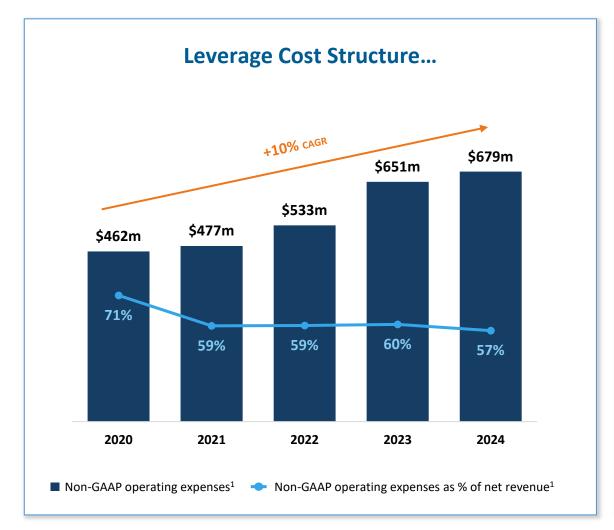
Track Record of Strong Net Revenue Growth

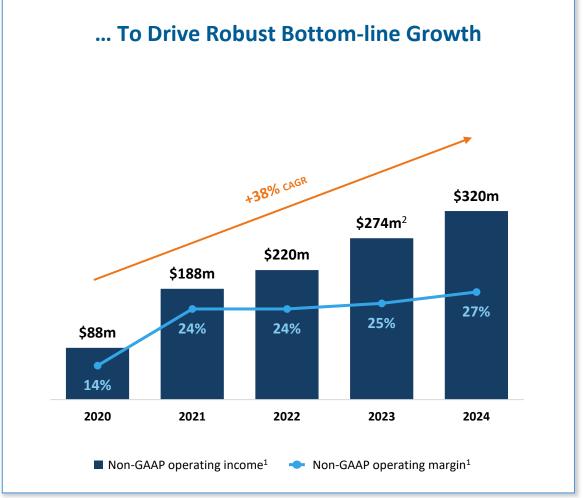






Clear Path to Generating Meaningful Cash Flows from Operations







U.S. Commercial Portfolio Spanning Recovery and Rescue

	Recovery	Medicines	Rescue Medicine
	Durable Growth Driver with Strong Patent Protection Genericized Market		Strong Patent Protection
	Sublocade® (buprenorphine extended-release) injection for subcutaneous use ® 100mg·300mg	Suboxone Sublingual (buprenorphine and naloxone) Film	OPVEE* (nalmefene) NASAL SPRAY
IP Protection	12 Orange Book patents (2031 – 2038)	Genericized	2 Orange Book patents (2038 – 2042)
Indication	Long-acting injectable for moderate to severe opioid use disorder	Daily self-administered treatment for moderate to severe opioid use disorder	Nasal spray for emergency treatment of known or suspected opioid overdose



2025: A Transition Year

Foundational Leadership Additions

Strengthening expertise and leadership with Board of Directors (BOD) and Executive Team additions



Dr. David WheadonBOD Chair



Joe CiaffoniChief Executive Officer



Daniel Ninivaggi BOD Independent Non-Executive Director



Patrick Barry
Chief Commercial Officer

Current U.S. Dynamics

2025 U.S. NR Headwinds:

- SUBLOCADE NR impacted by funding gaps in the Criminal Justice System (CJS) channel
- SUBOXONE® Film NR declining due to generic competition
- PERSERIS discontinuation

Strengthening U.S. Capital Markets Presence:

- London Stock Exchange (LSE) listing cancellation effective July 25, 2025
- Anticipate inclusion in Russell U.S. indexes on June 30, 2025

Refocused Pipeline on OUD

Investigational Candidate	Preclinical	Phase 1	Phase 2	Phase 3	Anticipated Milestones	IP Protection
INDV-6001 (Opioid Use Disorder) (3-month long-acting buprenorphine)					Last Patient Last Visit Q4 2025	2043
INDV-2000 (Opioid Use Disorder) (Selective Orexin-1 (OX1) receptor antagonist)					Last Patient Last Visit H1 2026	2037



Transition Year Focus





Deliver 2025 Operating Plan



Grow SUBLOCADE



Advance the OUD Pipeline



Strengthen the Balance Sheet





SUBLOCADE®



Bipartisan Commitment to Addressing Opioid Crisis in the U.S.



U.S. Illicit Opioid Use Could Be 20 Times Higher Than Previously Estimated







WTAS: Widespread Industry Support of Bipartisan SUPPORT Act

April 8, 2025

The **SUPPORT** for Patients and Communities Reauthorization Act of 2025 (H.R. 2483) reauthorizes key public health programs focused on prevention, treatment, and recovery for patients with substance use disorder that were established in the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act, which was signed into law in 2018.



Secretary Kennedy Renews Public Health Emergency Declaration to Address National Opioid Crisis

March 18, 2025

The U.S. Department of Health and Human Services (HHS) announced today that Secretary Robert F. Kennedy, Jr. renewed the public health emergency declaration addressing our nation's opioid crisis, which will allow sustained federal coordination efforts and preserve key flexibilities that enable HHS to continue leveraging expanded authorities to conduct certain activities in response to the opioid overdose crisis.



LAI Buprenorphine Medications are Under-Penetrated in the Treatment of OUD

8.9m¹

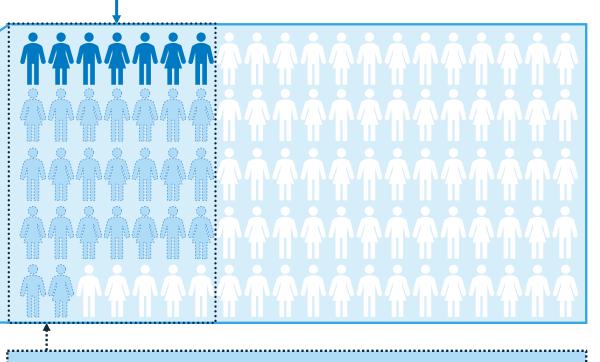
Misuse opioids in U.S. (Total Addressable Market)

5.9m¹

OUD diagnosed in U.S. (Service Addressable Market)

2.0m²

Received Buprenorphine Medication Assisted Treatment (BMAT) Current 7% LAI usage in BMAT population allows for significant potential expansion



HCPs Expect LAI Usage to Increase to 20-30% of the BMAT population³



American Society of Addiction Medicine (ASAM) BMAT Guidelines

ASAM Clinical Guideline¹

Treatment Goals with Buprenorphine¹











Engage patients in recovery activities, including psychosocial interventions



ASAM Clinical Consideration^{1,2}

For Individuals using High-Potency Synthetic Opioids (HPSO)

• Expert consensus based on limited available evidence suggests that the high plasma buprenorphine concentrations at steady state and continuous exposure offered by extendedrelease buprenorphine may help stabilize² some individuals with extensive HPSO exposure

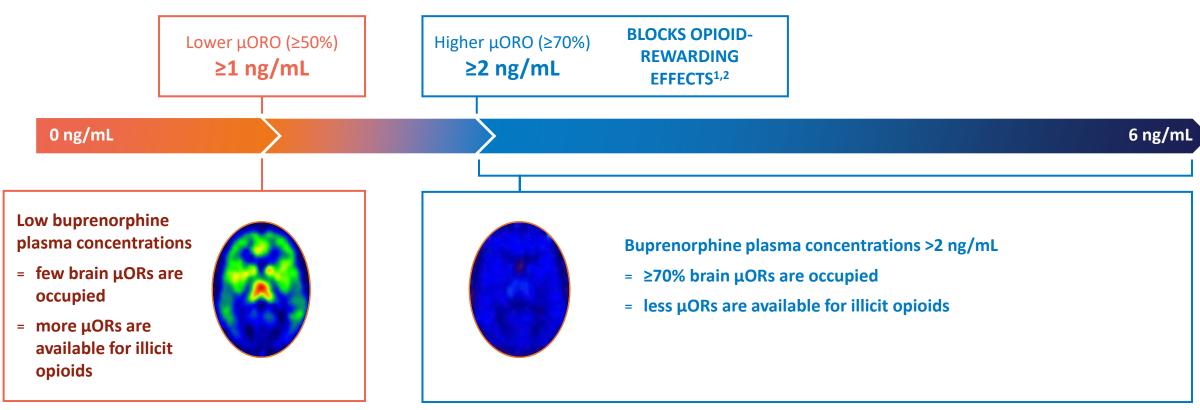
Length of Treatment¹

• While limited, research suggests treatment of <3 months has limited benefit; **SIGNIFICANTLY LONGER DURATIONS** are associated with more positive outcomes



≥2 ng/mL Buprenorphine Blood Plasma Levels are Needed to Help Protect Most Patients from Opioid-Rewarding Effects^{1,2}

As buprenorphine plasma levels increase, the number of receptors available for opioids decreases, resulting in a decrease in opioid-rewarding effects. 1,3,4

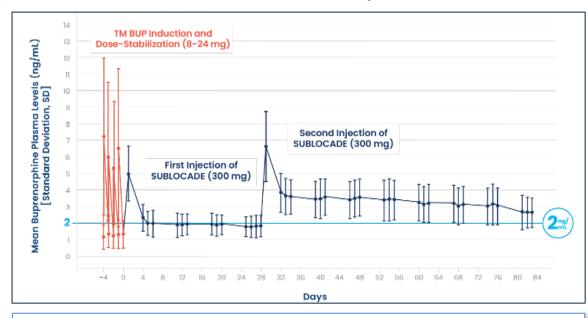


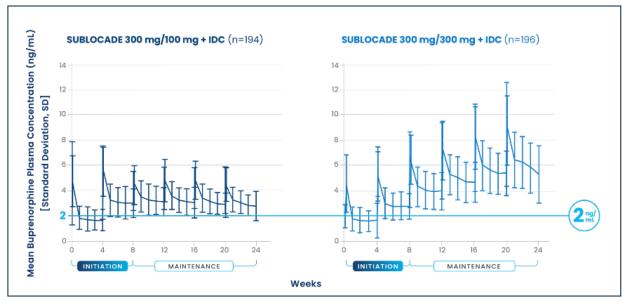


SUBLOCADE Delivers Continuous, Long-Lasting Protection All Month with a 43 to 60 Day Half-Life^{1,2,3}

Mean Buprenorphine Levels During TM* BUP Induction, Dose-Stabilization, and After the First 2 Injections of SUBLOCADE⁴

Mean Weekly Buprenorphine Concentrations^{5,6}





- A peak occurred around 24 hours, the first measurement postinjection, then slowly decreased to a plateau around 2 ng/mL for the first injection and 3 ng/mL for the second injection^{1,4}
- SUBLOCADE helped provide stable plasma levels with continuous buprenorphine delivery all month without daily fluctuation^{1,4}

 SUBLOCADE delivers target therapeutic buprenorphine plasma level of ≥2 ng/mL throughout the dosing interval in most patients after the second injection of 300 mg⁷



Longer SUBLOCADE Treatment Shown to Improve Patient Outcomes

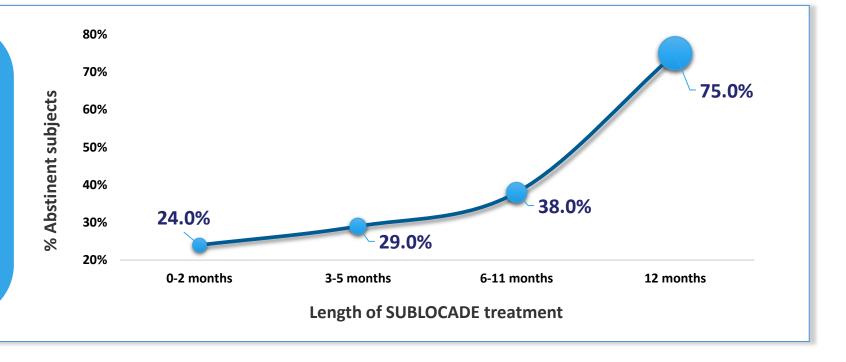


75%

Continuous 12-month self-reported abstinence

if subjects stayed on SUBLOCADE for 12 months

The longer the SUBLOCADE treatment duration, the higher the likelihood of continuous self-reported abstinence 12 months after treatment cessation





SUBLOCADE Helps Transform Recovery

SUBLOCADE Offers Month Long Continuous Protection from Opioid-Rewarding Effects



Continuous Protection
From the Start



Long-Lasting Effects



Reliable Dosing

- Effective blockade from day 1 the only monthly LAI with rapid initiation
- Higher therapeutic levels (2ng/mL+) to address threats of synthetics

- Longest half-life (43-60 days) of approved buprenorphine LAIs
- Proven treatment retention with reduced illicit opioid use

- Straightforward monthly dosing
- One decision, once a month to put the focus on patient recovery



- Most prescribed LAI for OUD with over 350k patients treated since launch
- Fit-for-purpose medication positioned to be durable growth driver



New SUBLOCADE Label Benefits

Label Updates Further Differentiate SUBLOCADE for Today's Opioid Crisis Driven by the Proliferation of Synthetic Opioids

START PATIENTS ON SUBLOCADE SOONER: Only monthly LAI to initiate on Day 1 (no 7-day oral induction).

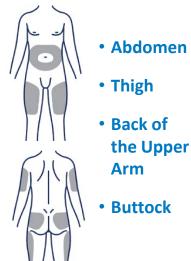
EARLER 2nd INJECTION: Helps patients reach 2+ ng/mL earlier – enables continuous protection.

CLINICALLY RELEVANT: Rapid initiation studied in majority fentanyl positive patients & high-risk users.



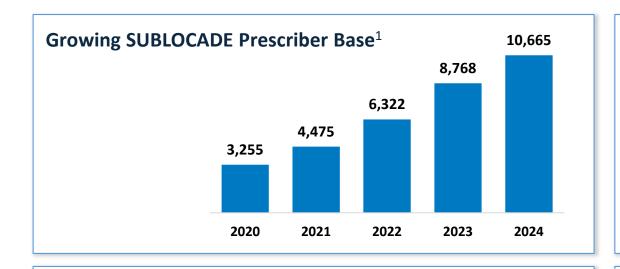
ADDITIONAL INJECTION SITES:

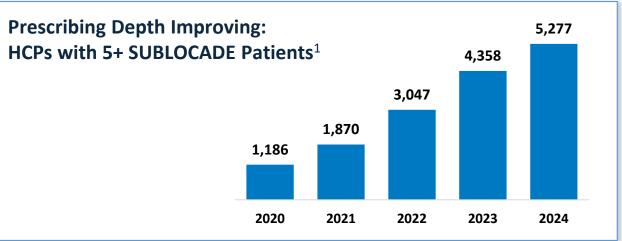
Choice supports patient preference and buy-in. Includes all four sites from Day 1.



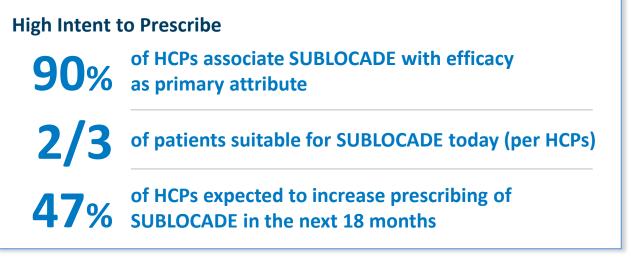


Strong Fundamentals Position SUBLOCADE for Growth











SUBLOCADE U.S. Commercial Focus

GOAL: SUBLOCADE as #1 LAI Choice

- **Enhanced competitiveness across all key channels**
- Driving broad, rapid HCP awareness of new label benefits (including "Peer-to-Peer" education)
- **Operated** Upgraded efficacy story and campaign
- **"Surround Sound" targeting HCPs via media outlets**

GOAL: LAI First Line in All Care Settings

- Activate patients through direct-to-consumer (DTC) campaign
- Pull through strong payor access, including robust commercial coverage
- Improve efficiency of distribution model to ensure treatment delivery to patients
- CJS funding enablement at the state and local levels

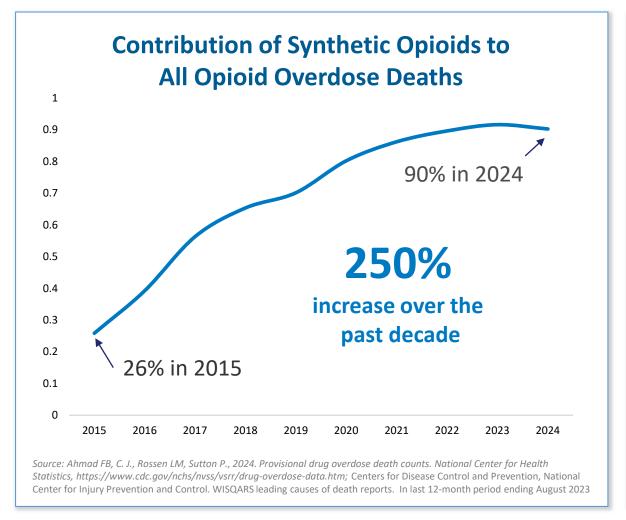


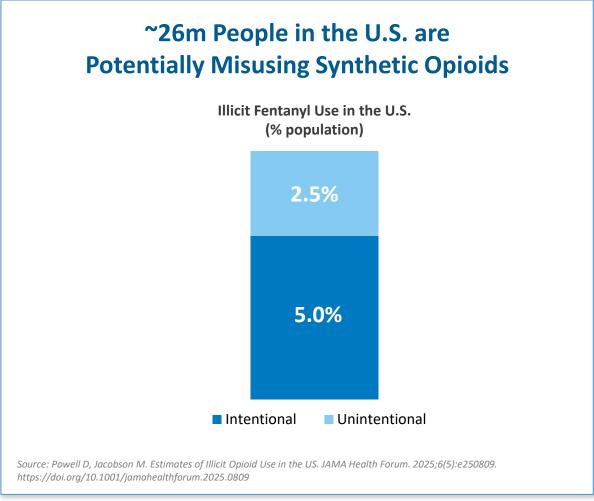


OPVEE®



Potent Synthetic Opioids (Fentanyl) are Driving U.S. Overdose Crisis







OPVEE Provides Rapid, Potent, Long-Lasting Reduction of Respiratory Depression¹ to Address the Current Wave of Synthetic Opioid Overdoses



Triple Threat of Synthetic Opioid Pharmacology such as Fentanyl

Rapid

Potent

Long-Lasting

- The first and only nasal rescue medicine **specifically indicated for synthetic opioids**, like fentanyl, as well as non-synthetic opioids
- Developed for **rapid absorption** by incorporating Intravail® into its formulation and using a proven nasal spray device
- **Differentiated** by a higher affinity at μ opioid receptors
- Data indicates fast, strong and long-lasting reduction of respiratory depression in a simulated opioid overdose

BARDA² Contract

- OPVEE development supported through federal grants from BARDA and NIDA³
- 10-year BARDA contract of up to \$110M⁴

OPVEE Patent Estate

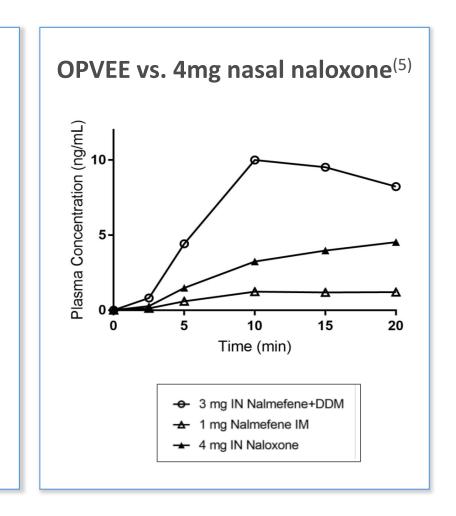
- Regulatory Exclusivity to May 2026
- Two Orange Book Patents
 - ✓ 11,458,091 (July 2038)
 - ✓ 12,290,596 (August 2042)
- · Two patents pending



Scientific Evidence Confirms OPVEE's Potential to Improve and Sustain Reversal of an Opioid Overdose

OPVEE compared with 4mg nasal naloxone

	OPNT0003 (3mg)	Naloxone (4mg)
Affinity at μ opioid receptors	1.0 ⁽¹⁾	5.4 ⁽¹⁾
Plasma concentrations at 5 minutes (ng/ml)	4.43 ⁽³⁾	1.5 ⁽²⁾
T _{max} (minutes)	15 ⁽³⁾	30 ⁽⁴⁾
C _{max} (ng/ml)	10 ⁽³⁾	4.83 ⁽⁴⁾
Half-life (hours)	11 ⁽³⁾	2.08 (4)







OUD Focused Pipeline

Trial	Patients & Population	Design	Primary Endpoints	Estimated Completion
INDV-6001 3-month long-acting buprenorphine Phase II NCT06576843	122 Patients Moderate to severe OUD	Multiple dose Phase II PK study	Evaluate PK, safety and tolerability of INDV-6001 following multiple doses in participants with OUD	Last Patient Last Visit Q4 2025
INDV-2000 Selective Orexin-1 receptor antagonist Phase II NCT06384157	300 Patients Moderate to severe OUD	Placebo or 3 dosing regimes of INDV-2000	Efficacy – Proportion (probability) of patients without treatment failure ¹ by the end of week 12	Last Patient Last Visit H1 2026



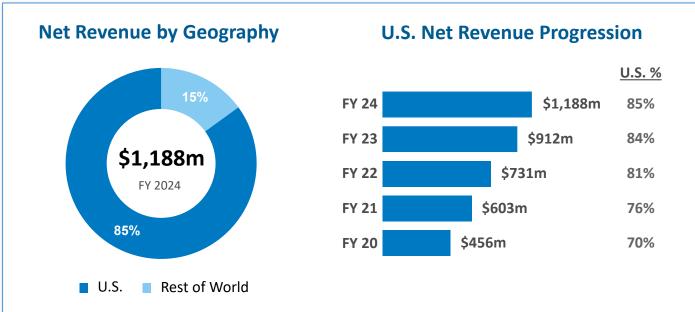


Financials



Capital Markets Footprint to Align with U.S. Focused Business





Context & Expected Benefits

- U.S. NR makes up 85% of total NR for FY 2024, with anticipated growth
- Over 70% of Indivior's shareholders based in the U.S.
- Majority of stock trading volume conducted through Nasdaq listing
- Reduces the costs and complexities of maintaining a secondary listing
- Potential for further U.S. index inclusion in the future



On Track to Achieve FY 2025 Guidance – Reaffirmed April 24, 2025¹

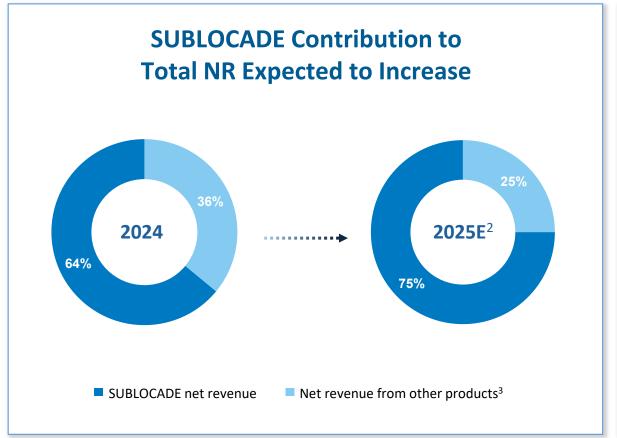
	Q1 2025 Results	2025 Financial Guidance
Total Net Revenue (NR)	\$266m	\$955 - \$1,025m
SUBLOCADE NR ²	\$176m	\$725 - \$765m
OPVEE NR	nm	\$10 - \$15m
Non-GAAP Gross Margin %3	83%	Low to mid 80% range
Non-GAAP Operating Expenses ³	\$152m	\$610 - \$625m
SG&A	\$130m	\$525 - \$535m
R&D	\$22m	\$85 - \$90m
Non-GAAP Operating Profit ³	\$69m	\$185 - \$225m

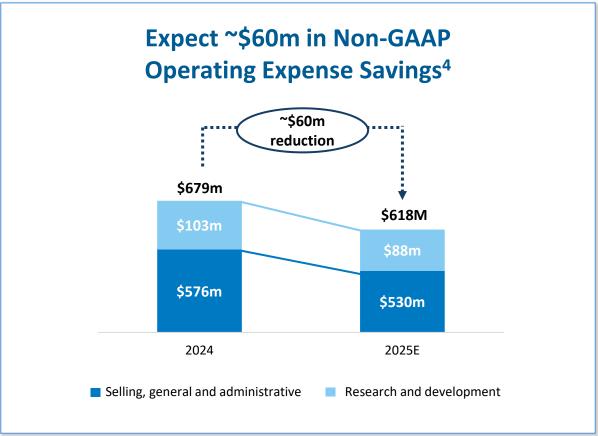
Q1 2025 Key Financial Themes

- Overall Q1 2025 results in-line with FY 2025 guidance expectations
- On track to achieve expected OPEX savings – continue to expect ~\$60m⁴ of net savings in FY 2025 versus FY 2024
- Expect to generate \$185-\$225m of non-GAAP operating profit and positive cash flow from operations



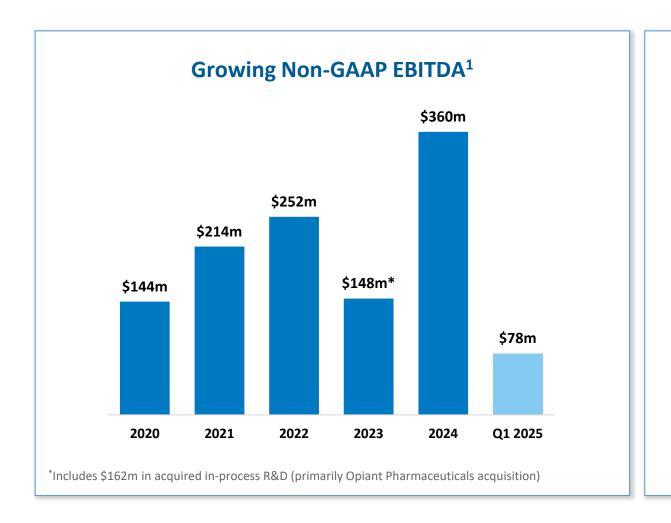
Transition Year: Evolution of the Business in 2025¹







Generating Significant Cash Flow with Strong Balance Sheet



Key Balance Sheet Items

\$400m of cash and investments as of Q1 2025

\$350m term loan maturing in 2030 with \$50m revolving credit facility provides financial flexibility

~1.0x adjusted leverage ratio²

\$400m of share repurchases conducted since 2021



Transition Year Focus





Deliver 2025 Operating Plan



Grow SUBLOCADE



Advance the OUD Pipeline



Strengthen the Balance Sheet





Appendix



Q1 2025 Financial Highlights

OPERATING RESULTS: (REPORTED AND NON-GAAP¹)

\$ mil	Q1 2025	Q1 2024	Change
Net Revenue (NR):	\$266	\$284	(6)%
U.S. NR	222	241	(8)%
ROW ² NR	44	42	3%
Gross Profit:	\$221	\$246	(10)%
Gross Margin	83%	87%	(400) bps
Operating Expenses:	(\$155)	(\$171)	(9)%
Operating Expenses – Non-GAAP:	(\$152)	(\$170)	(11)%
Selling and Marketing	(67)	(67)	-
Administrative and General	(63)	(75)	(16)%
Research and Development	(22)	(28)	(19)%
Litigation Settlement	-	-	-
Op. Profit / (Loss)	\$66	\$75	(12)%
Non-GAAP	\$69	\$76	(10)%
Earnings Per Share	\$0.38	\$0.45	(15)%
Non-GAAP	\$0.41	\$0.42	(2)%

KEY TAKEAWAYS: (VS Q1 2024 UNLESS OTHERWISE INDICATED)

Total NR decline of 6% (5% at constant FX):

- U.S. NR down 8%; lower SUBOXONE Film and PERSERIS discontinuation were main drivers
- ROW NR up 3% (1% at constant FX); growth in new products (SUBLOCADE and SUBOXONE Film) more than offset legacy tablet products (SUBUTEX)

SUBLOCADE NR of \$176m (2)% YOY reflecting solid volume dispense growth in the OHS channel that was more than offset by volume dispense decline in the justice channel as well as by unfavorable price/channel mix

U.S. Film NR reflects increased generic competitive activity resulting in lower U.S. oral BMAT share (within expectations) and lower pricing

Gross margin lower reflecting Q1 2024 favorable manufacturing variances

Non-GAAP operating expense¹ expenses down 11% primarily reflecting previously announced streamlining actions and branded fee estimate change partially offset by increased commercial investments behind U.S. SUBLOCADE

R&D expenses decreased 19% reflecting focused pipeline activities on Phase 2 OUD assets (INDV-2000 and INDV-6001)

Non-GAAP operating profit¹ down 10% driven by lower NR; Diluted EPS down 2% driven primarily by lower share count from fourth completed \$100m share repurchase program



Q1 2025 Financial Reconciliations¹

¹ We have not provided the forward-looking GAAP equivalents for certain forward-looking N	on-GAAP metrics, including Non-
GAAP Operating Profit, Non-GAAP Gross Margin, Non-GAAP SG&A, and Non-GAAP Operating	g Expense, or GAAP reconciliations of any
of the aforementioned, as a result of the uncertainty regarding, and the potential variability	of, reconciling items such as
extraordinary litigation settlement expense. The Company has relied upon the exception in	item 10(e)(1)(i)(B) of Regulation S-K to
exclude such reconciliations, as the reconciliations of these non-GAAP guidance metrics to t	heir corresponding GAAP equivalents are
not available without unreasonable effort.	



Three Months Ended March 31,	Q1	2025	Q1 2024	
GAAP selling, general and administrative expenses	\$	132 \$	143	
Adjustments within SG&A				
Corporate Initiative Transition ¹		2	0	
Acquisition-related costs ²		_	2	
Less: Adjustments in selling, general and administrative expenses		2	2	
Non-GAAP selling, general and administrative expenses	\$	130 \$	142	

- 1. Includes expenses related to severance and share-based compensation.
- 2. Non-recurring costs related to the acquisition and integration of the aseptic manufacturing site acquired in November 2023.

Three Months Ended March 31,	Q1 2025	Q1 2024
GAAP operating income	\$ 66 \$	75
Adjustments in selling, general and administrative expenses	2	2
Litigation settlement expenses	1	_
Non-GAAP operating income	\$ 69 \$	76

Three Months Ended March 31,	Q1 2025	Q1 2024
GAAP tax expense	\$ (11) \$	(11)
Tax on non-GAAP adjustments	(1)	(1)
Tax non-GAAP adjustments	1	(5)
Less: Adjustments in tax expenses	_	(6)
Non-GAAP tax expense	\$ (11) \$	(17)

We define Non-GAAP effective tax rate as Non-GAAP tax expense divided by Non-GAAP income before taxation.

Three Months Ended March 31,	Q1 2025	Q1 2024
GAAP net income	\$ 47 \$	61
Adjustments in selling, general and administrative expenses	2	2
Litigation settlement expenses	1	_
Adjustments in tax expenses	_	(6)
Non-GAAP net income	\$ 51 \$	57

Non-GAAP earnings per share Non-GAAP diluted earnings per share \$ 0.41 \$ 0.42

Shares used in computing non-GAAP earnings per share		
Diluted	125	137

FY 2020–2024 Non-GAAP Operating Income Reconciliations

Reconciliation of Net Income to Non-GAAP Operating Income (\$m)

	GAAP IFRS				
	<u>2024</u>	<u>2023</u>	<u>2022</u>	<u>2021</u>	<u>2020</u>
Net Income	7	(126)	(42)	205	(148)
Net Finance Income	(22)	(42)	(10)	(4)	(0)
Net Finance Expense	(23) 41	(43) 35	(19) 27	(4) 27	(9) 26
Income Tax Expense	13	(19)	(43)	(15)	(25)
Total Adjustments	281	265	297	(25)	244
Acquired In-process R&D	1	162	-	-	-
Non-GAAP Operating Income	320	274	220	188	88
Net Revenue	1,188	1,093	903	791	647
Non-GAAP Operating Margin	27 %	25%	24%	24%	14%



FY 2020–2024 Non-GAAP Operating Expense Reconciliations

	GAAP		IFRS		
	<u>2024</u>	<u>2023</u>	<u>2022</u>	<u>2021</u>	<u>2020</u>
Total Operating Expenses, net	919	1,072	827	451	706
Other operating expense (income), net	(4)	9	8	32	
Acquired In-process R&D	(1)	(162)	-		
Non-GAAP adjustments	(235)	(268)	(302)	(6)	(244)
Non-GAAP operating expenses	679	651	533	477	462
Net Revenue	1,188	1,093	901	791	647
Non-GAAP operating expense %	57%	60%	59%	60%	71%



FY 2020–2025 Q1 EBTIDA Reconciliations

Reconciliation of EBITDA GAAP------IFRS------01 2025 FY 2024 FY 2023 FY 2022 FY 2021 FY 2020 47 **Net Income** (126)(42)205 (148)Add Back: Interest Income (4) (23)(43)(19)(4) (9)Interest Expense 27 12 41 35 26 Income Tax Expense / (Benefit) 11 13 (25)(19)(43)(15)Non-GAAP adjustments in Operations 281 297 265 (25)244 Dep/Amort (excluding ROU Amort) 17 11 15 18 9 Share-Based Compensation Expense 24 21 16 11 **Total Adjustments** 31 353 270 287 9 262 **EBITDA 78** 360 144 245 214 114

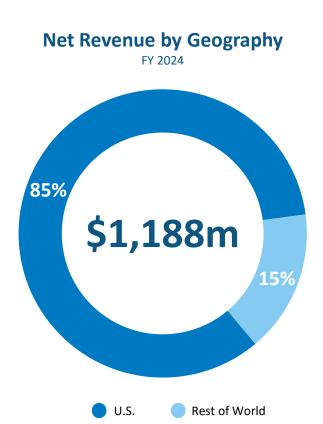


FY 2024 Leverage Reconciliation

Reconciliation of Leverage Ratio	
	GAAP
	FY 2024
Total Gross Debt	350
Operating Income	38
Leverage Ratio	9.2
Non-GAAP adjustments in Operations	281
Dep/Amort (excluding ROU Amort)	17
Share-Based Compensation Expense	24
Total Adjustments	322
EBITDA	360
Adjusted Leverage	1.0



Global Markets



		SUBLOCADE (SUBUTEX®PR (ROW))	SUBOXONE Film ¹
North America	U.S.	•	•
	Canada	•	•
Europe & Middle East	France	•	•
	Italy	•	•
	Germany	•	•
	Denmark, Norway ²	•	•
	Sweden	•	•
	Finland	•	•
	Switzerland	•	
	UK	•	•
	Israel	•	•
Australasia	Australia	•	•



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 single dose of a transmucosal buprenorphine product or who are already being treated with buprenorphine.

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 See full prescribing information for complete boxed warning.

- Serious harm or death could result if administered intravenously.
- 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.

CONTRAINDICATIONS

Hypersensitivity to buprenorphine or any other ingredients in SUBLOCADE.

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.

Risk of Serious Injection Site Reactions: Likelihood of may increase with inadvertent intramuscular or intradermal administration. Evaluate and treat as appropriate. The most common injection site reactions are pain, erythema and pruritus with some involving abscess, ulceration and necrosis.

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 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 patients have tolerated 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.



OPVEE® (nalmefene) nasal spray

INDICATION AND USAGE

OPVEE nasal spray is an opioid antagonist indicated for the emergency treatment of known or suspected overdose induced by natural or synthetic opioids in adults and pediatric patients aged 12 years and older, as manifested by respiratory and/or central nervous system depression.

OPVEE nasal spray is intended for immediate administration as emergency therapy in settings where opioids may be present.

OPVEE nasal spray is not a substitute for emergency medical care.

HIGHLIGHTED SAFETY INFORMATION

CONTRAINDICATIONS

Hypersensitivity to nalmefene or to any of the other ingredients.

WARNINGS AND PRECAUTIONS

<u>Risk of Recurrent Respiratory and Central Nervous System Depression</u>: While the duration of action of nalmefene is as long as most opioids, a recurrence of respiratory depression is possible, therefore, keep patient under continued surveillance and administer repeat doses of OPVEE using a new nasal spray with each dose, as necessary, while awaiting emergency medical assistance.

<u>Limited Efficacy with Partial Agonists or Mixed Agonist/Antagonists</u>: Reversal of respiratory depression caused by partial agonists or mixed agonists/antagonists, such as buprenorphine and pentazocine, may be incomplete. Larger or repeat doses may be required.

<u>Precipitation of Severe Opioid Withdrawal</u>: Use in patients who are opioid dependent may precipitate opioid withdrawal. In neonates, opioid withdrawal may be life-threatening if not recognized and properly treated. Monitor for the development of opioid withdrawal.

<u>Risk of Cardiovascular (CV) Effects</u>: Abrupt postoperative reversal of opioid depression may result in adverse CV effects. These events have primarily occurred in patients who had preexisting CV disorders or received other drugs that may have similar adverse CV effects. Monitor these patients closely in an appropriate healthcare setting after use of nalmefene hydrochloride.

Risk of Opioid Overdose from Attempts to Overcome the Blockade: Attempts to overcome opioid withdrawal symptoms caused by opioid antagonists with high or repeated doses of exogenous opioids may lead to opioid intoxication and death.

ADVERSE REACTIONS

Most common adverse reactions (incidence at least 2%) are nasal discomfort, headache, nausea, dizziness, hot flush, vomiting, anxiety, fatigue, nasal congestion, throat irritation, rhinalgia, decreased appetite, dysgeusia, erythema, and hyperhidrosis.

For more information about OPVEE and the full Prescribing Information visit www.opvee.com

