UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

☑ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2024
OR
☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Commission file number: 001-37835

Indivior PLC

(Exact name of registrant as specified in its charter)

England and Wales	98-1204773
State or other jurisdiction of **incorporation or organization**	(I.R.S. Employer Identification No.)

10710 Midlothian Turnpike Suite 125
North Chesterfield, VA 23235
(address of principal executive offices)(zip code)
Registrant's telephone number, including area code:
(804) 379-1040

Securities Registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Ordinary shares, $0.50 nominal value per share	INDV	The Nasdaq Stock Market LLC
	INDV	London Stock Exchange

Securities registered pursuant to section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☑

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☑

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☑ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☑ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

☑	Large accelerated filer	☐	Accelerated filer
☐	Non-accelerated filer	☐	Smaller reporting company
		☐	Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☑

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☑

The aggregate market value of the voting and non-voting common equity held by non-affiliates at June 28, 2024 was approximately $2.15 billion based on the Nasdaq closing price for such shares on that date. For purposes of this calculation, the registrant has assumed that all of its directors and executive officers are affiliates.

As of March 1, 2025, the number of outstanding ordinary shares was 124,655,858.

DOCUMENTS INCORPORATED BY REFERENCE

None.

TABLE OF CONTENTS

TABLE OF CONTENTS	i
GLOSSARY	1
IMPORTANT CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS	5
ABOUT THIS ANNUAL REPORT	7
PART I	8
Item 1. Business.	8
Overview	8
Industry Overview	12
Indivior Products	16
Competition	19
Research and Development	19
Pipeline	21
Manufacturing and Supply	21
Sales, Marketing and Distribution	23
Intellectual Property	28
Regulatory Overview	29
Environmental	42
Human Capital	43
Other Information and Corporate Governance	44
Item 1A. Risk Factors.	45
Item 1B. Unresolved Staff Comments.	100
Item 1C. Cybersecurity.	100
Item 2. Properties.	102
Item 3. Legal Proceedings.	102
Item 4. Mine Safety Disclosures.	102
PART II	102
Item 5. Market for Registrant's Common Equity, Related Shareholder Matters and Issuer Purchases of Equity Securities.	102
Item 6. [Reserved]	103
Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.	104
Item 7A. Quantitative and Qualitative Disclosures About Market Risk.	120
Item 8. Financial Statements and Supplementary Data.	121
Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure.	161
Item 9A. Controls and Procedures	161
Item 9B. Other Information.	161
Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.	161
PART III	162
Item 10. Directors, Executive Officers and Corporate Governance.	162
Election of Directors	164
Family Relationships	168
Agreement with Significant Shareholder	168
Code of Ethics	168
Shareholder Nominations for Directors	168
Audit & Risk Committee	169
Audit Committee Financial Expert	169

Insider	170
Policies	170
Item 11. Executive Compensation.	171
Total Compensation for the Chair and Non-Executive Directors	171
Compensation of Executive Directors and Senior Managers	172
Annual Incentive Plan (“AIP”)	172
Indivior PLC Long-Term Incentive Plan (“LTIP”)	174
Indivior Share Plans	174
The Indivior 2024 Long-Term Incentive Plan (the “LTIP”)	174
The Indivior 2024 U.K. Savings Related Share Option Plan (the “Sharesave Plan”)	178
The Indivior U.S. Employee Stock Purchase Plan (the “ESPP”)	180
The Indivior Deferred Bonus Plan 2018 (the “DBP”)	182
Indivior PLC Employee Benefit Trust	184
Indivior Inc. Profit Sharing and 401(k) Plan (the “401(k) Plan”)	184
Indivior Inc. Deferred Compensation Plan (“DCP”)	184
Deeds of Indemnity	185
Malus and Clawback	185
Indivior PLC Executive Compensation Clawback Policy	186
Executive Financial Recoupment Program	186
Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Shareholder Matters.	187
Share Ownership	187
Major Shareholders	187
Item 13. Certain Relationships and Related Transactions, and Director Independence.	190
Item 14. Principal Accountant Fees and Services.	191
PART IV	193
Item 15. Exhibits and Financial Statement Schedules.	193
Item 16. Form 10–K Summary.	198
SIGNATURES	199

GLOSSARY

Aelis means Aelis Farma, a French company from whom we obtained an exclusive option for AEF0117, a synthetic CB1 specific signaling inhibitor designed to treat cannabis-related disorders.

AGM means Annual General Meeting

ANDA means an additional new drug application filed with the FDA.

AUD means alcohol use disorder.

BARDA means the U.S. Biomedical Advanced Research and Development Authority.

BMAT means buprenorphine-medically assisted treatment, the process to treat OUD patients treated with Buprenorphine (as opposed to methadone).

CHMP means the Committee for Medicinal Products for Human Use, which is the relevant scientific committee in most cases with which one files marketing authorization applications under the EMA.

CIA refers to the Corporate Integrity Agreement which Indivior Inc. entered into in July 2020 with HHS-OIG. The five-year CIA requires, among other things, that Indivior Inc. implement measures designed to ensure compliance with the statutes, regulations, and written directives of U.S. Medicare, U.S. Medicaid, and all other U.S. federal healthcare programs, as well as with the statutes, regulations, and written directives of the U.S. Food and Drug Administration.

CJS means criminal justice system.

CMO means a contract manufacturing organization.

CMS means the Centers for Medicare and Medicaid Services.

CNS means central nervous system.

Companies Act mean the U.K. Companies Act 2006 as amended, and the regulations made thereunder, which is the principal legislation under which we operate, and under which our ordinary share capital has been created.

Compliance Measures means certain compliance measures set forth in Section I of Addendum A to the Resolution Agreement which is filed as Exhibit 10.2 hereto.

CREST means the system for the paperless settlement of trades in securities and the holding of uncertificated securities in accordance with the CREST Regulations operated by Euroclear U.K. and International Limited.

CRO means a contract research organization, a third-party that performs clinical research on our behalf.

CRSP (formerly known as the Center for Research in Securities Prices) is a U.S. based provider of equity indices.

CVR means contingent value rights issued in connection with the acquisition of Opiant by a subsidiary of Indivior to the shareholders of Opiant. Each CVR represents the obligation of Indivior Inc. to make cash payments upon achievement of certain worldwide net sales milestones during the period from October 1, 2023 to September 30, 2030.

DATA 2000 means the Drug Addiction and Treatment Act of 2000.

DEA means the United States Drug Enforcement Agency.

Demerger means the acquisition of the specialty pharmaceutical business unit of RB by Indivior PLC, which became effective on December 23, 2014.

Demerger Agreement refers to that certain agreement entered into on November 17, 2014 between Indivior PLC and RB, Reckitt Benckiser Healthcare (U.K.) Limited, RB Pharmaceuticals Limited and RBP Global Holdings Limited to affect the Demerger and to govern the relationship between RB and Indivior PLC following the Demerger.

DIs means depositary interests issued through CREST by Computershare Investor Services PLC representing a beneficial interest in an ordinary share.

DOJ means the U.S. Department of Justice.

EMA means the European Medicines Agency.

Exchange Act means the U.S. Securities Exchange Act of 1934, as amended.

FCP means our Fine Chemical Plant at which we manufacture the active pharmaceutical ingredient buprenorphine.

FDA means the U.S. Food and Drug Administration.

FFDCA means the Federal Food, Drug, and Cosmetic Act under which the FDA derives its authority to regulate pharmaceuticals.

FTC means the U.S. Federal Trade Commission.

FTC Order means that certain Stipulated Order for Permanent Injunction and Equitable Monetary Relief in the United States District Court for the Western District of Virginia, Abingdon, between the FTC and Indivior Inc. entered November 20, 2020. As part of the resolution with the FTC and as detailed in the text of the FTC Order, for a ten-year period Indivior Inc. is required to make specified disclosures to the FTC and is prohibited from certain conduct.

Government Agreements means the CIA, FTC Order, and Resolution Agreement (including the Compliance Measures).

GBP means British pound sterling, the official currency of the United Kingdom.

Group means Indivior PLC and, as the context requires, its consolidated subsidiaries.

HCl means buprenorphine hydrochloride, the active pharmaceutical ingredient used in the formulation of SUBLOCADE long-acting injection, SUBOXONE Film, SUBUTEX Tablet, and SUBOXONE Tablet.

HCP means healthcare provider, and may refer to a physician, physician's assistant, or nurse, under appropriate circumstances.

HHS-OIG means the Health and Human Services Office of the Inspector General.

ICFR means internal control over financial reporting

ICH means International Conference on Harmonization, which publishes guidelines by which clinical trials of medicinal products in the EU must be conducted.

IND means an investigative new drug application filed with the FDA.

Indivior Inc. is an indirect wholly owned United States subsidiary of the Company and directly or through its subsidiaries the entity that commercializes our products and runs the Company's operations in the U.S.

IPR&D means in-process research and development.

LAI means long-acting injectable.

LSE means the London Stock Exchange.

MAT means medication-assisted treatment.

MHRA means the U.K. Medicines and Healthcare products Regulatory Agency.

Most of World means all countries globally where Indivior sells or operates, excluding the United States and, where the U.K. is disclosed separately, the U.K.

MOUD means medication for opioid use disorder, which is the use of medications, in combination with counseling and behavioral therapies, to provide a "whole-patient" approach to the treatment of substance use disorders. Medications used in MOUD are approved by the FDA and MOUD programs are clinically driven and tailored to meet each patient's needs.

Nasdaq means the Global Select Market of The Nasdaq Stock Market LLC.

NDA means a new drug application submitted to the NDA for FDA review, which generally must include data from at least two well-controlled clinical trials demonstrating safety and effectiveness, as well as characterization of the drug product and a description of the manufacturing process, controls and facilities.

Note Purchase Agreement means the Company's 2024 debt agreement. See *Item 8. Financial Statements—Audited Consolidated Financial Statements - Note 12. Debt*.

NPV means net present value.

OHS means an Organized Health System, which is a network of physician organizations (such as a hospital system) that provides or manages the provision of a coordinated continuum of healthcare services to a defined population.

Opiant means Opiant Pharmaceuticals, Inc., a specialty pharmaceutical company developing medicines for addictions and drug overdose. We completed our acquisition of Opiant on March 2, 2023.

Opioid MDL means the multi-district litigation in which the Company has been named as a defendant in more than 400 civil lawsuits alleging that manufacturers, distributors, and retailers of opioids engaged in a longstanding practice to market opioids as safe and effective for the treatment of long-term chronic pain to increase the market for opioids and their own market share, or alleging individual personal injury claims.

OPVEE, means OPVEE® (nalmefene) nasal spray, which is an opioid receptor antagonist approved by the FDA to reverse opioid overdose. OPVEE is indicated for the emergency treatment of known or suspected opioid 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 (nalmefene) nasal spray is intended for immediate administration as emergency therapy in settings where opioids may be present. OPVEE (nalmefene) nasal spray is not a substitute for emergency medical care.

OUD means opioid use disorder.

Raleigh Manufacturing Facility means the approximately 80,000 square foot facility in Raleigh NC which we purchased in In November 2023 to provide additional manufacturing capacity.

RB means Reckitt Benckiser Group PLC.

RB Group means RB and its subsidiaries.

REMS means a risk evaluation and mitigation strategy. The FDA has the authority to require the manufacturer to provide a REMS that is intended to ensure that the benefits of a drug product (or class of drug products) outweigh the risks of harm.

Resolution Agreement refers to an agreement by and among Indivior PLC, Indivior Inc., the United States Attorney's Office for the Western District of Virginia, and the United States Department of Justice's Consumer Protection Branch made as of July 24, 2020 by which the Company settled with DOJ, the FTC,

and U.S. state attorneys general the criminal and civil liability in connection with a multi-count indictment brought in April 2019 by a grand jury in the Western District of Virginia, a civil lawsuit joined by the DOJ in 2018, and an FTC investigation. See *Item 8. Financial Statements—Audited Consolidated Financial Statements - Note 11. Accrued Litigation Settlement Expenses* of this Report for more information.

SEC means the United States Securities and Exchange Commission.

Securities Act means the U.S. Securities Act of 1933, as amended.

SOFR means the Secured Overnight Financing Rate benchmark interest rate published by the Federal Reserve Bank of New York.

SUD means substance use disorder.

U.S. GAAP means accounting principles generally accepted in the United States of America.

WHO means the World Health Organization.

IMPORTANT CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This annual report contains certain statements that are forward-looking. Forward-looking statements include, among other things, express and implied statements regarding: the Company's financial guidance including revenue, operating and profit/gross margins for 2025 and its medium- and long-term growth outlook; expected operational savings and expected benefits from our reinvestment efforts; assumptions regarding expected changes in market share and expectations regarding the extent and impact of competition and near-term Criminal Justice System funding challenges; assumptions regarding future exchange rates; our assumptions regarding the absence of material changes to Medicaid eligibility and/or other changes to federal funding levels due to executive actions; strategic priorities, strategies for value creation, and operational goals; our expectations that we can reach a final settlement related to the provision we recorded regarding opioid litigation (including the Opioid MDL) brought by certain municipalities and tribal nations and the material terms and conditions of the final settlement agreement, including the ultimate timing and structure of payments and product distribution, injunctive relief, and scope of releases; expected future growth and expectations for sales levels for particular products, and expectations regarding the future impact of factors that have affected sales in the past; expected market growth rates, growing normalization of medically assisted treatment for opioid use disorder, and expanded access to treatment; our product development pipeline and potential future products, 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; expectations regarding future production and costs at the Company's Raleigh Manufacturing Facility; expected capital expenses and investments; our expectation that we will meet our obligations as they come due over the next 12 months from cash on hand and operations, 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," "can," "outlook," "guidance," the negatives thereof, and variations thereon and similar expressions. By their nature, such 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.

The forward-looking statements in this annual report are made based upon our current expectations and beliefs concerning future events and involve a number of known and unknown risks and uncertainties. Such forward-looking statements are based on numerous assumptions regarding our present and future business strategy and the environment in which we operate, which may prove to be inaccurate. In particular, our actual results, performance or achievements or industry results could be affected by, among other things:

- The substantial litigation to which we are or may become a party;
- Our reliance on third parties to manufacture commercial supplies of most of our products, conduct our clinical trials and at times to collaborate on products in our pipeline;
- Our ability to comply with legal and regulatory settlements, healthcare laws and regulations, requirements imposed by regulatory agencies and payment and reporting obligations under government pricing programs;
- Risks related to the manufacture and distribution of our products, most of which contain controlled substances;
- Market acceptance of our products as well as our ability to commercialize our products and compete with other market participants;
- The fact that a substantial portion of our revenue derives from a small number of key proprietary products;

- Competition;
- The uncertainties related to the development of new products, including through acquisitions, and the related regulatory approval process;
- Our dependence on third-party payors for the reimbursement of our products and the increasing focus on pricing and competition in our industry;
- Unintended side effects caused by the clinical study or commercial use of our products;
- Our use of hazardous materials in our manufacturing facilities;
- Our ability to successfully execute acquisitions, partnerships, joint ventures, dispositions or other strategic acquisitions;
- Our ability to protect our intellectual property rights and the substantial cost of litigation or other proceedings related to intellectual property rights;
- The risks related to product liability claims or product recalls;
- The significant number of laws and regulations that we are subject to, including due to the international nature of our business;
- Macroeconomic trends and other global developments such as pandemics and government responses thereto;
- The terms of our debt instruments, changes in our credit ratings and our ability to service our indebtedness and other obligations as they come due;
- Changes in applicable tax rate or tax rules, regulations or interpretations and our ability to realize our deferred tax assets;
- Volatility in our share price due to factors unrelated to our operating performance; and
- Such other factors as set out in "*Item 1A. Risk Factors*" and "*Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations*."

Forward-looking statements contained in this annual report apply only at the date of this annual report. We undertake no obligation to update or revise any forward-looking statement, whether as a result of new information, future developments, or otherwise.

ABOUT THIS ANNUAL REPORT

As used herein, references to "we," "us," the "Company," "Indivior," "Indivior PLC," "Indivior Group" or the "Group," or similar terms in this Form 10-K mean Indivior PLC and, as the context requires, its consolidated subsidiaries. Our Consolidated Financial Statements appearing in this annual report on Form 10-K are prepared in U.S. dollars and in accordance with U.S. GAAP.

This annual report includes certain trademarks, service marks and trade names that we own or otherwise have the right to use. SUBLOCADE®, SUBUTEX Prolonged Release®, PERSERIS®, SUBOXONE® Film, SUBOXONE® Tablet, SUBUTEX® Tablet, and INDIVIOR® are registered trademarks of Indivior U.K. Limited, and OPVEE® is a registered trademark of Indivior Inc. All rights reserved. Solely for convenience, our trademarks, service marks and trade names referred to in this annual report may appear without the ® or ™ symbol, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights to these trademarks, service marks and trade names. Also, this annual report contains additional trademarks, trade names, and service marks belonging to other parties, which are the property of their respective owners. We do not intend our use or display of other parties' trademarks, trade names, or service marks to imply, and such use or display should not be construed to imply a relationship with, or endorsement or sponsorship of us by, these other parties.

Statements made in this annual report on Form 10-K concerning the contents of any contract, agreement or other document are summaries of such contracts, agreements or documents and are not intended to be complete; such descriptions are qualified in their entirety by reference to the full text of such contract, agreement or other document that may be filed as an exhibit to this annual report, and you may read the document itself for a complete description of its terms. Such exhibits may contain representations and warranties by the parties thereto, which were made only for purposes of that agreement and as of specified dates; are subject to limitations agreed upon by the contracting parties, including being qualified by confidential disclosure schedules; may have been made for the purposes of allocating contractual risk between the parties to the agreement instead of establishing these matters as facts; and are subject to standards of materiality applicable to the contracting parties that may differ from those applicable to investors. Investors should not rely on the representations, warranties and covenants or any descriptions thereof as characterizations of the actual state of facts or condition of the Company or any of its subsidiaries or affiliates. Moreover, information concerning the subject matter of the representations, warranties and covenants may have changed after the date of any such agreement, which subsequent information may or may not be fully reflected in the Company's public disclosures.

PART I

Item 1. Business.

Overview

Indivior is a global pharmaceutical company working to help change patients' lives by developing medicines to treat substance use disorders ("SUDs"). As a pioneer in developing evidence-based treatments for opioid use disorder ("OUD"), our vision is that the millions of people across the globe suffering from SUDs will have access to evidence-based treatment to change lives. As a leader in addiction treatment, Indivior is dedicated to transforming SUD from a global human crisis to a recognized and treated chronic disease.

Headquartered in the U.S. in Richmond, Virginia, Indivior employs more than 1,000 individuals globally and its portfolio of products is available in more than 30 countries worldwide.

Our core products include the following approved treatments:

- SUBLOCADE (buprenorphine extended-release monthly injection);
- SUBOXONE Film (buprenorphine and naloxone sublingual film);
- SUBOXONE Tablet (buprenorphine and naloxone sublingual tablets); and
- SUBUTEX Tablet (buprenorphine sublingual tablets),

all of which are treatments for OUD, and

- OPVEE (nalmefene) nasal spray for opioid overdose reversal.

Product availability varies across the countries in which Indivior treatments are available, including in terms of dosage form, strength and indication.

The Company sells its products in the U.S. and in other selected areas of the world, such as much of Europe, Canada, Australia and through distribution partners in other parts of the world. Our core geographic market (based on the country where the sale originates) is the U.S., which accounted for 85%. 83%, and 81% of net revenues for the years ended December 31, 2024, 2023, and 2022, respectively.

Our business was initially developed and managed as a separate division of Reckitt Benckiser Group PLC ("RB" and, together with its subsidiaries, the "RB Group"), a public limited company incorporated under the laws of England and Wales. Indivior PLC was incorporated on September 26, 2014 for the purpose of acquiring the specialty pharmaceutical business unit from RB (the "Demerger"). Following the Demerger, which was effective on December 23, 2014, Indivior PLC has operated as a standalone business.

Treatment of OUD

The treatment of OUD as a therapeutic area emerged in the early 1920s. The U.S. government's efforts to address OUD through supply regulation and control, and to address public health concerns through scientific innovation, influenced a gradual shift in research interest towards developing a treatment for OUD.

In 1966, RB led the breakthrough discovery of buprenorphine and developed, in partnership with the U.S. National Institute on Drug Abuse ("NIDA"), buprenorphine for the treatment of OUD. SUBUTEX Tablet (buprenorphine sublingual tablet) was our first approved product specifically indicated for the treatment of OUD. SUBUTEX Tablet was launched in France in February 1996 by Schering-Plough, which licensed the global marketing rights to the buprenorphine products from RB Group. Shortly thereafter, SUBUTEX Tablet was approved in additional EU countries. SUBOXONE Tablet (buprenorphine/naloxone) sublingual tablet was approved across the EU by the EMA in September 2006.

In the U.S., the enactment of the Drug Addiction and Treatment Act of 2000 ("DATA 2000") was a significant development in the history of addiction treatment. Previously, treatment options for OUD in the U.S. were limited: either abstinence-based programs that have a high rate of relapse, or methadone clinics (the only medication-assisted treatment option). Methadone clinics in the U.S. provide daily dosing and may be unpopular with opioid-dependent individuals owing to inconvenience and the significant societal stigma associated with methadone. As a result, many opioid-dependent individuals remained untreated.

Under DATA 2000, office-based physicians who had completed appropriate training were able to obtain a federal waiver to treat a limited number of opioid-dependent patients with medications specifically approved by the U.S. Food and Drug Administration (FDA) for the treatment of OUD, and to prescribe and/or dispense these medications in their office-based settings. By permitting treatment for OUD in the privacy of physicians' offices with take-home doses, DATA 2000 was significant in creating access to treatment and beginning to treat OUD as a medical condition like other chronic diseases.

In December 2022, Congress enacted the Mainstreaming Addiction Treatment Act (MAT Act) which eliminated the requirement for a health care practitioner (HCP) to apply for a separate waiver through the Drug Enforcement Administration (DEA) to dispense certain treatments (including buprenorphine) for maintenance or detoxification of patients with OUD. Indivior believes the elimination of these requirements as part of this legislation will help to normalize the view of addiction as a chronic brain disease and expand access to evidence-based buprenorphine treatment. The Company supports efforts to encourage more HCPs to provide medication for OUD.

Indivior Global Integrity & Compliance Program

Indivior has developed and maintained a Corporate Compliance function and Program dating back to before its demerger from RB Group. It has since undergone continuous learning and evolution of its capabilities, including:

- hiring an executive committee level Chief Integrity and Compliance Officer in 2018 who reports directly to the CEO and also to the Board;
- using external consultants and relevant best practice standards and benchmarks to evaluate and assist with evolution of its Global Integrity & Compliance Program; and
- accelerating the build-out of its updated Integrity & Compliance team structure, including hiring additional credentialed personnel.

This team now includes more than 20 professionals who have established and support administration of the defined and communicated "Indivior Global Integrity & Compliance Program Framework" which is based on the elements of an effective compliance program as defined by governing authorities. Our Integrity & Compliance team supports the business and functions in the assessment and mitigation of healthcare compliance risks and co-leads with the Legal team compliance with our obligations under the Government Agreements (i.e., CIA, DOJ Compliance Measures, and the FTC Order. It is responsible for administering our Code of Conduct and related healthcare compliance policies, procedures and guidance with integrated controls. In addition, it works to ensure an appropriate tone at the top, promotion of a "speak-up" culture, develops various integrity and ethics initiatives, including Integrity & Compliance team and business-led risk monitoring, educates on relevant risks to help support strong risk monitoring, and is responsible for administering the Company's Global Integrity & Compliance Program, together with the executive committee who are the members of the Indivior Compliance Committee.

Product Development

Launch of SUBUTEX Tablets, SUBOXONE Tablets, and SUBOXONE Film in the U.S.

The FDA approved SUBUTEX Tablet (buprenorphine) and SUBOXONE Tablet (buprenorphine/naloxone) in October 2002 and we launched sales of these products in the U.S. in 2003. Subsequently, in August 2010, the FDA approved SUBOXONE Film (buprenorphine/naloxone) sublingual film, which dissolves more quickly than SUBUTEX and SUBOXONE Tablets. We discontinued the U.S. distribution of

SUBUTEX Tablets in 2011 and SUBOXONE Tablets in 2013. In 2020, the Company's U.S. sales force ceased promoting SUBOXONE Film as part of the Resolution Agreement with the Department of Justice ("DOJ"), discussed below, and ceased all detailing of the product in that year, though it remains available for sale.

Our SUBOXONE Film product faces four generic competitors in the U.S., and a fifth is expected in early 2025. Despite the launches of these generic formulations of tablets and film and branded competition, SUBOXONE Film has maintained a share of the buprenorphine-based OUD treatment market (by mg volume) of approximately 16% in 2024.

Launch of SUBLOCADE in the U.S.

The FDA approved SUBLOCADE (buprenorphine extended-release) injection for subcutaneous use in 2017 and we launched sales of this product in 2018. As the first long-acting buprenorphine-based injectable approved by the FDA for the treatment of moderate to severe OUD, SUBLOCADE became the largest product by net revenue for the Company by the second quarter of 2022.

Approval and Launch of OPVEE for Overdose Reversal in the U.S.

In May 2023, the FDA approved OPVEE (nalmefene) nasal spray for the emergency treatment of known or suspected opioid 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 (nalmefene) nasal spray is intended for immediate administration as emergency therapy in settings where opioids may be present. OPVEE (nalmefene) nasal spray is not a substitute for emergency medical care. We acquired OPVEE as part of our acquisition of Opiant Pharmaceuticals, discussed below. We began marketing OPVEE in the U.S. in October 2023.

In September 2023, we were awarded a contract by the U.S. Biomedical Advanced Research and Development Authority (BARDA) (i) for the procurement of finished, packaged OPVEE held as vendor-managed inventory as a medical countermeasure in the event of a synthetic opioid community or mass casualty event, and (ii) to support FDA-required post-marketing requirement studies, a three-year stability study to support shelf-life extension, and real world evidence studies. This funding covers technical expertise for further clinical development and regulatory approval of OPVEE for use in children under 12 years of age. The contract also has an initial purchase and options for purchases and delivery of OPVEE over another 9 years at guaranteed pricing through 2033. Product delivered pursuant to the contract is expected to become part of the U.S. Strategic National Stockpile, which is the U.S.' national repository of antibiotics, vaccines, chemical antidotes, antitoxins, and other critical medical supplies. The role of the U.S. Strategic National Stockpile is to supplement state and local supplies during public health emergencies.

Launch of PERSERIS in the U.S.

The FDA approved PERSERIS as the first once-monthly subcutaneous extended-release injectable suspension of risperidone indicated for the treatment of schizophrenia in adults in 2018. We launched commercial sales of PERSERIS in the U.S. in 2019.

However, on July 9, 2024, the Company announced that it would immediately cease all promotion and marketing activities related to PERSERIS. The Company believed this action was in the best interests of shareholders due to the highly competitive market and impending changes that were expected to intensify payor management in the treatment category in which PERSERIS participates. Analysis of forthcoming changes suggested that there was no longer a path forward for PERSERIS that was financially viable.

Product Availability Outside the U.S.

In Europe, generic versions of the SUBUTEX Tablets and SUBOXONE Tablets have been available since 2010 and 2018, respectively. Despite strong competition, our Group's total share of oral buprenorphine medication-assisted treatment ("BMAT") (by mg volume) remained significant at 50%, 51%, and 49% in 2024, 2023, and 2022, respectively. In Canada, our SUBOXONE Tablets product faces two

generic competitors. In addition, we face competition from branded oral buprenorphine-based tablets and historically well-established methadone oral formulations.

We distribute SUBLOCADE (under the name SUBUTEX Prolonged Release in Europe) primarily in the U.S., Australia, Canada, Finland, Israel, and Sweden.

We distribute SUBOXONE Film primarily in the U.S., Australia, Canada, Finland, Israel, Italy, Malaysia, and Sweden.

We distribute SUBOXONE Tablets primarily in Belgium, Canada, Germany, and the U.K, and SUBUTEX Tablets primarily in Australia, France, Germany, Israel, Norway, Switzerland, and the U.K.

Development Pipeline

In addition to our commercially available products our product pipeline includes two new drug candidates for the treatment of OUD.

Agreements with DOJ, FTC and HHS-OIG Regarding Marketing and Promotional Practices

In 2020 the Company and certain of its subsidiaries reached agreements with the DOJ, the U.S. Federal Trade Commission ("FTC"), the U.S. Attorney's Office for the Western District of Virginia, and U.S. state attorneys general to resolve potential criminal and civil liability arising from an indictment brought in 2019 by a grand jury in the Western District of Virginia, a civil lawsuit in which the DOJ partially intervened and an investigation by the FTC, all of which generally concerned Indivior, Inc. and certain of its subsidiaries' marketing and promotional practices related to SUBOXONE Film, and SUBOXONE Tablet. The 2019 indictment followed a federal criminal grand jury investigation that began in 2013.

As part of the agreement with the DOJ ("Resolution Agreement"), a wholly owned subsidiary of Indivior PLC pleaded guilty to a single count of making false statements relating to healthcare matters in 2012 in violation of 18 U.S.C. Section 1035 related to SUBOXONE Film, and was excluded from participating in government healthcare programs. The exclusion did not pertain to the rest of the Company and did not limit access to our medications for patients in the U.S. Under the terms of the agreements, DOJ dismissed all charges in the 2019 indictment against the rest of the Company and its subsidiaries and the Company agreed to make payments to federal and state authorities totaling $600 million (plus applicable interest of 1.25% on a portion of that total amount). Pursuant to the resolution agreement, aggregate payments of $263 million (including interest) have been made through December 31, 2024. An additional payment of $52 million was made in January 2025 and two annual installments of $50 million plus interest will be due in January 2026 and 2027, with the final installment of $200 million plus interest due in December 2027.

As part of the resolution, the Company and Indivior Inc. agreed to significant compliance and reporting obligations under the Resolution Agreement with DOJ and a stipulated injunction with the FTC, and Indivior Inc. agreed to a Corporate Integrity Agreement ("CIA") with the U.S. Department of Health and Human Services Office of Inspector General (HHS-OIG). See (i) "*Item 1A. Risk Factors—*"*Compliance with the terms and conditions of our Corporate Integrity Agreement, the Resolution Agreement with the U.S. Attorney's Office for the Western District of Virginia and the U.S. Department of Justice's Consumer Protection Branch, and the Stipulated Order for Permanent Injunction and Equitable Monetary Relief with the FTC, requires significant resources and management time and, if we fail to comply, we could be subject to criminal charges, penalties, or, under certain circumstances, excluded from government healthcare programs, which would materially adversely affect our business,*" (ii) *Item 8. Financial Statements—Audited Consolidated Financial Statements - Note 11. Accrued Litigation Settlement Expenses* for more information. We have filed copies of the Resolution Agreement, the Corporate Integrity Agreement, and the Stipulated Order for Permanent Injunction and Equitable Monetary Relief between the FTC and Indivior Inc. as Exhibits 10.2, 10.3, and 10.4, respectively, to this annual report. We have complied and continue to comply with our reporting obligations under each of the agreements and our obligations to make investments in our Global Integrity & Compliance Program to promote compliance and drive continuous learning and evolution of an effective compliance program. We expect to complete our obligations under the CIA later this year.

Recent Developments

Transition of Primary Listing to Nasdaq

Effective June 27, 2024, we transitioned our primary stock exchange listing to Nasdaq from the London Stock Exchange ("LSE"). We continue to have a secondary listing on the LSE where our ordinary shares trade on the Equity Shares (Transition) category.

Label Expansion for SUBLOCADE

On February 24, 2025, we announced that the U.S. Food and Drug Administration (FDA) approved label changes in the U.S. for SUBLOCADE including a rapid initiation protocol and alternative injection sites. Healthcare providers can now initiate treatment with SUBLOCADE after a single dose of transmucosal buprenorphine and a one-hour observation period to confirm tolerability. Also, SUBLOCADE can now be administered subcutaneously in the abdomen, thigh, buttock, or back of the upper arm, offering patients and healthcare providers increased flexibility in treatment administration.

These FDA label changes can provide important benefits for patients and healthcare providers. Rapid initiation may lessen some of the practical obstacles to treatment induction, which may increase the likelihood that patients and providers will start therapy quickly, thereby shortening the time to achieve SUBLOCADE's therapeutic levels that provide continuous buprenorphine concentrations above 2ng/mL. Additionally, the ability to select a different injection site may provide patients more flexibility so that they may be inclined to continue their treatment. More options for healthcare providers to administer SUBLOCADE will streamline the course of treatment and improve integration into different healthcare environments.

Share Repurchase Programs

On November 17, 2023, Indivior commenced a share repurchase program of up to $100 million, which was completed on August 2, 2024. The Company repurchased and canceled 5,944,547 ordinary shares at an average purchase price of approximately $16.96. The cost was approximately $101 million, which includes directly attributable transaction costs.

On July 25, 2024, Indivior announced a new non-discretionary $101 million share repurchase program that commenced on August 5, 2024, which was completed on January 31, 2025. The Company repurchased and canceled 9,415,726 ordinary shares as part of this program, equivalent to approximately 6.4% of diluted shares outstanding, at an average purchase price of approximately $10.71.

Refinancing of Long-Term Debt

On November 4, 2024, we repaid the outstanding balance under our existing credit agreement and announced that our wholly-owned subsidiary, RBP Global Holdings Limited had entered into a Note Purchase Agreement with Piper Sandler Finance LLC as agent and certain purchasers for the issuance of up to $400 million of senior secured notes, comprised of a $350 million of term notes and up to $50 million of variable notes at any time outstanding, (the “Note Purchase Agreement”). Proceeds from the new term notes were used to fully repay the exiting term loan and pay transaction fees and expenses, and will also be used for general corporate purposes. *See* *Item 7. Management's Discussion & Analysis—Liquidity and Capital Resources*.

Industry Overview

Substance Use and its Impact

According to the United Nations Office on Drugs and Crime World Drug Report 2022, World Drug Report 2024, there number of people who use drugs globally has risen to 292 million in 2022, a 20% increase over 10 years.

People who use drugs regularly are likely to experience negative health consequences. They are also more at risk of contracting infectious diseases such as HIV and hepatitis C, and to experience overdose and

suffer premature death. Furthermore, an association exists between SUD and co-occurring or comorbid mental health disorders (for example, depression, anxiety or psychosis). There is also an association between SUD and socioeconomic disadvantage, low educational attainment, increased difficulty in finding and remaining in employment, and financial instability and poverty.

World Health Organization's (WHO) *Global Status Report on Alcohol and Health and Treatment of Substance Use Disorders* published in June 2024 reported that 2.6 million deaths per year globally were attributable to alcohol consumption, accounting for 5% of all deaths, and 0.6 million deaths to psychoactive drug use.

The threat SUD poses to global health has long been recognized, and as such strengthening the prevention and treatment is included in the United Nations' Sustainable Development Goals for 2030.

Overdose deaths continue to be significant in the U.S. According to the latest data from the U.S. Center for Disease Control & Prevention (CDC) there were 97,000 fatal overdoses over the previous 12-month period ending July 2024 of which 67,952 were linked to natural and synthetic opioids

Substance Use Disorder: The Disease

Substance Use Disorder ("SUD") has been described as a "medical disorder that affects the brain and changes behavior." Various substances may be involved including alcohol, illicit drugs, prescription medications, and even some over-the-counter medicines.

The National Institute on Drug Abuse ("NIDA"), the Substance Abuse and Mental Health Services Administration ("SAMHSA") and the National Institutes of Health ("NIH") all describe SUD as a long-term and relapsing condition characterized by the individual compulsively seeking and using drugs despite adverse consequences.

Since SUD is marked by periods of recovery and symptom recurrence, or relapse, it resembles other chronic diseases like hypertension and type-2 diabetes. These diseases are lifelong conditions that require continual effort to manage. Symptoms will likely return during periods where treatment compliance is low or absent, and symptoms will likely diminish when compliance to treatment begins again in earnest.

In 2023, 48.5 million people aged 12 or older (or 17%) had a substance use disorder (SUD) in the past year, including 28.9 million who had an alcohol use disorder (AUD), 27.2 million who had a drug use disorder (DUD), and 7.5 million people who had both an AUD and a DUD, according to SAMHSA's 2023 Survey on Drug Use and Health.

There is no single cause of SUD; people begin using substances for many reasons and one person's path to addiction may look drastically different from that of another. The prevailing view is that no one thing can predict someone's risk of developing a SUD—rather, the interaction of the person's unique biology and their environment influences how the drug will impact a person's susceptibility to becoming addicted.

Opioid Use Disorder

Opioids are a major concern in many countries because of the severe health consequences associated with their use, including non-fatal and fatal overdose.

OUD is a growing global public health crisis which still carries significant stigma in many countries. OUD is often perceived as a moral failing and sign of personal weakness rather than a chronic and relapsing disease affecting the brain that can be managed and responds to treatment. As a consequence, we believe coherent action to deal with sufferers and addiction is generally lacking.

According to the United Nations' World Drug Report 2024, an estimated 60 million people used opioids in 2022, representing 1% of the global population. In 2022, opioid use in North America remains high, with 3% of the adult population reporting past-year use (9 million users).

In addition, the number of deaths from opioid overdose in the U.S. continues to remain high, twice the level just a decade ago. The majority of opioid-related overdose deaths in the U.S. are now the result of fentanyl being ingested as a substitute for heroin or with drugs such as cocaine and methamphetamine that had been adulterated, or “cut,” with the opioid. Fentanyl is 30 to 50 times more potent than heroin and can cause rapid and profound respiratory depression. Individuals may not be aware that they have been exposed to fentanyl-laced drugs including heroin, prescription opioids, or psychostimulants.

Against the context of the dramatic rise in deaths from opioid overdose, Indivior is doing more to understand the interaction between fentanyl and buprenorphine. According to a peer-reviewed study conducted by the University of Leiden in Leiden, Netherlands and completed in 2019, sustained high-plasma concentrations of buprenorphine (similar to those provided by SUBLOCADE at steady-state) significantly reduced fentanyl-induced respiratory depression in opioid-tolerant participants.

The European market is smaller than the U.S. market with an estimated 860,000 high-risk opioid users, according to the European Union Drugs Agency European Drug Report 2024. The report also found that opioid use was reported as the main reason for entering specialist drug treatment by 63,000 clients in 2022, representing 25% of all those entering drug treatment in Europe.

According to the Australian Institute of Health and Welfare, in 2023 on an average day, 53,300 clients received pharmacotherapy treatment for their OUD across Australia. There is increasing awareness among healthcare providers in Australia of the misuse of opioid analgesics and the need for treatment. Recent policy changes to address this concern in Australia include re-classifying products containing Codeine so that they must be dispensed by a pharmacist rather than being available over the counter.

Similarly, according to the Canadian Centre on Substance Use and Addiction, approximately 10% of Canadian adults who used opioid medications, or 351,000 persons, reported problematic use, and approximately 153,000 are in treatment according to data from IQVIA (a health information provider). Outside of the U.S., Canada, and Australia, approximately 269 million people aged 15 to 64 suffer from drug use disorders or drug dependence, according to the United Nations Office on Drugs and Crime. Treatment services are generally very underdeveloped (with the exception of Australia and New Zealand), the key challenge being to convince governments to treat addiction as a chronic medical disease rather than a social disorder.

Treatment for Opioid Use Disorder

Medication for opioid use disorder ("MOUD") is the use of medications, in combination with counseling and behavioral therapies, to provide a “whole patient” approach to the treatment of OUD. Medications used in MOUD are approved by the FDA and MOUD programs are clinically driven and tailored to meet each patient’s needs.

Research shows that a combination of medication and psychosocial support can successfully treat these disorders, and for some people struggling with addiction, MOUD can help sustain recovery. MOUD is also used to prevent or reduce opioid overdose.

MOUD is primarily used for the treatment of addiction to opioids such as heroin and prescription pain relievers that contain opiates. The prescribed medication normalizes brain chemistry, blocks the euphoric effects of opioids, relieves physiological cravings, and normalizes body functions without the negative and euphoric effects of the substance. MOUD has been shown to be more effective than medication or counseling alone in treating OUD.

A common misconception about MOUD is that some of the medicines used simply substitute one drug for another. However, these medications may restore healthy brain function, which leads to improvements in behaviors associated with addiction. Longer-term use of these medications is associated with improved outcomes.

Treatment methods in the EU differ from those in the U.S. While U.S. patients can obtain a 30-day prescription and self-administer treatment, such as SUBOXONE Film, prescribed by a treating physician, supervised dosing in the EU requires a daily visit to the clinic for many patients. Methadone and generics

are also generally more broadly available as social funding puts pressure on prices, and treatment is more highly regulated. However, the harm reduction mindset is now changing towards recovery and the EU has begun to recognize the need to implement treatment systems that allow patients to return to a more normal lifestyle.

Treatment access

Despite the prevalence of SUD, including opioid misuse, and the existence of effective treatments, including medication for opioid use disorder, most people who need treatment do not seek or receive it. In 2022, an estimated 4% of U.S. adults (9,367,000) needed OUD treatment. Among these, 55% (5,167,000) received OUD treatment, and 25% (2,353,000) received medications for OUD. Source - Treatment for Opioid Use Disorder: Population Estimates—United States, 2022 Morbidity and Mortality Weekly Report.

People in urgent need of treatment are often unaware of their treatment options, have limited access to treatment and counseling, or simply do not seek it out because they are afraid of being stigmatized. In addition, access is also limited by numerous legal restrictions for pharmacological treatment, inadequate training of clinicians, and the number of HCPs who are willing to treat this population.

During 2023, our INSUPPORT® Community Reentry Program ("CRP") reached a celebrated milestone of receiving over 100 program enrollments. INSUPPORT was created to provide information aimed at helping eligible patients with the process of obtaining Indivior medicines and to enhance our existing patient transition of care offerings. CRP was designed for patients released from the CJS who are experiencing a gap in insurance coverage. Eligible patients may receive up to two months of SUBLOCADE® (buprenorphine extended-release) subcutaneous injection at no cost while awaiting reinstatement of health insurance.

Focus on the Criminal Justice System

In the U.S., a substantial share of persons suffering from OUD repeatedly cycle through the criminal justice system. Further, persons exiting the criminal justice system have been shown to be 40 times more likely to suffer from opioid overdose than persons in the general population.

While as recently as 2019 buprenorphine was rarely available to patients in criminal justice settings, such treatment is increasingly becoming available. The shift has been spurred by research findings and pronouncements from industry and professional medical societies that evidence-based treatment for OUD in correctional settings saves lives, which in turn has shaped changes in law and policy. Treatment for OUD in correctional settings has been shown to reduce overdose deaths by 75%, reduce recidivism by 32%, and reduce transmission of HIV and hepatitis.

Public policy is trending toward increasing treatment of SUD and serious mental illness in criminal justice settings. Congress continues considering legislation authorizing Medicaid coverage of persons in correctional settings. The Centers for Medicare & Medicaid Services (CMS) has published guidance to states on how they can apply to the agency for Medicaid funding to support treatment of patients with OUD and mental illness in the criminal justice system up to 90 days pre-release.

The U.S. Department of Justice (DOJ) issued guidance in April 2022 underscoring the rights of persons with OUD to treatment under the Americans with Disabilities Act, including in correctional settings. States have been increasingly enacting legislation and appropriations, and seeking federal waiver authority, to expand treatment availability in criminal justice settings.

Opioid Overdose Reversal

In addition to OUD treatments, we provide OPVEE (nalmefene) nasal spray for overdose reversal. A large and growing addressable market for opioid overdose reversal agents exists in the U.S., such as first responders, including fire departments, emergency medical services, law enforcement, and other community groups. We expect the primary customers for OPVEE to include state health departments, substance abuse centers, federal agencies, and eventually consumers through pharmacies fulfilling

physician-directed or standing order prescriptions. The co-prescribing of opioid overdose reversal agents alongside prescription opioids has also driven growth of overdose reversal agents.

Indivior Products

Our marketed products are described below:

Product	Active Ingredient(s)	Delivery Method	Main Markets	2024[1] Global Net Sales *(in millions)*
Opioid Use Disorder				
Long-Acting Injectable				$756
SUBLOCADE / SUBUTEX Prolonged Release extended-release Injectable	Buprenorphine	Extended-release injectable suspension	U.S., Australia, Canada, Finland, Israel, and Sweden	
Sublingual				$374
SUBOXONE Film	Buprenorphine and Naloxone	Sublingual film that adheres under the tongue or on the inside of the cheek for direct absorption into the bloodstream	U.S., Australia, Canada, Finland, Israel, Italy, Malaysia, and Sweden	
SUBOXONE Tablet	Buprenorphine and Naloxone	Sublingual tablet that is placed under the tongue to dissolve	Belgium, Canada, Germany, and U.K.	
SUBUTEX Tablet	Buprenorphine	Sublingual tablet that is placed under the tongue to dissolve	Australia, France, Germany, Israel, Norway, Switzerland, and U.K.	
Opioid Overdose Reversal				$15
OPVEE nasal spray	Nalmefene	Nasal spray	U.S.	

(1) See "*Item 7. Management's Discussion & Analysis—Operating Results*" for data for each of the last three financial years.

SUBLOCADE Long-acting injectable (buprenorphine) extended-release injection

As the first long-acting buprenorphine-based injectable approved by the FDA for the treatment of moderate to severe OUD, SUBLOCADE is a highly differentiated treatment. Our RECOVER extension study, which was a 24-month observational study of individuals who participated in the Phase 3 SUBLOCADE study, assessed life changes in patients with OUD who received SUBLOCADE as part of a randomized clinical efficacy study. It showed that SUBLOCADE may translate into (1) increased abstinence from illicit opioids compared to placebo; (2) improved patient-reported quality-of-life outcomes (such as health status, employment and insurance status, and healthcare resource utilization); and (3) improved recovery post-treatment. Administration of monthly subcutaneous injections of SUBLOCADE also eliminates the risk of missing daily doses that might result in subtherapeutic plasma levels (see below), potentially leading to relapse to opioid-seeking and opioid-taking behaviors. Finally, because SUBLOCADE may only be administered by a healthcare practitioner via a closed distribution system whereby the patient never has access to the drug, it is expected to reduce the potential for diversion or misuse.

The logic that underpins this technology lies in a deep understanding of the relationship between buprenorphine plasma levels, whole-brain mu-opioid receptor occupancy (MOR) in the brain, and the key clinical pharmacodynamic effects of withdrawal suppression and opioid blockade. Clinical studies confirmed that the minimum threshold plasma concentration of buprenorphine needed to effectively block the subjective drug-liking effects of a full opioid agonist such as hydromorphone is 2 ng/mL, which translated into at least 70% MOR occupancy for the entire one-month period. These unique pharmacokinetic and

pharmacodynamic properties of SUBLOCADE also translated into clinical efficacy and safety and better patient outcomes.

The expected benefits of these levels of receptor occupancy/opioid blockade are that:

- Patients would likely experience substantially reduced levels of cravings associated with addiction;
- Patients should receive no gratification from abuse of opioids;
- Levels of adherence and compliance with treatment should be significantly improved because it is administered once monthly and late administration of up to 14 days is not expected to affect clinical efficacy;
- It is designed to protect patients right from the start of treatment, through every day of the month, including moments of vulnerability;
- For physicians, there should be positive clinical and patient outcomes using this technology;
- For physicians and wider society, there should be reduced levels of potential diversion and abuse compared to sublingual buprenorphine—once injected, the buprenorphine cannot easily be extracted and diverted; and
- For payors, the benefit should come in reduced costs from higher compliance, better clinical outcomes and reduced abuse and diversion.

On February 24, 2025, we announced that the U.S. Food and Drug Administration (FDA) approved label changes for SUBLOCADE including a rapid initiation protocol and alternative injection sites. Healthcare providers can now initiate treatment with SUBLOCADE after a single dose of transmucosal buprenorphine and a one-hour observation period to confirm tolerability. Also, SUBLOCADE can now be administered subcutaneously in the abdomen, thigh, buttock, or back of the upper arm, offering patients and healthcare providers increased flexibility in treatment administration.

These FDA label changes can provide important benefits for patients and healthcare providers. Rapid initiation may lessen some of the practical obstacles to treatment induction, which may increase the likelihood that patients and providers will start therapy quickly, thereby shortening the time to achieve SUBLOCADE's therapeutic levels that provide continuous buprenorphine concentrations above 2ng/mL. Additionally, the ability to select a different injection site may provide patients more flexibility so that they may be inclined to continue their treatment. More options for healthcare providers to administer SUBLOCADE will streamline the course of treatment and improve integration into different healthcare environments.

We currently distribute SUBLOCADE (under the name SUBUTEX Prolonged Release in Europe) primarily in the U.S., Australia, Canada, Finland, Israel, and Sweden.

SUBOXONE Film (buprenorphine and naloxone) sublingual film

SUBOXONE Film was initially launched in the U.S. in 2010 and is currently approved in the U.S. and sold in more than 30 other countries. It is one of only four products currently approved by the FDA for the treatment of OUD in both the induction and maintenance phases of treatment (although several are approved for “treatment of opioid dependence”). SUBOXONE Film was developed as an alternative to the sublingual tablet.

SUBOXONE Film was developed through an exclusive agreement with Aquestive (formerly known as Monosol), utilizing its proprietary technology, to deliver SUBOXONE Film in a fast-dissolving sublingual film.

SUBOXONE Film containing 2 mg buprenorphine and 0.5 mg naloxone, and 8 mg buprenorphine and 2 mg naloxone, was first approved for the maintenance treatment of OUD in the U.S. in August 2010. Additional dosage strengths of SUBOXONE Film containing 4 mg buprenorphine and 1 mg naloxone, and 12 mg buprenorphine and 3mg naloxone, were subsequently approved in the U.S. in August 2012 and in

Australia in May 2014. SUBOXONE Film was also approved in the U.S. in April 2014 for use in the induction phase of buprenorphine-based treatment of OUD. In addition, in September 2015 the FDA approved the buccal (against the cheek) route of administration for SUBOXONE Sublingual Film.

The Company's U.S. sales force ceased promoting SUBOXONE Film as required by the Resolution Agreement with the DOJ and ceased all detailing of the product in 2020, though it remains available for sale. For more information, see *Item 8. Financial Statements—Audited Consolidated Financial Statements - Note 16. Commitments and Contingencies*.

We currently distribute SUBOXONE Film primarily in the U.S., Australia, Canada, Finland, Israel, Italy, Malaysia, and Sweden.

SUBOXONE Tablet (buprenorphine and naloxone) sublingual tablet

SUBOXONE Tablet is a fixed-dose combination of buprenorphine and naloxone in the ratio of four parts buprenorphine to one part naloxone. SUBOXONE Tablet was designed to discourage intravenous abuse of the tablet formulation in patients dependent on full opioid agonists (e.g., heroin and morphine). Naloxone is a potent antagonist at opioid receptors.

SUBOXONE Tablet containing 2 mg buprenorphine and 0.5 mg naloxone, and 8 mg buprenorphine and 2 mg naloxone, was approved in the U.S. by the FDA in October 2002 as an orphan drug for maintenance treatment of opioid dependence.

SUBOXONE Tablet is distributed primarily in Belgium, Canada, Germany, and U.K. (We discontinued distribution of SUBOXONE and SUBUTEX Tablets in the U.S. market in March 2013.)

SUBUTEX Tablet (buprenorphine) sublingual tablet

SUBUTEX Tablet containing 0.4 mg, 2 mg, and 8 mg buprenorphine was first approved for the treatment of opioid dependence in France in July 1995 and was launched in the French market in February 1996. In April 2003, 2 mg and 8 mg tablets were subsequently approved in the U.S. and launched but were discontinued from sale in the U.S. market in September 2011. We primarily distribute SUBUTEX tablets primarily in Australia, France, Germany, Israel, Norway, Switzerland, and U.K.

OPVEE (nalmefene) nasal spray

On May 22, 2023, the FDA approved OPVEE (nalmefene) nasal spray for the emergency treatment of known or suspected opioid 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 (nalmefene) nasal spray is intended for immediate administration as emergency therapy in settings where opioids may be present. OPVEE (nalmefene) nasal spray is not a substitute for emergency medical care. OPVEE contains 2.7 mg nalmefene.

Nalmefene works quickly by blocking the brain opioid receptors. In a clinical model of opioid-induced respiratory depression in opioid-experienced, non-dependent subjects, OPVEE had an onset of action of 2.5 to 5 minutes and fully reversed respiratory depression as early as 5 minutes after OPVEE administration. Other clinical data include a terminal plasma half-life of approximately 11 hours. While the duration of action of nalmefene is as long as most opioids, a recurrence of respiratory depression is possible. We currently only distribute OPVEE in the U.S.

Discontinuation of marketing and promotion of PERSERIS

In July 2024, the Company discontinued the marketing and promotion of PERSERIS due to impending market changes that would make the product no longer financially viable. The Company has continued to supply PERSERIS to avoid disruption to patient care but no longer deploys a dedicated sales force.

Competition

We operate in a highly competitive industry. While we seek patent and trademark protection where appropriate, several of our branded products face competition from generic products in key markets as well as competition from alternative products and treatments.

For example, SUBLOCADE is patent protected in the U.S., Australia, Canada, the U.K., Ireland, France, Germany, Italy, Spain, Denmark, Finland, Norway, the Netherlands, Switzerland, Sweden, Israel, Japan, Mexico and New Zealand. However, Camurus, in partnership with its U.S. marketing partner Braeburn, obtained FDA approval of its LAI buprenorphine product BRIXADI® in the U.S. Outside the U.S., this product (marketed as BUVIDAL®) enjoys first mover advantage in all countries except Canada. It is well established in the Nordics (Norway, Sweden, Finland, and Denmark) and Australia, and available in other parts of Europe.

Our SUBOXONE Film product already faces five generic competitors in the U.S. We have seen the market share of our film product decline to an average share of 16% in 2024 and expect further declines if other competing products become available or if existing participants choose to disrupt the market in line with industry analogs. We no longer promote SUBOXONE Film in the U.S. as discussed above. In contrast, no generic competition is present in Australia. In Europe and Canada, SUBOXONE Film enjoys patent protection until 2030.

In Europe, generic versions of the SUBUTEX Tablets have been available since 2010 and SUBOXONE Tablets since 2018. In addition, we face competition from branded oral buprenorphine-based tablets and historically well-established methadone oral formulations. In Canada, our SUBOXONE Tablets product faces two generic competitors. We have seen our market share of SUBOXONE Tablets eroding overtime.

OPVEE is the first nalmefene nasal spray approved by the FDA for the emergency treatment of known or suspected opioid overdose in adults and pediatric patients aged 12 years and older, as manifested by respiratory and/or central nervous system depression. OPVEE (nalmefene) nasal spray is intended for immediate administration as emergency therapy in settings where opioids may be present. OPVEE (nalmefene) nasal spray is not a substitute for emergency medical care. It competes with branded and generic naloxone nasal sprays including Narcan® (naloxone HCl) Nasal Spray 4 mg (which is not available without a prescription), 4 mg naloxone generic equivalents, and KLOXXADO® (naloxone HCl) Nasal Spray 8 mg. It also competes with naloxone or nalmefene administered by syringe and over-the-counter ("OTC") intranasal naloxone HCl.

The introduction of generic or branded products that compete with the Company's products or heightened competition amongst existing participants could impact both the market share of the Company's products and pricing and, therefore, adversely impact its results of operations. The introduction of generic products typically leads to a loss of sales of a branded product and/or a decrease in the price at which branded products can be sold. In addition, legislation enacted in the U.S. and several EU countries allows for, and in a few instances in the absence of specific instructions from the prescribing physician, mandates the dispensing of generic products rather than branded products where a generic version is available.

Research and Development

We invest in research and development to create innovative medications and services that address the needs of patients with the complex chronic condition of SUD. These efforts include the development of new medications that are designed to minimize diversion and misuse, increase compliance with treatment, support public health, improve patient outcomes and expand access to treatment for areas of SUD where no pharmacotherapy is currently available.

Chronic addictive behaviors are characterized by compulsive drug and alcohol use, loss of control over drug-seeking and drug-taking, and an intense drive to take the drug at the expense of other behaviors, with little regard for subsequent consequences. From a psychiatric perspective, SUD has aspects of both impulse control disorders and compulsive disorders. In addictive and compulsive disorders, which have prominent motivational drivers, dysfunction in the brain's cortical regions significantly affects cognitive

regulatory processes such that the individual fails to inhibit self-defeating urges or desires appropriately. This failure to resist repetitive, maladaptive behaviors is a key clinical feature of SUD, and aspects of decision-making are compromised either directly (i.e., a dysfunctional inhibitory system) or indirectly (i.e., a dysfunctional reward system).

Indivior has a long history of supporting the SUD treatment community: it discovered buprenorphine in 1966 and has been involved in manufacturing and supplying buprenorphine to patients as a treatment for OUD. See *Heidbreder C, Fudala PJ, Greenwald MK (2023) History of the discovery, development, and FDA-approval of buprenorphine medications for the treatment of opioid use disorder. Drug and Alcohol Dependence Reports. https://doi.org/10.1016/j.dadr.2023.100133.* Indivior has built a portfolio of treatments for OUD and a pipeline of new molecules. Indivior launched the first buprenorphine-based medication for the treatment of OUD in France in 1996. The Company's medications are now available in more than 30 countries and include buprenorphine sublingual tablets (SUBUTEX), buprenorphine and naloxone sublingual tablets (SUBOXONE), buprenorphine and naloxone sublingual film (SUBOXONE Film), and the first FDA-approved once-monthly injectable buprenorphine formulation (SUBLOCADE). All along, Indivior has invested in education programs on evidence-based treatment models that have helped change modern addiction medicine and transform the perception of SUD from a global human crisis to a chronic disease that should be recognized and treated.

Our research and development personnel also have experience in opioid overdose reversal as a result of our acquisition of Opiant Pharmaceuticals, Inc. in March 2023. Members of our Research and Development staff contributed to the regulatory approval of OPVEE (nalmefene) nasal spray 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. On September 27, 2023, the U.S. Biomedical Advanced Research and Development Authority (BARDA) awarded us a $32 million contract to support FDA-required post-marketing requirement studies, 3-year stability studies to support shelf-life extension, real world evidence studies, and procurement of packaged OPVEE held as vendor-managed inventory as a medical countermeasure in the event of a synthetic opioid community or mass casualty event.

Our research and development team is led by our Chief Scientific Officer, Dr. Christian Heidbreder, a leading authority in the development of SUD treatments, and consists of approximately 100 persons distributed across the following sub-functions:

- **Global Chemistry, Manufacturing, and Controls ("CMC")** includes capabilities spanning formulation development, analytical development, chemical development, process development, and technology transfer. Indivior CMC facilities based in Hull (United Kingdom) and Fort Collins (Colorado, USA) are equipped with cutting-edge technologies including pilot plant storage, formulation laboratories, analytical laboratories, chemistry laboratories, stability chambers, office spaces, and support spaces. These facilities are also built to environmental and energy-saving standards, including the installation of a solar panel farm to increase use of renewable energy.
- **Global Medicines Development** encompasses all required functions to support clinical and nonclinical development, from early to late stage clinical development including pivotal Phase 3 trials and post-marketing commitment and requirement studies: (1) medical, scientific writing, publications and communication; (2) clinical development and operations; (3) data and statistical sciences; (4) clinical pharmacology and nonclinical sciences; (5) epidemiology; (6) clinical, medical and safety compliance, and (7) translational medicine.
- **Global Regulatory Affairs** focuses on (1) regulatory strategy; (2) regulatory CMC and compliance; (3) regulatory operations; (4) global labeling and advertisement/promotion; and (5) local regulatory affairs in North America (US and Canada), Europe and Middle-East (EEA (31 countries), Switzerland, Israel, South Africa, Botswana, Lebanon, Kuwait, Qatar, Bosnia, Turkey, Algeria), and Australasia (Australia, New Zealand, Indonesia, Malaysia, Singapore, Vietnam, Hong Kong & Taiwan).

Our research and development function endeavors to conduct all clinical trials (Phase I through Phase IV) in partnership with Clinical Research Organizations. During Phase II and Phase III clinical trials,

we also engage contractors with the relevant capabilities because the formulation of the medication must be finalized and the scalability of production proven. During the various phases of clinical trials, the number of participants in, and consequently the expenses related to, the project increase significantly. Please refer to "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations" for further details of research and development expenses during the financial periods included in this annual report.

Pipeline

Our research and development activities are focused on building on our leadership position in the treatment of opioid use disorder ("OUD"). However, our pipeline reflects only potential products, and any product requires completion of clinical trials to demonstrate safety and efficacy, and approval by the FDA. See "*Item 1A—Risk Factors—Clinical trials for the development of products, including our key pipeline products, may be unsuccessful and our product candidates may not receive authorization for manufacture and sale.*"

INDV-2000 Selective Orexin-1 Receptor Antagonist

We are developing INDV-2000 (Selective Orexin-1 Receptor Antagonist), as a non-opioid treatment for moderate to severe OUD. On June 10, 2024 we announced the dosing of the first subject with INDV-2000 in a Phase 2 double-blind, placebo controlled, randomized, dose-ranging study to assess the safety and efficacy of INDV-2000 over 3 months in treatment-seeking individuals with OUD. The purpose of this proof-of-concept study is to measure safety and efficacy and to determine the dose-response relationship for INDV-2000 in participants with moderate to severe OUD who are treatment-naïve, have recently initiated or completed short-term medically supervised opioid withdrawal with transmucosal (TM) buprenorphine, and are interested in transitioning to a non-opioid treatment. We expect this study to be completed by the end of 2025. The U.S. patents for INDV-2000 expire in 2037.

INDV-6001 Sustained Release LAI Prodrug of Buprenorphine

INDV-6001 is potentially the first three-month LAI buprenorphine for the treatment of OUD. In 2023, the Company secured global rights from Alar Pharmaceuticals to develop, manufacture, and commercialize INDV-6001 and a portfolio of buprenorphine-based LAI. The Company made an upfront payment of $10 million, which is in addition to the $5 million option payment made by the Company in the first quarter of 2023. The licensor would be entitled to potential milestone payments upon the achievement of various developmental, regulatory, and commercial goals, and entitled to royalties in the low double digit to mid-teens as a percentage of net revenue. The U.S. patents for INDV-6001 expire in 2039.

In September 2024, we commenced a multiple dose clinical Phase 2 Pharmacokinetic study which we expect to complete by the end of 2025.

Decision to Not Exercise Option For AEF0117 Aelis

On September 4, 2024, we noted Aelis Farma's announcement of the results from its clinical Phase 2B trial with AEF0117, a synthetic CB1 specific signaling inhibitor designed to treat cannabis-related disorders. This clinical Phase 2B study was part of the strategic collaboration between Aelis Farma and Indivior, which included an exclusive option for Indivior to license the global rights to AEF0117, and was designed to evaluate the efficacy and safety in treatment-seeking participants with moderate to severe Cannabis Use Disorder. Given the lack of separation from placebo on primary and secondary endpoints, and before seeing further additional favorable clinical data, we announced that we do not currently expect to exercise our option.

Manufacturing and Supply

Raw Materials

Active Pharmaceutical Ingredients ("API")

The Company sources a large portion of its active pharmaceutical ingredients ("API") from its own manufacturing facilities.

The API used in our buprenorphine products are manufactured at our Fine Chemical Plant ("FCP") located in Hull, United Kingdom. FCP manufactures the buprenorphine HCl API used in the manufacture of SUBOXONE Film, SUBUTEX Tablet, and SUBOXONE Tablet and the buprenorphine base API ("buprenorphine") used in the formulation of SUBLOCADE long-acting injection. Historically, a third party has manufactured the buprenorphine base and the FCP will be capable of manufacturing the base beginning in 2025. FCP has the capacity to produce all of our current buprenorphine related requirements with approximately 25% demonstrated capacity remaining. We believe there are adequate supplies of the raw materials used to manufacture buprenorphine, and the ingredient is readily available from other suppliers (although it would require significant time to qualify and obtain regulatory approval to change suppliers).

We procure the naloxone HCl active pharmaceutical ingredient mainly from a single supplier for both SUBOXONE Tablet and SUBOXONE Film, although this is readily available from other suppliers (it would require significant time to qualify and obtain regulatory approval to change suppliers).

Buprenorphine and products containing buprenorphine are classified as Schedule III controlled narcotics in the U.S. and require permits for import and export. An annual importation assessment value for buprenorphine and products containing buprenorphine is set by each importing country through the International Narcotics Control Board (the "INCB"). Once the assessment value has been reached for a given country, no additional import permits may be issued unless proper justification for an assessment value increase is provided to the respective country's governing body, which reports to the INCB. While this process has not impacted product supply to our patients in the past, it presents a manufacturing and product supply risk that must be monitored and managed closely.

We procure the active ingredient (nalmefene HCl) and the absorption enhancer (dodecyl maltoside) for OPVEE from single suppliers.

SUBLOCADE

SUBLOCADE (buprenorphine extended-release) injection for subcutaneous use is manufactured under an agreement with Curia. We provide the buprenorphine base, polymer and syringe assembly used in the manufacture of SUBLOCADE. Curia has two manufacturing facilities located in Burlington, Massachusetts and Albuquerque, New Mexico. Manufacture of all SUBLOCADE output for the U.S. and Canadian markets is approved at both facilities, while output intended for the Most of World currently is approved only at the Burlington facility. We plan to obtain approval to manufacture SUBLOCADE for the Most of World at the Albuquerque facility.

In addition, we are improving our Raleigh Manufacturing Facility to potentially manufacture SUBLOCADE to better secure its long-term supply. However, it will take time and investment in equipment and validation testing before we can make regulatory submissions to gain approval for commercial manufacture of SUBLOCADE at this site. See "*Item 1A.—Risk Factors—We rely on third parties to manufacture commercial supplies of most of our products, whose facilities and processes must meet stringent regulatory requirements.*"

We rely on third parties to manufacture and package the products, and to perform quality assurance and quality testing.

SUBOXONE Film

SUBOXONE Film is manufactured under an exclusive license and supply agreement with Aquestive Therapeutics. Under the terms of the agreement, Aquestive is the exclusive global manufacturer and primary packager of SUBOXONE Film and is prohibited from developing any other film product containing buprenorphine without our written consent. We provide both the buprenorphine HCl and the naloxone HCl used in the manufacture of SUBOXONE Film.

Aquestive has two manufacturing facilities located in Portage, Indiana. Manufacturing and primary packaging of all SUBOXONE Film output for most markets is approved at both facilities.

SUBOXONE and SUBUTEX Tablets

We contract with RB to manufacture SUBOXONE and SUBUTEX Tablets. We provide both buprenorphine HCl and naloxone HCl used in the manufacture of SUBOXONE and SUBUTEX Tablets. RB manufactures and performs the packaging of all SUBOXONE and SUBUTEX tablets globally at its facility in Hull, United Kingdom.

OPVEE (nalmefene) nasal spray

We have contracted for the commercial supply of OPVEE with Kindeva Drug Delivery (formerly Summit BioSciences). SpecGx LLC provides the nalmefene HCl and Aegis Therapeutics, LLC provides the dodecyl maltoside (an absorption enhancer) used in the manufacture of OPVEE.

Our exclusive license agreement with Aegis Therapeutics obligates us to pay a tiered low to mid-single digit royalty on net sales, and a potential time sales milestone of $2 million for this nalmefene-dodecyl maltoside combination product. PCI Pharma Services performs tertiary packaging of the commercial product.

Additional Manufacturing and Distributions Processes

We outsource to third parties certain aspects of the manufacturing and distribution process, including packaging our products with tamper evident pouches or child resistant components, in serialized cardboard cartons, and securely storing products, fulfilling orders, and providing other customer service functions.

Sales, Marketing and Distribution

Our sales, marketing, and distribution processes for our products begin with a focus on the patient. Our products are intended for patients who suffer from OUD or opioid overdose, each a highly stigmatized disease or disease state. These patients are found not just in private physician offices, but also in emergency rooms, hospitals, addiction or rehabilitation centers, OHSs and, frequently, as part of their journey with addiction, as incarcerated individuals in the criminal justice system. Accordingly, we focus our sales and marketing efforts not just on physicians in private practice but also to healthcare providers situated in these diverse treatment environments.

Our sales, marketing, and distribution efforts vary by market.

United States

We derive approximately 85% of our net revenues, and an even larger portion of our profitability, from the U.S. market. Unlike many markets in the Most of World, the U.S. market is not a single payor market. Instead, our activities are directed at a patchwork of federal and state agencies, organized health systems, criminal justice systems, and healthcare providers who provide treatment and assistance for patients suffering from OUD.

Payors and Reimbursement

We have dedicated professionals responsible for obtaining access and eliminating barriers to care at the national, regional, and state payor level, including every state Medicaid program. We have coverage from approximately 90% of payors for our OUD products, including almost all commercial insurance payors, and the Veterans' Administration, the Department of Defense, and the Bureau of Indian Affairs.

A significant portion of our customers are reimbursed through the Medicaid plans of states and the District of Columbia, primarily because most individuals suffering from OUD are not employed or do not have employer-based health coverage.

We have begun offering OPVEE to various government entities and community agencies. These organizations typically receive grant funding related to the opioid epidemic which can be used for overdose reversal medications.

Organized Health Systems ("OHS")

Many patients who use our products are found at OHSs, such as health systems including hospitals and addiction treatment centers. OHS are an important channel for our products because they have the resources and administration to appropriately handle controlled substances that are prescribed, delivered, and stored, and are equipped to administer the requirements applicable to our products, including REMS. Our account teams call on key decision makers at OHSs to expand access to our products. Our goal is to ensure access to our products by establishing treatment protocols (both medical and logistical), removing barriers to access, gaining formulary access where needed, and ensuring that protocols are in place to ensure compliance with applicable DEA, state, and local requirements regarding the storage of controlled substances. As part of this process, the sales team focuses on effectively communicating the scientific rationale and the benefits of our products to HCPs, appropriately balanced with safety information, and the account teams and medical team focus on educating key decision makers about potentially better adherence, increased continuity of care, and overall cost and resource optimization in the total treatment plan.

Criminal Justice Systems ("CJS")

We also have dedicated teams for customers in the CJS, including various types of prisons, such as state departments of corrections, county jails, and federal prisons, along with specialty treatment courts. A specialty treatment court is a court with expertise in substance abuse disorders which may offer alternative and deferred prosecution arrangements for appropriate persons.

For prisons, our dedicated teams attempt to increase access to our products, overcome logistical barriers to care, and promote particular products, but do not call on HCPs behind the walls of the prisons.

For specialty treatment courts, our Criminal Justice Access Directors, including approximately 46 trained and experienced professionals, educate judges, prosecutors, social workers, and patients about the benefits of our products. The patient is ultimately referred to an HCP, either in a private office or federally qualified health center, where the decision to use medication for OUD, such as SUBLOCADE, is the patient's decision with the assistance of his or her HCP. At these referral sites and locations, our sales personnel coordinate with the HCPs and their staff to ensure understanding of the scientific rationale and the benefits of our products, appropriately balanced with safety information.

Commercialization Activities

Our commercial activities in the U.S. are currently focused on SUBLOCADE long-acting injectable and OPVEE nasal nalmefene spray. Our sales force does not promote SUBOXONE Film in the U.S. Our sales organization in the U.S. comprises approximately 255 trained and experienced pharmaceutical professionals, which we call Clinical Specialists, who are managed by Area Sales Directors. Clinical Specialists act as a vital link between the various stakeholders within the addiction community, including key opinion leaders, counselors, treatment advocates, pharmacists, nurses and healthcare providers in specialized treatment centers. We believe that our clear focus on patient needs helps deepen customer relationships which then allows the team the time to engage in clinical and logistical discussions that dramatically improve patient access to treatment with SUBLOCADE.

Our Clinical Specialists are supported by dedicated and experienced professionals in our managed care group who create access to treatment for patients by partnering with U.S. commercial payors and federal, state, and local governmental payors.

OPVEE

Our commercialization efforts for OPVEE are not targeted at patients initially. Instead, we expect the primary customers for OPVEE will be:

• Single state authorities / grant administrators;

• Naloxone Coordinators;

• State/County/City Departments of Health;

• Veterans Affairs;

• Community based organizations groups;

• Substance abuse centers and opioid treatment programs;

• Law Enforcement;

• Department of Corrections;

• Fire/Emergency services; and

• Targeted Healthcare Providers prescribing overdose reversal agents; prescriptions would be filled at retail pharmacy and picked up by the patient.

Our commercialization strategy for OPVEE includes ensuring access to OPVEE via inclusion in state standing orders, enabling public funding, establishing relevant state emergency medical protocols, and securing adjustments to state Good Samaritan laws, through the work of our government affairs and medical teams.

In September 2023 we were awarded a contract by BARDA for the procurement of finished, packaged OPVEE held as vendor-managed inventory as a medical countermeasure in the event of a synthetic opioid community or mass casualty event. The role of BARDA is to supplement state and local supplies during public health emergencies. The contract also has options for purchases and delivery of OPVEE over 10 years at guaranteed pricing through 2033. We delivered two orders to BARDA in 2024 for 200,000 doses.

Ultimately, or goal is to establish OPVEE as a differentiated brand by developing real world evidence, driving awareness by providing education to key stakeholders, and establishing OPVEE as the standard of care with the rise of synthetic opioids like fentanyl.

Advocacy, Education, and Patient Support

We collaborate with patient organizations, stakeholders and policymakers to achieve our vision that the millions of people across the globe suffering from SUDs will have access to evidence-based treatment to change lives. Our advocacy agenda focuses on expanding access to treatment, advancing treatment equity, and increasing focus on patients in correctional settings.

Our educational and engagement efforts have focused on expanding the availability of treatment options beyond the clinical setting in the U.S. in order to give patients the flexibility to receive appropriate treatment in the privacy of a physician's office.

We also advocate for access to evidence-based treatment in correctional settings to ensure that resources are focused where challenges are greatest.

Equity in treatment is a barrier to care for patients. For instance, patients in correctional settings sit outside the insurance system and are ineligible by federal law for Medicaid benefits. We work to advance initiatives to increase patient access to medical care while incarcerated as well as access to care and coverage as they re-enter their communities. We also advocate to eliminate other barriers to care, including prior authorizations, step edits, and deductibles.

We have various programs to help patients access our products. For example, we sponsor a commercial co-pay assistance program that helps patients meet co-payment obligations imposed by their commercial insurance.

Additionally, we sponsor an insurance reimbursement hub to facilitate the dispensing of our products that HCPs and pharmacies may access via telephone to confirm coverage and level of benefits. We also provide patient access specialists to problem solve access issues, coverage, and coding (after a product has been ordered).

There has been enhanced scrutiny of company-sponsored patient assistance programs, both from government enforcement and payors.

Medical Affairs Team

Our Medical Affairs Team, which supports HCPs and health administrators and includes Medical Science Liaisons and Medical Outcomes Value Liaisons responsible for responding to unsolicited off-label questions, clarifying data related to our products, working with study investigators, and developing and delivering real world evidence regarding the usage and potential benefits or risks of a medical product derived from an analysis of real-world data. Our Medical Affairs team is separate from sales and marketing.

Marketing

Our marketing efforts are focused on reaching the sufferers of the diseases that our products treat and the HCPs who treat them. In each of our markets, our commercial activities are supported by strategic planning, business analytics and measurement, and quarterly territory plans, ensuring that each market and sales territory is effectively resourced to maximize market access, and to increase appropriate use of our products.

In the U.S., our marketing team is responsible for developing marketing and sales materials, product websites, conference presentations and presence, and media plans which are reviewed by our Promotions Review Committee (PRC) consisting of medical, regulatory, and legal team members to assess compliance with rules and regulations as appropriate. We also provide reimbursement support for our U.S. markets. In addition, we have established strong marketing expertise in increasing disease state and treatment awareness, embedded in various platforms including digital and traditional media. We employ third party vendors, such as advertising agencies, market research firms and suppliers of marketing and other sales support-related services, to assist with our commercial activities.

The challenges that we face in the sales process for our products include:

- understanding of the science that underpins the SUBLOCADE value propositions,
- considerations related to buprenorphine being a controlled substance that is subject to regulation in the countries where our products are marketed,
- SUBLOCADE having been approved by the FDA with a REMS,
- SUBLOCADE requiring secure, refrigerated storage and the requirement that SUBLOCADE be administered by an HCP, and
- developing strategies to ensure market acceptance of OPVEE, competing with an established product, and serving customers, most of which are expected to be incremental to our existing customer base.

To assist our sales and marketing efforts, we invest in data infrastructure and related professionals to derive insights from our data. These insights allow us to prioritize our marketing efforts, identify obstacles and barriers to treatment, and suggest new approaches.

Distribution

We distribute our products in more than 30 countries. Based on the country where sales originate, we derived 85%, 83%, and 81% of our net revenues from the U.S. in 2024, 2023, and 2022, respectively.

The distribution of our buprenorphine products is more complicated than other specialty pharmaceutical products because buprenorphine is regulated in the U.S. as a Schedule III drug by the FDA, and similarly restricted by law enforcement authorities in the Most of World. Additionally, certain products, like SUBLOCADE, utilize a restricted delivery network. Additionally, to ensure proper administration, SUBLOCADE may only be administered by an HCP and are not dispensed to the patient directly. To ensure that our products are available to HCPs and patients, we utilize specialty distributors and a network of several hundred specialty pharmacies that are equipped to adhere to these special requirements.

(The FDA requires a REMS for SUBOXONE Film and for SUBLOCADE Injection. The goal of the SUBLOCADE REMS program is to mitigate the risk of serious harm or death that could result from intravenous self-administration by ensuring healthcare settings and pharmacies are certified and only provide SUBLOCADE directly to a healthcare provider for administration by a healthcare provider to the patient. SUBOXONE Film is part of the Buprenorphine Transmucosal Products for Opioid Dependence ("BTOD") shared REMS program, the goals of which are to: 1) mitigate the risks of accidental overdose, misuse, and abuse, and 2) inform prescribers, pharmacists, and patients of the serious risks associated with buprenorphine-containing products.)

In contrast, SUBOXONE Film may be dispensed directly to a patient by a pharmacy with an appropriate DEA license. Accordingly, a substantial portion of our sales are to pharmaceutical wholesalers, specialty pharmacies, and distributors who, in turn, sell our products to pharmacies, hospitals, and other customers, including federal and state entities.

Our three largest customers (which are wholesale pharmaceutical companies in the U.S.) accounted for 55%, 54%, and 55% of global net revenues in 2024, 2023, and 2022, respectively. Our largest customer in each year accounted for 19%, 19%, and 22% of our net revenues in 2024, 2023, and 2022, respectively. These customers are our primary purchasers of SUBOXONE Film in the U.S., and as sales of SUBLOCADE grow, which is sold mostly through specialty pharmacies and specialty distributors, the relative importance of these three largest customers declines. Our fourth largest customer is one of these specialty pharmacies.

Logistics

We use central third-party logistics and warehouses that comply with applicable local regulations for storage and distribution of our products into the supply chain. Our third-party logistics provider specializes in integrated operations that include warehousing and transportation services that can be scaled and customized to our needs based on market conditions and the demands and delivery service requirements for our medicines and materials. Their services eliminate the need to build dedicated internal infrastructures that would be difficult to scale without significant capital investment. Our third-party logistics provider warehouses all medicines in controlled FDA-registered facilities in the U.S., or which meet applicable requirements outside the U.S. Orders are prepared and shipped through an order entry system to ensure adequate supply and delivery of our medicines.

Most of World

Our commercial activities are currently focused on SUBLOCADE long-acting injectable (also called SUBUTEX Prolonged Release), SUBUTEX Tablet, SUBOXONE Tablet and SUBOXONE Film. Depending on the size and demands of the relevant markets, dedicated teams of clinical liaisons, health policy liaisons, or a combination of both, work to accelerate access to treatment for patients.

In Canada and in approved markets in Europe and Australia, we have a field force of sales specialists. In markets where these products either are not approved or are unable to be promoted under local regulation, we have medical affairs personnel responsible for responding to medical information requests and for providing information consistent with local treatment protocols with respect to such products. Such

medical affairs personnel are separate from sales and marketing personnel. In certain European markets, we have a sales team and a separate team of medical science liaisons supporting our rolling launches of SUBLOCADE and SUBOXONE Film.

Outside the U.S. and Europe, we directly market SUBLOCADE, SUBOXONE Film, and SUBOXONE Tablets in in Canada and SUBLOCADE, SUBOXONE Film, and SUBUTEX Tablets in Australia. We also utilize distributors in certain markets outside the U.S. where we do not market our products directly.

Intellectual Property

We own or license several patents and patent rights in the U.S. and other countries covering or relating to certain of the products and pipeline products mentioned above and have created brand names and also registered trademarks where appropriate for our products. Generally, and where possible, we rely upon patent protection to ensure market exclusivity for the life of the patent. We consider the overall protection of our patents, trademarks, and license rights to be of material value and take actions to protect these rights from infringement or misuse where appropriate.

The majority of an innovative product's commercial value is usually realized during the period in which the product has market exclusivity. In the branded pharmaceutical industry, an innovator's product's market exclusivity is generally determined by two forms of protection: patent rights held by the innovator company; and any regulatory forms of exclusivity to which the innovator is entitled. In the U.S. and some other countries, when market exclusivity expires and generic versions of a product are approved and marketed, there are often very substantial and rapid declines in the branded product's sales. The rate of this decline varies by country and by therapeutic category; however, following patent expiration, branded products often continue to have some market viability based either upon the goodwill generated by the product name, which typically benefits from trademark protection, or upon the difficulties associated with replicating the product formulation or bioavailability.

Patents are a key determinant of market exclusivity for most branded pharmaceuticals as they can provide the innovator with the right to exclude others from practicing an invention related to the product. Patents may cover, among other things, the active ingredient(s), various uses of a drug product, pharmaceutical formulations, drug delivery mechanisms, the manufacture of products and processes for the manufacture of products, and intermediate compounds useful in the manufacture of products. Protection for aspects of individual products extends for varying periods in accordance with the expiry dates of patents in the various countries. The protection afforded, which may also vary from country to country, depends upon the type of patent, its scope of coverage and the availability of meaningful legal remedies in the country. However, patents and other forms of protection can never protect us from all forms of competition, such as from similar products or from alternatives. See, for example, "*Item 1. Business—Competition*."

Many developed countries provide certain non-patent incentives for the development of pharmaceuticals. For example, the U.S., EU and Japan each provides for a minimum period of time after the approval of certain new drugs during which the regulatory agency may not rely upon the innovator's data to approve a competitor's generic copy. For example, OPVEE enjoys regulatory exclusivity in the U.S. through May 2026. Regulatory exclusivity is also available in certain markets as incentives for research on new indications, orphan drugs (drugs that demonstrate promise for the diagnosis or treatment of rare diseases or conditions) and medicines that may be useful in treating pediatric patients. Regulatory exclusivity is independent of any patent rights and can be particularly important when a drug lacks broad patent protection. However, most regulatory forms of exclusivity do not prevent a second innovative competitor from gaining regulatory approval prior to the expiration of regulatory exclusivity when the second innovative competitor has conducted its own safety and efficacy studies on its drug, even when that drug is identical to that marketed by the first innovator.

We estimate the likely market exclusivity period for each of our branded products on a case-by-case basis. It is not possible to predict with certainty the length of market exclusivity for any of our branded products because of the complex interaction between patent and regulatory forms of exclusivity, the relative success or lack thereof of potential competitors' experience in product development and inherent uncertainties concerning patent litigation. There can be no assurance that a particular product will enjoy

market exclusivity for the full period of time that we currently estimate or that the exclusivity will be limited to the estimate.

We also rely on trade secrets, know-how and inventions, which are not protected by patents and try to protect this information by entering into confidentiality agreements with parties that have access to it, such as our corporate partners, collaborators, licensees, employees, and consultants. We also license or assign certain intellectual property rights to third parties.

The Company (generally Indivior U.K. Limited) also owns or licenses, patent rights (i.e., granted patents or pending applications) in certain key jurisdictions in respect to our products and pipeline products. The patent rights listed below are those which are critical to our products:

Product	Patent Type	Application or Patent No.	Expiration Date
SUBLOCADE	Method	9,272,044	June 6, 2031
		10,198,218	June 6, 2031
		10,592,168	June 6, 2031
		10,646,484	June 15, 2038
		11,000,520	November 6, 2035
		11,839,611	November 6, 2035
		(application) 17/283,931	October 11, 2039
		(application) 18/920,176 (application) PCT US2024/052003	October 18, 2044
		(application) 18/931,350	October 30, 2044
	Formulation	8,921,387	January 6, 2032
		8,975,270	Sept. 5, 2031
		9,498,432	June 6, 2031
		9,782,402	June 6, 2031
		9,827,241	June 6, 2031
		10,558,394	June 25, 2031
	Means Plus Function	(application) 17/985,253	November 6, 2035
OPVEE[1]	Formulation and Methods	11,458,091	July 10, 2038
		(application) 17/881,306	August 4, 2042
		(application) 18/436,976	May 15, 2039
		(application) 18/753,188	November 9, 2037
		(application) 17/291,979	November 7, 2039
		(application) 18/174,858	November 7, 2039

[1] OPVEE enjoys regulatory exclusivity in the U.S. through May 2026.

Licensed Technology

We own Patent No. 11,458,091, which includes claims covering combinations of nalmefene and Intravail® (dodecyl maltoside, an absorption enhancer) in a nasal formulation which expires in 2038. Our exclusive license agreement with Aegis Therapeutics obligates us to pay a tiered low to mid-single digit royalty on net sales, and a potential one-time sales milestone of $2 millions for OPVEE.

Regulatory Overview

Our activities are subject to a rigorous regulatory framework on a local and international level that conditions and affects our activities. The process of obtaining regulatory approvals and the subsequent compliance with applicable laws, regulations and other requirements require the expenditure of substantial time and financial resources. The following is a summary of the regulatory landscape applicable to our business and the reimbursement programs applicable to our products in the key markets in which we operate.

United States

Overview

Pharmaceutical companies operate in a highly regulated environment. In the U.S., we must comply with laws, regulations and other requirements promulgated by numerous federal and state authorities, including the FDA and other agencies and divisions of the Department of Health and Human Services, the Drug Enforcement Agency ("DEA"), and other agencies of the DOJ, the Consumer Product Safety Commission, the Environmental Protection Agency, the U.S. Bureau of Customs and Border Protection (the "CBP"), and state agencies such as boards of pharmacy. Applicable legal requirements govern to varying degrees the research, development, manufacturing, commercialization and sale of our prescription pharmaceutical products, including pre-clinical and clinical testing, approval, production, labeling, sale, distribution, import, export, post-market surveillance, advertising, dissemination of information and promotion. Failure to comply with applicable legal requirements can result in product recalls, seizures, injunctions, refusal to approve or withdrawal of approval of product applications, monetary fines or criminal prosecution.

Food and Drug Administration

The FDA's authority to regulate pharmaceuticals comes primarily from the Federal Food, Drug, and Cosmetic Act ("FFDCA"). In addition to reviewing NDAs for branded drugs and additional new drug applications ("ANDAs") for generic drugs, the FDA has the authority to ensure that pharmaceuticals introduced into interstate commerce are neither "adulterated" nor "misbranded." Adulterated means that the product or its manufacture does not comply with FDA quality and related standards. A drug is adulterated if, among other things: (i) it is prepared under unsanitary conditions such that it may have been contaminated or may cause injury to patients, (ii) its manufacture does not comply with cGMP, (iii) it does not comply with an official compendium, (iv) its strength, purity or quality differs from that which it purports to possess, or (v) if it is manufactured, processed or held in a facility which refuses FDA inspection. Misbranded means, among other things, that the labeling of, or advertising or promotional materials for, the product contains false or misleading information, fails to conform to the FDA approval for the drug, or fails to include required information about risks.

In order to market and sell a new drug product in the U.S., a drug manufacturer must file with the FDA an NDA that shows the safety and effectiveness of the new drug. In order to market and sell a generic version of an already-approved drug product, a drug manufacturer must file an ANDA that shows that the generic version is, with narrow exceptions, the same active ingredient, dosage form, strength and route of administration as a previously approved reference product, and "bioequivalent" to that reference product, meaning that it is absorbed at the same rate and to the same extent as the reference product. The FDA classifies certain generic drugs as "therapeutically equivalent," meaning that they are expected to have the same clinical effect and safety as the branded drug product. Alternatively, a manufacturer may submit an NDA under FFDCA section 505(b)(2) for a drug product that has some differences from an already-approved drug product, but that relies in whole or in part on the findings of safety and/or effectiveness of a previously approved reference product, or on medical literature. A section 505(b)(2) NDA must demonstrate that the proposed product is safe and effective notwithstanding the differences from the approved drug product.

Clinical Trials and Marketing Approval

The path leading to FDA approval of an NDA for a new drug begins when the drug product is merely a chemical formulation in the laboratory. In general, the process involves the following steps:

(i) completion of formulation, laboratory and animal testing in accordance with good laboratory practices ("GLP"), which characterizes the drug product from a pre-clinical perspective and provides preliminary evidence that the drug product is safe to test in human beings;

(ii) filing with the FDA an Investigational New Drug Application ("IND") which once effective will permit the conduct of clinical trials (testing in human beings under adequate and well-controlled conditions) in the U.S.;

(iii) designing and conducting clinical trials to show the safety and efficacy of the drug product in accordance with good clinical practice ("GCP") and other requirements;

(iv) submitting the NDA for FDA review, which generally must include data from at least two well-controlled clinical trials demonstrating safety and effectiveness, as well as characterization of the drug product and a description of the manufacturing process, controls and facilities;

(v) satisfactory completion of FDA pre-approval inspections regarding the conduct of the clinical trials and manufacturing at the designated facility or facilities in accordance with current Good Manufacturing Practices ("cGMP");

(vi) if applicable, completion of an FDA Advisory Committee meeting in which the FDA requests views and recommendations from outside experts in evaluating the NDA;

(vii) final FDA approval of the full prescribing information, labeling and packaging of the drug product; and

(viii) in some cases, commitments to meet post-approval requirements, including ongoing monitoring and reporting of adverse events related to the drug product, implementation of a Risk Evaluation and Mitigation Strategy ("REMS") program, if applicable, and conduct of any agreed post-marketing requirement or post-marketing commitment studies.

Clinical trials are typically conducted in four sequential phases, although they may overlap. The four phases are as follows:

(i) Phase I trials are typically small (fewer than 100 study subjects and often involving healthy volunteers) and are primarily designed to determine the pharmacokinetics and toxicity of the drug product.

(ii) Phase II trials usually involve 100 to 300 participants and are designed to determine whether the drug product produces any clinically significant effects in patients with the intended disease or condition and to provide further information about safety and dosing. If the results of these trials show promise, then larger Phase III trials may be conducted.

(iii) Phase III trials are often multi-institution studies that involve a large number of participants and are designed to show efficacy and safety in the intended treatment population. Phase III (and some Phase II) trials are designed to be pivotal trials. The goal of a pivotal trial is to establish the safety and efficacy of a drug product with sufficient robustness for purposes of regulatory approval.

(iv) Phase IV studies are conducted following approval. In some cases, the FDA requires post marketing requirement studies or post-marketing commitment studies after the NDA has been approved. Such post-marketing clinical studies or surveillance programs are intended to obtain more information about the risks of harm, benefits and optimal use of the drug product by evaluating the results of the drug product in a larger number of patients. The FDA may require post-approval studies either at the time of approval or, if it becomes aware of new safety information, after approval.

A drug manufacturer may conduct clinical trials either in the U.S. or outside the U.S., but in all cases must comply with GCP and must ensure that there is: (i) a legally effective informed consent process when enrolling participants; (ii) an independent review by an Institutional Review Board or ethics committee to minimize and manage the risks of harm to participants; and (iii) ongoing monitoring and reporting of adverse events related to the drug product.

In addition, under the Pediatric Research Equity Act 2003 ("PREA") as amended, all NDAs must include assessments on a drug in pediatric patients unless the applicant receives a waiver or deferral. A drug sponsor may also seek to conduct a clinical trial of a drug product on pediatric patients based on a written request from the FDA in order to obtain a form of marketing exclusivity as permitted under the Best

Pharmaceuticals for Children Act 2002, as amended. Under PREA, FDA may require post-approval studies assess the safety and effectiveness of the indication in pediatric patients.

The path leading to FDA approval of a section 505(b)(2) NDA for a drug product that has differences from an already approved product is somewhat shorter. In a section 505(b)(2) NDA, the drug sponsor relies, in whole or in part, on investigations to which the sponsor does not have a right of reference to establish that its proposed product is safe and effective. For example, a section 505(b)(2) NDA may rely on published literature or on the FDA's prior finding of safety and effectiveness of another company's product. Section 505(b)(2) NDAs are typically used for new products with differences from previously approved products such as in dosage forms, dosage strengths, route of administration or indication and where, therefore, an ANDA may not be used. New clinical trial data may also be needed to establish that the proposed product is safe and effective given its differences.

Under the U.S. Prescription Drug User Fee Act 1992, as amended, the FDA has the authority to collect fees from drug manufacturers who submit NDAs and section 505(b)(2) NDAs for review and approval. For U.S. fiscal year 2024, the user fee rate has been set at $4,310,002 for an NDA and $2,155,002 for an NDA not requiring clinical data, generally certain section 505(b)(2) NDAs.

ANDA process

The path leading to FDA approval of an ANDA is very different from that of an NDA. By statute, the drug manufacturer does not complete pre-clinical studies and safety and efficacy clinical trials, and instead focuses on a showing of sameness and bioequivalence to a previously approved Reference Listed Drug ("RLD"), typically a branded drug approved under an NDA. Sameness means, with limited exceptions, the same active ingredient or ingredients, dosage form, strength, route of administration and labeling. Bioequivalence is generally established by studies that involve comparing the absorption rate and concentration levels of a generic drug in the human body to that of the RLD. In the event that the generic drug behaves in the same manner in the human body as the RLD, the two drug products are considered bioequivalent. The FDA considers a generic drug therapeutically equivalent, and therefore the drug is generally substitutable under state pharmacy dispensing law, where it is shown to be the same as and bioequivalent to the RLD. Legislation enacted in most states in the U.S. allows or, in some instances mandates, that a pharmacist dispense an available generic drug that has been rated therapeutically equivalent when filling a prescription for a branded product, in the absence of specific contrary instructions from the prescribing physician. ANDA filings must include information on manufacturing processes, controls, and facilities comparable to an NDA.

In 2010, Congress passed into law the Generic Drug User Fee Act to address the FDA's backlog, which at the time was over 2,000 ANDA filings. This legislation granted the FDA authority to collect, for the first time, user fees from generic drug manufacturers who submit ANDA filings for review and approval, and the fees collected help the FDA fund the drug approval process. For U.S. fiscal year 2025, the user fee rate is set at $1,891,664 for an ANDA submitted by a large size operation generic applicant. The FDA will also collect from generic drug manufacturers a separate fee where they reference a so-called Drug Master File for a contract manufacturer, and separate annual manufacturing facility fees for API and finished drug products.

Aside from the backlog described above, the timing of FDA approval of ANDA filings depends on other factors, including whether an ANDA holder has challenged any listed patents to the reference listed drug (the "RLD") and whether the RLD is entitled to one or more periods of non-patent data or marketing exclusivity under the FFDCA, as discussed elsewhere in this section.

Patent and non-patent exclusivity periods

A sponsor of an NDA is required to identify in its application any patent that claims the drug or a use of the drug subject to the application. Upon NDA approval, the FDA lists these patents in a publication referred to as the Orange Book. Any person that files a section 505(b)(2) NDA that relies upon reference to an approved NDA for which the patents are listed, or an ANDA to secure approval of a generic version of the previously approved drug, must make a certification in respect of listed patents. If the ANDA or section

505(b)(2) NDA applicant certifies that there are no listed patents or that the listed patents have expired, the FDA may approve the application immediately. If the applicant certifies that the patents have not expired, the FDA may only approve the application upon expiry of the patents. Alternatively, the applicant may certify that the listed patents are invalid, unenforceable and/or not infringed by the proposed drug. The applicant must give notice to the holder of the NDA for the RLD and the patent holder (if different) of the bases upon which the patents are challenged. If the NDA holder or patent owner sues the applicant for infringement within 45 days, the FDA may not approve the ANDA or section 505(b)(2) NDA until the earliest of: (i) 30 months after receipt of the notice by the holder of the NDA for the RLD; (ii) entry of a district court of appellate court judgment holding the patent invalid, unenforceable or not infringed; (iii) such other time as the court may order; or (iv) the expiry of the patent. If an infringement suit is not initiated within 45 days of notice to the NDA holder, the FDA may approve the application immediately.

A key motivation for ANDA applicants to challenge patents is the 180-day market exclusivity period (“generic exclusivity”) granted to the developer of a generic version of a product that is the first to submit an ANDA with a Paragraph IV certification. For a variety of reasons, there are situations in which a company may not be able to take advantage of an award of generic exclusivity. The determination of when generic exclusivity begins and ends is complicated and is subject to several forfeiture provisions.

The holder of the NDA for the RLD may also be entitled to certain non-patent exclusivity during which the FDA cannot accept for filing or approve an application for a competing generic product or section 505(b)(2) NDA product. Generally, if the RLD is a new chemical entity, the FDA may not accept for filing any application that references the innovator’s NDA for five years from the approval of the innovator’s NDA. However, this five-year period is shortened to four years where an applicant’s ANDA includes a Paragraph IV certification, and the 30-month stay on FDA approval is lengthened accordingly. In other cases, where the innovator has provided certain clinical study information essential for approval, the FDA may accept for filing, but may not approve, an ANDA or section 505(b)(2) application that references the corresponding aspect of the innovator’s NDA for a period of three years from the approval of the innovator’s NDA. Certain additional periods of exclusivity may be available, such as orphan exclusivity if the RLD is indicated for use in a rare disease or condition, or pediatric exclusivity if the RLD is studied for pediatric patients based on a written request from the FDA.

Risk Evaluation and Mitigation Strategies ("REMS")

The FDA has the authority to require the manufacturer to provide a REMS that is intended to ensure that the benefits of a drug product (or class of drug products) outweigh the risks of harm. The FDA may require that a REMS include elements to assure safe use to mitigate a specific serious risk of harm, such as requiring that prescribers have particular training or experience or that the drug product is dispensed in certain healthcare settings. The FDA has the authority to impose civil penalties on or take other enforcement action against any drug manufacturer who fails properly to implement an approved REMS. Separately, there are prohibitions on a drug manufacturer using an approved REMS to delay generic competition. The FDA has been active in instituting class-wide and product-specific REMS for opioid drug products.

The FDA requires a REMS for SUBOXONE Film and for SUBLOCADE Injection. SUBOXONE Film is part of the Buprenorphine Transmucosal Products for Opioid Dependence ("BTOD”) shared REMS program, the goals of which are to: 1) mitigate the risks of accidental overdose, misuse, and abuse, and 2) inform prescribers, pharmacists, and patients of the serious risks associated with buprenorphine-containing products. The goal of the SUBLOCADE REMS program is to mitigate the risk of serious harm or death that could result from intravenous self-administration by ensuring healthcare settings and pharmacies are certified and only provide SUBLOCADE directly to a healthcare provider for administration by a healthcare provider to the patient.

Other products for which the Company secures NDA approval in the U.S. in the future may become subject to a REMS specific to the product or shared with other products in the same class of drug, if the FDA determines that additional steps beyond labeling are required to help ensure the benefits of the medication outweighs its risks.

Quality assurance requirements

The FDA enforces requirements to ensure that the methods used in, and the facilities and controls used for, the manufacture, processing, packaging, and holding of drugs conform to cGMP. The cGMP requirements that the FDA enforces are comprehensive and cover all aspects of manufacturing operations, from receipt of raw materials to finished product distribution, and are designed to ensure that the finished products meet all the required identity, strength, quality, and purity characteristics. Ensuring compliance requires a continuous commitment of time, money, and effort in all operational areas.

The FDA conducts pre-approval and post-approval inspections of facilities engaged in the development, manufacture, processing, packaging, testing, and holding of the drugs subject to NDAs and ANDA filings. Prior to approval, if the FDA concludes that the facilities to be used do not or did not meet cGMP, it will not approve the application. Corrective actions to remedy the deficiencies must be performed and are usually verified in a subsequent inspection.

The FDA also conducts periodic post-approval inspections of drug manufacturing facilities to assess their cGMP status. Adverse inspections can lead to FDA inspection observations, warning letters, seizure, recalls, injunctions, and shutdown of facilities. In addition, where products or components for manufacturing are being imported into the U.S., the FDA may issue an import alert to prevent shipments into the country. In addition, if the FDA concludes that a company is not in compliance with cGMP requirements, sanctions may be imposed that include preventing that company from receiving the necessary licenses to export its products, preventing further approvals for applications involving the facility or facilities and issue and classifying that company as an "unacceptable supplier," thereby disqualifying that company from selling products to governmental agencies.

Reporting requirements

Pharmaceutical manufacturers are subject to adverse event reporting requirements during clinical trials and following approval, with expedited reporting for certain serious adverse events and periodic reporting for other adverse events. To comply with these requirements, manufacturers must have robust procedures for surveillance, receipt, evaluation, and reporting of adverse events. Manufacturers must also submit annual reports to FDA for each approved product and field alert reports where there is a quality or labeling issue with a product already distributed to the market.

Labeling and marketing

For all pharmaceuticals sold in the U.S., the FDA and other regulatory and law enforcement bodies also regulate sales and marketing to ensure that drug product claims made by manufacturers are not false, misleading or otherwise improper. Manufacturers are required to file copies of all product-specific promotional materials with the FDA's Office of Prescription Drug Promotion at the time of their first use. Failure to implement a robust internal company review process and to comply with FDA requirements regarding labeling and promotion increases the risk of enforcement action by the FDA, the DOJ, or the states.

In addition, the FDA has the authority to require labeling changes after approval of a drug if it becomes aware of new safety information.

Import and export requirements

To import pharmaceuticals into the U.S., the importer must file an entry notice and bond with the Customs and Board Protection ("CBP"). All drugs are subject to FDA examination before release by the CBP. Any article that appears to be in violation of the FFDCA may be refused admission and a notice of detention and hearing may be issued. If the FDA ultimately refuses admission, the CBP may issue a notice for redelivery and assess liquidated damages for up to three times the value of the drugs.

Products for export from the U.S. are subject to foreign countries' import requirements and the exporting requirements of the FDA. For example, international sales of drugs manufactured in the U.S. that are not approved by the FDA for use in the U.S. are subject to FDA export requirements. FDA will provide a

certificate of pharmaceutical product ("eCPP") directly to a requesting country to provide assurance that the product has been approved for export from the U.S. and that the manufacturing facilities are in compliance with cGMP. To obtain this certificate, the drug manufacturer must apply to the FDA.

Drug Enforcement Administration

The U.S. Drug Enforcement Agency ("DEA") is the federal agency in the U.S. responsible for enforcement of the Controlled Substances Act ("CSA"). The CSA classifies drugs and other substances based on identified potential for dependence and abuse. Schedule I controlled substances are those with a high abuse potential and have no currently accepted medical use; thus they cannot be lawfully marketed or sold. Schedule II/IIN substances have a high potential for abuse which may lead to severe psychological or physical dependence. Many narcotics and stimulants are Schedule II controlled substances. Schedule III/IIIN substances have a potential for abuse less than substances in Schedules I or II and abuse may lead to moderate or low physical dependence or high psychological dependence. Examples of Schedule III substances are products containing not more than 90 milligrams of Codeine per dosage (Tylenol® with Codeine) and buprenorphine, the active ingredient in SUBLOCADE and SUBOXONE. Consequently, the manufacture, storage, distribution, and sale of these substances are all highly regulated.

DEA regulations make it extremely difficult for a manufacturer in the U.S. to import finished dosage forms of controlled substances manufactured outside the U.S., particularly for Schedule II controlled substances and narcotics in other Schedules. These rules reflect a broader enforcement approach by the DEA to regulate the manufacture, distribution and dispensing of legally produced controlled substances. Accordingly, drug manufacturers who market and sell finished dosage forms of controlled substances in the U.S. often manufacture or have them manufactured in the U.S.

The DEA also requires drug manufacturers to design and implement a system that identifies suspicious orders of controlled substances, such as those of unusual size, those that deviate substantially from a normal pattern and those of unusual frequency, prior to completion of the sale. A compliant suspicious order monitoring system includes well-defined due diligence, "know your customer" efforts and order monitoring.

To meet its responsibilities, the DEA conducts periodic inspections of registered establishments that handle controlled substances. Annual registration is required for any facility that manufactures, tests, distributes, dispenses, imports or exports any controlled substance. The facilities must have the security, control and accounting mechanisms required by the DEA to prevent loss and diversion. Failure to maintain compliance, particularly as manifested in loss or diversion, can result in regulatory action. The DEA may seek civil penalties, refuse to renew necessary registrations or initiate proceedings to revoke those registrations. In certain circumstances, violations could lead to criminal proceedings.

Individual states also regulate controlled substances, and manufacturers, distributors and third-party active pharmaceutical ingredient suppliers and manufacturers, are subject to such regulation by several states with respect to the manufacture and distribution of these products.

Government benefit programs

Statutory and regulatory requirements for Medicaid, Medicare, Tricare (the uniformed services healthcare program for active duty service members, active duty family members, National Guard and Reserve members and their family members, retirees and retiree family members, survivors, and certain former spouses worldwide) and other government healthcare programs govern provider reimbursement levels for government beneficiaries, including requiring that pharmaceutical companies pay rebates to individual states based on Medicaid utilization of the manufacturer's products. The federal and state governments may continue to enact measures in the future aimed at containing or reducing payment levels for prescription pharmaceuticals paid for in whole or in part with government funds. In the new Congress convening in 2025, federal policy makers may offer proposals to reform the Medicaid program, which could affect the pharmaceutical industry.

From time to time, legislative or regulatory changes are made to government healthcare programs that impact our business. For example, the Medicare Prescription Drug Improvement and Modernization Act

2003 (“Medicare Part D”) created a new outpatient prescription drug coverage program for people with Medicare through a new system of private market drug benefit plans. This law provides an outpatient prescription drug benefit to seniors and individuals with disabilities in the Medicare program.

Further, the Inflation Reduction Act of 2022, or IRA, among other things, requires the U.S. Department of Health and Human Services Secretary to negotiate, with respect to Medicare units and subject to a specified cap, the price of a set number of certain high Medicare spend drugs and biologicals per year starting in 2026, penalizes manufacturers of certain Medicare Parts B and D drugs for price increases above inflation, and makes several changes to the Medicare Part D benefit, including a limit on annual out-of-pocket costs, and a change in manufacturer liability under the program. Congress continues to consider various policy proposals that may result in pressure on the prices of prescription drugs in the government health programs.

In addition, the Patient Protection and Affordable Care Act (“Affordable Care Act”) has changed the way healthcare services are delivered and financed by both government and private insurers in the U.S. The overall impact of the Affordable Care Act reflects several uncertainties; the impact to our business is largely attributable to changes in the Medicare Part D coverage gap, the imposition of an annual fee on branded prescription pharmaceutical manufacturers and increased rebates payable to state Medicaid programs. There are several other provisions in the legislation that collectively have additional impact, including originator average manufacturer price for new formulations and the expansion of the ceiling prices under section 340B of the Public Health Service Act, as amended (the “340B Program”) to new entities.

Further, federal policy makers have taken steps toward expanding healthcare coverage beyond the Affordable Care Act, which could have ramifications for the pharmaceutical industry. In 2025, some federal lawmakers may continue with these efforts. In the 119th Congress, however, there also may be renewed attempts to alter the Affordable Care Act. Additional legislative changes, regulatory changes, or guidance could be adopted, which may impact marketing approvals and reimbursement for our products. For example, there has been increasing legislative, regulatory, and enforcement interest in the U.S. with respect to drug pricing practices. There have been several inquiries by the U.S. Congress and proposed and enacted federal and state legislation and regulatory initiatives designed to, among other things, bring more transparency to product pricing, evaluate the relationship between pricing and manufacturer patient programs, and reform government healthcare program reimbursement methodologies for drug products.

Healthcare fraud and abuse laws; Privacy

Federal and state healthcare laws and regulations restrict business practices in the pharmaceutical industry. These laws may impact, among other things, our current and future business operations and proposed sales, marketing and education programs and constrain the business or financial arrangements and relationships with healthcare providers and other parties through which we market, sell and distribute our products. These laws include anti-kickback and false claims laws and regulations, data privacy and security, and transparency laws and regulations, including, without limitation, those laws described below.

The U.S. federal Anti-Kickback Statute (AKS) prohibits any person or entity from, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce or in return for purchasing, leasing, ordering or arranging for or recommending the purchase, lease or order of any item or service reimbursable under federal healthcare programs, including Medicare and Medicaid. The term “remuneration” has been broadly interpreted to include anything of value. The AKS has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. Several courts have interpreted the AKS’s intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the AKS has been violated.

A person or entity does not need to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. Violation of the AKS carries criminal penalties and fines as well as administrative sanctions under the Civil Money Penalties Law. In addition, the government may assert that a claim including items or services resulting from a violation of the AKS constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act.

Federal civil and criminal false claims laws and civil monetary penalties laws, including the federal civil False Claims Act, which can be enforced by individuals through civil whistleblower and qui tam actions, prohibit any person or entity from, among other things, knowingly presenting, or causing to be presented, a false claim for payment to the federal government or knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. A claim includes "any request or demand" for money or property presented to the U.S. government. Several pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the companies' marketing of products for unapproved, and thus non-reimbursable, uses. Most U.S. states have equivalents of these federal laws that apply to state healthcare programs, and those state laws may be broader than their federal counterparts.

The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, created additional federal criminal statutes that prohibit, among other things, knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private third-party payors and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Also, many states have similar fraud and abuse statutes or regulations that apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

In addition, we may be subject to data privacy and security regulations promulgated by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their respective implementing regulations, impose specified requirements on certain types of individuals and entities relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's security standards directly applicable to "business associates," defined as independent contractors or agents of covered entities, which include certain healthcare providers, healthcare clearinghouses and health plans, that create, receive, maintain or transmit individually identifiable health information in connection with providing a service for or on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce HIPAA and seek attorney's fees and costs associated with pursuing federal civil actions.

The federal regulations addressing the Confidentiality of Substance Use Disorder Patient Records, codified at 42 C.F.R. Part 2 (Part 2), strictly restrict the circumstances under which patient records relating to diagnosis of or treatment for a substance use disorder may be used and disclosed by any person or organization other than the treating provider. Recently, the Part 2 regulations have been modified to permit increased sharing for approved purposes and to better align the requirements of Part 2 and HIPAA to reduce confusion about the interaction of those different regulations, but such modifications now require persons or entities holding Part 2 records and experiencing a breach of unsecured Part 2 records to notify affected individuals and the Secretary of HHS about such breach to the same extent as breaches of unsecured protected health information must be reported pursuant to HIPAA. In addition, state laws governing the privacy and security of health information in certain circumstances, including laws addressing behavioral health diagnosis and treatment—many of which are not pre-empted by HIPAA—differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. The federal Physician Payments Sunshine Act (Sunshine Act) requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare &

Medicaid Services (CMS) information related to payments or other transfers of value made to physicians, advanced practice providers, and teaching hospitals. The Sunshine Act also requires applicable manufacturers and applicable group purchasing organizations to report annually to CMS ownership and investment interests held by physicians and their immediate family members.

We may also be subject to state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, marketing expenditures or drug pricing, and state and local laws that require the registration of pharmaceutical sales representatives.

Because of the breadth of these laws and the narrowness of available statutory exceptions and regulatory safe harbors, it is possible that some of our business activities could be subject to challenge under one or more of such laws. If we were found to be in violation any of the federal and state laws described above or any other governmental regulations that apply to us, including any violation of the CIA, we may be subject to significant criminal, civil and administrative penalties including damages, fines, imprisonment, disgorgement, contractual damages, reputational harm, diminished profits and future earnings, disgorgement, exclusion from participation in government healthcare programs and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

We must comply with the FCPA worldwide and similar anti-bribery laws in non-U.S. jurisdictions such as the U.K. Bribery Act of 2010, which generally prohibit companies and their intermediaries from making improper payments to non-U.S. officials for the purpose of obtaining or retaining business. Because of the predominance of government-sponsored healthcare systems around the world, most of our customer relationships outside the U.S. are with governmental entities and are therefore subject to such anti-bribery laws. See also, *"Item 1A. Risk Factors—We are subject, directly or indirectly, to a variety of U.S. and international laws and regulations related to fraud and abuse and transparency. Enforcement actions under such laws have increased in recent years. If we fail to comply, or have not fully complied, with such laws, we could face substantial penalties."*

European Union and U.K.

Overview

In the EU and U.K., medicinal products are subject to extensive pre- and post-marketing regulation by regulatory authorities at both the EU and national levels. Additional rules also apply at the national level relating specifically to controlled substances.

Following a referendum in 2016, the U.K. formally left the EU on January 31, 2020 and the transition period, during which EU laws continued to apply to the U.K., expired on December 31, 2020.

A significant proportion of the regulatory framework in the U.K. applicable to medicinal products is currently derived from European Union Directives and Regulations, and since January 1, 2021, the EU laws which have been transposed into U.K. law through secondary legislation continue to be applicable in the U.K. as retained EU law, although any new EU law developments have ceased to apply in the U.K. from that date. The divergence between the U.K. and the EU regimes may increase as time passes, including for example, with respect to EU law developments to which the U.K. is not subject, such as the Clinical Trials Regulation. There have been no new significant legislative enactments in the U.K. since its exit from the EU with respect to medicinal products which would materially deviate the U.K.'s overall regulatory position from the EU law at the time the U.K. exited the EU. However, there are important procedural and other differences, such as the requirement to obtain a U.K.-specific marketing authorization, for example.

There are several ongoing U.K. government consultations relevant to medicinal products, most notably with respect to clinical trials and the future regulatory landscape in the U.K. is uncertain.

The position in Northern Ireland differs in certain respects from that of the rest of the United Kingdom (England, Scotland, and Wales) as Northern Ireland has chosen to retain some EU rules following the U.K.'s departure from the EU.

Clinical trials and marketing approval

Clinical trials of medicinal products in the EU must be conducted in accordance with EU and national regulations and the International Council for Harmonization ("ICH") guidelines on GCP. Prior to commencing a clinical trial, the sponsor must obtain a clinical trial authorization from the competent authority and a positive opinion from an independent ethics committee. The application for a clinical trial authorization must include, among other things, a copy of the trial protocol and an investigational medicinal product dossier containing information about the manufacture and quality of the medicinal product under investigation.

Under the EU Regulation on Clinical Trials (Regulation (EU) 536/2014) which came into force as of January 31, 2022, and replaces the existing Directive 2001/20/EC, a centralized procedure is in place where the sponsor submits the application for a clinical trial through an EU portal. The application is then evaluated and approved or rejected by the respective member state where the trial is to take place. If more than one member state is concerned, the application will be reviewed in a coordinated process with one member state acting as "reporting" member state. Any subsequent substantial changes to the trial protocol or other information submitted with the clinical trial applications must be approved by the member states concerned. The EU Regulation on Clinical Trials provides for certain transitional rules for clinical trials applied for before it came into effect and gives sponsors a choice as to whether to apply the previous rules until January 31, 2023.

The U.K. regulatory framework in relation to clinical trials is derived from secondary national U.K. legislation implementing the EU Directive 2001/20/EC. The U.K. is not subject to the new EU Regulation on Clinical Trials and the details of the future regulation of clinical trials in the U.K. are as yet uncertain.

After completion of the required clinical testing, a drug manufacturer must obtain a marketing authorization in line with Regulation EC 726/2004 (and as transposed into national laws) before it may place its medicinal product on the market in the EU. There are various application procedures available depending on the type of product involved. The centralized procedure gives rise to marketing authorizations that are valid throughout the EU and, by extension (after national implementing decisions), in Norway, Iceland and Liechtenstein, which, together with the EU member states, comprise the EEA. Applicants file marketing authorization applications with the EMA where they are reviewed by a relevant scientific committee, in most cases the Committee for Medicinal Products for Human Use ("CHMP"). The EMA forwards CHMP opinions to the European Commission, which uses them as the basis for deciding whether to grant a marketing authorization. The centralized procedure is compulsory for medicinal products that (i) are derived from biotechnology processes; (ii) contain a new active substance (not yet approved on November 20, 2005) indicated for the treatment of certain diseases, such as HIV/AIDS, cancer, diabetes, neurodegenerative disorders, viral diseases or autoimmune diseases and other immune dysfunctions; (iii) are orphan medicinal products; or (iv) are advanced therapy medicinal products, such as gene or cell therapy medicines.

For those medicinal products for which the centralized procedure is not available, the applicant must submit marketing authorization applications to the national medicines regulators through one of three procedures: (i) a national procedure, which results in a marketing authorization in a single EU member state; (ii) the decentralized procedure, in which applications are submitted simultaneously in two or more EU member states; and (iii) the mutual recognition procedure, which must be used if the product has already been authorized in at least one other EU member state, and in which the EU member states are required to grant an authorization recognizing the existing authorization in the other EU member state, unless they identify a serious risk to public health. A national procedure is only possible for one-member state; as soon as an application is submitted in a second member state the mutual recognition or decentralized procedure will be triggered. Marketing authorizations granted under a national procedure are also initially valid for five years but can be renewed indefinitely.

Marketing authorization applications for generic medicinal products do not need to include the results of pre-clinical and clinical trials but can instead refer to the data included in the marketing authorization of a reference product for which regulatory data exclusivity has expired. If a marketing authorization is granted for a medicinal product containing a new active substance, that product benefits from eight years of data exclusivity during which generic marketing authorization applications referring to the data of that product may not be accepted by the regulatory authorities, and a further two years of market exclusivity during which such generic products may not be placed on the market. The two-year period may be extended to three years if during the first eight years a new therapeutic indication with significant clinical benefit over existing therapies is approved.

In the U.K., the EU centralized procedure described above no longer applies and a separate application will be required to the U.K. Medicines and Healthcare products Regulatory Agency ("MHRA") for a U.K. marketing authorization. The MHRA may consider marketing authorizations approved in the European Economic Area (EEA) member states through decentralized or mutual recognition procedures, which may accelerate the process of granting a marketing authorization in the U.K.

In the EU, companies developing a new medicinal product must agree to a Pediatric Investigation Plan ("PIP") with the EMA and must conduct pediatric clinical trials in accordance with that PIP unless a waiver applies, for example because the relevant disease or condition occurs only in adults. The marketing authorization application for the product must include the results of pediatric clinical trials conducted in accordance with the PIP, unless a waiver applies, or a deferral has been granted, in which case the pediatric clinical trials must be completed at a later date. Products that are granted a marketing authorization on the basis of the pediatric clinical trials conducted in accordance with the PIP are eligible for a six-month extension of the protection under a supplementary protection certificate (if any is in effect at the time of approval). This pediatric reward is subject to specific conditions and is not automatically available when data in compliance with the PIP are developed and submitted. In the U.K., after January 1, 2021, PIP applications were required to be submitted separately to the MHRA though EU PIPs agreed prior to that date were adopted as U.K. PIPs as at that date. The U.K. MHRA PIP application system mirrors the EU system and the MHRA has said it will continue to follow the EU guidelines on such applications. The MHRA will take account of whether an EU PIP is already granted when deciding whether to grant a U.K. PIP. The MHRA strongly encourages parallel submission to EMA and MHRA.

Pharmacovigilance and risk management

The holders of a marketing authorization are subject to extensive pharmacovigilance and risk management obligations under Directive 2001/83/EC and Regulation EC 726/2004.

According to EMA, pharmacovigilance "is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine-related problem." In the EU and the U.K., the holders of a marketing authorization must establish and maintain a pharmacovigilance system with the overall aim to monitor and ensure the safety of a medicinal product and appoint an individual qualified person for pharmacovigilance who is responsible for oversight of that system. They are also required to establish and maintain a pharmacovigilance system master file detailing the pharmacovigilance system. On request, the system master file must be made available to the competent authorities for inspection. In the U.K., if the qualified person does not reside or operate in the U.K., there will need to be a national pharmacovigilance contact person who does reside or operate in the U.K. Key pharmacovigilance obligations include the recording of suspected serious adverse reactions to the medicinal product in and outside the EU and promptly reporting them through the centralized EudraVigilance database. In addition, the holders of a marketing authorization are required to submit periodic safety update reports ("PSURs").

All new marketing authorization applications must include an RMP describing the risk management system that the holder of the marketing authorization will put in place and documenting measures to prevent or minimize the risks associated with the product. The regulatory authorities may also impose specific obligations as a condition of the marketing authorization. Such risk-minimization measures or post-authorization obligations may include additional safety monitoring, more frequent submission of PSURs or the conduct of additional clinical trials or post-authorization safety studies.

Promotional restrictions

In the EU and U.K., all advertising and promotional activities for the product must be consistent with the approved summary of product characteristics, and therefore all off-label promotion is prohibited. Direct-to-consumer advertising of prescription medicines is also prohibited. Although general requirements for advertising and promotion of medicinal products are established under EU and U.K. legislation, the details are governed by national regulations and can differ from one country to another.

Manufacturing and importing

Medicinal products may only be manufactured in the EU, or imported into the EU from another country, by the holder of a manufacturing authorization. The manufacturer or importer must comply with the EU GMP and have a qualified person who is responsible for certifying that each batch of product placed on the market in a member state has been manufactured in accordance with the laws in force in that member state and in accordance with the requirements of the marketing authorization. If a medicinal product is imported from outside the EU, each batch of product must undergo a full qualitative analysis, a quantitative analysis of at least all the active substances and all the other tests or checks necessary to ensure the quality of medicinal products in accordance with the requirements of the marketing authorization. Manufacturing facilities are subject to periodic inspections by the competent authorities for compliance with EU GMP and may, if products are produced for another market, also be subject to inspections under the GMP requirements applicable in that market. The position in the U.K. is broadly equivalent, save that a U.K. specific manufacturer's license is required from the MHRA (in addition to the U.K. marketing authorization), which also requires compliance with EU GMP. For the purposes of EU legislation, the U.K. is now classified as a "third country."

The manufacture, import, export, storage, distribution, and sale of controlled substances are subject to additional regulation at the national level in the EU and U.K. In many EU member states, the regulatory authority responsible for medicinal products is also responsible for controlled substances. In the U.K. and in certain EU member states, responsibility is split and in the U.K., the Home Office is responsible for controlled substances while the MHRA is responsible for medicinal products. Generally, any company manufacturing or distributing a medicinal product containing a controlled substance in the EU or U.K. will need to hold a controlled substances license from the competent national authority and will be subject to specific record-keeping and security obligations. Separate import or export certificates are required for each shipment into or out of the country.

Pricing and reimbursement

Pricing and reimbursement remain mostly within the discretion of the respective member state. However, the member states must at least comply with the Transparency Directive (Directive 89/105/EEC), which primarily provides procedural obligations. Governments influence the price of medicinal products in the EU and the U.K. through pricing and reimbursement rules and control of national healthcare systems that fund a large part of the cost of those products to patients. Some member states operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed. To obtain reimbursement or pricing approval, some of these member states may require the completion of clinical trials that compare the cost-effectiveness of a particular product candidate to currently available therapies. Other countries allow companies to fix their own prices for medicinal products but monitor and control company profits. Such differences in national pricing regimes may create price differentials across Europe. The downward pressure on healthcare costs in general, particularly prescription medicines, has become intense. As a result, barriers to entry of new products are becoming increasingly high and patients are unlikely to use a drug product that is not reimbursed by their government.

In addition, in most European countries, physicians are encouraged or even required to prescribe generic rather than branded products and many governments also advocate generic substitution by requiring or permitting pharmacists to substitute a different company's generic version of the branded drug product that was originally prescribed.

Most of World

Current markets

After the U.S. and Europe, our largest markets are Canada and Australia, where we market our products pursuant to standards set by Health Canada and the Therapeutic Goods Administration, respectively. We also market our products in certain other developed countries. The laws, guidelines and standards promulgated by the relevant regulatory authorities that regulate the development, testing, manufacturing, marketing, and selling of pharmaceuticals in each of these jurisdictions are broadly similar to those in the U.S. and Europe, although the precise requirements vary from country to country.

We also market our products in various emerging markets, where regulatory review and oversight processes continue to evolve. At present, such countries typically require prior regulatory approval or marketing authorization from large, developed markets (such as the U.S., European Union, Canada and Australia) before they will initiate or complete their review. Some countries also require the applicant to conduct local clinical trials as a condition of marketing authorization. Many emerging markets continue to implement measures to control drug product prices, such as implementing direct price controls or advocating the prescribing and use of generic drugs.

Environmental

Our Fine Chemical Plant manufactures the buprenorphine hydrochloride ("HCl") and buprenorphine base active pharmaceutical ingredient used in the formulation of SUBLOCADE long-acting injection, SUBOXONE Film, SUBUTEX Tablet, and SUBOXONE Tablet. The FCP stores and uses hazardous materials as part of the manufacturing process; however, these aspects of the process are tightly controlled and, we believe, represent low risk to the surrounding environment.

Our approximate 80,000 square foot manufacturing plant in Raleigh, N.C. currently manufactures pharmaceutical products only for third party customers. Unlike the FCP, the Raleigh Manufacturing Facility does not use hazardous chemicals as part of its manufacturing processes at this time.

Our operations, like those of other pharmaceutical companies, involve the use of substances regulated under environmental laws, primarily in manufacturing processes and, as such, we are subject to numerous federal, state, local and non-U.S. environmental protection and health and safety laws and regulations. Environmental laws are complex, frequently amended and have generally become more stringent over time. Environmental agencies may require that we reimburse the government for costs incurred at these sites or otherwise pay for the cost of investigation and clean-up of these sites, including compensation for damage to natural resources. Also, certain environmental laws can impose liability on the current or former owners or operators of real property or facilities for the costs of investigation, removal or remediation of hazardous substances or materials at such properties, or at properties to which parties have disposed of hazardous substances. These laws can impose liability without regard to fault, and such liability may be joint or several with the previous owners or operators.

Human Capital

Our goal is to be an employer of choice and provide a fair, equitable, and conducive working environment free from discrimination and harassment. Indivior regards its employees as fundamental to its long-term success and provides a variety of training, development, and communication programs to ensure its business activities are always conducted in line with its guiding principles and stakeholder expectations.

At Indivior, we value our distinctive culture and believe it is a key source of sustainable competitive advantage. Our 50+ person Culture Champions network is well established and has helped us to implement many initiatives aimed at strengthening and building our culture. We also conduct an annual survey of employees to monitor engagement levels and act on feedback received through this process. In 2024, we remained certified as a Great Place To Work for all countries entered.

The table below sets forth the average monthly number of persons employed by the Company, excluding Directors, by business function during the years indicated.

Business function	2024	2023	2022
Operations	811	735	675
Management	225	208	178
Research and development	116	108	75
Average number of employees	1,152	1,051	928

As of December 31, 2024, the Company employed 1,051 people worldwide, of which 1,030 were full-time employees. Of these, 747 were located in the U.S., 274 were located in Europe, the Middle East, Africa, or Canada, and 30 were located in Australia.

Certain of our employees are represented by unions or works councils. We believe that we have a good relationship with our employees and with the unions and works councils that represent certain employees.

As of December 31, 2024, women or minorities held 31% (4 of 13) of the seats on our Board of Directors. As of December 31, 2024, 51% of our employees were women. Additionally, 34% of senior managers (including members of our Executive Committee who are not directors of Indivior PLC and directors of each subsidiary company) were women.

Other Information and Corporate Governance

The Company's legal name is Indivior PLC. Indivior PLC is a public limited company incorporated under the laws of England and Wales that was incorporated on September 26, 2014. The principal legislation under which the Company operates is the U.K. Companies Act 2006. The registered office address of Indivior PLC is: 234 Bath Road, Slough, Berkshire, U.K., SL1 4EE and its telephone number is +1 (804) 379-1090. The Company's website is https://www.indivior.com/. Information on the Company's website does not constitute a part of and is not incorporated by reference into this Annual Report.

Our ordinary shares are listed on the Global Select Market of The Nasdaq Stock Market LLC and on the Equity Shares (Transition) category of the London Stock Exchange under the ticker symbol "INDV."

The Company is subject to the information reporting requirements of the Exchange Act applicable to foreign private issuers, and under those requirements files reports with the SEC. The SEC maintains a website at http://www.sec.gov from which this Annual Report and those other reports or other information may be accessed. We also make our electronic filings with the SEC available at no cost on the Company's website, www.indivior.com/en/investors, as soon as reasonably practicable after we file such material with, or furnish it to, the SEC. Upon the filing of this Annual Report on Form 10-K, the Company has assumed an obligation to file annual reports on Form 10-K, quarterly reports on Form 10-Q, and file or furnish Current Reports on Form 8-K rather than reports on Form 6-K.

Foreign Private Issuer Status

As a foreign private issuer, we are exempt from the rules under the Exchange Act related to the furnishing and content of proxy statements, and our officers, directors, and principal shareholders are exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act.

We provide information with respect to our Board of Directors, Executive Officers, and corporate governance policies and principles on our website, www.indivior.com/en/about-us. Specifically, the Company makes available on its website, under the headings *"About Us — Corporate Governance"* (i) its codes of conduct or ethics for the Board, senior financial officers, and employees, and (ii) the committee charters of the Company's board committees. If the Company makes changes in, or provides waivers from, the provisions of any of its codes of ethics that the SEC requires it to disclose, the Company intends to disclose these events in the "*Corporate Governance*" section of its website.

Item 1A. Risk Factors.

Summary of Risk Factors

You should carefully consider the risks described below, together with all of the other information in this annual report on Form 10-K. The risks and uncertainties below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we believe to be immaterial may also adversely affect our business. If any of the following risks occur, our business, financial condition, and results of operations could be seriously harmed, our stock price might decline, and you could lose all or part of your investment.

Risks Related to our Business

- We are subject to substantial litigation and ongoing investigations and information requests.
- We rely on third parties to manufacture commercial supplies of most of our products.
- Compliance with legal and regulatory settlements requires significant resources and, if we fail to comply, we could be subject to penalties or excluded from government healthcare programs.
- Congress may reduce spending on Medicaid.
- We are subject to additional risks because we import, manufacture, and distribute controlled substances.
- We are subject to risks related to the manufacture of our products.
- We receive substantial revenue from a small number of key proprietary products.
- We depend on our ability to commercialize our products and acceptance of our products by physicians, patients, and healthcare payors.
- Several factors affect the rate at which our revenues may grow.
- We operate in a highly competitive industry.
- We rely on some third parties to develop our pharmaceutical pipeline and conduct clinical trials.
- Clinical trials for the development of products may be unsuccessful.
- We depend on third-party payors for reimbursement for our products.
- The clinical study or commercial use of our products may cause unintended side effects.
- We face additional risks when we manufacture for others.
- We may fail to develop or acquire other new products or compounds.
- Acquisitions, partnerships, joint ventures, dispositions, and other business combinations or strategic transactions involve several inherent risks.
- We may be subject to adverse public opinion.
- Failure to retain key personnel or attract new personnel could have an adverse effect on us.
- We use hazardous materials in our manufacturing facilities.

Risks Related to Intellectual Property

- We may incur substantial costs as a result of intellectual property litigation or other proceedings.
- We may not be able to protect our intellectual property rights throughout the world.
- We may fail to obtain and maintain patents and protect other proprietary rights.
- Our employees may wrongfully use or disclose alleged trade secrets of their former employers.

Risks Related to Regulatory or Legal Matters

- The regulatory approval process is expensive, time-consuming, and uncertain.
- Regulatory agencies may impose limitations or post-approval requirements on our products.
- Guidelines published by professional societies, insurance carriers, physician groups, science foundations, and other organizations may affect the use of the Company's products.
- Product liability and product recalls could have a material adverse effect on us.
- We are subject to federal, state, local, and foreign healthcare laws and regulations.
- We may fail to comply with payment and reporting obligations under governmental pricing programs.
- We are subject to healthcare fraud and abuse, transparency, and false claims laws.
- We are subject to anti-corruption laws and regulations.
- The pharmaceutical industry faces significant government scrutiny regarding pricing and competition.

Risks Related to our Financial Condition and Tax Matters

- Recently proposed tariffs on pharmaceutical products, and potential reciprocal responses by other countries, may adversely affect our revenues or profitability.
- We are subject to macroeconomic trends in the markets where we operate.
- Any reduction in annual sales may adversely affect our liquidity.
- The recent pandemic and governmental and societal responses thereto have adversely affected our business and may continue to do so.
- Our insurance coverage may not be adequate.
- Our $350 million term loan contains covenants that could limit our ability to plan for or respond to changes in our business.
- We may not be able to generate sufficient cash to service all of our indebtedness.
- Our effective tax rate may increase, and changes in tax rules and regulations, or interpretations thereof, may adversely affect our financial condition.
- Our deferred tax assets may not be realized.
- If a U.S. person is treated as owning at least 10% of our ordinary shares, such holder may be subject to adverse U.S. federal income tax consequences.

Risks Related to Our Ordinary Shares

- Our ordinary shares are subject to market price volatility.
- Our ordinary shares are listed to trade on more than one stock exchange, and this may result in price variations.
- The rights afforded to our shareholders are governed by English law.
- Provisions of our Note Purchase Agreement and the U.K. City Code on Takeovers and Mergers may delay or prevent an otherwise beneficial takeover attempt of us.
- Our business strategy may involve transactions which may dilute existing shareholders' interests.
- Securities or industry analysts may fail to publish research or may publish inaccurate or unfavorable research about our business.
- We may not pay dividends in the future.
- We are a holding company with no business operations of our own and depend on our subsidiaries for cash, including in order to pay dividends.

Risks Related to Information Security and Data Privacy

- We are at risk for business interruptions or breaches of data security.
- We are required to maintain the privacy and security of personal information.

Risks Related to Our International Status and Operations

- We are subject to various risks related to the local and international nature of our business.
- We are exposed to risks related to currency exchange rates.

Risks Related to Being a Publicly Traded Company in the U.S.

- We may fail to maintain effective internal controls over financial reporting.
- We are a foreign private issuer and expect to lose our foreign private issuer status in the future.
- We have changed to U.S. generally accepted accounting principles.
- We are subject to risks related to changes in accounting standards, assumptions, and estimates.
- The obligations associated with being a public company in the U.S. are significant.

Risks Related to our Company and Its Business

We are currently, in the past have been, and in the future may be, subject to substantial litigation that could cause us to incur significant legal expenses, divert management's attention, and result in harm to our business.

We have been, and may in the future become, involved in various legal proceedings, regulatory proceedings, and government enforcement actions. Such proceedings may include claims for, or the possibility of, damages or fines and penalties involving substantial amounts of money or other relief, including but not limited to civil or criminal fines and penalties. For example:

- In 2019, the U.S. Attorney's Office for the Western District of Virginia brought an indictment, followed by a superseding indictment, against the Company in connection with our marketing and promotional practices related to SUBOXONE Film and SUBOXONE and SUBUTEX Tablets (the "2019 Indictment"). The indictment charged Indivior Inc. and Indivior PLC with health care fraud, mail fraud, wire fraud, and conspiracy to commit the same. It generally alleged that the Company had falsely represented that SUBOXONE film was safer and less susceptible to misuse, abuse, diverse, and inadvertent pediatric exposure than SUBOXONE tablets, purportedly to delay approval of generic versions of SUBOXONE tablets and retain market share. Pursuant to a Resolution Agreement made on July 24, 2020 as part of a global resolution with the U.S. Attorney's Office for the Western District of Virginia, the DOJ's Consumer Protection Branch, the FTC, and several U.S. state attorneys general, an indirect wholly owned subsidiary of Indivior PLC pleaded guilty to a single count of making false statements relating to healthcare matters in 2012 (the "Resolution Agreement"). The DOJ dismissed all charges in the indictment, and the Company agreed to a total of $600 million in fines, and agreed to substantial reporting and compliance obligations related to its U.S. operations, among other things. The Resolution Agreement is filed as Exhibit 10.2 to this annual report.

- In January 2021, the Company announced it had reached an agreement with Reckitt Benckiser Group plc ("RB") to resolve claims that RB issued in the Commercial Court in London in November 2020, seeking indemnity under the Demerger Agreement entered into on November 17, 2014 between RB and Indivior to effect the Demerger and to govern the relationship between RB and the Company following the Demerger. Pursuant to the settlement, RB agreed to withdraw its $1.4 billion claim and to release the Company from any claim for indemnity under the Demerger Agreement relating to the DOJ and FTC settlements that RB entered into in July 2019, as well as other claims for indemnity arising from those matters. The Company agreed to pay RB a total of $50 million and released RB from any claims to seek damages relating to the Company's settlement with the DOJ and the FTC.

- In July 2022, the Company settled antitrust, patent infringement, and wrongful injunction claims with the manufacturer of a generic buprenorphine/naloxone film drug product for approximately $72 million and approximately $15 million for similar claims made by a second manufacturer of such a generic film drug product in October 2023.

- During 2023, Indivior Inc. settled civil antitrust cases filed by a class of direct purchasers, a class of end payors, and 41 states and the District of Columbia that had been consolidated in multi-district litigation pending in the U.S. District Court for the Eastern District of Pennsylvania (the "Antitrust MDL") for $385 million, $30 million, and $103 million, respectively. During 2024, Indivior settled state-court cases in Virginia, Kentucky, and Pennsylvania with all of the remaining insurance companies who had asserted claims similar to those asserted in the Antitrust MDL but opted out of the Antitrust MDL end payor class for a combined total of $125 million, payable through December 2025.

We are also subject to several significant unresolved matters. For example,

- The Company has been named as a defendant in more than 400 civil lawsuits alleging that manufacturers, distributors, and retailers of opioids engaged in a longstanding practice to market

opioids as safe and effective for the treatment of long-term chronic pain to increase the market for opioids and their own market share, or alleging individual personal injury claims (the "Opioid MDL"). Most of these cases have been consolidated and are pending in a federal multi-district litigation in the U.S. District Court for the Northern District of Ohio. Nearly two-thirds of the cases in the Opioid MDL were filed by cities and counties, while nearly one-third of the cases were filed by private plaintiffs, most of whom assert claims relating to neonatal abstinence syndrome ("NAS"). Pursuant to mediation, the Company reached agreement on the amount of a potential settlement. However, the parties still must negotiate material terms and conditions of the final settlement agreement, including the structure and scope of the release. The proposed settlement would resolve claims by cities and counties, but would not resolve private plaintiff cases against the Company and would not resolve claims brought outside of the MDL.

- the Company has been named as a defendant in numerous lawsuits alleging that SUBOXONE Film was defectively designed and caused dental injury, and that the Company failed to properly warn of the risks of such injuries. The plaintiffs generally seek compensatory damages, as well as punitive damages and attorneys' fees and costs. These lawsuits and claims follow a June 2022 required revision to the Prescribing Information and Patient Medication Guide about dental problems reported in connection with buprenorphine medicines dissolved in the mouth to treat opioid use disorder. This revision was required by the FDA of all manufacturers of these products. Applications to file class actions based on similar allegations as in the Dental MDL, but also relating to SUBOXONE Tablets, were filed in Quebec and British Columbia against various subsidiaries of the Company, among other defendants, in April 2024. Product liability cases such as these typically involve issues relating to medical causation, label warnings and reliance on those warnings, scientific evidence and findings, actual/provable injury and other matters.

- On September 21, 2022, certain shareholders issued representative and multiparty claims against Indivior PLC in the High Court of Justice for the Business and Property Courts of England and Wales, King's Bench Division (the "High Court"). The claims made in both the representative and multiparty actions generally allege that Indivior PLC violated the U.K. Financial Services and Markets Act 2000 ("FSMA 2000") by making false or misleading statements or material omissions in public disclosures, including the 2014 Demerger Prospectus, regarding an alleged product-hopping scheme regarding the switch from SUBOXONE Tablets to SUBOXONE Film. On December 5, 2023, the High Court handed down a judgment allowing the Company's application to strike out the representative action. This decision was affirmed by the court of appeals on January 23, 2025. On February 20, 2025, the claimants notified the Company that they intend to appeal the judgment in the representative action to the U.K. Supreme Court. The multi-party proceeding remains pending.

The amount of time that is required to resolve legal or regulatory proceedings is unpredictable and any litigation or claims against us, even those without merit, may cause us to incur substantial costs, divert management's attention from the day-to-day operation of our business, and materially harm our stock price and reputation. In addition, we are obligated to indemnify and advance expenses to certain individuals and entities involved in certain of these and related proceedings. Any adverse judgment in or settlement of any pending or any future litigation could result in significant payments, fines and penalties that could have a material adverse effect on our business, results of operations, financial condition and reputation.

Moreover, the outcome of these legal proceedings may differ from the Company's expectations because the outcomes of litigation, including regulatory matters, are often difficult to reliably predict. Although the Company maintains general liability insurance, the amount of liability that may result from certain of these risks may not be covered by, or could exceed, the applicable insurance coverage. See "*Our insurance coverage may not be adequate,*" below. Various factors or developments can lead the Company to change current estimates of liabilities and, to the extent applicable, related insurance receivables, or make such estimates for matters previously not susceptible of reasonable estimates, such as a significant judicial ruling or judgment, a significant settlement, significant regulatory developments or changes in applicable law. A future adverse ruling, settlement or unfavorable development could result in future charges that could have a material adverse effect on the Company's results of operations or cash flows in any

particular period. In addition, negative publicity related to these proceedings may negatively impact the Company's reputation.

For a more detailed discussion involving the Company's legal proceedings and associated accounting estimates, see *Item 8. Financial Statements—Audited Consolidated Financial Statements - Note 16. Commitments and Contingencies* of this Report, especially at the captions "Civil Opioid Litigation" and "Dental Allegations" which provide information regarding additional matters that we believe may be significant to the Company as of the date of the filing of this annual report.

We rely on third parties to manufacture, package, test, and distribute our products and their facilities and processes must meet stringent regulatory requirements.

The Company relies almost exclusively on third parties, including contract manufacturing organizations, to manufacture, package, test, and distribute our products. The manufacturing of our products, which include oral solid dose tablet products, film products, a nasal spray product, and terminally sterilized and aseptically filled injectables, is subject to stringent global regulatory, quality, and safety standards, including current Good Manufacturing Practice ("cGMP"). Some of our products, including SUBOXONE Film, SUBLOCADE long-acting injectable, and OPVEE nasal spray, are significantly more complicated to manufacture than tablet products. We have limited control over the performance of our third-party manufacturers and are currently dependent on our third-party contract manufacturing partners whom we manage via supply and quality agreements.

Similarly, the Company relies on a third-party logistics vendor and a network of specialty pharmacists and specialty distributors to fulfill orders and distribute our products in the U.S. and logistics and distribution partners to distribute our products worldwide. This process is complicated because most of our products contain controlled substances that require special handling, such as import and export permits, adherence to a risk evaluation and mitigation strategy ("REMS") protocol, and import restrictions on controlled substances. See also, Item 1A. Risk Factors—"*We are subject to additional risks because we import, manufacture, and distribute controlled substances.*"

We or our third-party manufacturers may encounter difficulties in production, such as issues with production costs and yields, process controls, quality control, and quality assurance, including testing of stability, impurities and impurity levels, sterility, and other product specifications by validated test methods, compliance with strictly enforced global and regional regulations, and disruptions or delays caused by man-made or natural disasters, pandemics or epidemics, or other business interruptions, including, for example, pandemics and government responses thereto. In November 2023 we purchased an approximately 80,000 square foot facility in Raleigh NC (the "Raleigh Manufacturing Facility") to provide additional manufacturing capacity. Once validated and given regulatory approval, it should meet anticipated demand for the next several years. However, there can be no assurance that such efforts will be successful. If such efforts are successful, we presently expect to begin production there in 2026 and potentially to begin realizing cost savings in 2027. To the extent we do not have redundant manufacturing capacity, we may suffer supply disruptions which would reduce growth in our net revenues and in turn have a material adverse effect on our business, financial condition, and results of operations.

If we or any of our third-party manufacturers cannot successfully manufacture material that conforms to our specifications and the applicable regulatory authorities' strict regulatory requirements or pass regulatory inspection, we or our third-party manufacturers will not be able to ensure an adequate supply of products and/or secure or maintain regulatory approval for the manufacturing facilities. In addition, we have no direct control over the ability of third-party manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or any other applicable regulatory authorities do not approve these facilities for the manufacture of our products or if they withdraw any such approval in the future, or if the supply of our primary active ingredients or manufacture our products is somehow interrupted, we may need to find alternative manufacturing facilities, which may significantly impact our ability to develop, obtain regulatory approval for or market our products. To the extent our manufacturing facility or that of any third-party manufacturers that we engage with respect to our products are different from those currently being used for commercial supply in the U.S., studies will have to be completed, and the FDA will need to approve such facilities prior to our sale of any product manufactured using these facilities. Any delay or interruption

in our ability to meet commercial demand for our products will result in the loss of potential revenues and could adversely affect our ability to gain market acceptance for these products. In addition, any delay or interruption in the supply of clinical trial supplies could delay the completion of clinical trials, increase the costs associated with maintaining clinical trials, and, depending upon the period of delay, require us to commence new clinical trials at additional expense or terminate clinical trials completely, which in turn could have a material adverse effect on our business financial condition, and results of operations.

Compliance with the terms and conditions of our Corporate Integrity Agreement, the Resolution Agreement with the U.S. Attorney's Office for the Western District of Virginia and the U.S. Department of Justice ("DOJ")'s Consumer Protection Branch, and the Stipulated Order for Permanent Injunction and Equitable Monetary Relief with the U.S. Federal Trade Commission ("FTC"), along with a similar injunction with certain State Attorneys General, requires significant resources and management time and, if we fail to comply, we could be subject to criminal charges, penalties, or, under certain circumstances, excluded from government healthcare programs, which would materially adversely affect our business.

We operate on a global basis and the pharmaceutical industry is both highly competitive and highly regulated. Complying with all applicable laws and regulations, industry standards, and our Code of Conduct are core to the Company's mission, culture, and practices. The Company has policies and procedures to identify (e.g., through reporting of concerns and monitoring), analyze and investigate potential or actual violations of law, regulation, or policy and, if necessary, take appropriate remedial or corrective actions. Effective procedures and controls assist in helping to ensure that we provide reliable information and prevent and detect potential fraud or misconduct. Failure to comply with applicable laws and regulations may subject the Company to civil, criminal, and administrative liability, including but not limited to the imposition of substantial monetary penalties, fines, damages and restructuring of the Company's operations through the imposition of compliance or integrity obligations, and have a potentially adverse impact on the Company's prospects, reputation, results of operations and financial condition.

In 2020, Indivior Inc. entered into a Corporate Integrity Agreement ("CIA") with the U.S. Department of Health and Human Services Office of the Inspector General ("HHS-OIG") which expires in July 2025, provided however that certain provisions of the CIA may continue for up to 120 days after HHS-OIG's receipt of: (a) Indivior Inc's final Annual Report or (b) any additional materials requested by HHS-OIG, whichever is later. The CIA was part of the Company's resolution of federal criminal and civil charges related to our film and tablet products. In particular, the 2019 Indictment charged Indivior Inc. and Indivior PLC with health care fraud, mail fraud, wire fraud, and conspiracy to commit the same. The 2019 Indictment generally alleged that the Company had falsely represented that SUBOXONE Film was safer and less susceptible to misuse, abuse, diversion, and inadvertent pediatric exposure than SUBOXONE and SUBUTEX Tablets, purportedly to delay approval of generic versions of SUBOXONE tablets and retain market share. The 2019 Indictment were dismissed as part of a resolution agreement with the DOJ in which the Company did not admit to any wrongdoing, except that subsidiary Indivior Solutions, Inc. ("Solutions") pleaded guilty to a one-count felony information charging Solutions with making false statements to MassHealth (the administrator of Medicaid and the Children's Health Insurance Program (CHIP) in Massachusetts) in October 2012. The resolution agreement also settled civil claims alleging that the Company caused false claims to be submitted to government healthcare programs.

The CIA imposes significant compliance obligations on Indivior Inc.'s business and practices and requires Indivior Inc. to engage an Independent Review Organization and a Board Compliance Expert (in CIA years 1 and 3) to assess Indivior Inc.'s compliance program. The CIA also sets forth monetary penalties that may be imposed on a per-day basis for failure to comply with certain obligations in the CIA. The CIA requires procedures under which Indivior Inc. must notify HHS-OIG of certain reportable events, and must notify HHS-OIG if it fails to meet the requirements under the CIA. The CIA requires Indivior Inc. to file annual reports describing steps it has taken to implement the terms of the CIA, certifications from certain employees that their department or functional area is compliant with certain laws and regulations, and a certification from the Compliance Officer and Chief Executive Officer that Indivior Inc. is in compliance with the CIA, to the best of their knowledge. The CIA also requires an annual resolution from the Compliance, Ethics & Sustainability Committee (formerly known as the Nominating & Governance Committee) of the

Company's Board of Directors that it has reviewed the effectiveness of the Company's compliance program. In the event that HHS-OIG determines Indivior Inc. to be in material breach of certain requirements of the CIA, including, without limitation, repeated violations or any flagrant violation of the CIA, a failure by Indivior Inc. to report a reportable event and take corrective action, a failure to engage and use an independent review organization, among others, Indivior Inc. may be subject to exclusion from participation in the U.S. federal healthcare programs, which would have a severe impact on the Company's ability to comply with the financial covenants in the Company's term loan, maintain sufficient liquidity to fund its operations, generate future revenue, and would ultimately impact the Company's viability. Further, we expect to continue most of our compliance programs following the conclusion of the term of the CIA.

The Resolution Agreement imposes several significant compliance obligations on the Company, separate from the CIA, including without limitation certain reporting obligations and the requirement that the Company's Chief Executive Officer (a) certifies on an annual basis that, to the best of their knowledge, after a reasonable inquiry, the Company was in compliance with the U.S. Federal Food, Drug and Cosmetic Act (and implementing regulations) and has not committed healthcare fraud, or (b) provides a certified list of all non-compliant activities and steps taken to remedy the activity. The Resolution Agreement also requires an annual resolution from the Company's Board of Directors that it has reviewed the effectiveness of the Company's Compliance Measures set forth in Section I of Addendum A to the Resolution Agreement. A material breach of the Resolution Agreement could reinstate the indictment against the Company. Our obligations under the Resolution Agreement continue until December 2027, although we have the option to end the agreement after late 2025 by prepaying the remaining amount owed.

The FTC Stipulated Order contains specific notice and reporting requirements related to certain activities, including (i) notice of filing a Citizen Petition along with certain information; (ii) notice of filing of a New Drug Application for new drug formulations related to Indivior approved drugs, (iii) requirement to provide additional information about certain launch activities related to the new drug formulation; (iv) certain restrictions on pricing of the old drug formulations and activities regarding those old drug formulations for a period of time; (v) notice of FDA Approval of a drug or if Indivior Inc. obtains a drug through a license, acquisition or through obtaining control of an entity; (vi) notice of certain corporate activities such as a dissolution, merger, acquisition of Indivior Inc.; (vii) an obligation to provide the States (defined below) with certain information and interviews necessary to evaluate compliance with the Settlement Order; and (viii) an obligation to provide reports to the States explaining how Indivior has complied with the Settlement Order, if requested. The Company may be punished for contempt of court, including, but not limited to criminal contempt, if it fails to comply with any terms of the FTC Stipulated Order or Resolution Agreement. The obligations in the FTC Stipulated Order expire in November 2030.

Similarly, in June 2023, Indivior Inc. reached agreement with the Attorneys General of 41 States and the District of Columbia (the "States") to resolve allegations that Indivior Inc. violated the Sherman Act and laws of the States by engaging in anticompetitive activities designed to impede competition from generic equivalents of the brand-name drug SUBOXONE, which Indivior Inc. disputes. As part of the settlement, Indivior Inc. also agreed to certain compliance and reporting obligations under a Stipulated Final Judgment and Dismissal with Prejudice (the "Settlement Order"). These obligations are similar to those in the FTC Order. The obligations in the Settlement Order expire concurrently with those of the FTC Stipulated Order in November 2030.

The Company's policies, procedures and protocols are designed to prevent and detect failures to comply with the terms of the CIA, the Resolution Agreement, the FTC Order, and the Settlement Order; however, there can be no assurance that a relevant failure that bypasses established controls will be prevented or detected. Any failure to comply with such terms may subject the Company to criminal charges and penalties, or, under certain circumstances, could exclude the Company from U.S. government healthcare programs, which could have a material adverse effect on the Company's business, financial condition and results of operation.

Congressional action to reduce spending may result in cuts to Medicaid which in turn might impair access to our products in the U.S., thereby adversely affecting our revenues and results of operations.

Congress is considering proposals to enact significant cuts to Medicaid via its fiscal 2026 budget that may include as much as $880 billion in cuts from Medicaid and health spending projections over 10 years. Approval of such a budget does not mean immediate reductions in Medicaid but rather sets off a long legislative process. Many barriers remain to enacting major Medicaid cuts.

Any cuts in Medicaid may impair access to our products in the U.S., thereby adversely affecting our revenues and results of operations.

We are subject to additional risks because we import, manufacture, and distribute controlled substances.

Our key products in the U.S. for opioid use disorder, SUBLOCADE long-acting injectable extended-release injection, SUBOXONE Film sublingual film, and outside the U.S., SUBLOCADE (called SUBUTEX Prolonged Release in the EU), SUBOXONE and SUBUTEX sublingual tablets, contain the active ingredient buprenorphine, which is a controlled substance under the Controlled Substance Act (CSA) and similar laws in other countries. Buprenorphine is a partial agonist opioid. Compared to a full opioid agonist, buprenorphine has less maximal euphoric effect and a ceiling on its ability to cause respiratory depression. While we market these products only for the treatment of opioid use disorder, the use of any opioid is highly stigmatized. Many people who are non-prescribers may fail to distinguish between drugs of abuse and drugs intended for treatment. The lack of distinction between the types and mechanisms of opioids, like buprenorphine, versus other opioids which have indications for pain, is widely misunderstood. These perceptions and misunderstandings may cause a variety of problems for the Company, including adverse publicity and cause some persons or entities to decline to do business with us. See for example, Item 1A. Risk Factors—"*We may be subject to adverse public opinion,"* and —"*Failure to retain key personnel or attract new personnel could have an adverse effect on us."*

Products designed to treat drug addiction, by their nature, face additional risks. Drug addiction is a difficult environment in which to market our products. Societally, there is a stigma that prevents many persons who suffer from OUD or other types of addiction from coming forward to receive treatment because of potential reputational damage, societal scrutiny, and other factors. Patients with OUD often suffer from other co-morbidities, including poor general health and mental health issues like schizophrenia, which may impact one's understanding of the disease or affect their ability to obtain treatment. Similarly, drug addiction can result in job loss or unemployment, indebtedness, and criminal problems including incarceration which may make it more difficult for someone to obtain treatment. Other challenges include the misuse, diversion, or abuse of our products.

Regulators may impose additional requirements because of the nature of our products. Buprenorphine and products containing buprenorphine are classified as Schedule III controlled substances in the U.S. by the Drug Enforcement Agency (DEA) and similarly restricted by law enforcement authorities in the Most of World that are signatories to the WHO Single Convention on Narcotic Drugs (1961). Other molecules considered as product candidates, such as INDV-6001, may have more stringent classification (i.e., Schedule II) or ambiguous classifications.

Products containing opioids often require a risk evaluation and mitigation strategy (REMS) to mitigate potential risks which may be associated with the use of a product and to inform patients and prescribers of those risks. For example, the FDA requires a REMS for SUBLOCADE and SUBOXONE Film. The SUBLOCADE REMS restricts the distribution of the product so that SUBLOCADE is dispensed directly to certified healthcare settings and pharmacies for administration by a healthcare professional. This closed distribution system should help mitigate the risk related to the potential for misuse and diversion by the patient, since the product is not dispensed directly to the patient. Other products that we sell in the future may become subject to a REMS specific to the product or shared with other products in the same class of drug. The cost to implement the REMS may be high, which may in turn have a material adverse effect on our business, financial condition, and results of operations.

Individual states have also established controlled substance laws and regulations. Though state-controlled substance laws often mirror federal law, they may separately schedule our products or our product candidates as well. We or our partners may also be required to obtain separate state registrations, permits or licenses in order to be able to manufacture, distribute, administer or prescribe controlled substances for clinical trials or commercial sale, and a failure to meet applicable regulatory requirements could lead to enforcement and sanctions by the states in addition to those from the DEA or otherwise arising under federal law.

U.S. facilities conducting research, manufacturing, distributing, importing or exporting, or dispensing controlled substances must be licensed and must comply with the security, control, recordkeeping and reporting obligations under the CSA, DEA regulations, and corresponding state requirements. The ability to do so is considerably more difficult for molecules and product candidates with a Schedule I or II classification, or ambiguous classification. In addition, the DEA and state regulatory bodies conduct periodic inspections of certain registered establishments that handle controlled substances. Obtaining and maintaining the necessary registrations and complying with regulatory obligations may result in the delay of the importation, manufacturing, distribution or clinical research of our commercial products and product candidates. Furthermore, a failure to comply with CSA, DEA or state regulations by us or any of our third-party manufacturers can result in regulatory action, which can lead to criminal or civil penalties, the refusal to renew necessary registrations or proceedings to restrict, suspend or revoke applicable registrations.

A partial or total loss of revenue due to these delays or failure to comply with these regulations could have a material adverse effect on our business, results of operations and financial condition. Further, individual distributors and pharmacies may have their own legal, regulatory or business policy requirements that could impose restrictions or limits the distribution of prescription products. A partial or total loss of revenue from one or more such shipments could have a material adverse effect on our business, results of operations and financial condition.

We are subject to risks related to the manufacture and distribution of our products globally and must meet stringent current Good Manufacturing Practices.

All facilities and manufacturing techniques used for the manufacture of our products must be operated in conformity with the mandatory manufacturing standards (often referred to as current good manufacturing practice (cGMP)) of the FDA, the U.K. Medicines and Healthcare products Regulatory Agency (“MHRA”), the Irish Health Products Regulatory Authority (HPRA), and other regulatory authorities. Manufacturing facilities are subject to periodic unannounced inspections by the FDA, MHRA, HPRA, and other regulatory authorities. Failure to comply with applicable legal and regulatory requirements, and with the manufacturing details filed as part of our marketing authorization, subjects our manufacturing facilities or the facilities of our third-party manufacturers to possible legal or regulatory action, such as inspectional observations (e.g., Form FDA 483 notices), warning letters, suspension of manufacturing, product seizure, withdrawal of the product from the market, administrative, civil and criminal penalties, among other enforcement remedies. Therefore, such enforcement actions may adversely affect our ability to manufacture, or our third-party suppliers’ ability to supply, finished products.

For example, our Raleigh Manufacturing Facility was inspected by the FDA in January 2024 and July 2024 by two separate divisions (biologics, drugs) of the FDA regarding cGMP practices related to products we make for third parties. The FDA provided observations on its Form FDA 483, which is the document used by the FDA to highlight and summarize potential quality or regulatory issues or infractions at the end of each inspection. The observations were categorized as "Voluntary Action Indicated." We have responded to the FDA with a remediation action plan to address observations from both inspections and have completed all planned remediation actions.

Also, the manufacturing and distribution of our products globally are highly exacting and complex, due in part to strict regulatory and manufacturing requirements. Problems may arise during manufacturing and distribution for a variety of reasons, including but not limited to equipment malfunction, failure to follow specific protocols and procedures, testing nonconformities (e.g., sterility failure), failure to follow and provide oversight in cGMP, defective raw materials, product theft or diversion within our legal chain of

custody, restricted supply of raw materials or components due to geopolitical disruption or pandemic, and environmental factors.

Our manufacturing facilities, and those owned by third-party contract manufacturing organizations ("CMOs"), also maintain high direct and indirect labor costs due to the complexity of manufacturing processes, often requiring specialized personnel. As such internal labor costs are largely fixed, we are unable to offset such costs if we experience any interruptions or delays in the manufacturing process, product or regulatory approval delays or product suspensions or recalls. In addition, any significant personnel shortages at our manufacturing facilities, whether temporary or prolonged, may cause significant interruptions to our manufacturing facilities and to our supply of products. While some of these costs may be borne directly by third-party CMOs, we may also incur costs directly for additional safety stock and supplies, repairs, and capital expenditures for improvements, even if not required to do so contractually, or indirectly for lost sales. We may also suffer from lost sales as a result of stock outs. This is more pronounced outside the U.S. market where packaging and labeling batches for particular markets tend to be quite small, and require substantial lead time. Please refer to *"Item 1. Business—Manufacturing,"* for more information.

We have either a single or dual source of supply for the raw materials, product components, and drug products used in most of our marketed products, drug product candidates under development, and their respective APIs (including buprenorphine). Single sourcing puts us at risk of a potential interruption to supply in the event of manufacturing, quality or compliance difficulties. In the event of any supply chain disruption or product quality issues, our suppliers or third-party manufacturers may not have adequate contingency plans in place that enable them to continue to supply or manufacture our products within contractual deadlines or at all. If any of our suppliers or third-party manufacturers fails or refuses to supply us for any reason, it would take a significant amount of time and expense to implement and execute the necessary technology and design transfer to, and to qualify, a new supplier or manufacturer, as applicable. Often, as a general guide, this transfer time averages 36 months and is based on several factors. The FDA and similar international or national regulatory bodies must approve our filings which identify the manufacturers of the active and inactive pharmaceutical ingredients and certain packaging materials used in our products. If there are delays in qualifying new suppliers or facilities or a new supplier is unable to meet the FDA's or similar international regulatory body's requirements for approval, there could be a shortage of the affected products for the marketplace or for use in clinical studies, or both, which could negatively impact our anticipated revenues and could potentially cause us to breach contractual obligations with customers or to violate local laws requiring us to deliver the product to those in need. Any delay in supplying, or any failure or refusal to supply, products to, or delays in manufacturing by, our suppliers, or any catastrophe or natural or man-made disaster affecting such third-party manufacturing facilities or suppliers, could result in our inability to meet current and future state commercial demands for our products, which in turn could materially adversely affect our business, prospects, results of operations and financial condition. The Company's supply monitoring and contingency planning processes include proactive management of inventories throughout the supply-to-patient delivery process and initiatives to identify and qualify alternative sites and/or suppliers. Despite these mitigating measures, if major delays, interruptions, or quality events occur at those contracted suppliers, contracted manufacturers, or packaging organizations, the delivery of products to our patients could be significantly disrupted, which could materially adversely affect the sales of our products and accompanying revenues. Further, any interruption in supply could result in delays in meeting our contractual obligations and could damage our relationships with our licensees, including the loss of manufacturing and supply rights and/or revenues.

We receive substantial revenue from our key proprietary products and our success depends on our ability to successfully commercialize new products.

Historically, our business has been dependent on the sale of products containing buprenorphine. We developed SUBUTEX Tablets, SUBOXONE Tablets, SUBOXONE Film and SUBLOCADE for the treatment of OUD.

We have attempted to expand to other products that are not buprenorphine but the sales of those products have been limited compared to the sales of our buprenorphine products. For example, in October

2023, we launched OPVEE (nalmefene) nasal spray for the emergency treatment of known or suspected opioid 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. However, to date, sales of OPVEE have been limited. Also, in 2019, we launched commercial sales of PERSERIS, once-monthly subcutaneous extended-release injectable suspension of risperidone indicated for the treatment of schizophrenia in adults. However, on July 9, 2024 we announced that we would cease marketing PERSERIS.

Our oral buprenorphine products, including SUBOXONE Film, SUBOXONE Tablets, and SUBUTEX Tablets, are subject to substantial competition. Revenues from film and tablet products are declining. Further, we agreed in the Resolution Agreement to not employ a sales force to promote or sell SUBOXONE Film in the U.S., and we do not sell SUBOXONE or SUBUTEX Tablets in the U.S. As a result, sales of SUBLOCADE have become increasingly important to our revenue growth and financial results.

Our operating plan assumes that SUBLOCADE, SUBOXONE Film, SUBOXONE Tablets, and SUBUTEX Tablets will remain the treatment of choice for OUD patients who can benefit from MAT in the countries where we sell these products. There is no guarantee that we can maintain sales at or near historical levels, or that sales will continue to grow. In this regard, our ability to maintain or increase sales are subject to a number of risks and uncertainties including (i) competition from the introduction of branded competition or generic versions of our products; (ii) pricing pressure from, changes in policies by, or restrictions on reimbursement imposed by, third-party payors, including governments, and our ability to maintain adequate coverage and reimbursement for our products; (iii) increased rebates required to maintain access to our products; (iv) challenges to our intellectual property around SUBLOCADE; and (v) continued acceptance of SUBLOCADE by physicians and patients. In addition, Congress continues to consider various policy proposals that may result in pressure on the prices of prescription drugs in government healthcare programs in efforts to decrease government spending. See "*Congressional action to reduce spending may result in cuts to Medicaid which in turn might impair access to our products in the U.S., thereby adversely affecting our revenues and results of operations,*" above. Further, as organized health systems consolidate, in part due to private equity activity, we may be required to increase rebates, which would reduce the profitability of our products. Any significant negative developments relating to these risks could have a material adverse effect on our revenues from these products and, in turn, on our business, financial condition, cash flows and results of operations and the market price of our ordinary shares.

Further, the biopharmaceutical and biotechnology industries are characterized by rapidly advancing technologies. Our future success will depend in part on our ability to maintain a competitive position. If we fail to stay at the forefront of technological change to create and develop product candidates, we may be unable to compete effectively. Our competitors or technological change may limit the commercial value of our products or product candidates by advances in existing technological approaches or the development of new or different approaches, potentially eliminating the advantages of our proprietary products and product candidates.

Our ability to generate revenues from our products is subject to attaining significant market acceptance among physicians, other qualified HCPs, patients, specialty distributors, and healthcare payors and our ability to successfully develop and execute commercialization strategies for each of our products. Failure to do so would adversely impact our financial condition and prospects.

A substantial majority of our resources are focused on the commercialization of our current products. Our current products, and other products or product candidates that we may develop or acquire, may not attain market acceptance among physicians and other HCPs to administer our products, patients, specialty distributor, healthcare payors or the medical community. If any of our commercial strategies are unsuccessful or we fail to successfully modify our strategies over time due to changing market conditions, our ability to increase market share for our products, grow revenues and sustain profitability will be harmed.

Our success will also depend in large part on our ability to continue to successfully manufacture and commercialize new products in the complex markets into which they are sold.

For example, SUBLOCADE, approved in 2017 as the first once-monthly subcutaneous extended-release injectable suspension of buprenorphine. We initiated commercial sales of SUBLOCADE in 2018. It took us until 2020 before we reached $100 million in annual net revenues for SUBLOCADE. In the U.S., a competitor introduced its own subcutaneous extended-release injectable suspension of buprenorphine in 2023.

We believe the degree of market acceptance and our ability to generate revenues from our products depends on several factors, including:

- the timing of market introduction of our products as well as competitive products;
- our ability to manufacture in sufficient quantities in compliance with requirements of regulatory agencies and at acceptable quality and pricing levels in order to meet commercial demand and where applicable demand for samples;
- our ability to secure formulary approvals for products at a substantial number of targeted hospitals and Organized Health Systems ("OHSs") and criminal justice systems ("CJSs");
- our ability to implement and maintain agreements with wholesalers and distributors on commercially reasonable terms, and their performance, over which we have limited control;
- our ability to receive adequate levels of coverage and reimbursement for products from commercial health plans and government health programs;
- our ability to train, deploy and support qualified customer-facing field teams which include a sales force, a managed care team, account teams that target OHS and CJS, as well as a channel team;
- market demand for our products through our marketing and sales activities and other arrangements established for their promotion;
- the efficacy and safety of our products;
- potential or perceived advantages or disadvantages of our products over alternative treatments, including the cost of treatment and relative convenience and ease of administration;
- the prevalence of the disease or condition for which the product is approved and the projected growth of the markets in which our products compete;
- the effect of current and future healthcare laws and legislation and regulation controlling the conditions of treatment and the distribution of the products for OUD and overdose reversal treatments;
- our ability to increase overall public awareness of the opioid epidemic and approved treatments, as well as increasing access to BMAT treatments for patients via regulatory and legislative actions to increase access;
- the extent to which physicians diagnose and treat the conditions that our products are approved to treat, physicians' willingness to prescribe the product, and our ability to educate physicians with respect to new products;
- the prevalence and severity of any side effects;
- the price of our products, both in absolute terms and relative to alternative treatments, including the impact of past or expected future product price increases;
- the extent to which physicians and patients delay visits or writing or filling prescriptions for our products and the extent to which operations of healthcare facilities, including infusion centers, are reduced;
- product labeling or product insert requirements of the FDA or other regulatory authorities;

- the nature of any post-approval risk management plans mandated by regulatory authorities; see "*We are subject to additional risks because we import, manufacture, and distribute controlled substances*," above, and
- the convenience of prescribing, administrating and initiating patients on the product.

We have also had commercial products that have not yet been successful. For example, the FDA approved PERSERIS as the first once-monthly subcutaneous extended-release injectable suspension of risperidone indicated for the treatment of schizophrenia in adults in 2018. We launched commercial sales of PERSERIS in the U.S. in 2019. PERSERIS then faced increased competition four years later from a new competitor and a number of well-established competitors and could face additional competition in the future. On July 9, 2024, we announced that the Company would cease all sales and marketing activities related to PERSERIS. The decision was based on expectations regarding future pricing that suggested that PERSERIS would no longer be financially viable. As a result, we incurred charges for severance related to reduced headcount, manufacturing contract termination fees, and write-downs of inventory and equipment.

As for a product that is still relatively new in its launch, we recently devoted significant resources to acquire Opiant Pharmaceuticals, Inc. and its product, OPVEE, which the FDA approved in 2023. However, because most of the potential customers for OPVEE are incremental to the customers for our current OUD products, we may face challenges building a sales force and delivery network to serve these new customers. Our ability to realize the benefits from our acquisition of Opiant depends on our ability to successfully commercialize OPVEE. We launched OPVEE in October 2023 and to date have had only limited sales. If we are unsuccessful at convincing State authorities and first responders to increase their rate of adoption of OPVEE, our results of operations could suffer.

Any factors preventing or limiting the market acceptance or commercialization of our products could cause us to recognize charges as we did with PERSERIS and could have a material adverse effect on their sales and hence our business, results of operations and financial condition.

Revenues generated by sales of our products depend on the availability from third-party payors for reimbursement for our products and the extent of cost-sharing arrangements for patients (e.g., patient co-payment, co-insurance, and deductible obligations) and cost-control measures imposed, and any reductions in payment rate or reimbursement or increases in our or in patients' financial obligation to payors could result in decreased sales of our products and/or decreased revenues.

In both U.S. and non-U.S. markets, sales of our products depend, in part, on the availability of reimbursement from third-party payors such as state and federal governments, including Medicare and Medicaid in the U.S. and similar programs in other countries, managed care providers and private insurance plans. Deterioration in the timeliness, certainty and amount of reimbursement for our products, the existence of barriers to coverage of our products, increases in our financial obligation to payors, including government payors, limitations by healthcare providers on how much, or under what circumstances, they will prescribe or administer our products or unwillingness by patients to pay any required co-payments, or deductible amounts, could reduce the use of, and revenues generated from, our products and could have a material adverse effect on our business, financial condition, cash flows and results of operations.

The U.S. federal and state governments and private payors are under intense pressure to control healthcare spending even more tightly than in the past. Cost cutting is a key initiative of the current Administration and Congress is considering various proposals to reduce funding for the Medicare and Medicaid programs. These pressures are further compounded by consolidation among distributors, retailers, private insurers, managed care organizations, and other private payors, resulting in an increase in their negotiating power, particularly with respect to our products. In addition, these pressures are intensified by increased, adverse publicity about pricing for pharmaceuticals. These prices are sometimes characterized as excessive, leading to government investigations and legal proceedings regarding pharmaceutical pricing practices.

In the U.S., federal and state legislatures, health agencies and third-party payors continue to focus on containing the cost of healthcare, including by comparing the effectiveness, benefits and costs of similar treatments. Any adverse findings for our products may reduce the extent of reimbursement for our products. Economic pressure on state budgets may also result in states increasingly seeking to limit coverage or payment for drugs, including but not limited to price control initiatives, discounts and other pricing-related actions. Over the past several years, several states have enacted drug pricing transparency laws that require companies to report on drug price increases and justify how drug prices were set, and we expect additional state or federal drug pricing initiatives to be proposed and enacted in the future. In addition, state Medicaid programs are increasingly requesting that manufacturers pay supplemental rebates and require prior authorization by the state program for use of any drug.

For example, in the U.S. market, when generic versions of a product are available, payors may impose access restrictions on the branded product, such as requiring prior authorization, imposing high patient co-pays, or precluding coverage altogether. In some cases, similar restrictions might apply when a therapeutic alternative is available. In addition, when a new product is approved, the availability of government and private reimbursement, any applicable coverage restrictions and the amount of reimbursement are all uncertain. The prices for certain of our products, when commercialized, may be high compared to other pharmaceutical products. As a result, we may encounter difficulty in obtaining satisfactory pricing and reimbursement for our new products. The failure to obtain and maintain pricing and reimbursement at satisfactory levels for our products may adversely affect our results of operations and prospects.

We may also be adversely affected by disenrollments from government benefit programs such as Medicaid. At the start of the COVID-19 public health emergency (PHE), Congress enacted the Families First Coronavirus Response Act (FFCRA), which included a requirement that Medicaid programs keep people continuously enrolled through the end of the PHI, in exchange for enhanced federal funding. Primarily due to the continuous enrollment provision, Medicaid enrollment grew substantially compared to before the pandemic and the uninsured rate has dropped. However, as part of the Consolidated Appropriations Act (CAA), signed into law in December 2022, Congress de-linked the continuous enrollment provision from the PHE thus ending continuous enrollment on March 31, 2023. During the unwinding of the continuous enrollment provision, millions of people lost Medicaid which could reverse recent gains in coverage, which we believe impacted sales of SUBLOCADE in 2024, though not everyone who loses Medicaid will become uninsured and some persons will be eligible for re-enrollment. The new Congress, sworn in January 3, 2025, is considering various changes to Medicaid financing to reduce costs, which could lead to more individuals losing coverage. These proposals include including lowering the minimum 50% Federal Medical Assistance Percentage (FMAP) match rate, reducing Medicaid expansion matching rates, implementing Medicaid per capita caps, and imposing work requirements.

Managed care organizations continue to seek price discounts and, in some cases, impose restrictions on the coverage of particular drugs. Government efforts to reduce Medicaid expenses may lead to increased use of managed care organizations by Medicaid programs, which may in turn result in managed care organizations influencing prescription decisions for a larger segment of the population and a corresponding constraint on prices and reimbursement for our products. Further, the Inflation Reduction Act of 2022, or IRA, which, among other things, requires the HHS Secretary to negotiate, with respect to Medicare units and subject to a specified cap, the price of a set number of certain high-spend drugs and biologicals per year starting in 2026, penalizes manufacturers of certain Medicare Parts B and D drugs for price increases above inflation, and makes several changes to the Medicare Part D benefit, including a limit on annual out-of-pocket costs, and a change in manufacturer liability under the program that could negatively affect us. Indirect effects of the IRA impacted market pricing of PERSERIS, our once-monthly subcutaneous extended-release injectable suspension of risperidone indicated for the treatment of schizophrenia in adults which was a contributing factor that led to our decision announced on July 9, 2024 to discontinue marketing of PERSERIS and eliminate its sales force. Congress and the Administration continue to examine various policy proposals that may result in pressure on the prices of prescription drugs in government health programs.

Reimbursement guidelines and incentives provided to prescribing physicians by third party payors may have a significant impact on the prescribing physicians' willingness and ability to prescribe our products.

The demand for, and the profitability of, our products could be materially harmed if state Medicaid programs, the Medicare program, other healthcare programs in the U.S. or elsewhere, or third party commercial payors in the U.S. or elsewhere deny reimbursement for our products, limit the indications for which our products will be reimbursed, or provide reimbursement only on unfavorable terms.

As part of the overall trend toward cost containment, third party payors often require prior authorization for, and require reauthorization for continuation of, prescription products or impose step edits, which require prior use of another medication, usually a generic or preferred brand, prior to approving coverage for a new or more expensive product. Such restrictive conditions for reimbursement and an increase in reimbursement-related activities can extend the time required to fill prescriptions and may discourage patients from seeking treatment. We cannot predict actions that third party payors may take, or whether they will limit the access and level of reimbursement for our products or refuse to provide any approvals or coverage. From time to time, third party payors have declined to provide reimbursement for our products, and others may do so in the future.

Third party payors increasingly examine the cost-effectiveness of pharmaceutical products, in addition to their safety and efficacy, when making coverage and reimbursement decisions. We may need to conduct expensive pharmacoeconomic and/or clinical studies in order to demonstrate the cost-effectiveness of our products, and we are developing real-world evidence about the use of our products to provide information about the safety, effectiveness, of our products. If our competitors offer their products at prices that provide purportedly lower treatment costs than our products, or otherwise suggest that their products are safer, more effective or more cost-effective than our products, this may result in a greater level of access for their products relative to our products, which would reduce our sales and harm our results of operations. In some cases, for example, third party payors try to encourage the use of less expensive generic products through their prescription benefit coverage and reimbursement and co-pay policies. Because some of our products compete in a market with both branded and generic products, obtaining and maintaining access and reimbursement coverage for our products may be more challenging than for products that are new chemical entities for which no therapeutic alternatives exist.

Third party pharmacy benefit managers, or PBMs, other similar organizations and payors can limit coverage to specific products on an approved list, or formulary, which might not include all of the approved products for a particular indication, and to exclude drugs from their formularies in favor of competitor drugs or alternative treatments, or place drugs on formulary tiers with higher patient co-pay obligations, and/or to mandate stricter utilization criteria. Formulary exclusion effectively encourages patients and providers to seek alternative treatments, make a complex and time-intensive request for medical exemptions, or pay 100% of the cost of a drug. In addition, we engage with certain PBMs, other similar organizations and third party payors may exert negotiating leverage by requiring incremental rebates, discounts or other concessions from manufacturers in order to maintain formulary positions, which could continue to result in higher gross-to-net deductions for affected products to ensure patients have access to our products. Payors could decide to exclude our products from formulary coverage lists, impose step edits that require patients to try alternative, including generic, treatments before authorizing payment for our products, limit the types of diagnoses for which coverage will be provided or impose a moratorium on coverage for products while the payor makes a coverage decision. An inability to maintain adequate formulary positions could increase patient cost-sharing for our products and cause some patients to determine not to use our products. Any delays or unforeseen difficulties in reimbursement approvals could limit patient access, depress therapy adherence rates, and adversely impact our ability to successfully commercialize our products. If we are unsuccessful in maintaining broad coverage for our products, our anticipated revenue from and growth prospects for our products could be negatively affected.

In many countries outside the U.S., procedures to obtain price approvals, coverage and reimbursement can take considerable time after the receipt of marketing authorization. Many European countries periodically review their reimbursement of medicinal products, which could have an adverse impact on reimbursement status. In addition, we expect that legislators, policymakers and healthcare insurance funds in the EU member states will continue to propose and implement cost-containing measures, such as lower maximum prices, lower or lack of reimbursement coverage and incentives to use cheaper, usually generic,

products as an alternative to branded products, and/or branded products available through parallel import to keep healthcare costs down.

In Europe and many other countries, government-sponsored healthcare systems are the primary payors for healthcare expenditures, including payment for drugs. We expect that these countries will continue to act to reduce expenditure on drugs, including mandatory price reductions, patient access restrictions, suspensions of price increases, increased mandatory discounts or rebates, preference for generic products, reduction in the amount of reimbursement and greater importation of drugs from lower-cost countries. Any such cost-control measures would likely reduce our revenues. In addition, certain countries set prices by reference to the prices in other countries where our products are marketed. Thus, the inability to secure adequate prices in a particular country may not only limit the marketing of products within that country, but may also adversely affect the ability to obtain acceptable prices in other markets.

There can be no assurance that our products will obtain favorable reimbursement status in any country. The failure to obtain and maintain reimbursement, or an adequate level of reimbursement, for our products may have a material adverse effect on our business, prospects, results of operations and financial condition. See also Item 1A. Risk Factors—"*The pharmaceutical sector is facing increased government scrutiny from competition and pricing authorities around the world, and any failure to comply, may expose us to significant damages and commercial restrictions that can materially and adversely affect our business.*"

Our revenues may grow at a slower than expected rate or decrease due to many factors.

We cannot be assured that we will be able to maintain or increase sales of our products. Factors that may cause revenues from our products to grow at a slower than expected rate, decrease or cease altogether, include, among others:

- potential changes to government funding at the federal, state, and local levels;
- the perception of physicians and other members of the healthcare community as to our products' safety and efficacy relative to that of competing products and the willingness or ability of physicians and other members of the healthcare community to prescribe, dispense and/or administer, and patients to use, our products;
- unfavorable publicity concerning us, our products, similar classes of drugs or the industry generally;
- the cost-effectiveness of our products, the impact of price changes in the market, and the reimbursement policies of government and third-party payors;
- the cost and availability of raw materials necessary for the manufacture of our products;
- the successful manufacture of our products on a timely and cost-effective basis;
- the size of the markets for our products, and patient and physician satisfaction with our products;
- significant changes in the competitive landscape for our products, including any approval of generic versions of our products or other branded products that may compete with our products;
- adverse event information relating to our products or to similar classes of drugs;
- changes to the labels of our products, or of products within the same drug classes, to add significant warnings or restrictions on use;
- regulatory developments and actions related to the manufacture, commercialization or continued use of our products, including FDA actions such as the issuance of a REMS or warning letter, or conduct of an audit by the FDA or another regulatory authority in which a manufacturing or quality deficiency is identified;

- the extent and effectiveness of the sales, marketing and distribution support for our products, including our licensees' decisions as to the timing and volume of product orders and shipments, the timing of product launches, and product pricing and discounting;
- exchange rate valuations and fluctuations;
- U.S. and global political changes and/or instability, and any related changes in applicable laws and regulations, that may impact resources and markets for our products; and
- the potential negative impact of current and future healthcare laws and legislation and regulation controlling the conditions of treatment and the distribution of the product including, with respect to OUD or overdose reversal treatments, new governmental or regulatory guidelines or policies limiting the prescription of opioids to patients.

We operate in a highly competitive industry, which includes companies with greater resources, including larger R&D and sales organizations, and more experience working with large and diverse product portfolios, than us. The approval and launch of generic or branded products that compete with SUBLOCADE, SUBOXONE Film, SUBOXONE Tablet, and SUBUTEX Tablet could have a material adverse effect on our business, prospects, results of operations and financial condition.

The manufacture and sale of pharmaceuticals are highly competitive. We face competition from a number of sources, some of which may target the same indications as do our products and product candidates. As our competitors develop or market alternatives for the treatment of our target indications, our commercial opportunities may be reduced or eliminated.

Our competitors may have substantially greater financial, operational and human resources than we do. Companies with more extensive resources and larger research and development expenditures have a greater ability to fund clinical trials and other development work necessary for regulatory applications. There is also a risk that our competitors may launch competing products before we are able to complete all of the regulatory milestones required to launch our own product. Competitors may also have a greater ability to offer higher rebates, discounts, chargebacks or other incentives to gain commercial advantage, and may be more successful than us in acquiring or licensing new products for development and commercialization. Smaller or earlier-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies.

If any product that competes with one of our products or product candidates is approved, our sales of that product could decrease, the effect of which would be heightened by our product and geographic concentration, which could have an adverse impact on our business, prospects, results of operations and financial condition. For example, SUBLOCADE now faces competition from BRIXADI in the U.S., and OPVEE competes with Narcan® and other generic products and other types of overdose reversal drugs, discussed below. Our products also compete with various alternatives including oral buprenorphine, methadone, and other drugs indicated for OUD, and intravenous overdose reversal agents.

In addition, many pharmaceutical companies are able to deploy more personnel to market and sell their products than us. Each of our sales representatives is responsible for a territory of significant size. The continued growth of our current products and the launch of any future products may require the expansion of our sales force and sales support organization internationally and we may need to commit significant additional funds, management and other resources to the growth of our field organization. We may not be able to achieve any such necessary growth in a timely or cost-effective manner or at all or realize a positive return on our investment. Likewise, if our R&D organization is not appropriately sized to effectively develop our current pipeline and future pipeline projects, the commercial net present value of our current pipeline and any future pipeline projects may be diminished. This in turn could materially and adversely affect our business prospects, results of operations, and financial position. Critically, investment in a novel asset pipeline is required to ensure the sustainability of Indivior through the launch of new medicines as our existing products face increasing competition through generics and alternatives.

The pharmaceutical and biotechnology industries are also characterized by continuous product development and technological change. Our products could, therefore, be rendered obsolete or uneconomic through the development of new products with unique advantages (including, e.g., new chemical entities that may be safer, more effective or more convenient than our products) or by technological advances in manufacturing or production by our competitors. In particular, several of our branded products face competition from generic products in key markets as well as competition from alternative products or treatments. Among other things, competition could continue to require us to increase further the level of rebates and other offsets to gross revenues, particularly in our U.S. operations, and could impact potential volume growth of any particular product, which could reduce our net revenues and therefore our results of operations in future periods.

Branded Products

The introduction of branded products that compete with our products may lead to a loss of sales of our products and/or a decrease in the price at which our products can be sold. For example, SUBLOCADE is distributed primarily in the U.S., Australia, Canada, Finland, Israel, and Sweden. However, Camurus, in partnership with Braeburn Pharmaceuticals, Inc., in 2023 obtained FDA approval of its LAI buprenorphine product which now competes with SUBLOCADE in the U.S. Additionally, we expect that Camurus may eventually seek approval in Canada. Camurus' product is already well established in Sweden, Finland, Norway, and Australia, and is available in additional countries. We are seeing more dual prescribing HCPs, and we believe this trend will continue as HCPs obtain familiarity with both medications. Any of the foregoing competitive developments could have a material adverse effect on our business, prospects, results of operations and financial condition. Among other things, developments of this nature have in the past, and could in the future, require the Company to increase further the level of rebates and discounts and other offsets to gross revenues, particularly in its U.S. operations, as well as impact potential volume growth of any affected products, which, in turn, could reduce net revenues and, therefore, its results in future periods.

In addition, we could face competition even where we have patent protection. As noted above, Camurus developed an alternative to our product that ostensibly uses technology which does not infringe our patents. Alternatively, a competitor might seek to compete by asserting that our patent is either invalid, not infringed by their product, or not enforceable. Patients and HCPs may also use alternatives to our products, such as methadone.

Similarly, OPVEE (nalmefene) nasal spray competes against branded and generic naloxone nasal sprays, including Narcan® (naloxone HCl) Nasal Spray 4 mg (which is available without a prescription), along with 4 mg naloxone generic equivalents, and Kloxxado® (naloxone HCl) Nasal Spray 8 mg, as well as naloxone or nalmefene administered by syringe.

Generic Products

The introduction of generic products typically leads to a loss of sales of the branded product and/or a decrease in the price at which branded products can be sold, particularly when there is more than one generic product available in the market. In addition, legislation enacted in the U.S. allows for the dispensing of generic products and, in some instances, the dispensing of generic products rather than branded products may be required (in the absence of specific instructions from the prescribing physician). If we fail to obtain or maintain adequate patent protection, we may not be able to prevent third parties from launching generic or biosimilar versions of SUBLOCADE.

Our SUBOXONE Film product has faced four generic competitors in the U.S. for some time, and we expect a fifth competitor in early 2025. We have seen our market share of film decline from greater than 50% in 2018 to an average share of 16% in 2024 and expect further declines as other competing products become available or if existing participants choose to disrupt the market in line with industry analogs. Additionally, we no longer promote SUBOXONE Film in the U.S. and no longer sell or market our SUBUTEX Tablets and SUBOXONE Tablets in the U.S. Where we sell out tablet products globally, we generally face generic competition. For a detailed discussion of the competition that we face with respect to our current marketed products, technology platforms and product indications, please see the section entitled

"Competition" in "*Item 1. Business*" in this annual report. If we are unable to compete successfully in this highly competitive industry, our business, financial condition, cash flows and results of operations could be materially adversely affected.

Most of our pharmaceutical pipeline relies on collaborations with third parties, which may adversely affect the development and sale of our products.

We depend on alliances with other companies, including pharmaceutical and biotechnology companies, vendors and service providers, for the development of a portion of the products in our pharmaceutical pipeline and for the commercialization and sales of certain of our commercial products. For example, we have collaborations with third parties under which we share development rights, obligations and costs and/or commercial rights and obligations. See "*Item 1. Business Overview—Pipeline*."

Our agreements with development partners typically require substantial up-front investments, potential milestone or option payments, and royalties on net sales to the development partner. For example, through our agreements with multiple collaboration partners, we have aggregate potential financial obligations of up to approximately $98 million upon the completion of all development milestones and additional potential financial obligations of an aggregate of $252 million if all sales milestones are met. Development milestones generally are payable upon the attainment of certain milestones towards and including the approval of a new product and by definition would be triggered if at all prior to the sale of such products. Sales milestones are payable upon the attainment of specified commercial sales levels. Similarly, we have potential obligations of up to $68 million in connection with a Contingent Value Agreement entered into in connection with the acquisition of Opiant Pharmaceuticals, Inc., a Delaware corporation ("Opiant") based upon future sales of OPVEE reaching certain levels. See "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations—*B. Liquidity and Capital Resources,*" at the caption "*CVR Agreement*." While these payments, if triggered, would require substantial resources, at the same time they reflect increased value of products or potential products as development or sales milestones are attained.

Also, failures by these parties to meet their contractual, regulatory, or other obligations to us or any disruption in the relationships between us and these third parties, could have a material adverse effect on our pharmaceutical pipeline and business. In addition, our collaborative relationships for R&D and/or commercialization and sales often extend for many years and have given, and may in the future give, rise to disputes regarding the relative rights, obligations and revenues of us and our collaboration partners, including the ownership or prosecution of intellectual property and associated rights and obligations. This could result in the loss of intellectual property rights or protection, delay the development and sale of potential pharmaceutical products, affect the effective sale and delivery of our commercialized products and lead to lengthy and expensive litigation, administrative proceedings or arbitration.

There is also a trend in the specialty pharmaceutical industry of seeking to "outsource" drug development by acquiring companies with promising drug candidates. We face substantial competition from historically innovative companies, as well as companies with greater financial resources than us, for such acquisition targets.

In addition, we rely on contract research organizations and other third parties to assist in managing, monitoring and otherwise carrying out our clinical trials, including with respect to site selection, contract negotiation and data management. We do not control these third parties and, as a result, may not be able to prevent delays, interruptions, or other issues with respect to the clinical trials conducted by such third parties. They may fail to perform their contractual duties, comply with regulations or meet expected deadlines. If we, contract research organizations, our clinical investigators, or other third parties assisting us or our study sites fail to comply with applicable GCP requirements, the clinical data generated in the relevant clinical trials may be deemed unreliable and the FDA or its non-U.S. counterparts may require us to perform additional clinical trials before approving our marketing applications.

Clinical trials must be conducted with products manufactured, labeled and supplied under the FDA's and non-U.S. regulatory agencies' cGMP regulations and in strict compliance with local regulatory requirements (e.g., compliance with Investigational New Drug (IND) application in the U.S. and Clinical Trial Application (CTA) in Europe. Our failure, or the failure of third parties conducting clinical trials on our behalf,

to comply with these regulations may require us to repeat or redesign clinical trials, which would delay the regulatory approval process or expose us to regulatory sanctions.

If our clinical trials do not meet regulatory requirements, or if the third parties conducting our clinical trials need to be replaced, our clinical trials may be extended, delayed, suspended or terminated. In addition, any delay or interruption in the supply of clinical trial supplies could delay the completion of clinical trials, increase the costs associated with maintaining clinical trials, and, depending upon the period of delay, require us to commence new clinical trials at additional expense or terminate clinical trials completely. If any of these events occur, we may not be able to obtain regulatory approval for our product candidates or succeed in our efforts to create approved line extensions for our existing products or generate additional useful clinical data in support of these products, which would adversely affect our business, prospects, results of operations and financial condition.

See also Item 1A. Risk Factors—"*If we fail to develop or acquire other new products or compounds for development, our business, prospects, results of operations and financial condition could be materially adversely affected.*"

Clinical trials for the development of products, including our key pipeline products, may be unsuccessful and our product candidates may not receive authorization for manufacture and sale.

Before obtaining regulatory approvals for the commercial sale of each product under development, we must demonstrate, through pre-clinical, clinical and other studies, that the product is safe and effective for the claimed use or uses, and also demonstrate that the product is of appropriate quality. No assurance can be provided that a clinical study will demonstrate that a particular product candidate safely provided hypothesized benefits.

Our lead development products are INDV-2000 (selective orexin-1 receptor antagonist) for which two Phase 1 clinical trials (single and multiple ascending dose studies) have been completed and for which we initiated a clinical Phase 2 proof-of-concept study in the second quarter of 2024; and INDV-6001 (buprenorphine based LAI) for which we initiated a multiple-dose pharmacokinetic Phase 2 clinical study in the third quarter of 2024. However, the results from early clinical trials may not be indicative of results obtained in later and larger clinical trials, and therefore these product candidates may fail to show the desired safety and efficacy in later clinical trials despite having progressed successfully through initial clinical testing. In that case, the FDA or the equivalent regulatory authority in jurisdictions outside the U.S. may determine that our data are not sufficiently compelling to warrant marketing approval and may require us to engage in additional clinical trials or provide further analysis which may be costly and time-consuming and substantially delay the receipt of such regulatory approval, which may delay the launch of any potential product or ultimately decline to provide approval.

Also, the development process takes many years and can be very expensive. Many companies in the pharmaceutical industry have suffered significant setbacks in drug development and there can be no guarantee that FDA approval will ultimately be obtained for any given product. The number and duration of pre-clinical studies and clinical trials that are required vary depending on the product candidate, the indication being evaluated, the trial results and the regulations applicable to the particular product candidate. Such clinical and other studies can be delayed or halted for a variety of reasons, including:

- challenges in identifying clinical development pathways, including appropriate clinical trial protocol design, particularly where there is no regulatory precedent;
- delays or failures in obtaining regulatory authorization to commence a trial because of safety concerns of regulators relating to our product candidates or similar product candidates of our competitors or failure to follow regulatory guidelines;
- delays or failures in obtaining clinical materials and sufficient quantities of the product candidate for use in trials;
- delays or failures in reaching an agreement on acceptable terms with prospective study sites;

- delays or failures in obtaining approval of our clinical trial protocol from an institutional review board or ethics committees to conduct a clinical trial at a prospective study site;
- delays in identifying, recruiting, or enrolling patients to participate in a clinical trial;
- failure of clinical investigators to comply with FDA and other regulatory agencies' good clinical practice ("GCP") requirements;
- unforeseen safety issues, including negative results from ongoing pre-clinical studies and adverse events associated with product candidates;
- inability to monitor patients at multiple study sites adequately during or after treatment;
- disagreements with collaborative partners on the planning and execution of product development; or
- insufficient funds to complete the trials.

For example, regulatory approval to conduct clinical studies for one of our non-opioid OUD treatments was delayed due to a clinical hold originating with FDA's concerns related to a third-party's product, rather than our own product. Also, in September 2024, following a Phase II clinical trial that failed to meet its primary endpoint, we made the decision to not exercise our option for AEF0117, a synthetic CB1-specific signaling inhibitor, which we had acquired in June 2021 from the French company Aelis Farma.

We rely on clinical investigators and clinical sites to enroll patients and sometimes third parties to manage our trials and to perform related data collection and analysis. However, while we can set certain contractual expectations, we may be unable to control the amount and timing of resources that the clinical sites which conduct the clinical testing may devote to our clinical trials.

Our clinical trials also may be delayed or terminated due to the inability of our clinical investigators to enroll enough qualified patients. Patient enrollment depends on many factors, including the size of the patient population, the nature of the trial protocol, the proximity of patients to clinical sites and the eligibility criteria for the trial. If our clinical investigators and clinical sites fail to enroll a sufficient number of patients in our clinical trials or fail to enroll them on our planned schedule, we may face increased costs, delays or termination of the trials, which could delay or prevent us from obtaining regulatory approvals for our product candidates.

Our agreements with clinical investigators and clinical sites for clinical testing and for trial management services place substantial responsibilities on these parties, which could result in delays in, or termination of, our clinical trials if these parties fail to perform as expected. For example, if any of our clinical trial sites fail to comply with FDA-approved GCPs, we may be unable to use the data gathered at those sites. If these clinical investigators, clinical sites or other third parties do not carry out their contractual duties or obligations or fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to their failure to adhere to our clinical protocols or for other reasons, our clinical trials may be extended, delayed or terminated, and we may be unable to obtain regulatory approval for, or successfully commercialize, our product candidates.

The clinical study or commercial use of our products may cause unintended side effects or adverse reactions, or incidents of misuse may occur, which could adversely affect our products, business and share price.

The administration of drugs to humans carries the inherent risk of product liability claims whether or not the drugs are actually the cause of an injury. Our products may cause, or may be perceived to have caused, injury or clinically significant drug interactions or may produce undesirable or unintended side effects, and we may not learn about or understand those effects until the products have been administered to study participants or patients for a prolonged period of time. Additionally, incidents of product misuse may occur. We cannot be certain that the clinical or commercial use of our products will not produce undesirable or unintended side effects that have not been evident in the use of, or in clinical trials conducted for, such

products to date. Risks can vary widely based on individual health conditions, demographics, and concurrent medications. Indivior follows strict regulatory guidelines and quality standards to ensure the safety and efficacy of our products via ongoing monitoring, including post-marketing safety surveillance.

For example, the Company has been named as a defendant in numerous lawsuits alleging that SUBOXONE Film was defectively designed and caused dental injury, and that the Company failed to properly warn of the risks of such injuries. See *Item 8. Financial Statements—Audited Consolidated Financial Statements - Note 16. Commitments and Contingencies*. Product liability cases such as these typically involve issues relating to medical causation, label warnings and reliance on those warnings, scientific evidence and findings, actual/provable injury and other matters. These lawsuits and claims followed required revision in the U.S. to the Prescribing Information and Patient Medication Guide about dental problems reported in connection with buprenorphine medicines dissolved in the mouth to treat opioid use disorder. This revision was required by the FDA of all manufacturers of these products. See Item 1A. Risk Factors—*"The FDA, the DEA, or other regulatory agencies may impose limitations or post-approval requirements on approvals for our products"* and *"Product liability and product recalls could have a material adverse effect on us,"* below.

Additionally, simply sponsoring a clinical trial carries with it exposure for other tort liability. It is possible that an unrelated product or procedure required to be performed as part of the protocol for our clinical trial could cause harm or be perceived to cause harm to a subject, due to an adverse reaction or otherwise. In that case, we could be seen as being at fault because we sponsored the clinical trial and designed the protocol that required that the product be used or procedure be done.

These events, among others, could result in product recalls or additional regulatory controls (including additional regulatory scrutiny and requirements for additional labeling or risk mitigation measures) or product liability claims. If there is a liability finding, various factors could affect reimbursement of payment by insurers, including (i) the scope of the insurers' purported defenses and exclusions to avoid coverage, (ii) the outcome of negotiations with insurers, (iii) delays in or avoidance of payment by insurers and (iv) the extent to which insurers may become insolvent in the future. Additionally our product liability insurance coverage may be inadequate to satisfy liabilities that arise and we may be unable to obtain adequate coverage at an acceptable cost. This could prevent or limit the development or commercialization of our products. In addition, the reporting of adverse drug reactions and product quality complaints involving our products, including instances of product misuse, and public rumors about such events could cause our product sales or share price to decline or experience periods of volatility. These types of events could have a material adverse effect on our business, financial condition, cash flows and results of operations.

We face additional risks as a manufacturer that manufactures pharmaceutical products for others and, in the future, for ourselves.

With the 2023 purchase of our Raleigh Manufacturing Facility, we assumed obligations to manufacture drugs and other products for third parties. We purchased the Raleigh Manufacturing Facility with a view towards eventually manufacturing some of our products there in order to ensure supply security. There may also be potential to improve manufacturing costs. However, before doing so, we will need to (i) perform our obligation under existing contracts and meet related regulatory requirements with respect to those products, and (ii) invest in additional capital equipment and testing before we can secure our long-term supply. As a result, we face additional risks, and the risks discussed in this report may apply to both our business as well as our activities as a contract manufacturer of products for others.

a. *Onerous contracts*. In connection with our acquisition of the Raleigh Manufacturing Facility, the Company assumed onerous contracts and carries a provision of $6 million. The facility continues to manufacture products for customers based on the terms of contracts that existed pre-acquisition and the expected costs to fulfill these contracts are in excess of the economic benefits expected to be received by the Company. We expect the minimum performance period in the onerous contracts to have ended by June 30, 2025.

b. *Expected operating losses*. In addition to the provision for onerous contracts which we recognized at the time of acquisition, we expect to incur incremental operating costs over the next year for items such

as depreciation of excess capacity, incremental compensation expense from additional headcount, and incremental information technology and other expenses, resulting in expected operating losses for the Raleigh Manufacturing Facility.

c. *Expected investment in capital equipment.* In order to produce Indivior products at the Raleigh Manufacturing Facility, we will need to invest in the build-out of an aseptic syringe filling suite with supporting manufacturing process equipment and warehouse expansion that will need to be qualified, followed by the technology transfer of our manufacturing process to be validated for regulatory approval. We expect to make capital expenditures of approximately $50 million to $70 million in 2025, primarily to establish and scale manufacturing of SUBLOCADE at the Raleigh Manufacturing Facility. Any changes to our cost estimates or delays in obtaining regulatory approval of our manufacturing site may increase our expenses or delay our ability to manufacture our own products at the Raleigh Manufacturing Facility and correspondingly delay expected cost savings.

d. *Quality Control and Product Safety.* As a manufacturer of pharmaceutical products for third parties, we are responsible for ensuring the quality, safety, and efficacy of the pharmaceutical products we manufacture. Any deviations from quality standards or safety concerns could result in FDA enforcement actions, product recalls, legal liabilities, damage to our reputation, and financial losses.

e. *Product Liability and Litigation.* The pharmaceutical industry is susceptible to product liability claims and lawsuits. Any adverse events, side effects, or alleged defects in the pharmaceutical products we manufacture could result in litigation, regulatory actions, and financial liabilities.

f. *Data Integrity and Record Keeping.* Accurate and compliant recordkeeping is crucial in the pharmaceutical industry. Any issues related to data integrity or recordkeeping practices may result in regulatory actions, warning letters, or sanctions by the FDA.

g. *Regulatory Changes and Uncertainties.* Our operations are subject to evolving regulatory requirements, policies, and interpretations by the FDA. Changes in regulations or guidelines could require us to modify our manufacturing processes, quality control measures, or documentation practices, which may result in additional costs or delays.

h. FDA Inspections and Audits. We are regularly subject to inspections and audits of our manufacturing facilities by the FDA and other regulators to assess compliance with current Good Manufacturing Practices (cGMPs) and other regulatory standards. Any deficiencies or non-compliance identified during these inspections could lead to warning letters, import bans, product recalls, or delays in approvals, which could adversely affect our business and reputation. See Item 1A. Risk Factors—"*We are subject to ongoing obligations and continued regulatory inspection by the FDA and equivalent foreign regulatory agencies, and we may be subject to penalties and litigation and large incremental expenses if we fail to comply with regulatory requirements or experience problems with our products,*" below.

i. *Ability to Secure Supply.* Whether we can achieve our goals of enhancing supply security will depend on whether we can successfully integrate the Raleigh Manufacturing Facility and its workforce into our operations, our ability to install, validate, and secure FDA approval of a new manufacturing line, and our ability to operate the facility efficiently.

If we fail to develop or acquire other new products or compounds for development, our business, prospects, results of operations and financial condition could be materially adversely affected.

A key element of our long-term strategy is to develop or acquire and commercialize a portfolio of other products or product candidates in addition to our current products, through business or product acquisitions. Because we dedicate only a small portion of our own resources towards proprietary drug discovery, the success of this strategy depends in large part upon the combination of our regulatory, development and commercial capabilities and expertise and our ability to identify, select and acquire approved or clinically enabled product candidates for therapeutic indications that complement or augment our current products, or that otherwise fit into our development or strategic plans on terms that are acceptable to us. For example,

- We are developing INDV-6001 (buprenorphine-based LAI) for the treatment of OUD in collaboration with Alar Pharmaceuticals Inc.
- We are developing INDV-2000 (Selective Orexin-1 Receptor Antagonist), a non-opioid treatment for moderate to severe opioid use disorder.
- In 2023, we completed the acquisition of Opiant, a specialty pharmaceutical company that developed OPVEE for opioid overdose reversal.

See "*Item 1.Business —Pipeline*," for more information.

Identifying, selecting and acquiring promising products or product candidates requires substantial technical, financial and human resources expertise. Efforts to do so may not result in the actual acquisition or license of a particular product or product candidate, potentially resulting in a diversion of our management's time and the expenditure of our resources with no resulting benefit. In addition, we face substantial competition from historically innovative companies, as well as companies with greater financial resources than us, for such acquisition targets. If we are unable to identify, select and acquire suitable products or product candidates from third parties or acquire businesses at valuations and on other terms acceptable to us, or if we are unable to raise the capital required to acquire businesses or new products, our business and prospects will be limited.

In addition, any growth through business development will depend upon us identifying and obtaining product candidates, our ability to develop those product candidates and the availability of funding to acquire, complete the development of, obtain regulatory approval for and commercialize these product candidates. Doing so is complex and we may not be able to successfully manage the risks or other anticipated and unanticipated problems in connection with an acquisition or in-licensing, and may not be able to realize the anticipated benefits of any acquisition or in-licensing for a variety of reasons, including the possibility that a product candidate proves not to be safe or effective in later clinical trials, a product fails to reach its forecast commercial potential or the integration of a product or product candidate gives rise to unforeseen difficulties and expenditures. It is common for multiple products and product candidates to be evaluated for the same indication by multiple parties at the same time, and we cannot predict whether the expected commercial potential for our products will come to fruition. Any failure in identifying and managing these risks and uncertainties effectively would have a material adverse effect on our business, prospects, results of operations and financial condition.

To continue to grow our business over the longer term, we plan to commit resources to product acquisition and in-licensing, product development, clinical trials of product candidates and expansion of our commercial, development, manufacturing and other operations. Acquisition opportunities that we pursue could materially affect our liquidity and capital resources and may require us to incur additional indebtedness, seek equity capital or both. Our ability to raise additional capital may be adversely impacted by worsening global economic conditions and the recent disruptions to, and volatility in, the credit and financial markets in the U.S. and worldwide resulting from the effects of inflationary pressures, potential future bank failures or otherwise. In addition, under U.K. law we must have authority from our shareholders to issue any ordinary shares, including ordinary shares that are part of our authorized but unissued share capital, and we currently have such authorization until May 2025. An inability to borrow or raise additional

capital in a timely manner and on attractive terms could prevent us from expanding our business or taking advantage of acquisition opportunities and could otherwise have a material adverse effect on our business and growth prospects. In addition, if we use a substantial amount of our funds to acquire or in-license products or product candidates, we may not have sufficient additional funds to conduct all of our operations in the manner we would otherwise choose.

Moreover, any product candidate we acquire may require additional, time-consuming development or regulatory efforts prior to commercial sale or prior to expansion into other indications, including pre-clinical studies if applicable, and extensive clinical testing and approval by the FDA and applicable foreign regulatory authorities. All product candidates are prone to the risk of failure that is inherent in pharmaceutical product development, including the possibility that the product candidate will not be shown to be sufficiently safe and/or effective for approval by regulatory authorities. In addition, we cannot assure that any such products that are approved will be manufactured or produced economically, successfully commercialized or widely accepted in the marketplace or be more effective or desired than other commercially available alternatives. Any failure in identifying and managing these risks and uncertainties effectively would have a material adverse effect on our business, prospects, results of operations and financial condition, and any unsuccessful effort may require us to write down prior investments.

See also Item 1A. Risk Factors—"*We receive substantial revenue from our key proprietary products and our success depends on our ability to successfully commercialize new products.*"

Acquisitions, partnerships, joint ventures, dispositions, and other business combinations or strategic transactions involve several inherent risks, any of which could result in the benefits anticipated not being realized and could have an adverse effect on our business, financial condition, and results of operations.

Acquisitions are an important part of our growth model and we regularly consider and enter into strategic transactions, including mergers, acquisitions, investments and other growth, market and geographic expansion strategies, with the expectation that these transactions will result in increases in sales, cost savings, synergies and various other benefits. For example, in March 2023 we acquired Opiant Pharmaceuticals in exchange for $146 million in cash and potential future payments of up to $68 million upon the completion of certain sales milestones pursuant to a contingent value rights agreement. See *Item 8. Financial Statements—Audited Consolidated Financial Statements - Note 18. Asset Acquisitions.* We also made a number of smaller acquisitions in 2023.

In the future, our ability to acquire additional companies or products synergistic with our current businesses may be limited by antitrust regulators who may be particularly vigilant in our markets because we serve at-risk populations and because we already market several products in the space.

We may fail to realize anticipated benefits from such transactions or partnerships, or any future ones, we may be exposed to additional liabilities or compliance violations of any acquired business or joint venture and we may be exposed to litigation in connection with any transaction. Furthermore, we may have trouble identifying suitable acquisition targets in the future. Our ability to deliver the expected benefits from any strategic transactions is subject to numerous uncertainties and risks, including our acquisition assumptions; our ability to integrate personnel, labor models, financial, supply chain and logistics, IT and other systems successfully; disruption of our ongoing business and diversion of management time; the need to hire additional management and other critical personnel; and increasing the scope, geographic breadth and complexity of our operations.

In addition, the integration of acquired businesses may create complexity in our financial systems and internal controls and make them more difficult to manage or cause us to fail to meet our financial reporting obligations. Any impairment of goodwill or other assets acquired in a strategic transaction or charges to earnings associated with any strategic transaction as well as any failure by the acquired business to produce the expected margins or cash flows, may materially reduce our profitability. Furthermore, we may finance these strategic transactions by incurring additional debt or raising equity, which could increase leverage or impact our ability to access capital in the future.

We may be subject to adverse public opinion.

The pharmaceutical industry is frequently subject to adverse publicity on many topics, including product recalls and research and discovery methods, as well as political controversy over pharmaceutical pricing, and the impact of novel techniques and therapies on humans, animals, and the environment, among others. Among our products, we manufacture and market buprenorphine-based medications for the treatment of moderate-to-severe opioid use disorder. While these medications are indicated to treat opioid use disorder, they are opioids and may be viewed negatively by the public. Negative publicity about us or our products, about the medications for the treatment of opioid use disorder, or about the industry as a whole, may adversely affect our corporate reputation, which could impact our operations, impair our ability to gain market acceptance for our products or lead to government intervention, which in turn could have an adverse impact on our business, prospects, results of operations and financial condition.

For example, our 2020 settlement with the DOJ created substantial adverse publicity and may have made it more difficult for some to distinguish our company, which works to address the opioid crisis, from those companies that created or exacerbated the opioid crisis. See *"Item 1: Business — Overview."* In announcing the settlement, the DOJ made a point to note that our medicines are opioids. This and other potential adverse publicity may reduce the willingness of third parties to do business with us, including credit providers and other investors, technology licensors, advocacy organizations, or potential employees, and may harm our ability to engage with policymakers on public policy issues critical to our business. For instance, in recent years, some state and federal officials were unwilling to meet with us to discuss policy issues while we were under government investigation, as were some third party groups.

Failure to retain key personnel or attract new personnel could have a material adverse effect on us.

We rely upon several key executives and employees who have an in-depth and long-term understanding of the industry and the disease space and our technologies, products, programs, collaborative relationships and strategic goals. Key personnel include experienced employees with specific expertise and the ability to compliantly interact with healthcare providers, key opinion leaders, and key decision makers across the healthcare industry.

On February 27, 2024, we announced that the Company has appointed Joe Ciaffoni, currently an Independent Non-Executive Director of the Company, as Chief Executive Officer. The terms of his appointment are subject to, and effective upon, the approval by shareholders of a new remuneration policy at the Company's AGM in May 2025, and there is no assurance that such approval will be obtained. By mutual agreement, Mark Crossley will be stepping down as Chief Executive Officer and as a Board Director and is expected to remain as CEO until at least the date of the Company's AGM in May 2025. If shareholders fail to approve the remuneration policy at the Company's AGM, there is no assurance that we would be able to secure the services of Mr. Ciaffoni or others with similar qualifications, which could have a material adverse impact on the business.

In particular, we must compete with other pharmaceutical and life sciences companies to recruit, hire, train and retain sales and marketing personnel as well as research and development personnel. Competition for such personnel in the pharmaceutical and biotechnology industries is intense, and there can be no assurance that we will be able to recruit or retain such personnel. If our sales force and sales organization are not appropriately sized to promote any current or potential future products adequately, the commercial potential of our current products and any future products may be diminished.

We do not carry "key person" insurance. The loss of the services of any of our key executives or employees could delay or prevent the successful completion of some of our vital activities. Any employee may terminate his or her employment at any time without notice or with only short notice and without cause or good reason. The resulting loss of institutional knowledge may have a material adverse effect on our operations and future growth.

As a result of the above factors, any failure to retain key personnel or attract new personnel could have a material adverse effect on our business, prospects, results of operations and financial condition.

We use hazardous materials in our manufacturing facilities, and any claims relating to the improper handling, storage, release or disposal of these materials could be time-consuming and expensive.

Our operations are subject to complex and increasingly stringent environmental, health and safety laws and regulations in the countries where we operate and, in particular, in the U.K. and U.S. where we have manufacturing and R&D facilities. The costs of compliance with environmental, health and safety laws and regulations are significant. If an accident or contamination involving pollutants or hazardous substances occurs, an injured party could seek to hold us liable for any damages that result, and any liability could exceed the limits or fall outside the coverage of our insurance. We may not be able to maintain insurance with sufficient coverage on acceptable terms, or at all. Costs, damages and/or fines may result from the presence, investigation and remediation of such contamination at properties currently or formerly owned, leased or operated by us or at off-site locations, including where we have arranged for the disposal of hazardous substances or waste. In addition, we may be subject to third-party claims, including for natural resource damages, personal injury and property damage, in connection with such contamination, or in some cases for contamination or pollutants at properties we own caused by prior owners. We have developed and implemented a proprietary risk mitigation program to preemptively identify and address environmental, health, safety and security risks; however, there can be no assurance that a violation of current or future environmental, health or safety laws or regulations will not occur. Any violations, even if inadvertent or accidental, or the cost of compliance with any resulting order, fine or liability that may be imposed, could materially adversely affect our business, financial condition, cash flows and results of operations.

Risks Related to Intellectual Property

We may incur substantial costs as a result of litigation or other proceedings relating to patents and other intellectual property rights, and we may be unable to protect our rights to, or commercialize our products.

Litigation and other similar proceedings, such as *inter partes* reviews in the U.S. (which are initiated by third parties to challenge the validity of a patent) relating to infringement, validity or misappropriation of patent and other intellectual property rights in the pharmaceutical and life sciences industry are common. We may receive notifications of challenges to the validity of our patents or alleged infringement of patents owned by third parties. For example, we incurred significant costs in connection with the ANDA proceedings relating to SUBOXONE Film in the U.S. from 2013 through 2023 and were ultimately unable to enforce our patents against two of the challengers. If we choose to go to court to prevent a third party from infringing our patents, our licensed patents or our partners' patents (where we have the right to do so), that allegedly infringing third-party has the right to ask the court to rule that these patents are invalid and/or should not be enforced against that third-party.

Separately, other third parties may allege that patents on our other products or product candidates are not valid. These lawsuits are expensive and, as with the SUBOXONE ANDA litigation, could cost the Company several million dollars per year. They are time-consuming and could divert management's attention from the day-to-day operation of our business. In addition, there is a risk that a court will decide that these patents are not valid or not infringed and that we do not have the right to prevent the other party from using the patented subject matter. There can be no assurance that these, or other litigation that we may file in the future, will be successful in preventing the infringement of our patents, that we will be able to successfully defend the validity of our patents, that any such litigation will be cost-effective, or that the litigation will have a satisfactory result for us. In addition, such litigation diverts the attention of management and development personnel. Failure to stop infringement of our patents or an unsatisfactory result in litigation would adversely affect our business and results of operations.

Additionally, when enforcing such patents, we risk being subject to potential liability as a result of counterclaims and related damages, including potential antitrust violations, among other things. For example, Dr. Reddy's Laboratories ("DRL") and Alvogen pursued claims for wrongful injunction damages, and further asserted antitrust counterclaims against the Company, after the Company sought to enforce particular patent claims against DRL and Alvogen. The Company reached settlements with DRL and

Alvogen in 2022 and 2023, respectively. See *Item 8. Financial Statements—Audited Consolidated Financial Statements - Note 11. Accrued Litigation Settlement Expenses*.

A third-party may claim that we or our manufacturing or commercialization partners are using inventions covered by the third-party's patent rights, or that we or such partners are infringing, misappropriating or otherwise violating other intellectual property rights, and may go to court to stop us from engaging in our ordinary course operations and activities, including manufacturing or selling our products. There is a risk that a court could decide that we or our partners are infringing, misappropriating or otherwise violating third-party patents or other intellectual property rights, which could have a material adverse effect on our business and results of operations. In addition, such litigation diverts the attention of management and development personnel.

We may initiate or defend legal proceedings relating to our patents alongside a collaborator or third-party with an interest or right in the relevant patents. In this scenario, our strategy for asserting or defending our rights might be impacted by that of our co-claimant or co-defendant which, in turn, may have an adverse impact on our existing commercial relationship.

In the pharmaceutical and life sciences industry, like other industries, it is not always clear to industry participants, including the Company, which patents cover various types of products or methods. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we are sued for patent infringement, we would need to demonstrate that our products or methods do not infringe the patent claims of the relevant patent and/or that the patent claims are invalid or unenforceable, which we may not be able to do, and which could in turn result in our being required to pay substantial sums. These sums potentially include damages, legal fees, and increased damages if we are found to have infringed such rights willfully. Further, if a patent infringement suit is brought against us, our research, development, manufacturing, or sales activities relating to the product or product candidate that is the subject of the suit may be delayed, materially affected, or terminated by the grant of an injunction against us.

We cannot be certain that others have not filed patent applications for inventions covered by our licensors' or our issued patents or pending applications, or that we or our licensors were the first inventors. Our competitors may have filed, and may in the future file, patent applications covering subject matter similar to those of the Company. Any such patent application may have priority over our or our licensors' patents or applications and could further require us to obtain rights to patent rights covering such subject matter. In the U.S., if another party has filed a patent application on inventions similar to those of the Company, we may have to participate in an interference or deviation proceeding declared by the USPTO to determine the priority of invention in the U.S. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful, resulting in a loss of our U.S. patent position with respect to such inventions.

As a result of patent infringement claims, or in order to avoid potential infringement claims, we or our collaborators may choose to seek, or be required to seek, a license from the third-party, which would be likely to include a requirement to pay license fees or royalties or both. These licenses may not be available on acceptable terms, or at all. Even if a license can be obtained on acceptable terms, the rights may be non-exclusive, which would potentially give our competitors access to the same intellectual property rights. If we are unable to enter into a license on acceptable terms, we, or our collaborators, could be prevented from commercializing one or more of our product candidates, or forced to modify such product candidates, or cease some aspect of our business operations, which could adversely affect our business, prospects, results of operations or financial condition.

The cost to us of any patent litigation or other proceedings, even if resolved in our favor, could be substantial. Some of our competitors may be able to sustain the costs of complex patent and other intellectual property litigation more effectively than we can because they have substantially greater resources than the Company. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue its operations.

Any of the foregoing could have a material adverse effect on our business, prospects, results of operations and financial condition.

We may not be able to protect our intellectual property rights throughout the world which could have an adverse effect on our business, results of operations and financial condition.

Filing, prosecuting and defending patents relating to all of our product candidates and technologies throughout the world would be prohibitively expensive. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products, and further, may export otherwise infringing products to territories where we have patent protection but where enforcement is more difficult. These products may compete with our future products in jurisdictions where we do not have any issued patents and our patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, which could make it difficult for us to stop infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert efforts and attention from other aspects of our business, which could adversely affect our operations and financial condition. Moreover, our patent rights can be challenged in post-grant or *inter partes* review. For example, our patents for SUBLOCADE were challenged in the EU patent office under two separate European opposition proceedings. However, both of those proceedings were dismissed.

Failure to obtain and maintain patents and protect other proprietary rights, including in-licenses of such rights from third parties, may adversely affect us.

Our success depends, in large part, on our ability to obtain and maintain patent and other intellectual property protection, particularly for our drug, compound, product, delivery, formulation and methods of treatment technologies and associated manufacturing processes in relation to both our products and our product candidates. The process of obtaining patents can be lengthy and expensive. We own, or in-license, several patent rights in the U.S. and other countries covering certain products and have also developed brand names and trademarks for other products. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our proprietary technologies and future products are covered by valid and enforceable patents or are effectively maintained as trade secrets or confidential information within the Company. Our existing patents, and any future patents we obtain, may not be sufficiently broad to prevent others from using our technologies or from developing competing products and technologies. If third parties disclose or misappropriate our proprietary rights, it may materially and adversely impact our business, prospects, results of operations and financial condition. Moreover, our ability to obtain and enforce patents and other proprietary rights is critical to our business strategy and success.

The patent positions of many pharmaceutical and life sciences companies are highly uncertain and involve complex legal and factual questions. In some cases, the legal principles that apply to these cases may be changing or unresolved. As a result, the validity and enforceability of our patents cannot be predicted with certainty. In addition, we cannot guarantee that:

- we were the first to make the inventions covered by each of our issued patents and pending patent applications;
- we were the first to file patent applications for these inventions;
- patents will be granted in connection with any of our currently pending or future applications;
- other companies will not independently develop similar or alternative technologies or duplicate any of our technologies by inventing around our claims;

- a third-party will not challenge our proprietary rights, and if challenged that a court will hold that our patents are valid and enforceable;
- any patents issued to us or our collaboration partners will cover our products as ultimately developed, or provide us with any competitive advantages, or will not be challenged by third parties;
- we will develop additional proprietary technologies that are patentable; or
- the patents of others will not have an adverse effect on our business.

We also rely on trade secrets and other unpatented confidential information to maintain our competitive position but there can be no assurance that others may not independently develop the same or similar products or technologies, and may also obtain patents and other intellectual property protection for them. We have sought to protect trade secrets and confidential information, in some cases through the provisions of confidentiality and non-use agreements with our employees, consultants, advisers and partners.

Nevertheless, it may not always be possible to prevent the disclosure of our trade secrets and other confidential information and for us to obtain an adequate remedy in the event of unauthorized disclosure or use of such information. In addition, if our employees, consultants or partners develop inventions or processes independently that may be applicable to our products or technologies under development, such inventions and processes will not necessarily become our property, but may remain the property of those persons or their employers or the persons may be entitled to compensation in respect of those inventions. Protracted and costly litigation could be necessary to enforce and determine the scope of our proprietary rights.

We have entered into several collaborative arrangements for the development and commercialization of products including with Aquestive for the production of SUBOXONE Film and with Curia for the production of SUBLOCADE. In connection with such arrangements, we have shared certain of our proprietary knowledge with our partners, and it may not be possible or practical to prevent our partners from developing similar or functionally equivalent products. Any disputes between us and such partners may threaten our ability to continue using such proprietary knowledge and, in turn, could impact our ability to market our products. We have also engaged in collaborations, sponsored research agreements and other arrangements with academic researchers and institutions, some of which have received and may receive funding from government agencies. Although we have sought to retain ownership of all intellectual property rights pertaining to inventions that may result from such collaborations, there can be no assurance that governments, institutions, researchers or other third parties will not also attempt to claim certain rights to such inventions.

If we fail to obtain and maintain sufficient intellectual property protection for our current and future products and technologies and if third parties disclose or misappropriate our proprietary rights, our ability to successfully and fully exploit these products and technologies could be adversely affected, which in turn would adversely affect our business, prospects, results of operation and financial condition.

We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

As is common in the pharmaceutical industry, we employ individuals who were previously employed at other pharmaceutical, biotechnology, or medical device companies, including our competitors or potential competitors. Although no such claims against us are currently pending, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

Risks Related to Regulatory or Legal Matters

The regulatory approval process is expensive, time-consuming, and uncertain and may prevent us or our partners from obtaining approvals for the commercialization of some or all of our product candidates. Further, the FDA or other regulatory agencies may not agree with our regulatory approval strategies or components of our filings for our products and may not approve, or may delay the approval of, our products.

The research, development, testing, manufacturing, approval, labeling, advertising and promotion, distribution and import and export of pharmaceutical products are subject to extensive regulation, and regulations differ from country to country. We must obtain government approvals before marketing or selling our products. Approval in one jurisdiction does not ensure approval in other jurisdictions. The regulatory approval process is lengthy, expensive and uncertain, and we may be unable to obtain approval for our product candidates. The FDA in the U.S., and comparable regulatory agencies in other jurisdictions, impose substantial and rigorous requirements for the development, manufacture and commercialization of products, the satisfaction of which can take a significant number of years and can vary substantially based upon the type, complexity and novelty of the product.

For example, in the U.S., the process for obtaining marketing approval for a drug or biologic product candidate generally includes (a) conducting preclinical laboratory and animal testing and submitting the results to the FDA in an investigational new drug application (IND) requesting approval to test the product candidate in human clinical trials; (b) conducting adequate and well-controlled human clinical trials to establish the safety and efficacy of the product candidate in the desired indication; (c) submitting an NDA, biologics license application (BLA), or supplemental NDA/BLA, as appropriate, and (d) completing inspections by the FDA of the facilities where the product candidate is manufactured, analyzed and stored to demonstrate compliance with cGMP, and any requested FDA audits of the clinical trial sites that generated the data supporting the application.

In addition, regulation is not static, and regulatory agencies, including the FDA, evolve in their staff, interpretations, and practices and may impose more stringent requirements than currently in effect, which may adversely affect our plans for product development, approval, manufacture and/or commercialization. The approval procedure and the time required to obtain approval also vary among countries. Regulatory agencies may have varying interpretations of the same data, and approval by one regulatory agency does not ensure approval by regulatory agencies in other jurisdictions. In addition, the ultimate decision by the FDA or other regulatory agencies regarding drug approval may not be consistent with prior communications due to the evolution of new information or changes in clinical practice during the development and registration processes.

The product approval process can last many years, be very costly and still be unsuccessful. For example, the development of SUBLOCADE from concept to commercial launch took approximately eight years. Regulatory approval by the FDA or other regulatory agencies can be delayed, limited or not granted at all. A product may fail to demonstrate safety and efficacy for each target indication in accordance with applicable regulatory agencies' standards for many reasons, including:

- data from preclinical testing and clinical trials may be interpreted by applicable regulatory agencies in ways different from how we or our licensees interpret it;
- regulatory agencies may not agree with our or our licensees' regulatory approval strategies, plans for accelerated development timelines, components of our or our licensees' filings such as clinical trial designs, conduct and methodologies, or the sufficiency of our or our licensees' submitted data to meet their requirements for product approval;
- regulatory agencies might not approve our or our licensees' manufacturing processes or facilities, or those of the contract research organizations (CROs) and contract manufacturing organizations who conduct research or manufacturing work on our or our licensees' behalf;

- failure by our clinical investigational sites and the records kept at such sites, including any clinical trial data, to be in compliance with the FDA's good clinical practices (GCP), or other applicable legislation governing GCP, or to pass FDA, European Medicines Agency or other relevant regulatory agency's inspections of clinical trials;
- regulatory agencies may change their requirements for approval or post-approval marketing; and
- adverse medical events during the trials could lead to requirements that trials be repeated or extended, or that a program be terminated or placed on clinical hold, even if other studies or trials relating to the program are successful.

In addition, disruptions at the FDA and other regulatory agencies that are unrelated to our Company or our products could cause delays to the regulatory approval process for our products. For example, if a prolonged U.S. government shutdown occurs as a result of political or economic conditions or if a future pandemic were to be more severe, the FDA's ability to timely review and process regulatory submissions could be significantly impacted. Similarly, recent actions by the current administration have reduced headcount in some agencies, which may cause delays.

Further, any adverse events or other data generated during the course of clinical trials of our product candidates and/or our currently marketed products could result in action by FDA or an equivalent regulatory authority. Such safety findings may restrict our ability to sell or adversely affect the commercialization of currently marketed products. Specifically, clinical trial safety data could result in FDA requiring changes to the clinical development program, labeling, including additional warnings or additional boxed warnings, or requiring us to take other actions that could have an adverse effect on patient and prescriber acceptance of our products. See also Item 1A. Risk Factors—"*We are subject to ongoing obligations and continued regulatory review by the FDA and equivalent foreign regulatory agencies, and we may be subject to penalties and litigation and large incremental expenses if we fail to comply with regulatory requirements or experience problems with our products.*"

Any failure to obtain, or delay in obtaining, regulatory approval for our products will prevent or delay their commercialization and could have a material adverse effect on our business, financial condition, cash flows and results of operations. In addition, any failure to obtain, or delay in obtaining, approval for our products could have a material impact on our shareholders' confidence in the strength of our development capabilities and/or our ability to generate significant revenue from our development program and could result in a significant decline in our share price. Further, even product candidates that receive regulatory approval may face additional regulatory hurdles or otherwise be unable to achieve expected market acceptance. See Item 1A. Risk Factors —"*The FDA, the DEA, or other regulatory agencies may impose limitations or post-approval requirements on approvals for our products*" and "*Our ability to generate revenues from our products is subject to attaining significant market acceptance among physicians, patients, and healthcare payors*."

The FDA, the DEA, or other regulatory agencies may impose limitations or post-approval requirements on approvals for our products.

Even if regulatory approval to market a product is granted by the FDA or other regulatory agencies, the approved label for the product may not be consistent with our initial expectations or commercial plans because of limitations on what can be discussed or limitations or requirements related to the labelling or indication. The FDA or other regulatory agencies may also impose limitations on the clinical data that may be included in the label for the product or the indicated uses for which, or the manner in which, the product may be marketed, or may impose additional post-approval requirements. Our business could be materially adversely affected if we do not complete these post-approval requirements and, as a result, the FDA or other regulatory agencies require us to change the label for such product or if there are limitations or requirements on such label, or if such post-approval requirements significantly restrict the marketing, sale or use of such product.

For example, in January 2022 the FDA issued a warning about dental problems associated with buprenorphine medicines dissolved in the mouth to treat opioid use disorder and required that all

manufacturers of these products provide a warning in their prescribing label and their patient Medication Guide. Following such change, the Company has been named as a defendant in lawsuits filed in the Northern District of Ohio and other courts in which individual plaintiffs claim that SUBOXONE caused them to suffer dental cavities, tooth loss, or other damage to their teeth. See *Item 8. Financial Statements—Audited Consolidated Financial Statements - Note 16. Commitments and Contingencies*. Other regulatory agencies may follow the FDA on this change; for example, Health Canada required similar changes in 2023.

We may be required to include, as part of an NDA, a proposed REMS the goal of which is to mitigate potential risks that may be associated with the use of a product and to inform patients and prescribers of those risks. We may also be required to include a plan for communication with healthcare providers, restrictions on a drug's distribution, or a medication guide to provide information to consumers about the drug's risks and benefits. For example, the FDA requires separate REMS for SUBLOCADE and SUBOXONE Film because they have distinct REMS goals. The goal of the REMS program for SUBLOCADE is to mitigate the risk of serious harm or death that could result from intravenous self-administration by a patient, whereas the goals for the shared Buprenorphine Transmucosal Products of Opioid Dependence (BTOD) REMS for which SUBOXONE is a part of are to (1) mitigate the risks of accidental overdose, misuse and abuse and (2) inform prescribers, pharmacists and patients of the serious risks associated with buprenorphine-containing products. Other products that we sell in the future may become subject to a REMS specific to the product or shared with other products in the same class of drug. Depending on the nature of the REMS, the cost to implement the REMS may be high, and the impact to the business may be significant.

FDA and other regulatory agencies may require post-approval or post-marketing studies as a condition for approval. For example, we were required to conduct seven post-marketing requirement studies and three post-marketing commitment studies in connection with the approval of SUBLOCADE. Likewise for OPVEE, Indivior is required to carry out four pediatric assessment studies and four post-marketing requirement studies to assess the risks of dodecyl maltoside (DDM).

In the EU or U.K., we may be required to adopt a risk management plan, and our products could be subject to specific risk minimization measures, such as restrictions on prescription or supply, the conduct of post-marketing safety or efficacy studies, or the distribution of patient and/or prescriber educational materials.

In addition, post-marketing obligations in the form of further clinical trials may be imposed to further expand on the evaluation of the risk/benefit profile of the product relative to any potential safety concerns. These trials typically occur after approval and according to pre-specified timelines set by regulatory authorities. Depending on the nature of the post-marketing commitment, trial completion can be a lengthy and expensive process. Failure to comply with any of these requirements may potentially lead to suspension of the marketing authorization for the product and other penalties. The costs and other consequences of non-compliance with any of the post-approval obligations described above could have an adverse impact on its business, prospects, results of operations and financial condition.

Further, if a product for which we obtain regulatory approval is a controlled substance or has been shown to have a drug abuse liability, such as INDV-6001, it will not become commercially available until after the DEA (or other applicable regulatory authority) provides its final schedule designation for the product, and may take longer and may be more restrictive than we expect or may change after its initial designation. In addition, a final designation that is more restrictive than we expect could adversely affect our ability to commercialize such product and could materially adversely affect our business, financial condition, cash flows and results of operations.

In addition, legislation and regulatory policies relating to post-approval requirements and restrictions on promotional activities for pharmaceutical products, or FDA, DEA or other regulatory agency regulations, guidance or interpretations with respect to such legislation or regulatory policy, may change, which may impact the development and commercialization of our products.

We are subject to ongoing obligations and continued regulatory inspection by the FDA and equivalent foreign regulatory agencies, and we may be subject to penalties and litigation and large incremental expenses if we fail to comply with regulatory requirements or experience problems with our products.

The FDA and other regulatory authorities track information on side effects and adverse events reported during clinical studies and after marketing approval. We are required to file periodic safety update reports with the authorities concerning adverse events. If, upon review, an authority determines that any events and/or reports indicate a trend or signal, they can require a change in a product label, restrict sales and marketing, require post-approval safety studies, require a labor-intensive collection of data regarding the risks and benefits of marketed products and ongoing assessments of those risks and benefits, and/or require other actions. Such safety findings could potentially lead to the withdrawal or suspension of the product from the market. The FDA also periodically inspects our records related to safety reporting. Following such inspections, the FDA may issue non-compliance notices on FDA Form 483 and warning letters that could cause us to modify certain activities. An FDA Form 483 notice, if issued, can list conditions FDA investigators believe may have violated relevant FDA standards. Failure to adequately and promptly correct the observations can result in a warning letter or other regulatory enforcement action. See also Item 1A. Risk Factors—"*We are subject to risks related to the manufacture and distribution of our products globally and must meet stringent current Good Manufacturing Practices.*"

The FDA also regulates advertising and promotional activities for products in the U.S., requiring advertising, promotional materials and labeling to be truthful and not misleading, and products to be marketed only for their approved indications and in accordance with the provisions of the approved label. The FDA actively investigates allegations of pre-approval and off-label promotion in order to enforce regulations prohibiting these types of activities. The FDA routinely issues informal and more formal communications such as untitled letters or warning letters regarding companies' activities.

The manufacture, quality control, labeling, packaging, safety surveillance, adverse event reporting, storage, advertising, promotion and record-keeping for products are subject to extensive and ongoing regulatory requirements which are becoming increasingly stringent. If we become aware of previously unknown problems or potential new safety risks associated with any of our products, a regulatory agency may impose restrictions on our products, our contract manufacturers or on us. If we, our products and product candidates, or the manufacturing facilities for our products and product candidates, fail to comply with applicable regulatory requirements, regulatory agencies have wide-ranging powers of enforcement, including the power to impose monetary penalties. In such instances, we could experience a significant drop in the sales of the affected products, our product revenues and reputation in the marketplace may suffer, and we could become the target of lawsuits, each of which could have a material adverse effect on our business, prospects, results of operations and financial condition.

The regulations, policies or guidance of regulatory agencies may change, and new or additional statutes or government regulations may be enacted that could prevent or delay regulatory approval of our product candidates or further restrict or regulate post-approval activities.

As a result of the breadth of these laws and regulations and the lack of definitive legal guidance in certain areas, it is possible that some of our business activities could be subject to challenge. Such challenges, irrespective of the underlying merit or the ultimate outcome of the matter, could have a material adverse effect on our business, prospects, reputation, results of operations and financial condition. Similarly, if we are unable to achieve and maintain regulatory compliance, we will not be permitted to market our drugs, which would materially adversely affect our business, results of operations and financial condition.

Guidelines and coverage determinations published by the government, professional societies, insurance carriers, physician groups, science foundations, and other organizations may affect the use of the Company's products.

Government agencies promulgate regulations and guidelines directly applicable to us and to our products. In addition, professional societies, practice management groups, insurance carriers, physicians'

groups, private health and science foundations, and organizations involved in various diseases also publish guidelines and recommendations to healthcare providers, administrators and payers, as well as patient communities. Recommendations by government agencies or other groups and organizations may relate to such matters as usage, dosage, route of administration and use of related therapies.

In the U.S., for example, a growing number of organizations are providing assessments of the value and pricing of biopharmaceutical products, and even organizations whose guidelines have historically been focused on clinical matters have begun to incorporate analyses of the cost effectiveness of various treatments into their treatment guidelines and recommendations. In addition, value assessments may come from private organizations that publish their findings and offer recommendations relating to the reimbursement of products by government and private payers. Some companies and payers have announced pricing and payment decisions based in part on the assessments of private organizations. In addition, government health technology assessment organizations in many countries make reimbursement recommendations to payers in their jurisdictions based on the clinical effectiveness, cost-effectiveness and service effects of new, emerging and existing medicines and treatments. Such recommendations have included and may in the future include reimbursement for certain of our products for a narrower indication than was approved by applicable regulatory agencies or may include recommending against reimbursement entirely.

Also, harm reduction advocates have advocated against OPVEE based on their narrow view that there is no need for OPVEE versus other products such as NARCAN and generic naloxone, by raising concerns about the relative likelihood or duration of precipitated withdrawal that OPVEE may have. Some states have taken action to limit or restrict access to OPVEE based on this pressure, and even where OPVEE remains available for prescribing by HCPs, their efforts may discourage state Medical Directors to add OPVEE to existing standing orders or protocols where it could be used in community settings. Further, some states' standing orders and protocols specify NARCAN by name, rather than as an opioid overdose reversal agent, which if left unchanged effectively blocks the sale of OPVEE in that state.

Such recommendations or guidelines may affect our reputation, and any recommendations or guidelines that result in decreased use, dosage or reimbursement of our products could have a material adverse effect on our product sales, business and results of operations.

Product liability and product recalls could have a material adverse effect on us.

The testing, manufacturing, marketing and sale of pharmaceutical products entail a risk of product liability claims, product recalls, litigation and associated adverse publicity. Unanticipated side effects of, or manufacturing defects in, our products could exacerbate a patient's condition or could result in serious injury or impairments or even death. This could result in product liability claims and/or recalls of one or more of our products. In many countries, including in EU member states and the U.K., national laws provide for strict (no-fault) liability.

Product liability claims may be brought by individuals seeking relief for themselves, or by or on behalf of groups seeking to represent a class of injured patients. Further, third-party payors, either individually or as a putative class or group action, may bring actions seeking to recover monies spent on products. The risk of product liability claims may also increase if we are subject to regulatory action by the FDA, the European Medicines Agency (the "EMA"), the U.K. Medicines and Health products Regulatory Agency ("MHRA"), or other competent authorities, or following a product recall. The cost of defending such claims is expensive even when the claims are without merit. A successful product liability claim against us could require us to pay a substantial monetary award. Moreover, an adverse judgment in a product liability suit, even if insured or eventually overturned on appeal, could generate substantial negative publicity about our products and business and inhibit or prevent the commercialization of other products.

For example, the Company has been named as a defendant in a large number of cases in the U.S., and a case in Canada purporting to represent a class of plaintiffs, which claim that SUBOXONE caused them to suffer dental cavities, tooth loss, or other damage to their teeth. The plaintiffs generally allege that the Company failed to properly warn physicians of the risk of dental injury, and further allege that SUBOXONE products were defectively designed. The plaintiffs generally seek compensatory damages, as well as

punitive damages and attorneys' fees and costs. Product liability cases such as these typically involve issues relating to medical causation, label warnings and reliance on those warnings, scientific evidence and findings, actual, provable injury and other matters. These cases are in their preliminary stages. See *Item 8. Financial Statements—Audited Consolidated Financial Statements - Note 16. Commitments and Contingencies*.

The Company has been informed by its primary insurance carrier that defense costs for this matter should begin to be reimbursed now that the Company's self-insurance retention has been exhausted but has issued a reservation of rights against payment of any liability costs. In the event of a liability finding, various factors could affect reimbursement or payment by insurers, if any, including (i) the scope of the insurers' purported defenses and exclusions to avoid coverage, (ii) the outcome of negotiations with insurers, (iii) delays in or avoidance of payment by insurers, and (iv) the extent to which insurers may become insolvent in the future. Moreover, although we carry product liability insurance, current coverage may not be adequate or may not be available at all or in part. Further, product liability insurance is difficult to obtain and may not be available in the future on acceptable terms or at all.

Product recalls may be issued at our discretion or at the discretion of our suppliers, government agencies, clients for whom we manufacture, and other entities that have regulatory authority over pharmaceutical sales. Any recall of our products could materially adversely affect our business by rendering us unable to sell that product for some time and by adversely affecting our reputation. In addition, product liability claims, product complaints or product quality issues reported by us (or others) to authorities as required by local regulations could result in an investigation (conducted by the FDA, the EMA, or the competent authorities of EU member states or other national authorities) into the safety or efficacy of our products, our manufacturing processes and facilities, or our marketing programs. An investigation could potentially lead to a recall of our products or more serious enforcement actions including seizure, injunction or criminal charges, proposed changes to the indications for which they may be used or suspension or withdrawal of approval. The Company has no insurance coverage for product recalls. Any of the foregoing could have a material adverse effect on our business, prospects, results of operations and financial condition. Further, product liability insurance may not be available for many claims relating to our opioid drug products due to contractual exclusions in our insurance policies.

We are subject to federal, state and foreign healthcare laws and regulations and implementation or changes to such healthcare laws and regulations could adversely affect our business and results of operations.

We are subject to extensive federal, state and foreign healthcare regulation. The healthcare system is highly regulated in the U.S., the EU, the U.K. and other countries where we operate and, as a pharmaceutical company that participates in government-regulated healthcare programs, we are subject to complex laws and regulations. Violation of the healthcare laws that we are subject to, or any other federal, state or foreign regulations, may subject us to significant administrative, civil and/or criminal penalties, damages, disgorgement, fines, exclusion, imprisonment, additional reporting requirements, and/or oversight from federal or other healthcare programs that could require the restructuring of our operations. Any of these could have a material adverse effect on our business and financial results. Any action against us for violation of these laws, even if we ultimately are successful in our defense, will cause us to incur significant legal expenses and divert our management's attention away from the operation of our business.

The U.S. and some foreign jurisdictions are considering or have enacted several legislative and regulatory proposals that change the healthcare system in ways that could impact our profitability. In the U.S. and abroad there is significant interest in implementing regulations and legislation with the stated goals of containing healthcare costs, improving quality, and/or expanding access. The pharmaceutical industry has been a focus of these efforts and has been significantly affected by major legislative initiatives, particularly in the U.S.

For example, the Affordable Care Act substantially changed the way healthcare is financed by both governmental and private insurers, and continues to significantly impact the U.S. pharmaceutical industry. In addition, drug pricing by pharmaceutical companies in the U.S. has come under increased scrutiny. Specifically, there have been state and U.S. congressional inquiries into pricing practices by pharmaceutical

companies. For example, Congress launched an inquiry into pharmacy benefit managers and their practices which are believed by some to have led to consolidation, lack of transparency, and spread pricing. U.S. policymakers have also studied the impact rebates (i.e., the return of part of the purchase price of a prescription drug in exchange for favorable formulary placement) may play in driving up overall drug prices. Significant developments that may adversely affect pricing in the U.S. include drug pricing and Medicare reforms by Congress, regulatory changes to Medicare Part B (physician-administered drugs) and Medicare Part D (prescription drug benefit), additional changes relating to the Affordable Care Act, and trends in the practices of managed care groups and institutional and governmental purchasers. The Affordable Care Act tax credits expire at the end of 2025 and, if not extended by Congress, the number of uninsured individuals could increase.

The pharmaceutical industry also faces uncertainty regarding the continuation of current drug pricing policy. For example, on November 20, 2020, HHS finalized the "rebate rule" by publishing regulations removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Medicare Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. However, the Inflation Reduction Act extended the moratorium on implementation, administration, or enforcement of this final rule until January 1, 2032.

The Inflation Reduction Act requires the HHS Secretary to negotiate, with respect to Medicare units and subject to a specified cap, the price of a set number of certain high Medicare spend drugs and biologicals per year starting in 2026, penalizes manufacturers of certain Medicare Parts B and D drugs for price increases above inflation, and makes several changes to the Medicare Part D benefit, including a limit on annual out-of-pocket drug costs starting at $2,000 in 2025, a $35 monthly cap on insulin payments, and a change in manufacturer liability under the program that could negatively affect us. Congress and the Administration may seek new legislative and/or administrative measures to control drug costs.

Governments across the world continue to consider and take action to lower drug prices. In the U.S., there is bi-partisan support for drug pricing reforms at both federal and state levels, which include potential legislative and regulatory actions to encourage the import of drugs, to price drugs according to a defined international pricing reference, to encourage more competition, and to undertake other initiatives. These, together with federal and state government fiscal constraints resulting from the COVID-19 pandemic which constrain public benefit health programs, pose direct and indirect downward pressure risk on drug prices. The Company continues to monitor potential legislative and regulatory changes and their impacts, advocating for the Company's products based on scientific studies and patient-centered outcomes. However, certain potential legislative and regulatory drug pricing changes could have an adverse impact on the Company's financial performance and results in the future.

In Europe, legislators, policymakers, and healthcare insurance funds continue to propose and implement cost-containing measures to keep healthcare costs down, due in part to the attention being paid to healthcare cost containment in Europe. Certain of these changes could impose limitations on the prices we will be able to charge for our products and any approved product candidates or the amounts of reimbursement available for these products from governmental agencies or third-party payers, which may increase the tax obligations on pharmaceutical companies such as ours, or may facilitate the introduction of generic competition with respect to our products.

With the intent of lowering prescription drug prices in the U.S., federal and state governments in the U.S. have enacted and continue to consider additional legislation and regulation applying international reference pricing to prescription drugs, otherwise limiting the pricing of prescription drugs, and authorizing the importation of drugs from countries outside the U.S. Such measures could have a material effect on our business, results of operations and financial condition.

The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, maintain profitability, or commercialize our current products and/or those for which we may receive regulatory approval in the future.

Failure to comply with payment and reporting obligations under the Medicaid Drug Rebate program or other governmental pricing programs in the U.S. could result in additional reimbursement requirements, penalties, sanctions and fines.

In the U.S., we participate in the Medicaid Drug Rebate and Medicare Part D programs and, by virtue of such participation, are also required by federal law to participate in the 340B Program and Federal Supply Schedule pricing program. These programs require us to pay certain rebates based on pricing data, such as (among others) average manufacturer price and best price, reported by us to the various federal agencies administering the programs.

Pricing and rebate calculations vary among products and programs. The calculations are complex and the calculation methodology is often subject to interpretation by us, governmental or regulatory agencies and the courts. If we become aware that our reporting for a prior period was incorrect or has changed as a result of the recalculation of the pricing data, we are obliged to resubmit the corrected data. Such restatements and recalculations can increase our costs for complying with the laws and regulations governing the various programs. Any corrections to our rebate calculations could result in either additional or reduced rebate liability for past periods, depending on the nature of the correction. Price recalculations may also affect the ceiling price at which we are required to offer our products to certain covered healthcare entities, such as safety-net providers under the 340B Program, as well as the prices under which our products are made available to federal government purchasers such as the U.S. Department of Veterans Affairs and the Department of Defense under the Veterans Health Care Act of 1992, as amended ("VHCA").

We are liable for errors associated with our submission of pricing data. In addition to retroactive rebates and the potential for 340B Program and VHCA refunds, if we are found to have knowingly submitted any false price or product information to the government, we may be liable for civil monetary penalties. Any failure to submit data on a timely basis could result in a civil monetary penalty for each day the information is late beyond the due date. We are currently defending such allegations, which we deny, in the matter *United States ex rel. Miller v. Reckitt Benckiser Group PLC et al.* See *Item 8. Financial Statements—Audited Consolidated Financial Statements - Note 16. Commitments and Contingencies*. In the case of the Medicaid Drug Rebate program, such failure could also be grounds for CMS to terminate our Medicaid drug rebate agreement, pursuant to which we participate in the Medicaid program. In the event that CMS terminates our rebate agreement, no federal payments would be available under Medicaid or Medicare Part B for our covered outpatient drugs. As another example, we can be subjected to civil monetary penalties under, or termination from, the 340B Program if we knowingly and intentionally overcharge covered entities.

CMS and HHS-OIG have previously indicated that they intend to pursue more aggressively companies that fail to report pricing data to the government in a timely manner. Governmental agencies may also make changes in program interpretations or requirements or conditions of participation, some of which may have implications for amounts that we previously estimated or paid. There can be no assurance CMS or any other government agency will find that our submissions are complete and correct.

Any of the foregoing could have a material adverse effect on our business, prospects, results of operations and financial condition.

We are subject, directly or indirectly, to a variety of U.S. and international laws and regulations related to fraud and abuse and transparency. Enforcement actions under such laws have increased in recent years. If we fail to comply, or have not fully complied, with such laws, we could face substantial penalties.

In the U.S., we are subject, directly or indirectly through our customers and other third parties, to various federal, state and local fraud and abuse and transparency laws. Our sales, marketing, patient support and medical activities may be subject to scrutiny under these laws. The U.S. federal healthcare program Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving anything of value to induce (or in return for) the referral of business, including the purchase, recommendation or prescription of a particular drug reimbursable under Medicare, Medicaid or other federally financed healthcare programs. The statute has been interpreted to apply to arrangements between pharmaceutical companies on one hand and patients, prescribers, purchasers and formulary

managers on the other. Although there are several statutory exemptions and regulatory safe harbors protecting certain common manufacturer business arrangements and activities from prosecution and administrative sanction, the exemptions and safe harbors are drawn narrowly and are subject to regulatory revision or changes in interpretation by the DOJ and HHS-OIG. Practices or arrangements that involve remuneration may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Violations of the federal Anti-Kickback Statute may be established without providing specific intent to violate the statute. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the statute has been violated. Violations of the Anti-Kickback Statute may be punishable by civil, criminal, and administrative fines and penalties, damages, imprisonment, and/or exclusion from participation in federal healthcare programs. For example, in August 2018 the U.S. District Court for the Western District of Virginia unsealed a declined *qui tam* complaint alleging causes of action under the federal and state False Claims Acts against certain entities within the Company predicated on best price issues and claims of retaliation. See *Item 8. Financial Statements—Audited Consolidated Financial Statements - Note 16. Commitments and Contingencies*.

The federal civil False Claims Act prohibits, among other things, any person from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment of federal funds, or knowingly making, or causing to be made, a false statement to get a false claim paid. A claim resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim. The False Claims Act also permits a private individual acting as a "whistleblower" to bring actions on behalf of themselves and the federal government alleging violations of the statute and to share in any monetary recovery. Violations of the False Claims Act may result in significant financial penalties (including mandatory penalties on a per claim or statement basis), treble damages and exclusion from participation in federal healthcare programs.

Pharmaceutical companies are subject to other federal false claims and statements laws, some of which extend to non-government health benefit programs. For example, the healthcare fraud provisions under the Health Insurance Portability and Accountability Act of 1996 and its implementing regulations, or HIPAA, impose criminal liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third party payors, or falsifying or covering up a material fact or making any materially false or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Violations of HIPAA fraud provisions may result in criminal, civil and administrative penalties, fines and damages, including exclusion from participation in federal healthcare programs.

The majority of individual states also have statutes or regulations similar to the federal anti-kickback law and the False Claims Act, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. Other states restrict whether and when pharmaceutical companies may provide meals or other items of value to healthcare professionals or engage in other marketing-related activities, and certain states and cities require the identification or licensing of sales representatives.

The Physician Payment Sunshine Act requires tracking of payments and transfers of value to physicians and teaching hospitals and ownership interests held by physicians and their families, and reporting to the federal government and public disclosure of these data. Since 2022, reporting is also required regarding payments and transfers of value provided to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, and certified nurse-midwives. A number of states now require pharmaceutical companies to report expenses relating to the marketing and promotion of pharmaceutical products and to report gifts and payments to healthcare providers in the states. Government agencies and private entities may inquire about our marketing practices or pursue other enforcement activities based on the disclosures in those public reports.

We are further subject in a similar manner to federal and state data privacy and security laws, such as HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, the Confidentiality of Substance Use Disorder Patient Records, codified at 42 C.F.R. Part 2 (Part 2), state consumer privacy laws, and state breach reporting requirements. Collectively, these laws may affect,

among other things, our current and proposed research, sales, marketing and educational programs, as well as other possible relationships with customers, pharmacies, physicians, payers, and patients. We are subject to similar data privacy and security laws in Europe and other countries, including the EU General Data Protection Regulation (2016/679), or GDPR, under which fines of up to €20.0 million or up to 4% of the annual global revenue of the infringer, whichever is greater, could be imposed for significant non-compliance. We are also subject to *qui tam*, or whistleblower lawsuits, under the False Claims Act. Compliance with these laws, including the development of a comprehensive compliance program, is difficult, costly and time-consuming.

Because of the breadth and evolving interpretations and requirements of these laws, the narrowness of available statutory and regulatory exemptions, and the wide array of U.S. and international authorities with overlapping regulatory jurisdiction, it is possible that some of our business activities could be subject to challenge under one or more of such laws. Any action against us alleging violation of these laws, whether brought by law enforcement, regulatory agencies or private *qui tam* actions brought by individual whistleblowers in the name of the government, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business, even if we successfully defend against those actions. If any enforcement actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have an impact on our business, including the imposition of significant civil, criminal and administrative sanctions, damages, disgorgement, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, imprisonment, integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings, and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

We have mechanisms in place to procure compliance with rules and regulations, and applicable self-regulatory industry codes by region that the Company has committed to follow. However, there can be no assurance that our policies and procedures will be followed at all times or will effectively detect and/or prevent violations of applicable compliance regimes by our employees and other relevant persons.

Failure to comply with anti-corruption laws and regulations, anti-money laundering laws and regulations, and/or economic sanctions could result in us becoming subject to fines or penalties.

We are subject to various federal and foreign laws and regulations regarding anti-bribery, anti-corruption, anti-money laundering, and economic sanctions. These include the U.K. Bribery Act of 2010 and the U.S. Foreign Corrupt Practices Act of 1977, as amended, which prohibits, among other things, payments, offers, or promises made for the purpose of improperly influencing any act or decision of a foreign official. The nature of our business means that we engage in significant interactions with foreign officials. We are also subject to economic sanctions and export controls rules and regulations imposed by, amongst others, the U.S. Department of the Treasury's Office of Foreign Assets Control, the U.S. Department of Commerce, other agencies of the U.S. government, HM Treasury and other agencies of the U.K. government, the European Union, and the United Nations. Any expansion, broadened or changed interpretation, variation, or addition to these rules and regulations could impose significant compliance costs on us.

We have mechanisms in place to procure compliance with applicable anti-corruption, anti-money laundering, and economic sanctions rules and regulations, and applicable self-regulatory industry codes by region that the Company has committed to follow. However, there can be no assurance that our policies and procedures will be followed at all times or will effectively detect and/or prevent violations of applicable compliance regimes by our employees, consultants, sub-contractors, agents and partners. As a result, in the event of non-compliance, we could be subject to legal proceedings, fines and/or civil or criminal penalties, the disgorgement of profits, damage to our reputation and resulting loss of revenue and profits, which could have a material adverse impact on our business, financial conditions and operations.

The pharmaceutical sector is facing increased government scrutiny from competition and pricing authorities around the world, and any failure to comply, may expose us to significant damages and commercial restrictions that can materially and adversely affect our business.

We are required to comply with competition laws in the territories where we do business around the world. Compliance with these laws has been the subject of increasing focus and activity by regulatory authorities (and private plaintiffs, where they have enforcement rights under the law), both in the U.S. and Europe, in recent years. Violations of such laws may have a material adverse effect on our reputation, business, financial condition, and results of operations. Our company has faced and may in the future face investigations and/or legal proceedings alleging that actions purportedly taken by our company violated such laws. For example, we were a party to civil claims settled in 2023 brought by state officials and private plaintiffs alleging that we violated U.S. federal and/or state antitrust and consumer protection laws. See *Item 8. Financial Statements—Audited Consolidated Financial Statements - Note 16. Commitments and Contingencies*. We may face additional claims from state officials and private plaintiffs in the future, and any such claims could materially and adversely affect our business. Also, on November 20, 2020, we entered into a Stipulated Order for Permanent Injunction and Equitable Monetary Relief in the U.S. District Court for the Western District of Virginia, Abingdon Division, with the FTC. As part of the resolution with the FTC, for a ten-year period ending in 2030, Indivior Inc. is required to make specified disclosures to the FTC and is prohibited from certain conduct. We reached a similar settlement with the Attorneys General of 41 States and the District of Columbia on June 13, 2023 related to the civil claims settlement discussed above, which also expires in 2030.

Companies operating in the pharmaceutical industry also face challenges to the validity or enforceability of listed patents and frequently agree to settlements of patent litigation. Regulatory authorities in the U.S. and Europe, including the FTC and the European Commission, increasingly scrutinize patent settlements. Additionally, competition law authorities may send formal or informal requests for information about particular settlement agreements, and there is a risk that governmental authorities, customers, other downstream purchasers or others may commence actions alleging violations of antitrust laws based on our settlement agreements.

The U.S. Congress and certain state legislatures in the U.S. have also passed, or proposed passing, legislation that could adversely impact the ability to settle patent litigation. For example, the State of California has enacted legislation that prohibits, with certain exceptions and safe harbors, various types of patent litigation settlements, and imposes substantial monetary penalties on companies and individuals who do not comply.

Following calls in recent years from policymakers and other stakeholders in many countries for governmental intervention to address the high prices of certain pharmaceutical products, we may become, from time to time, subject to governmental investigations, claims or other legal or regulatory actions regarding our pricing and/or other alleged exclusionary practices. It is not possible to predict the ultimate outcome of any such investigations, claims or proceedings or what other investigations or lawsuits or regulatory responses may result from such assertions, which could have a material adverse effect on our reputation, business, financial condition, and results of operations.

Risks Related to our Financial Condition and Tax Matters

Recently proposed tariffs on pharmaceutical products, and potential reciprocal responses by other countries, may adversely affect our revenues or profitability.

On February 18, 2025, President Trump said he was considering tariffs of 25% or more on pharmaceutical and other products. He indicated that such tariff rates might increase substantially over the course of the year to allow manufactures a phase-in period to allow potential on-shoring of manufacturing. It is unclear at this time whether and to what extent such tariffs will take place, or how affected countries may react. On the one hand, the administration has signaled that the tariffs are likely to take effect on April 1, 2025, but on the other hand, Trump Administration officials are meeting with trade representatives of affected countries and indicated that countries may be able to negotiate for lower tariffs. At this time, few details are available, and any impact on Indivior would depend on the terms of the tariff.

We import certain raw ingredients or intermediate products from the U.K., EU, and Australia. If implemented, we expect these tariffs to be applied by the U.S. to impact both SUBLOCADE and SUBOXONE Film as we manufacture the active pharmaceutical ingredient (API) for these products at our plant in the U.K. Additionally, our products move through various countries at various stages of the production cycle, and goods may move through multiple European countries, which could be subject to tariffs applied by the U.S.

In the event the U.S. implements tariffs, we may face retaliatory tariffs levied by impacted countries. We export a significant amount of our finished products from the U.S. to Canada, Australia, the U.K., and the EU.

We have limited ability to avoid any applicable tariffs in the short or medium term due to existing manufacturing commitments and the time needed to transfer technology and have a new manufacturing site validated by the FDA and other regulators. Our current plans to manufacture some of our requirements for SUBLOCADE at our Raleigh Manufacturing Facility beginning in late 2026 contemplate that the API would be provided by our existing U.K. plant.

We have limited capacity to raise prices to recover costs of tariffs because, for example, the federal Inflation Reduction Act limits US pharma price increases to no greater than a certain inflation rate, and increases in excess of inflation trigger a 100% excise tax.

Weakness in the economy, geopolitics, market trends, disruptions in our supply chain, uncertainty and other conditions in the markets in which we operate, particularly in the U.S., may adversely affect the profitability and financial stability of our customers, and could negatively impact our sales growth and results of operations.

Our financial performance depends in part on general economic and geopolitical conditions in the geographic markets in which we operate, particularly in the U.S., where we generated 85% our revenue in fiscal 2024. Further, as a global business, we are also subject to changes in economic conditions and cost inflation, interest rates, credit and capital markets, foreign exchange rates, political conditions, and tax policies. For example, in 2022, the U.S. experienced price inflation at its highest levels in 40 years, and inflation rates globally have been elevated. Global supply chain challenges continue to challenge all industries. Armed conflicts may compound supply chain challenges, possibly including shortages of materials and labor, increased demand for goods and services, constricted logistics capacity, and rising commodity and energy prices. Our agreements with some customers and government purchasers may limit our ability to raise prices commensurate with these cost increases. The Company has noted lead time extension, constricted capacity and minor disruption in some supply components. Numerous industries have suffered from supply chain disruptions or labor shortages that may affect us in unexpected ways. If major delays or shortages occur, the delivery of products to our patients could be disrupted and impact the Company's short-term financial performance. Any of these geopolitical or macroeconomic trends may have an adverse effect on our profitability, ability to generate revenue or fund operations, and ability to raise capital, which in turn could have a material adverse effect on our business, financial condition, and results of operations.

We may also be affected by other factors which ultimately might reduce demand for our products. While OUD rates remain high in the U.S., our largest market, recent data shows a reduction in overdose deaths. Further, authorities report increased abuse of other drugs including sedatives and anesthetics such as xylazine (also known as 'tranq') and ketamine, and amphetamines and stimulants such as methamphetamine, and our addiction and overdose recovery products are not indicated to treat the abuse of such drugs. Also, OUD rates might also be affected by the actions of governments to better restrict the manufacture of opioids outside the U.S. and the illegal import of such drugs into the U.S.

Our balance sheet is leveraged, and any reduction in annual sales may adversely affect our liquidity.

Our current liabilities exceed our current assets by over $100 million and total liabilities exceed our total assets by over $300 million. Any material change in net revenues, the timing of collections, and rebate payments may impact our liquidity in the near-term and our ability to meet our obligations in the long term.

For example, the Company offers rebates to healthcare authorities and under contractual arrangements with certain customers. The amount of the rebate varies based on sales channel and payor but can be significant. At December 31, 2024, the liability for returns and rebates was $565 million *See Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations - Critical Accounting Estimates - Returns, incentives and rebates*. Generally, we are paid in full shortly after delivery and accrue an estimate of our liability for rebates. Several months may pass between the original estimate of rebates due, confirmation of the amount, and subsequent payment of the liability. Until the final amount of the rebate or incentive is determined and paid, we benefit from the use of this cash. If our annual sales were to decline, the corresponding reduction of rebates payable would negatively impact our liquidity. We provided guidance on February 20, 2025 that we expect an accelerated decline in net revenues from SUBOXONE Film in 2025 due to increased generic competitive activity and the potential impact from a fifth buprenorphine/naloxone sublingual film generic in the U.S. market.

Any future pandemic, and governmental and societal responses thereto, may harm our business, results of operations, and financial condition.

The COVID-19 pandemic had a significant impact on the global healthcare delivery system. Many healthcare systems had to restructure operations to prioritize caring for COVID-19 patients and limit or cease other activities. Many governments, including in the U.S., U.K., and Canada, imposed stringent restrictions to seek to mitigate, or slow, the spread of COVID-19, including restrictions on international and local travel, public gatherings and participation in business meetings, as well as closures of workplaces, churches, schools, and other public sites.

Possible future pandemics may negatively affect us in a variety of ways, including restrictions on access to HCPs by our sales force, disruptions to the supply of our products to patients if we experience either a significant absence of our employees and/or employees at our contract manufacturing organizations, vendors and service providers due to infection and/or government containment measures, and/or capacity issues at our airfreight and road logistics providers. In addition, possible future pandemics may result in overall fewer patient visits to healthcare provider offices for non-pandemic reasons or essential treatments, as patients become unable or unwilling to make visits due to overburdened healthcare systems, safety concerns, quarantines and other travel restrictions, or elect to have remote consultations with their providers. In the past, this also impaired our ability to enroll new patients in clinical trials and the development of real-world evidence for our existing products that are used for regulatory submissions and to supplement our label. Any of the above factors could have a material adverse effect on our business, financial condition, and results of operations.

Our insurance coverage may not be adequate.

Our business exposes us to potential product liability and professional indemnity claims and other risks which are inherent in the research, pre-clinical and clinical evaluation, manufacturing, sales and marketing and use of pharmaceutical products. We have public liability (general liability) and product liability insurance. However, product liability insurance may be unavailable for many claims involving our opioid drug products due to contractual exclusions in our insurance policies. We also have insurance covering losses from property damage and business interruption, third-party named suppliers, marine and cargo, directors' and officers' liability, clinical trials, automobile (fleet vehicles), employers' liability, personal accident and travel, and cybersecurity.

We believe the insurance coverage currently in place generally is appropriate for a business of our current size, nature and financial position. However, coverage limits and indemnity provisions may not be adequate to cover all potential claims that could arise against us in the conduct of our business nor that

claims will arise from insurable risks or that in the future we will be able to obtain coverage that is appropriate due to cost, risk or otherwise. There are additional factors that could affect reimbursement of payment by insurers, including (i) the scope of the insurers' purported defenses and exclusions to avoid coverage, (ii) the outcome of negotiations with insurers, (iii) delays in or avoidance of payment by insurers and (iv) the extent to which insurers may become insolvent in the future. In addition, areas where insurance coverage, while potentially available, may carry premiums that are not commercially reasonable and/or may be difficult to obtain or maintain on commercially reasonable terms. Product liability insurance, particularly for buprenorphine products, is difficult to obtain and may not be available in the future on acceptable terms or at all. A successful claim or claims against us in excess of or outside of our insurance coverage may have a material adverse effect on our business, prospects, results of operations and financial condition.

Our term loan contains certain covenants that could limit our ability to plan for or respond to changes in our business.

The Company has a $350 million term loan extended pursuant to a Note Purchase Agreement, which includes two financial covenants. The first requires that the Total Leverage Ratio of the consolidated borrower group to be less than 3.0 to 1.0 (through September 30, 2026), and then less than 2.50 to 1.0 from December 31, 2026 and thereafter. The Total Leverage Ratio is generally defined as the ratio of (i) total debt less cash and cash equivalents (up to $50 million) to (ii) Adjusted EBITDA for the preceding 12-month period. (See *Item 8. Financial Statements—Audited Consolidated Financial Statements - Note 12. Debt* for explanation of Adjusted EBITDA). The second requires that the Interest Coverage Ratio of the consolidated borrower group to be at least 2.50 to 1.00. The Interest Coverage Ratio generally is defined as the ratio of Adjusted EBITDA to interest expense for the preceding 12-month period.

The Note Purchase Agreement also has several other affirmative covenants and generally subjects the Company to negative covenants customary for facilities of this nature, including a limitation on disposal of assets, a limitation on prepayments and redemptions of certain indebtedness, a limitation on further indebtedness, a limitation on liens, a limitation on further negative pledges, limitations on share buybacks and redemptions, dividends and other "restricted payments," a limitation on subsidiary distributions, limitations on investments, a limitation on mergers and acquisitions and other fundamental changes, limitations on sale and lease-back transactions, a restriction on changes to any material line of business (including the business of the restricted subsidiaries of the Borrower), restrictions on modifying the terms of certain debt and general restrictions on the organizational documents and fiscal year of the Borrower. These negative covenants are subject to various carve-outs, grace periods and qualifications and, in some instances, are also applicable to most subsidiaries of Indivior PLC.

We may not be able to generate sufficient cash to service all of our indebtedness and may be forced to take other actions to satisfy our obligations under our indebtedness.

We have a $350 million term loan, future contractual interest payments on this loan of approximately $174 million, and approximately $696 million of other contractual liabilities, mostly related to the settlement of prior litigation. See *Item 8. Financial Statements—Audited Consolidated Financial Statements - Note 11. Accrued Litigation Settlement Expenses*.

Our ability to make scheduled payments on our indebtedness or our other obligations or to refinance our indebtedness depends on our financial condition and operating performance and our ability to generate cash, which is subject to prevailing economic, industry and competitive conditions and to certain financial, business and other factors discussed in these "Risk Factors," many of which are beyond our control. In addition, we may elect to prepay some of our contractual liabilities due to governmental parties in order to reduce reporting and other requirements associated with such settlements. Any such prepayment would use a substantial portion of our cash and further reduce our ability to make scheduled payment on our other indebtedness.

The term loan matures on November 4, 2030 and there can be no assurance that we will be able to refinance our existing term loan at maturity, or obtain other or additional financing on attractive terms, if at all. At the maturity of our term loan and any other debt which we incur, if we do not have sufficient cash flows from operations and other capital resources to pay our debt obligations, or to fund our other liquidity

needs, or if we are otherwise restricted from doing so due to corporate, tax or contractual limitations, we may be required to refinance our indebtedness. Our involvement in the opioid industry has in the past, and may in the future, limit the number of business partners willing to lend to us. If we are unable to refinance all or a portion of our indebtedness or obtain such refinancing on terms acceptable to us, we may be forced to reduce or delay our business activities or capital expenditures, sell assets or raise additional debt or equity financing in amounts that could be substantial. The type, timing and terms of any future financing will depend on our cash needs and the prevailing conditions in the financial markets. We can provide no assurance that we will be able to accomplish any of these measures in a timely manner or on commercially reasonable terms, if at all.

Our ability to restructure or refinance our debt will depend in part on our financial condition at such time. Any refinancing of our debt could be at higher interest rates than our current debt and may require us to comply with more onerous covenants, which could further restrict our business operations. The terms of existing or future debt instruments may restrict us from adopting some of these alternatives. Furthermore, we may be unable to find alternative financing, and even if we could obtain alternative financing, it might not be on terms that are favorable or acceptable to us. If we are not able to refinance our debt, obtain additional financing or sell assets on commercially reasonable terms or at all, we may not be able to satisfy our debt obligations. In that event, borrowings under other debt agreements or instruments that contain cross-default or cross-acceleration provisions may become payable on demand, and we may not have sufficient funds to repay all our debts, including the term loan.

If our cash flows and capital resources are insufficient to fund payments of interest or principal on our outstanding debt or our obligations, we could face substantial liquidity problems and might be required to reduce or delay capital expenditures, sell assets or business operations, seek additional capital or restructure or refinance our term loan. We cannot ensure that we would be able to take any of these actions, that these actions would be successful and permit us to meet our scheduled obligations or that these actions would be permitted under the terms of existing or future debt agreements, including the agreement governing our term loan. In addition, any failure to make payments of interest and principal on our outstanding term loan on a timely basis would likely result in a reduction of our credit rating, which could harm our ability to incur additional indebtedness.

Our effective tax rate may increase, and changes in tax rules and regulations, or interpretations thereof, may adversely affect our financial condition.

As a global biopharmaceutical company, we are subject to taxation in several different jurisdictions. As a result, our effective tax rate is derived from a combination of applicable tax rates in the various places where we operate. In preparing our financial statements, we estimate the amount of tax that will become payable in each of these places. Our effective tax rate may fluctuate depending on several factors, including, but not limited to, the distribution of our earnings or losses between the jurisdictions where we operate and differences in the interpretation of tax laws. In addition, the tax laws of any jurisdiction in which we operate may change in the future, which could impact our effective tax rate. Tax authorities in the jurisdictions in which we operate may audit us. If we are unsuccessful in defending any tax positions adopted in our submitted tax returns, we may be required to pay taxes for prior periods, interest, fines or penalties, and may be obligated to pay increased taxes in the future, any of which could have a material adverse effect on our business, financial condition, cash flows and results of operations.

Our effective tax rates could be affected by numerous factors, such as changes in tax laws, regulations, administrative practices, principles and interpretations, the mix and level of earnings in a given taxing jurisdiction or our ownership or capital structures. Any current or future proposed changes to the tax rules that apply to corporations could materially affect our tax obligations and effective tax rate. In addition, the Organisation for Economic Co-operation and Development (OECD) has achieved widespread political agreement to work towards the implementation of a global minimum tax. As a result, it is possible that the Company's consolidated effective tax rate will increase in the short term. It is difficult to predict whether and when tax law changes will be enacted that would have a material adverse effect on our business, financial condition, results of operations and cash flows.

The application of tax law is subject to interpretation and is subject to audit by taxing authorities. Additionally, administrative guidance can be incomplete or vary from legislative intent, and therefore the application of the tax law is uncertain. While we believe the positions taken by the Company comply with relevant tax laws and regulations, taxing authorities could interpret our application of certain laws and regulations differently. Future tax controversy matters may result in previously unrecorded tax expenses, higher future tax expenses, or the assessment of interest and penalties.

Our deferred tax assets may not be realized.

On December 31, 2024 we had $280 million of deferred tax assets, net of valuation allowance, consisting of $135 million of net deferred tax assets in the U.S. and $142 million of net deferred tax assets in the U.K., respectively. It is possible that some or all of such deferred tax assets will not be realized, especially if we incur losses in either the U.S. or the U.K. in the future. Losses may arise from unforeseen operating events. Unless we are able to generate sufficient taxable income in the future, a substantial reduction in the carrying value of either our U.S. or U.K. deferred tax assets may be required, which would materially increase our expenses in the period the reduction is recognized and materially adversely affect our business, financial condition, and results of operations.

If a U.S. person is treated as owning at least 10% of our ordinary shares, such holder may be subject to adverse U.S. federal income tax consequences.

If a U.S. person is treated as owning (directly, indirectly, or constructively) at least 10% of the value or voting power of our ordinary shares, such person may be treated as a "U.S. shareholder" with respect to each "controlled foreign corporation" in our group. Because our group includes one or more U.S. subsidiaries, certain of our non-U.S. subsidiaries could be treated as controlled foreign corporations (regardless of whether or not we are treated as a controlled foreign corporation). A U.S. shareholder of a controlled foreign corporation may be required to report annually and include in its U.S. taxable income its pro rata share of "Subpart F income," "global intangible low-taxed income," and investments in U.S. property by controlled foreign corporations, regardless of whether we make any distributions. An individual that is a U.S. shareholder with respect to a controlled foreign corporation generally would not be allowed certain tax deductions or foreign tax credits that would be allowed to a U.S. corporation that is a U.S. shareholder with respect to a controlled foreign corporation. Failure to comply with these reporting and tax payment obligations may subject a U.S. shareholder to significant monetary penalties and may prevent the statute of limitations from starting with respect to such shareholder's U.S. federal income tax return for the year for which reporting was due. We cannot provide any assurances that we will assist investors in determining whether any of our non-U.S. subsidiaries is treated as a controlled foreign corporation or whether any investor is treated as a U.S. shareholder with respect to any such controlled foreign corporation or furnish to any U.S. shareholders information that may be necessary to comply with the aforementioned reporting and tax paying obligations. A U.S. investor should consult its advisors regarding the potential application of these rules to an investment in our ordinary shares.

Risks Related to Our Ordinary Shares

Our ordinary shares are subject to market price volatility and the market price may decline disproportionately in response to developments that are unrelated to our operating performance.

The market price of our ordinary shares has been, and in the future may be, volatile and subject to wide fluctuations as a result of a variety of factors including, but not limited to general economic conditions, developments with our pending litigation, period to period variations in operating results or changes in revenue or earning estimates by us, market and industry participants, and/or financial analysts, our failure to meet our stated guidance, our failure to comply with the rules under the Sarbanes-Oxley Act related to accounting controls and procedures, the discovery of material weaknesses and other deficiencies in our internal control and accounting procedures, and the other factors discussed in these risk factors. The market price could also be adversely affected by developments unrelated to our operating performance, such as the operating and share price performance of other companies that investors may consider comparable to us, speculation about us in the press and/or the investment community, unfavorable press, strategic actions by competitors (including acquisitions and restructurings, new competing products, and

new generic products), changes in market conditions, regulatory changes and broader market volatility and movements. Any or all of these factors could result in material fluctuations in the price of our ordinary shares, which could result in investors getting back less than they invested or a total loss of their investment.

In addition, where the market price of a company's shares has been volatile, the shareholders of such company may file securities class action litigation against that company based on various claims, such as securities fraud and other violations of securities laws. For example, an amended purported securities class action lawsuit was filed against Indivior PLC, Mark Crossley (the CEO of the Company), Ryan Preblick (the CFO of the Company), and Richard Simkin (the Chief Commercial Officer of the Company) on December 5, 2024, alleging violations of certain U.S. federal securities laws following a sudden drop in the market price of the Company's ordinary shares. See *Item 8. Financial Statements—Audited Consolidated Financial Statements - Note 16. Commitments and Contingencies*. See also the discussion of similar, but less common, U.K. litigation under the caption " *U.K. shareholder claims*" in *Item 8. Financial Statements—Audited Consolidated Financial Statements - Note 16. Commitments and Contingencies*.

Our operating results may fluctuate significantly.

We expect that any potential growth in revenue may fluctuate from quarter to quarter and year to year as a result of many factors, including the factors discussed in these Risk Factors. The results of any prior quarterly period should not be relied upon as an indication of our future operating performance. If our quarterly operating results fall below the expectations of investors or securities analysts, the price of our ordinary shares could decline substantially. Furthermore, any quarterly fluctuations in our operating results may, in turn, cause the price of our stock to fluctuate substantially.

Our ordinary shares are listed to trade on more than one stock exchange, and this may result in price variations.

Our ordinary shares are listed on both the Nasdaq and the LSE. From time to time, dual-listing may result in price variations between the exchanges due to a number of factors. Our ordinary shares trade in U.S. dollars on Nasdaq and in GBP on the LSE. In addition, the exchanges are open for trading at different times of the day and the two exchanges also have differing holiday schedules. Differences in the trading schedules, as well as volatility in the exchange rate of the two currencies, among other factors, may result in different trading prices for our ordinary shares on the two exchanges. Other external influences may have different effects on the trading price of our ordinary shares on the two exchanges.

We face a number of risks associated resulting from the relocation of our primary listing.

Effective June 27, 2024, we transitioned our primary stock exchange listing to Nasdaq from the LSE. We continue to have a secondary listing on the LSE where our ordinary shares trade on the Equity Shares (Transition) category. Accordingly our ordinary shares are now listed on both exchanges. As a result of the relocation of our primary listing we have ceased to be eligible for inclusion in certain U.K. and European equity indices. However, we are currently ineligible for inclusion in many U.S. equity indices, including the S&P 600, Russell 2000, and CRSP. Further, we may fail to satisfy the criteria to become eligible for consideration for inclusion in such indices, and even if we do inclusion in any index is at the discretion of the index provider. The price and liquidity of our ordinary shares may be adversely affected until we are included in U.S. equity indices.

The rights afforded to our shareholders are governed by English law. Not all rights available to shareholders under U.S. law will be available to holders of our ordinary shares.

Indivior PLC is organized under the laws of England and Wales. The rights of holders of our ordinary shares are governed by English law and our articles of association (the "Articles"), and these may not provide the level of legal certainty and transparency afforded by incorporation in a U.S. state. There can be no assurance that English law will not change in the future or that it will serve to protect investors in a similar fashion afforded under corporate law principles in the U.S., which could adversely affect the rights of investors. Rights afforded to shareholders under English law differ in certain respects from the rights of

shareholders in typical U.S. companies. In particular, English law currently significantly limits the circumstances in which the shareholders of English companies may bring derivative actions (i.e., legal actions brought by a shareholder on behalf of a company against a third-party). Under English law, in most cases, only Indivior PLC may be the proper plaintiff for the purposes of maintaining proceedings in respect of wrongful acts committed against it and, generally, neither an individual shareholder, nor any group of shareholders, has any right of action in such circumstances. In addition, English law does not afford appraisal rights to dissenting shareholders in the form typically available to shareholders in a U.S. company. It may not be possible for shareholders outside the U.K. to enforce any judgments in civil or commercial matters or any judgments in securities laws of countries other than the U.K. against some or all of the directors or executive officers of Indivior PLC who are resident in the U.K. or countries other than those in which judgment is made.

Provisions of our Note Purchase Agreement and the U.K. City Code on Takeovers and Mergers may deter or prevent an otherwise beneficial takeover attempt of us.

Provisions of the Note Purchase Agreement could deter or prevent an otherwise beneficial takeover attempt of us. For example, a change of control constitutes an Event of Default under the Note Purchase Agreement. The Note Purchase Agreement generally defines a Change of Control to mean (i) the acquisition by any Person or group of Capital Stock representing more than 35% of the total voting power of all of the outstanding voting stock of Indivior PLC, or (ii) the occupation of a majority of the seats on the board of directors of Indivior PLC by persons who were not members of the board of directors of Indivior PLC when we entered into the Note Purchase Agreement and whose election to the board of directors of Indivior PLC was not approved by a majority of our Board. Because a Change of Control would trigger an Event of Default under the Note Purchase Agreement, otherwise beneficial takeover attempts may be discouraged or delayed.

Similarly, protections found in provisions under the U.K. City Code on Takeovers and Mergers (the "Takeover Code") may discourage or delay a takeover attempt, including attempts that may be beneficial to holders of our ordinary shares. As a company incorporated in the United Kingdom with a listing on the Main Market of the London Stock Exchange, the Takeover Code currently applies to any takeover offer for us.

The Takeover Code provides a framework within which takeovers of certain companies organized in the United Kingdom are regulated and conducted. Accordingly, our shareholders are entitled to the protections afforded by the Takeover Code and the Takeover Panel, which operate principally to ensure that shareholders are treated fairly and are not denied an opportunity to decide on the merits of a takeover, and that shareholders of the same class are afforded equivalent treatment by an offeror. However, the framework within which takeover offers under the Takeover Code must be conducted may differ from the rules and practices that apply to takeover offers for publicly listed US corporations.

For example, under the Takeover Code, if following an approach by or on behalf of a potential bidder, the company is “the subject of rumor or speculation” or there is an “untoward movement” in the company’s share price, there is a requirement for the potential bidder to make a public announcement about a potential offer for the company or be forced to step away from a potential transaction for a period of time, or for the company to make a public announcement about its review of a potential offer. Due to the potential disclosure, some potential U.S bidders unfamiliar with the Takeover Code may chose not to make an offer or decide to not continue with a potential bid because they are concerned about this public announcement. Other requirements include that a mandatory cash offer to be made if either:

- a person acquires an interest in shares which, when taken together with the shares in which persons acting in concert with it are interested, increases the percentage of shares carrying voting rights in which it is interested to 30% or more; or
- a person, together with persons acting in concert with it, is interested in shares which in the aggregate carry not less than 30% of the voting rights of a company but does not hold shares carrying more than 50% of such voting rights and such person, or any person acting in concert with it, acquires an interest in any other shares which increases the percentage of shares carrying voting rights in which it is interested.

Our business strategy may involve future transactions that may harm the market price of our ordinary shares or require us to seek additional funds, and such funding may not be available on commercially favorable terms or at all and may cause dilution to our existing shareholders. The issuance of additional ordinary shares in connection with future acquisitions, any share incentive or share option plan, or otherwise, may dilute all other shareholdings.

In order to achieve our business strategy, we regularly review potential transactions related to technologies, products or product rights, and businesses that are complementary to our business, including mergers and acquisitions, licenses and collaborations, and development and supply, commercialization or co-promotion arrangements, among others. We may choose to enter into one or more of these or other transactions at any time, which may cause substantial fluctuations in the market price of our ordinary shares. Moreover, depending upon the nature of any transaction, we may experience a charge to earnings, which could also materially adversely affect our results of operations and could harm the market price of our ordinary shares.

In order to finance such transactions, we may require additional funds, and we may seek such funds through various sources, including debt and equity offerings, corporate collaborations, bank borrowings, arrangements relating to assets, monetization of royalty streams or other financing methods or structures. In particular, we may, for these and other purposes, issue additional equity or convertible equity securities which would cause our shareholders to suffer dilution to their percentage ownership of the Company, or the market price of our ordinary shares may be adversely affected. The source, timing and availability of any financings will depend on global economic conditions, credit and financial market conditions, interest rates and other factors. If we issue additional equity securities or securities convertible into equity securities, our shareholders will suffer dilution of their investment, and it may adversely affect the market price of our ordinary shares. If we issue additional debt securities, our existing debt service obligations will increase further. If we are unable to generate sufficient cash to meet these obligations and need to use existing cash or liquidate investments in order to fund our debt service obligations or to repay our debt, we may be forced to curtail our operations. We cannot be certain that additional financing will be available from any of these sources when needed or, if available, will be on acceptable terms. If we fail to obtain additional capital when we need it, we may not be able to execute our business strategy successfully and may have to give up rights to our product platforms, and/or products, or grant licenses on terms that may not be favorable to us.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our share price and trading volume could decline.

The trading market for our ordinary shares depends in part on the research and opinions that securities or industry analysts publish about us or our business which we do not control. If one or more of the analysts who cover us downgrade our rating, lower our price target, or publish inaccurate or unfavorable research about our business, our share price could decline. If one or more of these analysts cease coverage of our company or fail to publish reports on our company regularly, demand for our ordinary shares could decrease, which might cause our share price and trading volume to decline.

We may not pay dividends or repurchase our shares in the future. Our ability to pay dividends, repurchase our shares, or make other returns of capital in the future depends, among other things, on our financial performance.

There can be no guarantee that our historical performance will be repeated in the future, particularly given the competitive nature of the industry in which we operate, and our revenue, income and cash flow may significantly underperform market expectations. If our cash flow underperforms market expectations, then our capacity to pay a dividend, repurchase shares, or make other returns of capital may be adversely impacted. Any decision to declare and pay dividends or to make other returns of capital will be made at the discretion of the Board and will depend on, among other things, applicable law, regulation, restrictions (if any) on the payment of dividends and/or capital returns in our financing arrangements, our financial position, retained earnings, working capital requirements, finance costs, general economic conditions and other factors that the Board deems significant from time to time.

We last paid a dividend in July 2016. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future, including due to limitations that are currently imposed by our Note Purchase Agreement. Any return to shareholders therefore likely will be limited to the increase in the price of our ordinary shares, if any.

Similarly, while we have completed four share repurchase programs with an aggregate value of $400 million between July 2021 and January 2025, any future repurchase of shares is subject to the discretion of our Board and will depend on similar factors as those that affect decisions to pay dividends. There can be no assurance the Company will repurchase any additional shares beyond the programs already announced.

The Parent Company is a holding company with no business operations of its own and depends on its subsidiaries for cash, including in order to pay dividends or make share repurchases.

The Parent Company is a holding company with no independent operations and is dependent on earnings and distributions of funds from its operating subsidiaries for cash, including in order to pay dividends to its shareholders or make share repurchases. The Parent Company's ability to pay dividends to its shareholders or make share repurchases therefore depends on the ability of its subsidiaries to distribute earnings or pay dividends to the Parent Company, general economic conditions, restrictions under our Note Purchase Agreement and other factors the Board deems significant from time to time. The Parent Company's distributable reserves can be affected by reductions in profitability, impairment of assets and severe market turbulence.

Risks Related to Information Security and Data Privacy

Business interruptions or breaches of data security could disrupt our product sales and delay the development of our product candidates.

We are dependent on information technology systems and infrastructure, including mobile technologies, to operate our business. In the ordinary course of our business, we collect, store and transmit confidential information, including intellectual property, proprietary business information and personal information. It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. While we have implemented processes and controls to collect, store, and transmit such information in a secure manner, there can be no assurance that any measures we take will prevent potential cyber-attacks or other security breaches that could adversely affect the confidentiality and integrity of such confidential information.

Like many companies, we have experienced breaches of our data security, including phishing attacks and malware. To date, none have had a material effect on our business strategy, results of operations or financial condition. Were we to have a cybersecurity incident, it is reasonably likely that it could have a material adverse effect on our business and financial results. While we have taken a number of steps to prevent further cybersecurity incidents, we cannot estimate how likely any such incident would be.

We also use a number of third-party vendors who have or could have access to our confidential information. The size and complexity of our information technology systems, and those of third-party vendors with whom we contract, make such systems potentially vulnerable to breakdown, malicious intrusion, insider threat attacks, security breaches, ransomware, and other cyber-attacks, all of which would be costly to remedy. In addition, the use of mobile devices or cloud-based systems that access confidential information increases the risk of data security breaches, which could lead to the loss of confidential information, trade secrets or other proprietary information. Failures of or disruptions to our systems or the systems of third parties on whom we rely, particularly if prolonged, could result in breaches of data security and/or a loss of key data which would adversely affect our reputation, business and results of operations. While we have implemented security measures to protect our data security and information technology systems, our visibility into the data security processes and controls in place at our third party vendors is inherently limited and, as a result, such measures may not prevent the adverse effect of such events.

In addition, we may be impacted by data breaches or business interruptions occurring within our supply chain, with our customers, or their business partners. For example, in February 2024, a data breach occurred at a leading provider of revenue and payment cycle management that connects payers, providers, and patients within the U.S. healthcare system. Although we did not contract with this provider, the impact of this data breach significantly disrupted payers, providers and their patients which subsequently impacted SUBLOCADE's revenues in the first and second quarters of 2024, particularly affecting new patient and refill adjudications, which contributed to a decrease in SUBLOCADE's sequential dispense growth in the U.S. in the second quarter of 2024. For additional information regarding how we manage information resources and threats, see '*Item 1.C. Cybersecurity.*"

We are required to maintain the privacy and security of personal information in compliance with privacy and data protection regulations worldwide. Failure to meet the requirements could result in fines, penalties, or private actions, harm our business and damage our reputation with customers, suppliers, and associates.

We rely on systems, networks, products, and services, some of which are managed by third-party service providers to protect our information. Increased information security threats, more sophisticated cyber-attacks and a growing base of diversified threat actors continually pose a risk to all systems and data.

Additionally, we collect, store, and process personal information relating to many stakeholders, including our customers, suppliers, and associates. This information is increasingly subject to a variety of U.S. laws, including an increasing number of comprehensive and health-care-specific laws across various U.S. states, and other emerging privacy and cybersecurity laws internationally, at the federal level in the U.S., and across various U.S. states, that may carry significant potential penalties for noncompliance. We are also subject to a variety of international laws and regulations, such as the General Data Protection Regulation, as enacted in the European Union, the Data Protection Act in the U.K., Canada's Personal Information Protection and Electronic Documents Act, the Australian Privacy Act 1988 and its amendments, that may carry significant potential penalties for noncompliance.

The FTC also sets expectations surrounding the privacy and security of consumers' personal information. It asserts that failing to take appropriate steps to keep consumers' personal information secure or failing to provide a level of security commensurate to promises made to individuals about the security of their personal information (such as in a privacy notice) may constitute unfair or deceptive acts or practices in violation of Section 5(a) of the Federal Trade Commission Act ("FTC Act"). The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards. With respect to privacy, the FTC also sets expectations that companies honor the privacy promises made to individuals about how a company handles consumers' personal information; any failure to honor promises, such as the statements made in a privacy policy or on a website, may also constitute unfair or deceptive acts or practices in violation of the FTC Act. While we do not intend to engage in unfair or deceptive acts or practices, the FTC has the power to enforce promises as it interprets them, and events that we cannot fully control, such as data breaches, may result in FTC enforcement. Enforcement by the FTC under the FTC Act can result in civil penalties or enforcement actions.

These data privacy and data protection laws and regulations are typically intended to protect the privacy of personal information that is collected, processed, transmitted, and stored. In many cases, these laws apply not only to third-party transactions, but also to transfers of information between a company and its subsidiaries. While we have invested and continue to invest significant resources to comply with data privacy regulations, many of these regulations are new, complex, and subject to interpretation. Noncompliance with these laws could result in negative publicity, damage to our reputation, penalties, or significant legal liability. We could be adversely affected if legislation or regulations are revised or extended to require changes in our business practices or if governing jurisdictions interpret or implement their legislation or regulations in ways that negatively affect our business. The landscape of federal and state laws regulating personal information is constantly evolving, and compliance with these laws requires a

flexible privacy framework and substantial resources, and compliance efforts will likely be an increasing and substantial cost in the future.

Risks Related to Our International Status and Operations

We are subject to various risks related to the local and international nature of our business, including domestic and foreign laws, regulations, and standards. Failure to comply with such laws and regulations or the occurrence of unforeseen developments such as litigation could adversely affect our business.

Our business operates in several countries including the U.S., U.K., Canada, France, Germany, and Australia and our products are available in more than 30 countries worldwide. As a result, we are subject to specific risks of conducting business in different jurisdictions across these countries and other parts of the world. Our business is subject to a wide array of domestic and international laws, regulations and standards in jurisdictions where we operate, including advertising and marketing regulations, anti-bribery and corruption/money laundering laws, anti-competition regulations, data protection (including payment card industry data security standards) and cybersecurity requirements (including protection of information and incident responses), environmental protection laws, foreign exchange controls and cash repatriation restrictions, government business regulations applicable to us as a government contractor or supplier selling to governmental agencies, import and export requirements, intellectual property laws, labor laws, product compliance laws, supplier regulations regarding the sources of supplies or products, tax laws, zoning laws, unclaimed property laws and laws as well as regulations and standards applicable to other commercial matters. In particular, occupational health and safety or consumer product safety regulation may require that we take appropriate corrective action, including but not limited to product recall, in respect of products that we have distributed. Managing a product recall or other corrective action can be expensive and can divert the attention of management and other personnel for significant time periods. Moreover, we are also subject to audits and inquiries by government agencies in the normal course of business.

Failure to comply with any of these laws, regulations and standards could result in civil, criminal, monetary and non-monetary penalties as well as potential damage to the Company's reputation. Changes in these laws, regulations and standards, or in their interpretation, could increase the cost of doing business, including, among other factors, as a result of increased investments in technology and the development of new operational processes. Furthermore, while we have implemented policies and procedures designed to facilitate compliance with these laws, regulations, and standards, and applicable self-regulatory industry codes by region that the Company has committed to follow, but there can be no assurance that neither we nor our associates, contractors or agents will not violate such laws inadvertently, regulations and standards or our policies. Any product recall or other corrective action may negatively affect customer confidence in the relevant products and the Company itself, regardless of whether it is successfully implemented. Any such failure to comply or violation could individually or in the aggregate materially adversely affect our business, financial condition, results of operations and cash flows.

We are exposed to risks related to currency exchange rates.

We are incorporated in England and Wales but present our financial statements in this report in U.S. dollars. Based on the country where sales originate, we derived 85%, 83%, and 81% of our net revenues from the U.S. in 2024, 2023, and 2022, respectively. We also conduct business in the U.K., Europe and Australia, among other places. Our agreements with customers outside the U.S. often involve payments denominated in currencies other than U.S. dollars, which creates foreign currency translation risk. Our operating results are therefore subject to currency fluctuations in translating revenues and costs from those foreign currencies to U.S. dollars. Additionally, if in the future we expand our sales and operations into new markets, different currencies could expose us to additional currency translation risks. These risks increase with the varying strength of the U.S. dollar.

We generally do not actively hedge exchange rate fluctuations, although we attempt to balance large non-U.S. dollar liabilities with a similarly sized monetary assets in the same currency, which is sometimes referred to as a natural hedge. To the extent that we do not hedge our exposure to foreign currency exchange rate fluctuations, or to the extent that such hedging is structured ineffectively or does not offset

our exposure to exchange rate fluctuations, our business, financial condition, and results of operations could be materially adversely affected.

Exchange rate fluctuations between local currencies and the U.S. dollar also create risk in other ways, including but not limited to: (i) increasing the U.S. dollar cost of non-U.S. research and development expenses and the cost of sourced product components outside the U.S. (in the case of a weakening U.S. dollar); (ii) decreasing the value of our revenues denominated in other currencies (in the case of a strengthening U.S. dollar); (iii) distorting the value of non-U.S. dollar transactions and cash deposits; and (iv) affecting commercial pricing and gross margins of our products. These effects can have an adverse impact on our results of operations and financial condition and may also make it more difficult for investors to understand the relative strengths or weaknesses of our underlying business on a period-over-period comparative basis.

Risks Related to Being a Publicly-Traded Company in the U.S.

If we fail to maintain an effective system of internal control over financial reporting ("ICFR"), fail to comply with Section 404 of the Sarbanes-Oxley Act, or if we identify a material weakness, then we may not be able to accurately report our financial results or prevent fraud and, as a result, shareholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our ordinary shares and may cause other increases in operating costs.

We were first required to comply with the internal control evaluation and certification requirements of Section 404 of the Sarbanes-Oxley Act for our 2024 fiscal year. We have incurred, and expect that we may further incur, significant additional accounting, legal, and other expenses in connection with complying with the Sarbanes-Oxley Act. If we fail to maintain effective ICFR for any reason, such failure could harm our reputation, operations, financial reporting or financial results and could result in our conclusion that our ICFR is not effective. In addition, if it is determined that we are not in compliance with Section 404, we may be required to implement new internal control procedures and re-evaluate our financial reporting.

Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us, as and when required, conducted in connection with Section 404 or any subsequent testing by our independent registered public accounting firm, as and when required, may reveal deficiencies in our ICFR that may be deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inferior ICFR could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our ordinary shares.

A material weakness is a deficiency, or a combination of deficiencies, in ICFR, such that a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. In other words, a material weakness means there is an unmitigated risk the financial information we report contains material errors, or that we might be unable to detect fraud. Any system of internal controls, however well-designed and operated, is based in part on certain assumptions and can provide only reasonable, not absolute, assurances that the objectives of the system are met. If we cannot conclude that we have effective ICFR, investors could lose confidence in the reliability of our financial statements, which could lead to a decline in the trading price of our ordinary shares. Failure to comply with reporting requirements could also subject us to sanctions and/or investigations by Nasdaq or the SEC or other regulatory authorities.

We are a foreign private issuer. Should we no longer qualify as a foreign private issuer in the future, we may incur significant additional expenses. Also, as a foreign private issuer, we are not subject to SEC proxy rules. As a foreign private issuer, we are permitted to follow certain home country corporate governance practices in lieu of certain requirements applicable to domestic U.S. issuers. This may afford less protection to holders of our ordinary shares.

As of June 30, 2024, 63,953,605 shares were held for the benefit of 1,869 shareholders who were U.S. residents, comprising approximately 48% of our issued share capital. Because not more than 50% of our ordinary shares were held by shareholders resident in the U.S., we qualify as a "foreign private issuer" within the meaning of Rule 405 of the Securities Act, as amended (the "Securities Act") and Rule 3b-4 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). We thus are exempt from certain provisions of the Exchange Act that are applicable to U.S. public companies, including: (i) the sections of the Exchange Act regulating the solicitation of proxies, consents or authorizations in respect of a security registered under the Exchange Act; (ii) the sections of the Exchange Act requiring insiders to file public reports of their stock ownership and trading activities and liability for insiders who profit from trades made in a short period of time; and (iii) the rules under the Exchange Act requiring the filing with the SEC of quarterly reports on Form 10-Q containing unaudited financial and other specified information, or current reports on Form 8-K, upon the occurrence of specified significant events, although commencing with this filing we intend to voluntarily file such quarterly and current reports. Foreign private issuers are also exempt from compliance with Regulation Fair Disclosure, which is aimed at preventing issuers from making selective disclosures of material information.

The determination of foreign private issuer status is made annually on the last business day of an issuer's most recently completed second financial quarter. Accordingly, we will next make a determination with respect to our foreign private issuer status on June 30, 2025.

We will lose our foreign private issuer status if more than 50% of our issued ordinary share capital is held by U.S. residents as of June 30, 2025. If we lose our foreign private issuer status, the regulatory and compliance costs to us under U.S. securities laws as a U.S. domestic issuer will be significantly greater than the costs incurred as a foreign private issuer, and we have already begun to incur some of those costs.

In addition, as a foreign private issuer whose shares are listed on Nasdaq, we are permitted to follow certain home country corporate governance practices in lieu of certain Nasdaq requirements. As a company incorporated in the U.K. and which has a secondary listing on the Equity Shares (Transition) category of the LSE, we may follow our home country's practice with respect to, among other things, Nasdaq rules requiring shareholders to approve equity compensation plans and material revisions thereto. We discuss these below at Item 10., "Directors, Executive Officers and Corporate Governance—*Board Practices*." As a result, shareholders may not have the same protections afforded to shareholders of companies that are not foreign private issuers.

We have changed the financial reporting standards that we apply to our financial statements from IFRS to U.S. GAAP and, as a result, some of our financial data may not be easily comparable to historical financial results.

We have transitioned from IFRS to U.S. GAAP, and we will report our financial statements in the U.S. under U.S. GAAP for future periods. As a U.K. company, Indivior will also continue to comply with applicable U.K. legal requirements relating to the publication of financial reports and accounts under IFRS at the half-year and year end. In connection with this transition, we have invested significant resources and time to convert historical financial statements prepared under IFRS from prior fiscal years into U.S. GAAP financial statements. There have been and there may in the future be significant differences between U.S. GAAP and IFRS, including differences related to acquired in-process research and development costs, intangible assets, capitalized development costs, lease accounting, and income tax. As a result, our financial information and reported earnings for future periods within a fiscal year or any interim period could be significantly different. Consequently, one may not be able to meaningfully compare our financial statements under U.S. GAAP with our current or historical financial statements under IFRS.

Changes in accounting standards and subjective assumptions, estimates and judgments by management related to complex accounting matters, could significantly affect our financial results or financial condition.

Accounting standards, including both U.S. GAAP and IFRS, and related accounting pronouncements, implementation guidelines and interpretations with regard to a wide range of matters that are relevant to our business, such as revenue recognition, asset impairment, inventories, lease obligations, self-insurance, tax matters, pensions and litigation, and impairment of goodwill and other intangible assets are complex and involve many subjective assumptions, estimates and judgments. See, for example, "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations—*E. Critical Accounting Estimates*." These estimates may be more sensitive, particularly regarding assumptions pertaining to the difference between gross revenue and net revenue, than others in our industry or in other industries. Changes in accounting standards or their interpretation or changes in underlying assumptions and estimates or judgments could significantly change our reported or expected financial performance or financial condition.

The obligations associated with being a company publicly traded in the U.S. require significant resources and management attention, and changing laws, regulations and standards are creating uncertainty for U.S. public companies.

As a company publicly traded in the U.S., we incur legal, accounting and other expenses that we did not previously incur. We are subject to the reporting requirements of the Exchange Act and the Sarbanes-Oxley Act of 2002 ("Sarbanes-Oxley Act") which contain certain exemptions for FPIs, the listing requirements of Nasdaq, and other applicable securities rules and regulations. The Exchange Act requires that we file annual and other reports with respect to our business, financial condition, and results of operations. The Sarbanes-Oxley Act requires, among other things, that we establish and maintain effective ICFR. Furthermore, the establishment and the maintenance of the corporate infrastructure demanded of a company publicly traded in the U.S. may, in certain circumstances, divert management's attention from implementing our growth strategy, which could prevent us from improving our business, financial condition, and results of operations. We have made, and will continue to make, enhancements to our ICFR and accounting systems in order to meet our reporting obligations as a company publicly traded in the U.S. However, the measures we take may not satisfy these obligations. In addition, compliance with these rules and regulations has increased our legal and financial compliance costs and has made some activities more time-consuming and costly. These additional obligations may have a material adverse impact on our business, financial condition, results of operations and cash flow.

In addition, changing laws, regulations and standards relating to corporate governance, ESG matters, and public disclosure create uncertainty for public companies in the U.S., increasing legal and financial compliance costs and making some activities more time-consuming. These laws, regulations and standards are subject to varying interpretations, in many cases due to their lack of specificity and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We have invested, and expect to continue to invest, resources to comply with evolving laws, regulations and standards, and this investment may result in increased operating expenses and a diversion of management's time and attention from revenue-generating activities to compliance activities. If our efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to their application and practice, regulatory authorities may initiate legal proceedings against us and our business, financial condition, results of operations and cash flow could be adversely affected.

In addition, as a company publicly traded in the U.S., our shareholders may file securities class action litigation against that company based on various claims such as securities fraud and other violations of securities laws when the market price of a company's shares has been volatile. For example, an amended, purported securities class action lawsuit was filed against Indivior PLC, Mark Crossley (the CEO of the Company), Ryan Preblick (the CFO of the Company), and Richard Simkin (the Chief Commercial Officer of the Company) on December 5, 2024, alleging violations of certain U.S. federal securities laws following a

sudden drop in the market price of the Company's ordinary shares. See *16. Commitments and Contingencies*. The defense and disposition of litigation of this type could result in substantial costs and divert resources and the time and attention of our management, which could materially and adversely affect our business or financial condition. See also the discussion of similar, but less common, U.K. litigation under the caption " U.K. shareholder claims" in *Item 8. Financial Statements—Audited Consolidated Financial Statements - Note 16. Commitments and Contingencies."*

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity.

Risk management and strategy

The Company recognizes the increasing sophistication of cyber threats, including phishing, malware attacks, and ransomware, affecting industries worldwide. Because we collect, store and transmit confidential information, including intellectual property, proprietary business information, and personal information in the ordinary course of our business, we are often the subject of various cyber-attacks. We may also be targeted by organized crime because of the nature of our products. Therefore, the Company has a number of processes for assessing, identifying, and managing material risks from cybersecurity threats as outlined below. In particular, the Company's cybersecurity risk management and strategy efforts encompass various measures, including:

a. **Risk Assessment Framework:** The Company endeavors to assess cyber risks in an ever-evolving cybersecurity threat landscape and seeks to grow the maturity of its infrastructure to defend against these ever-evolving cybersecurity threats. The Company uses a risk assessment framework as part of its risk management process related to cybersecurity, which includes the evaluation of potential vulnerabilities, threats, and impacts on the organization's information systems and data. This includes assessing the likelihood and potential consequences of identified cyber risks and threats to the enterprise.

b. **Business Operating Standards:** The Company has established business operating standards, monitoring processes, and a business resilience program to support the continuity of operations in the face of potential disruptions.

c. **IT Strategy and Governance:** The Company maintains IT strategies, governance frameworks, policies, processes, and disaster recovery plans which are aligned with overall business continuity objectives.

d. **Incident Response Plan:** The Company maintains an incident response plan that outlines specific steps to be taken in the event of a cybersecurity incident. This plan includes procedures for containing the incident, mitigating its impact, and recovering affected systems and data.

e. **Security Measures:** The Company deploys a large number of processes and tools to attempt to secure its systems and protect sensitive data. Indivior's information security program is aligned with the NIST 800-53 CSF framework.

f. **Employee Training and Awareness:** The Company actively works to promote a culture of security awareness including by investing in ongoing employee training and awareness programs. The Company conducts security exercises and provides training modules that cover topics like recognizing phishing attempts and maintaining strong password practices.

g. **Third-Party Risk Management:** We also use a number of third-party vendors who have or could have access to our confidential information. The Company has established processes to evaluate and manage cybersecurity threats associated with certain third-party service providers. The Company continues to evolve its third-party risk review processes for new and existing, critical third-party service providers.

h. **Regular Audits and Assessments:** Periodic internal and external audits and assessments are conducted periodically to evaluate the effectiveness of the cybersecurity measures in place. These audits help in identifying areas for improvement and compliance with industry standards and regulations.

i. **Incident Simulations:** The Company conducts periodic incident simulation exercises to test the effectiveness of its incident response plans and the readiness of personnel to contain, remediate and minimize the impact in the event of a cybersecurity incident. These exercises help in refining response strategies and improving preparedness.

j. **Use of Experts:** From time to time, the Company engages a variety of third parties with expertise in cybersecurity to conduct independent assessments and provide recommendations for enhancing its cybersecurity posture.

k. **ERM Integration:** The Company integrates the results of the Company's cyber risk assessment into its Enterprise Risk Management process, which is designed to identify, assess, manage, report, and monitor risks and opportunities affecting the achievement of the Company's strategy and objectives.

Following a cybersecurity incident, and during its investigation and the formulation of a response, our processes also envision measures designed to contain and/or eradicate the incident and prevent further effects. Once it is determined that the incident has been resolved, we then work to establish appropriate controls (if applicable) to address similar future events and/or prevent another similar event from occurring in the future. To date, we have not experienced any previous cybersecurity incidents that have materially affected or are reasonably likely to materially affect our business strategy, results of operations, or financial condition.

Governance

The Audit & Risk Committee of the Board oversees the Company's cybersecurity efforts. The Company's cybersecurity efforts are managed by the Chief Information Security Officer ("CISO") who has over 20 years of experience as a security professional in the pharmaceutical industry.

The CISO reports directly to the Chief Information and Innovation Officer ("CIIO"), who has over 30 years of experience as an Information Technology ("IT") professional including 15 years in leadership roles in the pharmaceutical, medical device and diagnostics industry, and was formerly Chief Information Officer and VP Global Supply Chain, Immucor, VP Global Information Services, Smith & Nephew, Sr. IT Director, Medtronic, and Sr. Manager, Deloitte Consulting.

The Audit & Risk Committee receives updates on an annual basis from the CIIO and CISO on the Company's Cybersecurity strategy approach to IT and cybersecurity, including on the prevention, detection, mitigation, and remediation of cybersecurity incidents. The Audit & Risk Committee also receives briefings as necessary on cyber risks and current threats directly from external cybersecurity experts. The CISO oversees the Company's governance programs, tests compliance with standards, works to remediate known risks, and leads our employee training program.

The CISO is informed and monitors the latest developments in cybersecurity, including potential threats and innovative risk management techniques. In the event of a cybersecurity incident, the CISO is equipped with a specific incident response plan. This plan includes immediate actions to mitigate the impact and long-term strategies for remediation and prevention of future incidents. As is necessary, the CISO and the CIIO, working at the direction of the Chief Legal Officer and outside counsel, inform the Audit & Risk Committee of any cybersecurity incidents and inform the Board directly of any material cybersecurity incidents. See also "Item 1A. *Risk Factors—Business interruptions or breaches of data security could disrupt our product sales and delay the development of our product candidates.*"

Item 2. Properties.

The following table contains information regarding Company's principal physical properties.

Location	Tenure	Principal use
Richmond, Virginia	Lease	Office space
Hull, England	Owned[1]	Office space, research, and manufacturing facility
Hull, England	Owned	Research and development
Fort Collins, Colorado	Lease	Office space and research facility
Slough, England	Lease	Office space
Raleigh, North Carolina	Owned	Manufacturing, warehousing, and research and development facility

(1) The Hull, England property is leased for 150 years and accounted for as owned.

Item 3. Legal Proceedings.

The descriptions of our litigation and regulatory matters, and other matters, contained in *Item 8. Financial Statements—Audited Consolidated Financial Statements* - Note 16. Commitments and Contingencies to our financial statements are incorporated herein by reference.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Shareholder Matters and Issuer Purchases of Equity Securities.

Market for Ordinary Shares

The principal trading markets for the Company's ordinary shares are the Global Select Market of The Nasdaq Stock Market LLC and the Equity Shares (Transition) category of the London Stock Exchange. The Company's ordinary shares trade under the symbol "INDV" on both exchanges. Effective June 27, 2024, we have designated Nasdaq as our primary exchange.

Holders

Based upon information supplied from our transfer agent, there were approximately 1,027 shareholders of record of our Ordinary Shares as of January 31, 2025.

Dividends

We have not paid any dividends during the past three fiscal years and do not anticipate declaring or paying any cash dividends on our ordinary shares in the foreseeable future. Under English law, any payment of dividends would be subject to relevant legislation and our articles of association, which provide that payment of dividends be approved by our board of directors and, in some cases, our shareholders, and may only be paid from our distributable earnings available for the purpose, determined on an unconsolidated basis.

Recent Sales of Unregistered Securities

None.

Purchases of Equity Securities by the Issuer and Affiliated Purchases

Period	Total Number of shares purchased	Average price paid per share[2]	Total number of shares purchased as part of publicly announced plans or programs	Maximum number of shares that may yet be purchased under the plans or programs
Oct. 1 to Oct. 31[1]	2,356,185	$8.89	2,356,185	7,417,125
Nov. 1 to Nov. 30[1]	1,486,660	$10.18	1,486,660	5,930,465
Dec. 1 to Dec. 31[1]	828,753	$11.53	828,753	5,101,712

(1) Pursuant to that fourth share repurchase program announced July 25, 2024, for an aggregate purchase price up to no more than $100 million or 13,649,017 of ordinary shares, which program concluded on January 31, 2025.
(2) The average price paid per share on the London Stock Exchange was translated to U.S. dollars using the average exchange rate for the noted periods as follows: Jan. 1 to Jan. 31 (GB£1:U.S.$1.2699), Feb. 1 to Feb. 28 (GB£1:U.S.$1.2633), Mar. 1 to March 31 (GB£1:U.S.$1.2716), April 1 to April 30 (GB£1:U.S.$1.2529), May 1 to May 31 (GB£1:U.S.$1.2623), June 1 to June 30 (GB£1:U.S.$1.2724), July 1 to July 31 (GB£1:U.S.$1.2847), Aug. 1 to Aug. 31 (GB£1:U.S.$1.2916), Sept. 1 to Sept. 30 (GB£1:U.S.$1.3194), Oct. 1 to Oct. 31 (GB£1:U.S.$1.3081), Nov. 1 to Nov. 30 (GB£1:U.S.$1.2770), and Dec. 1 to Dec. 31 (GB£1:U.S.$1.2646).

Item 6. [Reserved]

Not applicable.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis of our financial condition and results of operations should be read together with our consolidated financial statements and the related notes in *Item 8. Financial Statements—Audited Consolidated Financial Statements*. Historically, we prepared our consolidated financial statements in accordance with International Financial Reporting Standards. As part of the Company's efforts to align with industry peers and prepare for the expected loss of foreign private issuer status, the Company elected to file its 2024 annual report on Form 10-K, including presentation of its consolidated financial statements in accordance with U.S. GAAP. The transition to US GAAP is reflected retrospectively for all periods from the Company's inception. The following discussion is based on our financial information prepared in accordance with U.S. GAAP and regulations of the SEC. Some of the information contained in this discussion and analysis or set forth elsewhere in this annual report, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. *Item 1A. Risk Factors* includes a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis, as well as *Important Cautionary Note Regarding Forward-Looking Statements*.

Overview

Indivior is a global pharmaceutical company working to help change patients' lives by pioneering life-transforming treatment for addiction, including SUBLOCADE (buprenorphine extended-release) injection for subcutaneous use, a long-acting injectable for opioid use disorder and OPVEE (Nalmefene) nasal spray for opioid overdose recovery.

References below to "2024," "2023," and "2022" are for the financial years ended December 31, 2024, 2023, and 2022, respectively.

Operating Results

The following table summarizes our key measures of financial condition and results of operations for the periods under review:

	For the years ended December 31,				
(in millions, except per share data)	2024	2023	2022	% Change 2024-2023	% Change 2023-2022
Net revenue	$ 1,188	$ 1,093	$ 901	9 %	21 %
Operating income (loss)[1]	$ 32	$ (156)	$ (81)	(120) %	93 %
Net income (loss)[1]	$ 2	$ (129)	$ (44)	(102) %	190 %
Earnings (loss) per share—diluted[1]	$ 0.02	$ (0.94)	$ (0.32)	(102) %	194 %

(1) On October 10, 2022, Indivior PLC completed a 5:1 share consolidation. The Company's basic and diluted weighted average number of shares outstanding, basic earnings (loss) per share, and diluted earnings (loss) per share reflect the share consolidation for all periods presented.

For the periods presented, the Company operated as one business segment, which is predominantly the development, manufacture and sale of buprenorphine-based prescription drugs for the treatment of opioid dependence and related disorders, and nalmefene nasal spray for emergency opioid overdose reversal. Substantially all our net revenue for such periods were derived from sales of SUBLOCADE and other buprenorphine-based sublingual products (including SUBOXONE Film and SUBOXONE Tablet). SUBLOCADE accounted for 64%, 58%, and 45% of our net revenue in 2024, 2023, and 2022, respectively. Other buprenorphine-based sublingual products accounted for 32%, 38%, and 52% of our net revenue in 2024, 2023, and 2022, respectively. In the U.S. market for buprenorphine-based treatments for opioid dependence, SUBOXONE Film had an average market share of 16%, 19% and 20% in 2024, 2023, and 2022, respectively, according to data from IQVIA.

The U.S. market is the largest contributor to our net revenue. The following table sets out a breakdown of net revenue as between the U.S. and the Most of World.

	For the years ended December 31,				
(in millions)	**2024**	**2023**	**2022**	**% Change 2024-2023**	**% Change 2023-2022**
United States	1,008	912	732	11 %	25 %
Most of World	179	181	169	(1) %	7 %
Total net revenue	**$ 1,188**	**$ 1,093**	**$ 901**	**9 %**	**21 %**

Key factors affecting operating results

Market growth

Our net revenue is impacted by the overall growth of the markets where we operate. Market growth is impacted by increased treatment penetration, which is a function of patient awareness and desire to seek treatment, as well as the number of certified physicians available to deliver treatment. Competitive pressures can drive pricing and can also influence decisions of third-party payors regarding inclusion of products on their list of approved drugs covered by insurance. To increase access to treatment for patients, we engage with government agencies, key opinion leaders in addiction and healthcare professionals to bring patient outcomes to the forefront of decision making. Additionally, we engage in non-branded marketing to increase awareness for patients and families impacted by addiction on a country-by-country basis as allowed by local regulations.

In 2024, the volume of U.S. buprenorphine medication-assisted treatments (BMAT) grew in mid-single digits. Market growth was adversely impacted by transitory items including Medicaid re-enrollment in many large states and an issue impacting patient coverage approvals with one of the largest pharmacy benefit managers. The Company continues to expect long-term U.S. growth to be sustained in the mid- to high-single digit percentage range due to increased overall public awareness of the opioid epidemic and approved treatments, together with regulatory and legislative actions to increase access to BMAT treatments. In 2024, the Company's share of the market growth was impacted by both competition in the LAI category, which we expect to continue, as well as competition in the oral category.

Distribution channels

In the U.S., we have distribution agreements with the three largest wholesalers, which accounted for 55%, 54%, and 55% of our global net revenue in 2024, 2023, and 2022, respectively. These wholesalers, in turn, distribute our products through various channels including the following:

- ***Commercial managed care***. This category comprises insurance programs intended to reduce the cost of providing health benefits and improve the quality of care to their members. One of the most common forms of managed care is the use of a panel or network of healthcare providers that provide care to enrollees. Also within commercial managed care is the Medicare Part D Program, a social insurance program administered by the U.S. government.
- ***Medicaid***. Medicaid is a jointly funded, Federal-State health insurance program that covers children, the aged, blind, and/or disabled and other people who are eligible to receive federally assisted income maintenance payments, including prescription drugs. We are obligated to offer “Best Price” under Medicaid, being the lowest price at which the manufacturer sells a drug to any purchaser in any pricing structure (inclusive of discounts and rebates).
- ***Federal***. This channel encompasses the provision of outpatient drugs to federal government purchasers, including the U.S. Department of Veterans Affairs and the Department of Defense, or under the 340B Program. Pricing discounts are provided separately for drugs provided under these programs.

- ***Pharmacy***. This channel covers end customers paying cash directly at the pharmacy. Often, we provide discount coupons to customers where cash is used for payment.

Our fourth largest customer in the U.S. is a specialty pharmacy group which primarily purchases SUBLOCADE and dispenses product to patients through the various channels listed above.

In the Most of World, distribution channels differ by country. For example, in France, we engage with different wholesalers, hospitals, pharmacies and individuals, while in Australia, we engage with a single pre-wholesaler that negotiates the import and onward distribution of the products across the country.

Pricing

We offer various types of price reductions for our products, particularly in the U.S., which are reflected in net revenue. In the U.S., we primarily offer:

- ***Medicaid, Medicare Part D, and Commercial rebates.*** These are rebates granted to Medicaid, U.S. federal agencies and commercial managed care providers that purchase products from us. The level of these rebates varies by channel and product. Patients covered by commercial insurance often benefit from coupons to reduce any out-of-pocket payments they would otherwise be required to make.
- ***Fees under distribution agreements.*** Wholesalers, specialty pharmacies and specialty distributors of the Company's products are generally offered various forms of consideration, including allowances/discounts, service fees and prompt payment discounts, for distributing the products. Wholesaler and specialty distributor allowances and service fees arise from contractual agreements and are estimated as a percentage of the price at which the Company sells product to them. In addition, customers are offered a prompt pay discount for payment within a specified contractual period.
- ***Chargebacks.*** Discounts that occur when contracted indirect customers purchase directly from wholesalers and specialty distributors. Contracted customers generally purchase a product at its contracted price. The wholesaler or specialty distributor, in turn, then generally charges back to the Company the difference between the wholesale acquisition cost and the contracted price paid to the wholesaler or specialty distributor by the customer.
- ***Returns.*** Returns are generally made if the product is damaged, defective, or otherwise cannot be used by the customer. In the U.S., the Company typically permits returns six months prior to and up to twelve months after the product expiration date. Outside the U.S., returns are only allowed in certain countries on a limited basis.

In Europe, changes to government policy or practices could adversely affect the level of reimbursement through government programs. In the U.S., proposals by legislators at both federal and state levels, regulators, and third-party payors continue to emerge with the aim of keeping healthcare costs down while expanding healthcare benefits. Similarly, in Europe, legislators, policymakers and healthcare insurance funds continue to propose and implement cost-containing measures to keep healthcare costs down, due in part to the attention being paid to healthcare cost containment and other austerity measures in Europe. Certain of these changes could impose limitations on the prices that the Company will be able to charge for its products and any approved product candidates. Further, an increasing number of EU member states and other foreign countries use prices for products established in other countries as "reference prices" to help determine the price of the product in their own territory. Consequently, a downward trend in prices of products in some countries could contribute to similar downward trends elsewhere.

Legal proceedings

The Company is involved in various lawsuits, claims, and other legal proceedings that arise in the ordinary course of business. These proceedings may involve compliance and trade practices, antitrust, commercial claims, product liability claims, intellectual property rights and securities, among others.

The Company records accruals for loss contingencies associated with these legal matters when it is probable that a liability will be incurred, and the amount of the loss can be reasonably estimated. The Company has accrued for these matters and will continue to monitor each related legal issue and adjust accruals as might be warranted based on new information and further developments in accordance with ASC 450-20-25, Contingencies. Developments in legal proceedings and other matters that could cause changes in the amounts previously accrued are evaluated each reporting period. Amounts accrued for legal contingencies often result from a complex series of judgments about future events and uncertainties that rely heavily on estimates and assumptions including timing of related payments.

Where the amount and timing of the payment is fixed, the obligation is not interest-bearing and the impact of discounting is significant, these obligations are recorded at their present value, generally using a discount rate appropriate to the obligation or approximating the risk-free rate at the time the Company entered into the obligation.

For further information regarding accrued litigation settlement expenses and other legal proceedings, refer to *Item 8. Financial Statements—Audited Consolidated Financial Statements—Note 11. Accrued Litigation Settlement Expenses* and *Note 16. Commitments and Contingencies*.

Discontinuation of marketing and promotion of PERSERIS (2024)

In July 2024, the Company discontinued the marketing and promotion of PERSERIS due to impending market changes that would make the product no longer financially viable. The Company has continued to supply PERSERIS to avoid disruption to patient care but no longer deploys a dedicated sales force.

Asset Acquisitions and Business Combinations (2023)

On March 2, 2023, the Company acquired 100% of the share capital of Opiant, which at the time was a publicly traded company in the U.S., for upfront cash consideration of $146 million and an additional amount to be potentially paid upon achievement of net sales milestones. Opiant was a specialty pharmaceutical company focusing on developing drugs for addictions and drug overdose. As a result of the acquisition, the Company added OPVEE, formerly the pipeline product OPNT003, an opioid overdose treatment well-suited to confront illicit synthetic opioids like fentanyl, to its portfolio. OPVEE was approved by the FDA in May 2023 and launched in October 2023.

The Consolidated Financial Statements for the year ended December 31, 2023 include the results of operations of the acquisition of Opiant since the acquisition date. As substantially all of the fair value of the gross assets acquired was concentrated in the value of the OPVEE in-process research and development asset, the acquisition was accounted for as an asset acquisition and total purchase consideration was allocated to the assets acquired and liabilities assumed based on their relative fair values as of the date of acquisition. The Company recorded a charge for in-process research and development associated with OPVEE for $120 million. As part of the acquisition, a subsidiary of Indivior issued Contingent Value Rights (“CVRs”) to the shareholders of Opiant. Total potential payments could be up to a maximum of $68 million over a period through September 30, 2030.

On July 31, 2023, the Company acquired full rights to the patents and other assets underlying INDV-2000 (oral Orexin-1 receptor antagonist) from C4X Discovery for $21 million, which was expensed as in-process research and development. As a result, the Company no longer has any obligation to pay future development or sales milestones or a royalty on net sales of this product candidate.

On October 11, 2023, the Company secured global rights to develop, manufacture, and commercialize Alar Pharmaceuticals Inc.’s (“Alar”) portfolio of buprenorphine-based ultra long-acting injectables, including lead asset ALA-1000 (now INDV-6001), which is potentially the first three-month LAI for OUD. The Company made an option payment of $5 million and an upfront payment of $10 million, each of which was expensed as in-process research and development. Alar is entitled to potential milestone payments if various developmental, regulatory, and commercial goals are achieved, and royalties in the low double digit to mid-teens as a percentage of net revenue.

On November 1, 2023, the Company acquired an aseptic manufacturing facility in the U.S. for upfront consideration of $5 million in cash and assumption of certain contract manufacturing obligations. The facility will be further developed to secure the long-term production and supply of SUBLOCADE.

The acquisition of the manufacturing facility has been accounted for as a business combination using the acquisition method of accounting. The assets acquired and liabilities assumed were recorded at fair value, with the excess of the purchase price over the fair value of the identifiable assets and liabilities recognized as $5 million of goodwill. A liability was recorded at fair value to reflect the present value of the expected losses from assumed contractual manufacturing obligations. Net operating losses attributable to these contractual obligations will be recorded against the liability from the date of acquisition through fulfillment of the contracts in late 2025.

See *Item 8. Financial Statements—Audited Consolidated Financial Statements - Note 18. Asset Acquisitions* and *Note 19. Business Combinations* for more information on these transactions.

Results of operations

Comparison of the years ended December 31, 2024 and December 31, 2023:

(in millions)	For the years ended December 31, 2024	2023	% Change
Net revenue	**$ 1,188**	**$ 1,093**	**9 %**
Cost of sales	231	174	32 %
Gross profit	**957**	**919**	**4 %**
Gross margin	81 %	84 %	**(3) %**
Selling, general and administrative	618	569	9 %
Research and development	107	116	(8)%
Acquired in-process research and development	1	162	(99)%
Litigation settlement expenses[1]	195	239	(18)%
Other operating expense (income), net	4	(9)	(146)%
Operating income (loss)	**32**	**(156)**	**(120) %**
Net interest (expense) income	(18)	8	(330)%
Income (loss) before income taxes	**14**	**(149)**	**(109) %**
Income tax (expense) benefit	(11)	20	(158)%
Net income (loss)	**$ 2**	**$ (129)**	**(102) %**

(1) *See Item 8. Financial Statements—Audited Consolidated Financial Statements—Note 11. Accrued Litigation Settlement Expenses.*

Net revenue. Our 2024 and 2023 net revenue was driven by sales of SUBLOCADE and other buprenorphine-based sublingual products (including SUBOXONE Film and SUBOXONE Tablet). In 2024 and 2023, SUBLOCADE accounted for 64% and 58% of our net revenue, other buprenorphine-based sublingual products accounted for 32% and 38%, and PERSERIS accounted for 3% and 4%, respectively. SUBLOCADE volume growth was the primary driver of the increase in 2024 net revenue as compared to 2023. In 2024, the first OPVEE orders from BARDA were fulfilled. Price changes were not a significant driver of the increase in net revenue.

The following table shows the Company's net revenue by major product line:

(in millions)	For the years ended December 31, 2024	2023	% Change
SUBLOCADE	756	630	20 %
Sublingual & other	377	421	(10) %
OPVEE	15	—	NM
PERSERIS	40	42	(5) %
Total net revenue	**$ 1,188**	**$ 1,093**	**9 %**

Total net revenue increased by $95 million, or 9%, to $1,188 million in 2024 from $1,093 million in 2023. The increase was primarily driven by double-digit year-over-year SUBLOCADE volume growth and the fulfillment of OPVEE orders from BARDA. Pricing was not material to net revenue growth. Higher net revenue from SUBLOCADE, which increased by $126 million, or 20%, from 2023 reflected further organized health system (OHS) channel penetration in the U.S. and increased new U.S. patient enrollments. 2024 SUBLOCADE growth was impacted by competition in the US LAI category and transitory items including Medicaid re-enrollment in many large states and an issue impacting patient coverage approvals with one of the largest pharmacy benefit managers. SUBOXONE Film net revenue declined 10% in 2024 and Film share averaged 16% and 19% in 2024 and 2023 and was 15% and 18% as of December 31, 2024 and 2023, respectively. In 2024, total net revenue from PERSERIS was $40 million, representing a 5% decrease from 2023 due to a decline in volume and the impact of discontinuation of PERSERIS in the second half of 2024.

The U.S. market is the largest contributor to our net revenue. Sales rebates, discounts and returns and other offsets to gross revenues are reflected in net revenue. The following table sets out a breakdown of net revenue between the U.S. and Most of World.

(in millions)	For the years ended December 31, 2024	2023	% Change
United States	1,008	912	11 %
Most of World	179	181	(1) %
Total net revenue	**$ 1,188**	**$ 1,093**	**9 %**

In 2024, U.S. net revenue increased by 11% to $1,008 million as compared to $912 million in 2023, primarily due to strong SUBLOCADE volume growth, supported by favorable mix between commercial and governmental channels for SUBOXONE and SUBLOCADE. Fulfillment of OPVEE orders from BARDA also contributed, offset by lower SUBOXONE revenue.

In 2024, net revenue attributable to Most of World decreased slightly from 2023 to $179 million. In 2024 and 2023, positive contributions from newer products (SUBLOCADE / SUBUTEX® Prolonged Release and SUBOXONE Film) were more than offset by the ongoing generic erosion of the legacy tablet business. In 2024 and 2023, SUBLOCADE / SUBUTEX Prolonged Release net revenue in Most of World was $52 million and $41 million, respectively.

Competitive dynamics and near-term Justice Systems funding challenges are expected to offset potential LAI category growth, resulting in modest SUBLOCADE net revenue growth in 2025. Competitive pressures, including from a potential fifth generic Film entrant, are expected to adversely impact both pricing and volume, resulting in an accelerated decline in Film net revenue in 2025. We also expect almost no revenues from PERSERIS in 2025 as a result of our decision to cease all marketing efforts in July 2024, although we continue to supply PERSERIS during a transition period. Together, these factors are expected to produce an overall decline in total net revenue and operating income in 2025 as compared to 2024.

We estimate provisions for rebates, discounts and returns based on contractual arrangements with customers or terms of the regulations and/or agreements applicable for transactions with healthcare

authorities, and in some cases on assumptions about the attainment of targeted volumes. We recognize returns, discounts, incentives and rebates in the period in which we recognize the underlying sales, as a reduction of gross revenues and as current liabilities on our Consolidated Balance Sheets under trade and other payables or reductions of accounts receivable. The outstanding amounts are affected by changes in gross sales, the provision for net product sales deductions and timing of payments/credits. Estimates, assumptions and judgements applied to determine the provision for rebates, discounts and returns are set out in *Item 8. Financial Statements—Audited Consolidated Financial Statements—Note 2. Summary of Significant Accounting Policies*."

The following table provides a summary of activities with respect to accrued rebates and product returns and prompt pay discounts for the years ended December 31, 2024 and 2023:

Accrued rebates and product returns and prompt pay discounts *(in millions)*	**2024**	**2023**
Opening balance at beginning of period	**$ 535**	**$ 432**
Provision related to sales made in:		
Current period	1,494	1,374
Prior period	(28)	9
Payments and credits	(1,436)	(1,280)
Closing balance at beginning of period	**$ 565**	**$ 535**

Accrued rebates and product returns includes chargebacks as these are paid by Indivior. Prompt pay discounts are recorded as offsets to accounts receivable as of December 31, 2024. Accrued rebates and product returns and prompt pay discounts increased to $565 million as of December 31, 2024 from $535 million as of December 31, 2023, primarily due to strong SUBLOCADE volume growth.

Cost of sales. Cost of sales increased by $57 million, or 32%, to $231 million in 2024 from $174 million in 2023. Cost of sales in 2024 includes $41 million of expenses related to the discontinuation of sales and marketing for PERSERIS and reflects the impact of cost inflation.

Gross margin, which we define as gross profit divided by net revenue, was 81% in 2024 as compared to 84% in 2023. The decrease in 2024 gross margin included the impact of $41 million of costs related to the discontinuation of sales and promotional activities for PERSERIS and cost inflation, partially offset by improved product mix from the continued growth of SUBLOCADE.

Selling, general and administrative expenses. Selling, general and administrative expenses increased by $49 million, or 9%, to $618 million in 2024 from $569 million in 2023. In 2024, selling, general and administrative costs reflect $12 million of costs related to the discontinuation of sales and marketing for PERSERIS and $12 million of severance costs. Higher sales and marketing investments related to SUBLOCADE and OPVEE and cost inflation were partially offset by lower sales and marketing costs due to discontinuation of PERSERIS. Prospectively, savings resulting from restructuring actions and discontinuation of PERSERIS marketing will be partially reinvested to support long-term SUBLOCADE growth.

Research and development expenses. Research and development expenses decreased by $9 million, or 8%, to $107 million in 2024 from $116 million in 2023. The decrease is primarily due to re-prioritization of pipeline activities on the Company's OUD assets as well as related cost savings.

Acquired in-process research and development expenses. Acquired in-process research and development expenses decreased by $161 million, or 99%, to $1 million in 2024 from $162 million in 2023. The decrease is primarily due to the 2023 acquisition of OPVEE and Orexin-1 receptor antagonist INDV-2000.

Litigation settlement expenses. Litigation settlement expenses decreased by $44 million, or 18%, to $195 million in 2024 from $239 million in 2023. The decrease is primarily due to variability in, and unpredictability of, the timing of settlements of major contingencies. See *Item 8. Financial Statements—Audited Consolidated Financial Statements - Note 11. Accrued Litigation Settlement Expenses*.

Other operating expense (income), net. In 2024, net other operating expense was $4 million and in 2023 net other operating income was $9 million. In 2024, net other operating expense included $9 million mark-to-market adjustments related to the decline in value of an equity investment. In 2023, net other operating income included $3 million of income recognized in relation to a supply agreement.

Net interest (expense) income. Net interest expense was $18 million in 2024 as compared to net interest income of $8 million in 2023. The increase in net interest expense reflected a $4 million write-off of unamortized deferred financing costs due to early extinguishment of the previous term loan, a decrease in earned interest income on lower cash and investment balances and increased borrowings under the Company's new debt facility. We expect interest expense to continue to exceed investment income.

Income tax (expense) benefit. Income tax expense in 2024 was $11 million, resulting in an effective tax rate of 76.0%, on the Company's earnings for 2024. The income tax benefit of $20 million in 2023 reflected an effective tax rate of 13.2% on the Company's earnings for 2023.

Comparison of the years ended December 31, 2023 and December 31, 2022

	For the years ended December 31,		
(in millions)	**2023**	**2022**	**%Change**
Net revenue	**$ 1,093**	**$ 901**	**21 %**
Cost of sales	174	151	15 %
Gross profit	**919**	**749**	**23 %**
Gross margin	84 %	83 %	**1 %**
Selling, general and administrative expenses(1)	569	469	**21 %**
Research and development expenses	116	74	57 %
Acquired in-process research and development expenses	162	—	NM
Litigation settlement expenses	239	296	**(19) %**
Other operating income, net	(9)	(8)	13 %
Operating loss	**(156)**	**(81)**	**93 %**
Net interest income (expense)	8	(8)	NM
Loss before income taxes	**(149)**	**(89)**	**67 %**
Income tax benefit	20	44	**(55) %**
Net loss	**$ (129)**	**$ (44)**	**193 %**

(1) The Company recognized provisions in 2023 and 2022 related to certain multi-district antitrust claims (refer to Item 8. Financial Statements—Audited Consolidated Financial Statements - *Note 16. Commitments and Contingencies*) and an intellectual-property-related matter.

Net revenue. Substantially all of the Company's 2023 and 2022 net revenue was derived from sales of SUBLOCADE, PERSERIS and other buprenorphine-based sublingual products (including SUBOXONE Film and SUBOXONE Tablet). In 2023 and 2022, SUBLOCADE accounted for 58% and 45% of our net revenue, PERSERIS accounted for 4% and 3%, and other buprenorphine-based sublingual products accounted for 39% and 52%, respectively. SUBLOCADE volume growth was the primary driver of the increase in 2023 net revenue as compared to 2022. Price changes were not a significant driver of the increase in net revenue.

The following table shows the Company's net revenue by major product line:

(in millions)	For the years ended December 31, 2023	2022	% Change
SUBLOCADE	630	408	54 %
Sublingual & other	421	464	(9) %
PERSERIS	42	28	50 %
Total net revenue	**$ 1,093**	**$ 901**	**21 %**

Total net revenue increased by $192 million, or 21%, to $1,093 million in 2023 from $901 million in 2022. The increase was primarily driven by strong year-over-year SUBLOCADE and PERSERIS volume growth, partly offset by a reduction in SUBOXONE Film share. Higher net revenue from SUBLOCADE, which increased by $222 million, or 54%, from 2022 reflected further organized health system (OHS) channel penetration in the U.S. and increased new U.S. patient enrollments. In 2023, total net revenue from PERSERIS was $42 million, representing a 50% increase from 2022 due to increasing awareness of the treatment across the U.S. healthcare system. SUBOXONE Film share averaged 19% and 20% and exited at 18% and 19% in 2023 and 2022, respectively.

The following table sets out a breakdown of net revenue as between the U.S. and the Most of World.

(in millions)	For the years ended December 31, 2023	2022	% Change
United States	912	732	25 %
Most of World	181	169	7 %
Total net revenue	**$ 1,093**	**$ 901**	**21 %**

In 2023, U.S. net revenue increased by 25% to $912 million as compared to $732 million in 2022, primarily due to strong SUBLOCADE volume growth and underlying BMAT market growth.

In 2023, net revenue attributable to the Most of World increased 7% to $181 million from $169 million in 2022. In 2023, positive contributions from new products (SUBLOCADE / SUBUTEX® Prolonged Release and SUBOXONE Film) were partly offset by ongoing competitive pressure on legacy tablet products. In 2023 and 2022, SUBLOCADE / SUBUTEX Prolonged Release net revenue in the Most of World was $41 million and $27 million, respectively.

We estimate provisions for rebates, discounts and returns based on contractual arrangements with customers or terms of the regulations and/or agreements applicable for transactions with healthcare authorities, and in some cases on assumptions about the attainment of targeted volumes. We recognize returns, discounts, incentives and rebates in the period in which we recognize the underlying sales, as a reduction of gross revenues and as current liabilities on our Consolidated Balance Sheets under trade and other payables or reductions of accounts receivable. The outstanding amounts are affected by changes in gross sales, the provision for net product sales deductions and timing of payments/credits. Estimates, assumptions and judgements applied to determine the provision for rebates, discounts and returns are set out in *Item 8. Financial Statements—Audited Consolidated Financial Statements - Note 2. Summary of Significant Accounting Policies*.

The following table provides a summary of activities with respect to accrued rebates and product returns, and prompt pay discounts for the years ended December 31, 2023 and 2022:

Accrued rebates and product returns and prompt pay discounts *(in millions)*	**2023**	**2022**
Opening balance at beginning of period	**$ 432**	**$ 550**
Provision related to sales made in:		
Current period	1,374	1,187
Prior period	9	(14)
Payments and credits	(1,280)	(1,291)
Closing balance at beginning of period	**$ 535**	**$ 432**

Accrued rebates and product returns and prompt pay discounts includes chargebacks as these are paid by Indivior. Accrued rebates and product returns and prompt pay discounts increased to $535 million in 2023 from $432 million in 2022, primarily due to strong SUBLOCADE volume growth.

Cost of sales. Cost of sales increased by $23 million, or 15%, to $174 million in 2023 from $151 million in 2022, driven by higher sales volumes in the U.S. and the impacts of cost inflation.

Gross margin, which we define as gross profit divided by net revenue, was 84% in 2023 as compared to 83% in 2022. The increase in 2023 gross margin reflected an improved product mix from the continued growth of SUBLOCADE, partly offset by cost inflation.

Selling, general and administrative expenses. Selling, general and administrative expenses increased by $100 million, or 21%, to $569 million in 2023 from $469 million in 2022. Approximately $22 million of this increase relates to acquisition-related and U.S. exchange listing costs. The remaining increase primarily reflects higher expenses related to increased SUBLOCADE commercial investments, the addition of the Opiant business and subsequent launch expenses for OPVEE, legacy legal defense costs and cost inflation.

Research and development expenses. Research and development expenses increased by $42 million, or 57%, to $116 million in 2023 from $74 million in 2022. The increase is primarily due to a greater activity level related to post-marketing studies for SUBLOCADE, process validation testing related to LAI capacity expansion and ongoing early-stage pipeline activities.

Acquired in-process research and development expenses. Acquired in-process research and development expenses increased to $162 million as a result of the acquisition of OPVEE, the Orexin-1 receptor antagonist INDV-2000, and the potential three-month LAI INDV-6001.

Litigation settlement expenses. Litigation settlement expenses increased primarily due to finalization of settlement negotiations with several anti-trust litigation parties. See *Item 8. Financial Statements—Audited Consolidated Financial Statements - Note 11. Accrued Litigation Settlement Expenses*.

Other operating income, net. Net other operating income was $9 million in 2023 and $8 million in 2022. In 2023, net other operating income included $3 million of income recognized in relation to a supply agreement. In 2022, net other operating income included a $5 million benefit related to an aged Directors' & Officers' insurance claim settlement.

Net interest income (expense). Net interest income was $8 million in 2023 as compared to net interest expense of $8 million in 2022. The change in net interest reflected higher interest rates earned on the Company's investments.

Income tax benefit. Income tax benefit in 2023 was $20 million, resulting in an effective tax rate of 13.2%. The income tax benefit of $44 million in 2022 reflected an effective tax rate of 49.3% on the Company’s earnings for 2022.

Liquidity and Capital Resources

Overview

The Company's financial condition is summarized as follows:

(In millions)	December 31, 2024	December 31, 2023
Financial assets:		
Cash and cash equivalents	$ 319	$ 316
Investments - short-term	1	94
Investments - long-term	27	41
Total cash and investments	**$ 347**	**$ 451**
Borrowings:		
Short-term borrowings	$ 18	$ 3
Long-term borrowings	$ 315	$ 237

Cash flows

	For the years ended December 31,		
(in millions)	2024	2023	2022
Net cash provided by (used in):			
Operating activities	$ 36	$ (300)	$ (4)
Investing activities	69	(95)	(222)
Financing activities	$ (102)	$ (64)	$ (101)

Operating activities

Net cash provided by operating activities was $36 million in 2024, an increase of $336 million, compared to net cash used in operating activities of $300 million in 2023. The increase was primarily due to 2023 litigation settlement outflows of $387 million, including the State, end payor and direct purchaser Antitrust MDL settlements. Net cash provided by operations in 2024 reflected ongoing operating performance partially offset by scheduled litigation settlement payments of $173 million. Refer to *Item 8. Financial Statements—Audited Consolidated Financial Statements—Note 10. Accrued Litigation Expenses* for additional details on the litigation-related settlement payments.

Net cash used in operating activities was $300 million in 2023 an increase of $296 million compared to the net cash used of $4 million in 2022. The additional outflow was primarily due to litigation settlement payments of $610 million, partially offset by increased accruals for government rebates and trade payables. The litigation settlement related outflows include the Antitrust MDL settlement payment of $103 million with States, transfer of $415 million into an escrow account for the settlement with the Antitrust MDL end payors and direct purchasers, and settlement payments of $24 million for intellectual property-related and other legal matters, in addition to the Group's previously scheduled litigation settlement payments totaling $68 million for the Department of Justice, Reckitt Benckiser and Dr. Reddy's Laboratories matters.

Investing activities

Net cash provided by investing activities was $69 million in 2024, an increase of $164 million, compared to net cash used in investing activities of $95 million in 2023. The prior year use of cash reflects a $129 million outflow for the Opiant acquisition, net of cash acquired. The current year inflows primarily reflect proceeds from maturity of debt investments, partly offset by capital expenditures.

Net cash used in investing activities was $95 million in 2023, $127 million less cash used as compared to net cash used of $222 million in 2022. Lower net cash outflows for investments in debt securities from

2022 to 2023 were partially offset by the acquisition of Opiant, net of cash acquired, for $129 million, and $45 million in IPR&D purchases in 2023.

We expect to spend approximately $50 million to $70 million on capital items in 2025, primarily to establish and scale manufacturing of SUBLOCADE at the Raleigh Manufacturing Facility (refer to *Item 8. Financial Statements—Audited Consolidated Financial Statements—Note 19. Business Combinations),* after which time we expect capital expenditures to revert to levels more in line with Indivior's history.

The Company expects to continue investing in development stage assets from time to time but presently has no commitment to do so.

Financing activities

Net cash used in financing activities increased by $38 million, from $64 million in 2023 to $102 million in 2024. Net cash used in financing activities in the current period primarily reflects shares repurchased and canceled offset by net proceeds from the change in debt after issuing the new Note Purchase Agreement and repaying the previous Term Loan. Cash paid for net settlement of employee share awards, net of cash received was materially consistent with 2023.

Net cash used in financing activities decreased by $37 million, from $101 million in 2022 to $64 million in 2023. Net cash used in financing activities in 2023 reflects shares repurchased and canceled, the extinguishment of debt assumed in the Opiant acquisition, principal portion of lease payments and quarterly amortization of the Group's term loan facility, partially offset by proceeds received from the issuance of shares for employee compensation agreements. In 2022, the outflow from financing activities primarily reflected shares repurchased and canceled.

Current Liabilities

Our current liabilities exceed our current assets by over $100 million and total liabilities exceed our total assets by over $300 million. Additionally, the Company could sustain negative working capital because of the timing of rebate payments relative to the collection of accounts receivable (see Item 1A Risk Factors, "*Our balance sheet is leveraged, and any reduction in annual sales may adversely affect our liquidity.")*

Debt

In November 2024, the Company refinanced its term loan, repaying in full the previous term loan and replacing it with a new Note Purchase Agreement with principal amount of $350 million that matures in November 2030 and a committed, revolving credit facility of $50 million. As of December 31, 2024, the revolver was undrawn. The Note Purchase Agreement contains financial and non-financial covenants customary for facilities of this nature, including a maximum leverage ratio, a minimum interest coverage ratio, a limitation on disposal of assets, prepayments and redemptions of certain indebtedness, further indebtedness, liens, negative pledges, and limits on share buybacks and redemptions, dividends and other "restricted payments," subsidiary distributions, investments, mergers and acquisitions and other fundamental changes, sale and lease-back transactions, and a restriction on changes to any material line of business, most of which are subject to various carve-outs, grace periods and qualifications. The Company was in compliance with all covenants as of December 31, 2024. See *Item 1A. Risk Factors* at "*Our term loan contains certain covenants that could limit our ability to plan for or respond to changes in our business."* and *Item 8. Financial Statements—Audited Consolidated Financial Statements - Note* 12. Debt for additional information. In addition, substantially all of the assets of the Company are pledged to secure this debt. The restrictions under the Note Purchase Agreement substantially limit our ability to obtain other financing, other than the $50 million revolving credit facility.

Capital Resources

The Company believes its existing cash and cash equivalents and investments together with cash generated from operations and debt will enable its anticipated cash needs to be met, including working capital, capital expenditures, litigation settlement payments, milestone payments, income taxes, repurchase of ordinary shares, debt repayments and other funding requirements, for at least the twelve-month period

following the issuance of this Form 10-K. The Company will have to sustain sales volume performance with no material change in the timing of its collections and rebate payments to maintain necessary liquidity in the near term and to meet our obligations in the long term. The Company is also subject to contingent liabilities as described in *Item 8. Financial Statements—Audited Consolidated Financial Statements—Note 16. Commitments and Contingencies*.

Capital Expenditures

	For the years ended December 31,		
(in millions)	**2024**	**2023**	**2022**
Purchases of property, plant and equipment	$ (29)	$ (8)	$ (5)
Purchases of in-process research and development and intangible assets	(2)	(45)	(1)
Total	**$ (31)**	**$ (53)**	**$ (6)**

The Company's capital expenditures for 2024 reflected the expansion of the Raleigh Manufacturing plant. Capital expenditures in 2023 and 2022 were primarily for equipment used in the manufacture of our products. The Company funded these expenditures from its existing cash balances.

IPR&D and intangible asset purchases for the years ended 2024, 2023 and 2022 were $2 million, $45 million, and $1 million, respectively, and were funded from existing cash balances. The 2023 cash paid includes $21 million for the acquisition of INDV-2000 (oral Orexin-1 receptor antagonist) from C4X Discovery and $15 million to secure the global rights to develop, manufacture, and commercialize Alar Pharmaceuticals Inc.'s portfolio of buprenorphine-based ultra LAI, including INDV-6001, the lead asset which is potentially the first three-month LAI for OUD.

Contractual Obligations

The table below sets forth the Company's anticipated contractual cash flows including bank debt, legal settlement payments (including expected interest payments), share repurchase liabilities and lease liabilities on an undiscounted basis as of December 31, 2024.

	December 31, 2024			
(in millions)	**Total**	**1 year or less**	**2-5 years**	**More than 5 years**
Debt	$ 524	$ 53	$ 215	$ 256
Litigation settlement liabilities	398	85	313	—
Commercial commitments	210	88	111	11
Capital expenditures	21	21	—	—
Lease liabilities	50	13	31	6
Share repurchase liabilities	5	5	—	—
Employee-related liabilities	12	—	—	12
Total	**$ 1,220**	**$ 265**	**$ 670**	**$ 285**

Potential milestone and royalty payments

The Company is party to collaboration and license arrangements for the development of pharmaceutical and digital products. Milestone payments will be due if various developmental, regulatory and commercial goals are achieved and in certain cases royalties will be payable as a percentage of net revenue, although the Company generally has the right to terminate these agreements at no cost. The Company has no significant milestone payments expected in 2025.

Agreements for contract manufacturing and supply of materials

The Company is obligated to purchase specified amounts of goods or services under various contract manufacturing and material supply agreements over periods ranging from 1 to 6 years. These agreements could require us to pay approximately $210 million (before annual price index adjustments).

CVR Agreement

In connection with the acquisition of Opiant, a subsidiary of Indivior issued Contingent Value Rights ("CVRs") to the shareholders of Opiant. Each CVR represents the obligation of Indivior Inc. to make cash payments upon achievement of certain worldwide net sales milestones during the period from October 1, 2023 to September 30, 2030.

Total potential payments could be up to a maximum of $68 million over a period of up to 7 years from the date of the first commercial sales of a new Opiant product. Refer to *Item 8. Financial Statements—Audited Consolidated Financial Statements—Note 18. Asset Acquisitions* for additional details on the CVR agreement.

Research and Development Expenses, Patents and Licenses, etc.

See "*Item 1. Business—Research and Development*," "*Item 1. Business—Intellectual Property*," and "*Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations—Operating Results.*"

Trend Information

For a discussion of trend information, see "*Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations—Operating Results.*"

Selected Quarterly Financial Data (Unaudited)

The Company adopted U.S. GAAP for the year ended December 31, 2024 and has presented all comparative periods in accordance with U.S. GAAP. Supplemental unaudited quarterly results of operations for 2024 is presented below:

	For the Quarters Ended 2024,				*Year Ended December 31,*
	March 31	**June 30**	**September 30**	**December 31**	**2024**
Net revenue	$ 284	$ 299	307	298	1,188
Cost of sales	38	79	66	48	231
Gross profit	**246**	**220**	**241**	**250**	**957**
Operating expenses:					
Selling, general and administrative	145	153	144	177	618
Research and development	28	26	22	31	107
Acquired in-process research and development	—	—	1	—	1
Litigation settlement	—	160	36	(1)	195
Other operating expense (income), net	—	—	4	—	4
Total operating expenses, net	**172**	**340**	**207**	**206**	**925**
Operating income (loss)	**73**	**(119)**	**34**	**44**	**32**
Other income and expenses:					
Interest income	7	6	5	5	23
Interest expense	(9)	(9)	(11)	(13)	(41)
Income (loss) before income taxes	**71**	**(122)**	**28**	**36**	**14**
Income tax (expense) benefit	(11)	24	(8)	(16)	(11)
Net income (loss)	**$ 60**	**$ (98)**	**21**	**20**	**2**

Critical Accounting Estimates

Management makes several estimates and assumptions regarding the future and significant judgments in applying the Company's accounting policies. Estimates and assumptions may affect the reported amount of assets and liabilities, disclosure of contingent assets and liabilities, and the reported amounts of revenues and expenses. These estimates are based on the Company's knowledge of the amount, events or actions; however, actual results may ultimately differ from those estimates. Estimates and underlying assumptions are reviewed on an ongoing basis and revisions to estimates are recognized prospectively. The key estimates and assumptions used in the financial statements are set out below.

Returns, incentives and rebates

The Company offers various types of reductions from list prices on its products. Products sold in the U.S. are covered by various programs (such as Medicare and Medicaid) under which products are sold at a discount. Rebates are granted to healthcare authorities, and under contractual arrangements with certain customers. Some wholesalers are entitled to chargeback incentives under specific contractual arrangements. Cash discounts may also be granted for prompt payment.

The discounts, incentives and rebates described above are estimated based on contractual arrangements with customers or terms of the relevant regulations and/or agreements applicable for transactions with healthcare authorities, and in some cases on assumptions about the attainment of targeted volumes. Several months may pass between the original estimate of rebates due and confirmation of the amount, which may increase the estimation risk. Please refer to the revenue accounting policy for further details.

Accruals for product returns are estimated based primarily on analysis of the Company's historical product return patterns, expected future returns, and contractual agreement terms. Estimated returns are accrued in the period the related revenue is recognized.

During 2024 and 2022, net revenue was increased by $28 million and $14 million, respectively, from performance obligations satisfied in prior years, primarily relating to changes in payor mix and resolution of aged accruals for U.S. government programs. During 2023, net revenue was reduced by $9 million from performance obligations satisfied in prior years, primarily relating to differences between invoices received from U.S. government programs as compared to the respective accruals held for those years. The estimates for U.S. governmental and commercial end-payor accruals are also reasonably expected to vary due to shifts between U.S. governmental end-payor sales and U.S. commercial end-payor sales. A 1 percentage point shift between these channels would impact the accrual by $4 million. Due to the number of variables contributing to the accruals for returns, incentives and rebates, further meaningful sensitivity is not able to be provided. Accruals for returns, incentives and rebates are disclosed in *Item 8. Financial Statements—Audited Consolidated Financial Statements—Balance Sheet*.

Determination of income tax provision

Significant judgment is required in determining our provision for income taxes. These judgments and estimates occur in the calculation of tax credits, benefits, and deductions and in the calculation of certain tax assets and liabilities, which arise from differences in the timing of recognition of revenue and expense for tax and financial statement purposes, as well as the interest and penalties related to uncertain tax positions. Changes to these estimates may result in a material increase or decrease in our tax provision in the current period or subsequent periods.

Recoverability of deferred tax assets

Also, we must assess the likelihood that we will be able to recover our deferred tax assets. If all or part of our deferred tax assets are not recoverable in the future, we must increase our provision for taxes and reduce our net deferred tax assets to the amount that is more likely than not to be recoverable. To recover deferred tax assets, we must be able to generate sufficient taxable income in the jurisdictions where the deferred tax assets are located. We consider forecasted income, including income that may be generated as a result of certain tax planning strategies, together with future reversals of existing taxable temporary differences, in determining the need for a valuation allowance. As of December 31, 2024, we believe our deferred tax assets are more likely than not to be recovered, with the exception of valuation allowance items as detailed in *Item 8. Financial Statements—Audited Consolidated Financial Statements - Note 4. Income Tax*. Our ability to realize deferred tax assets could be reduced in the future if our estimates of future forecasted income do not support the realization of our deferred tax assets. Should there be a change in our ability to realize our deferred tax assets, our tax provision would be affected in the period in which such change takes place.

Ongoing litigation

The Company is involved in litigation, arbitration and other legal proceedings. These proceedings typically are related to compliance and trade practices, commercial claims, product liability claims, intellectual property rights, and employment and wrongful discharge claims. For each claim or grouping of similar claims, management makes judgments regarding the relative merits and risks within the claims. These judgments inform the Company's defense strategies, whether a loss or settlement from the claims is probable and whether sufficient information exists to make a reliable estimate of he likely outcome of the claims. Provisions are recognized when the Company has a present legal or constructive obligation, an outflow of resource to settle the obligation when it is probable that a liability will be incurred, and the amount of loss can be reasonably estimated. Management has assessed as "contingent" matters that cannot be reliably estimated or are not considered probable at the current time. For more details of all the outstanding legal proceedings including those that have been deemed contingent, see *Item 8. Financial Statements—Audited Consolidated Financial Statements - Note 16. Commitments and Contingencies*.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

a. Quantitative Information about Market Risk

See *Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources.* In addition to the risks inherent in our operations, we are exposed to a variety of financial risks, such as market risk (including foreign currency exchange, cash flow and interest rate risk), credit risk and liquidity risk.

b. Qualitative Information about Market Risk

We invest cash equivalents and investments with the primary objective to preserve principal while also maximizing the income that we receive. We invest in highly-rated corporate bonds, commercial paper, and U.S. Treasuries for purposes other than trading which are reported at fair value or amortized cost, which approximates fair value for the nature and duration of instruments we use. These securities are subject to interest rate risk and credit risk. See *Item 8. Financial Statements—Audited Consolidated Financial Statements - Note 13. Financial Instruments and Fair Value Measurements.*

Interest on our Note Purchase Agreement is subject to fluctuation based on SOFR, which may impact future expense and cash flows. See *Item 8. Financial Statements—Audited Consolidated Financial Statements - Note 12. Debt.*

We operate in different territories around the world. Generally, the functional currency of our operations is that of the country in which it operates. One USD functional currency subsidiary has significant exposure to assets in Canadian Dollars and liabilities in British Pounds Sterling. The Canadian Dollar assets turn quickly and our strategy is to mitigate exposure to British Pounds with offsetting assets. However, we could be exposed to material foreign currency risk in these currencies.

Item 8. Financial Statements and Supplementary Data.

Indivior PLC
Consolidated Statements of Operations
(Amounts in millions, except per share data)

	Year Ended December 31,		
	2024	**2023**	**20**
Net revenue	**$ 1,188**	**$ 1,093**	**$ 90**
Cost of sales	231	174	15
Gross profit	**957**	**919**	**74**
Operating expenses:			
Selling, general and administrative	618	569	46
Research and development	107	116	7
Acquired in-process research and development	1	162	–
Litigation settlement	195	239	29
Other operating expense (income), net	4	(9)	(
Total operating expenses, net	**925**	**1,076**	**83**
Operating income (loss)	**32**	**(156)**	**(8**
Other income and expenses:			
Interest income	23	43	1
Interest expense	(41)	(35)	(2
Income (loss) before income taxes	**14**	**(149)**	**(8**
Income tax (expense) benefit	(11)	20	4
Net income (loss)	**$ 2**	**$ (129)**	**$ (4**
Earnings (loss) per share			
Basic	$ 0.02	$ (0.94)	$ (0.3
Diluted	$ 0.02	$ (0.94)	$ (0.3
Shares used in computing earnings (loss) per share			
Basic	132	137	1
Diluted	133	137	1

See Notes to Consolidated Financial Statements.

Indivior PLC
Consolidated Statements of Comprehensive Loss
(Amounts in millions)

	Year Ended December 31,		
	2024	**2023**	**2022**
Net income (loss)	**$2**	**$(129)**	**$(44)**
Other comprehensive (loss) income, net of tax			
Foreign currency translation	(6)	2	(6)
Other comprehensive (loss) income	(6)	2	(6)
Total comprehensive loss	**$(4)**	**$(127)**	**$(50)**

See Notes to Consolidated Financial Statements.

Indivior PLC
Consolidated Balance Sheets
(Amounts in millions, except per share data)

	Year Ended December 31,	
	2024	**2023**
Assets		
Current assets		
Cash and cash equivalents	$ 319	$ 316
Short-term investments	1	94
Accounts receivable, net of allowances of $3 (2024) and $2 (2023)	254	254
Inventories	178	135
Prepaid expenses and other current assets	53	52
Escrow settlement asset	—	415
Current tax receivable	34	—
Total current assets	**839**	**1,266**
Long-term investments	27	41
Property, plant and equipment, net	100	84
Operating lease right of use assets, net	39	40
Goodwill and other intangible assets, net	6	13
Deferred tax assets	280	288
Other non-current assets	29	28
Total assets	**$ 1,319**	**$ 1,760**
Liabilities and shareholders' deficit		
Current liabilities		
Accrued rebates and product returns	$ 562	$ 535
Accounts payable and accrued expenses	232	204
Accrued litigation settlement expenses, current	99	492
Current portion of long-term debt	18	3
Operating lease liabilities, current	10	9
Income taxes payable	7	8
Other current liabilities	11	40
Total current liabilities	**939**	**1,290**
Long-term debt, less current portion	315	237
Accrued litigation settlement expenses, non-current	365	359
Operating lease liabilities, non-current	32	34
Other non-current liabilities	18	31
Total liabilities	**1,668**	**1,951**
Commitments and contingencies (Note 15)		
Shareholders' deficit		
Common stock, par value $0.50 per share Issued shares: 125 (2024) and 137 (2023)	62	68
Additional paid-in capital	90	88
Share repurchase commitment	(10)	(23)
Accumulated other comprehensive loss	(36)	(30)
Accumulated deficit	(454)	(295)
Total shareholders' deficit	**(348)**	**(191)**
Total liabilities and shareholders' deficit	**$ 1,319**	**$ 1,760**

See Notes to Consolidated Financial Statements.

Indivior PLC
Consolidated Statements of Shareholders' Deficit
(Amounts in millions)

	Common Stock		Additional paid-in capital	Share Repurchase Commitment	Accumulated other comprehensive loss	Accumulated deficit	Total shareholders' equity (deficit)
	Shares	Amount					
Balance, December 31, 2021	**702**	**$ 70**	**$ 80**	**$ —**	**$ (26)**	**$ (3)**	**$ 121**
Net loss	—	—	—	—	—	(44)	(44)
Other comprehensive loss	—	—	—	—	(6)	—	(6)
Common stock issued	4	1	1	—	—	—	2
Common stock repurchased and canceled	(570)	(3)	—	—	—	(87)	(90)
Share-based compensation	—	—	16	—	—	—	16
Settlement of tax on equity awards	—	—	(10)	—	—	—	(10)
Share repurchase liability movement, net	—	—	—	(9)	—	—	(9)
Balance, December 31, 2022	**136**	**$ 68**	**$ 87**	**$ (9)**	**$ (32)**	**$ (134)**	**$ (20)**
Net loss	—	$ —	$ —	$ —	$ —	$ (129)	$ (129)
Other comprehensive income	—	—	—	—	2	—	2
Common stock issued	2	1	2	—	—	—	3
Common stock repurchased and canceled	(2)	(1)	—	—	—	(32)	(33)
Share-based compensation	—	—	21	—	—	—	21
Settlement of tax on equity awards	—	—	(22)	—	—	—	(22)
Share repurchase liability movement, net	—	—	—	(14)	—	—	(14)
Balance, December 31, 2023	**137**	**$ 68**	**$ 88**	**$ (23)**	**$ (30)**	**$ (295)**	**$ (191)**
Net income	—	$ —	$ —	$ —	$ —	$ 2	$ 2
Other comprehensive loss	—	—	—	—	(6)	—	(6)
Common stock issued	1	1	2	—	—	—	3
Common stock repurchased and canceled	(13)	(7)	—	—	—	(161)	(168)
Share-based compensation	—	—	24	—	—	—	24
Settlement of tax on equity awards	—	—	(22)	—	—	—	(22)
Share repurchase liability movement, net	—	—	—	13	—	—	13
Other	—	—	(2)	—	—	—	(2)
Balance, December 31, 2024	**125**	**$ 62**	**$ 90**	**$ (10)**	**$ (36)**	**$ (454)**	**$ (348)**

See Notes to Consolidated Financial Statements.

Indivior PLC
Consolidated Statements of Cash Flows
(Amounts in millions)

	Year Ended December 31,		
	2024	**2023**	**2022**
Cash flows from operating activities:			
Net income (loss)	**$ 2**	**$ (129)**	**$ (44)**
Adjustments to reconcile net income (loss) to net cash from operating activities:			
Depreciation and amortization	29	15	16
Share-based compensation expense	24	21	16
Impairment of tangible and intangible assets	8	—	—
Unrealized loss on equity investments	9	—	—
Deferred income taxes	6	(65)	(105)
Acquired in-process research and development	1	162	—
Impact from foreign exchange movements	(2)	(10)	(4)
Other adjustments, net		—	(1)
Change in operating assets and liabilities:			
Accounts receivable	(1)	(33)	(21)
Inventories	(45)	(15)	(30)
Other current and non-current assets	378	(410)	69
Accounts payable			
Accrued legal and settlement expenses	(387)	50	197
Other current and non-current liabilities	14	114	(97)
Net cash provided by (used in) operating activities	**36**	**(300)**	**(4)**
Cash flows from investing activities:			
Purchases of property and equipment	(29)	(8)	(5)
Purchases of in-process research and development and intangible assets	(2)	(45)	—
Acquisitions, net of cash acquired	—	(129)	—
Purchases of investments in debt securities	(17)	(45)	(245)
Sales and maturities of debt securities	117	129	27
Other proceeds from investing activities	—	3	1
Net cash provided by (used in) investing activities	**69**	**(95)**	**(222)**
Cash flows from financing activities:			
Proceeds from the issuance of common stock	3	3	2
Cash paid for repurchases of common stock	(173)	(33)	(90)
Proceeds from debt, net	332	—	—
Repayments of debt	(240)	(12)	(3)
Other	(2)	—	—
Settlement of tax on equity awards	(22)	(22)	(10)
Net cash used in financing activities	**(102)**	**(64)**	**(101)**
Net increase (decrease) in cash and cash equivalents	**3**	**(459)**	**(327)**
Exchange differences	—	1	(1)
Cash and cash equivalents at beginning of period	316	774	1,102
Cash and cash equivalents at end of period	**$ 319**	**$ 316**	**$ 774**

See Notes to Consolidated Financial Statements.

1. Business Overview

Indivior PLC and its subsidiaries (together, "Indivior" or the "Company") is a global pharmaceutical company working to help change patients' lives by pioneering life-transforming treatment for addiction, including SUBLOCADE (buprenorphine extended-release) injection for subcutaneous use, a long-acting injectable (LAI) for opioid use disorder and OPVEE (Nalmefene) nasal spray for opioid overdose recovery.

The principal accounting policies adopted in the preparation of these financial statements are set out below. Unless otherwise stated, these policies have been consistently applied to all the years presented.

2. Summary of Significant Accounting Policies

Basis of Presentation and Principles of Consolidation

The consolidated financial statements include the accounts of all the Company's subsidiaries and are prepared in conformity with accounting principles generally accepted in the United States ("U.S. GAAP"). All intercompany balances and transactions have been eliminated in consolidation. Columns and rows within tables may not add due to rounding. Percentages and per share data have been calculated using actual, non-rounded figures.

The Company previously prepared its consolidated financial statements in accordance with International Financial Reporting Standards. As part of the Company's efforts to align with industry peers and prepare for the expected loss of foreign private issuer status, the Company elected to file its 2024 annual report on Form 10-K, including presentation of its consolidated financial statements in accordance with U.S. GAAP. The transition to U.S. GAAP is reflected retrospectively for all periods from the Company's inception.

Fair Value Measurements

Fair value is the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. See *Note 13. Financial Instruments and Fair Value Measurements* for additional information on the fair value hierarchy used by the Company.

Foreign Currency Translation

The financial statements of each of the Company's subsidiaries are measured using the currency of the primary economic environment in which the entity operates (the functional currency), which is generally the local currency with the exception of manufacturing, treasury and holding companies where the functional currency is the U.S. dollar. The Company's presentation currency is the U.S. dollar. The financial statements of subsidiaries with functional currencies other than the U.S. dollar are translated into U.S. dollars using period-end exchange rates for assets and liabilities, historical exchange rates for shareholders' equity and weighted average exchange rates for operating results. Translation gains and losses are recognized in Consolidated Statements of Comprehensive Loss.

Use of Estimates and Judgments

The preparation of Consolidated Financial Statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported. Significant estimates are used in determining items such as accruals for returns, incentives and rebates, impairment of intangible assets, acquisitions, and ongoing litigation. Actual results may differ from those estimates.

Cash and Cash Equivalents

Cash and cash equivalents comprise cash in hand, current balances with banks and similar institutions, and short-term highly liquid investments with original maturities of less than three months and are recognized at cost, which approximates fair value.

Accounts Receivable, Net

Accounts receivables are initially recognized at their invoiced amounts less any adjustments for estimated deductions such as cash discounts. Provisions for expected credit losses are established using an expected credit loss model ("ECL") taking into account individual customer's credit risk based on financial position, past experience, and other relevant factors.

Charges for ECL are recognized in the Consolidated Statements of Operations within selling, general and administrative expense. The provision for ECL was approximately $3 million and $2 million at December 31, 2024, and 2023, respectively.

Concentration of Credit Risk

Financial instruments that potentially expose the Company to concentrations of credit risk are limited to cash and cash equivalents deposited with banks and other financial institutions, investment in debt securities, accounts receivable and other assets. The Company maintains its cash and cash equivalents with high credit quality financial institutions. Financial institution counterparties are subject to approval under the Company's counterparty risk policy and such approval is limited to financial institutions with a BBB rating or above. All the Company's investments in debt securities are of low credit risk based on investment-grade credit ratings from Standard and Poor's or Moody's (BBB-/Baa3 or higher).

As of December 31, 2024, 2023 and 2022 the Company had four separate customers representing greater than 10% of the net accounts receivable balance.

	Year Ended December 31,		
Percent of accounts receivable	**2024**	**2023**	**2022**
Customer A	25 %	21 %	25 %
Customer B	18 %	23 %	23 %
Customer C	17 %	17 %	15 %
Customer D	10 %	8 %	8 %

Investments

The Company's investments comprise holdings in equity and debt securities. Investments in equity securities which have readily available fair values are initially recorded and subsequently remeasured at fair value through earnings.

Investments in debt securities are initially recorded at fair value and remeasured based on the intended holding period. Investments classified as held to maturity investments are reported at amortized cost and realized gains or losses are reported in earnings. Held to maturity investments are classified as long-term investments, except for those with maturities less than 12 months from the end of the reporting period, which are classified as short-term investments. Declines in fair value below amortized cost related to credit losses (i.e., impairment due to credit losses) are included in the Consolidated Statements of Operations, with a corresponding allowance established. If the estimate of expected credit losses decreases in subsequent periods, the Company will reverse the credit losses through current period earnings and adjust the allowance accordingly.

Inventories

Raw materials and consumables, work in progress and finished goods are stated at the lower of cost or net realizable value determined by the first in, first out method. Cost comprises materials, direct labor, and an appropriate allocation of overhead expenses (based on normal operating capacity) required to get the inventory to its present location and condition. Net realizable value is the estimated selling price less applicable selling expenses. Write-down of inventory occurs in the general course of business and is recognized in cost of sales.

Property, Plant and Equipment

Property, plant, and equipment are carried at cost less accumulated depreciation and impairment, with the exception of land, which is stated at cost less impairment. Depreciation is provided over the estimated useful lives of the assets using the straight-line method. For this purpose, useful lives are determined within the following limits:

Assets	Expected useful life
Buildings	Not more than 20 years
Plant and Equipment	Not more than 10 years
Motor Vehicles and Computer Equipment	Not more than 4 years
Leasehold Improvements	Up to the expected lease term

The estimated useful lives and residual value of property, plant and equipment are assessed periodically and adjusted as required. Current facts and circumstances are periodically evaluated to determine if the carrying value of property, plant and equipment may not be recoverable and an impairment loss it to be recorded, see "*Impairment of Long-Lived Assets*" for more information.

Intangible Assets

Intangible assets are carried at cost less accumulated amortization and accumulated impairment. Intangible assets with finite useful lives are amortized over their useful lives.

Acquired computer software licenses and related implementation costs are capitalized at cost. These costs are amortized on a straight-line basis, generally over a period of up to five years. Acquired computer software primarily relates to SAP, the Company's ERP system. Amortization expense is included in selling, general and administrative expenses.

Marketed products include acquired distribution rights and post-approval milestone payments. These costs are amortized on a straight-line basis generally over the expected patent life of not more than 15 years. Amortization expense is recorded in cost of sales.

Gains and losses on the disposal of intangible assets are determined by comparing the asset's carrying value with any sale proceeds and are included in the Consolidated Statements of Operations.

Leases

The Company leases various buildings and equipment (including vehicles). Lease contracts are typically made for fixed periods of three to 10 years but may have termination or extension options. All leased buildings and equipment are classified as operating leases and the expense is recognized on a straight-line basis over the lease term. Options to extend or terminate the lease are included in the lease term when it is reasonably certain that the Company will exercise that option.

The Company recognizes a right-of-use asset ("ROU asset") and a corresponding liability ("lease liability") at the lease commencement date, measured on a present value basis.

Leases with a term of 12 months or less (short-term leases) are not recognized on the balance sheet. For short-term leases, the Company recognizes the lease payments as an operating expense on a straight-line basis over the term of the lease. The Company has made a policy election to separately account for lease and non-lease components.

Lease liabilities are measured at the present value of the remaining minimum lease payments over the lease term using the discount rate at lease commencement. Where the interest rate implicit in the lease can be determined, it is used to measure the liability. Where the interest rate implicit in the lease cannot be determined, the incremental borrowing rate at the lease commencement date is used. The incremental borrowing rate is the rate of interest the lessee would have to pay to borrow on a collateralized basis, over a similar term, an amount equal to the lease payments in a similar economic environment. Generally, the Company uses its incremental borrowing rate as the starting point for determining the discount rate, resulting in a range of rates from 4% to 12% depending upon type of lease and country of origin.

ROU assets are initially measured at cost, which comprises the initial amount of the lease liability, plus any initial direct costs incurred, less any lease incentives received. Subsequent to initial measurement, operating lease expense is recognized on a straight-line basis over the term of the lease with the ROU asset remeasured at the amount of the remeasured lease liability. ROU assets are assessed periodically for impairment whenever there is an indication the carrying amount may not be recoverable (see "*Impairment of Long-Lived Assets"* for more information).

Impairment of Long-Lived Assets

The Company periodically assesses potential impairments of its long-lived assets, namely, intangible assets, property, plant, and equipment and ROU assets. The carrying value of long-lived assets (both intangible and tangible) is reviewed for potential impairment whenever events or changes in circumstances indicate the carrying value of an asset (or asset group) may not be recoverable. We identify impairment by comparing the projected undiscounted cash flows to be generated by the asset (or asset group) to its carrying value. If an impairment is identified, a loss is recorded equal to the excess of the asset's net book value over its fair value, and the cost basis is adjusted. Goodwill and indefinite-lived intangible assets are reviewed for impairment at least annually during the fourth quarter, or more frequently if impairment indicators are present, by first assessing qualitative factors to determine whether it is more likely than not the fair value of the asset is less than its carrying amount. If we conclude it is more likely than not the fair value is less than the carrying amount, a quantitative test that compares the fair value of the intangible asset to its carrying value is performed to determine the amount of any impairment.

Employee and Retirement Benefits

Liabilities for wages and salaries, including non-monetary benefits, vacation and accumulating sick leave are recognized at the time of employees' services and are measured at the amounts expected to be paid when the liabilities are settled. These employee benefits are expected to be settled in the next twelve months and are included within accrued expenses.

Some of the Company's subsidiaries operate defined contribution plans, defined benefit pension plans, and/or provide post-retirement medical care to their retirees. The cost of providing pensions to employees who are members of defined contribution plans is charged to the income statement as services relating to those contributions are received. The Company has no further payment obligations in respect of such plans once the contributions have been paid. Other post-retirement benefits are not material.

Debt

Debt is initially recognized at fair value less attributable transaction costs, including legal and advisory and original issue discount costs. Transaction costs related to the debt placement are deferred against the loan balance and amortized over the term of the debt using the effective interest method. Transaction costs related to the undrawn revolving credit facility are deferred as a prepaid asset and amortized on a straight-line basis over the period the credit facility will be available. Subsequent to initial recognition, debt is stated at amortized cost, with any difference between cost and redemption value being recognized within interest expense in the Consolidated Statements of Operations over the term of the loan on an effective interest basis. Debt is classified as current or noncurrent based on timing of payments and expected maturity.

Contingencies

In the normal course of business, the Company is subject to loss contingencies such as legal proceedings and claims that arise out of our business that cover a wide range of matters, including, among others, government investigations, product liability and tax matters. Accruals are recognized when it is probable that a liability will be incurred, and the amount of loss can be reasonably estimated. Gain contingencies are not recognized until realized. Legal fees are expensed as incurred.

Revenue Recognition

Net revenue is generated from sales of pharmaceutical products, net of discounts and accruals for returns, incentives and rebates ("gross-to-net revenue deductions"). Direct customers are often

wholesalers, specialty pharmacies and specialty distributors of pharmaceutical products; indirect customers are often government-sponsored programs or commercial insurers with whom the Company has separate pricing and formulary agreements.

Net revenue is recognized when a contractual promise to a customer (performance obligation) has been fulfilled by transferring control over pharmaceutical products to the direct customer, substantially all of which is upon receipt of the products by the customer, and therefore all revenue is recognized at a "point in time." The amount of net revenue recognized is based on the consideration expected in exchange for pharmaceutical products, including reductions in revenue for rebates expected to be paid to indirect customers. The consideration Indivior receives may be fixed or variable. Variable consideration is only recognized when it is probable that a significant reversal will not occur when the uncertainty associated with the variable consideration is subsequently resolved. The Company has no material contracts with more than one performance obligation.

During 2023, U.S. Biomedical Advanced Research and Development Authority (BARDA) awarded the Company a contract which included initial purchase and options for purchases and delivery of OPVEE over another 9 years at guaranteed pricing through 2033.

Shipping and handling activities are not considered to be a separate performance obligation. All taxes assessed by a governmental authority that are imposed on our sales of product and collected from a customer are excluded from the measurement of the transaction price.

Management is required to determine the net transaction price in respect of each of its contracts with direct and indirect customers. In making such judgment, management assesses the impact of any variable consideration in the contract due to gross-to-net revenue deductions. These are estimated and recognized in the period in which the underlying performance obligation is fulfilled as a reduction of net revenue.

The following are the Company's significant categories of gross-to-net revenue deductions:

- Government and commercial rebates

The Company records accruals for rebates for governmental programs as a reduction of sales when the product is sold into the distribution channel. The Company pays rebates to individual U.S. states for all eligible units purchased under the Medicaid Drug Rebate Program in the U.S. ("Medicaid") based on a "per unit rebate" calculation, which is based on the Company's average manufacturer prices and applicable supplemental agreements.

Management estimates expected unit sales under Medicaid and adjusts its rebate accrual based on actual unit, per unit rebate amounts and changes in trends in Medicaid utilization.

Commercial rebates include amounts payable to payers and healthcare providers under contractual arrangements and may vary by product.

Government and commercial rebates are estimated using contracted rates, historical and estimated payer mix, historical utilization trends and payment processing time lag. Additionally, in developing estimates, management considers statutory rebate requirements, estimated patient mix, known market events or trends, channel inventory data obtained from third parties and other pertinent internal or external information. Management assesses and updates estimates each reporting period to reflect billing trends and other current information.

- Chargebacks

Chargebacks relate to discounts that occur when contracted indirect customers purchase directly from wholesalers and specialty distributors at a contracted price. The wholesaler or specialty distributor, in turn, then generally charges back to the Company the difference between the wholesale acquisition cost and the contracted price paid to the wholesaler or specialty distributor by the customer.

Management estimates the accrual for these chargebacks based on historical and expected utilization of these programs. Accruals for chargebacks are recorded within Accrued Rebates and Product Returns as they are settled by payment and not net-settled.

- Sales returns

Returns are generally made if the product is damaged, defective or otherwise cannot be used by the customer. In the U.S., the Company typically permit returns six months prior to and up to twelve months after the product expiration date. Outside the U.S., returns are only allowed in certain countries on a limited basis.

Accruals for product returns are estimated based primarily on analysis of the Company's historical product return patterns, expected future returns, and contractual agreement terms. Estimated returns are accrued in the period the related revenue is recognized.

- Sales discounts

Wholesalers, specialty pharmacies and specialty distributors of the Company's products are generally offered various forms of consideration, including discounts, allowances, service fees and prompt payment discounts, for distributing the products. Wholesaler and specialty distributor allowances and service fees arise from contractual agreements and are estimated as a percentage of the price at which the Company sells product to them. Accruals for wholesaler allowances and services fees are recorded within Accrued Rebates and Product Returns as they are settled by rebate payment and not net-settled. In addition, customers are offered a prompt pay discount for payment within a specified contractual period. Prompt pay discounts are classified as reductions of accounts receivable.

Management also takes account of factors such as levels of inventory in its various distribution channels, product expiry dates and information about potential entry of competing products into the market. In each case, the accruals made for allowances noted above are subject to continuous review and adjustment as appropriate, based on the most recent information available to management.

Adjustments to the accruals may be necessary based on actual utilization information submitted to the Company (in the case of accruals for rebates related to sales targets or contractual rebates), claims/invoices received (in the case of regulatory rebates and chargebacks) and actual return rates.

Government and commercial rebates, chargebacks, sales returns and sales discounts to customers are recorded as a reduction in sales. As on December 31, 2024, and December 31, 2023, liabilities in respect of sales returns and rebates totaled $562 million and $535 million of which 83% and 80% originated in the US in relation to Managed Care, Federal and Medicaid.

Cost of Sales

The cost of goods sold primarily consists of raw materials, third party manufacturing costs, freight and distribution costs, direct labor, cost of write-down of inventory to net realizable value and manufacturing overhead costs. Abnormal idle capacity is expensed as incurred within cost of sales.

Advertising Expense

Advertising expense includes the cost of promotional materials and activities, such as printed materials and digital marketing, marketing programs and speaker programs. Advertising expenses are expensed as incurred and are included in selling, general and administrative expenses. Advertising expenses were $68 million in 2024, $53 million in 2023 and $52 million in 2022.

Share-based Payments

Incentives in the form of shares are provided to employees under restricted share award plans. Restricted share awards are subject to either service conditions only or service and market conditions, specifically total shareholder return or relative to selected indices. Share-based compensation expense is

recorded ratably over the vesting period, regardless of whether the market condition has been satisfied, as an expense in selling, general and administrative expense in the Consolidated Statements of Operations with a corresponding increase in additional paid-in-capital. Forfeitures are estimated based on historical experience at the time of grant and revised in subsequent periods if actual forfeitures differ from those estimates. See *Note 15. Share-Based Payments* for more information.

Research and Development Expenses

Research and development costs are expensed as incurred. Research and development expenses are comprised of costs incurred in performing research and development activities including payroll and benefits, pre-clinical, clinical trial and related clinical manufacturing costs, manufacturing development and scale-up costs, product development and regulatory costs, contract services and other outside contractor costs, research license fees, depreciation and amortization of lab facilities and lab supplies costs incurred for the acquisition of assets for which there is no alternative future use beyond the development of unapproved pharmaceutical products.

For compounds acquired or licensed before regulatory approval, the Company records acquisition costs, upfront and milestone payments as IPR&D expense in the Consolidated Statements of Operations. Acquisition costs and upfront payments are recorded when incurred. The cost of milestones is recorded when probable, which for milestones with regulatory approval requirements is generally when the specific milestone has been achieved. Once a compound receives regulatory approval, any further milestone payments are recorded as acquired distribution rights within intangible assets, less accumulated amortization on a straight-line basis over the remaining agreement term or the expected product life cycle, whichever is shorter.

The Company accrues costs for clinical trial activities based upon estimates of the services received and related expenses incurred that have yet to be invoiced by the contract research organizations, clinical study sites, laboratories, consultants, or other clinical trial vendors that perform the activities.

Restructuring Costs

Restructuring charges are recognized as a result of significant changes in market conditions and actions taken to streamline operations and realize operational synergies. One-time employee termination costs are recognized at the time of communication to employees, unless future service is required, in which case the costs are recognized ratably over the future service period. Ongoing employee termination benefits are recognized as a liability when it is probable that a liability exists and the amount is reasonably estimable. The Company periodically evaluates and, if necessary, adjusts its estimates based on currently available information.

Interest Expense

Interest expense includes stated interest and amortization of deferred financing costs and debt discount incurred by the Company in connection with the refinancing of its term loan as discussed within *Note 12. Debt*. The Company amortizes the deferred financing costs and debt discount over the term of the debt, using the effective interest method.

Income Taxes

The Company accounts for income taxes under the asset and liability method, which requires the recognition of deferred tax assets (“DTAs”) and deferred tax liabilities (“DTLs”) for the expected future tax consequences of events that have been included in the financial statements. Under this method, the Company determines DTAs and DTLs on the basis of the differences between the financial statement and tax bases of assets and liabilities by using enacted tax rates in effect for the year in which the differences are expected to reverse. The effect of a change in tax rates on DTAs and DTLs is recognized in income in the period that includes the enactment date.

The Company recognizes DTAs to the extent that it believes these assets are more likely than not to be realized. In making such a determination, the Company considers all available positive and negative

evidence, including future reversals of existing taxable temporary differences, projected future taxable income, tax-planning strategies, carryback potential if permitted under the tax law, and results of recent operations. If the Company determines that it would be able to realize our DTAs in the future in excess of their net recorded amount, the DTA valuation allowance would be appropriately adjusted, which would reduce the provision for income taxes.

The Company records uncertain tax positions on the basis of a two-step process in which (1) it determines whether it is more likely than not that the tax positions will be sustained on the basis of the technical merits of the position and (2) for those tax positions that meet the more-likely-than-not recognition threshold, the Company recognizes the largest amount of tax benefit that is more than 50% likely to be realized upon ultimate settlement with the related tax authority.

Accrued interest and penalties payable for unrecognized tax benefits are included in either current or non-current income taxes payable. Interest and penalties related to unrecognized tax benefits are included in interest expense and SG&A expense, respectively.

Earnings (Loss) Per Share

Basic earnings (loss) per share is computed by dividing earnings available to common shareholders by the weighted average number of common shares outstanding for the period. Diluted earnings (loss) per share is computed using the weighted-average number of outstanding shares of ordinary shares and, when dilutive, the weighted-average number of potential common shares outstanding during the period which consist primarily of contingently issuable shares, assuming the vesting of restricted stock and current expected vesting of performance shares, which are added net of applying the treasury stock method.

Recently Adopted Accounting Standards

ASU 2023-07: Segment Reporting (Topic 280)—Improvements to Reportable Segment Disclosures

This update improves reportable segment disclosure requirements, primarily through enhanced disclosures about significant segment expenses and is required to be effective for the Company for fiscal periods beginning after December 15, 2023. As this accounting standard only impacts disclosures, it did not impact the Company's Consolidated Statements of Operations or Consolidated Balance Sheets.

ASU 2023-09: Income Taxes (Topic 740)—Improvements to Income Tax Disclosures

This update standardizes categories for the effective tax rate reconciliation, requires disaggregation of income taxes paid and additional income tax-related disclosures and is required to be effective for the Company for fiscal periods beginning after December 15, 2024. The Company has elected to adopt ASU 2023-09 for the 2024 fiscal year retrospectively. As this accounting standard only impacts disclosures, the adoption did not impact the Company's Consolidated Statements of Operations or Consolidated Balance Sheets.

Recently Issued Accounting Standards Not Yet Adopted

ASU 2024-03: Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40)—Disaggregation of Income Statement Expenses

This update requires disclosure in the notes to the financial statements of specified information about certain costs and expenses and is required to be effective for the Company for fiscal periods beginning after December 15, 2026. As this accounting standard only impacts disclosures, it will not impact the Company's Consolidated Statements of Operations or Consolidated Balance Sheets.

3. Segment, Geographic and Other Revenue Information

The Company derives revenues from customers through the development, manufacture and sale of buprenorphine-based prescription drugs for treatment of opioid dependence and related disorders. The Company offers a range of four different product lines, with the financial results reported on a consolidated basis and reviewed as a single component. The CEO is responsible for assessing performance of the

business, establishing and approving budgets, setting and evaluating performance goals, and making all key decisions aligned with strategic objectives of the Company. Accordingly, the CEO has been identified as the chief operating decision maker ("CODM"). The CEO reviews the Company's financial information on a consolidated basis for purposes of allocating resources and evaluating performance. Accordingly, the Company has concluded that it operates in a single operating and reportable segment for all periods presented. Please refer to *Note 1. Business Overview* for more information on the products and services of the Company.

The CODM uses income from operations to measure the profitability of the segment. This amount is determined in accordance with the accounting policies of the consolidated entity as described in *Note 2. Summary of Significant Accounting Policies*. These amounts are reported on the Consolidated Statements of Operations. The measure of segment assets is reported on the Consolidated Balance Sheets as total consolidated assets.

The CODM reviews net revenue and income from operations on a consolidated basis and compares to forecasted totals to evaluate financial performance. In addition, the CODM reviews the total disaggregated US net revenue by product line. No additional financial information is provided by product line. The financial data provided to the CODM is as follows:

	Year Ended December 31,		
	2024	**2023**	**2022**
US:			
SUBLOCADE*	$ 704	$ 588	$ 381
Sublingual & other[1]	250	282	323
OPVEE[2]	15	—	—
PERSERIS[3]	40	42	28
Total US	**1,008**	**912**	**732**
Most of World	179	181	169
Net revenue	**1,188**	**1,093**	**901**
Cost of sales	231	174	151
Gross profit	**957**	**919**	**749**
Operating expenses:			
Selling and marketing	255	236	218
Administrative and general	363	333	251
Total selling, general and administrative	**618**	**569**	**469**
Research and development	107	116	74
Acquired in-process research and development	1	162	—
Litigation settlement	195	239	296
Other operating expense (income), net	4	(9)	(8)
Total operating expenses, net	**925**	**1,076**	**831**
Operating income (loss)	**32**	**(156)**	**(81)**
Other income and expenses:			
Interest income	23	43	19
Interest expense	(41)	(35)	(27)
Income (loss) before income taxes	**14**	**(149)**	**(89)**
Income tax (expense) benefit	(11)	20	44
Net income (loss)	**$ 2**	**$ (129)**	**$ (44)**
*Total SUBLOCADE net revenue	$ 756	630	408

[1] Includes $3 million of revenue generated from onerous contracts at the Raleigh manufacturing facility in FY 2024. Refer note 18.
[2] 2024 OPVEE net revenue includes $15 million for two BARDA orders.
[3] Marketing and promotion activities for PERSERIS were discontinued in 2024.

Significant customers that amount to 10% or more of the Company's net revenues are as follows (in percentages of total net revenue for each year):

	Year Ended December 31,		
	2024	**2023**	**2022**
Customer A	19 %	19 %	17 %
Customer B	18 %	19 %	22 %
Customer C	18 %	16 %	16 %
Customer D	11 %	9 %	7 %

The following table summarizes the Company's long-lived assets, which include property, plant and equipment and right of use assets, by geographic area:

	Year Ended December 31,	
	2024	2023
United States	$ 74	$ 63
Most of World	65	62
Total long-lived tangible assets	**$ 139**	**$ 125**

Total capital expenditures were $29 million, $8 million and $5 million for year ended December 31, 2024, 2023 and 2022 respectively.

4. Income Tax

Income (loss) before income tax expense (benefit) by geographical area consisted of the following:

(in millions)	Year Ended December 31,		
	2024	2023	2022
Domestic	$ 28	$ 2	$ (171)
Foreign			
United States	(31)	(158)	77
Most of World excluding United Kingdom	17	7	5
Total income (loss) before tax	**$ 14**	**$ (149)**	**$ (89)**

Income tax expense (benefit) consisted of the following:

	Year Ended December 31,		
(in millions)	2024	2023	2022
Current			
Domestic	$ (6)	$ 48	$ 15
Foreign			
United States	8	(4)	47
Most of World excluding United Kingdom	3	1	(1)
Total current income tax expense (benefit)	**5**	**45**	**61**
Deferred			
Domestic	25	(65)	(79)
Foreign			
United States	(18)	—	(27)
Most of World excluding United Kingdom	(1)	—	1
Total deferred income tax expense (benefit)	**6**	**(65)**	**(105)**
Total income tax expense (benefit)	**$ 11**	**$ (20)**	**$ (44)**

In 2023, Finance (No. 2) Act 2023 (Pillar Two) was enacted in the U.K., introducing a global minimum effective tax rate of 15%. The legislation was also enacted or substantively enacted in other jurisdictions in which the Company operates. The Pillar Two legislation is effective for the Company's financial year beginning January 1, 2024. The Company performed an assessment exposure to Pillar Two income taxes and has determined it qualifies for one of the transitional safe harbors provided in territories with material pretax income in which it operates.

The following is a reconciliation of income tax expense with income taxes at the U.K. statutory rate:

(in millions)	Year Ended December 31,								
	2024			2023			2022		
	Amount	Percent		Amount	Percent		Amount	Percent	
U.K. Federal Statutory Tax Rate[1]	$ 4	25.0	%	$ (35)	23.5	%	$ (17)	19.0	%
Nontaxable or Nondeductible Items									
Imputed Expense	(13)	(90.9)	%	(12)	7.9	%	(7)	7.8	%
Other Permanent Differences	2	11.6	%	(5)	3.3	%	—	—	%
Effect of Changes in Tax Laws or Rates Enacted in the Current Period	—	—	%	(3)	2.2	%	(25)	27.4	%
Effect of Cross-Border Tax Laws	3	22.7	%	3	(2.0)	%	2	(1.9)	%
Changes in Valuation Allowances	15	103.4	%	1	(0.7)	%	3	(3.7)	%
Other Adjustments									
Statutory Adjustments	2	16.2	%	(2)	1.3	%	(5)	6.2	%
Changes in Unrecognized Tax Benefits	(2)	(11.4)	%	1	(0.9)	%	(2)	1.7	%
Foreign Tax Effects									
United States									
Statutory Tax Rate Difference Between United States and United Kingdom	1	8.8	%	4	(2.7)	%	2	(2.1)	%
State & Local (Net of Federal)	—	—	%	—	—	%	6	(6.9)	%
Nontaxable or Nondeductible Items									
Imputed Income	12	79.5	%	12	(7.8)	%	8	(9.0)	%
Non-deductible Intangible Amortization	—	—	%	26	(17.4)	%	—	—	%
Other Permanent Differences	—	—	%	4	(2.7)	%	(1)	1.7	%
Tax Credits									
Research and Development Tax Credit	(2)	(15.5)	%	(2)	1.5	%	—	—	%
Foreign Tax Credits	(16)	(109.9)	%	(16)	10.1	%	(10)	11.6	%
Changes in Valuation Allowance	4	30.5	%	4	(2.4)	%	2	(2.5)	%
Other Foreign Jurisdictions	1	6.0	%	—	—	%	—	—	%
Total Effective Tax Rate	**$ 11**	**76.0**	**%**	**$ (20)**	**13.2**	**%**	**$ (44)**	**49.3**	**%**

[1] The enacted U.K. Statutory Corporation Tax rate increased to 25% as of April 1, 2023, providing a blended rate of 23.5% for the year ended December 31, 2023.

Deferred Taxes

Significant components of the Company's deferred tax assets and liabilities are as follows:

	Year Ended December 31,	
(in millions)	2024	2023
Deferred tax assets:		
Intangibles	$ 15	$ 27
Share-based compensation	7	6
Lease liabilities	5	4
Accruals and general expenses	22	20
Capitalized research and development	7	7
Inventory reserves	70	53
Litigation	24	23
Foreign tax credit carryforwards	10	6
Interest expense carryforwards	14	13
Outside basis in Investments	3	—
Tax loss carryforwards	156	162
Total deferred tax assets	**333**	**321**
Valuation allowance	(47)	(28)
Total deferred tax assets, net of valuation allowance	**286**	**293**
Deferred tax liabilities:		
Property, plant and equipment	(1)	(2)
Right of use assets	(5)	(3)
Total deferred tax liabilities	**(6)**	**(5)**
Total net deferred tax assets (liabilities)	**$ 280**	**$ 288**
Recognized as:		
Deferred tax assets—noncurrent	$ 286	$ 293
Deferred tax liabilities—noncurrent	$ (6)	$ (5)

As of December 31, 2024, the Company had foreign tax credit carryforwards of $10 million, if not used, will expire in 2031 through 2034, and R&D Credit carryforward of $1 million, if not used, will expire in 2042.

Valuation Allowances

As of December 31, 2024, 2023 and 2022, the Company had valuation allowances of $47 million, $28 million and $23 million, respectively.

A reconciliation of the beginning and ending valuation allowance was as follows:

	Year Ended December 31,		
(in millions)	2024	2023	2022
Balance at beginning of year	**$ 28**	**$ 23**	**$ 17**
Additions to valuation allowance charged to income tax expense	19	5	6
Balance at end of year	**$ 47**	**$ 28**	**$ 23**

Additions to valuation allowances of $19 million, $5 million, and $6 million for 2024, 2023 and 2022, respectively, were due to deferred tax assets recorded in connection with corporate interest expense restriction, net operating and capital losses in the U.K. and foreign tax credits in the U.S.

Unrecognized Tax Benefit

We are subject to income taxation in many jurisdictions. Unrecognized tax benefits reflect the differences between tax positions we have taken or expect to take on income tax returns and the amounts recognized in our financial statements. Resolution of the related tax positions with the relevant tax authorities may take many years to complete, and such timing is not entirely within our control.

The following table reconciles the beginning and ending amount of our gross unrecognized tax benefits:

	Year Ended December 31,		
(in millions)	2024	2023	2022
Balance at beginning of year	**$ 9**	**$ 7**	**$ 9**
Additions for tax positions of prior years	—	5	—
Reductions for tax positions due to lapse of statutes of limitations	(2)	—	(2)
Tax settlements	(3)	(3)	—
Balance at end of year	**$ 4**	**$ 9**	**$ 7**

As of December 31, 2024, 2023 and 2022, the unrecognized tax benefits that, if recognized, would impact the effective tax rate were $4 million, $9 million, and $7 million, respectively.

As of December 31, 2024, the Company had accrued interest of $1 million, $2 million and $2 million for 2024, 2023 and 2022, respectively. For the years ended December 31, 2024, 2023 and 2022, interest expense was nil, $1 million, and nil, respectively. As of December 31, 2024, the Company had accrued penalties of $1 million, $1 million and nil for 2024, 2023 and 2022, respectively. For the years ended December 31, 2024, 2023 and 2022, the penalty expense was nil, $1 million, and nil, respectively.

The total amount of unrecognized tax benefits relating to the Company's tax positions is subject to change based on future events including, but not limited to, the settlement of ongoing tax audits and assessments and the expiration of applicable statutes of limitations.

Income Taxes Paid

Income taxes paid, net of (refunds) received, consisted of the following:

	Year Ended December 31,		
(in millions)	2024	2023	2022
Domestic	$ 40	$ 33	$ 10
Foreign			
United States			
US Federal	2	(9)	37
US State and Local	2	5	9
New York state	*	3	*
Most of World	2	—	1
Total Taxes Paid	**$ 46**	**$ 32**	**$ 57**

* The amount of income taxes paid during the year does not meet the 5% disaggregation threshold.

Reinvestment of Unremitted Earnings

We consider foreign earnings of specific subsidiaries to be indefinitely reinvested. There is no deferred tax liability, recorded, if any on such amounts. If at some future date, the Company ceases to be permanently reinvested in these specific foreign subsidiaries, the Company may be subject to foreign withholding and other taxes on these undistributed earnings and may need to record a deferred tax liability for any outside basis difference on these specific foreign subsidiaries. At December 31, 2024, 2023 and 2022, we estimate the unrecorded, deferred tax liability to be, $2 million for each of the respective years.

Tax Return Examination Status

The Company files income tax returns in the U.K., U.S. and in various foreign, state and local jurisdictions. We are subject to tax audits in the various jurisdictions until the respective statutes of limitation expire. The Company is no longer subject to U.K. examinations by tax authorities for fiscal years before 2019 and U.S. federal income tax examinations by tax authorities for fiscal years before 2021. There are ongoing U.K. and U.S. state and local audits covering 2018-2022. An estimate of reasonably possible additional tax liabilities and interest that could arise on resolution of these examinations, including the impact from later periods is in the range of nil to $61 million.

5. Inventories

Inventories are comprised of:

	Year Ended December 31,	
	2024	2023
Raw materials and consumables	$ 33	$ 38
Work in progress	51	34
Finished goods	94	63
Total Inventories, net	**$ 178**	**$ 135**

Cost of sales included inventory write-downs of $36 million, $14 million and $6 million for the years ended December 31, 2024, 2023 and 2022 respectively. Inventory write-downs reflected in the carrying amounts above at December 31, 2024, 2023 and 2022 were $26 million, $13 million, and $10 million, respectively. The 2024 write-down included $21 million related to the discontinuation of marketing and promotion for PERSERIS.

6. Property, Plant and Equipment, Net

A summary of property, plant and equipment is as follows:

	Year Ended December 31,	
	2024	2023
Land and buildings	$ 76	$ 65
Plant and equipment	76	77
Construction in progress	38	23
Gross property, plant and equipment	**190**	**165**
Less: Accumulated depreciation	(90)	(81)
Total property, plant and equipment, net	**$ 100**	**$ 84**

The Company capitalizes interest expense, if material, as part of the cost of construction of property, plant and equipment. Interest expense capitalized in 2024 was $3 million. No interest was capitalized in 2023 or 2022.

Depreciation expense was $12 million, $7 million, and $7 million for the years ended December 31, 2024, 2023 and 2022, respectively. Depreciation expense is included in cost of sales, research and development, and selling, general and administrative expenses within the Consolidated Statements of Operations.

Property, plant and equipment impairment charges (related to the discontinuation of marketing and promotion for PERSERIS) of $8 million were recognized in cost of sales within the Consolidated Statements of Operations in the year ended December 31, 2024. No impairment charges were recognized on property, plant and equipment for the years ended December 31, 2023 or 2022.

7. Goodwill and Intangible Assets

	Year Ended December 31,	
	2024	2023
Goodwill	$ 2	$ 5
Marketed products	213	213
Software	38	39
Gross intangible assets	**253**	**257**
Less: Accumulated amortization	(246)	(244)
Total intangible assets, net	**$ 6**	**$ 13**

Acquired distribution rights for marketed products were fully amortized before 2022. Amortization expense of software is included in selling, general and administrative expenses within the Consolidated Statements of Operations and was $3 million, $3 million, and $3 million in 2024, 2023 and 2022, respectively. No impairment has been recorded. The estimated annual amortization expense for intangible assets, before tax, for the next five years is not material.

8. Investments

The Company has investments in corporate debt securities which are initially recorded at fair value, plus or minus directly attributable transaction costs, and remeasured based on the intended holding period. Interest income on debt securities is included interest income within the Consolidated Statements of Operations using the effective interest method. The Company's investments are classified as held to maturity investments and reported at amortized cost and realized gains or losses are reported in earnings. The following table summarizes the amortized cost of corporate debt securities, unrealized gains and losses, and the fair value for investments in held-to-maturity debt, disaggregated by class of instrument and underlying investment contractual maturity:

	Amortized Cost Basis	Fair Value
December 31, 2024		
Corporate Debt Securities		
Less than 1 year	$ 17	$ 17
1 year to 2 years	10	10
December 31, 2023		
Corporate Debt Securities		
Less than 1 year	$ 99	$ 98
1 year to 2 years	27	27

Gross unrealized gains and gross unrealized losses were not material in 2023 or 2024.

At December 31, 2024 and 2023, $27 million of debt securities were held by a separate cell of an insurance company as part of an agreement to fund insurance coverage. These debt securities are classified as non-current as access to the investments is subject to contractual restrictions through at least December 31, 2026, regardless of the underlying investment maturity.

Actual maturities may differ from contractual maturities because certain borrowers have the right to call or prepay certain obligations and as noted above for debt securities held by a separate cell of an insurance company. Held-to-maturity securities with a value of $27 million were sold in 2024 sufficiently close to their maturity such that changes in the market interest rate would not have significantly affected the securities' fair value; an insignificant gain was recognized. No impairment charges were incurred on any held-to-maturity securities in 2024, 2023 or 2022.

The Company also holds investments in equity securities which are initially recorded and subsequently recorded at fair value through earnings. The fair value of the equity securities is based on quoted market prices on the measurement date. See *Note 13. Financial Instruments and Fair Value Measurements* for further discussion.

9. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses include:

	Year Ended December 31,	
	2024	2023
Accounts payable	$ 63	$ 39
Accrued employee-related obligations	60	72
Accrued indirect tax and government fees	39	27
Accrued other expenses	71	66
Total accounts payable and accrued expenses	**$ 232**	**$204**

Accrued other expenses includes various unbilled costs covering marketing, research and development, legal, consulting and other.

10. Leases

The following tables summarizes the components of operating lease expense:

	Year Ended December 31,		
	2024	2023	2022
Operating lease cost	$ 12	$ 11	$ 8
Total operating lease expenses	**$ 12**	**$ 11**	**$ 8**

Cash paid for amounts included in the measurement of operating lease liabilities was $13 million in 2024, $11 million in 2023, and $9 million in 2022. Right-of-use assets recorded in exchange for executing new operating lease agreements were $10 million in 2024, $14 million in 2023, and $5 million in 2022.

Supplemental information related to leases is as follows:

	Year Ended December 31,	
	2024	2023
Weighted average remaining lease term (years)	4.5	4.4
Weighted average discount rate	8 %	7 %

Future lease payments for non-cancellable operating leases as of December 31, 2024, were as follows:

2025	$ 13
2026	12
2027	11
2028	7
2029	1
Thereafter	6
Total future lease payments	**50**
Less: Imputed interest	(8)
Total lease liability	**$ 42**

At December 31, 2024, the Company had no additional operating leases entered into that had not yet commenced.

11. Accrued Litigation Settlement Expenses

	Year ended December 31,					
	2024			2023		
	Current	Non current	Total	Current	Non current	Total
Accrued litigation settlement expenses						
DOJ-related	$ 52	$ 296	$ 348	$ 57	$ 344	$ 401
Antitrust claims	24	—	24	415	—	415
Opioid litigation	15	61	76	—	—	—
Other	8	8	16	20	15	35
Total accrued litigation settlement expenses	**$ 99**	**$ 365**	**$ 464**	**$ 492**	**$ 359**	**$ 851**

DOJ-Related

DOJ Resolution Agreement

In July 2020, the Company settled criminal and civil liability with the U.S. Department of Justice (DOJ), the U.S. Federal Trade Commission (FTC), and U.S. state attorneys general. Pursuant to the resolution agreement, aggregate payments of $263 million (including interest) have been made through December 31, 2024. An additional payment of $52 million was made in January 2025 and two annual installments of $50 million plus interest will be due in January 2026 and 2027, with the final installment of $200 million due in December 2027. The Company has the option to prepay. Interest accrues at 1.25% on certain portions of the resolution and will be paid with the installment payments. For non-interest-bearing portions, the liability

has been recorded at the NPV based on timing of the estimated payments using a discount rate equal to the interest rate on the interest-bearing portions.

Antitrust class and state claims

Multi-district antitrust class and state claims

Settlement agreements were entered into during 2023 with three plaintiff classes to fully resolve certain multi-district antitrust claims. The settlement amount payable to the direct purchaser class received final court approval in 2024. Indivior has no further obligations related to this matter.

Other antitrust claims

Certain antitrust cases filed in Virginia state court were settled and paid during 2024 by agreement of the parties for $85 million and mutual releases of claims and counterclaims.

The accrual of $24 million at December 31, 2024 relates to a settlement of the last remaining antitrust litigation. An installment of $15 million was paid in December 2024 and the remaining liability of $24 million December 31, 2024 reflects the NPV at the risk-free rate of the amounts to be paid in 2025. This final settlement resolves all of the Company's remaining legacy antitrust litigation.

Opioid litigation

The accrual of $76 million at December 31, 2024 reflects the present value of the agreed amount in a preliminary settlement between Indivior, the plaintiffs' executive committee and certain state attorneys general covering certain opioid litigation (including cases in the Opioid MDL) brought by municipalities and tribes. The outflow of resources is expected to occur over five years. The parties still must negotiate material terms and conditions of the final settlement agreement, including structure, and scope of releases. The provision is measured using a risk free rate and will be remeasured at a risk-adjusted rate upon reaching a final settlement agreement.

Other

Other at December 31, 2024 includes the remaining liability related to an indemnity settlement with Reckitt Benckiser.

See *Note 16. Commitments and Contingencies* for additional information on legal matters.

12. Debt

In 2024, the Company completed a refinancing of its term loan, repaying in full the previous term loan and replacing it with a new note purchase agreement with principal amount of $350 million and a committed, revolving credit facility of $50 million, both of which mature in November 2030. None of the $50 million revolving credit facility has been utilized.

As a result of the debt refinancing, the Company incurred a charge of $3 million for the write-off of unamortized deferred financing costs due to early extinguishment of the previous term loan (recorded in interest expense) and legal and advisory fees of $4 million incurred in conjunction with the new note purchase agreement (recorded in SG&A). The Company capitalized $21 million of deferred financing and original issue discount costs related to the new agreement, of which $18 million is netted against the total amount borrowed and is being amortized over the maturity period using the effective interest method, the remainder of which relates to the undrawn revolving credit facility and is being amortized on a straight-line basis to the maturity date.

The amount of the current and previous term loan of $333 million and $240 million in 2024 and 2023, respectively, is secured by the assets of certain subsidiaries of the Company, primarily in the form of guarantees issued by respective subsidiaries. In relation to these debts, interest paid was $32 million, $26 million, and $18 million in 2024, 2023, and 2022, respectively. Interest expense was $32 million, $27 million, and $19 million in 2024, 2023, and 2022, respectively.

The terms of the loan in effect at December 31, 2024, are as follows:

	Period	Interest Payable	Required Amortization	Required Total Leverage Ratio	Required Interest Coverage Ratio
Note Purchase Agreement	Through Sept. 30, 2026	SOFR + 5.5%	5%	No more than 3:1	At least 2.5:1
	From Dec. 31, 2026 and thereafter	SOFR + 5.5%	7.5%	No more than 2.5:1	At least 2.5:1
Revolving Credit Facility	Through Sept. 30, 2026	SOFR + 5.5%; 0.5% undrawn fee	N/A	No more than 3:1	At least 2.5:1
	From Dec. 31, 2026 and thereafter	SOFR + 5.5%; 0.5% undrawn fee		No more than 2.5:1	At least 2.5:1

The total leverage ratio is calculated as total debt less up to $50 million in cash, divided by Consolidated Adjusted EBITDA. The Note Purchase Agreement generally defines the interest coverage ratio to mean Consolidated Adjusted EBITDA divided by interest expense. For purposes of the Note Purchase Agreement and Revolving Credit Facility only, the Note Purchase Agreement generally defines "Consolidated Adjusted EBITDA" to mean Consolidated Net Income for such period plus, without duplication, amounts paid or expensed for: taxes; interest; depreciation or amortization; debt, equity, and similar capital issuance costs; letters of credit; capital leases; the acquisition or repayment of any debt securities; board of director fees and expenses; transaction costs and charges incurred in connection with transactions permitted under the Note Purchase Agreement; non-recurring litigation or claim settlement charges; non-cash compensation charges associated with any stock options, restricted stock or other equity instruments; any net after-tax extraordinary, nonrecurring or unusual gains or losses; expected cost savings reasonably anticipated to be realized within 18 months related to transactions, and related charges and costs; provided that each is counted only to the extent deducted in calculating Consolidated Net Income for such period, and minus certain items such as certain non-cash gains or income to the extent they increased Consolidated Net Income. The Company is in compliance with these and all other covenants.

Aggregate maturities of long-term debt obligations and interest are as follows:

2025	2026	2027	2028	2029	Thereafter
$ 53	$ 51	$ 57	$ 55	$ 52	$ 256

13. Financial Instruments and Fair Value Measurements

Financial instruments include cash and cash equivalents, accounts receivable, accounts payable, debt, investments in corporate debt securities and investments in equity securities. The carrying value of these financial instruments, excluding debt instruments and the Company's investments in corporate debt and equity securities, approximates fair value because of the short-term nature of these instruments.

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. The Company uses a fair value hierarchy which maximizes the use of observable inputs and minimizes the use of unobservable inputs when measuring fair value. There are three levels of inputs used to measure fair value with Level 1 having the highest priority and Level 3 having the lowest:

- Level 1 — Quoted prices (unadjusted) in active markets for identical assets or liabilities.

• Level 2 — Observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

• Level 3 — Unobservable inputs that are supported by little or no market activity. Level 3 assets or liabilities are those whose values are determined using pricing models, discounted cash flow methodologies, or similar techniques with significant unobservable inputs, as well as assets or liabilities for which the determination of fair value requires significant judgment or estimation.

If the inputs used to measure the financial assets and liabilities fall within more than one level described above, the categorization is based on the lowest level input that is significant to the fair value measurement of the instrument.

The Company's only financial instruments which are measured at fair value on a recurring basis are equity securities. The fair value of the equity securities is based on quoted market prices on the measurement date. Financial instruments measured at fair value on a recurring basis at December 31 are summarized below:

	Year Ended December 31,					
	2024			2023		
	Level 1	Level 2	Level 3	Level 1	Level 2	Level 3
Equity securities	$ 1	$ —	$ —	$ 10	$ —	$ —
Total	**$ 1**	**$ —**	**$ —**	**$ 10**	**$ —**	**$ —**

The Company recognized unrealized losses on the remeasurement of equity securities of $9 million and $nil in 2024 and 2023, respectively, which was recorded in other operating expense (income), net.

The fair value of long-term debt was $350 million as of December 31, 2024 and was valued using Level 2 inputs which are based upon the quoted market prices for the same or similar debt instruments. The fair value of short-term debt approximates the carrying value due to the short maturities of the debt instruments.

The fair value of the Company's corporate debt securities was $27 million and $126 million at December 31, 2024, and 2023. The fair value of the corporate debt securities held at amortized cost was calculated based on quoted market prices which would be classified as Level 1 in the fair value hierarchy above.

Financial assets and liabilities are offset, and the net amount reported in the Consolidated Balance Sheets when there is a legally enforceable right to offset and net settlement is intended.

14. Earnings (Loss) Per Share

The following table summarizes the calculation of basic and diluted loss per share for years ended December 31, 2024, 2023 and 2022:

	Year Ended December 31,		
	2024	2023	2022
Net income (loss)	**$ 2**	**$ (129)**	**$ (44)**
Basic weighted-average shares outstanding	132	137	139
Effect of potentially dilutive securities:			
Restricted stock awards[1]	—	—	—
Diluted weighted-average shares outstanding	**133**	**137**	**139**
Basic earnings (loss) per share	**0.02**	**(0.94)**	**(0.32)**
Diluted earnings (loss) per share	**0.02**	**(0.94)**	**(0.32)**

[1] The potential shares excluded from the diluted earnings (loss) per share computation because of the antidilutive impact were nil in 2024, 4 million in 2023, and 6 million in 2022.

The weighted average number of shares is adjusted for the number of shares granted to the extent market conditions have been met at the balance sheet date and determined using the treasury stock method.

Conditional awards of 2 million shares were granted under the Company's Long-Term Incentive Plan in 2024 and 2023, respectively. For 2024 and 2023, 3 million and 1 million share awards were excluded from the computation of diluted weighted average shares, after application of the treasury method, because the market criteria were not met at the balance sheet date.

15. Share-Based Payments

The Company operates three equity-settled executive and employee share plans. For share-based payment awards, the fair value at the grant date is calculated using appropriate pricing models.

Total pretax share-based compensation cost recorded in 2024, 2023 and 2022 was $24 million, $21 million and $16 million, respectively. Income tax benefits for stock-based compensation expense recognized in 2024, 2023 and 2022 were $5 million, $3 million, and $3 million, respectively.

Indivior Long-Term Incentive Plan (LTIP)

In 2015, a share-based incentive plan was introduced for employees (including executive directors) of the Company. The awards are conditional upon the satisfaction of both market conditions and service period, generally of three years. Awards granted to executive directors are subject to a further post-vesting period of two-years.

The LTIP award shares vest based on a comparison between the share performance of the Company and the share performance of other companies ("Comparators") within two indices: (1) The FTSE 250 and (2) the S&P 1500 Pharmaceutical and Biotech Index. The conditions are based on calculation of the Total Shareholder Return ("TSR") for the Company and the Comparators in the FTSE 250, and the TSR for the Comparators in the S&P 1500 Pharmaceutical and Biotech Index and into what percentile the Company falls as compared to the Comparators in each index. The vesting is as follows: a threshold (12.5% payout) for 50th percentile performance and maximum (100% payout) for 75th percentile performance; with interpolation in between. However, if the performance of the Company falls below the 50th percentile of the index, none of the shares will vest. An equal weight is given to the performance compared to the FTSE 250 and S&P 1500 Pharmaceutical and Biotech Index.

The fair values of awards granted under the LTIP are calculated using a Monte Carlo simulation method. As vesting of the LTIP award shares is based on relative market conditions, an open form model such as the Monte Carlo is required to take into consideration the parameters of the awards. The key assumptions in the simulation model are share price of the Company, expected volatilities of the Company considering a combination of historic and implied volatility, risk-free rate, and dividend yield.

A summary of the service-based restricted share awards and market-based share awards activity under the LTIP as of December 31, 2024, is presented below (values in thousands):

	Outstanding Service-based Restricted Share Awards	Outstanding Market-based Share Awards
Shares at December 31, 2022	**1,555**	**5,950**
Granted	352	1,409
Issued	(410)	(1,124)
Canceled/forfeited/adjusted	(330)	(907)
Shares at December 31, 2023	**1,167**	**5,328**
Granted	473	1,304
Issued	(335)	(973)
Canceled/forfeited/adjusted	(268)	(941)
Shares at December 31, 2024	**1,036**	**4,717**

In 2022, a 5:1 share consolidation was completed. Shareholders received 1 new ordinary share with a nominal value of $0.50 for every 5 previously existing ordinary shares with a nominal value of $0.10 each.

The weighted average fair value per share of the service-based restricted share awards granted was $19.44, $19.25 and $3.57 in fiscal years 2024, 2023 and 2022 (2022 value prior to share consolidation), respectively, based on the fair market value at the date of grant. The total fair value of restricted share awards issued was $12 million, $12 million and $9 million in 2024, 2023 and 2022, respectively.

The weighted average fair value per share of the market-based share awards granted per share was $14.58, $11.72 and $2.86 in fiscal years 2024, 2023 and 2022 (2022 value prior to share consolidation) respectively, calculated using the weighted average fair market value for each of the component goals at the date of grant. The total fair value of market-based share awards issued was $44 million, $44 million, and $21 million in fiscal years 2024, 2023 and 2022, respectively.

Total compensation cost for unvested awards not yet recognized at December 31, 2024 was approximately $17 million for market-based share awards and $8 million for service-based restricted share awards, respectively. Compensation cost is expected to be recognized over the remaining weighted-average period of 1.7 years for market-based share awards and 1.8 years for service-based restricted share awards.

Other Employee Plans

The Company operates a Her Majesty's Revenue and Customs approved (“HMRC-approved”) save as you earn (“SAYE”) plan for U.K. employees and US Employee Share Purchase Plan (ESPP) for US employees. The amounts recognized for these plans are not material for disclosure.

Share Options

The Company did not grant any share options in 2024, 2023 or 2022. The total fair value of share options exercised was approximately $3 million in 2024. No share options were exercised in 2023 or 2022.

16. Commitments and Contingencies

Legal Proceedings and Contingencies

The Company is involved in various lawsuits, claims, and other legal proceedings that arise in the ordinary course of business. These proceedings may involve compliance and trade practices, antitrust, commercial claims, product liability claims, intellectual property rights and securities, among others.

The Company records accruals for loss contingencies associated with legal matters when it is probable that a liability will be incurred, and the amount of the loss can be reasonably estimated. The Company has

accrued for these matters and will continue to monitor each related legal issue and adjust accruals as might be warranted based on new information and further developments. Developments in legal proceedings and other matters that could cause changes in the amounts previously accrued are evaluated each reporting period. Amounts accrued for legal contingencies often result from a complex series of judgments about future events and uncertainties that rely heavily on estimates and assumptions including timing of related payments.

Where the amount and timing of the payment is fixed, the obligation is not interest-bearing, and the impact of discounting is significant, these obligations are recorded at their present value, generally using a discount rate appropriate to the obligation or approximating the risk-free rate at the time the Company incurred the obligation.

The Company does not believe that any of the legal matters discussed below, except as otherwise specifically noted, will have a material adverse effect on its financial position or liquidity as the Company believes it has substantial defenses in the matters. However, the outcomes of the Company's legal proceedings and other contingencies are inherently unpredictable and subject to significant uncertainties. There can be no assurance that there will not be an increase in the scope of one or more of these pending matters or that any other future legal matters will not be material to Company's financial position, results of operations or cash flows for a particular period.

Certain ongoing legal proceedings or threats of legal proceedings to which the Company is a party, but in which the Company believes the possibility of an adverse impact is remote, are not discussed in this Note.

Antitrust Litigation and Consumer Protection

On November 27, 2024, Indivior Inc. and Indivior Solutions Inc. entered into a settlement agreement with Humana Inc. and certain of its affiliates, and Centene Corp. and certain of its affiliates to resolve all remaining antitrust litigation against the Company, including *Humana Inc. v. Indivior Inc.*, No. 21-CI-004833 (Ky. Cir. Ct.) (Jefferson Cnty), *Centene Corp. v. Indivior Inc.*, No. CL23000054-00 (Va. Cir. Ct.) (Roanoke Cnty), and *Carefirst of Maryland, Inc. et al. v. Reckitt Benckiser Inc., et al.*, Case. No. 2875 (Phila. Ct. Common Pleas). Under the agreement, Indivior Inc. and Indivior Solutions Inc. will pay a total of $40 million to the Humana and Centene companies. $15 million was paid in December 2024, with the remaining installments of $5 million and $20 million due on or before March 15, 2025 and December 15, 2025, respectively.

Civil Opioid Litigation

The Company has been named as a defendant in more than 400 civil lawsuits alleging that manufacturers, distributors, and retailers of opioids engaged in a longstanding practice to market opioids as safe and effective for the treatment of long-term chronic pain to increase the market for opioids and their own market shares for opioids, or alleging individual personal injury claims. Most of these cases have been consolidated and are pending in a federal multi-district litigation in the U.S. District Court for the Northern District of Ohio. *See In re National Prescription Opiate Litigation*, MDL No. 2804 (N.D. Ohio) (the "Opioid MDL"). Nearly two-thirds of the cases in the Opioid MDL were filed by cities and counties, while nearly one-third of the cases were filed by private plaintiffs, most of whom assert claims relating to neonatal abstinence syndrome ("NAS"). Cases brought by cities and counties outside of the MDL include, for example, 35 actions pending in New York state court, 8 writs filed in Pennsylvania state court, and actions brought in federal district courts in Florida and Georgia. Litigation against the Company in the Opioid MDL and the other federal courts is stayed. The New York state court has not yet entered a case management order. The Company has not yet been served with a complaint in any of the Pennsylvania state court matters.

Pursuant to mediation, the Company, the Plaintiffs' Executive Committee in the Opioid MDL, Tribal Leadership Committee, and certain state attorneys general reached agreement on the amount of a potential settlement. The Company has recorded a related provision of $76 million, reflecting the NPV of the agreed amount (See *Note 11. Accrued Litigation Settlement Expenses*). The parties, however, still must negotiate material terms and conditions of the final settlement agreement, including the ultimate timing and structure

of payments and product distribution, injunctive relief, and scope of the release. The proposed settlement would resolve claims by cities and counties, but would not resolve private plaintiff cases against the Company (whether in the MDL or proceeding separately).

With respect to cases outside the MDL that were not filed by cities or counties:

Indivior Inc. was named as a defendant in *San Miguel Hospital Corp. d/b/a Alta Vista Regional Medical Center v. Johnson & Johnson, et al.*, No. 1:23-cv-00903 (D.N.M.) on March 18, 2024. Indivior moved to dismiss the complaint in May 2024. Indivior's motion to dismiss remains pending.

On October 28, 2024, Indivior Inc. was named as one of numerous defendants in five individual complaints filed in West Virginia state court that were transferred to West Virginia's Mass Litigation Panel. *See In re Opioid Litigation*, No. 22-C-9000 NAS (W.V. Kanawha Cnty. Cir. Ct.) ("WV MLP Action"). All five of Indivior Inc.'s cases in the WV MLP Action involve claims related to NAS. Indivior Inc. moved to dismiss all five complaints. The MLP granted Indivior's motion to dismiss on April 17, 2023. The plaintiffs appealed, and the Intermediate Court of Appeals of West Virginia affirmed dismissal of all claims against Indivior on December 27, 2024. The plaintiffs filed a notice of appeal in the West Virginia Supreme Court as to all defendants, including Indivior, on February 27, 2025.

On October 28, 2024, Indivior Inc. was named along with dozens of other manufacturers and distributors in a putative class action brought by West Virginia school districts in federal district court. *See Marshall County Board of Education and Wetzel County Board of Education v. Cephalon, et al.*, No. 5:24-cv-00207 (N.D.W. Va.). Indivior Inc.'s response to the complaint is not yet due.

Additionally, on May 23, 2024, the Consumer Protection Division of the Office of the Attorney General of Maryland served on Indivior Inc. an administrative subpoena related generally to opioid products marketed and sold in Maryland. Indivior Inc.’s response to the subpoena remains ongoing.

The Company has begun its evaluation of all of the claims, believes it has meritorious defenses, and intends to vigorously defend itself in all actions that would not be resolved by the proposed settlement. Given the status and preliminary stage of litigation, no estimate of possible loss for those matters can be made at this time.

False Claims Act Allegations

In August 2018, the U.S. District Court for the Western District of Virginia unsealed a declined *qui tam* complaint alleging causes of action under the Federal and state False Claims Acts against certain entities within the Company predicated on best price issues and claims of retaliation. *See United States ex rel. Miller v. Reckitt Benckiser Group PLC et al.*, Case No. 1:15-cv-00017 (W.D. Va.). The suit also seeks reasonable attorneys’ fees and costs. The Company filed a Motion to Dismiss in June 2021, which was granted in part and denied in part on October 17, 2023. The relator filed a sixth amended complaint against only Indivior Inc. on December 7, 2023, which Indivior answered on March 18, 2024. Discovery has been stayed pending resolution of certain discovery disputes. The Company is evaluating the claims, believes it has meritorious defenses, and intends to vigorously defend itself. Given the status and preliminary stage of the litigation, no estimate of possible loss can be made at this time.

U.K. Shareholder Claims

On September 21, 2022, certain shareholders issued representative and multiparty claims against Indivior PLC in the High Court of Justice for the Business and Property Courts of England and Wales, King’s Bench Division. On January 16, 2023, the representative served its Particular of Claims setting forth in more detail the claims against the Group, while the same law firm that represents the representative also sent its draft Particular of Claims for the multiparty action. The claims made in both the representative and multiparty actions generally allege that Indivior PLC violated the U.K. Financial Services and Markets Act 2000 (“FSMA 2000”) by making false or misleading statements or material omissions in public disclosures, including the 2014 Demerger Prospectus, regarding an alleged product-hopping scheme regarding the switch from SUBOXONE Tablets to SUBOXONE Film. Indivior PLC filed an application to strike out the representative action. On December 5, 2023, the court handed down a judgment allowing the Company's

application to strike out the representative action. The court subsequently awarded certain costs to the Company. On January 23, 2024, the claimants requested permission to appeal the decision to the court of appeals. The appellate court affirmed the dismissal by order dated January 23, 2025. The claimants applied for permission to appeal to the Supreme Court on February 19, 2025. The Company opposed, and the court refused the application on February 27, 2025. The Company has begun its evaluation of the remaining claims, believes it has meritorious defenses, and intends to vigorously defend itself. Given the status and preliminary stage of the litigation, no estimate of possible loss can be made at this time.

U.S. Shareholder Claims

A class action lawsuit was filed against Indivior PLC, Mark Crossley (the CEO of the Company), and Ryan Preblick (the CFO of the Company) on August 2, 2024, alleging violations of certain U.S. federal securities laws. The putative class, as alleged, includes plaintiffs that purchased or otherwise acquired Indivior securities between February 22, 2024 and July 8, 2024. The court entered an order appointing a lead plaintiff on October 7, 2024, and the lead plaintiff filed an amended complaint on December 5, 2024, which additionally named Richard Simkin (the CCO of the Company) as a defendant. The defendants filed a motion to dismiss on January 10, 2025, which remains pending. The Group has begun its evaluation of the claims, believes it has meritorious defenses, and intends to vigorously defend itself. Given the status and preliminary stage of the litigation, no estimate of possible loss can be made at this time.

Opiant Shareholder Claims

On November 8, 2023, plaintiff James Litten filed a class action complaint in the Delaware Court of Chancery alleging that former officers and directors of Opiant Pharmaceuticals, Inc. ("Opiant") breached fiduciary duties of care, loyalty, and good faith in connection with Indivior PLC's 2022 acquisition of Opiant. The defendants moved to dismiss the complaint on January 26, 2024. On March 21, 2024, the plaintiff filed an amended complaint. The defendants moved to dismiss the amended complaint on June 21, 2024. The court heard argument on the motion to dismiss on January 17, 2025 and heard additional argument on February 19, 2025. The motion remains pending. The Company has begun its evaluation of the claims, believes it has meritorious defenses, and intends to vigorously defend itself. Given the status and preliminary stage of the litigation, no estimate of possible loss can be made at this time.

Dental Allegations

The Company has been named as a defendant in numerous lawsuits alleging that SUBOXONE Film was defectively designed and caused dental injury, and that the Company failed to properly warn of the risks of such injuries. The plaintiffs generally seek compensatory damages, as well as punitive damages and attorneys' fees and costs. Plaintiffs and potential plaintiffs related to these lawsuits generally can be grouped as follows:

Dental MDL Plaintiffs: Approximately 1,300 of these cases have been consolidated in multi-district litigation in the Northern District of Ohio. *See In Re Suboxone (Buprenorphine/Naloxone) Film Products Liability Litigation*, MDL No. 3092 (N.D. Oh.) (the "Dental MDL").

Dental MDL Schedule A Plaintiffs: One complaint filed in the Dental MDL on June 14, 2024 attached a schedule of nearly 10,000 plaintiffs (the "Schedule A Plaintiffs"). The parties negotiated a tolling agreement for the Schedule A Plaintiffs that would permit plaintiffs' counsel additional time to investigate issues such as whether and when the Schedule A Plaintiffs used any Indivior product before determining whether to file individual complaints that ultimately would be coordinated with the Dental MDL. Plaintiffs indicated to the court they will dismiss more than 1,400 plaintiffs in the future, pursuant to a mechanism to be provided by the court. On February 7, 2025, the plaintiffs filed an amended Schedule A that reduced the number of Schedule A claimants to 8,623.

State Court Plaintiffs: One complaint has been filed in New Jersey state court, and the parties have agreed to toll the claims of more than 850 other individuals in Delaware, New Jersey, and Virginia. Complaints have not yet been filed on behalf of the tolled individuals.

Product liability cases such as these typically involve issues relating to medical causation, label warnings and reliance on those warnings, scientific evidence and findings, actual/provable injury and other matters. These cases are in their preliminary stages. These lawsuits and claims follow a June 2022 required revision to the Prescribing Information and Patient Medication Guide about dental problems reported in connection with buprenorphine medicines dissolved in the mouth to treat opioid use disorder. This revision was required by the FDA of all manufacturers of these products. The Company has been informed by its primary insurance carrier that defense costs for the Dental MDL should begin to be reimbursed now that the Company's self-insurance retention has been exhausted. Additionally, the Company's primary insurance carrier has issued a reservation of rights against payment of any liability costs. In the event of a liability finding, various factors could affect reimbursement or payment by insurers, if any, including (i) the scope of the insurers' purported defenses and exclusions to avoid coverage, (ii) the outcome of negotiations with insurers, (iii) delays in or avoidance of payment by insurers and (iv) the extent to which insurers may become insolvent in the future. The Company has begun its evaluation of the claims, believes it has meritorious defenses, and intends to vigorously defend itself. Given the status and preliminary stage of the litigation, no estimate of possible loss can be made at this time.

Applications to file class actions based on similar allegations as in the Dental MDL, but also relating to SUBOXONE Tablets, were filed in Quebec and British Columbia against various subsidiaries of the Company, among other defendants, in April 2024. The Company has begun its evaluation of the claims, believes it has meritorious defenses, and intends to vigorously defend itself. Given the status and preliminary stage of the litigation, no estimate of possible loss ca n be made at this time.

17. Shareholders' Equity

Ordinary Shares

A summary of ordinary shares outstanding is as follows:

	Year Ended December 31,		
	2024	2023	2022
Balance at beginning of year	**137**	**136**	**702**
Shares repurchased and canceled	—	—	(18)
Share consolidation	—	—	(551)
Allotments to satisfy vesting/exercises of share-based compensation awards	1	2	4
Shares repurchased and cancelled (post share consolidation)	(13)	(2)	(1)
Balance at end of year	**125**	**137**	**136**

The Company has one class of ordinary shares with par value of $0.50 per share which carries the right to one vote at general meetings of the Company. Incremental costs directly attributable to the issue of ordinary shares, net of any tax effects, are recognized as a deduction from equity. The Company does not hold any shares as treasury shares. The Company is authorized to issue an additional allotment as needed each year at the Annual General Meeting up to a maximum of an amount equivalent to two-thirds of the shares in issue (of which one-third must be offered by way of rights issue).

On October 10, 2022, Indivior PLC completed a 5-for-1 share consolidation. Shareholders received 1 new share of ordinary shares with a nominal value of $0.50 each for every 5 previously existing shares of ordinary shares which had a nominal value of $0.10 each.

The Company does not anticipate the payment of dividends for the foreseeable future.

Accumulated other comprehensive loss

The accumulated other comprehensive loss includes the accumulated foreign exchange differences from the translation of the financial statements of the Company's foreign operations arising when the Company's entities are consolidated.

Accumulated deficit

At the inception of Indivior as an independent publicly-listed company, accumulated deficit of $1,295 million was recognized, representing the difference between the nominal value of the shares issued by the Company and the net investment in the Company by the former owner.

18. Asset Acquisitions

Opiant Acquisition

On March 2, 2023, the Company acquired 100% of the share capital of Opiant, which at the time was a publicly traded company in the U.S., for upfront cash consideration of $146 million and an additional amount to be potentially paid upon achievement of net sales milestones. Opiant was a specialty pharmaceutical company focusing on developing drugs for addictions and drug overdose. As a result of the acquisition, the Company added OPVEE, formerly the pipeline product OPNT003, an opioid overdose treatment well-suited to confront illicit synthetic opioids like fentanyl, to its addiction treatment and science portfolio. OPVEE was approved by the FDA in May 2023 and launched in October 2023.

For the acquisition of Opiant, substantially all of the fair value of the gross assets acquired (excluding cash and cash equivalents, deferred tax assets, and goodwill resulting from the effects of deferred tax liabilities) was concentrated in the IPR&D associated with OPVEE. Accordingly, the Company accounted for the transaction as an asset acquisition. With the closing of this transaction, a relative fair value approach was taken for allocating the purchase consideration to the acquired assets and liabilities with no goodwill recognized. The Company used a multi-period excess earnings method, a form of the income approach, to determine the fair value of the IPR&D of $120 million, which was immediately expensed.

As part of the acquisition of Opiant, the Company agreed to provide a maximum of $8.00 per share in Contingent Value Rights ("CVR") post-acquisition. The Company will pay $2.00 per CVR for each of the following net revenue thresholds achieved by OPVEE, during any period of four consecutive quarters prior to the seventh anniversary of the U.S. commercial launch: (i) $225 million, (ii) $300 million and (iii) $325 million. The remaining (iv) $2.00 per CVR would be paid if OPVEE achieves net revenue of $250 million during any period of four consecutive quarters prior to the third anniversary of the U.S. commercial launch. The potential undiscounted payout of contingent consideration ranges from zero to $68 million based on the achievement of the milestones. No liabilities were recognized as of December 31, 2023 or 2024 since the net revenue thresholds have not been reached.

The cash outflow for the acquisition was $124 million, net of cash acquired. Direct transaction costs of $10 million are included in this cash outflow and expensed as a component of acquired IPR&D. Of the $146 million upfront consideration, $2 million represents acceleration of vesting of employee share compensation and has been recognized as a post-combination expense. As part of the acquisition, the Company assumed outstanding debt of $10 million which was settled and included as a cash outflow from financing activities.

Additional acquisition-related costs of $16 million were incurred in 2023 and included in selling, general, and administrative expenses, primarily relating to severance, acceleration of vesting of Opiant employee share compensation, and short-term retention accruals.

The following table summarizes the net assets acquired:

Net assets acquired	
Cash and cash equivalents	$ 30
Inventories	3
Right-of-use assets	2
IPR&D	120
Deferred tax assets	15
Other assets	6
Trade and other payables	(10)
Lease liabilities	(2)
Debt	(10)
Total net assets acquired, inclusive of expensed IPR&D	**$ 154**

19. Business Combinations

On November 1, 2023, the Company acquired an aseptic manufacturing facility (the "Facility") in the U.S. for upfront consideration of $5 million in cash and assumption of certain contract manufacturing obligations. The Facility will be further developed to secure the long-term production and supply of SUBLOCADE.

The acquisition was accounted for as a business combination using the acquisition method of accounting. The assets acquired and liabilities assumed were recorded at fair value, with the excess of the purchase price over the fair value of the identifiable assets and liabilities recognized as goodwill. A liability was recorded at fair value to reflect the present value of the expected losses from assumed contractual manufacturing obligations. Net operating losses attributable to these contractual obligations will be recorded against the liability from the date of acquisition through fulfillment of the contracts in early 2025.

As of December 31, 2024, committed capital spend for the Facility is approximately $21 million.

Identifiable assets acquired and liabilities assumed

As the acquisition was completed in late 2023, the provisional fair value of assets acquired and liabilities assumed at the date of acquisition was disclosed in the Consolidated Financial Statements for the year ended December 31, 2023. In 2024, based on new information obtained about facts and circumstances that existed as of the acquisition date, the Company adjusted the provisional fair values for acquired property, plant and equipment and the assumed onerous contract provision, with a net reduction to goodwill of $3 million. The measurement period was closed on March 31, 2024. The following table provides the total consideration and acquisition date fair values of assets acquired and liabilities assumed and the adjusted values:

Net assets acquired	At Date of Acquisition	Measurement Period Adjustment	Adjusted Values
Property, plant and equipment	$ 28	$ (2)	$ 26
Deferred tax assets	2	(1)	1
Trade and other payables	(1)	—	(1)
Contractual liabilities	(29)	6	(23)
Total net assets acquired	**$ —**	**$ 3**	**$ 3**

Goodwill arising from the acquisition has been recognized as follows, reflecting the Q1 2024 measurement period adjustments:

	At Date of Acquisition	Measurement Period Adjustment	Adjusted Values
Consideration transferred	$ 5	$ —	$ 5
Less: Fair value of net assets acquired	—	(3)	(3)
Goodwill	**$ 5**	**$ (3)**	**$ 2**

The goodwill is primarily attributable to Indivior-specific synergies relating to accelerated in-sourcing of SUBLOCADE production and the skills and technical talent of the Facility's workforce.

20. Restructuring

Discontinuation of PERSERIS Marketing and Promotion

In July 2024, the Company announced the discontinuation of promotion and marketing support for PERSERIS, resulting in a headcount reduction of approximately 130 employees and termination of related contract manufacturing agreements. The decision was taken in consideration of regulatory changes announced during Q2 2024 which are expected to adversely intensify payor management of the treatment category in which PERSERIS competes and would make PERSERIS no longer financially viable. While the Company will continue to supply PERSERIS for the foreseeable future, the expected adverse impacts represented an impairment indicator for PERSERIS-related assets, resulting in year to date impairment charges and other expenses as detailed below. Charges of $53 million recorded in 2024 included inventory provisions and impairment of tangible assets, contract termination costs and severance. No additional costs are expected to be incurred.

Impairment charges, provisions, write downs and other	2024
Charged to cost of sales:	
Plant and equipment	$ 8
Inventory	21
Contract termination and related supplier charges	12
Sub-total: Cost of sales	**41**
Charged to SG&A:	
Severance	**7**
Other expenses	**5**
Sub-total: SG&A	**12**
Total charges	**$ 53**

Contract termination fees of $5 million and severance of $6 million were paid in 2024.

21. Subsequent Events

In February 2025, the Company announced that Mark Crossley will be stepping down as Chief Executive Officer and as a Board Director by mutual agreement. Mr. Crossley is expected to remain as CEO until at least the date of the Company's annual general meeting (AGM) in May 2025. The Separation Agreement includes a one-year severance, continuation of benefits, and allows for potential vesting of all share-based compensation awards to the extent the original grant date market conditions met. These costs will be expensed in 2025.

The Company plans to appoint Joe Ciaffoni, currently an Independent Non-Executive Director of the Company, as the new Chief Executive Officer. The terms of his appointment are subject to, and effective upon, the approval by shareholders of a new remuneration policy at the Company's AGM in May 2025.

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Shareholders of Indivior PLC

Opinions on the Financial Statements and Internal Control over Financial Reporting

We have audited the consolidated financial statements, including the related notes, as listed in the index appearing under Item 15 a) 1., and the schedule of condensed financial information of the registrant as of December 31, 2024 and 2023 and for the years ended December 31, 2024, 2023 and 2022 appearing under Item 15, of Indivior PLC and its subsidiaries (the "Company") (collectively referred to as the "consolidated financial statements"). We also have audited the Company's internal control over financial reporting as of December 31, 2024, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2024 and 2023, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2024 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2024, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the COSO.

Basis for Opinions

The Company's management is responsible for these consolidated financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express opinions on the Company's consolidated financial statements and on the Company's internal control over financial reporting based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

Our audits of the consolidated financial statements included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of

records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Critical Audit Matters

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that (i) relates to accounts or disclosures that are material to the consolidated financial statements and (ii) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Medicaid Rebate Accruals

As described in Note 2 to the consolidated financial statements, the Company records accruals for rebates for governmental programs as a reduction of sales when the product is sold into the distribution channel. The Company pays rebates to individual U.S. states for all eligible units purchased under the Medicaid Drug Rebate Program in the United States (Medicaid) based on a "per unit rebate" calculation, which is based on the Company's average manufacturer prices and applicable supplemental agreements. Management estimates expected unit sales under Medicaid and adjusts the Company's rebate accrual based on actual unit, per unit rebate amounts and changes in trends in Medicaid utilization. These rebates are estimated using historical and estimated payer mix, historical utilization trends and payment processing time lag. Additionally, in developing estimates, management considers statutory rebate requirements, estimated patient mix, known market events or trends, channel inventory data obtained from third parties and other pertinent internal or external information. As of December 31, 2024, the Company's accrued rebates and product returns balance was $562 million, of which a majority relates to Medicaid.

The principal considerations for our determination that performing procedures relating to the Medicaid rebate accruals is a critical audit matter are (i) the significant judgment by management when developing the estimate of the Medicaid rebate accruals and (ii) a high degree of auditor judgment, subjectivity, and effort in performing procedures and evaluating management's significant assumptions related to expected unit sales under Medicaid and the actual unit, per unit rebate amounts and changes in trends in Medicaid utilization.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included testing the effectiveness of controls relating to Medicaid rebate accruals. These procedures also included, among others (i) developing an independent estimate of the Medicaid rebate accruals by utilizing third-party data related to product demand and price changes, the terms of the specific rebate programs, the historical trend of actual rebate claims paid, and known market events; (ii) comparing the independent estimate to management's estimate to evaluate the reasonableness of management's estimate; and (iii) testing, on a sample basis, rebate claims paid by the Company.

/s/ PricewaterhouseCoopers LLP

Richmond, Virginia

March 3, 2025

We have served as the Company's auditor since 2022.

Management's Report on Internal Control over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934, as amended. Indivior's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. Internal control over financial reporting includes those policies and procedures that:

- pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles;
- provide reasonable assurance that receipts and expenditures are being made only in accordance with the authorizations of management and directors; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of assets that could have a material effect on the Consolidated Financial Statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Management assessed the effectiveness of Indivior's internal control over financial reporting as of December 31, 2024. Management based this assessment on criteria for effective internal control over financial reporting described in *Internal Control—Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO").

Based on this assessment, management determined that, as of December 31, 2024, the Company maintained effective internal control over financial reporting.

PricewaterhouseCoopers LLP, an independent registered public accounting firm, who audited the Consolidated Financial Statements of the Company included in this report, has audited the effectiveness of the Company's internal control over financial reporting as of December 31, 2024, as stated in their report which appears herein.

Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Disclosure Controls and Procedures

Management with the participation of the Chief Executive Officer and Chief Financial Officer, carried out an evaluation of the effectiveness of Indivior PLC's disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended, as of the end of the period covered by this report. Based on that evaluation, the Chief Executive Officer and Chief Financial Officer concluded that Indivior PLC's disclosure controls and procedures were effective as of December 31, 2024.

Management's Report on Internal Control over Financial Reporting

Management's Report on Internal Control over Financial Reporting is included in Item 8. *Financial Statements and Supplementary Data*.

Changes in Internal Control over Financial Reporting

There was no change in the Company's ICFR that occurred during the year ended December 31, 2024 that has materially affected, or is likely to materially affect, the Company's ICFR.

Item 9B. Other Information.

(1) Indivior PLC appointed Joe Ciaffoni, currently an Independent Non-Executive Director of the Company, as Chief Executive Officer. The terms of his appointment are subject to, and effective upon, the approval by shareholders of a new remuneration policy at the Company's AGM in May 2025. By mutual agreement, Mark Crossley will be stepping down as Chief Executive Officer and as a Board Director following a distinguished tenure leading the Company. Mr. Crossley will remain with Indivior to support the transition, ensuring stability and continuity for the business, and is expected to remain as CEO until at least the date of the Company's AGM in May 2025.

(2) Robert Schriesheim notified the Board of his resignation therefrom on March 2, 2025, with immediate effect. Mr. Schriesheim stated that his resignation was not due to any disagreements or issues with regards to the Company's accounting or financial statements.

(3) During the quarter ended December 31, 2024, no director or officer of the Company adopted or terminated a "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," as each term is defined in Item 408(a) of SEC Regulation S-K.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Executive Officers

The following table sets forth the names and positions of the members of our executive officers as of the date of this annual report. Except as otherwise indicated, the business address for each member of our Senior Management is 10710 Midlothian Turnpike, Suite 125, North Chesterfield, VA, 23235, U.S.

Name	Position
Mark Crossley[1]	Chief Executive Officer
Ryan Preblick	Chief Financial Officer
Jeff Burris	Chief Legal Officer
Cindy Cetani	Chief Integrity & Compliance Officer
Angela Colon-Mahoney	Chief Human Resources Officer
Dr. Christian Heidbreder	Chief Scientific Officer
Kathryn Hudson[2]	Company Secretary
Vishal Kalia	Chief Strategy & Operating Officer
Richard Simkin	Chief Commercial Officer
Hillel West[2]	Chief Manufacturing & Supply Officer

(1) See "Item 9B-Other Information" at page 161.
(2) The business address for Ms. Hudson and Mr. West is 234 Bath Road, Slough, Berkshire, SL1 4EE, United Kingdom.

Mark Crossley, age 55, has been Chief Executive Officer since June 2020. He joined the Company in 2012 as Global Finance Director with responsibilities for finance, information systems, and procurement. He was appointed Chief Strategy Officer in October 2014. Mr. Crossley was appointed to the Board in February 2017 and served as CFO from 2017 to 2019. He was appointed Chief Financial & Operations Officer in July 2019, with oversight of the finance, information technology, manufacturing, supply, quality, and procurement functions. Prior to joining Indivior, Mr. Crossley spent 13 years at Procter & Gamble in various finance leadership roles including Corporate Portfolio, Strategic and Business Planning (Female Beauty), as well as multiple roles in Corporate Treasury and its Baby Care division. He also enjoyed an eight-year career with various operational and staff assignments in the U.S. Coast Guard. Mr. Crossley has a wealth of financial and pharmaceutical industry experience and knowledge. His extensive career experience across multiple disciplines covering strategy, finance, information technology and systems, treasury, supply, and procurement allows him to bring a valuable perspective to the Board. This, complemented with an understanding of the risks and opportunities within the pharmaceutical industry, is highly valued by the Board. Mr. Crossley graduated from the U.S. Coast Guard Academy with a BS in Management and Economics and received an MBA from Boston College.

Ryan Preblick, age 49, was appointed Chief Financial Officer in November 2020, having served as Interim CFO since June 2020. From November 2020 to December 2024, he served as an executive director on the Board. Mr. Preblick has been in a financial leadership capacity since joining Indivior in 2012 as U.S. Commercial Controller. Prior to his appointment as Interim CFO, Mr. Preblick was SVP-Global Finance & Commercial Operations. This included overseeing all key financial management, analysis, and reporting elements of the Company's global business. Prior to that, he was VP-U.S. Finance with responsibility overseeing all financial aspects of the U.S. business, the Company's largest business, including management, planning, analysis and reporting, government pricing and managed care contracting operations. Mr. Preblick began his career in corporate finance at Honeywell International and then spent twelve years at Altria Company (including Phillip Morris USA) in finance leadership roles of increasing responsibility working with Treasury, Financial Planning & Analysis, Market Analytics, Supply Chain, and Brand Decision Support. Mr. Preblick holds a BS in Finance from Penn State University and an MBA from the University of Richmond.

Jeff Burris, age 53, was appointed Chief Legal Officer in December 2021. He brings over 25 years of extensive legal, life sciences, and public company experience to Indivior, including over 16 years as the head of the legal function at various life sciences companies. Mr. Burris joined Indivior from Arbor Pharmaceuticals (now Azurity Pharmaceuticals) where he was VP, GC, Chief Compliance Officer & Secretary from October 2018 to October 2021. Prior to that, he was VP, GC, Chief Compliance Officer & Secretary at Alimera Sciences, a publicly-traded pharmaceutical company, from April 2015 to September 2018, and VP, GC & Chief Compliance Officer at CryoLife (now known as Artivion), a publicly-traded biotechnology company, from February 2008 to August 2014. Mr. Burris started his career in the corporate law group at Arnall Golden Gregory LLP focused on mergers, acquisitions, divestitures, contracting, and licensing work. He then moved in-house to Waste Management (WM), where he was Senior Counsel focused primarily on acquisitions and divestitures of WM's Southern Company. Mr. Burris holds a BA in History and Economics from the University of Tennessee and a JD from The University of Chicago Law School.

Cindy Cetani, age 59, was appointed as Chief Integrity & Compliance Officer in October 2018. Ms. Cetani brings to Indivior 35 years of U.S. and global leadership predominantly in the pharmaceutical industry, with a variety of cross-industry experience spanning life and health insurance. Ms. Cetani joined Indivior in 2018 from Novartis Pharmaceuticals Corp. (Novartis) where she served as Head of Compliance Operations, Company Integrity and Compliance at the Novartis headquarters in Basel, Switzerland. Prior to that role, she served as Chief Compliance Officer and U.S. Country Compliance Head and was responsible for administration of Novartis' U.S. compliance program and negotiation, implementation of, and compliance with Novartis' 5-year Corporate Integrity Agreement with the Department of Health and Human Services Office of Inspector General, and was a member of the executive committee and global and international compliance leadership teams. Before joining Novartis in 2003, Ms. Cetani was Director of Operations-Managed Markets at Pharmacia, led Advertising Compliance for Prudential Healthcare, and held various managerial roles at U.S. life insurance and mutual benefit life insurance companies. Ms. Cetani is certified as a Leading Professional in Ethics & Compliance (LPEC) by the Ethics & Compliance Initiative, holds her corporate directorship certification from the National Association of Corporate Directors, and holds a BS in Commerce and Finance (magna cum laude) from Rider College.

Angela Colon-Mahoney, age 49, was appointed Chief Human Resources Officer in September 2024. Ms. Colon-Mahoney is an accomplished senior executive with over two decades of experience within and beyond human resources and operations through multiple executive and leadership positions across prominent organizations such as Otsuka Pharmaceutical, The Estee Lauder Companies, Tyco International, Mercer Delta, and Unilever. Most recently, Ms. Colon-Mahoney was the CHRO at Otsuka Pharmaceuticals leading the development and execution of Otsuka's human resources strategy and business services. During her tenure, she led multiple executive and organization transformations, mergers, and divestitures, and implemented a highly effective CEO and executive succession program. Under her leadership, Otsuka achieved recognition as a Best Place To Work (Forbes' Magazine) and a leader in employee mental health benefits. Ms. Colon-Mahoney has been recognized as a strategic leader in enhancing organizational effectiveness, talent development, and business performance, and for championing behavioral health initiatives, exemplifying her commitment to fostering inclusive workplaces and driving positive societal change. She continues to shape the conversation on important topics through her insights and contributions navigating the critical intersection of business, leadership, and human capital management. Ms. Colon-Mahoney holds a BA in Psychology from Saint John's University and an MS in Organization Change Management from The New School University.

Dr. Christian Heidbreder, age 62, has served as Chief Scientific Officer since December 2014. Dr. Heidbreder combines 30 years of leadership experience in the neurosciences spanning the academic, governmental, and industrial sectors across Europe and the U.S. He has authored and co-authored over 450 peer-reviewed scientific publications, reviews, and published conference proceedings with more than 10,000 citations. Dr. Heidbreder began his career as a researcher and made a mark in the halls of Academia at the University of Louvain in Belgium, at the National Institute on Drug Abuse in Baltimore, and at the Swiss Federal Institute of Technology in Zürich. He subsequently held positions of increasing responsibility at SmithKline-Beecham's Neuroscience Department in the U.K., GSK's R&D Centre of Excellence for Drug Discovery in Psychiatry in Italy, Altria's Health Sciences Department in the U.S., and

RBP in the U.S. and the U.K. Following the demerger of the Pharmaceuticals component of RBP in December 2014, Dr. Heidbreder joined Indivior as Chief Scientific Officer to provide strategic global leadership for worldwide R&D and Medical Affairs operations and drive the development of new pharmacotherapies in the area of addiction and related co-morbidities. Dr. Heidbreder is an Affiliate Professor in the Department of Pharmacology & Toxicology of the Virginia Commonwealth University School of Medicine and a Governance Fellow of the National Association of Corporate Directors. He also served as a member of the National Advisory Council on Drug Abuse from 2018 to 2022 and has been a member of the National Institutes of Health Helping to End Addiction Long-term Multi-Disciplinary Working Company from 2018 to 2023. Dr. Heidbreder holds BA, MA, and PhD degrees from the University of Louvain and a Certificate in Strategic Innovation from the Wharton Business School.

Kathryn Hudson, age 50, has served as Company Secretary since June 2015. Ms. Hudson is a Chartered Secretary who has over twenty years of experience working for U.K.-listed companies. Prior to joining Indivior, she was Company Secretary of Kingfisher plc, a constituent of the FTSE 100 and one of Europe's largest retailers, Deputy Company Secretary of Burberry Company plc, the FTSE 100 global luxury goods group, and Deputy Company Secretary of ICAP PLC, a FTSE 100 Interdealer Broker. Ms. Hudson is a fellow of the Chartered Governance Institute.

Vishal Kalia, age 44, was appointed Chief Strategy & Operating Officer in November 2024, having served as Chief Impact & Strategy Officer from January 2024 and Chief Strategy Officer from March 2023. Mr. Kalia began his career with Indivior in 2016 as Head of Marketing and New Product Launch, followed by Head of Business Unit for Addiction Sciences leading the successful launch of SUBLOCADE, followed by SVP Responsible for Treatment Access (Channel, Managed Care), Organized Health Systems, Criminal Justice System, Patient Support Programs, Customer Marketing, and Business Strategy. Prior to joining Indivior, Mr. Kalia worked at global companies including Reckitt Benckiser and Nestle in a number of global and regional roles, leading global category development, launching several breakthrough innovation, lifecycle management, award winning brand communications, and global success models. Mr. Kalia holds a Bachelors of Commerce and Accountancy from DAVV University and a Masters of International Marketing Management from Leeds University.

Richard Simkin, age 54, has served as Chief Commercial Officer since January 2015. He began his career with Reckitt Benckiser plc (formerly Reckitt & Colman plc) (RB) in 1987 and held various roles in operations, sales, and marketing with increasing responsibility. Prior to his role with RB, Mr. Simkin held the position of Global Category Director for one of the core categories within the RB Group (RBG) where he was responsible for driving strategy and new product development. He also held a number of general manager positions within RBG, including as GM-Portugal beginning in 2008. In 2012, Mr. Simkin was appointed President-North America of RBP and moved to the U.S. where he led the U.S. and Canadian teams in introducing market competition and preparing pre-launch activities related to the product pipeline. Mr. Simkin holds an MBA from the University of Lincoln (formerly the University of Lincolnshire and Humberside).

Hillel West, age 57, was appointed Chief Manufacturing & Supply Officer in February 2020. Mr. West has more than 30 years of experience in operations management, strategy, and business development across the U.S., Europe, Asia-Pacific, and emerging markets. He joined Indivior from Teva Pharmaceuticals where he held roles of increasing responsibility over his 14-year tenure including Head of Specialty Medicines Supply, Head of Global Supply Chain and Operations Strategy, and VP-Integration & Separation Management. He was previously a Senior Director at PwC Management Consulting for nine years in New York, Israel, and Czechia, partnering with a number of U.S. Fortune 500 CPG, Food, and Pharma manufacturers and leading engagements in supply chain strategy and organizational and process transformation. Mr. West holds a Bachelor of Chemical Engineering (Hons) from Monash University (Australia) and an MBA from Columbia University.

Election of Directors

The following table sets forth the names and positions of the members of our Board as of the date of this annual report. Except as otherwise indicated, the business address of each of the directors is 234 Bath Road, Slough, Berkshire SL1 4EE, United Kingdom.

Name	Position	Director Since	Term Expires[1]
Dr. David Wheadon	Chair and Independent Non-Executive Director	Jun. 2024	[2]
Mark Crossley[3]	Chief Executive Officer and Executive Director	Feb. 2017	[4]
Juliet Thompson	Lead Independent Director	Mar. 2021	Mar. 2027
Peter Bains	Independent Non-Executive Director	Aug. 2019	Jul. 2025
Joe Ciaffoni[3]	Independent Non-Executive Director	Dec. 2024	[2]
Dr. Keith Humphreys	Independent Non-Executive Director	Nov. 2023	[2]
Jo LeCouilliard	Independent Non-Executive Director; Designated Non-Executive Director for Workforce Engagement	Mar. 2021	Mar. 2027
Daniel Ninivaggi	Independent Non-Executive Director	Jan. 2025	[2]
Barbara Ryan	Independent Non-Executive Director	Jun. 2022	Jun. 2025
Robert Schriesheim[3]	Independent Non-Executive Director	Dec. 2024	[2]
Mark Stejbach	Independent Non-Executive Director; Designated Non-Executive Director for Workforce Engagement	Mar. 2021	Mar. 2027

(1) The dates listed represent the end of the respective Director's term of office on the Board per their letter of appointment. All directors are subject to election or re-election by shareholders at each Annual General Meeting.
(2) The letters of appointment of Drs. Wheadon and Humphreys and Messrs. Ciaffoni, Ninivaggi, and Schriesheim do not contain a fixed end to their term of office on the Board.
(3) See "Item 9B-Other Information" at page 161.
(4) Per his employment with the Company, Mr. Crossley serves at the request of the Board and may be removed at any time. His business address is 10710 Midlothian Turnpike, Suite 125, North Chesterfield, VA, 23235, United States.

Dr. David Wheadon, age 67, has served as Chair of the Board since January 2025 and as a non-executive director since June 2024. The Board values Dr. Wheadon's extensive experience in the pharmaceutical industry, including executive responsibility for regulatory affairs, patient safety, quality, research, and advocacy. Dr. Wheadon previously served as SVP of global regulatory affairs, patient safety, and quality assurance at AstraZeneca Plc from December 2014 to July 2019. Prior to that, he was EVP-Research & Advocacy at Juvenile Diabetes Research Foundation International Inc. from May 2013 to December 2014, SVP-Scientific & Regulatory Affairs at Pharmaceutical Research and Manufacturers of America (PhRMA) from January 2009 to May 2013, and VP-Global Pharmaceutical Regulatory & Medical Science and Group VP-Global Pharmaceutical Regulatory Affairs at Abbott Laboratories from 2005 to 2009. Dr. Wheadon also held senior regulatory and clinical development leadership positions at GlaxoSmithKline Plc and Eli Lilly and Company. He is a non-executive director of Sotera Health Company (NASDAQ: SHC), Vaxart, Inc. (NASDAQ: VXRT), where he serves as Chair of the Compensation Committee, ConnectiveRx, and Seaport Therapeutics. He also serves as a member of the Board of Trustees of Mount Sinai Health System. Dr. Wheadon received his MD from Johns Hopkins University School of Medicine and an AB in Biology from Harvard University, and completed his postdoctoral training in Psychiatry at Tufts/New England Medical Center.

Mark Crossley—Chief Executive Officer. See biography at page 162.

Juliet Thompson, age 58, has served as an independent non-executive director since March 2021 and as Lead Independent Director since October 2023. Ms. Thompson has over 30 years of finance, banking, and board experience with significant focus on the healthcare sector. The Board values Ms. Thompson's experience as a proven FTSE 250 audit chair and a former investment banker who has spent her career advising pharmaceutical and biotech companies. Ms. Thompson currently serves as a non-executive director and Chair of the Audit Committees of Novacyt S.A., OrganOx Limited, and ANGLE plc. From 2013 until her retirement in in 2015, Ms. Thompson led the life sciences and clean tech teams at Stifel Financial Corp. where she advised CEOs and CFOs in the healthcare sector. Prior to joining Stifel, from 2003 to

2013, Ms. Thompson was employed by Nomura Code and advised companies in the healthcare and clean tech sectors on their financing and strategic options. She worked on over 50 transactions including IPO's, secondary offerings, private placements, and M&A. She played a leading role in setting up Code Securities, which was acquired by Nomura (becoming Nomura Code) but remained independent. Previously, she served on the boards of GI Dynamics, Inc., a Boston-based medical device company developing products for patients with type 2 diabetes and obesity, from 2017 to 2020, and Vectura plc from 2017 to 2021. Ms. Thompson holds a BSc in Economics from the University of Bristol and qualified as a Chartered Accountant and holds an ACA from the Association of Chartered Certified Accountants.

Peter Bains, age 67, has served as an independent non-executive director since August 2019. He brings international experience across the biopharma industry spectrum and a deep commercial understanding of sustained delivery coupled with investment appraisal and contracting skills. The Board values Mr. Bains' experience in understanding the risks and opportunities present in these industries. He currently serves as Group CEO (a non-Board appointment) of Biocon Limited, an Indian public company focused on contract services and generics. Mr. Bains is Non-Executive Chair of ILC Therapeutics, a private U.K.-based biotechnology company and pioneer in the discovery and development of hybrid interferon drugs, and is a non-executive director of both Apterna Limited and MiNA Therapeutics Limited. Mr. Bains has over 30 years of experience in the pharmaceutical and biotechnology industries, including a 23-year career at GlaxoSmithKline, where he held numerous senior operational and strategic roles. He also served as CEO of Sosei Group Corporation, a Tokyo-listed biotech company, from 2010 to 2018, as CEO of Syngene International, which he successfully took public on the Mumbai Exchange, from 2010 to 2016, and as a member of the board of Mereo BioPharma Group plc (NASDAQ: MREO), a public biopharmaceutical company focused on innovative therapeutics in both oncology and rare diseases, from 2015 to 2021. Mr. Bains holds a BSc (Combined Honours) in Physiology/Zoology from Sheffield University.

Joe Ciaffoni, age 53, has served as an independent non-executive director since December 2024. He is an accomplished public company CEO with over 30 years of experience in pharmaceuticals and biotech, serving global and U.S. organizations of all sizes. The Board values Mr. Ciaffoni's track record of success at the intersection of strategy and operations across diverse models and therapeutic areas, including launching successful products, optimizing commercial operations, and enhancing patient access to important therapies. He previously served as President and CEO and on the board of Collegium Pharmaceuticals, Inc. (NASDAQ: COLL) from 2018 to 2024, having joined as EVP and COO in 2017. Prior to joining Collegium, Mr. Ciaffoni served as President, U.S. Branded Pharmaceuticals at Endo International plc, held various positions of increasing responsibility at Biogen (including SVP, Global Speciality Medicines Group), and served as EVP and COO of Shionogi Inc. and President of Shionogi Pharmaceuticals. He also previously served in various commercial roles at Schering-Plough (now Merck), Sanofi-Synthelabo (now Sanofi), and Novartis. Mr. Ciaffoni holds a BA in Communications and an MBA from Rutgers University.

Dr. Keith Humphreys, age 58, has served as an independent non-executive director since November 2023. The Board values Dr. Humphreys' over 30 years of experience in the field of clinical psychology and substance use disorders, having been awarded an Officer of the Order of the British Empire (OBE) in September 2022 for his services to science and policy on addiction. Dr. Humphreys currently serves as Esther Ting Memorial Professor in the Department of Psychiatry and Behavioral Sciences at Stanford University. He was previously a Senior Policy Advisor in the White House Office of National Drug Control Policy in the Obama Administration and is an Honorary Professor of Psychiatry at the Institute of Psychiatry, King's College, London. Dr. Humphreys holds a BA in Psychology from Michigan State University and an AM in Clinical/Community Psychology and PhD in Psychology from the University of Illinois.

Jo LeCouilliard, age 61, has served as an independent non-executive director since March 2021 and as a Designated Non-Executive Director for Workforce Engagement since October 2023. The Board values Ms. LeCouilliard's experience as a healthcare industry veteran with over 25 years of healthcare management experience gained in Europe, the U.S., and Asia. Much of her career has been in pharmaceuticals at GlaxoSmithKline where, amongst other roles, she headed the U.S. vaccines business and Asia Pacific Pharmaceuticals business and led a program to modernize the commercial model. Ms. LeCouilliard was previously COO at the BMI group of private hospitals in the U.K. She currently serves as a non-executive director and Chair of the Remuneration & Nominations Committee at the Italian-listed

pharmaceutical company Recordati S.p.A., and as a member of the board of directors of Washington Topco Ltd, the holding company of GlobalData Healthcare. She has previously served as a non-executive director and Chair of the Board at the U.K.-listed Alliance Pharma plc, as a non-executive director and Chair of the Audit & Risk Committee at the U.K.-listed Niox Group PLC (previously Circassia Group plc), and as a non-executive director at Frimley Park NHS Foundation Trust in the U.K., at Cello Health PLC, and at the Duke NUS Medical School in Singapore. Ms. LeCouilliard is a Chartered Accountant holding an ACA from the Institute of Chartered Accountants in England & Wales and holds a Masters in Natural Sciences from the University of Cambridge.

Daniel Ninivaggi, age 60, has served as an independent non-executive director since January 2025. The Board values Mr. Ninivaggi's significant public company experience as a director and executive, his strong background in operations and capital allocation, and his legal and finance expertise. Mr. Ninivaggi currently serves as Non-Executive Chairman and Chair of the Finance Committee of Garrett Motion Inc. (NASDAQ: GTX), a global supplier of turbochargers and other powertrain components to light vehicle, commercial vehicle, and industrial end markets. From August 2021 until March 2024, he served as CEO and subsequently Executive Chairman of Lordstown Motors Corp. (formerly NASDAQ: RIDE), an electric vehicle automaker. Prior to that, Mr. Ninivaggi served as President and CEO of Icahn Enterprises L.P. (NASDAQ: IEP), the principal investment vehicle of Carl Icahn; as Co-CEO of Federal-Mogul Holdings Corp. (a public-company subsidiary of IEP now part of Apollo Global Management); and as CEO of Icahn Automotive Group, LLC and a Managing Director of IEP. Prior to joining IEP, he spent six years at Lear Corporation (NYSE: LEA), holding various senior executive positions. In addition to those positions noted above, Mr. Ninivaggi has served as a director of numerous other public and private companies, including Hertz Global Holdings, Inc., Navistar International Corporation, Icahn Enterprises G.P. Inc. (the general partner of Icahn Enterprises), CVR Energy Inc., XO Holdings, Tropicana Entertainment Inc., Motorola Mobility Holdings Inc., and CIT Group, Inc. Mr. Ninivaggi began his career at Skadden, Arps, Slate, Meagher & Flom LLP before joining Winston & Strawn LLP, where he became partner specializing in corporate law. He holds a BA from Columbia University, an MBA from the University of Chicago Graduate School of Business, and a JD degree (with distinction) from Stanford University School of Law.

Barbara Ryan, age 65, has served as an independent non-executive director since June 2022. She was a Wall Street sell-side research analyst covering the U.S. Large Cap Pharmaceutical Industry for more than 30 years before founding Barbara Ryan Advisors, a capital markets and communications firm, in 2012. The Board values Ms. Ryan's deep experience in equity and debt financings, M&A, valuation, SEC reporting, financial analysis, and corporate strategy across a broad range of life sciences companies. Ms. Ryan is the Founder of Fabulous Pharma Females, a non-profit organization whose mission is to advance women in the biopharmaceutical industry. She is a Senior Advisor at Ernst & Young (a part-time role) and a non-executive director of INVO Bioscience, Inc. (NASDAQ: INVO), MiNK Therapeutics, Inc. (NASDAQ: INKT), serving as Chair of the Audit Committee, and Azitra, Inc. (NYSE: AZTR), serving as Chair of the Compensation Committee, OcuTerra Therapeutics, and Safecor Health.

Robert Schriesheim, age 64, has served as an independent non-executive director since December 2024. The Board values Mr. Schriesheim's expertise in corporate finance, strategy, and capital markets, as well as his knowledge in public company governance and board practices of other corporations. He is chairman of Truax Partners LLC and leads large, complex transformations in partnership with Boards, CEOs, and institutional investors as an investor and director. Mr. Schriesheim has served on 12 public boards ranging from under $1 billion in revenue to Fortune 500, including as chairman, and has served as CFO of four public companies varying in revenue from $1 billion to $40 billion. He also serves as an Adjunct Associate Professor of Finance with a focus on corporate governance at The University of Chicago Booth School of Business. Mr. Schriesheim previously served as CFO of Sears Holdings, Hewitt Associates, and Lawson Software, and held executive roles at seed venture firm ARCH Development Partners, LLC, Global TeleSystems, SBC Equity Partners, Ameritech, AC Nielsen, and Brooke Group Ltd. Mr. Schriesheim has been a director of Skyworks Solutions, Inc. (NASDAQ: SWKS) since 2006 and Houlihan Lokey, Inc. (NYSE: HLI) since 2015, serving as Lead Independent Director and as Chair of the Audit Committee. Effective March 1, 2025, he will join the board of Alight, Inc. (NYSE: ALIT). Mr. Schriesheim previously served on a number of other public boards including Frontier Communications (as Chair of the Finance Committee overseeing the company during its Chapter 11 proceedings), NII Holdings, Forest City Reality Trust (Chair

of the Audit Committee), Lawson Software, Co-Chairman of MSC Software, and Dobson Communications. Mr. Schriesheim earned an AB in Chemistry from Princeton University and an MBA from the University of Chicago Booth School of Business.

Mark Stejbach, age 61, has served as an independent non-executive director since March 2021 and as a Designated Non-Executive Director for Workforce Engagement since October 2023. The Board values Mr. Stejbach's over 35 years of experience in biotech and pharmaceuticals, including senior roles in a broad range of commercial functions including marketing, sales, economic affairs, managed care, and finance. Mr. Stejbach most recently served as SVP & Chief Commercial Officer at Alkermes plc, a publicly traded global biopharmaceutical company focused on development and commercialization of addiction and schizophrenia treatments. Prior to his role at Alkermes, Mr. Stejbach served as the Chief Commercial Officer at Tengion, Inc. from 2008 to 2012 and previously held senior positions at Merck and Biogen. He also previously served as Senior Commercial Advisor to EIP Pharma Inc., a private company advancing CNS-focused therapeutics to benefit patients with neurodegenerative diseases. Mr. Stejbach currently serves as a director of Nirsum Laboratories, Inc. and previously served as a non-executive director of Flexion Therapeutics, Inc. (NASDAQ: FLXN), which marketed a “buy-and-bill” LAI for the treatment of osteoarthritis, from 2016 until its acquisition in 2021. Mr. Stejbach holds an MBA from the Wharton School, University of Pennsylvania and a BS in mathematics from Virginia Tech.

Family Relationships

There are no family relationships between any director, executive officer, or person nominated or chosen by the Company to become a director or executive officer.

Agreement with Significant Shareholder

Relationship Agreement with the Oaktree Parties

On December 16, 2024, Indivior PLC entered into a Relationship Agreement with Oaktree Value Opportunities Fund, L.P., Oaktree London Liquid Value Opportunities Fund (VOF), L.P., Oaktree Phoenix Investment Fund, L.P. and Boston Patriot Arlington ST LLC (together, the "Oaktree Parties"). Pursuant to this agreement, among other things, Indivior PLC agreed to (i) appoint Robert Schriesheim, Joe Ciaffoni, and Daniel Ninivaggi (together, the "New NEDs") to the Board, (ii) appoint the New NEDs as members of the Nomination Committee and the Operational Committee of the Board, and (iii) from January 1, 2025 until the expiry of the Relationship Agreement, have a maximum of 11 directors on the Board. Indivior PLC also agreed that the Board will unanimously recommend to shareholders the re-appointment of the New NEDs to the Board at the 2025 Annual General Meeting of Indivior PLC. Please refer to *Item 13—Certain Relationships and Related Transactions, and Director Independence*, for more information about the Relationship Agreement.

Code of Ethics

We have adopted (i) a Global Code of Conduct that applies to all of our employees, officers, and directors, and (ii) a Code of Ethics for Senior Financial Officers that applies to our principal executive officer, principal financial officer, and principal accounting officer, copies of both of which are available on our website at www.indivior.com under the captions "About Us", "Corporate Governance", and "Global Conduct Policies". Any amendments to or waivers of the Global Code of Conduct or the Code of Ethics for Senior Financial Officers that require disclosure under applicable law or listing standards will be disclosed on our website at www.indivior.com. We undertake to provide a copy to any person, without charge, upon written request to Company Secretary, Indivior PLC, 10710 Midlothian Turnpike, Suite 125, North Chesterfield, Virginia 23235.

Shareholder Nominations for Directors

Pursuant to Indivior PLC's Memorandum and Articles of Association, shareholders may nominate any person to serve as a Director under the following conditions: The shareholder must be entitled to vote at the meeting and must deliver to the Company's office not less than seven nor more than 42 days before the day

of the meeting: (a) a letter stating that the shareholder intends to nominate another person for appointment as a director; and (b) written confirmation from that person that they are willing to be appointed.

Audit & Risk Committee

The Audit & Risk Committee has responsibility for, among other things, monitoring the financial integrity of the financial statements of the Company along with PricewaterhouseCoopers LLP, our external auditors in that process. It focuses in particular on compliance with accounting policies and ensuring that an effective system of internal financial controls is maintained. The ultimate responsibility for reviewing and approving the annual report and accounts and other interim financial reports remains with the Board. The Audit & Risk Committee shall meet not less than four times a year to coincide with key dates in the Company's financial reporting cycle. The Audit & Risk Committee also meets on an ad hoc basis when necessary.

The responsibilities of the Audit & Risk Committee set out in its Charter cover external audit, internal audit, financial and narrative reporting, internal controls and risk management, and the systems and procedures for detecting fraud. The Charter also sets out the authority of the Audit & Risk Committee to carry out its responsibilities.

The members of our Audit & Risk Committee are Juliet Thompson (Chair), Jo LeCouilliard, Barbara Ryan, and Mark Stejbach. Our Board has determined that each member is independent within the meaning of SEC rules and regulations and Nasdaq listing standards and possesses the required level of financial literacy as required by Nasdaq.

Audit Committee Financial Expert

SEC rules and regulations and Nasdaq listing standards require that the Audit & Risk Committee be comprised of at least three members who are all independent and possess requisite financial literacy, including at least one member who qualifies as an "audit committee financial expert." Our Board has determined that each of Ms. Thompson and Ms. LeCouilliard qualify as an "audit committee financial expert" as defined in the SEC rules and satisfies the financial sophistication requirement of Nasdaq.

Corporate Governance Guidelines

During the year, the Board undertook a comprehensive review of its governance framework to ensure it supports the Company as it continues its transition to the requirements of a U.S.-listed domestic filer, while also meeting the requirements of an "Equity Shares (Transition)" issuer in the U.K. Pursuant to that review, effective January 1, 2025, the Board adopted new Corporate Governance Guidelines which describe the principles and practices the Board will follow in carrying out its responsibilities. In addition, each Board Committee's Terms of Reference has been replaced by a US-style Charter. To further align with U.S. practices, the Remuneration Committee changed its name to the Compensation Committee and the Senior Independent Director was re-designated the Lead Independent Director. These changes are designed to meet the governance expectations and requirements to which a U.S.-listed domestic filer is expected to adhere. The new Corporate Governance Guidelines and Board Committee Charters are available at www.indivior.com.

Board Practices

As a foreign private issuer, we are permitted to follow certain home country corporate governance practices instead of those otherwise required under Nasdaq's rules for domestic U.S. issuers, provided that we disclose which requirements we are not following and describe the equivalent home country requirement. However, notwithstanding our ability to follow the corporate governance practices of our home country, England, in most cases we have elected to adhere to the corporate governance rules of Nasdaq applicable to U.S. domestic registrants that are not "controlled" companies. The corporate governance practices that we follow in lieu of Nasdaq's corporate governance rules are as follows:

- We have established various equity compensation plans as described in Item 11 of this report, below. Under English law, subject to the provisions of a company's constitutional documents and the rules of the applicable equity compensation plan, a company with a Transition Segment

Secondary Listing does not require shareholder approval to establish or materially amend an equity compensation arrangement pursuant to which stock may be acquired by officers, directors, employees, or consultants of the company. Neither the Company's Articles of Association nor the Committee Charter contain any such shareholder approval requirement. We have implemented such plans following approval by only the Company's Compensation Committee, in lieu of the requirement to comply with Rule 5635(c), which otherwise would require shareholder approval prior to the issuance of securities under such plans.

Insider Trading Policies

The Company has adopted a Group-Wide Dealing Policy and a Dealing Code that governs the purchase, sale, and other dispositions of the Company's securities by directors, senior management, and employees that are reasonably designed to promote compliance with applicable insider trading laws, rules and regulations, and any listing standards applicable to the registrant. The Dealing Code also prohibits the pledging and hedging of Company securities. In addition, with regard to the Company's trading in its own securities, it is the Company's policy to comply with the federal securities laws and the applicable exchange listing requirements.

Item 11. Executive Compensation.

Total Compensation for the Chair and Non-Executive Directors

The table below sets out the total remuneration received by the Chair and the Non-Executive Directors for the year ended December 31, 2024.

	2024[1]
	'000
Dr. David Wheadon[2]	$76.5
Juliet Thompson	£119.5
Peter Bains	£99.3
Joe Ciaffoni[3]	$4.0
Dr. Keith Humphreys	$131.4
Jo LeCouilliard	£99.9
Barbara Ryan	$146.6
Robert Schriesheim[3]	$4.0
Mark Stejbach	$162.4
Graham Hetherington[4]	£282.7
Jerome Lande[4][5]	$109.1
Dr. A. Thomas McLellan[6]	$20.4

Note: Daniel Ninivaggi was appointed as an Independent Non-Executive Director and as a member of the Nomination Committee on January 31, 2025. As such, he did not receive any fees in 2024.

(1) The amounts include fees and benefits. Fees are paid in their local currency. Since 2016, a fixed exchange rate (GB£1:U.S.$1.4434) has been applied to translate U.K. amounts into U.S. dollars, effectively setting fees at that time, on both a U.K. and U.S. basis. Benefits comprise the grossed-up cash value of travel and subsistence costs incurred in the normal course of business in relation to attendance at Board meetings held in the U.K. and in fulfilling the Non-Executive Director's role, and the cost of providing professional support for the completion of U.K. tax returns for U.S. tax residents; these costs were translated to U.S. dollars using the average exchange rate for the 2024 financial year (GB£1:U.S.$1.2782).

(2) Dr. Wheadon was appointed as an Independent Non-Executive Director and as a member of the Compensation, Nomination, and Science Committees on June 1, 2024. The fee shown for 2024 is from the date of his appointment to December 31, 2024. Dr. Wheadon was subsequently appointed as Chair of the Board and Chair of the Nomination Committee on January 28, 2025.

(3) Mr. Ciaffoni and Mr. Schriesheim were each appointed as an Independent Non-Executive Director and as a member of the Nomination Committee on December 17, 2024. The fee shown for each for 2024 is from the date of their appointment to December 31, 2024.

(4) Mr. Hetherington and Mr. Lande retired from the Board on December 31, 2024.

(5) Mr. Lande stepped down as a member of the Nomination Committee on May 31, 2024.

(6) Dr. McLellan retired from the Board on February 29, 2024.

Compensation of Executive Directors and Senior Managers

The table below sets forth the remuneration of the Executive Directors and Senior Managers for the financial year ended December 31, 2024.

	Mark Crossley $'000	Ryan Preblick[1] $'000	All Other Senior Managers Combined $'000
Fixed Pay			
Base Salary	871.8	539.9	4,232.9
Taxable Benefits[2]	63.3	65.0	756.1
Retirement Benefits[3]	29.3	29.3	374.4
Total Fixed Pay	964.4	634.2	5,363.4
Variable Pay			
Annual Incentive Plan (AIP)[4]	357.4	132.8	1,049.3
Long Term Incentive Plan (LTIP)	0.0	0.0	68.4[6]
Total Variable Pay	357.4	132.8	1,117.7
Total Pay	1,321.8	767.0	6,481.1

(1) Mr. Preblick stepped down as an Executive Director on December 31, 2024. Mr. Preblick continues in his role as Chief Financial Officer and he remains a member of the Executive Committee.

(2) Taxable benefits consist primarily of healthcare, car allowance, life and disability insurance, and professional support for the completion of U.S. and U.K. tax returns. Taxable benefits included a car allowance ($19,500 each for Mr. Crossley and Mr. Preblick) and premiums for medical coverage ($22,300 for Mr. Crossley and $32,800 for Mr. Preblick).

(3) Executive Directors and Senior Managers may receive contributions into a defined contribution plan, a cash allowance, pension benefits in the form of company profit-sharing or matching contributions into the U.S. qualified 401(k) plan or a combination thereof. Mr. Crossley and Mr. Preblick received profit-sharing contributions of $13,800 (4% of eligible base salary) and matching contributions of $15,500 (75% on elected deferrals up to 4.5% of eligible base salary) to their 401(k) plan accounts.

(4) The maximum Annual Incentive Plan ("AIP") opportunity for the Chief Executive Officer is 200% of his base salary. The maximum AIP opportunity for the Chief Financial Officer is 120% of his base salary. The maximum AIP opportunity for our Senior Managers ranges from 100% to 140% of their base salary. For our Executive Directors, the AIP is paid 75% in cash, with the remaining 25% deferred into conditional shares for two years under the Company's Deferred Bonus Plan. See "Deferred Bonus Plan 2018 ("DBP")," beginning on page 182. For Senior Managers, the AIP is paid in cash. For fiscal year 2024, the Compensation Committee set stretching performance targets in the context of the business plan for 2024 and taking account of external forecasts. These targets were set by reference to the key strategic drivers for the business: global net revenues for SUBLOCADE and U.S. net revenues for PERSERIS. The targets were reviewed by the Committee at its November 2024 meeting in light of the discontinuation of PERSERIS. The PERSERIS targets were updated from full year to half year (i.e., January to June) and the weighting reduced by half. For threshold performance 12.5% of the maximum bonus would be paid, for target performance 50% of the maximum bonus would be paid, and 100% of the maximum bonus would be paid for the delivery of exceptional performance significantly above both internal and external expectations. Achievement of the performance targets is calculated on a straight-line basis between threshold and target and between target and maximum. In addition, an ESG metric acted as a potential modifier to the overall AIP payout by which the overall AIP payout could be reduced by up to 10% if certain ESG targets were not met during the year; all objectives under the ESG modifier were met and the Committee chose not to exercise its discretion to reduce the overall AIP payout. Overall performance resulted in a formulaic payout of 20.5% of maximum.

(5) The value of the awards has been estimated based on the number of shares expected to vest (6,702) at the three-month average share price of Indivior shares for the last quarter of the 2024 financial year (795.5p) and converted to U.S. dollars using the average GBP/U.S.$ exchange rate over the same period (GB£1:U.S.$1.2832).

Annual Incentive Plan ("AIP")

In addition to base salary, an annual bonus opportunity exists for all employees, including the Executive Directors and Senior Managers. The maximum AIP opportunity for the Chief Executive Officer is 200% of his base salary. The maximum AIP opportunity for the Chief Financial Officer is 120% of his base salary. The maximum AIP opportunity for our Senior Managers ranges from 100% to 140% of their base salary. For our Executive Directors (the Chief Executive Officer and Chief Financial Officer), the AIP is paid 75% in cash, with the remaining 25% deferred into conditional shares for two years under the Company's Deferred

Bonus Plan. See "The Deferred Bonus Plan 2018 ("DBP")," beginning on page 182. For Senior Managers, the AIP is paid in cash.

Performance measures under the AIP are designed to align to the key strategic drivers for the year ahead and are developed alongside the Company's annual financial plans. The Compensation Committee has discretion to adjust the formulaic bonus outcomes both upward and downward (including to zero) to ensure alignment of pay with the underlying performance of the Company, e.g., in the event performance is impacted by unforeseen circumstances outside Management control.

For the 2024 financial year, the Compensation Committee set stretching performance targets in the context of the business plan for 2024 and taking account of external forecasts. These targets were set by reference to the key strategic drivers for the business: global net revenues for SUBLOCADE, U.S. net revenues for PERSERIS and OPVEE, and advancement of pipeline assets. The PERSERIS targets were updated from full year to half year (i.e., January 1 to June 30) and the weighting reduced by half. For threshold performance 12.5% of the maximum bonus would be paid, for target performance 50% of the maximum bonus would be paid, and 100% of the maximum bonus would be paid for the delivery of exceptional performance significantly above both internal and external expectations. Achievement of the performance targets is calculated on a straight-line basis between threshold and target and between target and maximum. In addition, an ESG metric acted as a potential modifier to the overall AIP payout by which the overall AIP payout could be reduced by up to 10% if certain ESG targets were not met during the year; the Committee chose not to exercise its discretion to reduce the overall AIP payout as the relevant ESG targets were met. Overall performance resulted in a formulaic payout of 20.5% of maximum.

In line with our Remuneration Policy, 25% of the 2024 bonus payable under the AIP to the Executive Directors was automatically deferred into conditional shares under the DBP. The deferred conditional share awards vest after two years subject to continued employment as well as malus provisions.

	Date of Grant	Number of shares under award	Closing share price at date of grant	Aggregate fair market value as of the date of grant[1] $'000	Vesting Date
Mark Crossley	Mar. 14, 2024	16,959	1631.0p	354.5	Mar. 14, 2026
Ryan Preblick[2]	Mar. 14, 2024	6,302	1631.0p	131.7	Mar. 14, 2026

(1) The market value used to determine the number of shares subject to awards was 1,633p, being the average mid-market closing price of Indivior shares on the business day immediately preceding the date of grant and converted to U.S.$ using the closing exchange rate on the day immediately preceding the date of grant (GB£1:U.S.$1.2802).
(2) Mr. Preblick stepped down as an Executive Director on December 31, 2024. Mr. Preblick continues in his role as Chief Financial Officer and he remains a member of the Executive Committee.

Indivior PLC Long-Term Incentive Plan ("LTIP")

On March 8, 2024, the Chief Executive Officer and Chief Financial Officer were granted conditional awards over shares with a value equal to 400% of their base salary, being the maximum cap under the 2024 Remuneration Policy.

	Date of Grant	Number of shares under award at maximum[1]	Closing Share Price at date of grant	Aggregate fair market value as of the date of grant $'000	Performance period	Vesting date	Release Date	
Mark Crossley	Mar. 8, 2024	157,732	1671.0p	3,487.0	Jan. 2024 – Dec. 2026	Mar. 8, 2027	Mar. 8, 2029	[2]
Ryan Preblick[3]	Mar. 8, 2024	97,692	1671.0p	2,159.7	Jan. 2024 – Dec. 2026	Mar. 8, 2027	Mar. 8, 2029	[2]
All Other Senior Managers Combined	Mar. 8, 2024	676,730	1671.0p	14,960.6	Jan. 2024 – Dec. 2026	Mar. 8, 2027	Mar. 8, 2027	

(1) The market value used to determine the number of shares subject to awards was 1728.2p, being the average mid-market closing price of Indivior shares on the five business days immediately preceding the date of grant and converted to U.S.$ using the closing exchange rate on the day immediately preceding the date of grant (GB£1:U.S.$1.2792).
(2) Awards granted to the Executive Directors under the LTIP are subject to a two-year post-vesting holding period and are then released to the Executive Director.
(3) Mr. Preblick stepped down as an Executive Director on December 31, 2024. Mr. Preblick continues in his role as Chief Financial Officer and he remains a member of the Executive Committee.
(4) Conditional awards include the right to receive an amount equal in value to any dividends payable on the number of vested shares between the date of grant and the release date.

Indivior Share Plans

We have established the following plans, the key terms of which are summarized below.

The Indivior 2024 Long-Term Incentive Plan (the "LTIP")

The Indivior Long-Term Incentive Plan (the "Expired LTIP") expired on November 5, 2024. The rules of the Expired LTIP applied to LTIP awards made prior to that date; the terms of the Expired LTIP are set out in Item 6 of our 2023 Annual Report on Form 20-F at the caption "*The Indivior Long-Term Incentive Plan (the "LTIP")*" which is incorporated herein by reference.

The current LTIP was adopted by the Board on February 21, 2024, approved by shareholders at the Annual General Meeting on May 9, 2024, and amended by the Compensation Committee on September 30, 2024; the LTIP applies to awards made after May 9, 2024.

Administration of the LTIP

The LTIP is administered by the Compensation Committee or, in the case of awards not being made to directors, such other committee as authorized by the Company (the "LTIP Committee").

Eligibility

The LTIP Committee may select any employee of the Company, including any Executive Director, to participate in the LTIP.

Awards

An award under the LTIP may take the form of:

- a nil-cost option, which is a right to buy ordinary shares on vesting for nothing or a nominal amount;
- a market value option, which is a right to buy ordinary shares at a price set by reference to their market value at the award date;
- a conditional award, which is a right to receive ordinary shares on vesting; or
- free shares, which is the receipt of ordinary shares for nothing or a nominal amount but subject to the risk of forfeiture prior to vesting.

Awards may be satisfied by the issue of new ordinary shares, the transfer of treasury shares, or by paying an equivalent amount in cash.

Awards are personal to the participant and may not be transferred except on death. No payment is required for the grant of an award.

Timing

Awards may only be granted within 42 days following: the announcement of the Company's results for any period; the removal of any restrictions imposed on the Company which have previously prevented an award from being granted; any date on which changes to legislation or regulations affecting share plans are announced, effected, or made; or at any other time if the LTIP Committee considers that exceptional circumstances exist. No awards may be granted under the LTIP after the date of the Company's 2034 Annual General Meeting.

Individual limit

Under the 2021 Remuneration Policy, the maximum annual award that may be made to any individual in respect of any financial year will be the lower of 300,000 ordinary shares or 400% of base salary.

Plan limits

With respect of any awards granted prior to September 30, 2024, the LTIP is subject to the limit that on any date, the aggregate nominal amount of ordinary shares that may be allocated under the LTIP may not, when added to the nominal amount of ordinary shares allocated in the previous 10 years under all employee share plans of the Company, exceed 10% of the then equity share capital of the Company.

With respect of any awards granted on or after September 30, 2024, the aggregate number of ordinary shares which may be granted under the LTIP shall not exceed 19,000,000 ordinary shares (whether satisfied by the issue of new ordinary shares, the transfer of treasury shares, or the transfer of existing ordinary shares). Any award settled in cash shall not be counted against the limit.

For these purposes, ordinary shares are treated as allocated when they are issued or transferred in satisfaction (directly or indirectly) of a person's right under an award. No account will be taken of (i) ordinary shares acquired for a price equal to their market value at or about the date of acquisition and whose cost is borne by the employee; or (ii) an award to the extent to which the LTIP Committee considers that it will be satisfied by the transfer of existing ordinary shares other than treasury shares.

Performance conditions

Each award may, or in the case of Executive Directors of the Company must, be subject to one or more performance conditions, at least one of which must be linked to the performance of the Company, which will determine whether and to what extent the participant will receive ordinary shares. Performance conditions are normally measured over a period of three years. For Executive Directors the performance conditions are measured on one occasion only; there is no re-testing.

The LTIP Committee may waive or change performance conditions if events happen as a result of which the LTIP Committee reasonably considers it appropriate to make the change, provided that any changed performance conditions will not be materially easier or more difficult to satisfy.

Vesting of awards

Awards will normally only vest in accordance with the performance conditions at the end of the performance period or, if later, three years after the date of grant. Awards granted to the Executive Directors under the LTIP are subject to a two-year post-vesting holding period and are then released to the Executive Director.

Each award may, to the extent that it vests, be adjusted by the LTIP Committee to include the dividends payable on the vested shares during the period starting with the date the award is granted and ending with the date on which the award vests or the option is exercised. The adjustment will be made, as the LTIP Committee may decide, either by paying an amount equal to the dividends in cash or by paying that amount in ordinary shares. Dividend equivalents will be paid to any relevant participant as soon as practicable after entitlement to the ordinary shares under the award or, in the case of an option, after exercise.

In the case of conditional awards, the ordinary shares are issued or transferred to the participant as soon as reasonably practicable upon vesting while in the case of options, the award becomes exercisable on vesting and may be exercised during the exercise period specified at the time of grant.

Alternatively, the LTIP Committee may decide to satisfy awards on vesting by a cash payment.

Malus and Clawback

Awards are granted subject to the Company's malus and clawback policies, under which the Company may clawback awards (including a reduction of the number of ordinary shares under an award and forfeiture of ordinary shares delivered) if certain trigger events (including a material misstatement of the Company's results, serious misconduct by the participant, or serious reputational damage to the Company) occur.

Termination of employment

If a participant ceases to be employed within the Company for any reason other than misconduct, he is entitled to retain any awards which have vested.

If a participant ceases to be employed within the Company, his unvested awards lapse unless he leaves for a permitted reason. A permitted reason is death, injury, ill-health, disability, redundancy, retirement with his employer’s agreement, the sale of the company or business in which the participant works and such other reason as the LTIP Committee may decide.

Where a participant leaves for a permitted reason and the award is subject to a performance condition, the award will vest after the end of the performance period and be released on the normal release date. Alternatively, the LTIP Committee may decide that the extent to which the award will vest will be measured in accordance with a determination of the performance conditions and other conditions at the end of the financial year in which the cessation of employment occurs. The award will also be reduced pro rata to reflect the period from the date of cessation of employment until the date of the end of the performance period as a proportion of the performance period, unless the LTIP Committee decides otherwise.

In the case of death, the performance conditions will not apply and the award will vest and be released on the date of death, but the award will be reduced on a time pro-rated basis. If the award is not subject to performance conditions, the award will vest on the normal vesting date unless the LTIP Committee decides otherwise. Options that have already vested, or which vest following termination of employment, may be exercised within the 12 months following their release.

Change of control

Special rules apply in the event of a change of control, including a change of control resulting from a scheme of arrangement or a takeover.

Unless the LTIP Committee decides otherwise, awards will vest (if at all) on the date of the change of control, but only to the extent that any performance conditions have been satisfied at that date as determined by the LTIP Committee and the extent to which the award vests shall be reduced pro rata to reflect the period from the date of the event until the date of the end of the performance period as a proportion of the performance period.

In the event of a change of control, participants may or the LTIP Committee may require that participants surrender their awards in return for substitute awards over shares in the acquiring company or another company. The LTIP Committee may allow awards to vest on a similar basis in the event of a demerger or other corporate events.

Listing

So long as the ordinary shares are listed on the Official List and traded on the London Stock Exchange, the Company will apply for any new ordinary shares issued under the LTIP to be admitted to the Official List and for permission to trade in those ordinary shares. Ordinary shares issued under the LTIP will rank equally in all respects with existing ordinary shares except for any rights attaching to the ordinary shares by reference to a record date prior to the date of allotment.

Variation of Capital

On any variation of the Company's share capital, or in the event of a demerger, special dividend or other circumstances which the LTIP Committee considers appropriate, the LTIP Committee may adjust the number or class of ordinary shares or securities comprised in an option or conditional award and, in the case of an option, the option price.

Benefits non-pensionable

Benefits under the LTIP will not form part of a participant's remuneration for pension purposes.

Amendments

The LTIP Committee may, without the approval of the Company, amend the LTIP through any minor changes to benefit the administration of the LTIP, to comply with or take account of the provisions of any proposed or existing legislation or changes to any applicable legislation, or to obtain or maintain favorable tax, exchange control or regulatory treatment for participants or for any company in the Company.

Except as described above, no amendment which is to the advantage of existing or future participants may be made, without the prior approval of the Company in general meeting, to those provisions dealing with eligibility, limitations on the number of ordinary shares which may be issued under the plan, or the rights of a participant in the event of a capitalization issue, rights issue or open offer, sub-division or consolidation of shares or reduction of capital or any other variation of capital of the Company.

HM Revenue and Customs in the United Kingdom ("HMRC") registered options

The LTIP allows options to be granted in satisfaction of the conditions of Schedule 4 of the Income Tax (Earnings and Pensions Act) 2003, as amended (the "ITEPA").

U.S. Participants

The LTIP contains a part to ensure that options granted to and held by U.S. participants have an exercise price that is at least fair market value, and that conditional awards granted to and held by such U.S. participants either meet the requirements of the short-term deferral exemption to Section 409A of the U.S. Internal Revenue Code 1986, as amended, or are compliant therewith.

Canadian Participants

The LTIP contains a part to ensure that an award made to a participant who is subject to taxation under the laws of Canada is not taxed as a "Salary Deferral Arrangement." All awards subject thereto are administered and interpreted in a manner which complies with such intent.

The Indivior 2024 U.K. Savings Related Share Option Plan (the "Sharesave Plan")

The Indivior U.K. Savings Related Share Option Plan (the "Expired Sharesave Plan") expired on November 30, 2024. The rules of the Expired Sharesave Plan applied to grants of options made prior to that date; the terms of the Expired Sharesave Plan are set out in Item 6 of our 2023 Annual Report on Form 20-F at the caption "*The Indivior Savings-Related Share Option Plan (the "Sharesave Plan")*" which is incorporated herein by reference.

The current Sharesave Plan was approved by Shareholders at the Annual General Meeting on May 9, 2024, and amended by the Compensation Committee on September 30, 2024; the Sharesave Plan applies to grants of options made after May 9, 2024.

Administration

The Sharesave Plan is administered, in accordance with its rules, by the Board or a duly authorized committee thereof.

Eligibility

All employees (including directors working 25 hours or more per week) who have a qualifying period (if any) of continuous service (commencing not earlier than five years prior to the Date of Grant) as the Directors may in their absolute discretion and from time to time determine of continuous service with the Company, or any subsidiary nominated to join in the Sharesave Plan, and who receive general earnings to which section 15 of the Income Tax (Earnings and Pensions) Act 2003 applies are eligible to participate. The Board may invite other employees of the Company to participate.

Options

Options will entitle the holder to acquire ordinary shares. Options will be personal to the participant and may not be transferred. No payment will be required for the grant of an option. No options will be granted under the Sharesave Plan after the date of the Company's 2034 Annual General Meeting.

Timing

Invitations to participate will normally be issued within 30 days (or 42 days if applications are scaled down) following: the announcement of the Company's results for any period or its issue of any prospectus, listing particulars or other document containing equivalent information relating to the ordinary shares; a day on which an announcement is made of a new prospectus for certified SAYE (Save As You Earn) savings arrangements (within the meaning of section 703(1) of the Income Tax (Trading and Other Income) Act 2005) for the purposes of Schedule 3 to the Income Tax (Earnings and Pensions) Act 2003; a day on which an announcement is made of amendments to be made to the Income Tax (Earnings and Pensions) Act 2003 (so far as those changes affect savings-related share option plans approved by HMRC) or a day on which any such amendments come into force; the date of any general meeting of the Company's shareholders; or at any other time if the Board determines that the circumstances are sufficiently exceptional to justify the grant of an option. No awards may be granted under the Sharesave Plan after the date of the Company's 2034 Annual General Meeting.

Exercise price

The price payable per ordinary share on exercise of an option granted under the Sharesave Plan may not be less than an amount equal to 80% of the market value of an ordinary share (or such other percentage as shall from time to time be specified in paragraph 28(1)(b) of Schedule 3 of the Income Tax

(Earnings and Pensions) Act 2003) or, if greater, and ordinary shares are to be acquired by subscription, the nominal value of an ordinary share.

Individual limit

Each eligible employee will be given the opportunity to apply for an option, the total exercise price of which does not exceed the aggregate of the monthly contributions made and any bonus due under the Sharesave contract to be entered into as a condition of the grant of the option. The aggregate maximum monthly contribution payable by an employee under all Sharesave contracts linked to the options granted under the Sharesave Plan may not exceed such sum as may from time to time be permitted by statute and approved by the directors.

Plan limits

With respect of any options granted prior to September 30, 2024, the aggregate nominal amount of new ordinary shares in respect of which options may be granted may not exceed 10% of the nominal amount of the equity share capital of the Company, less the total nominal amount of any new ordinary shares allocated in the previous 10 years under all employee share plans of the Company.

With respect of any options granted on or after September 30, 2024, the aggregate number of ordinary shares which may be granted under the Sharesave Plan shall not exceed 1,000,000 ordinary shares (whether satisfied by the issue of new ordinary shares, the transfer of treasury shares, or the transfer of existing ordinary shares). Any option settled in cash shall not be counted against this limit.

For these purposes, allocation means the issue of new ordinary shares or the transfer of treasury shares in satisfaction (directly or indirectly) of a person's rights under an award. No account will be taken of ordinary shares acquired by an employee where the ordinary shares are acquired for a price equal to their market value at or about the date of acquisition and the cost of those ordinary shares is borne by the employee. No account will be taken of an award if and to the extent to which the Board considers that it will be satisfied by the transfer of existing ordinary shares other than treasury shares. Any ordinary shares allocated, or remaining to be allocated, to the trustee of any trust which were used, or which are to be used, to satisfy awards granted under an employee share plan must be treated as having been allocated, or as remaining to be allocated, in respect of those awards unless the ordinary shares were acquired by the trustee pursuant to a rights issue or other opportunity offered to the trustee in respect of ordinary shares other than ordinary shares previously allocated to it. Where an award is granted in consideration of the release by the holder of an award previously granted to such holder under an employee share plan, then the earlier award is ignored and the later award is deemed to have been granted at the same time as the earlier award.

Exercise of options

Options will normally be exercisable in whole or in part during the period of six months starting on the bonus date. The bonus date is the date on which the bonus under the related Sharesave contract is payable. In normal circumstances this will be the third or fifth anniversary of the starting date of the Sharesave contract and will depend upon the election made by the participant at the time of grant.

Whenever an option is exercised, it may only be exercised with monies not exceeding the amount of the aggregate monthly contributions made and any bonus due under the related Sharesave contract.

Termination of employment

If the participant dies, his personal representatives may exercise his options in the 12 months following his death or, if earlier, the bonus date. If a participant ceases to be employed within the Company for a permitted reason, the participant may exercise his options in the six months following the termination of his employment. A permitted reason is injury, disability, redundancy, retirement, the transfer or sale outside the Company of the company or business in which the participant works or, in the case of any option which the participant has held for at least three years, where the employee does not return after maternity leave or

ceases employment not by reason of dismissal for misconduct. If a participant ceases to be employed for any other reason, his option will lapse.

For these purposes, a participant will not be treated as ceasing to be employed within the Company for so long as he remains employed by a company which is an associated company of the Company.

Change of control

The exercise of options will also be permitted in the event of a change in control, a reorganization, a court-sanctioned compromise or arrangement applicable to or affecting all of the ordinary shares, a takeover offer or a voluntary winding up of the Company. In the event of a change in control of the Company, participants may surrender their options in return for substitute options over shares in the acquiring company.

Listing

Application will be made for admission to the Official List of new ordinary shares issued under the Sharesave Plan and for permission to trade in those ordinary shares. Ordinary shares issued on the exercise of options will rank equally in all respects with existing ordinary shares except for rights attaching to ordinary shares by reference to a record date prior to the date of allotment.

Variation of Capital

If there is a variation in the share capital of the Company, the Board may adjust options in such manner as it determines to be appropriate.

Benefits non-pensionable

Benefits under the Sharesave Plan will not form part of a participant's remuneration for pension purposes.

Amendments

If and for so long as the ordinary shares are admitted to the Official List of the London Stock Exchange, no amendment which is to the advantage of employees or participants may be made to those provisions dealing with eligibility, individual or Sharesave Plan limits, the basis for entitlement to and the terms of the ordinary shares or the adjustment of options without the prior approval of the Company in general meeting, except for minor amendments to benefit the administration of the Sharesave Plan, to take account of a change in legislation or to obtain or maintain favorable tax, exchange control or regulatory treatment for participants or eligible employees or for a member of the Company. Subject to the foregoing, the Board may amend the Sharesave Plan in any respect.

The Indivior U.S. Employee Stock Purchase Plan (the "ESPP")

The ESPP was approved by shareholders at the Annual General Meeting of the Company held on May 12, 2016, and amended by resolution of the Board on September 24, 2020 and by resolution of the Compensation Committee on February 14, 2023 and September 30, 2024. It is the intent of the Company to have the ESPP qualify as an "employee stock purchase plan" under Section 423 of the U.S. Internal Revenue Code of 1986, including any amendments or replacements of such section.

Administration

The ESPP is administrated by our Board or a duly authorized committee thereof.

Eligibility

All individuals who are eligible employees of the Company or participating subsidiaries are eligible to participate in the ESPP. An employee is ineligible if (i) upon enrollment in the ESPP, they would own directly or indirectly an aggregate of 5% or more of the total combined voting power or value of the Company or a

subsidiary's shares; (ii) they work 20 hours a week or less; or (iii) they work for five months or less of the calendar year.

Options

Under the ESPP, participants are granted options to purchase ordinary shares from the Company. As of each enrollment date, each participant is automatically granted an option to purchase a number of ordinary shares representing their savings but subject to a maximum number of ordinary shares with a market value at the date of grant of $10,000. Options may either be options to subscribe for newly-issued ordinary shares or for existing ordinary shares purchased in the market. The rights of the participant shall not be transferable. No option shall be granted under the ESPP after the date as of which the ESPP is terminated by the Board in accordance with the termination provisions or, in any event after, the tenth anniversary of the ESPP's approval by the Company's shareholders.

Timing

Participation in the ESPP is voluntary. Eligible employees who meet the specified requirements are able to enroll in the ESPP on the first day of each six-month period commencing with the first regular payroll period on or after each successive January 1 or July 1 (each an "Accumulation Period"). Any eligible employee may consent to enrollment in the ESPP by completing and signing an enrollment form (which authorizes the payroll deductions).

Exercise Price

The exercise price shall be eighty-five percent (85%) of the lower of (i) the fair market value of an ordinary share on the enrollment date on which the option is granted; or (ii) the fair market value of an ordinary share on the purchase date but, in the case of newly issued ordinary shares, not lower than the par value of an ordinary share. The Board may establish a different purchase price, though it may not be less than (i) the purchase price set forth above and (ii) in the case of newly issued ordinary shares, than the par value per ordinary share. Also, in such case, the Board must determine such different purchase price at least thirty (30) days prior to the Accumulation Period for which it is applicable.

Payroll Deductions

To participate in the ESPP, eligible employees must elect and authorize to have deductions made from their pay on each payday during the Accumulation Period to which the enrollment form relates. Each participant designates a percentage of their base earnings to be deducted. The minimum deduction is one percent (1%) and the maximum is ten percent (10%), of base earnings per Accumulation Period.

Plan limits

The number of ordinary shares reserved under the ESPP is 25,000,000. With respect of any options granted prior to September 30, 2024, the ESPP will be subject to the limit that on any date, the aggregate number of new ordinary shares which may be issued (or treasury shares transferred) under the ESPP may not, when added to the number of new ordinary shares allocated in the previous 10 years under all employee share plans of the Company, exceed 10% of the equity share capital of the Company in issue at that time.

Exercise of awards

An award will normally be deemed to have been exercised on the specific trading day during an Accumulation Period on which ordinary shares are purchased under the ESPP. For each Accumulation Period, the purchase date is the last trading day occurring in such Accumulation Period. Whenever an award is exercised it will be for the number of ordinary shares (including partial or fractional shares) which the funds accumulated in their account at such purchase date will purchase at the applicable purchase price.

Termination of employment

Participation in the ESPP terminates immediately when a participant ceases to be employed with the Company or a participating subsidiary for any reason whatsoever, including but not limited to termination of employment, whether voluntary or involuntary, or on account of death, disability or retirement, or if the participating subsidiary employing the participant ceases to be a participating subsidiary. As soon as administratively practicable after termination, the Company shall pay the participant or legal representative all amounts accumulated in the participant's account.

Change of Control

A participant's accumulated savings at the relevant date will be used to exercise their options under the ESPP in the event of a change of control, takeover offer, scheme of arrangement or winding up of the Company.

Listing

Application will be made for admission to the Official List of any new ordinary shares issued under the ESPP and for permission to trade in those ordinary shares. Ordinary shares issued on the exercise of options will rank equally in all respects with existing ordinary shares except for rights attaching to ordinary shares by reference to a record date prior to the date of allotment.

Variation of Capital

In the event of any reorganization, recapitalization, stock split, stock dividend, combination of shares, merger, consolidation, acquisition of property or shares, separation, asset spin-off, stock rights offering, liquidation or other similar change in the capital structure of the Company, the Board shall make such adjustment, if any, as it deems appropriate in the number, kind and purchase price of the ordinary shares available for purchase under the ESPP. In the event of liquidation of the Company, each option to purchase ordinary shares shall terminate but the participant holding such an option shall have the right to exercise their option prior to such termination.

Benefits non-pensionable

Benefits under the ESPP do not form part of a participant's remuneration for pension purposes.

Amendments

The Board may amend or modify the ESPP at any time, provided that no amendment that would amend to the advantage of participants (i) the definition of eligible employees entitled to participate in the ESPP, (ii) the maximum number of ordinary shares reserved for sale and issuance under the ESPP, (iii) the number, kind and purchase price of the ordinary shares available for purchase in order to permit the enlargement of a participant's rights under the ESPP, (iv) the maximum fair market value option amount that a participant may be granted in a calendar year under the ESPP, or (v) the requirements of any securities exchange on which the ordinary shares are traded unless in each case it has been authorized by shareholders of the Company in a general meeting. The committee authorized to administer the ESPP may, without such approval, make minor amendments to benefit the administration of the ESPP, to take account of a change in legislation or to obtain or maintain favorable tax, exchange control or regulatory treatment for participants in the ESPP or for the Company. Subject to the preceding paragraph, the committee authorized to administer the ESPP shall have the power to amend the ESPP and perform such acts as it deems necessary to promote the best interests of the Company.

The Indivior Deferred Bonus Plan 2018 (the "DBP")

In line with our Remuneration Policy, the DBP requires the Executive Directors to defer 25% of their annual bonus in the form of ordinary shares of the Company for a period of time. The DBP was adopted by the Board on July 19, 2018, and subsequently amended on November 19, 2018, February 14, 2023, and September 30, 2024. The DBP only applies to Executive Directors (the Chief Executive Officer and, until

December 31, 2024, the Chief Financial Officer). The DBP is intended to comply with section 409A of the U.S. Internal Revenue Code of 1986.

Administration of the DBP

The DBP is administered, in accordance with its rules, by the Compensation Committee or another duly authorized committee of the Board (the "DBP Committee").

Eligibility

The DBP Committee may grant an award under the DBP to any employee (including an Executive Director) who was a participant in any annual bonus plan operated by the Company during the financial year immediately preceding the proposed date of grant as a means of deferring part of that employee's annual bonus into ordinary shares of the Company.

Awards

Awards may be granted in the form of (i) options to acquire ordinary shares of the Company, (ii) conditional share awards or (iii) phantom shares awards, in each case as the DBP Committee may determine in its absolute discretion. Prior to granting an award, the DBP Committee shall determine the number of ordinary shares or notional shares subject to an award where the market value of such ordinary shares or notional shares, as applicable, shall not exceed 25% (or such other percentage as the DBP Committee may determine) of the individual's annual bonus.

Timing

Awards may only be granted within 42 days commencing on the day immediately after the announcement of the Company's results for any period or the day on which the DBP Committee considers that exceptional circumstances exist which justify the grant of awards.

Vesting of awards

Awards will typically vest after a period of two years from the date of grant or such other period or periods as the DBP Committee considers appropriate. Ordinary shares transferred under the DBP will rank equally in all respects with existing ordinary shares then in issue except for any rights attaching to such ordinary shares by reference to a record date before the date of such transfer.

The DBP includes a clawback provision under which the DBP Committee may reduce awards, recover awards or make certain other adjustments to awards if (and in respect of vested awards only, before the second anniversary of such award's vesting date) the DBP Committee determines in its absolute discretion that there was a material misstatement of the Company's results for any financial year before an award was granted, there was serious misconduct by the participant, or at any time during or after any financial year before an award was granted there was serious reputational damage to any member of the Company.

Termination of employment

If, prior to an award vesting, a participant ceases to be employed within the Company due to voluntary resignation, misconduct or the Company becomes aware of facts or circumstances that would have entitled it to dismiss the participant for misconduct, such participant's unvested awards shall lapse. If, prior to an award vesting, a participant ceases to be employed within the Company for any other reason, then such participant's unvested award shall continue subject to the rules of DBP.

Change of control

Special rules apply in the event of a change of control, including a change of control resulting from a scheme of arrangement pursuant to the Companies Act or a takeover. Unless the DBP Committee decides otherwise, awards will vest on the date of the relevant event.

The DBP Committee may determine that participants may surrender their awards in return for substitute awards over shares in the acquiring company or another company. The DBP Committee may allow awards to vest on a similar basis in the event of a voluntary winding-up of the Company.

Dividends

Subject to the determination of the DBP Committee, participants shall be entitled on the vesting of any award either (a) to be paid a cash amount equal to the dividend that the participant would have accrued had the participant held the number of ordinary shares under the award from the date of grant until the vesting date or (b) to receive an additional number of ordinary shares that could have been acquired with the amount of cash dividends payable on the ordinary shares under the award.

Variation of Capital

On any variation of the Company's share capital, such as a rights issue, super dividend, demerger, dividend in specie or any capitalization issue or other similar event, awards may be adjusted in such manner as the DBP Committee considers appropriate. If any such event, in the opinion of the DBP Committee, would materially affect the value of an award, the DBP Committee may permit awards to vest on or prior to the date of such event.

Amendments

The DBP Committee may amend the DBP from time to time. However, except for minor amendments to benefit the administration of the DBP, to take account of changes in law, tax or regulatory treatment or to take account of local laws where participants are situated, no amendment that would adversely and materially affect the existing rights of a participant may be made unless with the written consent of the participant or a majority of the participants affected by the amendment.

Indivior PLC Employee Benefit Trust

In 2016, we established an employee benefit trust with an independent trustee, based in Jersey, Channel Islands, to purchase and hold shares in Indivior to be used to satisfy awards and/or options granted to eligible employees under our share plans established from time to time.

The trustee has waived its rights to receive dividends on any shares that it holds. The employee benefit trust held 100,210 ordinary shares and Depositary Interests as at January 31, 2025.

Indivior Inc. Profit Sharing and 401(k) Plan (the "401(k) Plan")

The 401(k) Plan is a defined contribution plan and is intended to be a qualified retirement plan under the U.S. Internal Revenue Code of 1986. The purpose of the 401(k) Plan is to enable eligible employees to save for retirement. As well as retirement benefits, the 401(k) Plan provides certain benefits in the event of death, disability, or other termination of employment. The 401(k) Plan is for the exclusive benefit of eligible employees and their beneficiaries.

Eligible employees may elect to defer a percentage of their eligible compensation into the 401(k) Plan, and the Company will match 75% of the first 6% of an eligible employee's contributions. Additionally, the Company automatically contributes an amount equal to 4% of an eligible employee's eligible compensation to the employee's 401(k) Plan, representing a profit-sharing contribution.

Indivior Inc. Deferred Compensation Plan ("DCP")

We maintain a Deferred Compensation Plan ("DCP") that provides a select group of Management and other highly compensated employees in the U.S., including Executive Directors and Senior Managers, as determined by the committee administering the DCP, with an opportunity to defer the receipt of portions of their compensation. The DCP is intended to comply with section 409A of the U.S. Internal Revenue Code of 1986. The DCP allows highly compensated employees who are unable, due to limits that the Internal Revenue Service ("IRS") imposes on 401(k) plans, to save a proportionate amount of their eligible compensation for retirement within the 401(k) Plan, to defer compensation in excess of IRS limits.

Under our DCP, for each financial year, participants may elect to defer up to 75% of their base salary and up to 100% of their bonus. Employees hired before January 1, 2011 are eligible for a Company match on 401(k) deferrals in excess of the annual IRS limit up to 4.5% of eligible compensation. Amounts contributed to the DCP are invested in one or more investment options as elected by a participant or absent such election, the committee administering the DCP. Participants can elect to have the benefits associated with compensation deferred in a financial year paid on June 1 of a year at least two financial years after the financial year in which such compensation was deferred. Otherwise, and subject to certain exceptions, benefits under the DCP are paid in a lump sum or in a fixed amount annually over a period not to exceed 10 years starting 60 days (or for certain employees, six months) after termination of employment of the participant.

Deeds of Indemnity

The Company also entered into a deed poll of indemnity (the "Deed Poll") on November 5, 2014 for the benefit of the officers, directors, company secretary or any position equivalent to any of the foregoing ("Beneficiaries") of the Company or any body corporate that is a group undertaking of the Company ("Group Company"). Under the Deed Poll, the Company undertakes to indemnify each Beneficiary against any and all liability suffered or incurred by that Beneficiary in respect of that Beneficiary's acts or omissions while, or in the course of acting or purporting to act as, an officer of any Group Company or which otherwise arises by virtue of that Beneficiary holding or having held such position, in each case, to the extent arising out of or in connection with, directly or indirectly, any investigation, demand, claim, action or proceeding brought or threatened against that Beneficiary or any other person in any jurisdiction.

The Deed Poll does not extend to any liability incurred by the Beneficiary (1) to pay a fine imposed in criminal proceedings, (2) to pay a sum payable to a regulatory authority by way of a penalty in respect of non-compliance with any requirement of a regulatory nature, (3) in defending any criminal proceedings in which the Beneficiary is convicted, (4) in defending civil proceedings brought by the Company, in which judgment is given against the Beneficiary, or (5) in connection with an application for relief in which the court refuses to grant the Beneficiary relief. The Deed Poll also does not apply to the extent that the Beneficiary has been indemnified or reimbursed by any other insurance, where there has been gross negligence, fraud or willful default by the Beneficiary or where the Beneficiary has improperly derived a personal benefit or profit.

The Company may advance such funds to a Beneficiary as the Company, in its reasonable discretion, considers appropriate for the Beneficiary to meet expenditures incurred in defending any criminal or civil proceedings in connection with any alleged negligence, default, breach of duty or breach of trust by the Beneficiary or in defending himself in an investigation by a regulatory authority or against action proposed to be taken by a regulatory authority in connection with any alleged negligence, default, breach of duty or breach of trust by the Beneficiary.

The Deed Poll also provide that the Company will use reasonable endeavors to purchase and maintain insurance cover for directors' and officers' liabilities on reasonable commercial terms in respect of each Beneficiary for so long as the Beneficiary is a director or employee of any Group Company and for at least six years thereafter.

Malus and Clawback

The Compensation Committee has the discretion to scale back or cancel LTIP awards, extend the performance period or defer the exercise period prior to the satisfaction of awards or after the end of any relevant holding period in the event that results are materially misstated for part of the performance period applicable to an award, an individual's conduct has amounted to gross misconduct or in the event of serious reputational damage to Indivior. Where LTIP awards have vested, the Committee has the discretion to "claw back" awards or reduce amounts of other payments due to the individual up to the fifth anniversary of the grant of awards in the circumstances described above.

Indivior PLC Executive Compensation Clawback Policy

The Company's Executive Compensation Policy forms part of its Malus & Clawback policy, adopted during the year. The policy requires Indivior to recover incentive based compensation if (i) there is a restatement of the Company's financial statements due to material non-compliance with any financial reporting requirement under securities laws, or that would result in a material misstatement if not corrected for prior periods; and (ii) a covered executive has received incentive-based compensation in excess of what they should have received if such compensation was instead calculated using the corrected Company financial statements.

Executive Financial Recoupment Program

As part of the Company's Corporate Integrity Agreement with the Office of the Inspector General of the U.S. Department of Health and Human Services, an Executive Financial Recoupment Program was implemented (the "Recoupment Program"). Under the terms of the Recoupment Program, up to two years of performance pay may be put at risk of forfeiture and/or recoupment for certain U.S.-based executives (which includes both serving Executive Directors).

Forfeiture and/or recoupment may be applied in the event that it is determined that there has been a "Triggering Event"; a Triggering Event includes significant misconduct (violation of law or regulation or a significant violation of an Indivior policy) related to covered activities, or, significant misconduct related to covered activities by subordinate employees in the business unit for which the relevant executive had responsibility that is not an isolated incident and which the relevant executive knew or should have known was occurring.

Forfeiture and/or recoupment under the Recoupment Program may be applied to awards granted after November 20, 2020 and will cease to apply to awards on July 24, 2025 or the date on which the Company's obligations under the Corporate Integrity Agreement expire (if later).

Compensation Committee Interlocks and Insider Participation

The members of the Compensation Committee during the last completed fiscal year were Jo LeCouilliard (Chair), Peter Bains, Barbara Ryan, David Wheadon, and Graham Hetherington. Dr. Wheadon was appointed a member of the Compensation Committee on June 1, 2024, and Mr. Hetherington stepped down as a member of the Compensation Committee upon his retirement from the Board on December 31, 2024.

None of the listed individuals was or has been an officer or employee of the Company or had any relationship requiring disclosure under Item 404 of Regulation S-K.

Compensation Committee Report

The Compensation Committee is responsible for determining the specific compensation packages for the Chair, the Executive Directors, and members of Senior Management. It is also responsible for determining general compensation policy and monitoring workforce compensation arrangements. The Compensation Committee shall meet not less than quarterly.

The responsibilities of the Compensation Committee set out in its Charter cover setting levels of compensation and determination and monitoring of the compensation policy, approval of the design of, and determining targets for, performance-related pay programs and approval of the design and implementation of all long-term incentive arrangements. The Charter also sets out the reporting responsibilities and the authority of the Compensation Committee to carry out its responsibilities.

The members of the Compensation Committee are Jo LeCouilliard (Chair), Peter Bains, Barbara Ryan, and David Wheadon. Our Board has determined that each member is independent under Nasdaq listing standards.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Shareholder Matters.

Share Ownership

The information at "*Item 13. Certain Relationships and Related Transactions, and Director Independence*," is incorporated herein by reference.

In addition, the following executives hold options over shares in Indivior PLC as follows:

Executive	Share Plan	Security	Total Purchase Price	Per Share Exercise Price	Vesting Date	Expiry Date	Number of Shares
Kathryn Hudson	Sharesave (1)	ordinary shares	n/a	£13.40	3/1/2026	8/31/2026	671
Kathryn Hudson	Sharesave (1)	ordinary shares	n/a	£10.49	3/1/2027	8/31/2027	884
Hillel West	Sharesave (1)	ordinary shares	n/a	£4.80	3/1/2026	8/31/2026	2,500
Hillel West	Sharesave (1)	ordinary shares	n/a	£10.49	3/1/2029	8/31/2029	1,807

(1) Reflects options granted to senior managers under the rules of the Indivior U.K. Savings-Related Share Option Plan, which is a tax qualified plan available to all U.K.-based employees. Eligible employees may enter into a savings contract, saving up to £500 per month, with the opportunity to buy shares at 20% discount to market value at the time of invitation upon completion of the savings period.

Major Shareholders

As of June 30, 2024, 63,953,605 shares were held for the benefit of 1,869 shareholders who were U.S. residents, comprising approximately 48% of our issued share capital.

The table below sets forth information with respect to the beneficial ownership of our ordinary shares, based on notifications made by such shareholders under the U.K. Financial Conduct Authority's Disclosure and Transparency Rules or statements made by such investors in their respective filings with the U.S. SEC as of February 28, 2025 by:

1. each of our directors, executive officers and senior managers individually and as a group; and

2. each person, or group of affiliated persons, who is known by us to own beneficially more than 3% of our ordinary shares.

Beneficial ownership is determined in accordance with the rules and regulations of the SEC. In computing the number of shares beneficially owned by a person and the percentage ownership of that person, we have included shares that the person has the right to acquire within 60 days, including through the exercise of any option, warrant or other right or the conversion of any other security. These shares, however, are not included in the computation of the percentage ownership of any other person.

All ordinary shares have the same voting rights.

NAME AND ADDRESS OF BENEFICIAL OWNER	NUMBER OF SHARES BENEFICIALLY OWNED	TOTAL PERCENTAGE[1]
Major Shareholders:		
Two Seas Capital LP[2]	12,007,514	9.64 %
Oaktree Capital Holdings, LLC[3]	9,521,980	7.64 %
Deerfield Partners, L.P.[4]	8,883,160	7.13 %
The Goldman Sachs Group, Inc.[5]	8,092,710	6.50 %
Directors[6][7]		
Dr. David Wheadon	10,000	*
Mark Crossley[8]	97,671	*
Peter Bains	10,800	*
Joe Ciaffoni	56,000	*
Dr. Keith Humphreys	2,379	*
Jo LeCouilliard	1,490	*
Daniel Ninivaggi	15,000	*
Barbara Ryan	0	*
Robert Schriesheim	80,233	*
Mark Stejbach	13,924	*
Juliet Thompson	3,850 [9]	*
Senior Management[10][11]		
Jeff Burris	*	*
Cindy Cetani	*	*
Angela Colon-Mahoney	*	*
Dr. Christian Heidbreder	*	*
Kathryn Hudson[12]	* [13]	*
Vishal Kalia	*	*
Ryan Preblick	*	*
Richard Simkin	*	*
Hillel West[12]	*	*
All Directors and Senior Managers as a Group	**1,002,467** [9][13]	*

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* Represents beneficial ownership of less than one percent of our outstanding ordinary shares.

(1) Based on 124,570,449 ordinary shares outstanding as of February 28, 2025, which comprise our entire issued and outstanding share capital as of that date.

(2) The business address for Two Seas Capital LP, Two Seas Capital GP LLC, and Sina Toussi (altogether, the "Two Seas Parties") is 32 Elm Place, 3rd Floor, Rye, NY 10580, United States. Based on the Company's review of a Schedule 13D-Amendment No. 4 filed by the Two Seas Parties on January 17, 2025, the Two Seas Parties share voting and investment control of 12,007,514 ordinary shares.

(3) The business address for Oaktree Capital Holdings, LLC ("OC Holdings"), Oaktree Capital Group Holdings GP, LLC ("OC Group Holdings"), Brookfield Asset Management ULC ("Brookfield"), Oaktree Fund GP I, L.P. ("Oaktree GP I"), Oaktree Value Opportunities Fund, L.P. ("OVO Fund"), Oaktree London Liquid Value Opportunities Fund (VOF), L.P. ("VOF"), Oaktree Capital Management, L.P. ("OC Management"), and Oaktree Phoenix Investment Fund, L.P. ("OPI Fund") (and altogether, the "Oaktree Parties") is 333 South Grand Avenue, 28th Floor, Los Angeles, CA 90071, United States. Based on the Company's review of a Schedule 13D-Amendment No. 1 filed by the Oaktree Parties on November 6, 2024, the Oaktree Parties hold an aggregate of 9,521,980 ordinary shares as follows: OVO Fund is the direct holder of and shares voting and investment control of 5,545,556 ordinary shares; VOF is the direct holder of and shares voting and investment control of 2,351,370 ordinary shares; OPI Fund is the direct holder of and shares voting and investment control of 268,780 ordinary shares; OC Management is the investment manager to Boston Patriot Arlington St LLC, an SMA account which directly holds 1,356,274 ordinary shares, over which OC Management shares voting and investment control; Oaktree GP I is the indirect general partner of OVO Fund, VOF, and OPI Fund, and as such may be deemed to beneficially own and share voting and investment control of an aggregate of 8,165,706 ordinary shares; OC Holdings is the indirect general partner of OVO Fund, VOF, OPI Fund, and Oaktree GP I, and as such may be deemed to beneficially own and share voting and investment control of an aggregate of 9,521,980 ordinary shares; OC Group Holdings is the indirect owner of the Class B Units of OC Holdings, and as such may be deemed to beneficially own and share voting and investment control of an aggregate of 9,521,980 ordinary shares; and Brookfield is the indirect owner of the Class A1 Units of OC Holdings, and as such may be deemed to beneficially own and share voting and investment control of an aggregate of 9,521,980 ordinary shares.

(4) The business address for Deerfield Partners, L.P., Deerfield Mgmt., L.P., Deerfield Management Company, L.P., and James E. Flynn (altogether, the "Deerfield Parties") is 345 Park Avenue South, 12th Floor, New York, NY 10010, United States. Based on the Company's review of a Schedule 13G-Amendment No. 1 filed by the Deerfield Parties on February 13, 2025, the Deerfield Parties share voting and investment control of 8,883,160 ordinary shares.
(5) The business address for The Goldman Sachs Group, Inc. and Goldman Sachs & Co. LLC (altogether, the "Goldman Sachs Parties") is 200 West Street, New York, NY 10282, United States. Based on the Group's review of a Schedule 13G filed by the Goldman Sachs Parties on February 6, 2025, the Goldman Sachs Parties share voting and investment control of 8,092,710 ordinary shares.
(6) Except as otherwise indicated, the business address for each of our Directors is 234 Bath Road, Slough, Berkshire, SL1 4EE, United Kingdom.
(7) Dr. McLellan retired from the Board on February 29, 2024, and Mr. Hetherington and Mr. Lande retired from the Board on December 31, 2024. At the time of their departures from the Board, Dr. McLellan, Mr. Hetherington, and Mr. Lande beneficially owned 1,509, 21,651, and 63 ordinary shares, respectively.
(8) The business address for Mr. Crossley is 10710 Midlothian Turnpike, Suite 125, North Chesterfield, VA 23235, United States.
(9) This amount includes 1,925 ordinary shares held by the spouse of Ms. Thompson.
(10) Except as otherwise indicated, the business address for each member of our Senior Management is 10710 Midlothian Turnpike, Suite 125, North Chesterfield, VA 23235, United States.
(11) Mr. Fogle retired as Chief Human Resources Officer on December 31, 2024. At the time of his departure, Mr. Fogle beneficially owned 60,346 ordinary shares.
(12) The business address for Ms. Hudson and Mr. West is 234 Bath Road, Slough, Berkshire, SL1 4EE, United Kingdom.
(13) This amount includes 2,150 ordinary shares held by the spouse of Ms. Hudson.

Changes in the percentage ownership by major shareholders are set out below. The information in the table below is based on the notifications made by such shareholders as of the dates indicated under the U.K. Financial Conduct Authority's Disclosure and Transparency Rules or statements made by such investors in their respective filings with the U.S. SEC.

	December 31, 2022	December 31, 2023	December 31, 2024
Two Seas Capital LP	5.13 %	10.09 %	9.61 %
Oaktree Capital Holdings, LLC	— %	— %	7.62 %
Deerfield Partners, L.P.	— %	— %	7.11 %
The Goldman Sachs Group, Inc.	— %	— %	6.48 %

Equity Compensation Plan Information

The following table provides information, as of December 31, 2024, with respect to our ordinary shares that may be issued, subject to certain vesting requirements, under existing and future awards under our 2024 LTIP, 2024 Sharesave Plan, ESPP, 2014 LTIP, 2014 Sharesave Plan, and DBP.

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans
Equity compensation plans approved by security holders	5,829,172	22.3p	39,510,049
Equity compensation plans not approved by security holders	48,182	—	1,000,000
Total	5,877,354	22.1p	40,510,049

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The Audit & Risk Committee has adopted a Related Party Transactions Policy (the “RPT Policy”), which provides the procedures for the review, approval, and ratification of related party transactions, and which governs the Company’s accounting, disclosure, and reporting of related party transactions. Under the RPT Policy, a 'related party' is any entity or person over which the Company exercises control, common control, joint control, or significant influence; any Person Discharging Managerial Responsibilities (“PDMR”), including Directors and members of the Executive Committee; any director nominee; shadow director; beneficial owner of more the 5% of the Company’s voting securities; or any immediate family member of one of the foregoing persons. A 'related party transaction' is any financial transaction, arrangement, or relationship (including any indebtedness or guarantee of indebtedness), or any series of similar transactions, arrangements, or relationships in which the Company (and/or any of its consolidated subsidiaries) is or was a participant and in which a related party has or will have a direct or indirect material interest, where the amount involved exceeds the lesser of $120,000 in any fiscal year or $100,000 in aggregate.

The Audit & Risk Committee conducts a reasonable prior review of all related party transactions and considers the relevant facts and circumstances in determining whether to approve, ratify, revise, or terminate a related party transaction. The Audit & Risk Committee approves only those transactions that are in the best interests of the Company and its shareholders.

Since the beginning of the Company's last fiscal year, the Company has had no transactions with related persons requiring approval under the Company's RPT Policy or disclosure pursuant to Item 404 of Regulation S-K, except for Relationship Agreements with Scopia and the Oaktree Parties, as described below.

The Nomination Committee is responsible for reviewing the Register of Directors' Conflicts of Interest, as well as reviewing and evaluating additional external appointments for the Directors of Indivior PLC and members of the Executive Committee, and making recommendations to the Board.

The Nomination Committee is also responsible for considering the independence of the Non-Executive Directors and their other commitments and if these are likely to give rise to a potential conflict of interest. On the recommendation of the Committee, the Board confirmed that each of the Non-Executive Directors, following the retirement of Jerome Lande, remained independent.

Relationship Agreement with Scopia Capital Management

The Company entered into an agreement titled Relationship Agreement with Scopia Capital Management LP (“Scopia”) on March 24, 2021 (as further amended on July 7, 2022, April 26, 2023, and November 17, 2023, the “Relationship Agreement”). In recognition of Scopia’s ownership of approximately 16.9% of the Company’s shares as at March 24, 2021, the Company agreed to appoint Jerome Lande as a Representative Director. Scopia agreed to certain standstill provisions (for example to vote on ordinary course resolutions in accordance with the Board’s recommendation). The parties further agreed that Scopia would not exercise voting rights in excess of 15% of the outstanding shares. The Relationship Agreement terminated on December 31, 2024 and Mr. Lande has resigned from the Board.

Relationship Agreement with the Oaktree Parties

On December 16, 2024, Indivior PLC entered into a Relationship Agreement with Oaktree Value Opportunities Fund, L.P., Oaktree London Liquid Value Opportunities Fund (VOF), L.P., Oaktree Phoenix Investment Fund, L.P. and Boston Patriot Arlington ST LLC (together, the "Oaktree Parties") pursuant to which Indivior PLC agreed to (i) appoint Robert Schriesheim, Joe Ciaffoni, and Daniel Ninivaggi (together, the "New NEDs") to the Board, (ii) appoint the New NEDs as members of the Nomination Committee and the Operational Committee of the Board, and (iii) from January 1, 2025 until the expiry of the Relationship Agreement have a maximum of 11 directors on the Board. Indivior PLC also agreed that the Board will unanimously recommend to shareholders the re-appointment of the New NEDs to the Board at the 2025 Annual General Meeting of Indivior PLC.

The Relationship Agreement further provides that, until the expiration of the Relationship Agreement, the Oaktree Parties will not, and will take reasonable steps to ensure that each of their affiliates will not, (i) remove or publicly propose the removal of any member of the Board, (ii) put forward or propose any resolution, agenda item or amendment thereto at a general meeting of Indivior PLC, (iii) nominate any person to the Board, (iv) require the Board to call a general meeting of Indivior PLC, (v) require circulation of a statement relating to a proposed resolution or any other business to be dealt with at a general meeting of the Company, (vi) make any public proposal to change (a) the Board or management, (b) the capitalization or capital allocation program and practices of Indivior PLC, or (c) Indivior PLC's business or corporate structure, or (vii) vote against the recommendation of the Board on any Ordinary Course Resolution, or solicit or knowingly urge any shareholder of Indivior PLC to take the foregoing actions. The Relationship Agreement also contains mutual non-disparagement and no litigation covenants.

The Relationship Agreement will terminate on December 31, 2025, provided that the Oaktree Parties may terminate the Relationship Agreement earlier if Indivior PLC breaches certain provisions of the Relationship Agreement. The foregoing description of the Relationship Agreement does not purport to be complete and is qualified in its entirety by reference to the Relationship Agreement, which is filed as Exhibit 10.13 hereto and incorporated herein by reference.

Item 14. Principal Accountant Fees and Services.

PricewaterhouseCoopers LLP (U.K.) has been our statutory auditor for the Company since incorporation.

PricewaterhouseCoopers LLP (U.S.) has audited our financial statements for the periods ended December 31, 2024, 2023, 2022, 2021, and 2020. PricewaterhouseCoopers LLP (U.S.) is an independent registered public accounting firm, registered with the Public Company Accounting Oversight Board (United States).

Fees to Independent Registered Public Accounting Firm

The following table shows the aggregate fees incurred by the Company for professional services by PricewaterhouseCoopers LLP (U.S.) and PricewaterhouseCoopers (U.K.) (collectively, "PwC"), as well as reimbursement of out-of-pocket costs directly related to delivery of the respective services, for fiscal years 2024, and 2023:

	For the years ended December 31,	
(in millions)	2024	2023
Audit Fees	$ 7.9	$ 6.0
Audit-Related Fees	—	—
Tax Fees	—	—
All Other Fees	—	—
Total	$ 7.9	$ 6.0

Audit Fees. This category includes fees billed or expected to be billed for professional services for the integrated audits of our Consolidated Financial Statements, including the audit of the effectiveness of ICFR. This category also includes, when applicable, reviews of our quarterly reports on Form 10-Q, statutory audits or other financial statement audits of subsidiaries, and consents related to SEC registration statements.

Audit-Related Fees. This category includes fees billed or expected to be billed for assurance and other services that are reasonably related to the performance of the audits of our Consolidated Financial Statements and effectiveness of ICFR that are not reported under the audit fees category above. These services consist of service organization control reports, other audit and attest services, services provided in connection with certain agreed upon procedures and other attestation reports, financial accounting, reporting and compliance matters, and risk and internal control reviews.

Tax Fees. This category includes fees billed or expected to be billed for tax-related services, including tax compliance, tax planning, and tax advice.

All Other Fees. This category includes fees billed or expected to be billed for non-audit services and subscription-based services, including software licenses, benchmarking services, training, and other advisory services.

The Audit & Risk Committee considered the non-audit services performed by, and fees paid to, PwC in 2024 and determined that such services and fees are compatible with the independence of PwC.

Audit & Risk Committee Pre-Approval Policy

Under the terms of its charter, the Audit & Risk Committee must pre-approve all services (including the fees and terms of such services) to be performed for us by our independent registered public accounting firm, except the Committee Chair may approve services costing less than $250,000 and the Chief Financial Officer may approve fees less than $50,000 for engagements that have already been pre-approved by the Committee.

The Audit & Risk Committee may form and delegate authority to subcommittees consisting of three or more members when appropriate, including the authority to grant pre-approvals of audit and permitted non-audit services, as long as the decisions of such subcommittee(s) to grant pre-approvals are presented to the full Audit & Risk Committee at its next scheduled meeting. In 2024 and 2023, all of the services provided by our independent registered public accounting firm were reviewed and approved by the Audit & Risk Committee.

PART IV

Item 15. Exhibits and Financial Statement Schedules.

a)

1. Financial Statements: The following financial statements for Indivior are included in Item 8, *Financial Statements and Supplementary Data*:

Consolidated Statements of Operations for the Years Ended December 31, 2024, 2023 and 2022
Consolidated Statements of Comprehensive Loss for the Years Ended December 31, 2024, 2023 and 2022
Consolidated Balance Sheets as of December 31, 2024 and 2023
Consolidated Statements of Shareholders' Deficit for the Years Ended December 31, 2024, 2023 and 2022
Consolidated Statements of Cash Flows for the Years Ended December 31, 2024, 2023 and 2022
Notes to Consolidated Financial Statements
Report of Independent Registered Public Accounting Firm (PCAOB Firm 238)

2. Financial Statement Schedules: The following financial statement schedule is attached to this report.

Schedule I – Condensed Financial Information of the Registrant

All other schedules are omitted because they are not applicable, not required, or the information is included in the financial statements or the notes thereto.

3. Exhibits: Certain of the following Exhibits have been previously filed with the Securities and Exchange Commission pursuant to the requirements of the Securities Act of 1933 and the Securities Exchange Act of 1934. Such exhibits are identified by the parenthetical references following the listing of each such exhibit and are incorporated herein by reference.

Exhibit No.	Description
2.1†	Contingent Value Rights Agreement dated as of March 2, 2023 between Indivior, Inc., Computershare Inc. and Computershare Trust Company, N.A. (incorporated by reference to Exhibit 4.21 to registration statement on Form 20-F filed May 23, 2023).
3.1	Memorandum and Articles of Association of Indivior PLC (adopted by a special resolution on 30 October 2014, as amended by a special resolution on 23 December 2014 and on 30 September 2022) (incorporated by reference to Exhibit 1.1 to registration statement on Form 20-F filed May 23, 2023).
4.1	Form of Share Certificate (incorporated by reference to Exhibit 2.1 to registration statement on Form 20-F filed May 23, 2023).
4.2	Description of Securities Registered under Section 12 of the Exchange Act (incorporated by reference to Exhibit 2.2 to Annual Report on Form 20-F filed March 6, 2024).
10.1†	Note Purchase Agreement dated as of November 4, 2024 among RBP Global Holdings Limited, Indivior Global Holdings Limited, the persons from time to time party thereto as Notes Parties, Piper Sandler Finance LLC as Administrative Agent, and the Purchasers identified on Schedule 1.01(a) (incorporated by reference to Exhibit 10.1 to Report on Form 6-K filed November 8, 2024).
10.2	Resolution Agreement by and among Indivior PLC, Indivior Inc., the United States Attorney's Office for the Western District of Virginia, and the United States Department of Justice's Consumer Protection Branch made as of July 24, 2020 (incorporated by reference to Exhibit 4.3 to registration statement on Form 20-F filed May 23, 2023).

Exhibit No.	Description
10.3	Corporate Integrity Agreement between the Office of Inspector General of the Department of Health and Human Services and Indivior Inc. made as of July 24, 2020 (incorporated by reference to Exhibit 4.4 to registration statement on Form 20-F filed May 23, 2023).
10.4	Stipulated Order for Permanent Injunction and Equitable Monetary Relief in the United States District Court for the Western District of Virginia, Abingdon, between the Federal Trade Commission and Indivior Inc. entered November 20, 2020 (incorporated by reference to Exhibit 4.5 to Annual Report on Form 20-F filed March 6, 2024).
10.5	Final Judgment and Dismissal with Prejudice with Attorneys General of 41 states and the District of Columbia in Antitrust MDL made June 2, 2023 (incorporated by reference to Exhibit 4.25 to Annual Report on Form 20-F filed March 6, 2024).
10.6	Settlement Agreement among Indivior Inc. and a class of direct purchasers made October 22, 2023 (incorporated by reference to Exhibit 4.26 to Annual Report on Form 20-F filed March 6, 2024).
10.7	Lease of Land and Buildings at Dansom Lane, Hull HU8 7DS, by and between Reckitt Benckiser Healthcare (U.K.) Limited and RB Pharmaceuticals Limited, dated December 1, 2014 (incorporated by reference to Exhibit 4.7 to registration statement on Form 20-F filed May 23, 2023).
10.8.1†	Copacker Supply Agreement by and between Reckitt Benckiser Healthcare (U.K.) Limited and RB Pharmaceuticals Limited, dated December 23, 2014 (incorporated by reference to Exhibit 4.14.1 to registration statement on Form 20-F filed May 23, 2023).
10.8.2†	First Amendment to Copacker Supply Agreement Reckitt Benckiser Healthcare (U.K.) Limited and Indivior U.K. Limited, formerly known as RB Pharmaceuticals Limited, as amended and restated on March 29, 2019 (incorporated by reference to Exhibit 4.14.2 to registration statement on Form 20-F filed May 23, 2023).
10.9.1†	Commercial Exploitation Agreement by and between Aquestive Therapeutics (f/k/a MonoSol Rx), LLC and Reckitt Benckiser Pharmaceuticals Inc., dated August 15, 2008 (as amended on August 19, 2009, November 13, 2009, March 30, 2010, October 13, 2010, December 15, 2010, December 9, 2011, December 1, 2012, October 14, 2013 (by Addendum A), July 30, 2014 (by Addendum B), January 12, 2017, November 25, 2019, December 29, 2020, and March 2, 2023)(incorporated by reference to Exhibit 4.15.1 to registration statement on Form 20-F filed May 23, 2023).
10.9.2†	Supplemental Agreement by and between MonoSol Rx, LLC, Indivior Inc., and Indivior U.K. Limited, dated September 24, 2017 (incorporated by reference to Exhibit 4.15.2 to registration statement on Form 20-F filed May 23, 2023).
10.10†#	Master Packaging and Supply Agreement effective as of October 1, 2023 by and between Sharp Packaging Services, LLC, Indivior Inc., and Indivior U.K. Limited.
10.11.1†	Master Development and Supply Agreement made January 1, 2022 by and between Curia Massachusetts, Inc. and Indivior U.K. Limited (incorporated by reference to Exhibit 4.17 to registration statement on Form 20-F filed May 23, 2023).
10.11.2†	Master Development and Supply Agreement effective the August 1, 2023 by and between Curia New Mexico, LLC and Indivior U.K. Limited (incorporated by reference to Exhibit 4.17.2 to Annual Report on Form 20-F filed March 6, 2024).
10.12.1†	License Agreement between Opiant Pharmaceuticals, Inc. and Aegis Therapeutics, LLC effective January 1, 2017 (incorporated by reference to Exhibit 4.24 to registration statement on Form 20-F filed May 23, 2023).
10.12.2†#	Amendment to the License Agreement between Indivior Inc., Indivior U.K. Limited, and Aegis Therapeutics, LLC made November 2020, 2024.
10.13†#	Relationship Agreement made as of December 16, 2024 by and among Indivior PLC, Oaktree Value Opportunities Fund, L.P., Oaktree London Liquid Value Opportunities Fund (VOF), L.P., Oaktree Phoenix Investment Fund, L.P. and Boston Patriot Arlington ST LLC.
10.14#*	The Indivior Inc. Incentive Compensation Policy.
10.15*	Trust Deed in respect of the Indivior PLC Employee Benefit Trust (incorporated by reference to Exhibit 4.10 to registration statement on Form 20-F filed May 23, 2023).
10.16*	Rules of the Indivior PLC Long-Term Incentive Plan (incorporated by reference to Exhibit 4.9 to registration statement on Form 20-F filed June 5, 2023).
10.17#*	Rules of the Indivior 2024 Long-Term Incentive Plan.

Exhibit No.	Description
10.18*	The Indivior PLC Savings-Related Share Option Plan (incorporated by reference to Exhibit 4.11 to registration statement on Form 20-F filed June 5, 2023).
10.19*	Rules of the Indivior 2024 U.K. Savings Related Share Option Plan, incorporated by reference to Exhibit 99.3 to Registration Statement on Form S-8 Filed October 24, 2024.
10.20#*	The Indivior PLC U.S. Employee Stock Purchase Plan.
10.21*	Rules of the Indivior Group Deferred Bonus Plan (incorporated by reference to Exhibit 99.4 to registration statement on Form S-8 filed October 24, 2024).
10.22#*	Form of Director Employment Agreement
10.23.1#*	Employment Agreement with Mark Crossley made as of June 29, 2020.
10.23.2#*	Amendment to Employment Agreement with Mark Crossley made as of April 25, 2024.
10.23.3#*	Separation Agreement by and between Indivior, Inc. and Mark Crossley as of February 26, 2025.
10.24.1#*	Employment Agreement with Ryan Preblick made as of November 19, 2020.
10.24.2#*	Amendment to Employment Agreement with Ryan Preblick made as of April 25, 2024.
10.25#*	Form of Executive Confidentiality, Proprietary Rights and Non-Competition Agreement
19.1#	Group-Wide Dealing Policy
19.2#	Dealing Code
21.1#	Subsidiaries of the Registrant
23.1#	Consent of PricewaterhouseCoopers LLP (US)
31.1#	Certification of Chief Executive Officer under Section 302 of the Sarbanes-Oxley Act of 2002.
31.2#	Certification of Chief Financial Officer under Section 302 of the Sarbanes-Oxley Act of 2002.
32.1#	Certification of Chief Executive Officer under Section 906 of the Sarbanes-Oxley Act of 2002.
32.2#	Certification of Chief Financial Officer under Section 906 of the Sarbanes-Oxley Act of 2002.
97.1#*	Indivior PLC Malus & Clawback Policy.
101.1#	Inline Interactive Data File
101.INS#	Inline XBRL Instance Document—this instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document
101.SCH#	Inline XBRL Taxonomy Extension Schema Document
101.CAL#	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF#	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB#	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE#	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104#	Cover Page Interactive Data File (embedded within the Inline XBRL document)

† Confidential treatment requested as to certain portions, which portions have been omitted
* Management Contract
# Filed herewith

Indivior PLC
Schedule I
(Dollars in millions)

Parent Company Information

Cash dividends and/or share repurchase programs, if any, are made by Indivior PLC (the "Parent Company"). The Parent Company's primary source of income and cash flow is dividends and loans from its subsidiaries, which are restricted by our note purchase agreement (see *Item 8. Financial Statements —Audited Consolidated Financial Statements - Note 12. Debt*). The Note Purchase Agreement contains customary negative covenants limiting these subsidiaries' ability to dividends, loans and other restricted payments, subject to certain exceptions and baskets. The stand-alone condensed financial statements of the Parent Company are presented below in accordance with SEC regulations when such restrictions exist. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future.

Parent Company Condensed Statements of Net Income (Loss) and Comprehensive Loss

	Year Ended December 31,		
	2024	**2023**	**2022**
Revenues	$ —	$ —	$ —
Operating expenses	(34)	(32)	(34)
Operating loss	**(34)**	**(32)**	**(34)**
Equity earnings (losses) in subsidiaries	30	(104)	(18)
Loss before income taxes	**(4)**	**(136)**	**(52)**
Income tax benefit	6	7	8
Net income (loss)	**2**	**(129)**	**(44)**
Comprehensive loss	**$ (4)**	**$ (127)**	**$ (50)**

Indivior PLC
Schedule I
(Dollars in millions)

Parent Company Condensed Balance Sheets

	Year Ended December 31,	
	2024	**2023**
Assets		
Current assets		
Cash and cash equivalents	$ 7	$ 34
Amounts due from subsidiaries	2	1
Other current assets	16	6
Total current assets	**25**	**41**
Deferred tax assets	13	19
Total assets	**$ 38**	**$ 60**
Liabilities and shareholders' deficit		
Current liabilities		
Accounts payable	$ 19	$ 34
Amounts due to subsidiaries	9	17
Total current liabilities	**28**	**51**
Equity in net deficit of subsidiaries	350	185
Other non-current liabilities	8	15
Total liabilities	**386**	**251**
Shareholders' deficit		
Common stock	62	68
Additional paid-in capital	91	88
Share repurchase commitment	(10)	(23)
Accumulated other comprehensive income	(36)	(30)
Accumulated deficit	(456)	(296)
Total shareholders' deficit	**(348)**	**(191)**
Total liabilities and shareholders' deficit	**$ 38**	**$ 60**

Indivior PLC
Schedule I
(Dollars in millions)

Parent Company Condensed Statements of Cash Flow

	Year Ended December 31,		
	2024	**2023**	**2022**
Net cash used in operating activities	**$ (25)**	**$ (58)**	**$ (15)**
Cash flows from investing activities:			
Dividends from subsidiaries	190	83	152
Net cash provided by investing activities	**190**	**83**	**152**
Cash flows from financing activities:			
Proceeds from the issuance of common stock	3	4	2
Shares repurchased and canceled	(173)	(33)	(90)
Other	(22)	(22)	(10)
Net cash used in financing activities	**(192)**	**(51)**	**(98)**
Net (decrease) increase in cash and cash equivalents	**(27)**	**(26)**	**39**
Cash and cash equivalents at beginning of period	34	60	21
Cash and cash equivalents at end of period	**$ 7**	**$ 34**	**$ 60**

(1) Introduction and basis of presentation

The Parent Company financial statements have been prepared using the same accounting principles and policies as described in the notes to our Consolidated Financial Statements except for the investment in the subsidiaries are accounted for using the equity method of accounting. Any material contingencies, long-term obligations and guarantees have been separately disclosed in the accompanying Consolidated Financial Statements. These condensed parent company financial statements are not the general-purpose financial statements of the reporting entity. These condensed financial statements of the Parent Company should be read in conjunction with the consolidated financial statements of Indivior PLC and its consolidated subsidiaries (the "Company") and the notes thereto included in *Item 8. Financial Statements—Audited Consolidated Financial Statements*. These financial statements have been provided to comply with Rule 4-08(e) of Regulation S-X.

Use of Estimates

The use of estimates is inherent in the preparation of financial statements in accordance with generally accepted accounting principles. Actual results could differ from those estimates.

(2) Supplemental Disclosures of Cash Flow Information

The Parent Company receives dividends from its subsidiaries primarily to repurchase common stock and fund its operating costs. During the periods presented, the dividends received were in excess of current year equity in subsidiary earnings, and thus was considered to be a return of investment and is classified as a cash inflow from investing activities.

Item 16. Form 10–K Summary.

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, on the 3rd day of March, 2025.

INDIVIOR PLC (Registrant)

By: /s/ Ryan Preblick
Ryan Preblick, Chief Financial Officer

/s/ Mark Crossley Mark Crossley	Chief Executive Officer and Executive Director (Principal Executive Officer)	February 24, 2025
/s/ Ryan Preblick Ryan Preblick	Chief Financial Officer (Principal Financial Officer)	February 24, 2025
/s/ Woodrow Anderson Woodrow Anderson	Senior Vice President—Group Controller (Principal Accounting Officer)	February 24, 2025
/s/ Dr. David Wheadon Dr. David Wheadon	Chair and Independent Non-Executive Director	February 19, 2025
/s/ Juliet Thompson Juliet Thompson	Lead Independent Director	February 20, 2025
/s/ Peter Bains Peter Bains	Independent Non-Executive Director	February 23, 2025
/s/ Joe Ciaffoni Joe Ciaffoni	Independent Non-Executive Director	February 19, 2025
/s/ Dr. Keith Humphreys Dr. Keith Humphreys	Independent Non-Executive Director	February 20, 2025
/s/ Jo LeCouilliard Jo LeCouilliard	Independent Non-Executive Director	February 19, 2025
/s/ Dan Ninivaggi Dan Ninivaggi	Independent Non-Executive Director	February 24, 2025
/s/ Barbara Ryan Barbara Ryan	Independent Non-Executive Director	February 19, 2025
/s/ Mark Stejbach Mark Stejbach	Independent Non-Executive Director	February 19, 2025