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Indivior PLC
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April 24, 2025

Indivior Announces Results for the First Quarter Ended March 31, 2025; FY 2025 Guidance Unchanged

- Total Net Revenue (NR) of 266m in Line with Expectations
- SUBLOCADE® NR of 176m is Consistent with FY 2025 Guidance of 725m to 765m
- On Track to Deliver Gross Annual Operating Expense Savings of Over 100m in FY 2025

Unaudited, m	Q1 2025	Q1 2024	% Change[2]
Net Revenue	**266**	**284**	**(6)%**
Operating Income	**66**	**75**	**(12)%**
Net Income	**47**	**61**	**(23)%**
Diluted EPS[2] ( )	**0.38**	**0.45**	**(15)%**
Non-GAAP Measures			
Non-GAAP Operating Income[1]	**69**	**76**	**(10)%**
Non-GAAP Net Income[1]	**51**	**57**	**(11)%**
Non-GAAP Diluted EPS[1,2] ( )	**0.41**	**0.42**	**(2)%**

[1] Non-GAAP measures exclude the impact of non-recurring items and other adjustments. Refer to "Reconciliation of GAAP to non-GAAP financial information" on page 11. Non-GAAP measures are not a substitute for, or superior to, results presented in accordance with US GAAP.

[2] Percentages and per share data have been calculated using actual, non-rounded figures.

The "Company" refers to Indivior PLC and its consolidated subsidiaries.

"Our first quarter results were in line with our planning assumptions and consistent with our FY 2025 outlook," said Mark Crossley, Chief Executive Officer. "Net revenue performance was primarily impacted by intensified generic competition for SUBOXONE Film in the U.S. and the discontinuation of PERSERIS in the prior year. SUBLOCADE continued to grow solidly year-over-year in organized health systems (OHS), but as expected, net revenue declined modestly due to near-term impacts from funding gaps among certain justice system customers. We expect to generate SUBLOCADE growth again in the second half of FY 2025 from our increased marketing investments and the important FDA-approved label changes that further improve the patient and physician experience."

"As previously announced, I will be stepping down as CEO of Indivior next month. It has been an honor to lead the Company over the past five years and I would like to add a personal note of thanks to all my colleagues for tirelessly pursuing our goal of making meaningful recovery from addiction humanly possible. The opioid epidemic remains one of the greatest health challenges of our time and our mission and vision are as relevant as ever. I believe that our team, under Joe Ciaffoni's leadership, will deliver the next chapter of growth and value creation for Indivior."

Q1 2025 Product Highlights

- **SUBLOCADE (buprenorphine extended-release) Injection:** Overall Q1 2025 NR of 176m (2)% vs. Q1 2024. As expected, the modest year-over-year decline in SUBLOCADE NR in Q1 2025 reflected solid dispense volume growth in the organized health system (OHS) channel, more than offset by an expected dispense volume decline in the justice system channel due to near-term funding gaps among certain customers as well as unfavorable pricing/channel mix. Total U.S. patients on a 12-month rolling basis at the end of Q1 2025 were approximately 170,700 (+14% vs. Q1 2024 and unchanged vs. Q4 2024). Q1 2025 U.S. units dispensed were approximately 151,900 (+2% vs. Q1 2024 and (6)% vs. Q4 2024).
- **OPVEE® (nalmefene) nasal spray:** Q1 2025 NR was immaterial. Near-term launch focus is on supporting policy changes to enable broader access to nalmefene opioid rescue treatments and on increasing product trial among targeted users.
- **SUBOXONE® (buprenorphine/naloxone) Film:** U.S. SUBOXONE Film net revenue declined in Q1 2025 due to intensified competitive activity from generic film providers. U.S. SUBOXONE Film share of oral buprenorphine medication assisted treatment (BMAT) was 14.8% in Q1 2025 (Q1 2024: 17.5%), in-line with the Company's expectations.

SUBLOCADE Label Update

On February 24, 2025, the FDA approved label changes for SUBLOCADE, including a rapid initiation protocol and alternative injection sites, which further improve the patient and physician experience and mark an advancement in the treatment of moderate to severe opioid use disorder (OUD). Key SUBLOCADE label changes include:

- **Rapid Initiation Protocol:** Healthcare providers can now initiate treatment with SUBLOCADE after a single dose of transmucosal buprenorphine and a one-hour observation period to confirm tolerability. In addition, the second injection of SUBLOCADE may be administered as early as one week after the first injection to rapidly achieve and maintain target plasma buprenorphine levels (>2-3 ng/mL) to control symptoms of craving and withdrawal, particularly in synthetic opioid users.
- **Alternative Injection Sites**: 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.

Pipeline Update

- **INDV-2000** (Selective OREXIN-1 Receptor Antagonist): Phase 2 proof of concept study. First subject first visit achieved

June 10, 2024. Estimated last subject last visit is now expected in H1 2026 (previously Q4 2025). The delay is due to a lower than expected conversion rate from subject screening to study enrollment.

- **INDV-6001** (3-Month Buprenorphine Long-acting Injectable): Multiple dose clinical Phase 2 Pharmacokinetics (PK) study. First subject first visit achieved September 17, 2024. Estimated last subject last visit is Q4 2025.

Share Repurchase Program

Indivior's fourth 100m share repurchase program was completed on January 31, 2025. Under this program, the Company repurchased and canceled 9,415,726 Indivior ordinary shares at a weighted average purchase price of 10.62.

FY 2025 Guidance Unchanged

The Company's guidance for FY 2025 under U.S. GAAP is unchanged.

Guidance assumes no material change in exchange rates for key currencies compared with FY 2024 average rates, notably USD/GBP and USD/EUR. Guidance also assumes no material change to Medicaid eligibility policy and/or other changes to Federal funding levels due to executive actions. Guidance also does not include any potential impacts from tariffs imposed by the U.S. government or any retaliatory tariffs that may be imposed by other countries.

	FY 2025
Net Revenue (NR)	955m to 1,025m (-17% at the mid-point vs. FY 2024)
SUBLOCADE NR	725m to 765m (-1% at the mid-point vs. FY 2024)
OPVEE NR	10m to 15m
SUBOXONE Film Market Share	Accelerated NR decline in FY 2025 reflecting increased generic competitive activity and the potential impact from a fifth buprenorphine/naloxone sublingual film generic in the U.S. market
Non-GAAP Gross Margin	Low to mid-80s % range
Non-GAAP SG&A	(525m) to (535m)
Non-GAAP R&D	(85m) to (90m)
Non-GAAP Operating Income	185m to 225m

U.S. OUD Market Update

In Q1 2025, U.S. BMAT grew mid-single digits in volume terms. 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 awareness of the opioid epidemic and approved treatments and ongoing destigmatization efforts. Regulatory and legislative actions are also expected to increase access to BMAT treatments.

Financial Performance in Q1 2025

Total NR in Q1 2025 decreased 6% to 266m (Q1 2024: 284m) at actual exchange rates (5% decrease at constant exchange rates[1]).

U.S. NR decreased 8% in Q1 2025 to 222m (Q1 2024: 241m). In Q1 2025, U.S. SUBLOCADE NR decreased 3% to 163m (Q1 2024: 168m). The decrease in U.S. NR was primarily driven by the decline in SUBOXONE Film due to intensified generic competition that resulted in lower oral BMAT market share and lower pricing. The decline in PERSERIS (risperidone) extended release injection NR also contributed to the decline in U.S. NR due to discontinuation of promotion for the treatment in July 2024. SUBLOCADE NR was modestly lower year-over-year as described above.

Rest of the World NR increased 3% at actual exchange rates in Q1 2025 to 44m (Q1 2024: 42m; +1% at constant exchange rates[1]). In both periods, positive contributions from new products (SUBLOCADE / SUBUTEX® Prolonged Release and SUBOXONE Film) were partially offset by ongoing generic erosion of the legacy SUBUTEX (buprenorphine) tablet business. In Q1 2025, SUBLOCADE / SUBUTEX Prolonged Release NR increased 1m to 13m (Q1 2024: 12m) at actual exchange rates.

Gross margin in Q1 2025 was 83% (Q1 2024: 87%). The year-over-year decline primarily reflects favorable manufacturing variances for SUBLOCADE inventory sold in the same year-ago quarter.

SG&A expense in Q1 2025 was 132m (Q1 2024: 143m). Non-GAAP SG&A expense in Q1 2025 decreased 8% to 130m (non-GAAP Q1 2024: 142m) and primarily reflects benefits from streamlining actions taken in 2024, including narrowing the Company's commercial focus on OUD treatments and discontinuing PERSERIS in July 2024. Q1 2025 SG&A expense also benefited from a low to mid-single digit million change in estimate related to Indivior's share of the Branded Fee.

R&D expense in Q1 2025 was 22m (Q1 2024: 28m) and decreased 19% reflecting the Company's actions to refocus its development pipeline on its Phase 2 OUD assets (INDV-2000 and INDV-6001).

Operating income was 66m in Q1 2025 (Q1 2024: 75m). The change reflects lower NR and higher cost of sales, partially offset by decreased operating expenses (SG&A and R&D combined).

After excluding non-GAAP adjustments of 3m and 2m in Q1 2025 and Q1 2024, respectively, Q1 2025 non-GAAP operating income decreased 10% to 69m (Q1 2024: 76m). The decrease primarily reflects the drivers discussed above.

Net interest expense was 7m in Q1 2025 (Q1 2024: 2m) reflecting the Company's new borrowing secured in Q4 2024.

Tax expense was 11m in Q1 2025, resulting in an effective tax rate of 19% (Q1 2024: 11m, effective rate 16%). Both periods benefited from U.K. innovation deductions and intragroup financing transactions. In Q1 2025, this benefit was partially offset by a U.K. global minimum top-up tax. In Q1 2024, the Company recognized a share-compensation excess tax benefit. This excess tax benefit is excluded from the Company's non-GAAP results.

Net income in Q1 2025 was 47m and non-GAAP net income was 51m (Q1 2024 net income: 61m, non-GAAP net income: 57m). The decline in net income primarily reflects lower NR and higher net interest expense, partly offset by lower operating expenses (SG&A and R&D combined).

Diluted earnings per share in Q1 2025 were 0.38 and non-GAAP diluted earnings per share were 0.41 (Q1 2024: 0.45 diluted earnings per share and non-GAAP diluted earnings per share of 0.42). The modest decrease in non-GAAP diluted earnings per share in Q1 2025 includes the impact of the lower number of ordinary shares outstanding as a result of the Company's share repurchase programs.

[1] Net revenue at constant exchange rates is an alternative performance measure used by management to evaluate underlying performance of the business and is calculated by applying the prior year exchange rate to current year net revenue in the currencies of the non-U.S. entities.

Balance Sheet & Cash Flow

Cash and investments totaled 400m at the end of Q1 2025, an increase of 53m versus 347m at the end of 2024. The increase was due to a combination of cash generated by operations and reduced net working capital due to the late receipt of government rebate invoices totaling approximately 100m, as reflected in the increase in Accrued Rebates and Product Returns on the balance sheet. These benefits were partially offset by litigation settlement payments of 65m.

Cash provided by operating activities in Q1 2025 was 75m (Q1 2024 cash used in operating activities: 37m), reflecting cash from operations and the late receipt of government rebate invoices, partly offset by litigation settlement payments. Cash used in operations in Q1 2024 reflected litigation settlement payments, partly offset by cash from operations.

Cash used in investing activities in Q1 2025 was 5m (Q1 2024 cash provided by investing activities: 25m) primarily reflecting capital expenditures in Q1 2025. Cash provided by investing activities in 2024 was driven by maturities of investment securities.

Cash used in financing activities in Q1 2025 was 17m (Q1 2024: 56m) reflecting lower cash outflows in Q1 2025 for share repurchases and net settlement of equity awards partially offset by higher repayments under the new debt facility.

Revision to Previously Issued Financial Statements

Indivior has revised its previously issued financial statements to correct the methodology used to accrue for the Company's share of the annual U.S. fee imposed on drug manufacturers (the 'Branded Fee'). This resulted from an immaterial overstatement of SG&A of 6m in 2024, 4m in 2023, 4m in 2022, and 2m before 2022. The adjustments increase operating income and impact the quarters evenly over the respective year. The cumulative impact to Accounts Payable and Accrued Expenses at December 31, 2024 was 16m.

The discussion of financial performance and the financial statements included in this announcement reflect the revised results for Q1 2024. The revised financial statements for the impacted periods noted will be included in the Company's Form 10-Q as of March 31, 2025.

Webcast Details

A live webcast presentation will be held on April 24, 2025, at 13:00 GMT (8:00 am EDT). The details are below. Materials will be available on the Company's website prior to the event at www.indivior.com. Please copy and paste the below web links into your browser.

The webcast link is: https://edge.media-server.com/mmc/p/yn37cxqk

Participants may access the presentation telephonically by registering with the following link (please cut and paste into your browser):

https://register-conf.media-server.com/register/BI4482694d7c294502b6a4dedd62e88c5b

(*Registrants will have an option to be called back directly immediately prior to the call or be provided a call-in # with a unique pin code following their registration)*

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This announcement does not constitute an offer to sell, or the solicitation of an offer to subscribe for or otherwise acquire or dispose of shares in the Company to any person in any jurisdiction to whom it is unlawful to make such offer or solicitation.

About Indivior

Indivior is a global pharmaceutical company working to help change patients' lives by developing medicines to treat opioid use disorder (OUD). Our vision is that all patients around the world will have access to evidence-based treatment for OUD and we are dedicated to transforming OUD from a global human crisis to a recognized and treated chronic disease. Building on its global portfolio of OUD treatments, Indivior has a pipeline of product candidates designed to expand on its heritage in this category. Headquartered in the United States in Richmond, VA, Indivior employs over 1,000 individuals globally and its portfolio of products is available in over 30 countries worldwide. Visit www.indivior.com to learn more. Connect with Indivior on LinkedIn by visiting www.linkedin.com/company/indivior.

Non-GAAP Financial Measures

This announcement includes financial measures that are not measures defined by US GAAP, such as non-GAAP selling, general and administrative expenses, non-GAAP operating income, non-GAAP net income and non-GAAP diluted earnings per share. These non-GAAP financial measures are not a substitute for, or superior to, results presented in accordance with US GAAP. Non-GAAP results as presented by the Company are not necessarily comparable to similarly titled measures used by other companies. As a result, these performance measures should not be considered in isolation from, or as a substitute analysis for, the Company's results as reported in accordance with US GAAP. Management performs a quantitative and qualitative assessment to determine if an item should be considered for adjustment.

Management may use the Company's non-GAAP financial measures to better understand trends in the business and these non-GAAP financial measures may be useful to investors. Non-GAAP financial measures adjust for non-recurring items and other items representing significant expenses or income that we believe do not reflect the Company's ongoing operations or the adjustment of which may help with the comparison to prior periods. Non-recurring items and other adjustments are excluded from non-GAAP financial measures consistent with the internal reporting provided to management and the Directors. Examples of such items could include income or restructuring and related expenses from the reconfiguration of the Company's activities and/or capital structure, impairment of current and non-current assets, gains and losses from the sale of intangible assets, certain costs arising as a result of significant and non-recurring regulatory and litigation matters, and certain tax related matters.

We have not provided the forward-looking U.S. GAAP equivalents for certain forward-looking non-U.S. GAAP metrics as a

We have not provided the forward-looking U.S. GAAP equivalents for certain forward-looking non-U.S. GAAP metrics as a result of the uncertainty and potential variability of reconciling items. Accordingly, the Company has relied upon the exception in item 10(e)(1)(i)(B) of Regulation S-K to exclude such reconciliations, as the reconciliations of these non-U.S. GAAP guidance metrics to their corresponding U.S. GAAP equivalents are not available without unreasonable effort.

Columns and rows within financial tables may not foot due to rounding. Percentages and per share data have been calculated using actual, non-rounded figures.

Important Cautionary Note Regarding Forward-Looking Statements

This announcement 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 gross margins for 2025 and its medium- and long-term growth outlook; 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 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; assumptions regarding future exchange rates; expected timing of our previously-announced CEO transition; our expectations that we can reach a final settlement related to the provision we recorded regarding opioid litigation (including the 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 growth in the number of BMAT treatments administered in the U.S., growing normalization of medically assisted treatment for opioid use disorder, and expanded access to treatment; our product development pipeline and potential future products, including the timing of clinical trials, expectations regarding regulatory approval of such product candidates, the timing of such approvals, and the timing of potential commercial launch of such products or product candidates, and eventual annual revenues of such future products; 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," the negatives thereof, and variations thereon and similar expressions. By their nature, forward-looking statements involve risks and uncertainties as they relate to events or circumstances that may or may not occur in the future.

Actual results may differ materially from those expressed or implied in these forward-looking statements due to a number of factors, including: lower than expected future sales of our products; greater than expected impacts from competition; failure to achieve market acceptance of OPVEE; unanticipated costs including the effects of potential tariffs and potential retaliatory tariffs; whether we are able to identify efficiencies and fund additional investments that we expect to generate increased revenues, and the timing of such actions; and litigants with whom we are otherwise unable or unwilling to agree to final terms, or who choose to "opt out" of proposed settlements. For additional information about some of the risks and important factors that could affect our future results and financial condition, see "Risk Factors" in Indivior's Annual Report on Form 10-K filed March 3, 2025 and our other filings with the U.S. Securities and Exchange Commission.

We have based the forward-looking statements in this report on our current expectations and beliefs concerning future events. Forward-looking statements contained in this report speak only as of the day they are made and, except as required by law, we undertake no obligation to update or revise any forward-looking statement, whether due to new information, future developments or otherwise.

Consolidated statements of operations

Three Months Ended March 31,	**Q1 2025**	Q1 2024
Net revenue	**266**	284
Cost of sales	**44**	38
Gross profit	**221**	246
Selling, general and administrative	**132**	143
Research and development	**22**	28
Litigation settlement	**1**	-
Operating income	**66**	75
Interest income	**4**	7
Interest expense	**(12)**	(9)
Income before income taxes	**59**	73
Income tax expense	**(11)**	(11)
Net income	**47**	61
Earnings per share		
Basic	**0.38**	0.45
Diluted	**0.38**	0.45

Consolidated balance sheets

	Mar 31, 2025	Dec 31, 2024
Assets		
Current assets		
Cash and cash equivalents	372	319
Short-term investments	1	1
Accounts receivable, net of allowances of 2 (2025) and 3 (2024)	243	254
Inventories	163	167
Prepaid expenses	56	31
Current tax receivable	29	33
Other current assets	20	21
Total current assets	**883**	827
Long-term investments	27	27
Property, plant and equipment, net	104	100
Operating lease right of use assets, net	37	39
Goodwill and other intangible assets, net	7	6
Deferred tax assets	279	277
Other non-current assets	39	39
Total assets	**1,375**	1,316
Liabilities and shareholders' deficit		
Current liabilities		
Accrued rebates and product returns	675	562

Accounts payable and accrued expenses	183	216
Accrued litigation settlement expenses, current	105	99
Current portion of long-term debt	18	18
Operating lease liabilities, current	11	10
Income taxes payable	12	7
Other current liabilities	3	11
Total current liabilities	**1,005**	924
Long-term debt, less current portion	311	315
Accrued litigation settlement expenses, non-current	297	365
Operating lease liabilities, non-current	30	32
Other non-current liabilities	17	18
Total liabilities	**1,660**	1,652
Shareholders' deficit		
Common stock, par value 0.50 per share Issued shares: 125 (2025) and 125 (2024)	62	62
Additional paid-in capital	93	90
Share repurchase commitment	-	(10)
Accumulated other comprehensive loss	(35)	(36)
Accumulated deficit	(406)	(443)
Total shareholders' deficit	**(285)**	(337)
Total liabilities and shareholders' deficit	**1,375**	1,316

Consolidated statements of cash flows

Three Months Ended March 31,	**Q1 2025**	**Q1 2024**
Cash flows from operating activities:		
Net income	**47**	**61**
Adjustments to reconcile net income to net cash from operating activities:		
Depreciation and amortization	5	5
Share-based compensation expense	6	6
Impairment of tangible and intangible assets	0	1
Deferred income taxes	(2)	3
Impact from foreign exchange movements	(1)	(1)
Other adjustments, net	1	1
Change in operating assets and liabilities	18	(113)
Net cash provided by (used in) operating activities	**75**	**(37)**
Cash flows from investing activities:		
Purchases of property and equipment	(5)	(2)
Purchases of in-process research and development and intangible assets	-	(1)
Purchases of investments in debt securities	(5)	(4)
Sales and maturities of debt securities	6	31
Net cash (used in) provided by investing activities	**(5)**	**25**
Cash flows from financing activities:		
Proceeds from the issuance of common stock	1	1
Cash paid for repurchases of common stock	(11)	(36)
Repayments of debt	(4)	(1)
Settlement of tax on equity awards	(3)	(20)
Net cash used in financing activities	**(17)**	**(56)**
Net increase (decrease) in cash and cash equivalents	**53**	**(68)**
Cash and cash equivalents at beginning of period	319	316
Cash and cash equivalents at end of period	**372**	**248**

Selected revenue and expense information

Three Months Ended March 31,	**Q1 2025**	Q1 2024
US:		
SUBLOCADE	163	168
Sublingual & other	54	63
PERSERIS[1]	4	11
Total U.S.	**222**	**241**
Rest of World	44	42
Net revenue	**266**	**284**
***Total SUBLOCADE net revenue**	**176**	**179**
Selling, general and administrative expenses:		
Selling and marketing	67	67
Administrative and general	65	77
Total selling, general and administrative expenses	**132**	**143**

[1] Marketing and promotion activities for PERSERIS were discontinued in July 2024.

Reconciliation of GAAP to non-GAAP financial information

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

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

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

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

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

Three Months Ended March 31,	Q1 2025	Q1 2024
GAAP net income	**47**	61
Adjustments in selling, general and administrative expenses	**2**	2
Litigation settlement expenses	**1**	-
Adjustments in tax expenses	**-**	(6)
Non-GAAP net income	**51**	57
Non-GAAP earnings per share		
Non-GAAP diluted earnings per share	0.41	0.42
Shares used in computing non-GAAP earnings per share		
Diluted	125	137

Non-GAAP diluted earnings/(loss) per share

Management believes that Non-GAAP diluted earnings/(loss) per share, adjusted for the impact of non-recurring items and other adjustments after the appropriate tax amount, may provide meaningful information on underlying trends to shareholders in respect of earnings per ordinary share. Weighted average shares used in computing non-GAAP diluted earnings per share are included in the table above. A reconciliation of GAAP net income to non-GAAP net income is included above.

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