



Q1 2023 Earnings Call

APRIL 27, 2023

Agenda

INTRODUCTION AND RECENT KEY EVENTS

Dave Ricks, Chair and Chief Executive Officer

Q1 2023 FINANCIAL RESULTS

Anat Ashkenazi, Chief Financial Officer

R&D UPDATE

Dan Skovronsky, M.D., Ph.D., Chief Scientific and Medical Officer

CLOSING REMARKS

Dave Ricks, Chair and Chief Executive Officer

QUESTION AND ANSWER SESSION

2023 **Q1 EARNINGS**

SAFE HARBOR PROVISION



This presentation contains forward-looking statements that are based on management's current expectations, but actual results may differ materially due to various factors. The company's results may be affected by factors including, but not limited to, the risks and uncertainties in pharmaceutical research and development; competitive developments; regulatory actions; the extent and duration of the effects of the COVID-19 pandemic; litigation and investigations; business development transactions; economic conditions; and changes in laws and regulations, including health care reform.

For additional information about the factors that affect the company's business, please see the company's latest Forms 10-K, 10-Q, and any 8-Ks filed with the Securities and Exchange Commission. Certain financial information in this presentation is presented on a non-GAAP basis. Investors should refer to the reconciliations included in this presentation and should consider the company's non-GAAP measures in addition to, not as a substitute for or superior to, measures prepared in accordance with GAAP.

The company undertakes no duty to update forward-looking statements
except as required by applicable law

STRATEGIC DELIVERABLES

PROGRESS SINCE THE LAST EARNINGS CALL



Invest in Current Portfolio



- **Gross Margin:** Non-GAAP gross margin of 78.4% in Q1
- **SG&A:** 12% increase in Q1 driven by launches of new products and indications

Invest in Future Innovation



- **R&D:** 23% increase in Q1 driven by late-stage assets
- **CAPEX:** Announced an additional \$1.6 billion investment in Boone County, Indiana manufacturing sites
- **Business Development:** Entered into agreements to sell the rights to Lilly's olanzapine portfolio and Baqsimi

Deliver Revenue Growth



- Revenue grew 10% in Q1, excluding revenue from COVID-19 antibodies¹
- Q1 revenue driven by 18% volume growth, excluding revenue from COVID-19 antibodies
- New Products and Growth Products² drove 20 percentage points of volume growth in Q1

Speed Life-Changing Medicines



- FDA approval of an expanded indication for **Verzenio**[®]
- Approval of **mirikizumab** in Japan, positive CHMP opinion in the EU, and a Complete Response Letter in the U.S.
- Regulatory submissions for **tirzepatide** obesity in the EU and **lebrikizumab** for atopic dermatitis in Japan
- Announced that **tirzepatide** achieved superior weight loss compared to placebo at 72 weeks in the Phase 3 SURMOUNT-2 study

Return Capital to Shareholders via

- **Dividend:** Distributed over \$1 billion via dividends in Q1
- **Share Repurchase:** \$750 million in Q1

¹ Sales for COVID-19 antibodies include bamlanivimab, etesevimab and bebtelovimab sold pursuant to Emergency Use Authorization or similar regulatory authorizations

² Refer to slide 8 for a list of New Products and Growth Products

KEY EVENTS SINCE THE LAST EARNINGS CALL



REGULATORY

- **OmvoH® (mirikizumab)** approved in Japan for ulcerative colitis, Europe's CHMP issued a positive opinion for mirikizumab, and the U.S. FDA issued a complete response letter for mirikizumab;
- Announced that the FDA approved an expanded indication for **Verzenio**, for the adjuvant treatment of adult patients with HR+, HER2-, node-positive early breast cancer at high risk of recurrence. This expanded indication removes the Ki-67 score requirement for patients;
- Europe's CHMP issued a positive opinion for **Jaypirca®** for the treatment of relapsed or refractory mantle cell lymphoma;
- Announced the regulatory submissions of **tirzepatide** for obesity in the EU and **lebrikizumab** for atopic dermatitis in Japan; and
- Based on the Phase 3 results from the DINAMO trial, the FDA accepted the supplemental New Drug Application for **Jardiance®**¹ for children 10 years and older with type 2 diabetes.

CLINICAL

- Announced that **tirzepatide** achieved superior weight loss compared to placebo at 72 weeks in the Phase 3 SURMOUNT-2 study;
- Presented data at the 2023 American Association for Cancer Research (AACR) from our Phase 1 study of **KRAS G12C** inhibitor;
- Presented data at AACR from CYCLONE-1, a single-arm unblinded study, which was the first to investigate **Verzenio** in prostate cancer;

CLINICAL (CONT.)

- Presented data at the 2023 International Conference on Alzheimer's and Parkinson's Disease (AD/PD) from TRAILBLAZER-EXT, a Phase 2 long-term study of our Phase 2 TRAILBLAZER-ALZ **donanemab** study;
- Presented the first clinical data at AD/PD for **remternetug** from an interim analysis of a Phase 1 double-blind, randomized multiple ascending dose study, which highlighted the speed and depth of amyloid plaque lowering in patients with Alzheimer's disease; and
- Announced that **solanezumab** did not slow the progression of cognitive decline due to Alzheimer's disease pathology when initiated in individuals with amyloid plaque but no clinical symptoms of the disease.

OTHER

- Announced price reductions of 70% for Lilly's most commonly prescribed **insulins** and an expansion of the Insulin Value Program that caps patient out-of-pocket costs at \$35 or less per month;
- Announced an additional \$1.6 billion investment in Lilly's two new **manufacturing sites** in Indiana, bringing the total commitment to \$3.7 billion; and
- Announced a collaboration with **International Agencies (Bangladesh) Ltd.** for human insulin to increase patient access and improve affordability for high-quality insulin for nearly one million people living with diabetes in Bangladesh.

¹ Jardiance is part of the Boehringer Ingelheim (BI) and Lilly Alliance, and BI holds the marketing authorization for Jardiance

RECONCILIATION OF GAAP REPORTED TO NON-GAAP ADJUSTED INFORMATION; CERTAIN LINE ITEMS (UNAUDITED)



Millions; except per share data

Q1 2023

	GAAP Reported	Adjustments	Non-GAAP Adjusted	YoY Non-GAAP Adjusted Change
TOTAL REVENUE	\$6,960	\$ -	\$6,960	(11)%
GROSS MARGIN	76.6%	1.8pp	78.4%	2.3pp
TOTAL OPERATING EXPENSE	3,839	-	3,839	15%
OPERATING INCOME	1,494	126	1,620	(38)%
OPERATING MARGIN	21.5%	1.8pp	23.3%	(10.1)p
OTHER INCOME (EXPENSE)	36	23	58	55%
EFFECTIVE TAX RATE	12.1%	0.7pp	12.8%	2.5pp
NET INCOME	\$1,345	\$119	\$1,464	(38)%
EPS	\$1.49	\$0.13	\$1.62	(38)%
Acquired IPR&D Charges per share*	\$0.10	\$ -	\$0.10	(33)%

*Acquired IPR&D of \$105 million (pre-tax)

Numbers may not add due to rounding; see slide 26 for a complete list of adjustments

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2023 Q1 EARNINGS

PRICE/RATE/VOLUME EFFECT ON REVENUE



Millions

Q1 2023

	<u>Amount</u>	<u>Price</u>	<u>FX Rate</u>	<u>Volume</u>	<u>Total</u>	<u>CER</u>
U.S.	\$4,436	(5)%	-	(10)%	(14)%	(14)%
EUROPE	1,091	(6)%	(6)%	13%	2%	8%
JAPAN	387	(0)%	(13)%	8%	(6)%	7%
CHINA	373	(20)%	(7)%	19%	(8)%	(1)%
REST OF WORLD	673	2%	(2)%	(11)%	(10)%	(9)%
TOTAL REVENUE	\$6,960	(5)%	(2)%	(4)%	(11)%	(9)%

Numbers may not add due to rounding

CER = price change + volume change

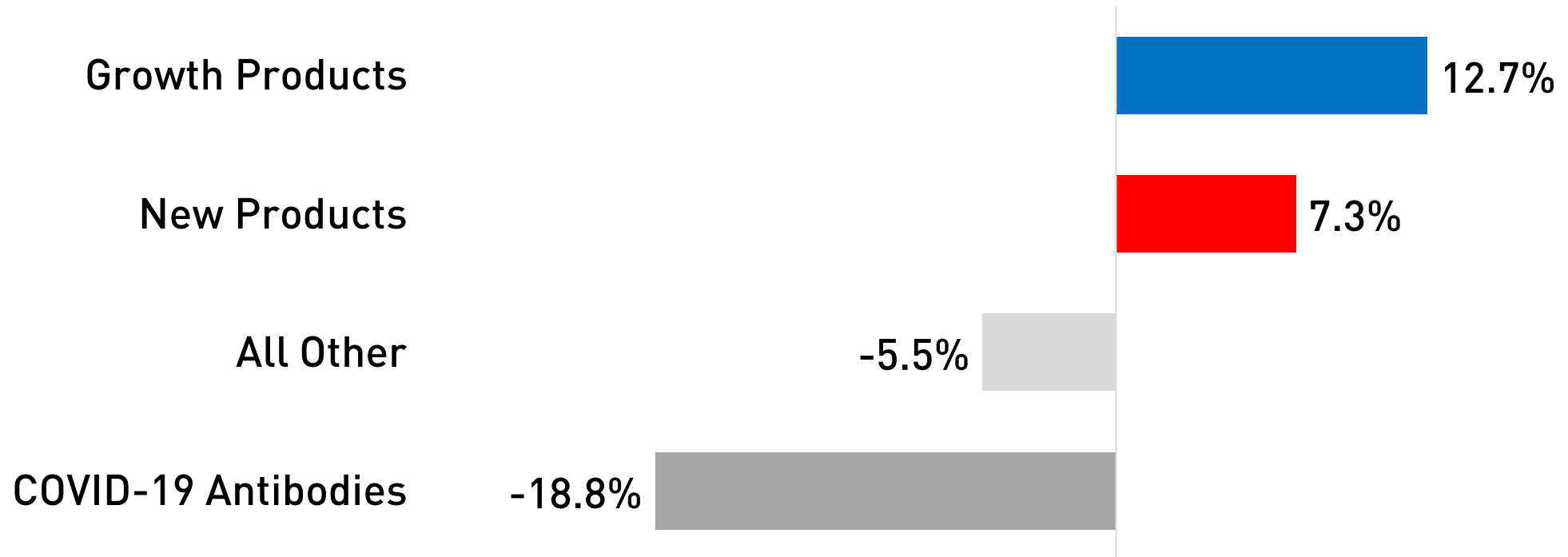
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2023 Q1 EARNINGS

PRODUCTS DRIVING WW VOLUME



Contribution to 4% Q1 WW Volume Decline



Numbers may not tie due to rounding

New Products: Jaypirca and Mounjaro®

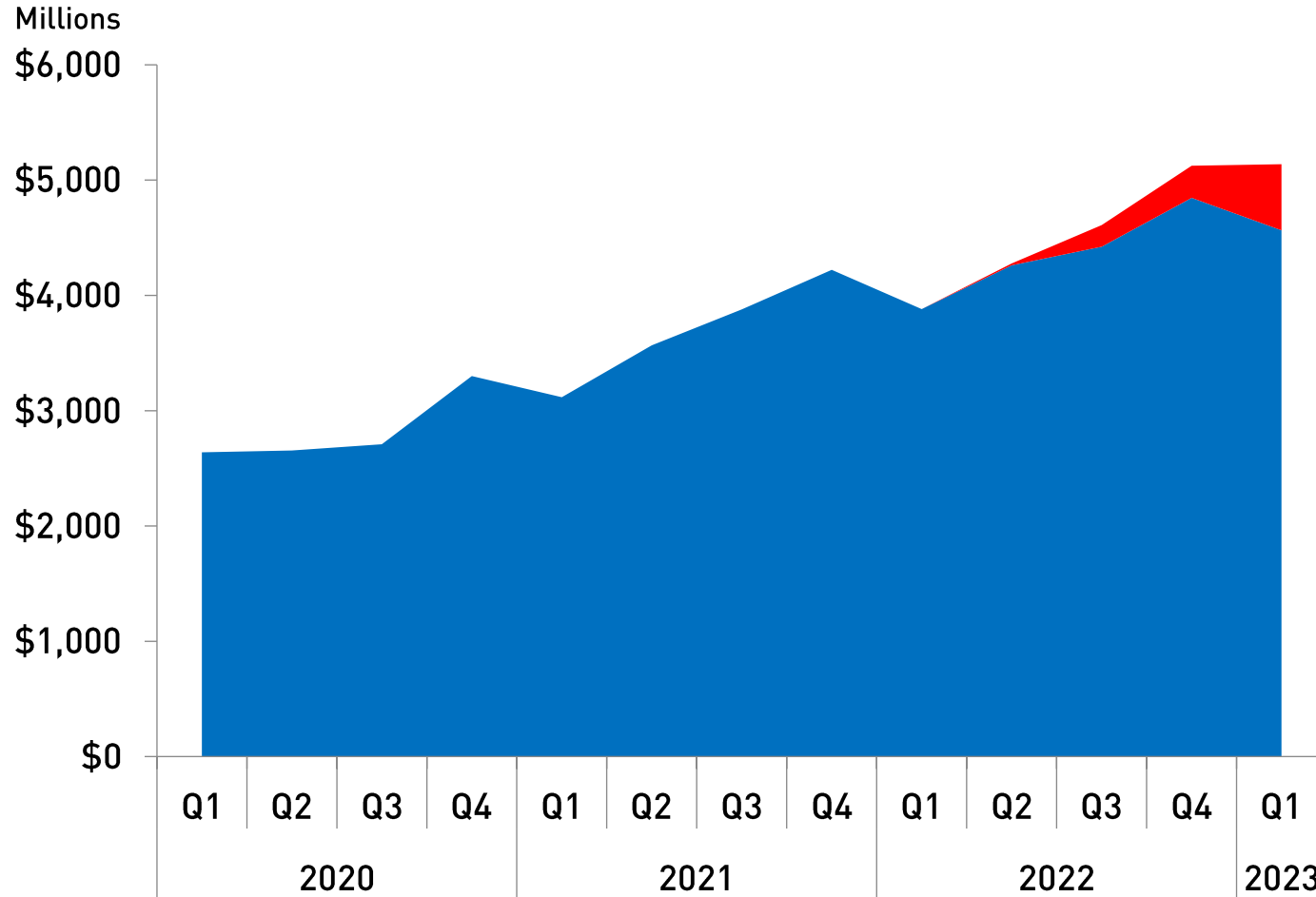
Growth Products: Cyramza®, Emgality®, Jardiance, Olumiant®, Retevmo®, Taltz®, Trulicity®, Tyvyt®, and Verzenio

COVID-19 Antibodies: bamlanivimab, etesevimab and bebtelovimab for the treatment of COVID-19 sold pursuant to Emergency Use Authorization or similar regulatory assumptions

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2023 Q1 EARNINGS

Q1 2023 UPDATE ON SELECT PRODUCTS



NEW PRODUCTS

MOUNJARO

- U.S. T2D launch in Q2 2022
- U.S. T2D injectable incretins TRx SOM nearly 20% at end of Q1 2023

JAYPIRCA

- U.S. MCL approval in Q1 2023

GROWTH PRODUCTS

JARDIANCE

- Market leader in U.S. with TRx SOM of 62%
- U.S. TRx grew nearly 32% vs. Q1 2022, outpacing the market

TALTZ

- U.S. TRx SOM nearly 6%
- U.S. TRx grew nearly 9% vs. Q1 2022, outpacing the market

TRULICITY

- U.S. T2D injectable incretins TRx SOM of 31%
- U.S. TRx grew nearly 17% vs. Q1 2022

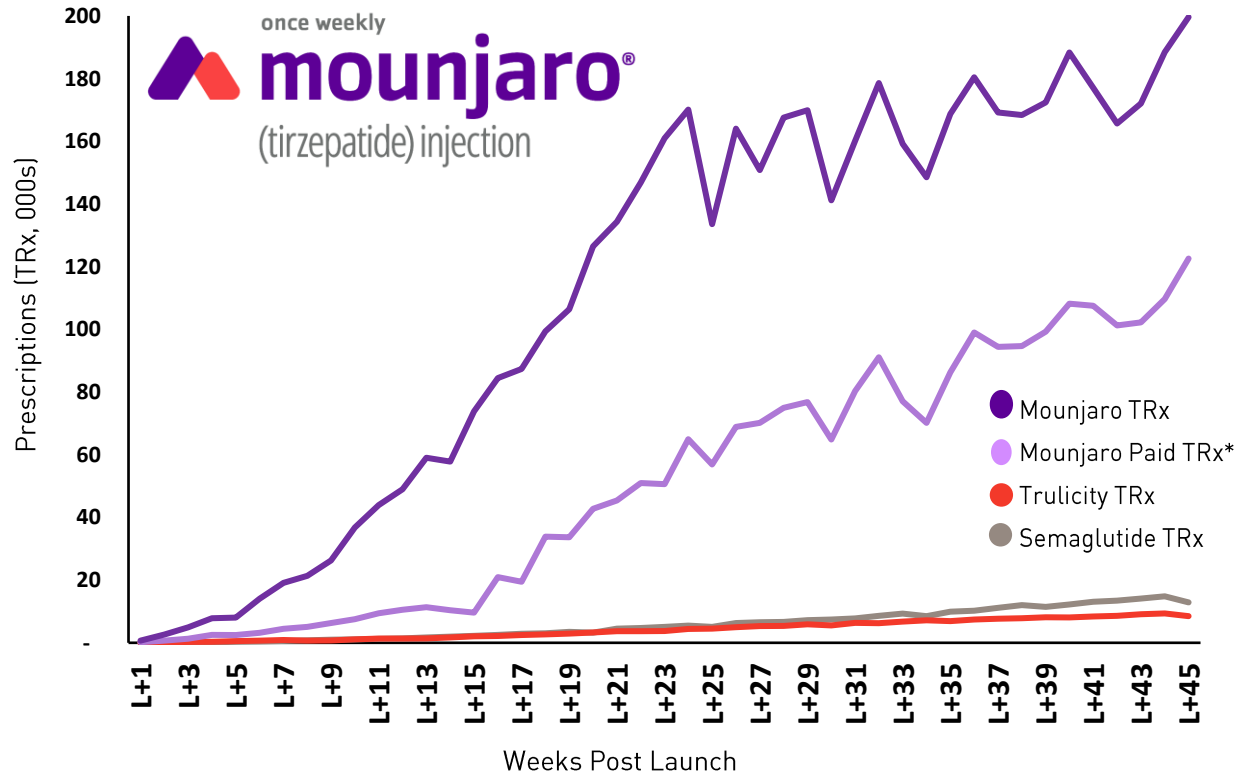
VERZENIO

- U.S. TRx grew 73% vs. Q1 2022
- Strong uptake in adjuvant breast cancer indication

New Products: Jaypirca and Mounjaro

Growth Products: Cyramza, Emgality, Jardiance, Olumiant, Retevmo, Taltz, Trulicity, Tyvyt, and Verzenio

MOUNJARO LAUNCH PROGRESS



Mounjaro volume has significantly outpaced prior launches in the type 2 diabetes injectable incretin class

- Robust U.S. uptake bolstered by strong efficacy and a positive customer experience
- As expected, script trajectory impacted in Q4 2022 following adjustments to the savings card program
- Access as of April 1st just under 60% for patients with type 2 diabetes across total commercial and Part D lives
- Percentage of paid prescriptions rose to over 55% in Q1 due to the Q4 copay program changes and improved access
- Focus on driving new-to-brand growth while continuing access expansion

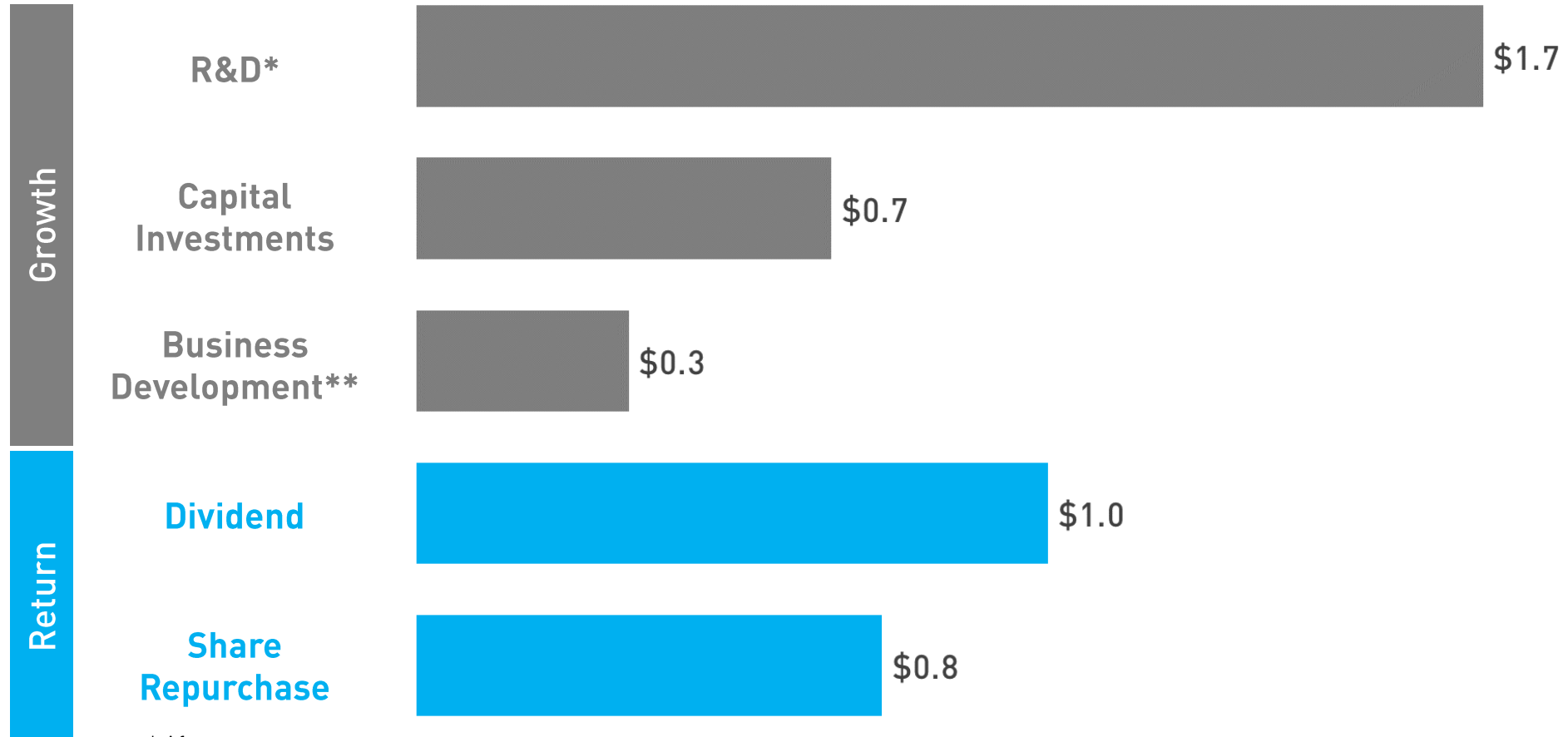
*Internal estimate of weekly paid TRx
IQVIA weekly data for week ending April 14, 2023 (type 2 diabetes injectable incretin class)

CAPITAL ALLOCATION



Billions

Q1 2023 Capital Allocation



* After tax

** Includes development milestones and cash outflows associated with equity investments

2023 GUIDANCE



	Prior	Updated	COMMENTS
REVENUE	\$30.3 – \$30.8 billion	\$31.2 – \$31.7 billion	Increased range by \$900 million driven by approximately \$650 million associated with updates to foreign exchange rate assumptions with the remainder attributable to underlying business performance
GROSS MARGIN % OF REVENUE (GAAP) GROSS MARGIN % OF REVENUE (NON-GAAP)	Approx. 77% Approx. 79%	Unchanged	
MKTG, SELLING & ADMIN.	\$6.9 – \$7.1 billion	\$7.0 – \$7.2 billion	Increased range to reflect updated foreign exchange rate assumptions
RESEARCH & DEVELOPMENT	\$8.2 – \$8.4 billion	\$8.3 – \$8.5 billion	Increased range to reflect updated foreign exchange rate assumptions and investment in our late-stage portfolio
ACQUIRED IPR&D	-	\$105 million	Incorporated IPR&D charges that have been incurred or realized as of the date of earnings; does not include any IPR&D charges associated with potential or pending business development transactions
OTHER INCOME/(EXPENSE)	\$(200) – \$(100) million	Unchanged	
TAX RATE	Approx. 13%	Unchanged	
EARNINGS PER SHARE (GAAP) EARNINGS PER SHARE (NON-GAAP)	\$7.90 – \$8.10 \$8.35 – \$8.55	\$8.18 – \$8.38 \$8.65 – \$8.85	Based on the above changes, full year non-GAAP EPS range increased by 30 cents; GAAP change impacted by \$0.02 Q1 loss on investments in equity securities through Q1 2023

2023 assumes shares outstanding of 904 million

FX assumptions: 1.09 (Euro), 133 (Yen) and 6.9 (Renminbi)

SURMOUNT PROGRAM

TIRZEPATIDE EVALUATED ACROSS A BROAD PATIENT POPULATION



Phase 3 Study	Est. Read-out Date	Study Size (pts)	Studied Doses	Study Duration	Primary Endpoint	Key Inclusion Criteria
SURMOUNT-1 Weight Management in Participants with Obesity/Overweight*	✓	2,539	5/10/15 mg	72 weeks (2-year additional treatment period**)	1) Percent change in body weight 2) Percentage of participants who achieve ≥5% body weight reduction	BMI ≥ 30 kg/m ² or ≥ 27 kg/m ² with ≥1 weight-related comorbidity
SURMOUNT-2 Weight Management in Participants with Obesity/Overweight with T2DM	✓	938	10/15 mg	72 weeks		BMI ≥ 27 kg/m ² with T2D (A1c 7-10%), treated with diet/exercise alone or any oral agent except DPP-4 inhibitors or GLP-1R agonists
SURMOUNT-3 Maximizing Weight Loss Following Intensive Lifestyle Program in Participants with Obesity/Overweight*	Mid-2023	806	MTD (10 or 15 mg)	84 weeks (incl. 12-wk intensive lifestyle lead-in)	Percent change in body weight from randomization (week 36) to week 88	BMI ≥ 30 kg/m ² or ≥ 27 kg/m ² with ≥1 weight-related comorbidity
SURMOUNT-4 Maintaining Weight Loss with Maximal Tolerated Dose Therapy in Participants with Obesity/Overweight*		783		88 weeks (incl. 36-wk open-label TZP lead-in)		
SURMOUNT-5 Comparing the Efficacy and Safety of tirzepatide to semaglutide 2.4mg in Participants with Obesity/Overweight	2025	~700	MTD (10 or 15 mg)	72 weeks	percent change in body weight from randomization to 72 weeks	BMI ≥ 30 kg/m ² or ≥ 27 kg/m ² with ≥1 weight-related comorbidity
SURMOUNT-MMO Investigating the Effect of tirzepatide on the Reduction on Morbidity and Mortality in Adults With Obesity	2027	~15,000	MTD (5/10/15 mg)	Up to 5 years	Time to first occurrence of any component event of composite, all-cause death, nonfatal MI, nonfatal stroke, coronary revascularization, or heart failure events that results in hospitalization/urgent visits	BMI ≥ 27 kg/m ² ; individuals ≥40 years of age with established cardiovascular disease (CVD) or the presence of cardiovascular risk factors

Note: Separate on-going trials in Japan (SURMOUNT-J) and China (SURMOUNT-CN)
 MTD = Maximum Tolerated Dose; BMI = Body Mass Index; T2DM = Type 2 Diabetes Mellitus; TZP = tirzepatide
 * Participants without T2DM; ** For those with pre-diabetes at randomization

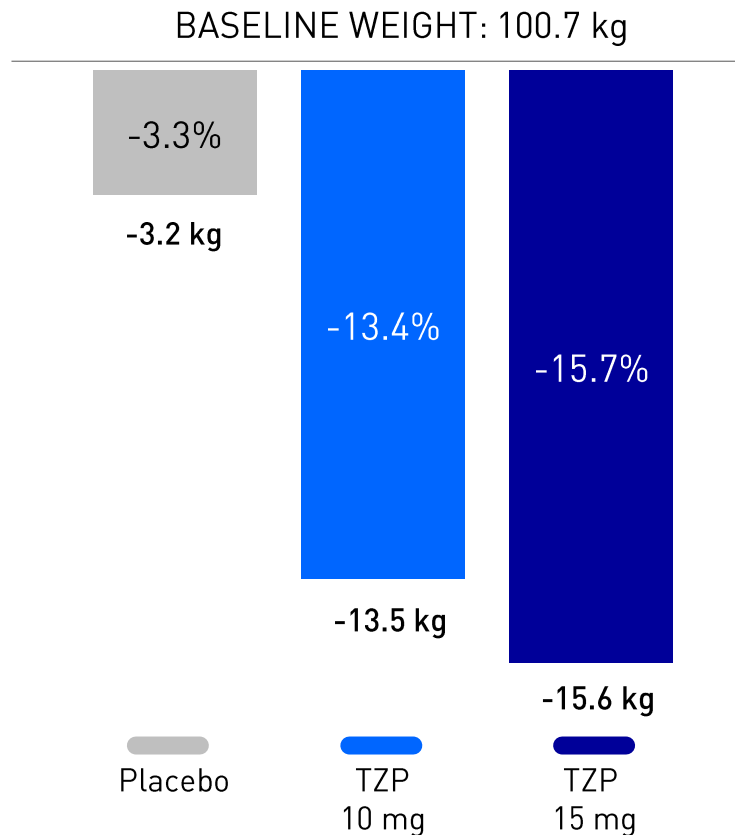
SURMOUNT-2: EFFICACY

PARTICIPANTS ON HIGHEST DOSE ACHIEVED 15.7% WEIGHT LOSS ON AVERAGE



MEAN BODY WEIGHT CHANGE AT 72 WEEKS

KEY EFFICACY RESULTS



- Both tirzepatide treatment arms demonstrated statistically superior and clinically meaningful weight loss compared to placebo
- In the 15 mg treatment arm, mean weight loss of 15.6 kg (34.4 pounds)
- In both tirzepatide treatment arms, patients achieved an average weight loss of roughly 30 pounds or more

TZP = tirzepatide

Note: Presented results for efficacy estimand which represents efficacy prior to discontinuation of study drug

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2023 Q1 EARNINGS

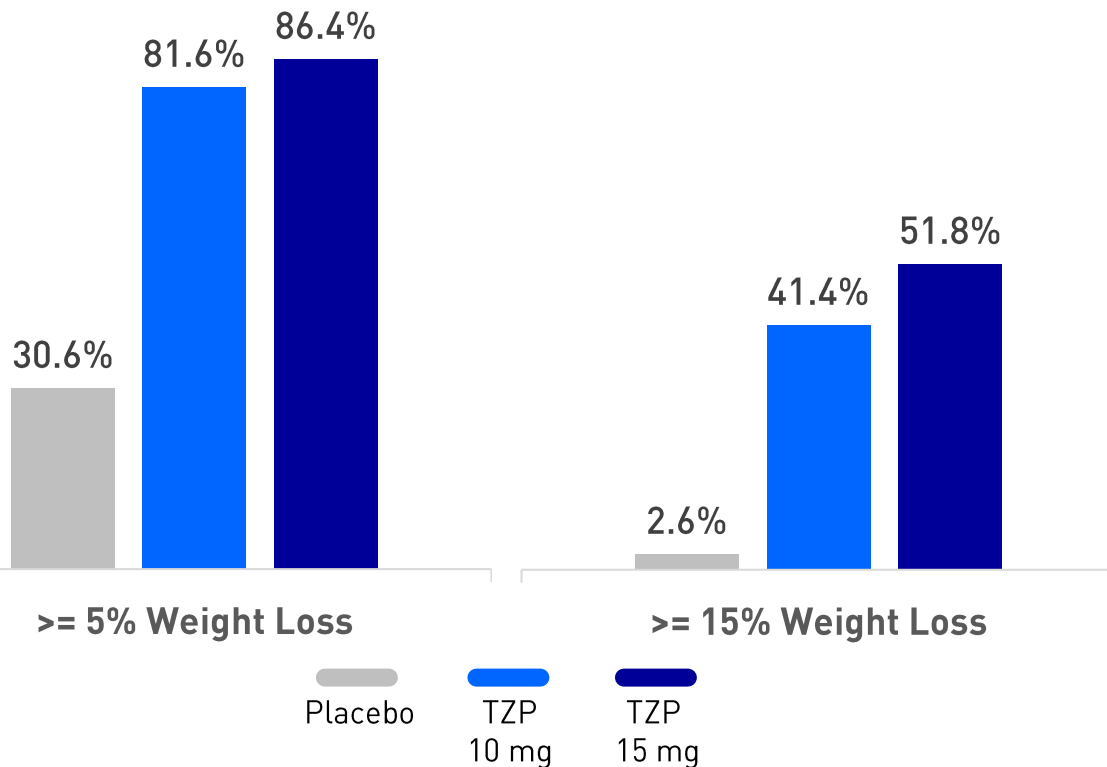
SURMOUNT-2: EFFICACY

MET THE CO-PRIMARY ENDPOINT OF ACHIEVING AT LEAST 5% BODY WEIGHT LOSS



PERCENTAGE OF PATIENTS ACHIEVING WEIGHT LOSS (%) TARGET

KEY EFFICACY RESULTS



- Greater than 81% of participants in the 10 mg arm and 86% of participants in the 15 mg arm achieved at least 5% body weight loss
- Over 50% of participants in the 15 mg treatment arm achieved at least 15% weight loss as a key secondary objective
- SURMOUNT-2 results substantiate the safety and efficacy package for completion of our submission to the U.S. FDA in the coming weeks

TZP = tirzepatide

Note: Results presented using the efficacy estimand which represents efficacy prior to discontinuation of study drug

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2023 Q1 EARNINGS

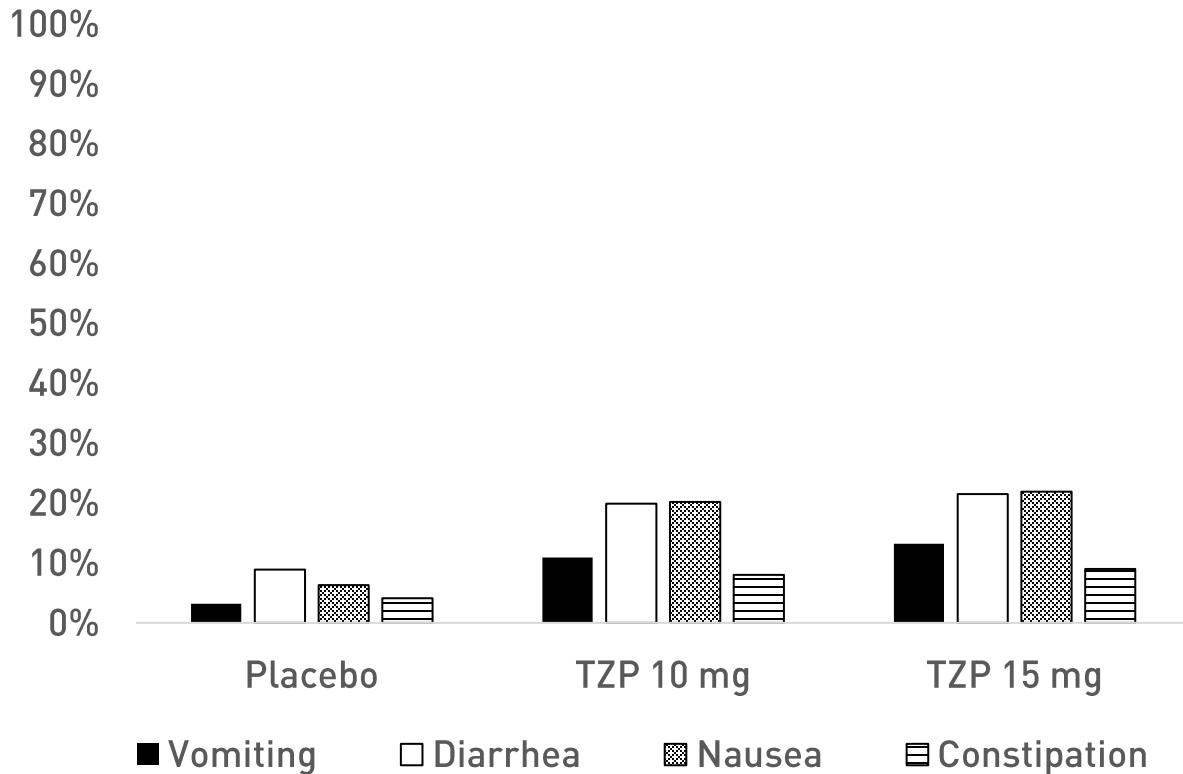
SURMOUNT-2: SAFETY AND TOLERABILITY DATA

OVERALL SAFETY PROFILE SIMILAR TO INCRETIN-BASED THERAPIES APPROVED FOR OBESITY



GI TOLERABILITY

KEY SAFETY RESULTS



- Most common reported AEs were GI-related, generally mild-to-moderate in severity, and usually occurred during dose escalation.
- Diarrhea and nausea were the most common reported adverse events and ranged from ~20-22% on tirzepatide vs ~6-9% on placebo
- Treatment discontinuation due to adverse events was 3.8% in the 10 mg arm and 7.4% in the 15 mg arm compared to 3.8% for placebo

GI = gastrointestinal; TZP = tirzepatide; AE = Adverse Events

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2023 Q1 EARNINGS

LILLY SELECT NME AND NILEX PIPELINE

April 24, 2023



SARM1 INHIBITOR Neurodegeneration	NOT DISCLOSED Pain	AT2R ANTAGONIST Pain
PYY ANALOG Diabetes	RET INHIBITOR II Cancer	RIPK1 INHIBITOR Immunology
NRG4 AGONIST Heart Failure	PI3K SELECTIVE Cancer	PNPLA3 siRNA NASH
KV1.3 ANTAGONIST Immunology	MAZDUTIDE ♦ Obesity	NOT DISCLOSED Diabetes
GITR ANTAGONIST Immunology	IDH1/2 INHIBITOR Cancer	KRAS G12C II Cancer
GIP/GLP COAGONIST PEPTIDE Diabetes	GIPR AGONIST LA Diabetes	GIPR AGONIST LA II Diabetes
CD200R MAB AGONIST Immunology	DACRA QW II Obesity	FGFR3 SELECTIVE Cancer
AMYLIN AGONIST LA Obesity	APOC3 siRNA CVD	CD19 ANTIBODY Immunology

PHASE 1

GBA1 GENE THERAPY Gaucher Disease Type 1	TIRZEPATIDE NASH
RETATRUTIDE Obesity	PIRTOBRUTINIB B-Cell Malignancies
ORFORGLIPRON Obesity	GBA1 GENE THERAPY Gaucher Disease Type 2
RELAXIN-LA Heart Failure	SSTR4 AGONIST Pain
RETATRUTIDE Diabetes	PERESOLIMAB Rheumatoid Arthritis
P2X7 INHIBITOR Pain	ORFORGLIPRON Diabetes
O-GLCNACASE INH Alzheimer's Disease	MUVALAPLIN (Lp(a) INHIBITOR) CVD
MEVIDALEN Symptomatic LBD	LPA siRNA CVD
GRN GENE THERAPY Frontotemporal Dementia	GBA1 GENE THERAPY Parkinson's Disease
ELTREKIBART (CXCR1/2L MAB) Hidradenitis Suppurativa	BTLA MAB AGONIST Systemic Lupus Erythematosus
SOLBINSIRAN (ANGPTL3 siRNA) CVD	

PHASE 2

TIRZEPATIDE Obstructive Sleep Apnea	TIRZEPATIDE MMO
TIRZEPATIDE Heart Failure pEF	TIRZEPATIDE CV Outcomes
SELPERCATINIB 1L NSCLC	SELPERCATINIB 1L Med Thyroid Cancer
SELPERCATINIB Adjuvant RET+ NSCLC	PIRTOBRUTINIB R/R MCL Monotherapy
PIRTOBRUTINIB R/R CLL Monotherapy	PIRTOBRUTINIB R/R CLL Combination
PIRTOBRUTINIB 1L CLL Monotherapy	MIRIKIZUMAB Crohn's Disease
IMLUNESTRANT Adjuvant Breast Cancer	EMPAGLIFLOZIN* Post MI
DONANEMAB Preclinical Alzheimer's Disease	ABEMACICLIB MBC Sequencing
ABEMACICLIB Hormone Sensitive Prostate Cancer	ABEMACICLIB Castrate Resistant Prostate Cancer
REMTERTNETUG Alzheimer's Disease	INSULIN EFSITORA ALFA (BASAL INSULIN-Fc) Diabetes
IMLUNESTRANT ER+ HER2- mBC	

PHASE 3

LEGEND

● NME
○ NILEX
* Commercial Collaboration

MOVEMENT SINCE January 30, 2023

📌 ADDITION or MILESTONE ACHIEVED
⬇️ REMOVAL

♦ Phase 3 in China with Innovent for T2DM and Obesity
⊙ Approval in Japan. Complete Response Letter issued by US FDA.
▶ Submission in EU. US submission pending.

TIRZEPATIDE Obesity
EMPAGLIFLOZIN* Chronic Kidney Disease
LEBRIKIZUMAB Atopic Dermatitis
DONANEMAB Alzheimer's Disease

REG REVIEW

MIRIKIZUMAB Ulcerative Colitis

APPROVED

REZPEGALDESLEUKIN Systemic Lupus Erythematosus	TRPA1 ANTAGONIST Pain
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SOLANEZUMAB Preclinical Alzheimer's Disease

POTENTIAL KEY EVENTS 2023

New since last update



Phase 3 Initiations

- ✓+ **Basal Insulin-Fc** for type 2 diabetes (QWINT-1)
- Tirzepatide** for chronic weight management (H2H vs semaglutide 2.4 mg)
- Retatrutide** for chronic weight management
- Orforglipron** for chronic weight management
- Orforglipron** for type 2 diabetes
- Remternetug** for early Alzheimer's disease (efficacy trials)

Phase 3 Data Disclosures

- Donanemab** for early Alzheimer's disease
- ✓+ **Tirzepatide** for chronic weight management (SURMOUNT-2)
- Tirzepatide** for chronic weight management (SURMOUNT-3)
- Tirzepatide** for chronic weight management (SURMOUNT-4)
- Mirikizumab** for Crohn's disease
- Abemaciclib** for castrate-resistant prostate cancer (CYCLONE-2)

Regulatory Submissions

- Tirzepatide** for chronic weight management (US/EU ✓+)
- ✓+ **Lebrikizumab** for atopic dermatitis (J)
- ✓+ **Empagliflozin** for chronic kidney disease¹ (US ✓+ /EU ✓+ /J ✓+)
- Donanemab** for early Alzheimer's disease² (US/EU/J)
- Pirtobrutinib** for MCL prior BTKi (J)

Regulatory Actions

- ✓ **Donanemab** for early Alzheimer's disease³ (US)
- Lebrikizumab** for atopic dermatitis (US/EU)
- Mirikizumab** for ulcerative colitis (US ✓ /EU/J ✓+)
- ✓+ **Pirtobrutinib** for MCL prior BTKi (US³ ✓+ /EU)
- Empagliflozin** for chronic kidney disease¹ (US/EU/J)
- Tirzepatide** for chronic weight management (US)

¹ In collaboration with Boehringer Ingelheim

² Under the traditional approval pathway

³ Under the FDA Accelerated Approval Program

Q1 2023 SUMMARY



- Excluding COVID-19 antibodies, **revenue grew** 10%, driven by 18% volume growth
- Continued to **speed life-changing medicines** to patients with:
 - The expanded label for **Verzenio** in adjuvant breast cancer in the U.S.;
 - The approval of **mirikizumab** in Japan;
 - The submissions of **tirzepatide** for chronic weight management in the EU and **lebrikizumab** for atopic dermatitis in Japan; and
 - A positive Phase 3 topline readout for SURMOUNT-2, the second global study evaluating **tirzepatide** for adults living with obesity or overweight
- Q1 **investment growth** driven by investments in new products and indications and late-stage pipeline
- Deployed over \$1 billion to shareholders via the **dividend** and completed \$750 million of **share repurchases**



Invest in Current Portfolio



Invest in Future Innovation



Deliver Revenue Growth



Speed Life-Changing Medicines

Return Capital to Shareholders



SUPPLEMENTAL SLIDES

2023 INCOME STATEMENT – REPORTED



Millions; except per share data

	Q1 2023	Change
TOTAL REVENUE	\$6,960	(11)%
GROSS MARGIN	76.6%	3.1pp
TOTAL OPERATING EXPENSE*	3,839	15%
OPERATING INCOME	1,494	(38)%
OPERATING MARGIN	21.5%	(9.3)pp
OTHER INCOME (EXPENSE)	36	NM
EFFECTIVE TAX RATE	12.1%	4.8pp
NET INCOME	\$1,345	(29)%
EARNINGS PER SHARE	\$1.49	(29)%

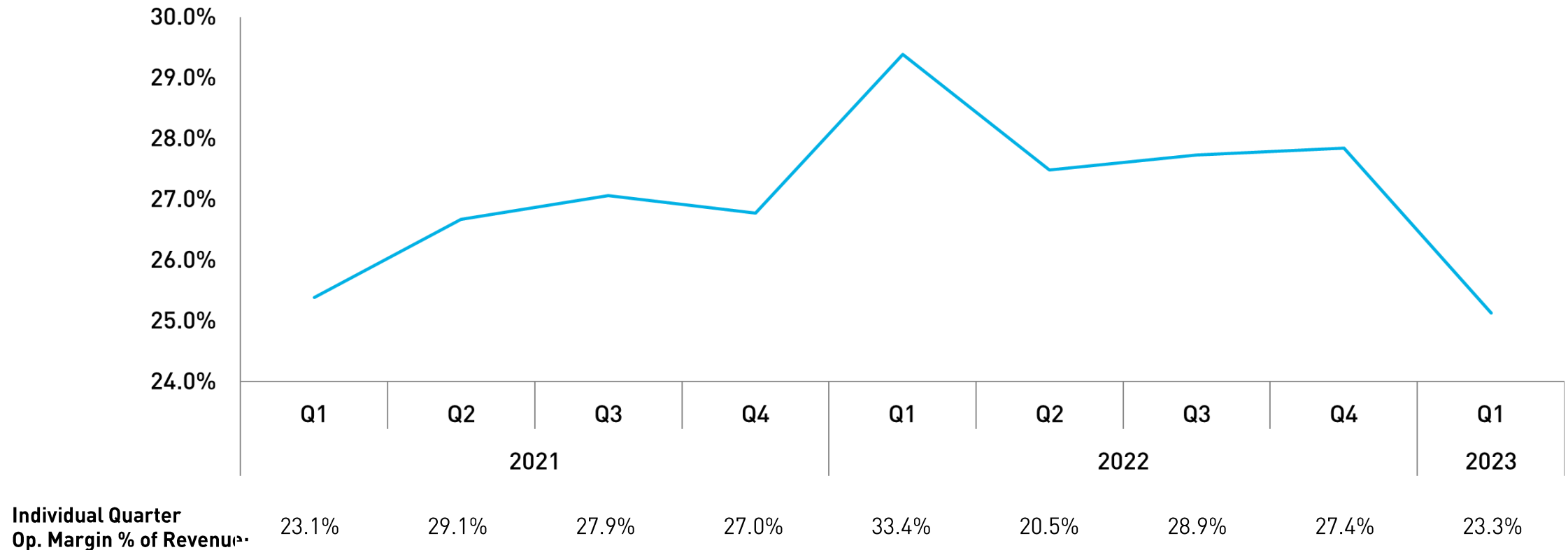
* Includes research and development expense, marketing, selling and administrative expense, acquired in-process research and development charges, and asset impairment, restructuring and other special charges.

NM – not meaningful

NON-GAAP OPERATING MARGIN % OF REVENUE



MOVING ANNUAL TOTAL



Op. Margin impact of Acquired IPR&D Charges	-4.6%	-0.6%	-2.6%	-5.5%	-2.1%	-6.8%	-0.9%	-3.3%	-1.5%
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The line in the graph is a moving annual total (i.e. trailing 4 quarters) while the row of numbers is from specific quarters.

EFFECT OF FX ON 2023 RESULTS



Year-on-Year Change

REPORTED	Q1 2023	
	With FX	w/o FX
TOTAL REVENUE	(11)%	(9)%
COST OF SALES	(21)%	(20)%
GROSS MARGIN	(7)%	(5)%
OPERATING EXPENSE	15%	17%
OPERATING INCOME	(38)%	(35)%
EARNINGS PER SHARE	(29)%	(25)%
NON-GAAP		
	With FX	w/o FX
TOTAL REVENUE	(11)%	(9)%
COST OF SALES	(20)%	(18)%
GROSS MARGIN	(8)%	(6)%
OPERATING EXPENSE	15%	17%
OPERATING INCOME	(38)%	(35)%
EARNINGS PER SHARE	(38)%	(35)%

Presentation includes GAAP and non-GAAP figures excluding impact of foreign exchange rates. Current period figures recalculated by keeping constant the exchange rates from the base period.

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2023 Q1 EARNINGS

EPS RECONCILIATION



	<u>Q1 2023</u>	<u>Q1 2022</u>	<u>% Change</u>
EPS (REPORTED)	\$1.49	\$2.10	(29)%
AMORTIZATION OF INTANGIBLE ASSETS	0.11	0.18	-
NET LOSSES (GAINS) ON INVESTMENTS IN EQUITY SECURITIES	0.02	0.34	-
EPS (NON-GAAP)	\$1.62	\$2.62	(38)%
Acquired IPR&D	\$0.10	\$0.15	(33)%

Numbers may not add due to rounding; see slide 25 for more details on these significant adjustments.

Q1 2023 INCOME STATEMENT NOTES



Q1 2023 NON-GAAP INFORMATION HAS BEEN ADJUSTED TO EXCLUDE:

- amortization of intangibles primarily associated with costs of marketed products acquired or licensed from third parties totaling \$125.8 million (pretax), or \$0.11 per share (after-tax); and
- net losses on investments in equity securities totaling \$22.6 million (pretax), or \$0.02 per share (after-tax).

Q1 2022 NON-GAAP INFORMATION HAS BEEN ADJUSTED TO EXCLUDE:

- amortization of intangibles primarily associated with costs of marketed products acquired or licensed from third parties totaling \$204.6 million (pretax), or \$0.18 per share (after-tax); and
- net losses on investments in equity securities totaling \$388.4 million (pretax), or \$0.34 per share (after-tax).

COMPARATIVE EPS SUMMARY 2022/2023



	1Q22	2Q22	3Q22	4Q22	2022	1Q23	2Q23	3Q23	4Q23	2023
Reported	2.10	1.05	1.61	2.14	6.90	1.49				
Non-GAAP	2.62	1.25	1.98	2.09	7.94	1.62				

Numbers may not add due to rounding

For a complete reconciliation to reported earnings, see slide 24 and our earnings press release dated April 27th, 2023

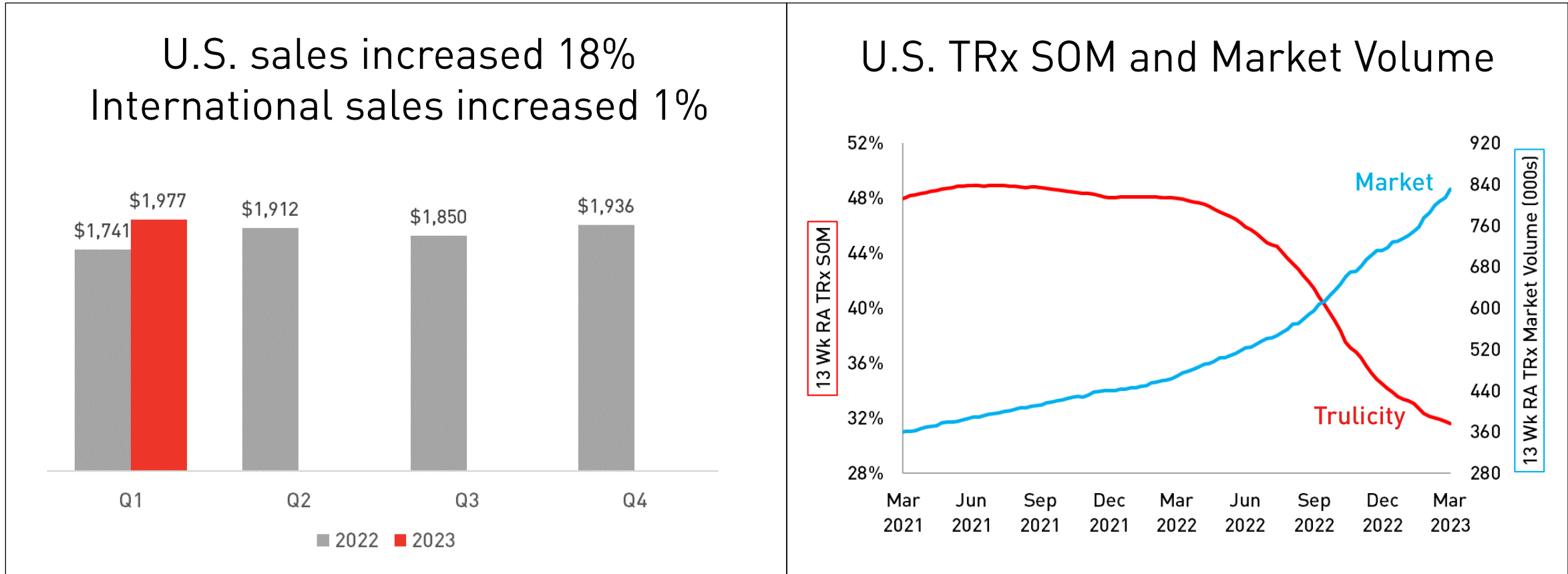
Not for promotional use

2023 Q1 EARNINGS

Q1 2023 TRULICITY SALES INCREASED 14%



Millions

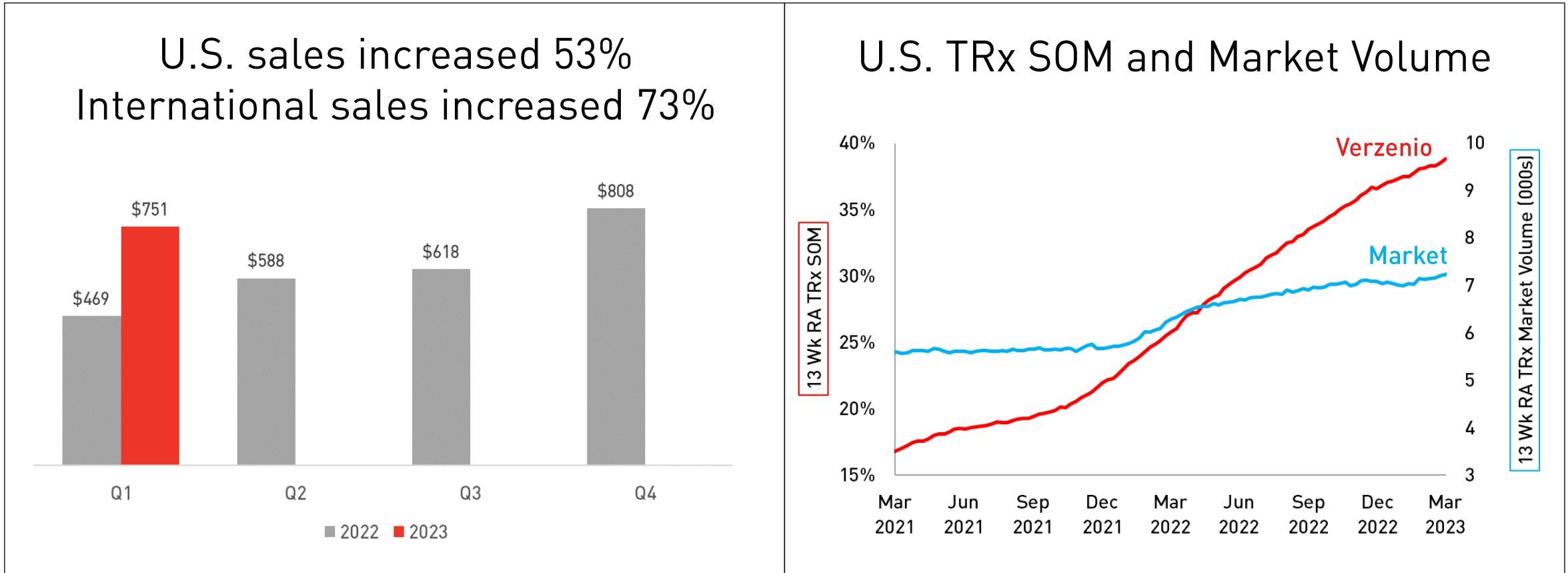


Source: IQVIA NPA TRx 3MMA, weekly data March 31, 2023; RA = rolling average
TRx data is representative of the injectable incretin market

Q1 2023 VERZENIO SALES INCREASED 60%



Millions

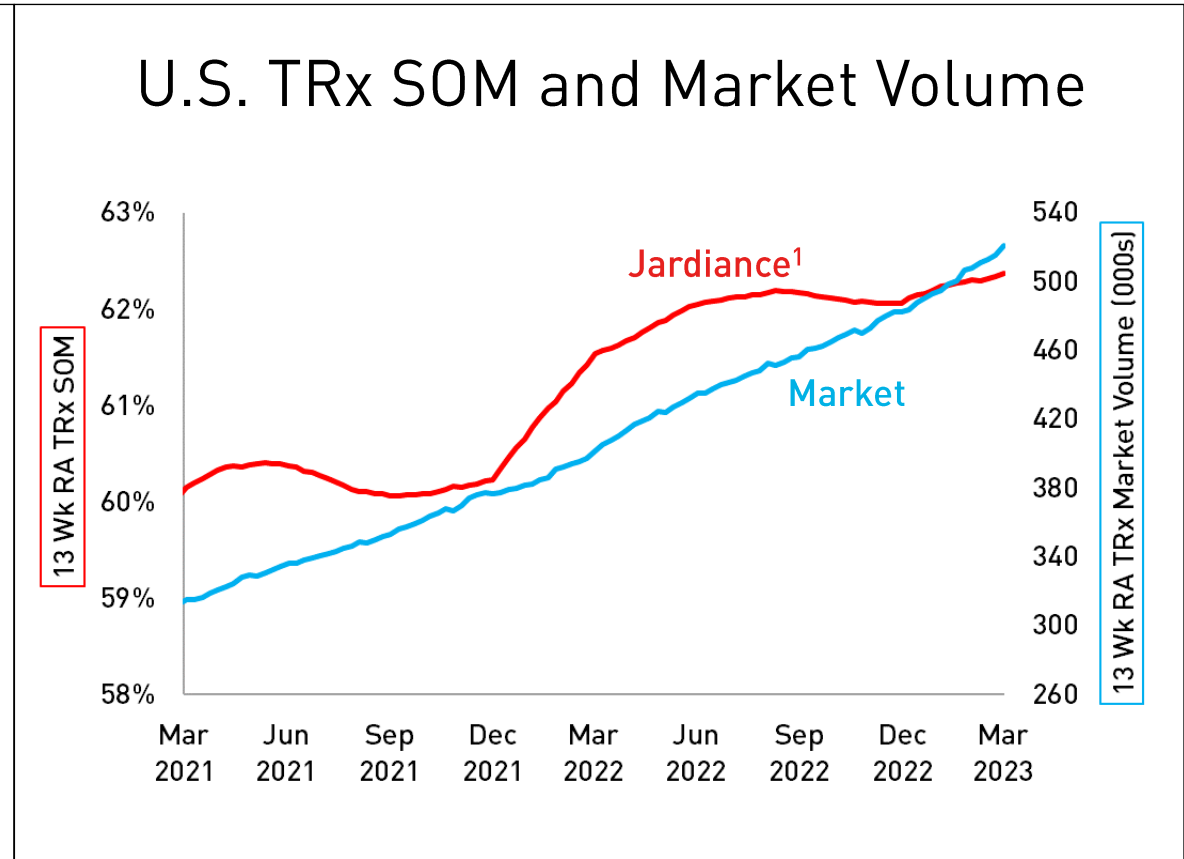
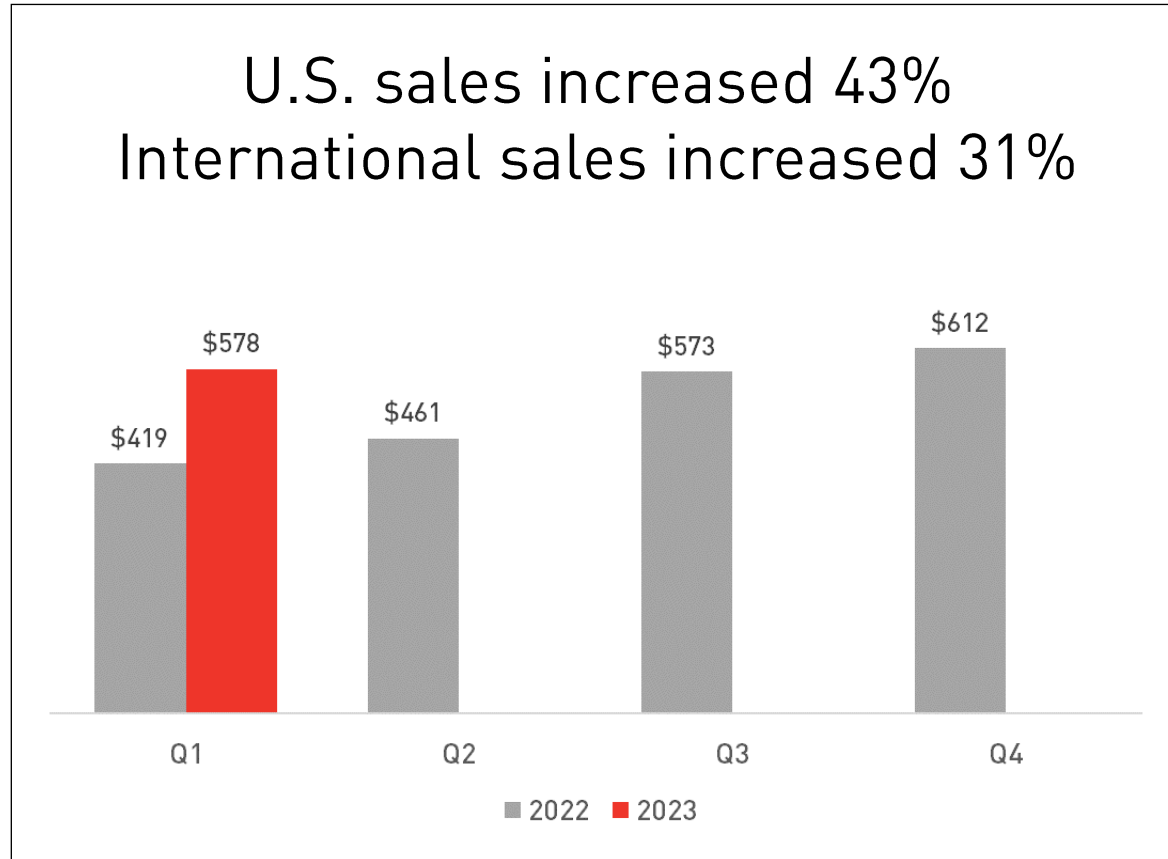


Source: IQVIA NPA TRx 3MMA, weekly data March 31, 2023; RA = rolling average

Q1 2023 JARDIANCE SALES INCREASED 38%



Millions



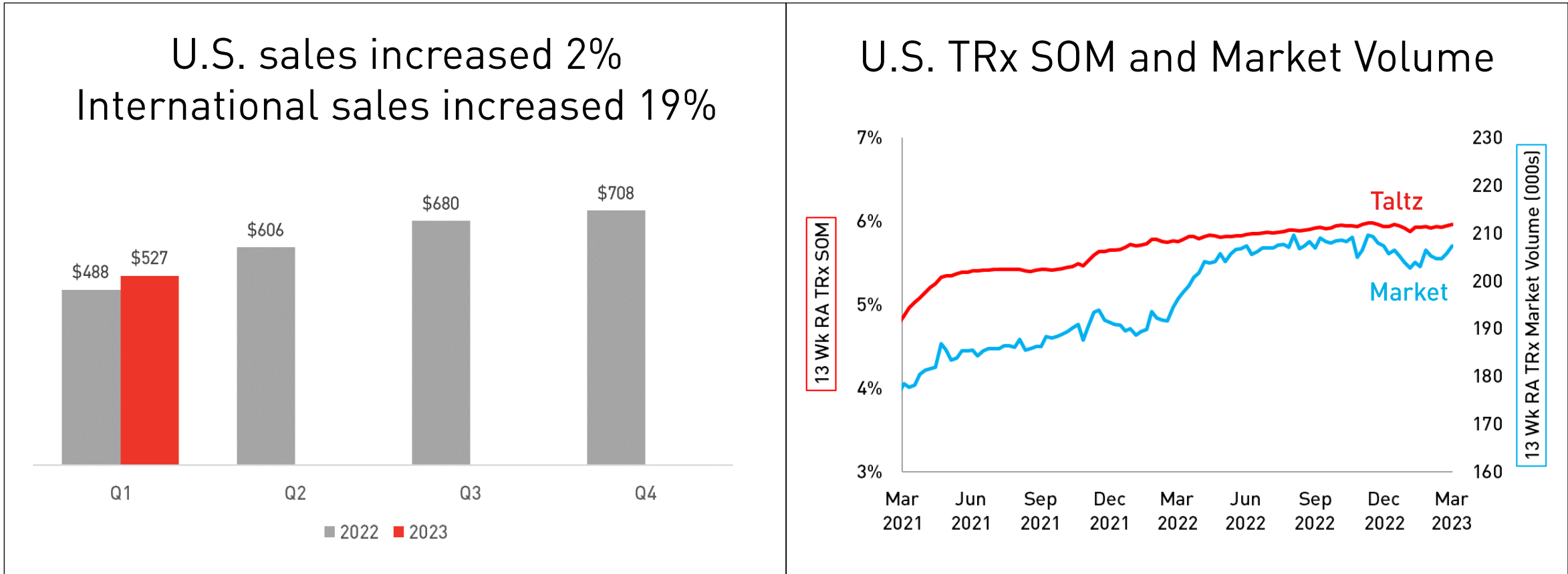
Source: IQVIA NPA TRx 3MMA, weekly data March 31, 2023; RA = rolling average
Jardiance is part of Lilly's alliance with Boehringer Ingelheim.

¹ Jardiance includes Glyxambi and Synjardy

Q1 2023 TALTZ SALES INCREASED 8%



Millions

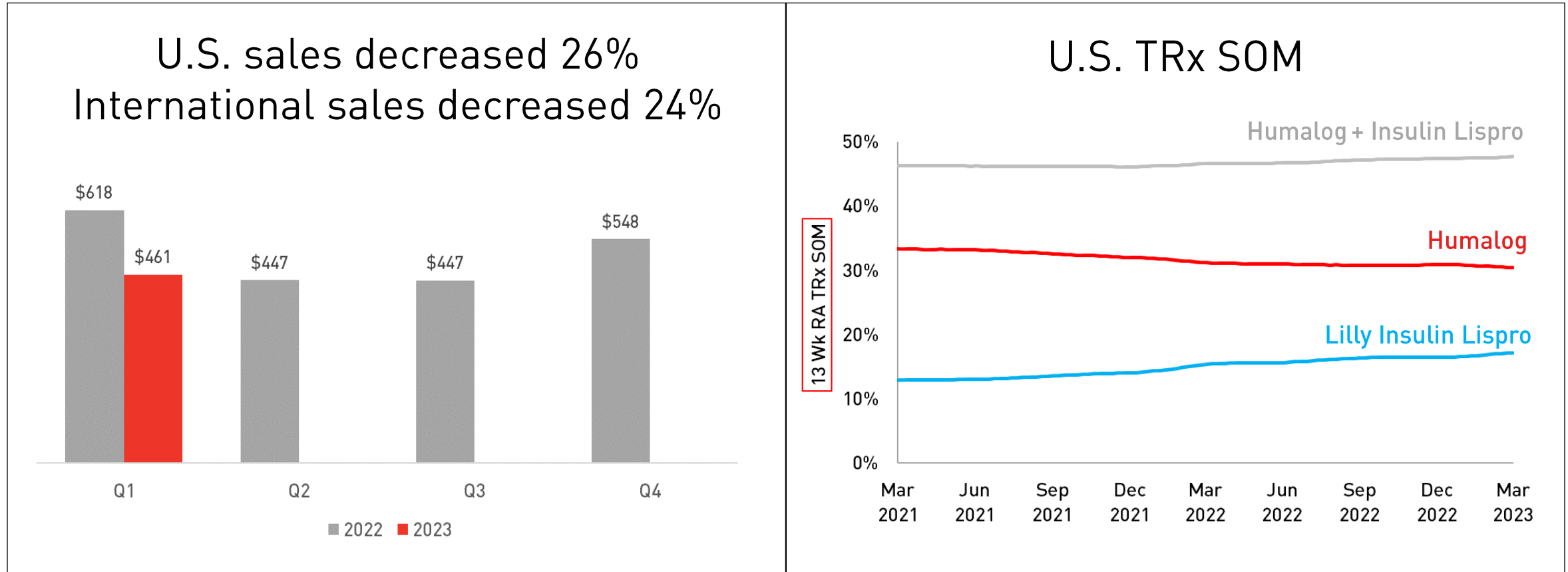


Source: IQVIA NPA TRx 3MMA, weekly data March 31, 2023; RA = rolling average
 TRx data is representative of the full molecule market

Q1 2023 HUMALOG SALES DECREASED 25%



Millions

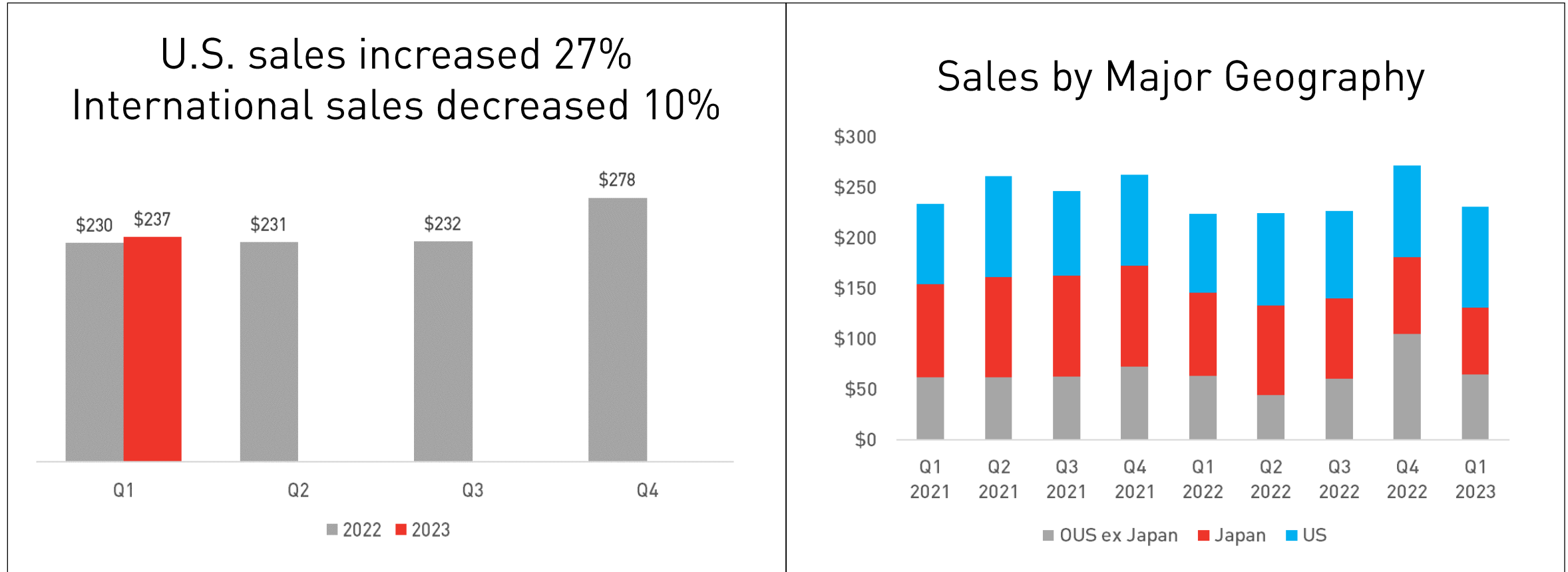


Source: IQVIA NPA TRx 3MMA, weekly data March 31, 2023; RA = rolling average

Q1 2023 CYRAMZA SALES INCREASED 3%



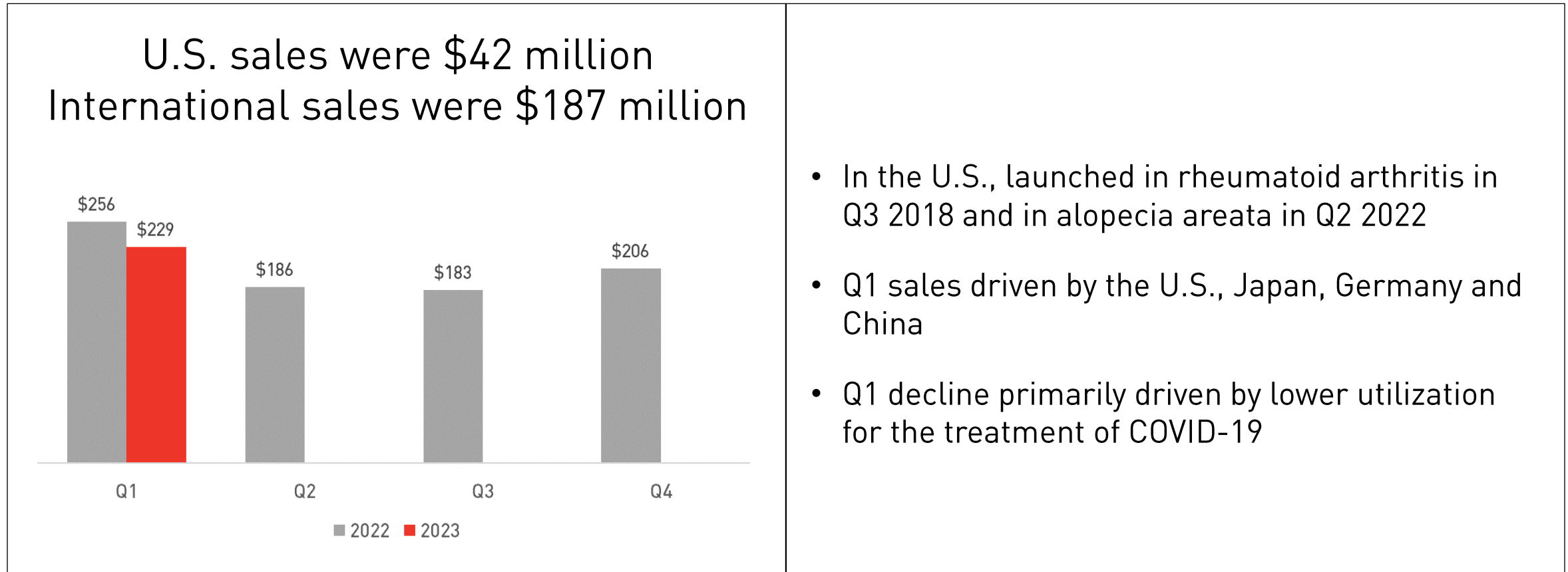
Millions



Q1 2023 OLUMIANT SALES DECREASED 10%



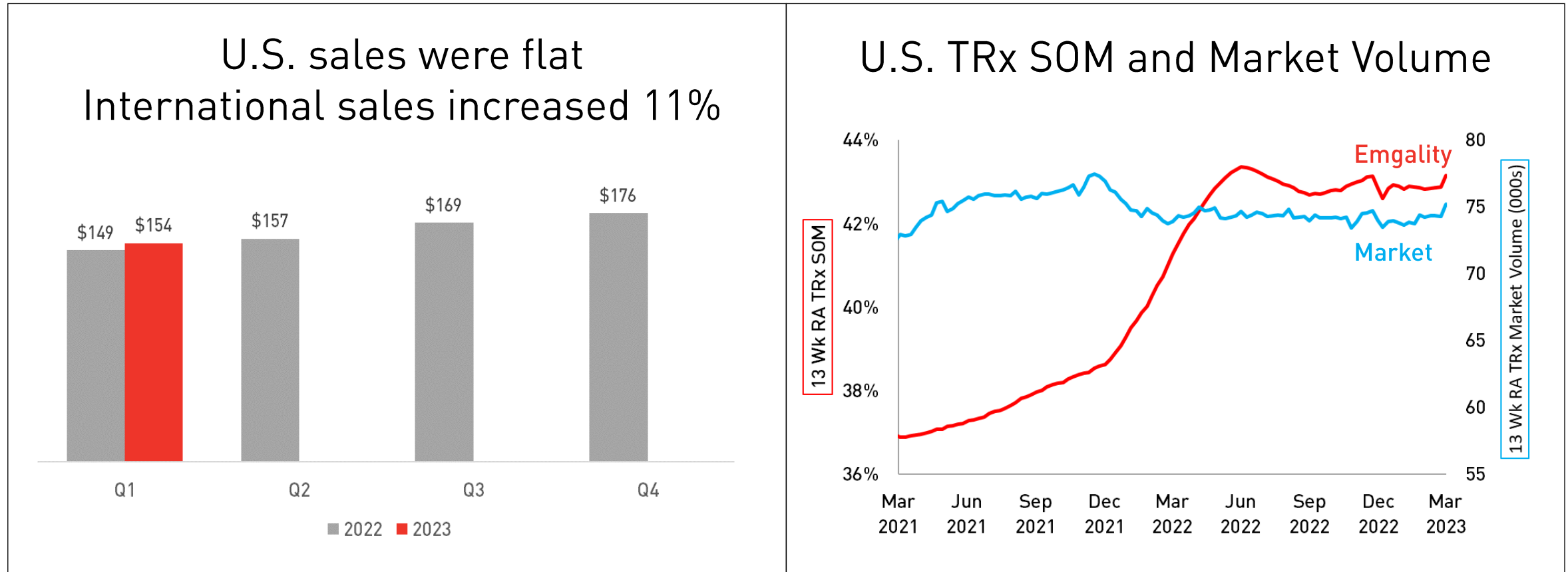
Millions



Q1 2023 EMGALITY SALES INCREASED 3%



Millions



Source: IQVIA NPA TRx 3MMA, weekly data March 31, 2023; RA = rolling average
TRx data is representative of the injectable CGRP market

SELECT TRIALS – INSULIN EFSITORA ALFA (BASAL INSULIN-FC)



Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
NCT05462756	Type 2 Diabetes	A Study of Insulin Efsitora Alfa (LY3209590) as a Weekly Basal Insulin Compared to Insulin Glargine in Adult Participants With Type 2 Diabetes on Multiple Daily Injections (QWINT-4)	3	670	Change from Baseline in HbA1c	Mar 2024	Mar 2024
NCT05275400	Type 2 Diabetes	A Study of Insulin Efsitora Alfa (LY3209590) Compared With Insulin Degludec in Participants With Type 2 Diabetes Currently Treated With Basal Insulin (QWINT-3)	3	986	Change from Baseline in Hemoglobin A1c (HbA1c)	May 2024	May 2024
NCT05662332	Type 2 Diabetes	A Study of Insulin Efsitora Alfa (LY3209590) Compared to Glargine in Adult Participants With Type 2 Diabetes Who Are Starting Basal Insulin for the First Time (QWINT-1)	3	670	Change from Baseline in Hemoglobin A1c (HbA1c)	Jul 2024	Jul 2024
NCT05463744	Type 1 Diabetes	A Study of Insulin Efsitora Alfa (LY3209590) Compared With Insulin Degludec in Participants With Type 1 Diabetes Treated With Multiple Daily Injection Therapy (QWINT-5)	3	692	Change from Baseline in Hemoglobin A1c (HbA1c)	May 2024	May 2024
NCT05362058	Diabetes	A Study of Insulin Efsitora Alfa (LY3209590) Compared to Degludec in Adults With Type 2 Diabetes Who Are Starting Basal Insulin for the First Time (QWINT-2)	3	912	Change from Baseline in Hemoglobin A1c (HbA1c)	Apr 2024	Apr 2024

* Molecule may have multiple indications

** Trial may have additional primary and other secondary outcomes

Source: clinicaltrials.gov, April 18, 2023

SELECT TRIALS – DONANEMAB



Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
NCT05108922	Mild Cognitive Impairment	A Study of Donanemab (LY3002813) Compared With Aducanumab in Participants With Early Symptomatic Alzheimer's Disease (TRAILBLAZER-ALZ 4)	3	200	Percentage of Participants Who Reach Complete Amyloid Plaque Clearance on Florbetapir F18 Positron Emission Tomography (PET) Scan (Superiority) on donanemab versus aducanumab	Sep 2022	Jul 2024
NCT04437511	Alzheimer Disease	A Study of Donanemab (LY3002813) in Participants With Early Alzheimer's Disease (TRAILBLAZER-ALZ 2)	3	1800	Change from Baseline on the integrated Alzheimer's Disease Rating Scale (iADRS)	Apr 2023	Aug 2025
NCT04640077	Alzheimer Disease	A Follow-On Study of Donanemab (LY3002813) With Video Assessments in Participants With Alzheimer's Disease (TRAILBLAZER-EXT)	2	90	Part A: Correlation between VTC and on-site assessment for PAIR 1 for Alzheimer's Disease Assessment Scale - Cognitive Subscale (ADAS-Cog13)	Sep 2023	Mar 2024
NCT05738486	Alzheimer Disease	A Study of Different Donanemab (LY3002813) Dosing Regimens in Adults With Early Alzheimer's Disease (TRAILBLAZER-ALZ 6)	3	800	Percentage of Participants with Any Occurrence of Amyloid-Related Imaging Abnormality-Edema/Effusion (ARIA-E)	Mar 2024	May 2025
NCT05508789	Alzheimer Disease	A Study of Donanemab (LY3002813) in Participants With Early Symptomatic Alzheimer's Disease (TRAILBLAZER-ALZ 5)	3	1500	Change from Baseline on the Integrated Alzheimer's Disease Rating Scale (iADRS)	Apr 2027	Jun 2027
NCT05026866	Alzheimer Disease	A Donanemab (LY3002813) Prevention Study in Participants With Alzheimer's Disease (TRAILBLAZER-ALZ 3)	3	3300	Time to clinical progression as measured by Clinical Dementia Rating - Global Score (CDR-GS)	Oct 2027	Nov 2027

* Molecule may have multiple indications

** Trial may have additional primary and other secondary outcomes

Source: clinicaltrials.gov, April 18, 2023

SELECT TRIALS – IMLUNESTRANT



Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
NCT04975308	Breast Neoplasms	A Study of Imlunestrant, Investigator's Choice of Endocrine Therapy, and Imlunestrant Plus Abemaciclib in Participants With ER+, HER2- Advanced Breast Cancer (EMBER-3)	3	860	Progression Free Survival (PFS) in the Intent-to-Treat (IIT) Population	Apr 2024	Aug 2027
NCT05514054	Breast Neoplasms	A Study of Imlunestrant Versus Standard Endocrine Therapy in Participants With Early Breast Cancer (EMBER-4)	3	6000	Invasive Disease-Free Survival (IDFS)	Oct 2027	Mar 2032

* Molecule may have multiple indications

** Trial may have additional primary and other secondary outcomes

Source: clinicaltrials.gov, April 20, 2023

SELECT TRIALS – JARDIANCE



Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
NCT04509674	Myocardial Infarction	EMPACT-MI: A Study to Test Whether Empagliflozin Can Lower the Risk of Heart Failure and Death in People Who Had a Heart Attack (Myocardial Infarction)	3	6522	Composite of time to first heart failure hospitalization or all-cause mortality	Aug 2023	Aug 2023

* Molecule may have multiple indications

** Trial may have additional primary and other secondary outcomes

Source: clinicaltrials.gov, April 18, 2023

SELECT TRIALS – LEBRIKIZUMAB



Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
NCT05369403	Atopic Dermatitis	A Study of Lebrikizumab (LY3650150) in Adult and Adolescent Participants With Moderate-to-Severe Atopic Dermatitis Previously Treated With Dupilumab (ADapt)	3	120	Percentage of Participants Achieving Eczema Area and Severity Index-75 (EASI-75) >75% Reduction in EASI Score	Oct 2023	Mar 2024
NCT05372419	Atopic Dermatitis	A Study of (LY3650150) Lebrikizumab to Assess the Safety and Efficacy of Adult and Adolescent Participants With Moderate-to-Severe Atopic Dermatitis and Skin of Color (ADmirable)	3	80	Percentage of Participants Achieving Eczema Area and Severity Index-75 (EASI-75) (≥75% reduction from baseline in EASI)	Mar 2024	Aug 2024
NCT05559359	Atopic Dermatitis	A Study of Lebrikizumab (LY3650150) in Participants 6 Months to <18 Years of Age With Moderate-to-Severe Atopic Dermatitis (ADorable-1)	3	300	Percentage of Participants Achieving Eczema Area and Severity Index-75 (EASI-75) ≥75% Reduction from Baseline in EASI Score	Jul 2024	Jul 2025
NCT04392154	Atopic Dermatitis	Long-term Safety and Efficacy Study of Lebrikizumab (LY3650150) in Participants With Moderate-to-Severe Atopic Dermatitis (ADjoin)	3	1000	Percentage of Participants Discontinued from Study Treatment due to Adverse Events through the Last Treatment Visit	Sep 2024	Sep 2024
NCT05735483	Atopic Dermatitis	A Study to Assess the Long-Term Safety and Efficacy of Lebrikizumab (LY3650150) in Participants 6 Months to <18 Years of Age With Moderate-to-Severe Atopic Dermatitis (ADorable-2)	3	250	Percentage of Participants Discontinued From Study Treatment due to Adverse Events (AEs)	Jun 2026	Jun 2026

* Molecule may have multiple indications

** Trial may have additional primary and other secondary outcomes

Source: clinicaltrials.gov, April 20, 2023

SELECT TRIALS – MIRIKIZUMAB



Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
NCT03926130	Crohn's Disease	A Study of Mirikizumab (LY3074828) in Participants With Crohn's Disease (VIVID-1)	3	1100	Percentage of Participants Achieving Clinical Response at Week 12 and Endoscopic Response at Week 52	Aug 2023	Dec 2023
NCT04232553	Crohn's Disease	A Long-term Extension Study of Mirikizumab (LY3074828) in Participants With Crohn's Disease (VIVID-2)	3	778	Percentage of Participants Achieving Endoscopic Response	Jan 2025	Apr 2027
NCT03518086	Ulcerative Colitis	An Induction Study of Mirikizumab in Participants With Moderately to Severely Active Ulcerative Colitis (LUCENT-1)	3	1281	Percentage of Participants With Clinical Remission at Week 12	Jan 2021	Mar 2024
NCT03524092	Ulcerative Colitis	A Maintenance Study of Mirikizumab in Participants With Moderately to Severely Active Ulcerative Colitis (LUCENT-2)	3	1177	Percentage of Participants in Clinical Remission at Week 40	Nov 2021	Mar 2025
NCT03519945	Ulcerative Colitis	A Study to Evaluate the Long-Term Efficacy and Safety of Mirikizumab in Participants With Moderately to Severely Active Ulcerative Colitis (LUCENT-3)	3	960	Percentage of Participants in Clinical Remission	Jun 2025	Apr 2029

* Molecule may have multiple indications

** Trial may have additional primary and other secondary outcomes

Source: clinicaltrials.gov, April 20, 2023

SELECT TRIALS – ORFORGLIPRON



Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
NCT05803421	Type 2 Diabetes	A Study of Daily Oral Orforglipron (LY3502970) Compared With Insulin Glargine in Participants With Type 2 Diabetes and Obesity or Overweight at Increased Cardiovascular Risk (ACHIEVE-4)	3	2620	Time to First Occurrence of Any Major Adverse Cardiovascular Event (MACE-4) [Myocardial Infarction (MI), Stroke, Hospitalization for Unstable Angina, or Cardiovascular (CV) Death]	Aug 2025	Sep 2025

* Molecule may have multiple indications

** Trial may have additional primary and other secondary outcomes

Source: clinicaltrials.gov, April 18, 2023

SELECT TRIALS – PIRTOBRUTINIB



Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
NCT04666038	Chronic Lymphocytic Leukemia	Study of LOXO-305 Versus Investigator's Choice (IdelaR or BR) in Patients With Previously Treated Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL) (BRUIN CLL-321)	3	250	To evaluate progression-free survival (PFS) of LOXO-305 monotherapy (Arm A) compared to investigator's choice of idelalisib plus rituximab (IdelaR) or bendamustine plus rituximab (BR) (Arm B)	Dec 2023	May 2027
NCT05023980	Chronic Lymphocytic Leukemia	A Study of Pirtobrutinib (LOXO-305) Versus Bendamustine Plus Rituximab (BR) in Untreated Patients With Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL) (BRUIN CLL-313)	3	250	To evaluate progression-free survival (PFS) of pirtobrutinib (Arm A) compared to bendamustine and rituximab (Arm B)	Nov 2024	Jul 2026
NCT04965493	Chronic Lymphocytic Leukemia	A Trial of Pirtobrutinib (LOXO-305) Plus Venetoclax and Rituximab (PVR) Versus Venetoclax and Rituximab (VR) in Previously Treated Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL) (BRUIN CLL-322)	3	600	To evaluate progression-free survival (PFS) of pirtobrutinib plus venetoclax and rituximab (Arm A) compared to venetoclax and rituximab (Arm B)	Oct 2025	Jan 2027
NCT05254743	Chronic Lymphocytic Leukemia	A Study of Pirtobrutinib (LOXO-305) Versus Ibrutinib in Participants With Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL) (BRUIN CLL-314)	3	650	Percentage of Participants Achieving Complete Response (CR) or Partial Response (PR): Overall Response Rate (ORR)	Mar 2028	Mar 2029
NCT04662255	Lymphoma, Mantle-Cell	Study of BTK Inhibitor LOXO-305 Versus Approved BTK Inhibitor Drugs in Patients With Mantle Cell Lymphoma (MCL) (BRUIN MCL-321)	3	500	To compare progression-free survival (PFS) of pirtobrutinib as monotherapy (Arm A) to investigator choice of covalent BTK inhibitor monotherapy (Arm B) in patients with previously treated mantle cell lymphoma (MCL)	Apr 2025	Apr 2025

* Molecule may have multiple indications

** Trial may have additional primary and other secondary outcomes

Source: clinicaltrials.gov, April 18, 2023

SELECT TRIALS – REMTERNETUG



Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
NCT05463731	Alzheimer Disease	A Study of Remternetug (LY3372993) in Participants With Alzheimer's Disease (TRAILRUNNER-ALZ 1)	3	600	Percentage of Participants Who Reach Amyloid Plaque Clearance on Amyloid PET Scan for Remternetug versus Placebo	Feb 2025	Feb 2026

* Molecule may have multiple indications

** Trial may have additional primary and other secondary outcomes

Source: clinicaltrials.gov, April 18, 2023

SELECT TRIALS – RETEVMO



Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
NCT04211337	Medullary Thyroid Cancer	A Study of Selpercatinib (LY3527723) in Participants With RET-Mutant Medullary Thyroid Cancer (LIBRETTO-531)	3	400	Progression Free Survival (PFS) by Blinded Independent Central Review (BICR)	May 2024	Nov 2026
NCT03157128	Non-Small Cell Lung Cancer	A Study of Selpercatinib (LOXO-292) in Participants With Advanced Solid Tumors, RET Fusion-Positive Solid Tumors, and Medullary Thyroid Cancer (LIBRETTO-001)	1 2	875	Phase 1: MTD; Phase 2: ORR	Mar 2024	Sep 2024
NCT04194944	Non-Small Cell Lung Cancer	A Study of Selpercatinib (LY3527723) in Participants With Advanced or Metastatic RET Fusion-Positive Non-Small Cell Lung Cancer (LIBRETTO-431)	3	250	Progression Free Survival (PFS) by Blinded Independent Central Review (BICR) (with Pembrolizumab)	Dec 2024	Jul 2027
NCT04819100	Carcinoma, Non-Small-Cell Lung	A Study of Selpercatinib After Surgery or Radiation in Participants With Non-Small Cell Lung Cancer (NSCLC) (LIBRETTO-432)	3	170	Event-Free Survival (EFS)	Aug 2028	Nov 2032

* Molecule may have multiple indications

** Trial may have additional primary and other secondary outcomes

Source: clinicaltrials.gov, April 18, 2023

SELECT TRIALS – TIRZEPATIDE



Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
NCT04184622	Obesity	A Study of Tirzepatide (LY3298176) in Participants With Obesity or Overweight (SURMOUNT-1)	3	2539	Percent Change from Baseline in Body Weight	Apr 2022	May 2024
NCT04657016	Obesity	A Study of Tirzepatide (LY3298176) In Participants After A Lifestyle Weight Loss Program (SURMOUNT-3)	3	806	Percent Change from Randomization in Body Weight	Apr 2023	May 2023
NCT04660643	Obesity	A Study of Tirzepatide (LY3298176) in Participants With Obesity or Overweight for the Maintenance of Weight Loss (SURMOUNT-4)	3	783	Percent Change from Randomization (Week 36) in Body Weight	Apr 2023	May 2023
NCT04844918	Obesity	A Study of Tirzepatide (LY3298176) in Participants With Obesity Disease (SURMOUNT-J)	3	261	Percentage of Participants who Achieve \geq 5% Body Weight Reduction	Jun 2023	Jun 2023
NCT05822830	Obesity	A Study of Tirzepatide (LY3298176) in Participants With Obesity or Overweight With Weight Related Comorbidities (SURMOUNT-5)	3	700	Percent Change from Baseline in Body Weight	Feb 2025	Mar 2025
NCT05556512	Obesity	A Study of Tirzepatide (LY3298176) on the Reduction on Morbidity and Mortality in Adults With Obesity (SURMOUNT-MMO)	3	15000	Time to First Occurrence of Any Component Event of Composite (All-Cause Death, Nonfatal Myocardial Infarction (MI), Nonfatal Stroke, Coronary Revascularization, or Heart Failure Events)	Oct 2027	Oct 2027

* Molecule may have multiple indications

** Trial may have additional primary and other secondary outcomes

Source: clinicaltrials.gov, April 18, 2023

SELECT TRIALS – TIRZEPATIDE (CONT.)



Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
NCT04255433	Type 2 Diabetes	A Study of Tirzepatide (LY3298176) Compared With Dulaglutide on Major Cardiovascular Events in Participants With Type 2 Diabetes (SURPASS-CVOT)	3	13299	Time to First Occurrence of Death from Cardiovascular (CV) Causes, Myocardial Infarction (MI), or Stroke (MACE-3)	Oct 2024	Oct 2024
NCT05260021	Type 2 Diabetes	A Study to Evaluate Tirzepatide (LY3298176) in Pediatric and Adolescent Participants With Type 2 Diabetes Mellitus Inadequately Controlled With Metformin or Basal Insulin or Both (SURPASS-PEDS)	3	90	Change From Baseline in Hemoglobin A1c (HbA1c)	Nov 2027	Dec 2027
NCT04166773	Nonalcoholic Steatohepatitis	A Study of Tirzepatide (LY3298176) in Participants With Nonalcoholic Steatohepatitis (SYNERGY-NASH)	2	196	Percentage of Participants with Absence of NASH with no Worsening of Fibrosis on Liver Histology	Jan 2024	Feb 2024
NCT05412004	Sleep Apnea	Obstructive Sleep Apnea Master Protocol GPF: A Study of Tirzepatide (LY3298176) in Participants With Obstructive Sleep Apnea (SURMOUNT-OSA)	3	469	Percent Change from Baseline in Apnea-Hypopnea Index (AHI)	Mar 2024	Mar 2024
NCT04847557	HFpEF	A Study of Tirzepatide (LY3298176) in Participants With Heart Failure With Preserved Ejection Fraction and Obesity (SUMMIT)	3	700	A Hierarchical Composite of All-Cause Mortality, Heart Failure Events, 6-minute Walk Test Distance (6MWD) and Kansas City Cardiomyopathy Questionnaire (KCCQ) Clinical Summary Score (CSS) Category	Jun 2024	Jul 2024
NCT05536804	CKD	A Study of Tirzepatide (LY3298176) in Participants With Overweight or Obesity and Chronic Kidney Disease With or Without Type 2 Diabetes (TREASURE-CKD)	2	140	Change from Baseline in Kidney Oxygenation in Participants With or Without T2D [Time Frame: Baseline, Week 52]; Blood oxygenation-level dependent magnetic resonance imaging (BOLD MRI)	Oct 2025	Nov 2025

* Molecule may have multiple indications

** Trial may have additional primary and other secondary outcomes

Source: clinicaltrials.gov, April 21, 2023

SELECT TRIALS – VERZENIO



Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
NCT03155997 ¹	Breast Cancer	Endocrine Therapy With or Without Abemaciclib (LY2835219) Following Surgery in Participants With Breast Cancer (monarchE)	3	5637	Invasive Disease Free Survival (IDFS)	Mar 2020	Jun 2029
NCT05169567	Breast Neoplasm	Abemaciclib (LY2835219) Plus Fulvestrant Compared to Placebo Plus Fulvestrant in Previously Treated Breast Cancer (postMonarch)	3	350	Progression-Free Survival (PFS)	Aug 2023	Feb 2026
NCT03706365	Prostate Cancer	A Study of Abiraterone Acetate Plus Prednisone With or Without Abemaciclib (LY2835219) in Participants With Prostate Cancer (CYCLONE 2)	2 3	350	Radiographic Progression Free Survival (rPFS)	Nov 2023	Jun 2026
NCT05288166	Prostatic Neoplasms	A Study of Abemaciclib (LY2835219) With Abiraterone in Men With Prostate Cancer That Has Spread to Other Parts of the Body and is Expected to Respond to Hormonal Treatment (Metastatic Hormone-Sensitive Prostate Cancer) (CYCLONE 3)	3	900	Radiographic Progression-Free Survival (rPFS) Assessed by Investigator	Oct 2025	Oct 2027

¹ Also lists NSABP Foundation Inc

* Molecule may have multiple indications

** Trial may have additional primary and other secondary outcomes

Source: clinicaltrials.gov, April 20, 2023

SELECT TRIALS – EARLY PHASE DIABETES AND OBESITY



Molecule	Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
LP(a) siRNA	NCT05565742	Lipoprotein Disorder	A Study of LY3819469 in Participants With Elevated Lipoprotein(a) [Lp(a)] (ALPACA)	2	254	Percent Change from Baseline in Time Averaged Lipoprotein(a) [Lp(a)]	Oct 2023	Oct 2024
Solbinsiran (ANGPLT3 siRNA)	NCT05256654	Dyslipidemias	A Study of LY3561774 in Participants With Mixed Dyslipidemia (PROLONG-ANG3)	2	175	Percent Change from Baseline for Apolipoprotein B (ApoB)	Jan 2024	Apr 2024
Muvalaplin (LP(a) Inhibitor)	NCT05563246	Lipoprotein Disorder	A Study of LY3473329 in Adult Participants With Elevated Lipoprotein(a) at High Risk for Cardiovascular Events (KRAKEN)	2	233	Percent Change from Baseline in Lipoprotein (a) Lp(a)	Jan 2024	Jan 2024
Relaxin-LA	NCT05592275	Heart Failure	A Study of LY3540378 in Participants With Worsening Chronic Heart Failure With Preserved Ejection Fraction (HFpEF)	2	432	Change from Baseline in Left Atrial Reservoir Strain (LARS)	Nov 2024	Jan 2025

* Molecule may have multiple indications

** Trial may have additional primary and other secondary outcomes

Source: clinicaltrials.gov, April 20, 2023

SELECT TRIALS – EARLY PHASE DIABETES AND OBESITY (CONT.)



Molecule	Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
PYY Analog Agonist	NCT05582096	Overweight	A Study of LY3457263 in Obese Participants	1	45	Number of Participants with One or More Treatment Emergent Adverse Events (TEAEs) and Serious Adverse Event(s) (SAEs) Considered by the Investigator to be Related to Study Drug Administration	May 2023	May 2023
GIP/GLP Coagonist Peptide	NCT05794243	Healthy	A Multiple-Dose Study of LY3493269 in Healthy Participants	1	70	Pharmacokinetics (PK): Area Under the Concentration-time curve (AUC) of LY3493269	Sep 2023	Sep 2023
DACRA QW II	NCT05380323	Overweight	A Study of LY3541105 in Healthy and Overweight Participants	1	160	Number of Participants with One or More Treatment Emergent Adverse Events (TEAEs) and Serious Adverse Event(s) (SAEs) Considered by the Investigator to be Related to Study Drug Administration	Sep 2023	Sep 2023
PYY Analog Agonist	NCT05377333	Diabetes Mellitus, Type 2	A Study of LY3457263 Alone and in Combination With Dulaglutide (LY2189265) in Participants With Type 2 Diabetes	1	86	Number of Participants with One or More Treatment Emergent Adverse Events (TEAEs) and Serious Adverse Event(s) (SAEs) Considered by the Investigator to be Related to Study Drug Administration	Sep 2023	Sep 2023
GIPR Agonist LA II	NCT05407961	Diabetes Mellitus, Type 2	A Study of LY3532226 in Participants With Type 2 Diabetes Mellitus	1	92	Part A: Number of Participants with One or More Treatment Emergent Adverse Events (TEAEs) and Serious Adverse Event(s) (SAEs) Considered by the Investigator to be Related to Study Drug Administration	Oct 2023	Oct 2023
Mazdutide	NCT05623839	Overweight	A Study of LY3305677 in Participants With Obesity Or Overweight	1	32	Number of Participants with One or More Treatment Emergent Adverse Events (TEAEs) and Serious Adverse Event(s) (SAEs) Considered by the Investigator to be Related to Study Drug Administration	Dec 2023	Dec 2023

* Molecule may have multiple indications

** Trial may have additional primary and other secondary outcomes

Source: clinicaltrials.gov, April 21, 2023

SELECT TRIALS – EARLY PHASE DIABETES AND OBESITY (CONT.)



Molecule	Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
Amylin Agonist LA	NCT05295940	Obesity	A Study of LY3841136 in Healthy and Overweight Participants	1	160	Number of Participants with One or More Treatment Emergent Adverse Events (TEAEs) and Serious Adverse Event(s) (SAEs) Considered by the Investigator to be Related to Study Drug Administration	Jan 2024	Jan 2024
NRG4 Agonist	NCT04840914	HFrEF	A Study of LY3461767 in Participants With Chronic Heart Failure With Reduced Ejection Fraction	1	50	Number of Participants with One or More Serious Adverse Event(s) (SAEs) Considered by the Investigator to be Related to Study Drug Administration	Mar 2024	Mar 2024
APOC3 siRNA	NCT05609825	Hypertriglyceridemia	A Study of LY3875383 in Healthy Participants and Participants With Hypertriglyceridemia	1	120	Number of Participants with One or More Treatment Emergent Adverse Events (TEAEs) and Serious Adverse Event(s) (SAEs) Considered by the Investigator to be Related to Study Drug Administration	Aug 2024	Aug 2024
PNPLA3 siRNA	NCT05395481	Non-Alcoholic Fatty Liver Disease	A Single-Ascending and Repeated Dose Study of LY3849891 in Participants With Nonalcoholic Fatty Liver Disease	1	176	Part A: Number of Participants with One or More Treatment Emergent Adverse Events (TEAEs) and Serious Adverse Event(s) (SAEs) Considered by the Investigator to be Related to Study Drug Administration	Nov 2024	Nov 2024

* Molecule may have multiple indications

** Trial may have additional primary and other secondary outcomes

Source: clinicaltrials.gov, April 21, 2023

SELECT TRIALS – EARLY PHASE IMMUNOLOGY



Molecule	Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
Peresolimab	NCT05516758	Rheumatoid Arthritis	A Study of Peresolimab (LY3462817) in Participants With Moderately-to-Severely Active Rheumatoid Arthritis (RESOLUTION-1)	2	420	Percentage of Participants Achieving American College of Rheumatology (ACR)20	Nov 2023	Jan 2025
BTLA MAB Agonist	NCT05123586	Systemic Lupus Erythematosus	A IMMA Master Protocol: A Study of LY3361237 in Participants With at Least Moderately Active Systemic Lupus Erythematosus	2	90	Percentage of Participants with Arthritis and/or Rash at Baseline Who Achieve Remission of Arthritis and/or Rash	Jan 2024	Apr 2024
CD19	NCT05042310	Healthy	A Study of LY3541860 in Healthy Japanese and Non-Japanese Participants	1	84	Number of Participants with One or More Treatment Emergent Adverse Events (TEAEs) and Serious Adverse Event(s) (SAEs) Considered by the Investigator to be Related to Study Drug Administration	Jul 2023	Jul 2023
GITR Antagonist Antibody	NCT05486208	Healthy	A Study of LY3844583 in Healthy Participants and Participants With Atopic Dermatitis	1	86	Number of Participants with One or More Adverse Events (AEs), Treatment Emergent Adverse Events (TEAEs) and Serious Adverse Event(s) (SAEs) Considered by the Investigator to be Related to Study Drug Administration	Jul 2023	Jan 2024

* Molecule may have multiple indications

** Trial may have additional primary and other secondary outcomes

Source: clinicaltrials.gov, April 18, 2023

SELECT TRIALS – EARLY PHASE NEURODEGENERATION



Molecule	Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
O-GlcNAcase Inh.	NCT05063539	Alzheimer Disease	A Study of LY3372689 to Assess the Safety, Tolerability, and Efficacy in Participants With Alzheimer's Disease	2	330	Change from Baseline to End Time Point in Integrated Alzheimer's Disease Rating Scale (iADRS)	May 2024	Jun 2024
SARM1 CNS Inhibitor	NCT05492201	Healthy	A Study of LY3873862 in Healthy Participants	1	90	Number of Participants with One or More Treatment Emergent Adverse Events (TEAEs) and Serious Adverse Event(s) (SAEs) Considered by the Investigator to be Related to Study Drug Administration	Apr 2023	Apr 2023
GRN Gene Therapy	NCT04408625	Frontotemporal Dementia	Phase 1/2 Clinical Trial of PR006 in Patients With Frontotemporal Dementia With Progranulin Mutations (FTD-GRN) (PROCLAIM)	1 2	15	Number of Adverse Events (AEs), Serious Adverse Events (SAEs), and Adverse Events Leading to discontinuation	Dec 2027	Dec 2027
GBA1 Gene Therapy	NCT04127578	Parkinson Disease	Phase 1/2a Clinical Trial of PR001 (LY3884961) in Patients With Parkinson's Disease With at Least One GBA1 Mutation (PROPEL)	1 2	20	Cumulative number of Treatment-Emergent Adverse Events (TEAEs) and Serious Adverse Events (SAEs)	Apr 2028	Apr 2028
GBA1 Gene Therapy	NCT04411654	Gaucher Disease, Type 2	Phase 1/2 Clinical Trial of PR001 in Infants With Type 2 Gaucher Disease (PROVIDE)	1 2	15	Number of Adverse Events (AEs), Serious Adverse Events (SAEs), and Adverse Events leading to discontinuation	Sep 2028	Sep 2028
GBA1 Gene Therapy	NCT05487599	Gaucher Disease	A Clinical Trial of PR001 (LY3884961) in Patients With Peripheral Manifestations of Gaucher Disease (PROCEED)	1 2	15	Incidence and severity of Treatment-emergent Adverse Events (TEAEs) and Serious Adverse Events (SAEs)	Sep 2030	Sep 2030

* Molecule may have multiple indications

** Trial may have additional primary and other secondary outcomes

Source: clinicaltrials.gov, April 4, 2023

SELECT TRIALS – EARLY PHASE ONCOLOGY



Molecule	Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
IDH1/2 Inhibitor	NCT04521686	Cholangiocarcinoma	Study of LY3410738 Administered to Patients With Advanced Solid Tumors With IDH1 or IDH2 Mutations	1	200	Recommended Phase 2 dose (RP2D)	May 2023	May 2023
KRAS G12C ¹	NCT04956640	Carcinoma, Non-Small-Cell Lung	Study of LY3537982 in Cancer Patients With a Specific Genetic Mutation (KRAS G12C)	1	400	Phase 1a: To determine the recommended phase 2 dose (RP2D) of LY3537982 monotherapy	Sep 2025	Sep 2025
IDH1/2 Inhibitor	NCT04603001	Acute Myeloid Leukemia (AML)	Study of Oral LY3410738 in Patients With Advanced Hematologic Malignancies With IDH1 or IDH2 Mutations	1	260	To determine the maximum tolerated dose (MTD)/recommended Phase 2 dose (RP2D)	May 2024	May 2024
PI3K Selective	NCT05307705	Breast Cancer	A Study of LOXO-783 in Patients With Breast Cancer/Other Solid Tumors (PIKASSO-01)	1	400	Phase 1a: To determine the MTD/RP2D of LOXO-783: Number of patients with dose-limiting toxicities (DLTs)	May 2025	May 2025
FGFR3 Selective	NCT05614739	Urinary Bladder Neoplasms	A Study of LOXO-435 in Patients With Cancer With a Change in a Gene Called FGFR3	1	140	Phase 1a: To determine the maximum tolerated dose/recommended phase 2 dose (MTD/RP2D) of LOXO-435: Number of patients with dose-limiting toxicities (DLTs)	Jun 2025	Jun 2025
RET Inhibitor II	NCT05241834	Carcinoma, Non-Small-Cell Lung	A Study of LOXO-260 in Cancer Patients With a Change in a Particular Gene (RET) That Has Not Responded to Treatment	1	110	Phase 1a: To determine the MTD/RP2D of LOXO-260: Dose limiting toxicity (DLT) rate	Apr 2026	Apr 2026

¹ Also lists Merck Sharp & Dohme LLC

* Molecule may have multiple indications

** Trial may have additional primary and other secondary outcomes

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Source: clinicaltrials.gov, April 21, 2023

SELECT TRIALS – EARLY PHASE PAIN



Molecule	Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
P2X7 Inhibitor	NCT05620563	Knee Osteoarthritis	A Chronic Pain Master Protocol (CPMP): A Study of LY3857210 In Participants With Osteoarthritis Pain (OA05)	2	125	Change from Baseline for Average Pain Intensity as measured by the Numeric Rating Scale (NRS)	May 2023	Jun 2023
P2X7 Inhibitor	NCT05630196	Chronic Low-back Pain	A Chronic Pain Master Protocol (CPMP): A Study of LY3857210 in Participants With Chronic Low Back Pain	2	125	Change from Baseline for Average Pain Intensity as measured by the Numeric Rating Scale (NRS)	Jun 2023	Jun 2023
P2X7 Inhibitor	NCT05620576	Chronic Pain	A Chronic Pain Master Protocol (CPMP): A Study of LY3857210 in Participants With Diabetic Peripheral Neuropathic Pain (NP05)	2	125	Change from Baseline for Average Pain Intensity as measured by the Numeric Rating Scale (NRS)	Oct 2023	Oct 2023

* Molecule may have multiple indications

** Trial may have additional primary and other secondary outcomes

Source: clinicaltrials.gov, April 14, 2023

Lilly