



2020 FOURTH QUARTER AND FULL YEAR FINANCIAL RESULTS

INNOVATING TO TRANSFORM THE LIVES OF PATIENTS

February 23, 2021



Jazz Pharmaceuticals®

Life-Changing Medicines. Redefining Possibilities.

Forward-Looking Statements

“Safe Harbor” Statement Under The Private Securities Litigation Reform Act of 1995

This communication contain forward-looking statements, including, but not limited to, statements related to Jazz Pharmaceuticals' future financial and operating results, 2021 financial guidance, growth prospects, 2021 and future goals, objectives and milestones, revenue diversification and the anticipated timing thereof; statements related to the proposed acquisition of GW Pharmaceuticals and the anticipated timing, results and benefits thereof; potential expansion of the company's pipeline; planned, ongoing and future clinical trials, including expected initiation of studies for JZP-385, Zepzelca and JZP-150, and presentations of data; geographic expansion activities, including potential approval of Sunosi in Canada; other product development and regulatory activities, including potential U.S. regulatory approval of JZP-458 for ALL/LBL and JZP-258 for idiopathic hypersomnia; ongoing and potential future product launches, including Sunosi, Zepzelca, Xywav, JZP-458 for ALL/LBL and JZP-258 for idiopathic hypersomnia, and expectations regarding timing and achievement of payer coverage; the company's expectations regarding timing, availability and inter-quarter variability of Erwinaze net product sales; the timing of the foregoing events and activities; and other statements that are not historical facts. These forward-looking statements are based on the company's current plans, objectives, estimates, expectations and intentions and inherently involve significant risks and uncertainties. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, which include, without limitation, risks and uncertainties associated with: Jazz Pharmaceuticals' and GW Pharmaceuticals' ability to complete the acquisition on the proposed terms or on the anticipated timeline, or at all, including risks and uncertainties related to securing the necessary regulatory and shareholder approvals, the sanction of the High Court of Justice of England and Wales and satisfaction of other closing conditions to consummate the acquisition; the occurrence of any event, change or other circumstance that could give rise to the termination of the definitive transaction agreement relating to the proposed transaction; risks related to diverting the attention of GW Pharmaceuticals and Jazz Pharmaceuticals management from ongoing business operations; failure to realize the expected benefits of the acquisition; significant transaction costs and/or unknown or inestimable liabilities; the risk of litigation in connection with the proposed transaction, including resulting expense or delay; the risk that GW Pharmaceuticals' business will not be integrated successfully or that such integration may be more difficult, time-consuming or costly than expected; Jazz Pharmaceuticals' ability to obtain the expected financing to consummate the acquisition; risks related to future opportunities and plans for the combined company, including the uncertainty of expected future regulatory filings, financial performance and results of the combined company following completion of the acquisition; GW Pharmaceuticals' dependence on the successful commercialization of Epidiolex/Epidyolex and the uncertain market potential of Epidiolex; pharmaceutical product development and the uncertainty of clinical success; the regulatory approval process, including the risks that GW Pharmaceuticals may be unable to submit anticipated regulatory filings on the timeframe anticipated, or at all, or that GW Pharmaceuticals may be unable to obtain regulatory approvals of any of its product candidates, including nabiximols and Epidiolex for additional indications, in a timely manner or at all; disruption from the proposed acquisition of GW Pharmaceuticals, making it more difficult to conduct business as usual or maintain relationships with customers, employees or suppliers; effects relating to the announcement of the acquisition or any further announcements or the consummation of the acquisition on the market price of Jazz Pharmaceuticals' ordinary shares; the possibility that, if Jazz Pharmaceuticals does not achieve the perceived benefits of the acquisition as rapidly or to the extent anticipated by financial analysts or investors, the market price of Jazz Pharmaceuticals' ordinary shares could decline; regulatory initiatives and changes in tax laws; market volatility; the ultimate duration and severity of the COVID-19 pandemic and resulting global economic, financial and healthcare system disruptions and the current and potential future negative impacts to the company's business operations and financial results; maintaining or increasing sales of and revenue from the company's oxybate products and other key marketed products; effectively launching and commercializing the company's other products and product candidates; the time-consuming and uncertain regulatory approval process, including the risk that the company's planned regulatory submissions may not be submitted, accepted or approved by applicable regulatory authorities in a timely manner or at all; the costly and time-consuming pharmaceutical product development process and the uncertainty of clinical success, including risks related to failure or delays in successfully initiating or completing clinical trials and assessing patients such as those being experienced, and expected to continue to be experienced, by the company as a result of the effects of the COVID-19 pandemic; protecting and enhancing the company's intellectual property rights; delays or problems in the supply or manufacture of the company's products and product candidates; complying with applicable U.S. and non-U.S. regulatory requirements; government investigations, legal proceedings and other actions; (continued on next page)

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Forward-Looking Statements

“Safe Harbor” Statement Under The Private Securities Litigation Reform Act of 1995 (Continued from Previous Slide)

obtaining and maintaining adequate coverage and reimbursement for the company’s products; identifying and acquiring, in-licensing or developing additional products or product candidates, financing these transactions and successfully integrating acquired product candidates, products and businesses; the company’s ability to realize the anticipated benefits of its collaborations and license agreements with third parties; the company’s ability to achieve expected future financial performance and results and the uncertainty of future tax and other provisions and estimates; and other risks and uncertainties affecting the company and GW Pharmaceuticals, including those described from time to time under the caption “Risk Factors” and elsewhere in Jazz Pharmaceuticals’ and GW Pharmaceuticals’ Securities and Exchange Commission (SEC) filings and reports, including the company’s Quarterly Report on Form 10-Q for the quarter ended September 30, 2020 and Annual Report on Form 10-K for the year ended December 31, 2019, GW Pharmaceuticals’ Annual Report on Form 10-K for the year ended December 31, 2019 and Quarterly Report on Form 10-Q for the quarter ended September 30, 2020, and future filings and reports by either company, including the Jazz Pharmaceuticals’ Annual Report on Form 10-K for the year ended December 31, 2020.

In addition, while the company expects the COVID-19 pandemic to continue to adversely affect its business operations and financial results, the extent of the impact on the company’s ability to generate sales of and revenues from its approved products, execute on new product launches, its clinical development and regulatory efforts, its corporate development objectives and the value of and market for its ordinary shares, will depend on future developments that are highly uncertain and cannot be predicted with confidence at this time, such as the ultimate duration and severity of the pandemic, governmental “stay-at-home” orders and travel restrictions, quarantines, social distancing and business closure requirements in the U.S., Ireland and other countries, and the effectiveness of actions taken globally to contain and treat the disease. Moreover, other risks and uncertainties of which the company is not currently aware may also affect the company’s forward-looking statements and may cause actual results and the timing of events to differ materially from those anticipated. The forward-looking statements made in this communication are made only as of the date hereof or as of the dates indicated in the forward-looking statements, even if they are subsequently made available by the company on its website or otherwise. The company undertakes no obligation to update or supplement any forward-looking statements to reflect actual results, new information, future events, changes in its expectations or other circumstances that exist after the date as of which the forward-looking statements were made.

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Non-GAAP Financial Measures

To supplement Jazz Pharmaceuticals' financial results and guidance presented in accordance with U.S. generally accepted accounting principles (GAAP), the company uses certain non-GAAP (also referred to as adjusted or non-GAAP adjusted) financial measures in this presentation and the accompanying tables. In particular, the company presents non-GAAP adjusted net income (and the related per share measure) and its line item components, as well as certain non-GAAP adjusted financial measures derived therefrom, including non-GAAP adjusted gross margin percentage and non-GAAP adjusted effective tax rate. Non-GAAP adjusted net income (and the related per share measure) and its line item components exclude from GAAP reported net income (and the related per share measure) and its line item components certain items, as detailed in the reconciliation tables that follow, and in the case of non-GAAP adjusted net income (and the related per share measure), adjust for the income tax effect of non-GAAP adjustments and, as applicable, the income tax benefit related to an intra-entity intellectual property asset transfer and the impact of the U.S. Tax Cuts and Job Act (U.S. Tax Act). In this regard, the components of non-GAAP adjusted net income, including non-GAAP cost of product sales, non-GAAP SG&A expenses and non-GAAP R&D expenses, are income statement line items prepared on the same basis as, and therefore components of, the overall non-GAAP adjusted net income measure.

The company believes that each of these non-GAAP financial measures provides useful supplementary information to, and facilitates additional analysis by, investors and analysts. In particular, the company believes that each of these non-GAAP financial measures, when considered together with the company's financial information prepared in accordance with GAAP, can enhance investors' and analysts' ability to meaningfully compare the company's results from period to period and to its forward-looking guidance, and to identify operating trends in the company's business. In addition, these non-GAAP financial measures are regularly used by investors and analysts to model and track the company's financial performance. Jazz Pharmaceuticals' management also regularly uses these non-GAAP financial measures internally to understand, manage and evaluate the company's business and to make operating decisions, and compensation of executives is based in part on certain of these non-GAAP financial measures. Because these non-GAAP financial measures are important internal measurements for Jazz Pharmaceuticals' management, the company also believes that these non-GAAP financial measures are useful to investors and analysts since these measures allow for greater transparency with respect to key financial metrics the company uses in assessing its own operating performance and making operating decisions.

These non-GAAP financial measures are not meant to be considered in isolation or as a substitute for comparable GAAP measures; should be read in conjunction with the company's consolidated financial statements prepared in accordance with GAAP; have no standardized meaning prescribed by GAAP; and are not prepared under any comprehensive set of accounting rules or principles. In addition, from time to time in the future there may be other items that the company may exclude for purposes of its non-GAAP financial measures; and the company has ceased, and may in the future cease, to exclude items that it has historically excluded for purposes of its non-GAAP financial measures. For example, commencing in 2020, the company no longer excludes upfront and milestone payments from the company's non-GAAP adjusted net income, its line item components and non-GAAP adjusted EPS. For purposes of comparability, non-GAAP adjusted financial measures for the three and twelve months ended December 31, 2019 and prior periods have been updated to reflect this change. Likewise, the company may determine to modify the nature of its adjustments to arrive at its non-GAAP financial measures. Because of the non-standardized definitions of non-GAAP financial measures, the non-GAAP financial measures as used by Jazz Pharmaceuticals in this press release and the accompanying tables have limits in their usefulness to investors and may be calculated differently from, and therefore may not be directly comparable to, similarly titled measures used by other companies.

Additional Information and Where to Find It

In connection with the proposed transaction, GW Pharmaceuticals intends to file a proxy statement with the SEC. Each of Jazz Pharmaceuticals and GW Pharmaceuticals may also file other relevant documents with the SEC regarding the proposed transaction. The definitive proxy statement (if and when available) will be mailed to shareholders of GW Pharmaceuticals. INVESTORS AND SECURITY HOLDERS ARE URGED TO READ THE PROXY STATEMENT (WHICH WILL INCLUDE AN EXPLANATORY STATEMENT IN RESPECT OF THE SCHEME OF ARRANGEMENT OF GW PHARMACEUTICALS, IN ACCORDANCE WITH THE REQUIREMENTS OF THE U.K. COMPANIES ACT 2006) AND ANY OTHER RELEVANT DOCUMENTS THAT MAY BE FILED WITH THE SEC, AS WELL AS ANY AMENDMENTS OR SUPPLEMENTS TO THESE DOCUMENTS, CAREFULLY AND IN THEIR ENTIRETY IF AND WHEN THEY BECOME AVAILABLE BECAUSE THEY CONTAIN OR WILL CONTAIN IMPORTANT INFORMATION ABOUT THE PROPOSED TRANSACTION.

Investors and security holders will be able to obtain free copies of the proxy statement (if and when available) and other documents containing important information about Jazz Pharmaceuticals, GW Pharmaceuticals and the proposed transaction, once such documents are filed with the SEC through the website maintained by the SEC at <http://www.sec.gov>. Copies of the documents filed with the SEC by Jazz Pharmaceuticals will be available free of charge on Jazz Pharmaceuticals' website at <https://www.jazzpharma.com>. Copies of the documents filed with the SEC by GW Pharmaceuticals will be available free of charge on GW Pharmaceuticals' website at <https://www.gwpharm.com>.

Participants in the Solicitation

Jazz Pharmaceuticals, GW Pharmaceuticals, their respective directors and certain of their executive officers and other employees may be deemed to be participants in the solicitation of proxies from GW Pharmaceuticals' security holders in connection with the proposed transaction. Information about GW Pharmaceuticals' directors and executive officers is set forth in GW Pharmaceuticals' proxy statement on Schedule 14A for its 2020 Annual General Meeting, which was filed with the SEC on April 7, 2020, and its Current Report on Form 8-K filed with the SEC on September 10, 2020 and subsequent statements of beneficial ownership on file with the SEC. Information about Jazz Pharmaceuticals' directors and executive officers is set forth in Jazz Pharmaceuticals' proxy statement on Schedule 14A for its 2020 Annual General Meeting, which was filed with the SEC on June 12, 2020 and subsequent statements of beneficial ownership on file with the SEC. Additional information regarding the persons who may, under the rules of the SEC, be deemed participants in the solicitation of GW Pharmaceuticals' security holders in connection with the proposed transaction, including a description of their direct or indirect interests, by security holdings or otherwise, will be set forth in the proxy statement when it is filed with the SEC.

No Offer Or Solicitation

This communication is not intended to and shall not constitute an offer to buy or sell or the solicitation of an offer to buy or sell any securities, or a solicitation of any vote or approval, nor shall there be any offer, solicitation or sale of securities in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such jurisdiction. No offer of securities shall be made in the United States absent registration under the U.S. Securities Act of 1933, as amended (Securities Act), or pursuant to an exemption from, or in a transaction not subject to, such registration requirements. The Jazz Pharmaceuticals securities to be delivered in the proposed transaction are anticipated to be delivered in reliance upon an available exemption from such registration requirements pursuant to Section 3(a)(10) of the Securities Act.

4Q20 Conference Call

Bruce Cozadd

Chairman and Chief Executive Officer

Overview

Dan Swisher

President and Chief Operating Officer

Commercial Performance

Rob Iannone, M.D., M.S.C.E.

Executive Vice President, Research & Development and CMO

Research & Development

Renée Galá

Executive Vice President and Chief Financial Officer

Financial Update

Kim Sablich

Executive Vice President, General Manager, North America

Q&A

Samantha Pearce

Senior Vice President, Europe and International

Q&A

Phil Jochelson, M.D.

Neuroscience Therapeutic Head

Q&A

Anne Borgman, M.D.

Hematology and Oncology Therapeutic Head

Q&A

Shawn Mindus

Senior Vice President, Strategy and Finance

Q&A



BUSINESS UPDATES

Focused Execution Drives Long-Term Value

Key Achievements 2020 and Early 2021



PIPELINE

**Xywav¹ for EDS and Cataplexy
in Narcolepsy**
FDA approval

JZP-458 for ALL
Initiated BLA submission
Real-Time Oncology Review

JZP-258 for IH
Compelling topline data
Completed rolling sNDA submission



TRANSACTIONS

GW Pharmaceuticals²
Company Acquisition

PharmaMar
U.S. and Canadian rights
to Zepzelca (lurbinectedin)

SpringWorks
Acquired FAAH inhibitor (JZP-150)

Redx Pharma
Collaboration on two cancer targets
Ras/Raf/MAP kinase pathway



COMMERCIAL

**Execute up to five key product
launches through 2020 and 2021**

Launched in 2020
Xywav (EDS and cataplexy in
narcolepsy)
Zepzelca (2L SCLC)
Sunosi (EDS in OSA and narcolepsy;
European rolling launch)

Preparing for 2021 U.S. Launches³
JZP-458 (ALL/LBL)
JZP-258 (IH)

Neuroscience Portfolio

OXYBATE XYREM + XYWAV COMBINED

- Revenue bottle volume growth compared to the prior year periods
 - 2% in 4Q20
 - 4% for FY20
- Average active patients
 - 15,300 in 4Q20
 - 2% increase compared to 4Q19

XYWAV

- Launched in the U.S. Nov. 2020
- ~1,900 active patients at the end 2020
- Entered into agreements that provide coverage for 2 of the 3 largest PBMs in the U.S., with total commercial coverage now exceeding 60% of lives
- On track for broad commercial payer coverage within first 6 – 9 months of launch

SUNOSI

- 9% increase in total U.S. scripts in 4Q20 compared to 3Q20
- >90% U.S. commercial lives covered
- European rolling launch progressing well
- Anticipate Canadian approval 1H21

JZP-258 FOR IH

- Compelling Phase 3 top-line results
- Completed rolling sNDA submission in February 2021
- Phase 3 results to be presented at an upcoming medical conference in 2Q21
- Targeting 4Q21 launch

JZP-385

- Start-up activities began in 4Q20 to enable initiation of Phase 2b trial in mid-2021 for essential tremor

JZP-150

- Phase 2 trial targeted to begin in late 2021

Delivering Meaningful Growth

Oncology Portfolio

JZP-458

- BLA submission initiated in 4Q20 under Real-Time Oncology Review
- Targeting U.S. launch in mid-2021
- Anticipate current JZP-458 development program will support efforts to seek approval in Europe and Canada
- Working with partner in Japan on regulatory strategy

ZEPZELCA

- Strong demand following U.S. launch July 2020
- New Drug Submission filed for Zepzelca in Canada
- Expect to initiate phase 3 trial for Zepzelca in combination with immunotherapy in 1L ES-SCLC in 2021

VYXEOS

- Anticipate label updates in U.S. and EU for R/R pediatric AML in 2021
- Continued geographic expansion underway

DEFITELIO

- Continued geographic expansion underway

2021 Goals

Aligned to Patient-Centric Strategy and Key Objectives



PATIENT-CENTRIC INNOVATION DRIVES OUR STRATEGY

Innovate to transform the lives of patients

- Expand our pipeline and diversify revenues through acquisitions, collaborations, and internal initiatives
- Build a high value portfolio of assets through disciplined portfolio management and capital allocation



CONTINUED COMMERCIAL EXECUTION EXCELLENCE

Targeted launches:

- JZP-458 in ALL/LBL mid-year 2021¹
- JZP-258 in IH 4Q21¹

Continue to focus on:

- Rapid U.S. adoption and broad access for Xywav
- Sunosi growth globally
- Driving Zepzelca as the treatment of choice for 2L SCLC patients



ROBUST AND PRODUCTIVE PIPELINE

Key Pipeline Milestones:

- Initiate phase 2b trial for JZP-385 in ET in mid-2021
- Initiate phase 2 trial for JZP-150 in PTSD in late 2021
- Initiate phase 3 trial for Zepzelca in combination with I/O in 1L ES-SCLC



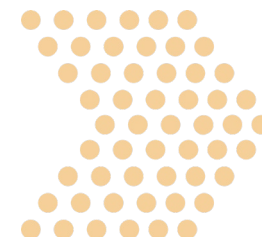
2021

5 key launches
through 2020
and 2021



2022

Nearly half of revenues
from products launched
since 2019²



2023

Majority of all oxybate
patients on Xywav

¹ Subject to FDA approval.

² Refers to Jazz expectations not taking into account the potential GW Pharmaceuticals transaction. Assuming the closing of the GW Pharmaceuticals transaction, Jazz expects >65% of 2022 revenues from products acquired or launched since 2019.



TRANSACTION OVERVIEW: GW PHARMACEUTICALS PLC

GW Acquisition Expected to Drive Substantial Shareholder Value

Creates an innovative, global, high-growth biopharma leader with a robust pipeline and one patient-centric mission

Epidiolex has near-term blockbuster potential

Combined Neuroscience business has global commercial and operational footprint to maximize value of Xywav, Epidiolex and other Neuroscience products

Accelerates revenue growth and diversification

Adding a third high-growth commercial franchise for critical unmet patient needs within:

1) sleep disorders 2) oncology 3) epilepsies

Robust pro forma pipeline in Neuroscience and Oncology to drive sustainable growth:

19 clinical development programs

GW's industry **leading cannabinoid platform and scientific expertise** significantly expands Jazz's neuroscience pipeline

Anticipated to be EPS accretive in first full year of combined operations and substantially accretive thereafter

Strong cash flow generation

Commitment to rapid deleveraging; targeting net leverage of $<3.5\times^1$ by the end of 2022



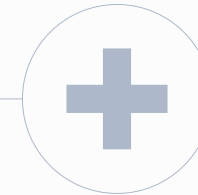
Combination Creates Global Neuroscience Leader



Global leaders
in complementary areas

**#1 Sleep Disorders
Franchise**

**Unparalleled Leader in
Cannabinoid Science**



SLEEP
DISORDERS



ONCOLOGY



EPILEPSIES  **Epidiolex[®]**
(cannabidiol)



Addition of third
high-growth commercial franchise
with blockbuster potential

Highly complementary
commercial and R&D capabilities

- Global commercial and operational footprint to commercialize, scale and maximize value
- Track record of successfully building neuroscience franchises

**Leveraging
Combined
Global Platform**

- Augments Jazz's growing European neuroscience footprint
- At the forefront of cannabinoid science and manufacturing expertise with robust clinical pipeline

Transaction Expected to Deliver Substantial and Sustainable Value

Disciplined Allocation of Capital in Alignment With Our Strategic Priorities

TRANSACTION ALIGNED TO CAPITAL ALLOCATION STRATEGY



Accelerates revenue growth and diversification



Leading cannabinoid platform significantly expands Jazz's neuroscience pipeline



Focused on operational excellence to maximize Total Shareholder Return (TSR)

LEVERAGING FINANCIAL STRENGTH

\$2.1B

Cash¹

\$Billions

Expected cash flow through 2025

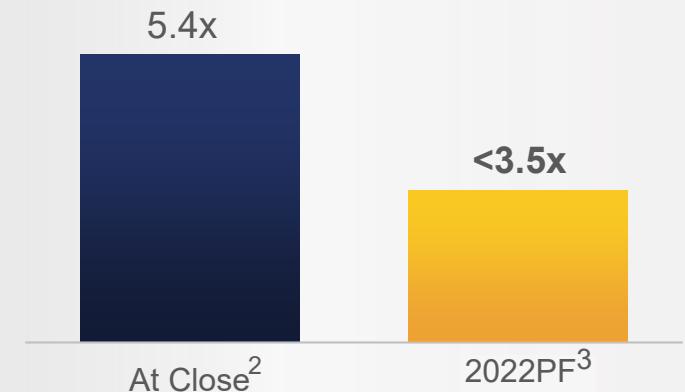
Optimized

Significant leverage capacity

DISCIPLINED USE OF CAPITAL

Expect to be EPS accretive in first full year

Commitment to de-lever; targeting <3.5x net leverage by end of 2022



Transaction Overview

Purchase Price

- Holders of GW ADSs, which each represent 12 GW ordinary shares, will be entitled to receive \$220 for each GW ADS
 - Representing \$200 in cash and \$20 in shares of Jazz stock, subject to a 10% collar centered on Jazz's closing share price on February 1, 2021
- Total transaction enterprise value of approximately \$6.7B, net of GW cash

Financial Impact

- Accelerated, double-digit top-line revenue growth
- Anticipated to be EPS accretive in first full year of combined operations and substantially accretive thereafter
- Enhanced revenue diversification; combined new product sales contribute >65% of revenue in 2022

Funding & Capital Impact

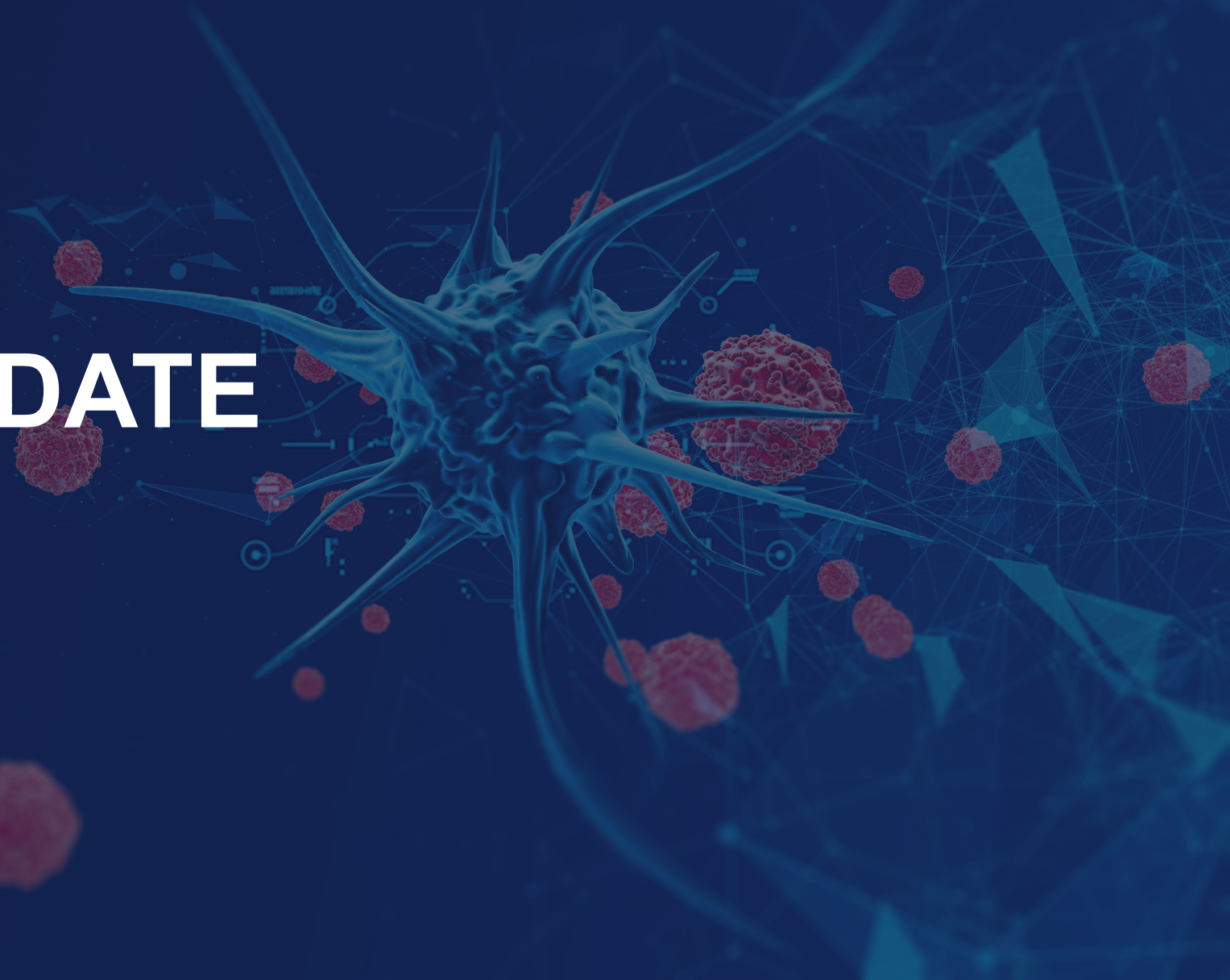
- Total transaction value of approximately \$7.2B
 - \$6.5B in cash, financed by cash on hand and new debt, while maintaining ample liquidity for operations
 - Approximately \$0.7B in Jazz shares
- Targeting less than 3.5x net leverage by the end of 2022

Approvals & Timing

- Transaction has been unanimously approved by both Jazz and GW Boards of Directors
- Anticipated closing in the second quarter of 2021
- Transaction subject to customary closing conditions, including regulatory approvals and approval of GW shareholders¹
- Until closing, both companies will continue to operate independently



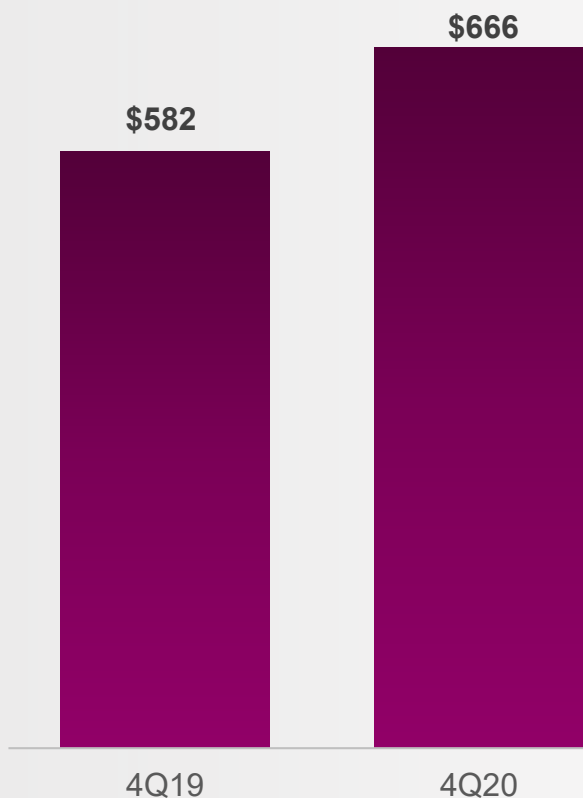
FINANCIAL UPDATE



Strong Performance with Increasingly Diversified Revenues

TOTAL REVENUES

\$ in millions



In millions, except % (unaudited)	4Q19	3Q20	4Q20	Δ 4Q20 vs 3Q20	Δ 4Q20 vs 4Q19
Xyrem® (sodium oxybate) oral solution	\$435	\$448	\$439	(2)%	1%
Sunosi® (solriamfetol)	3	9	9	(4)%	N/A
Xywav™ (calcium, magnesium, potassium, and sodium oxybates) oral solution ¹	--	--	15	N/A	N/A
Total Neuroscience Revenues	438	457	463	1%	6%
Vyxeos® (daunorubicin and cytarabine) liposome for injection	32	31	31	1%	(2)%
Zepzelca™ (lurbinectedin) for injection 4 mg ²	--	37	53	45%	N/A
Defitelio® (defibrotide sodium) /defibrotide	48	50	55	10%	16%
Erwinaze®/Erwinase® (asparaginase <i>Erwinia chrysanthemi</i>)	55	20	57	181%	3%
Total Oncology Revenues	134	138	196	42%	46%
Other	4	2	2	(15)%	(62)%
Total Net Product Sales	577	597	661	11%	15%
Royalties and contract revenues	5	4	4	7%	(19)%
Total Revenues	\$582	\$601	\$666	11%	14%

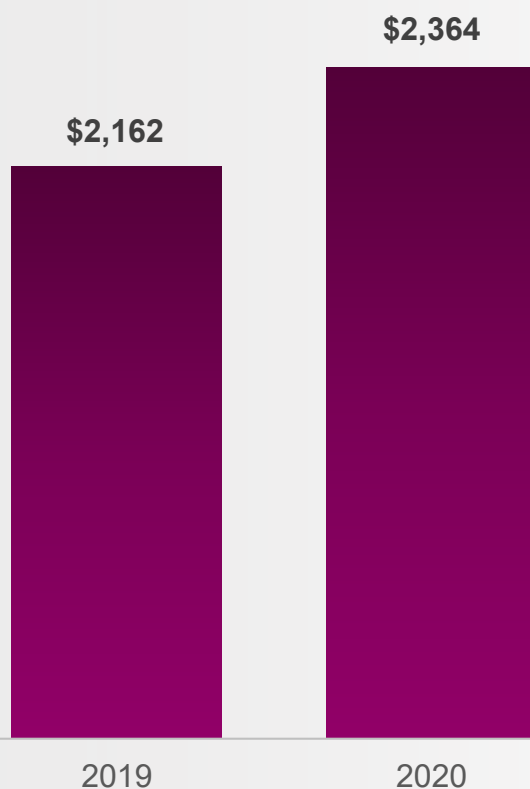
¹ Launched in the U.S. in November 2020.

² Launched in the U.S. in July 2020. Note: Amounts may not total due to rounding. Percentages calculated from amounts in thousands. N/A - Prior period comparison not meaningful.

Strong Revenue Growth Year over Year

TOTAL REVENUES

\$ in millions



In millions, except % (unaudited)	Year Ended		Δ
	2019	2020	
Xyrem	\$1,643	\$1,742	6%
Sunosi	4	28	N/A
Xywav ¹	--	15	N/A
Total Neuroscience	1,646	1,785	8%
Defitelio/defibrotide	173	196	13%
Erwinaze/Erwinase	177	147	(17)%
Vyxeos	121	121	0%
Zepzelca ²	--	90	N/A
Total Oncology	472	554	18%
Other	18	7	(61)%
Total Net Product Sales	2,136	2,347	10%
Royalties and contract revenues	26	17	(35)%
Total Revenues	\$2,162	\$2,364	9%

¹ Launched in the U.S. in November 2020. ² Launched in the U.S. in July 2020.

Note: Amounts may not total due to rounding. Percentages calculated from amounts in thousands. N/A - Prior period comparison not meaningful.

4Q20 Key Adjusted Line Items and Other Information¹

Operating expenses support growing development pipeline and up to 5 key launches through 2020-2021

In millions, except % (unaudited)	4Q19	3Q20	4Q20	Δ 4Q20 vs 3Q20	Δ 4Q20 vs 4Q19
Gross Margin	94.1%	93.3%	92.7%	(0.6) pp	(1.4) pp
SG&A Expense % of Total Revenues	\$197 33.9%	\$186 31.0%	\$225 33.9%	21% 2.9 pp	14% (0.0) pp
R&D Expense % of Total Revenues	\$90 15.5%	\$71 11.8%	\$84 12.6%	18% 0.8 pp	(7)% (2.9) pp
Acquired IPR&D	--	\$10	\$36	N/A	N/A
Operating Income Margin	44.8%	48.8%	40.9%	(7.9) pp	(3.9) pp
Effective Tax Rate	(0.9)%	13.6%	11.6%	(2.0) pp	12.5 pp

Note: Amounts may not total due to rounding. Percentages calculated from amounts in thousands.

N/A - Prior period comparison not meaningful.

¹ These financial measures are presented on a non-GAAP adjusted basis. Refer to the Appendix for more details on these non-GAAP adjusted financial measures, the most directly comparable GAAP reported financial measures and the related reconciliations between these financial measures.

2020 Key Adjusted Line Items and Other Information¹

Operating expenses support growing development pipeline and up to 5 key launches through 2020-2021

In millions, except % (unaudited)	Year Ended		Δ
	2019	2020	
Gross Margin	94.3%	94.0%	(0.3) pp
SG&A Expense	\$658	\$770	17%
% of Total Revenues	30.4%	32.6%	2.2 pp
R&D Expense	\$274	\$306	12%
% of Total Revenues	12.7%	13.0%	0.3 pp
Acquired IPR&D ²	\$62	\$251	N/A
Operating Income Margin ²	48.4%	37.9%	(10.5) pp
Effective Tax Rate ²	12.3%	17.1%	4.8 pp

Note: Amounts may not total due to rounding. Percentages calculated from amounts in thousands.

N/A - Prior period comparison not meaningful.

¹ These financial measures are presented on a non-GAAP adjusted basis. Refer to the Appendix for more details on these non-GAAP adjusted financial measures, the most directly comparable GAAP reported financial measures and the related reconciliations between these financial measures.

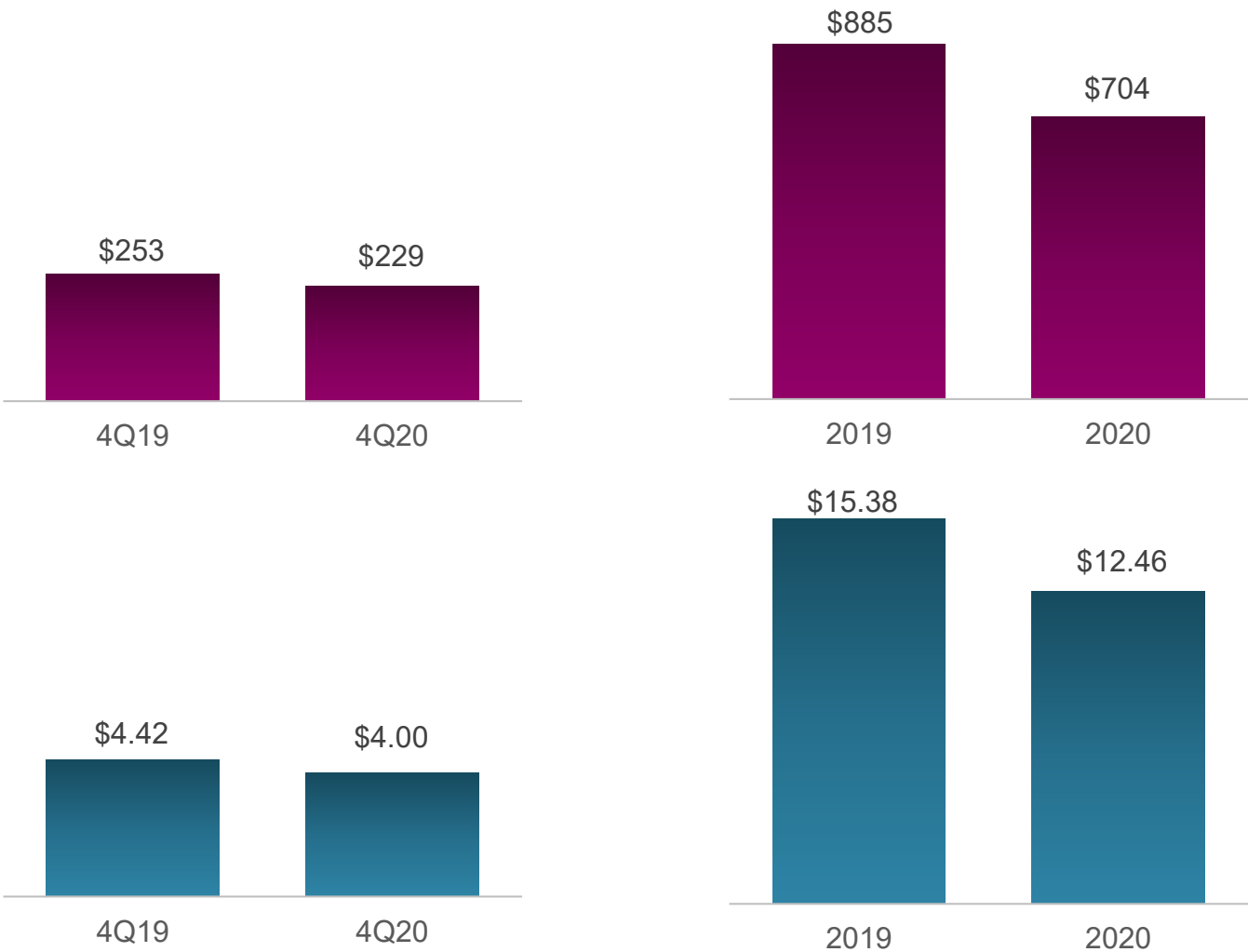
² Beginning in 2020, the company no longer excludes upfront and milestone payments from the company's non-GAAP adjusted net income, its line item components and non-GAAP adjusted EPS. For purposes of comparability, non-GAAP adjusted financial measures for the year ended December 31, 2019 have been updated to reflect this change.

Financial Performance

2020 ANI impacted by \$200M payment to PharmaMar for exclusive U.S. rights to Zepzelca¹

Adjusted Net
Income
(\$ in millions)

Adjusted Net
Income per Diluted
Share



Beginning in 2020, the company no longer excludes upfront and milestone payments from the company's non-GAAP adjusted EPS.¹

Refer to the Appendix for reconciliations of GAAP reported to non-GAAP adjusted financial measures. ¹ 2020 non-GAAP financial measures included acquired IPR&D expense of \$251 million primarily related to a \$200 million upfront payment to PharmaMar and a \$35 million upfront payment to SpringWorks. The post-tax impact of these payments to the company's 2020 non-GAAP adjusted net income and non-GAAP adjusted EPS was approximately \$205 million or \$3.67 per diluted share. For purposes of comparability, non-GAAP adjusted financial measures for the year ended December 31, 2019 have been updated to reflect this change.

Strong Cash Position

Well-positioned to execute on our near and long-term strategy



\$900M

Operating cash flow
2020¹

In millions (unaudited)	December 31, 2019	December 31, 2020
Cash, cash equivalents and investments	\$1,077	\$2,133
Total long-term debt (principal) ²	\$1,768	\$2,378
Undrawn revolving credit	\$1,600	\$1,600

¹ For the twelve months ended December 31, 2020. ² In June 2020, the company issued \$1B aggregate principal amount of 2.00% exchangeable senior notes due 2026 and in the year ended December 31, 2020, repurchased \$356M of the company's 1.875% exchangeable senior notes due 2021. The carrying value of the company's total debt as of December 31, 2019 and December 31, 2020 was \$1,607M and \$2,095M, respectively. The difference between principal and carrying values, at both dates, related to unamortized debt discount and debt issuance costs.

2021 Total Revenue Guidance

Expect Double Digit Growth

In millions	2021 Guidance ¹
Revenues	\$2,550 – \$2,700
Total Net Product Sales	\$2,540 – \$2,685
Neuroscience Net Sales	\$1,785 – \$1,885
Oncology Net Sales	\$715 – \$835

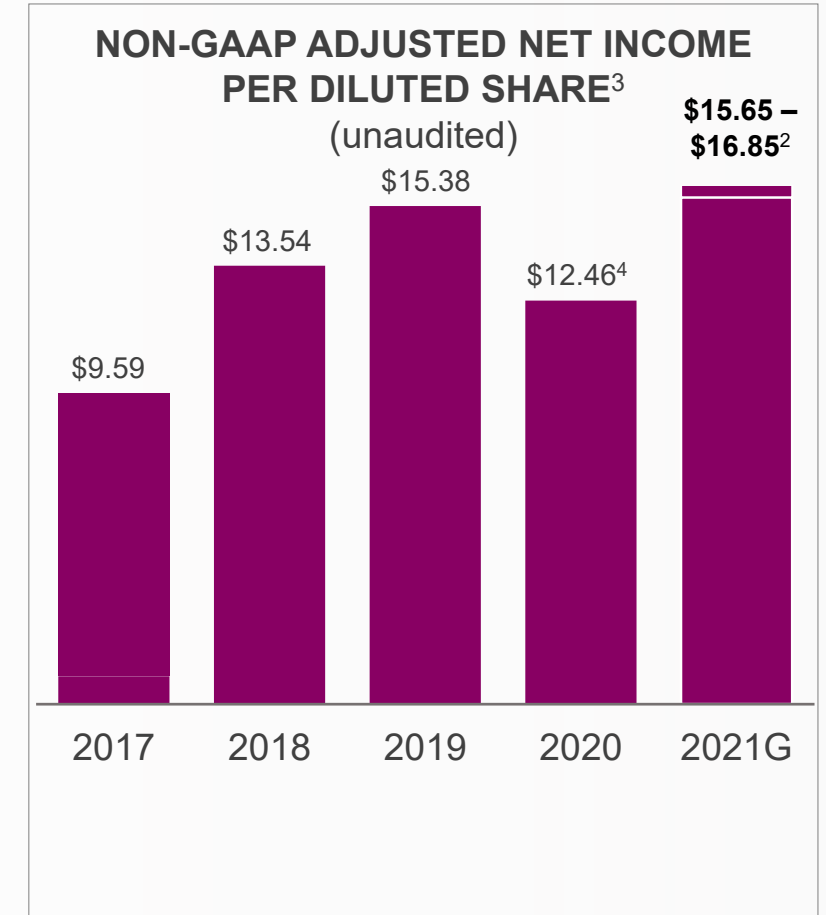
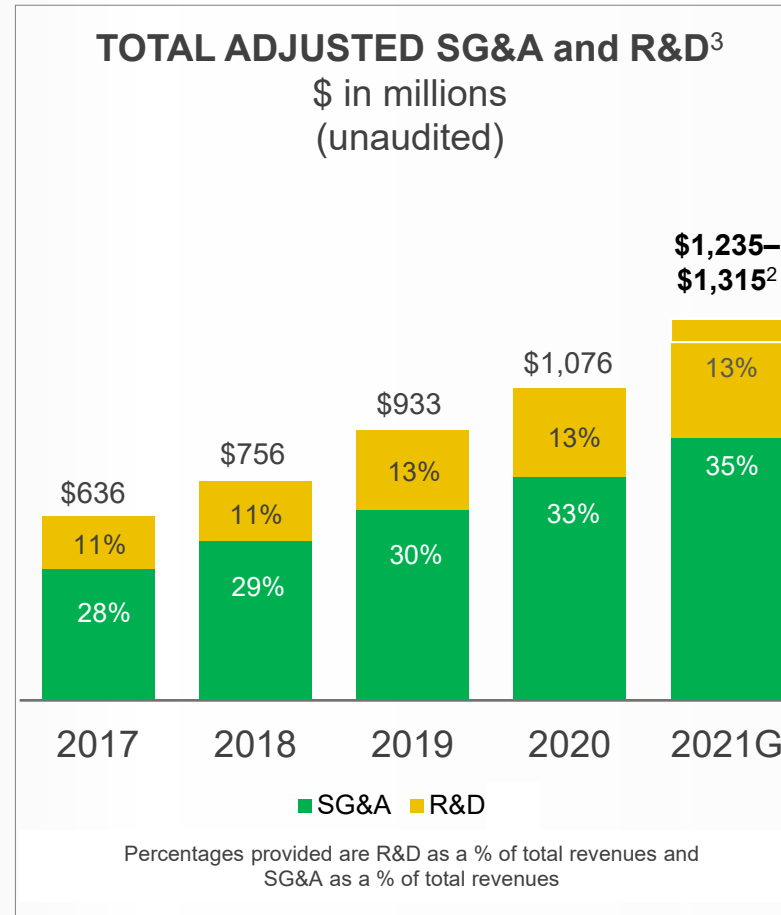
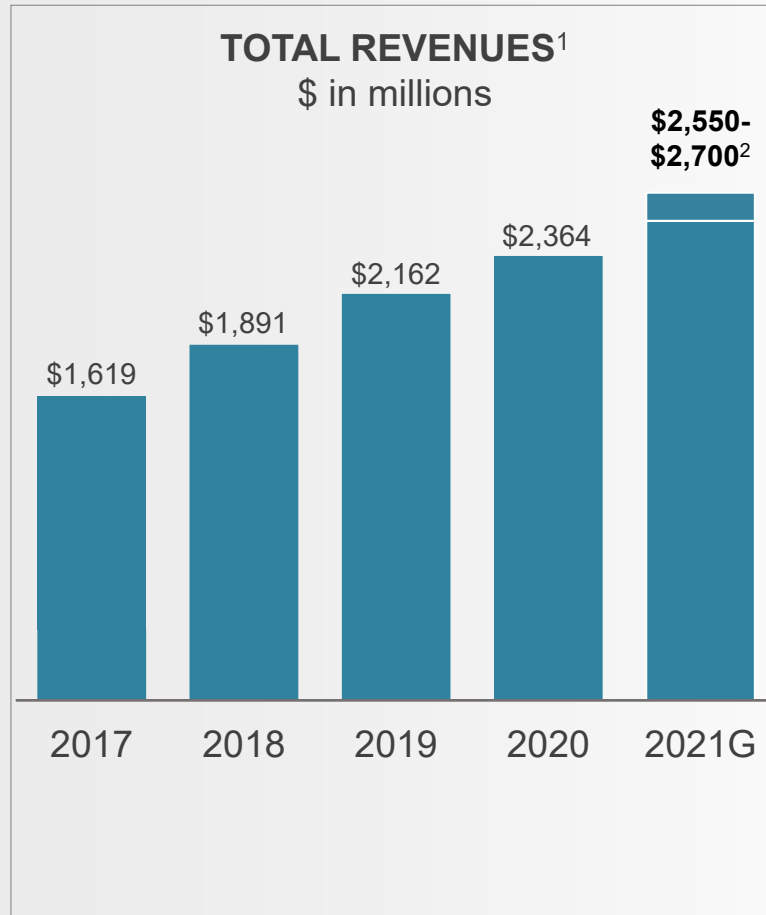
¹ 2021 Financial Guidance provided by Jazz Pharmaceuticals plc on and as of February 23, 2021. Jazz Pharmaceuticals' 2021 guidance does not reflect the proposed acquisition of GW Pharmaceuticals.

2021 Full-Year Financial Guidance

In millions, except per share amounts and %	GAAP ¹	Non-GAAP Adjusted ¹
Gross Margin	93%	93% ^{2,6}
SG&A Expense	\$1,032 – \$1,100	\$905 – \$945 ^{3,6}
<i>SG&A as % of Total Revenues</i>	<i>38% – 43%</i>	<i>34% – 37%</i>
R&D Expense	\$365 – \$410	\$330 – \$370 ^{4,6}
<i>R&D as % of Total Revenues</i>	<i>14% – 16%</i>	<i>12% – 15%</i>
Effective Tax Rate	18% – 20%	16% – 18% ^{5,6}
Net Income	\$485 – \$610	\$915 – \$985 ⁶
Net Income per Diluted Share	\$8.30 – \$10.45	\$15.65 – \$16.85 ⁶
Weighted-Average Ordinary Shares Used in Per Share Calculations	58 – 59	58 – 59

¹ 2021 Financial Guidance provided by Jazz Pharmaceuticals plc on and as of February 23, 2021. Jazz Pharmaceuticals' 2021 guidance does not reflect the proposed acquisition of GW Pharmaceuticals. ² Excludes \$8-\$10M of share-based compensation expense from estimated GAAP gross margin. ³ Excludes \$102-\$115 million of share-based compensation expense and \$25-\$40 million expenses relating to the proposed acquisition of GW Pharmaceuticals, which are expected to be incurred prior to transaction close, from estimated GAAP SG&A expenses. ⁴ Excludes \$35-\$40M of share-based compensation expense from estimated GAAP R&D expenses. ⁵ Excludes the income tax effect of adjustments between GAAP reported and non-GAAP adjusted net income. ⁶ Refer to the Appendix for reconciliations of these non-GAAP adjusted guidance measures to the most directly comparable GAAP measures.

Strong Top-Line Growth Enables Continued Investments for Further Revenue Diversification and R&D Portfolio Expansion



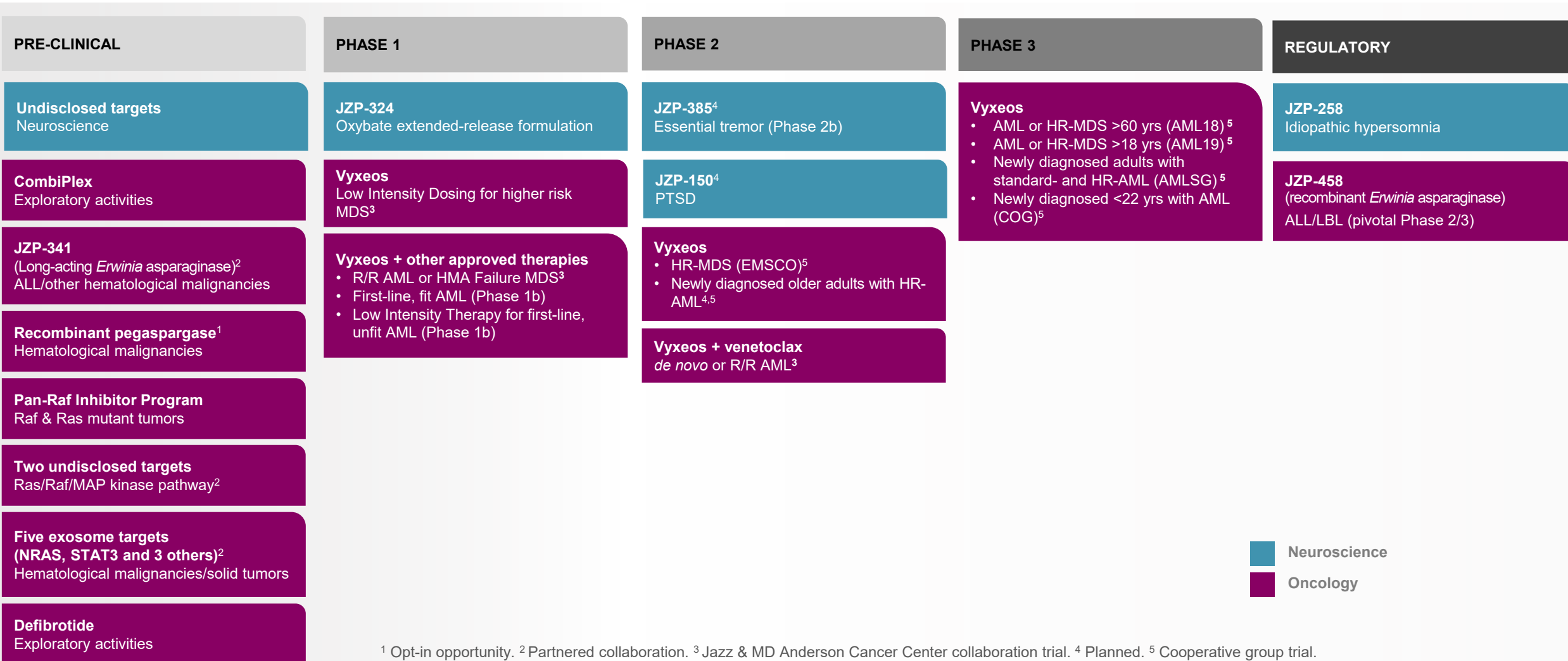
¹ 2017 to 2019 audited. ² G=Guidance. Guidance provided by Jazz Pharmaceuticals plc on and as of February 23, 2021. Jazz Pharmaceuticals' 2021 guidance does not reflect the proposed acquisition of GW Pharmaceuticals. ³ Reconciliations of GAAP net income to non-GAAP adjusted net income can be found in the Appendix at the end of this presentation. ⁴ Commencing in 2020, the company no longer excludes upfront and milestone payments from the company's non-GAAP adjusted net income, its line item components and non-GAAP adjusted EPS. The impact of this change to the company's 2020 non-GAAP adjusted net income and non-GAAP adjusted EPS was approximately \$205 million or \$3.67 per diluted share, respectively, primarily related to the post-tax impact of the upfront payments made to PharmaMar and SpringWorks in 2020. For purposes of comparability, non-GAAP adjusted financial measures for 2017 to 2019 have been updated to reflect this change.



APPENDIX

Robust and Productive Pipeline for Sustainable Growth

Targeted investments designed to fuel growth through 2025 and beyond



¹ Opt-in opportunity. ² Partnered collaboration. ³ Jazz & MD Anderson Cancer Center collaboration trial. ⁴ Planned. ⁵ Cooperative group trial.

Non-GAAP Financial Measures

To supplement Jazz Pharmaceuticals' financial results and guidance presented in accordance with U.S. generally accepted accounting principles (GAAP), the company uses certain non-GAAP (also referred to as adjusted or non-GAAP adjusted) financial measures in this presentation and the accompanying tables. In particular, the company presents non-GAAP adjusted net income (and the related per share measure) and its line item components, as well as certain non-GAAP adjusted financial measures derived therefrom, including non-GAAP adjusted gross margin percentage and non-GAAP adjusted effective tax rate. Non-GAAP adjusted net income (and the related per share measure) and its line item components exclude from GAAP reported net income (and the related per share measure) and its line item components certain items, as detailed in the reconciliation tables that follow, and in the case of non-GAAP adjusted net income (and the related per share measure), adjust for the income tax effect of non-GAAP adjustments and, as applicable, the income tax benefit related to an intra-entity intellectual property asset transfer and the impact of the U.S. Tax Cuts and Job Act (U.S. Tax Act). In this regard, the components of non-GAAP adjusted net income, including non-GAAP cost of product sales, non-GAAP SG&A expenses and non-GAAP R&D expenses, are income statement line items prepared on the same basis as, and therefore components of, the overall non-GAAP adjusted net income measure.

The company believes that each of these non-GAAP financial measures provides useful supplementary information to, and facilitates additional analysis by, investors and analysts. In particular, the company believes that each of these non-GAAP financial measures, when considered together with the company's financial information prepared in accordance with GAAP, can enhance investors' and analysts' ability to meaningfully compare the company's results from period to period and to its forward-looking guidance, and to identify operating trends in the company's business. In addition, these non-GAAP financial measures are regularly used by investors and analysts to model and track the company's financial performance. Jazz Pharmaceuticals' management also regularly uses these non-GAAP financial measures internally to understand, manage and evaluate the company's business and to make operating decisions, and compensation of executives is based in part on certain of these non-GAAP financial measures. Because these non-GAAP financial measures are important internal measurements for Jazz Pharmaceuticals' management, the company also believes that these non-GAAP financial measures are useful to investors and analysts since these measures allow for greater transparency with respect to key financial metrics the company uses in assessing its own operating performance and making operating decisions.

These non-GAAP financial measures are not meant to be considered in isolation or as a substitute for comparable GAAP measures; should be read in conjunction with the company's consolidated financial statements prepared in accordance with GAAP; have no standardized meaning prescribed by GAAP; and are not prepared under any comprehensive set of accounting rules or principles. In addition, from time to time in the future there may be other items that the company may exclude for purposes of its non-GAAP financial measures; and the company has ceased, and may in the future cease, to exclude items that it has historically excluded for purposes of its non-GAAP financial measures. For example, commencing in 2020, the company no longer excludes upfront and milestone payments from the company's non-GAAP adjusted net income, its line item components and non-GAAP adjusted EPS. For purposes of comparability, non-GAAP adjusted financial measures for the three and twelve months ended December 31, 2019 and prior periods have been updated to reflect this change. Likewise, the company may determine to modify the nature of its adjustments to arrive at its non-GAAP financial measures. Because of the non-standardized definitions of non-GAAP financial measures, the non-GAAP financial measures as used by Jazz Pharmaceuticals in this press release and the accompanying tables have limits in their usefulness to investors and may be calculated differently from, and therefore may not be directly comparable to, similarly titled measures used by other companies.

Reconciliation of GAAP Reported to Non-GAAP Adjusted Net Income

In millions, except per share amounts (unaudited)	4Q19	3Q20	4Q20
GAAP reported net income	\$ 74.0	\$ 148.2	\$ 133.4
Intangible asset amortization	173.5	66.7	67.1
Share-based compensation expense	25.9	30.4	31.4
Non-cash interest expense	12.0	15.8	16.0
Income tax effect of above adjustments	(32.2)	(19.0)	(19.2)
Non-GAAP adjusted net income	\$ 253.2	\$ 242.1	\$ 228.7
GAAP reported net income per diluted share	\$ 1.29	\$ 2.64	\$ 2.33
Non-GAAP adjusted net income per diluted share	\$ 4.42	\$ 4.31	\$ 4.00
Weighted-average ordinary shares used in diluted per share calculations	57.3	56.2	57.2

Note: Amounts may not total due to rounding.

Reconciliations of GAAP Reported to Non-GAAP Adjusted Information Certain Line Items

Quarter	In millions, except % (unaudited)	Cost of product sales	Gross margin	SG&A	R&D	Intangible asset amortization	Interest expense, net	Income tax provision (benefit)	Effective tax rate
4Q19	GAAP Reported	\$ 35.3	93.9%	\$ 214.3	\$ 97.4	\$ 173.5	\$ 18.2	\$ (34.5)	(84.7)%
	Non-GAAP adjustments:								
	Intangible asset amortization	--	--	--	--	(173.5)	--	--	--
	Share-based compensation expense	(1.3)	0.2	(17.3)	(7.3)	--	--	--	--
	Non-cash interest expense	--	--	--	--	--	(12.0)	--	--
	Income tax effect of above adjustments	--	--	--	--	--	--	32.2	83.8
	Total of non-GAAP adjustments	(1.3)	0.2	(17.3)	(7.3)	(173.5)	(12.0)	32.2	83.8
	Non-GAAP Adjusted	\$ 34.1	94.1%	\$ 196.9	\$ 90.1	\$ --	\$ 6.3	\$ (2.4)	(0.9)%
4Q20	GAAP Reported	\$ 50.2	92.4%	\$ 247.2	\$ 91.7	\$ 67.1	\$ 27.6	\$ 10.8	7.4%
	Non-GAAP adjustments:								
	Intangible asset amortization	--	--	--	--	(67.1)	--	--	--
	Share-based compensation expense	(1.9)	0.3	(21.8)	(7.7)	--	--	--	--
	Non-cash interest expense	--	--	--	--	--	(16.0)	--	--
	Income tax effect of above adjustments	--	--	--	--	--	--	19.2	4.2
	Total of non-GAAP adjustments	(1.9)	0.3	(21.8)	(7.7)	(67.1)	(16.0)	19.2	4.2
	Non-GAAP Adjusted	\$ 48.3	92.7%	\$ 225.4	\$ 84.0	\$ --	\$ 11.5	\$ 30.0	11.6%

Note: Amounts may not total due to rounding.

Reconciliations of GAAP Reported to Non-GAAP Adjusted Information Certain Line Items

Quarter	In millions, except % (unaudited)	Cost of product sales	Gross margin	SG&A	R&D	Intangible asset amortization	Acquired IPR&D	Interest expense, net	Income tax provision	Effective tax rate
3Q20	GAAP Reported	\$ 42.1	92.9%	\$ 207.3	\$ 78.6	\$ 66.7	\$ 10.0	\$ 27.4	\$ 19.3	11.5%
	Non-GAAP adjustments:									
	Intangible asset amortization	--	--	--	--	(66.7)	--	--	--	--
	Share-based compensation expense	(1.9)	0.4	(21.0)	(7.5)	--	--	--	--	--
	Non-cash interest expense	--	--	--	--	--	--	(15.8)	--	--
	Income tax effect of above adjustments	--	--	--	--	--	--	--	19.0	2.1
	Total of non-GAAP adjustments	(1.9)	0.4	(21.0)	(7.5)	(66.7)	--	(15.8)	19.0	2.1
	Non-GAAP Adjusted	\$ 40.2	93.3%	\$ 186.3	\$ 71.2	\$ --	\$ 10.0	\$ 11.6	\$ 38.3	13.6%

Note: Amounts may not total due to rounding.

Reconciliations of GAAP Reported to Non-GAAP Adjusted Information Certain Line Items

Year	In millions, except % (unaudited)	Cost of product sales	Gross margin	SG&A	R&D	Intangible asset amortization	Impairment Charge	Acquired IPR&D	Interest expense, net	Income tax provision (benefit)	Effective tax rate
2019	GAAP Reported	\$ 127.9	94.0%	\$ 736.9	\$ 299.7	\$ 354.8	\$ --	\$ 110.0	\$ 72.3	\$ (73.2)	(16.1)%
	Non-GAAP adjustments:										
	Intangible asset amortization	--	--	--	--	(354.8)	--	--	--	--	--
	Share-based compensation expense	(6.6)	0.3	(78.7)	(25.2)	--	--	--	--	--	--
	Acquired IPR&D asset acquisition	--	--	--	--	--	--	(48.3)	--	--	--
	Non-cash interest expense	--	--	--	--	--	--	--	(46.4)	--	--
	Income tax effect of above adjustments	--	--	--	--	--	--	--	--	85.9	3.7
	Income tax benefit related to intra-entity intellectual property asset transfer	--	--	--	--	--	--	--	--	112.3	24.7
	Total of non-GAAP adjustments	(6.6)	0.3	(78.7)	(25.2)	(354.8)	--	(48.3)	(46.4)	198.2	28.4
	Non-GAAP Adjusted	\$ 121.3	94.3%	\$ 658.2	\$ 274.5	\$ --	\$ --	\$ 61.7	\$ 25.9	\$ 125.0	12.3%
2020	GAAP Reported	\$ 148.9	93.7%	\$ 854.2	\$335.4	\$ 259.6	\$ 136.1	\$ 251.3	\$ 99.7	\$ 33.5	12.2%
	Non-GAAP adjustments:										
	Intangible asset amortization	--	--	--	--	(259.6)	--	--	--	--	--
	Share-based compensation expense	(7.4)	0.3	(84.4)	(29.2)	--	--	--	--	--	--
	Impairment charge	--	--	--	--	--	(136.1)	--	--	--	--
	Non-cash interest expense	--	--	--	--	--	--	--	(56.7)	--	--
	Loss on extinguishment of debt	--	--	--	--	--	--	--	(4.5)	--	--
	Income tax effect of above adjustments	--	--	--	--	--	--	--	--	112.5	4.9
	Total of non-GAAP adjustments	(7.4)	0.3	(84.4)	(29.2)	(259.6)	(136.1)	--	(61.1)	112.5	4.9
	Non-GAAP Adjusted	\$ 141.5	94.0%	\$ 769.8	\$306.1	\$ --	\$ --	\$ 251.3	\$ 38.6	\$ 146.0	17.1%



Reconciliation of GAAP Reported to Non-GAAP Adjusted Net Income

In millions, except per share amounts (unaudited)	2016	2017	2018	2019	2020
GAAP net income¹	\$ 396.8	\$ 487.8	\$ 447.1	\$ 523.4	\$ 238.6
Intangible asset amortization	102.0	152.1	201.5	354.8	259.6
Share-based compensation expense	98.8	106.9	102.4	110.6	121.0
Loss contingency	--	--	57.0	--	--
Impairment charges and disposal costs	--	--	44.0	--	136.1
Acquired IPR&D asset acquisition ²	--	--	--	48.3	--
Transaction and integration related costs	13.6	--	--	--	--
Expenses related to certain legal proceedings and restructuring	6.1	6.0	--	--	--
Non-cash interest expense	22.1	30.0	44.0	46.4	56.7
Loss on extinguishment and modification of debt	0.6	--	--	--	4.5
Income tax effect of above adjustments ²	(34.8)	(46.1)	(59.5)	(85.9)	(112.5)
Income tax benefit related to intra-entity intellectual property asset transfer	--	--	--	(112.3)	--
U.S. Tax Act impact	--	(148.8)	(7.5)	--	--
Non-GAAP adjusted net income ²	\$ 605.3	\$ 587.9	\$ 829.0	\$ 885.2	\$ 704.0
GAAP net income per diluted share¹	\$ 6.41	\$ 7.96	\$ 7.30	\$ 9.09	\$ 4.22
Non-GAAP adjusted net income per diluted share ²	\$ 9.78	\$ 9.59	\$ 13.54	\$ 15.38	\$ 12.46
Weighted-average ordinary shares used in diluted per share calculation	61.9	61.3	61.2	57.6	56.5

¹ 2016 to 2019 audited. ² Beginning in 2020, the company no longer excludes upfront and milestone payments from the company's non-GAAP adjusted net income, its line item components and non-GAAP adjusted EPS. For purposes of comparability, non-GAAP adjusted financial measures for 2016 to 2019 have been updated to reflect this change.

Note: Amounts may not total due to rounding.

Reconciliation of GAAP SG&A and R&D to Non-GAAP Adjusted SG&A and R&D

In millions (unaudited)	2017	2018	2019	2020	2021G
GAAP SG&A and R&D expense¹	\$ 742.6	\$ 910.1	\$ 1,036.6	\$ 1,189.6	\$ 1,397 – \$ 1,510
Share-based compensation expense	(101.1)	(95.8)	(103.9)	(113.6)	(137.0) – (155.0)
Loss contingency	--	(57.0)	--	--	--
Disposal costs	--	(1.1)	--	--	--
Expenses related to certain legal proceedings and restructuring	(6.0)	--	--	--	--
Transaction related costs	--	--	--	--	(25.0) – (40.0)
Non-GAAP adjusted SG&A and R&D expense	\$ 635.5	\$ 756.3	\$ 932.7	\$ 1,076.0	\$ 1,235 – \$ 1,315

2017 to 2019 audited.

G=Guidance. Guidance provided by Jazz Pharmaceuticals plc on and as of February 23, 2021. Jazz Pharmaceuticals' 2021 guidance does not reflect the proposed acquisition of GW Pharmaceuticals.

Note: Amounts may not total due to rounding.

Reconciliation of GAAP to Non-GAAP Adjusted 2021 Net Income Guidance

In millions, except per share amounts (unaudited)	2021 Guidance ¹
GAAP net income	\$485 – \$610
Intangible asset amortization	210 – 230
Share-based compensation expense	145 – 165
Transaction related costs	25 – 40
Non-cash interest expense	55 – 65
Income tax effect of above adjustments	(60) – (70)
Non-GAAP adjusted net income	\$915 – \$985
GAAP net income per diluted share	\$8.30 – \$10.45
Non-GAAP adjusted net income per diluted share	\$15.65 – \$16.85
Weighted-average ordinary shares used in per share calculations	58 – 59

¹ Guidance provided by Jazz Pharmaceuticals plc on and as of February 23, 2021. Jazz Pharmaceuticals' 2021 guidance does not reflect the proposed acquisition of GW Pharmaceuticals.

Summary of Share Repurchases Under Current Program

\$431M remaining amount authorized under current share repurchase program



Since 2013, the company has returned \$1.6B to shareholders through share repurchases

Share Repurchases	Dollar Amount Repurchased (in millions)	Shares Repurchased (in thousands)	Average Purchase Price Per Share
2020	\$147	1,201	\$121.98
2019	\$301	2,250	\$133.97
2018	\$524	3,530	\$148.33
2017	\$99	704	\$140.34
2016	\$18	175	\$105.71
Program Total	\$1,089	7,861	\$138.53

Note: Amounts may not total due to rounding.

Glossary of Terms

ALL = Acute Lymphoblastic Leukemia
AML = Acute Myeloid Leukemia
AMLSG = AML Study Group
ANI = Adjusted Net Income
BLA = Biologics License Application
COG = Children's Oncology Group
EBITDA = Earnings Before Interest, Tax, Depreciation & Amortisation
EDS = Excessive Daytime Sleepiness
EMSCO = European Myelodysplastic Syndromes Cooperative Group
EPS = Earnings Per Share
FDA = U.S. Food and Drug Administration
GAAP = U.S. Generally Accepted Accounting Principles
HMA = Hypomethylating Agent
HR-AML = High-Risk AML
HR-MDS = High-Risk MDS

IH = Idiopathic Hypersomnia
IPR&D = In-Process Research & Development
LBL = Lymphoblastic Lymphoma
MDS = Myelodysplastic Syndrome
OSA = Obstructive Sleep Apnea
Oxybate = (Xyrem and Xywav)
PharmaMar = Pharma Mar, S.A.
PTSD = Post-Traumatic Stress Disorder
R&D = Research & Development
R/R = Relapsed/Refractory
SCLC = Small Cell Lung Cancer
SG&A = Selling, General & Administrative
sNDA = Supplemental New Drug Application
SpringWorks = SpringWorks Therapeutics, Inc.

Warnings

XYREM

WARNING: CENTRAL NERVOUS SYSTEM DEPRESSION and ABUSE AND MISUSE.

• Central Nervous System Depression

Xyrem (sodium oxybate) is a CNS depressant. In clinical trials at recommended doses, obtundation and clinically significant respiratory depression occurred in adult patients treated with Xyrem [see Warnings and Precautions (5.1)]. Many patients who received Xyrem during clinical trials in narcolepsy were receiving central nervous system stimulants [see Clinical Trials (14)].

• Abuse and Misuse

Xyrem® (sodium oxybate) is the sodium salt of gamma-hydroxybutyrate (GHB). Abuse or misuse of illicit GHB, either alone or in combination with other CNS depressants, is associated with CNS adverse reactions, including seizure, respiratory depression, decreases in the level of consciousness, coma, and death [see Warnings and Precautions (5.2)].

Because of the risks of CNS depression and abuse and misuse, Xyrem is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the XYWAV and XYREM REMS [see Warnings and Precautions (5.3)].

VYXEOS

WARNING: DO NOT INTERCHANGE WITH OTHER DAUNORUBICIN AND/OR CYTARABINE-CONTAINING PRODUCTS

• VYXEOS has different dosage recommendations than daunorubicin hydrochloride injection, cytarabine injection, daunorubicin citrate liposome injection, and cytarabine liposome injection. Verify drug name and dose prior to preparation and administration to avoid dosing errors [see Warnings and Precautions (5.1)].

XYWAV

WARNING: CENTRAL NERVOUS SYSTEM DEPRESSION and ABUSE AND MISUSE.

• Central Nervous System Depression

XYWAV is a CNS depressant. Clinically significant respiratory depression and obtundation may occur in patients treated with XYWAV at recommended doses [see Warnings and Precautions (5.1, 5.4)]. Many patients who received XYWAV during clinical trials in narcolepsy were receiving central nervous system stimulants [see Clinical Trials (14.1)].

• Abuse and Misuse

The active moiety of XYWAV is oxybate or gamma-hydroxybutyrate (GHB). Abuse or misuse of illicit GHB, either alone or in combination with other CNS depressants, is associated with CNS adverse reactions, including seizure, respiratory depression, decreases in the level of consciousness, coma, and death [see Warnings and Precautions (5.2)].

Because of the risks of CNS depression and abuse and misuse, XYWAV is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the XYWAV and XYREM REMS [see Warnings and Precautions (5.3)].