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

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

January 11, 2021
Date of Report (Date of earliest event reported)

JAZZ PHARMACEUTICALS PUBLIC LIMITED COMPANY

(Exact name of registrant as specified in its charter)

Ireland	**001-33500**	**98-1032470**
(State or Other Jurisdiction of Incorporation)	**(Commission File No.)**	**(IRS Employer Identification No.)**

Fifth Floor, Waterloo Exchange, Waterloo Road, Dublin 4, Ireland, D04 E5W7
(Address of principal executive offices, including zip code)

011-353-1-634-7800
(Registrant's telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Ordinary shares, nominal value $0.0001 per share	**JAZZ**	**The Nasdaq Stock Market LLC**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

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

Item 2.02. Results of Operations and Financial Condition.

On January 11, 2021, at the virtual J.P. Morgan Annual Health Care Conference, Jazz Pharmaceuticals plc (the "Company") presented a corporate overview and financial update, which presentation included the Company's current expectations and other information with respect to certain financial and operating results for the quarter and year ended December 31, 2020. The presentation was announced by a widely disseminated press release and was made available to the public by audio webcast, and the slides that accompanied the presentation were made available to the public on the Company's website. A transcript of the relevant portion of the presentation relating to the aforementioned update is attached hereto as Exhibit 99.1, along with a copy of the relevant slides containing such information.

The information contained in this Item 2.02 and in the accompanying Exhibit 99.1 to this Current Report on Form 8-K shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information contained in this Item 2.02 and in the accompanying Exhibit 99.1 to this Current Report on Form 8-K shall not be incorporated by reference into any filing with the U.S. Securities and Exchange Commission made by the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Portion of transcript and related slides of presentation by Jazz Pharmaceuticals plc on January 11, 2021
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

JAZZ PHARMACEUTICALS PUBLIC LIMITED COMPANY

By: /s/ Neena M. Patil
Name: Neena M. Patil
Title: Senior Vice President and General Counsel

Date: January 12, 2021

Exhibit 99.1

Relevant portion of the transcript of the oral presentation by Jazz Pharmaceuticals plc at the virtual J.P. Morgan Annual Health Care Conference on January 11, 2021:

Bruce C. Cozadd - *Jazz Pharmaceuticals plc - Co-Founder, Chairman & CEO*

...

It is my distinct pleasure today to share an update on our significant accomplishments of 2020 and my excitement about this year. In 2020, thanks to the passion, innovation, integrity, collaboration and pursuit of excellence demonstrated by our 1,800 dedicated and talented employees around the world. We helped more patients, achieved record product revenues, advanced our pipeline and positioned the company for success.

...

With reference to Slide 2: On Slide 2, I point out that I will be making forward-looking statements. Of course, actual results may differ materially. And the forward-looking statements are subject to risks and uncertainties that are described in our SEC filings.

...

With reference to Slide 7: Slide 7 reviews our topline growth over the past five years and I think nicely demonstrates our double-digit compound annual growth rates in both neuroscience and oncology. I'm pleased to announce today that we do expect net sales in each franchise to fall within our previous guidance of $1.76 billion to $1.8 billion for neuroscience and $525 million to $565 million in oncology.

With reference to Slide 8: And if we look at total revenues on Slide 8, we'd like to confirm today that we expect total revenues will fall within our previous guidance of $2.32 billion to $2.38 billion for 2020. You'll also see that we expect continued topline growth in both 2021 and 2022. Importantly, the composition of those revenues is changing significantly. We've stated that we expect new product sales of Sunosi®, Zepzelca™, Xywav™, JZP-458, and JZP-258 to account for nearly 50 percent of our revenues by 2022. That's a dramatic change from our revenue mix this past year.

...

With reference to Slide 13: Let's spend a few minutes now on each of our two TAs, starting with neuroscience. On Slide 13, we have a snapshot of our neuroscience franchise, which we believe is poised for sustainable growth. Of course, we've long had a strong presence in narcolepsy, but with expansion into obstructive sleep apnea with Sunosi and an upcoming launch of JZP-258 in idiopathic hypersomnia, we see additional growth in treatments for sleep disorders.

...

With reference to Slide 14: Let's move to Slide 14 and focus in on Xywav, where we executed on a successful launch in November. Xywav is the only FDA-approved lower-sodium oxybate approved for the treatment of cataplexy and EDS in narcolepsy. We're out now, educating physicians and patients on the lifelong burden of narcolepsy and high-sodium intake. Our goal for Xywav is that the majority of all oxybate patients are benefitting from Xywav by 2023.

So how's the launch going? Very well. As we had expected, the large majority of Xywav prescriptions are for patients who've previously taken Xyrem. We're really pleased that the majority of oxybate-naïve patients getting a new oxybate prescription are being prescribed Xywav, and we remain on track to obtaining broad payer coverage. As you know, we were covered on Express Scripts' preferred formulary at the time of launch.

...

With reference to Slide 20: Let's now turn to our oncology franchise. On Slide 20, we provide a snapshot. We've seen continued double-digit growth in this portfolio and expect future growth and diversification fueled by the recent Zepzelca launch and our planned JZP-458 launch this year. Defitelio® and Vyxeos® remain important therapies for patients with significant unmet medical needs. And we have many pipeline programs exploring expanded indications for our existing agents as well as a set of innovative new targets.

With reference to Slide 21: On Slide 21, we spotlight Zepzelca, which was launched in July for the treatment of metastatic, small-cell lung cancer with disease progression on or after platinum-based chemotherapy. It was nice to see Zepzelca immediately included in NCCN guidelines, and we received positive feedback from physicians following their use of the agent.

We had a great first quarter of launch, with $37 million in third quarter sales, with additional growth in the fourth quarter. We believe Zepzelca has significant potential in second-line, small-cell lung cancer, where there are currently 17,000 patients a year receiving treatment, but also an additional 8,000 patients per year who've chosen not to receive second-line treatment based on the efficacy and tolerability of previously available treatments. And beyond that, we're excited to partner with PharmaMar to jointly develop lurbinectedin in other tumor types, and also to explore it in first-line, small-cell lung cancer in combination with immuno-oncology and other agents.

Questions and Answers

Jessica Macomber Fye - *JPMorgan Chase & Co, Research Division – Analyst*

... Maybe just to build off of one of the comments that you made, Bruce, about the Xywav launch. I think you said it's going very well. Can you elaborate that a little bit more? And maybe outline a framework to help us think about the near-term dynamics with the oxybate franchise?

...

Daniel N. Swisher - *Jazz Pharmaceuticals plc - President & COO*

... Thanks, Jess. So we just launched the product in November, but already with our well-established relationships with the sleep docs we've had very good engagement, both virtually and in person where possible. The focus of the business initially is patients already on Xyrem, giving them the opportunity to switch over and get on to Xywav and really get the benefit of for a lifelong therapy where there's an increased risk of cardiovascular disease. Yes, similar strong control and efficacy control, but without those risks. I'm also pleased, though, that in a short period of time, we're seeing a majority of new patients that are coming on to oxybate therapy are coming on to Xywav over Xyrem.

So in terms of the dynamics, our focus was really educating physicians. We're just starting to reach out now to patients that we've established that education with physicians. It's surprising to us how few physicians actually knew how much sodium was in a Xyrem dose. And so with sodium being — reducing sodium has been a modifiable risk factor this is a real benefit on moving over to Xywav.

So we priced at parity at the launch with Xyrem. We've got a suite of services as we're building up contracts with the PBMs, we're very pleased that we had ESI on a preferred national formulary at the time of launch. And so that's really sort of the focus at this point is the education, the ability to switch over and the feedback we're hearing from physicians and patients who have been using Xywav is very strong.

...

Jessica Macomber Fye - *JPMorgan Chase & Co, Research Division - Analyst*

... [Y]ou touched on kind of the suite of services as coverage kind of comes online. And one of the questions that we're getting is kind of how to interpret near-term oxybate revenue numbers, while you've got this switch dynamic happening that may be either a drag on gross-to-nets or involve free bottles. So can you kind of maybe lay out kind of what the key metrics you think are best for investors to focus on? And whether or not – and maybe address just this question of whether or not folks should be concerned about maybe a kind of optically lower revenue number in the short-term as this switch proceeds?

Bruce C. Cozadd - *Jazz Pharmaceuticals plc - Co-Founder, Chairman & CEO*

Yes. Before I hand it over to Dan, I'll just say, our goal is very clear, which is to make Xywav the oxybate product over the next couple of years. And while we're certainly watching early dynamics, and I'll let Dan address your question a little more directly. At Jazz we want to make sure people understand if they're worried about gross-to-nets in the near-term because the launch is going really well. We want to make sure patients and physicians understand this dynamic about long-term chronic use of a high sodium product and how they make the right choices again for patients and on the physician side. Dan?

Daniel N. Swisher - *Jazz Pharmaceuticals plc - President & COO*

Yes. I mean, just to sort of build on what Bruce said is we'll be updating, of course, with our earnings call and providing further guidance at that point for the oxybate franchise. We're not expecting meaningful revenue in the fourth quarter necessarily as we're ramping up patient experience and physician access. But as Bruce said, I mean, the primary driver for us is not about price. It's really to ensure that there's a seamless transition for the patients who could benefit and we believe all patients who are currently on oxybate therapy would benefit from Xywav. And so the ability to go gram per gram and have that transition and educate physicians and patients is the primary driver.

...

Jessica Macomber Fye - *JPMorgan Chase & Co, Research Division - Analyst*

... We've got a bunch of questions coming through on the portal. I'm just going to couple some that are similar to one another. One is, can you give any kind of number on conversion and the other one sort of read similar is what percentage of oxybate franchise patients are on Xywav?

Bruce C. Cozadd - *Jazz Pharmaceuticals plc - Co-Founder, Chairman & CEO*

Yes. We'll be giving more detail, Jess, when we get to our fourth quarter call towards the end of next month. And all we're saying at this point is we are seeing good adoption of Xywav, that most of the patients we're seeing on Xywav today do have oxybate experience in the past. But for oxybate naive patients, meaning this is their first time on either product, a majority of them are already going to Xywav.

...

Jessica Macomber Fye - *JPMorgan Chase & Co, Research Division - Analyst*

... And then another on Zepzelca here. You've talked about maybe a bolus of later line patients being treated in addition to second line patients. With some eventual kind of washing out of those later line patients as the product becomes more established in second line, where are we in that process?

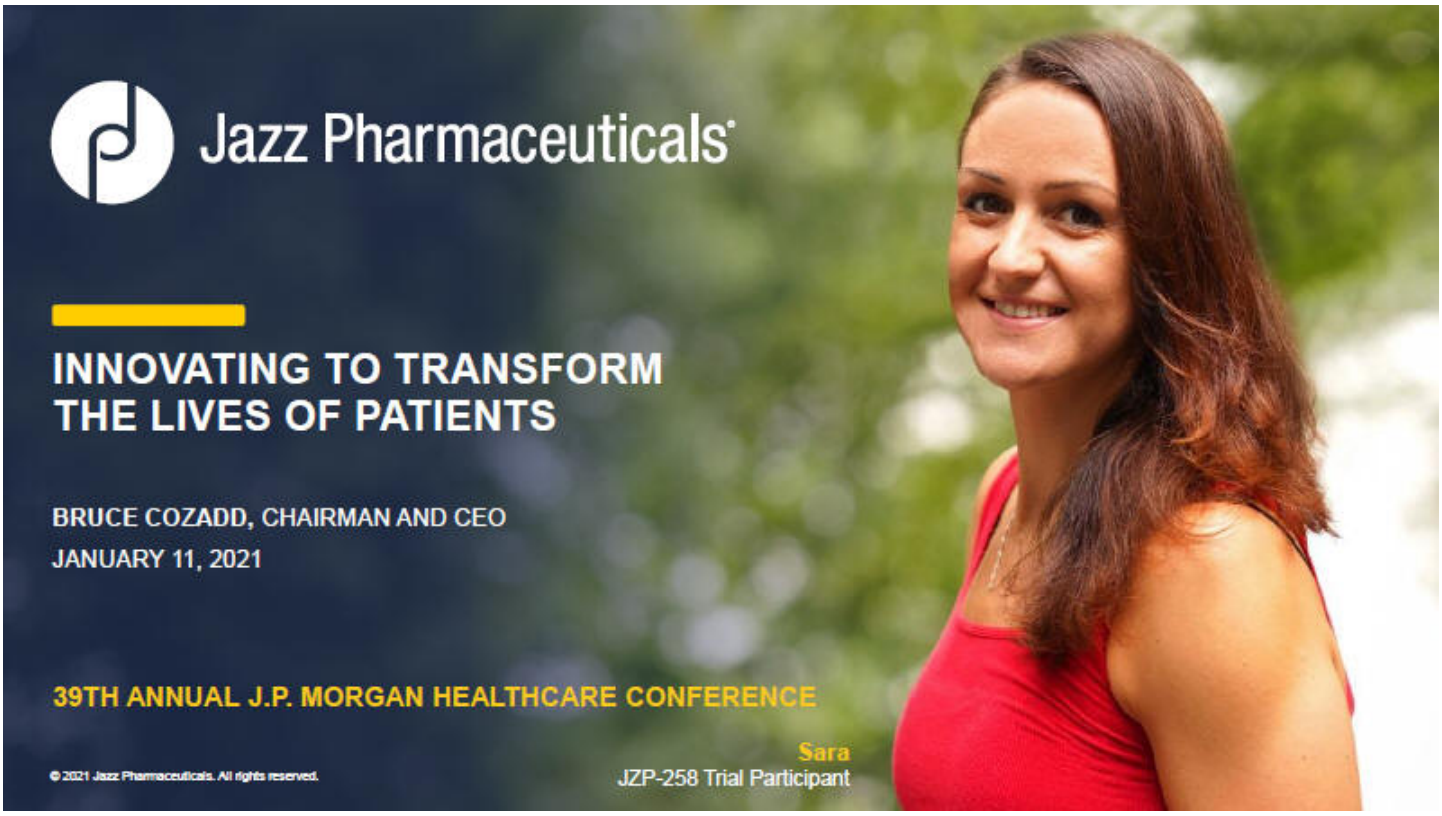
Daniel N. Swisher - *Jazz Pharmaceuticals plc - President & COO*

Okay. Well, we're really pleased with the way the launch has rolled out. And as we said in the presentation, we expect continued growth in sales in the fourth quarter and our objective is to have Zepzelca be the standard of care preferred treatment option in second line patients.

Not uncommon to other, other oncology launches at the time of launch, there's many patients that are in later lines of therapy that haven't had prior exposure to the treatment Zepzelca. And so we found through some chart reviews that we do have a certain number of third line and later patients where 95% of their second-line treatment options were actually made before Zepzelca was available.

We do expect that now we're getting good strong usage across all patient types, both platinum sensitive, platinum resistant, second line as well as later lines of therapy for patients who had not had prior exposure. But increasingly, we look to get patients sooner that are probably in second line. And as you can imagine, their prognosis is better and the duration of therapy should be higher. So we're very pleased with the way the launch is going and the feedback we're getting from physicians has been strong to date.

Relevant slides from Jazz Pharmaceuticals plc's presentation at the virtual J.P. Morgan Annual Health Care Conference on January 11, 2021:



Life-Changing Medicines. Redefining Possibilities.

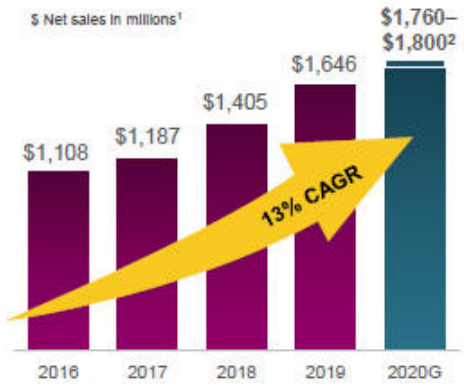
Forward-Looking Statements
"Safe Harbor" Statement Under The Private Securities Litigation Reform Act of 1995

This slide deck and the accompanying oral presentation contain forward-looking statements, including, but not limited to, statements related to Jazz Pharmaceuticals' future operating results and financial condition, including 2020 financial guidance; expectations regarding the company's future revenues, cash flow, growth and revenue diversification; the company's growth strategy, including pipeline expansion plans and corporate development efforts; ongoing, planned and potential product launches and expected or potential product sales; ongoing, planned and potential clinical trials and other product development and regulatory activities; 2021 and future goals and objectives; 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: 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; 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; 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 those 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, including those described from time to time under the caption "Risk Factors" and elsewhere in Jazz Pharmaceuticals plc's Securities and Exchange Commission filings and reports (Commission File No. 001-33500), including the company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2020 and future filings and reports by the company. 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 slide deck and the accompanying oral presentation 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.

Robust Financial Performance

Investing in Growth Drivers and Delivering Value

BUILDING A SUSTAINABLE NEUROSCIENCE FRANCHISE



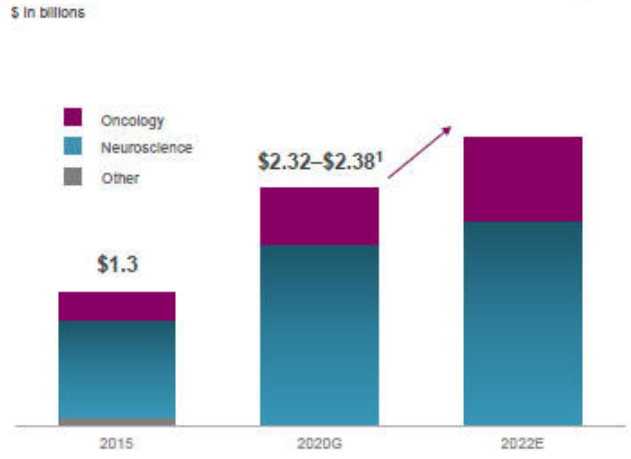
RAPIDLY SCALING OUR ONCOLOGY BUSINESS

[1] 2016 to 2019 audited; [2] G=Guidance. Guidance provided by Jazz Pharmaceuticals plc on and as of November 2, 2020. The company expects that, for the year ended December 31, 2020, reported net revenues will meet the guidance range provided on November 2, 2020. Jazz Pharmaceuticals has not finalized its financial results for the year ended December 31, 2020 and actual results may differ.

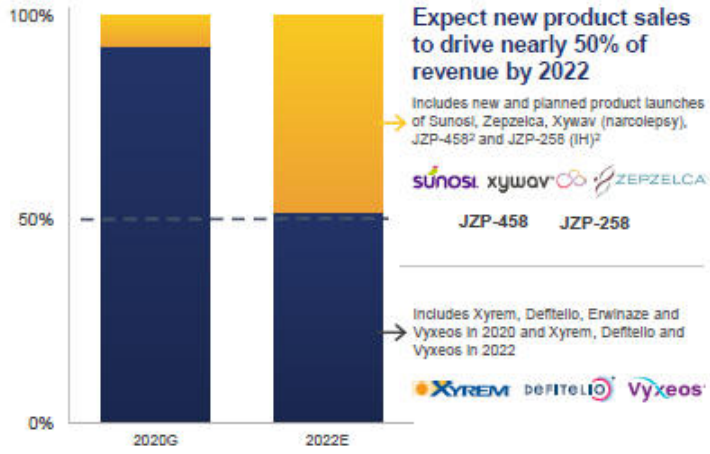
Commercial Portfolio of High Value Products

Continuing to Deliver Strong Revenue Growth and Diversification

AIMING FOR FURTHER TOP-LINE GROWTH...



...AND ENHANCED DIVERSIFICATION BY 2022



[1] E=Estimated, G=Guidance. Guidance provided by Jazz Pharmaceuticals plc on and as of November 2, 2020. The company expects that, for the year ended December 31, 2020, reported total revenues will meet the guidance range provided on November 2, 2020. Jazz Pharmaceuticals has not finalized its financial results for the year ended December 31, 2020 and actual results may differ; [2] Subject to FDA approval.

Delivering Growth, Value and Durability

Neuroscience

Strong Commercial Execution

#1 Sleep disorder medicine by sales since 2014 (Xyrem)

>50% of oxybate patients on Xywav by 2023

$1.76-1.8B 2020 Neuroscience net sales guidance[1]

3 On-market products

xywav

sunosi

XYREM (sodium oxybate) oral solution

Poised For Sustainable Growth

- Sleep franchise – enhanced durability with first and only FDA approved lower-sodium oxybate, Xywav[2]
- Sleep disorders – important growth opportunity given the high unmet medical needs
- Strong growth prospects for Sunosi in the U.S. and European markets (focus on narcolepsy, OSA and potential new indications)
- Expansion into new areas of unmet need including treatment of essential tremor and post-traumatic stress disorder (PTSD)
- Investing in pipeline with early in-licensed innovative assets with new MOAs

[1] The company expects that, for the year ended December 31, 2020, reported Neuroscience net revenues will meet the guidance range provided on November 2, 2020. Jazz Pharmaceuticals has not finalized its financial results for the year ended December 31, 2020 and actual results may differ.
[2] Xyrem and Xywav warnings: Central nervous system depression and abuse and misuse. For full details see U.S. prescribing information, summary in appendix

Executing a Successful Xywav Launch

xywav™

Launched November 2020 for the treatment of cataplexy or excessive daytime sleepiness (EDS) in narcolepsy

SODIUM MATTERS

- Xywav is the only lower-sodium oxybate approved for the treatment of cataplexy or excessive daytime sleepiness (EDS) in narcolepsy
- Unlocking the potential in narcolepsy; educating physicians and patients on the lifelong burden of narcolepsy and high sodium intake
- Goal that the majority of oxybate patients are benefiting from Xywav therapy by 2023

LAUNCH HIGHLIGHTS

- Launch progressing well
- Large majority of Xywav prescriptions are to patients who have previously taken Xyrem
- Majority of oxybate naïve patients being prescribed Xywav
- On track to obtaining broad payer coverage
  - Covered on the Express Scripts National Preferred Formulary for commercial lives on first day of launch

Rapidly Growing Our Oncology Business

Strong Commercial and Development Capabilities

Revenue Diversification Driver

~$2B
Oncology sales 2015-2019

3
Products contributed $100M+ each in 2019

$525-565M
2020 Oncology net sales guidance[1]

5
Key approvals since 2015

Poised For Meaningful Growth

- Continued double-digit growth in portfolio
- Future revenue growth and diversification fueled by recent Zepzelca launch and planned JZP-458 launch mid-2021
- Expansion into solid tumors with Zepzelca
- Important growth opportunities for JZP-458 through expanded treatment and globalization
- Defitelio and Vyxeos remain important therapies for patients with significant unmet medical needs
- Investing in a deep and broad pipeline of innovative targets

[1] The company expects that, for the year ended December 31, 2020, reported Oncology net revenues will meet the guidance range provided on November 2, 2020. Jazz Pharmaceuticals has not finalized its financial results for the year ended December 31, 2020 and actual results may differ.

Strong Start to Zepzelca Launch

Demonstrating Launch Execution Excellence

Launched July 2020 following FDA accelerated approval for the treatment of adult patients with metastatic SCLC with disease progression on or after platinum-based chemotherapy

LAUNCH HIGHLIGHTS

- Strong initial launch with 3Q revenues of $37M and growth in 4Q
- Similar share of use across platinum resistant and platinum sensitive 2L SCLC patients[1]
- Included in NCCN® Guidelines from launch
- Positive feedback from physicians and increased awareness through education and promotion[2]

STRATEGIC FIT

- Further diversifies commercial portfolio; expands into solid tumors
- Provides meaningful multi-hundred million dollar opportunity with 3–5 year route to peak
- Synergistic with existing portfolio
- SCLC opportunity: Currently ~17,000 patients per year treated; ~8,000 patients do not receive 2L treatment
- Joint development plan with PharmaMar includes:
  - Evaluation of other tumor types
  - 1L SCLC in combination with I/O and other agents

Jazz Pharmaceuticals

[1] Based on insurance claims data, ~ 3 month lag
[2] Based on Jazz market research

APPENDIX

Jazz Pharmaceuticals

Glossary of Terms

1L / 2L / 3L = First / Second / Third Line
ALL = Acute Lymphoblastic Leukemia
AML = Acute Myeloid Leukemia
AMLSG = AML Study Group
BLA = Biologics License Application
CAGR = Compound Annual Growth Rate
CAR-T = Chimeric Antigen Receptor T-cell Therapy
COG = Children's Oncology Group
DTC = Direct-to-Consumer
EDS = Excessive Daytime Sleepiness
EMSCO = European Myelodysplastic Syndromes Cooperative Group
ET = Essential Tremor
FAAH (i) = Fatty Acid Amide Hydrolase (Irreversible)
FDA = U.S. Food and Drug Administration
HMA = Hypomethylating Agent
HR-AML = High-Risk AML
HR-MDS = High-Risk MDS
IH = Idiopathic Hypersomnia
IND = Investigational New Drug Application
LBL = Lymphoblastic Lymphoma
M&A = Mergers & Acquisitions
MAP = Mitogen-activated Protein
MDACC = MD Anderson Cancer Center
MDS = Myelodysplastic Syndrome
MOA = Mechanism of Action
NCCN = National Comprehensive Cancer Network
OSA = Obstructive Sleep Apnea
PharmaMar = Pharma Mar, S.A.
PTSD = Post-Traumatic Stress Disorder
R&D = Research & Development
R/R = Relapsed / Refractory
SCLC = Small Cell Lung Cancer
SHA = Symphony Health
sNDA = Supplemental New Drug Application
SpringWorks = SpringWorks Therapeutics, Inc.
TSR = Total Shareholder Returns
TTCC = T-Type Calcium Channel

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)].