

## Jazz Pharmaceuticals plc

### Jazz: Deep Dive On Lurbinectedin - Top Catalyst For 2020

**Overweight/\$150**

Specialty Pharmaceuticals

**Company Note**

- Lurbinectedin – Top Catalyst for 2020 with an unusual setup.**

JAZZ shares are down -25% YTD (vs. DRG Index flat) and have also underperformed over the trailing twelve months (-15% vs DRG +11%). We attribute this in part to COVID-19 related factors, but also concerns on diversifying its mix from the Xyrem/oxybate franchise (~70% of 2020E sales). Our thesis on the stock is primarily based on the view that Jazz's pipeline outside of its oxybate franchise is underappreciated by the market. JAZZ has two key upcoming potential catalysts: 1) JZP-258 (lower sodium oxybate) PDUFA action date on July 21; and 2) Lurbinectedin (2L SCLC) PDUFA on August 16. In our view, most expect the former to be approved, and Lurbi is the bigger catalyst and driving the near-term debate for the stock. The setup for Lurbi is highly unusual as there are effectively two ways to win – the FDA approves on Ph2 monotherapy data (Aug 16 PDUFA), or Ph3 Atlantis trial ("combination trial") is successful which is due in 2H20. In this report, we did a deep dive analysis on the drug – net, we think it is attractive setup for JAZZ shares with Lurbi NPV potential of >\$30 and a low implied probability of success in current consensus numbers.

- What is the market expecting?** Consensus is currently modelling Lurbinectedin peak sales of \$240MM-\$250MM. Our quick math indicates at ~65% adoption at 4 month duration of therapy, this could be a \$700MM peak sales opportunity after deducting royalties. Thus, consensus expectations imply approximately ~35% PoS. Our view is the market is focused on the sleep franchise and this opportunity has gone under the radar, with most we have talked to fairly dismissive of the asset. The bifurcated setup at the implied PoS looks attractive to us. We see this as the key catalyst for 2020, which if successful, would help to diversify the mix. If the ATLANTIS trial fails, JAZZ still believes it can get FDA approval on the monotherapy data.

- Background:** On Dec. 19, Jazz licensed the U.S. rights to Lurbinectedin from Pharma Mar across all indications (incl. SCLC) for \$200MM upfront cash payment and up to \$800MM in potential milestone payments (+ tiered royalties on sales). There are ~30K new diagnosed cases of SCLC each year in the U.S. (2L treatment ~17K) and limited treatment options. The last FDA approved NCE was Topotecan in 1996 which is commonly used in 2L but with low response rates of ~17%.

- Inside is a detailed review of the opportunity. **We are hosting a call with a leading SCLC doctor on June 11 – please contact your Wells Fargo salesperson for details.**

\$	2019A		2020E		2021E
	EPS		Curr.	Prior	Curr. Prior
Q1 (Mar.)	3.67		0.45 A	NC	NE
Q2 (June)	4.05		3.54	NC	NE
Q3 (Sep.)	4.10		4.05	NC	NE
Q4 (Dec.)	4.42		4.09	NC	NE
FY	16.23		12.09	NC	16.36 NC
CY	16.23		12.09		16.36
FY P/EPS	6.9x		9.2x		6.8x
Rev.(MM)	2,162		2,227		2,410

Source: Company Data, Wells Fargo Securities, LLC estimates, and Reuters  
 NA = Not Available, NC = No Change, NE = No Estimate, NM = Not Meaningful  
 V = Volatile

Ticker	JAZZ
Price Target/Prior:	\$150/NC
Price (06/08/2020)	\$111.29
52-Week Range:	\$86-155
Shares Outstanding: (MM)	56.8
Market Cap.: (MM)	\$6,321.3
S&P 500:	3,232.39
Avg. Daily Vol.:	484,324
Dividend/Yield:	\$0.00/0.0%
LT Debt: (MM)	\$1,610.4
LT Debt/Total Cap.:	36.4%
ROE:	30.0%
3-5 Yr. Est. Growth Rate:	10.0%
CY 2020 Est. P/EPS-to-Growth:	0.9x
Last Reporting Date:	05/05/2020 After Close

NC = No Change

Source: Company Data, Wells Fargo Securities, LLC estimates, and Reuters

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**Please see page 10 for rating definitions, important disclosures and required analyst certifications. All estimates/forecasts are as of 06/09/20 unless otherwise stated. 06/08/20 21:10:58 ET**

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## What is Lurbinectedin and setup for JAZZ stock?

Jazz Pharmaceuticals (JAZZ) and Pharma Mar signed a \$1B exclusive licensing agreement in late 2019 that gives JAZZ the U.S. rights to Lurbinectedin, a small molecule oncogenic transcription inhibitor. The drug saw positive safety and efficacy results in a Ph. 2 monotherapy basket trial, and it is currently being evaluated as a monotherapy as well as in combination with doxorubicin in a Ph. 3 pivotal study that is expected to readout in 2H20. JAZZ and Pharma Mar are targeting relapsed small cell lung cancer (SCLC) as the first indication for Lurbinectedin.

### Exhibit 1. Lurbinectedin is a late stage pipeline opportunity for Jazz

<b>Differentiated Molecule</b>	<ul style="list-style-type: none"> <li>Lurbinectedin clinical data has shown significant response rate improvement over SOC in relapsed SCLC, along with improved safety, tolerability and administration profile</li> </ul>
<b>Development Status</b>	<ul style="list-style-type: none"> <li>Phase 2 monotherapy basket trial results presented at ASCO 2019 and World Lung 2019</li> <li>Lurbinectedin achieved its primary endpoint and demonstrated an ORR of 35.2%, which compares favorably to topotecan's historical ORR of 16.9% by investigator assessment.</li> <li>Post pre-NDA meeting, PharmaMar submitted an NDA in December 2019 under accelerated approval regulations</li> <li>Priority review requested with potential for approval and launch in 2020</li> </ul>
<b>Unmet Medical Need</b>	<ul style="list-style-type: none"> <li>Limited treatment options for relapsed SCLC</li> <li>~30,000 new cases of SCLC each year in the U.S.<sup>1</sup></li> </ul>
<b>Exclusivity</b>	<ul style="list-style-type: none"> <li>Granted Orphan Drug Designation by FDA in August 2018</li> <li>IP includes composition of matter patent expiring in 2024 (with patent term extension 2029); formulation patent expiry 2028</li> <li>Patent applications for combo therapy are pending and, if issued, could extend to 2031</li> </ul>

Source: Company filings

Pharma Mar received a \$200MM upfront payment and could receive up to \$800MM in potential milestone payments, as well as tiered royalties on future sales of lurbinectedin ranging from high teens up to 30%. The potential milestone payments are shown below.

### Exhibit 2. Potential Milestone Payments for Lurbi

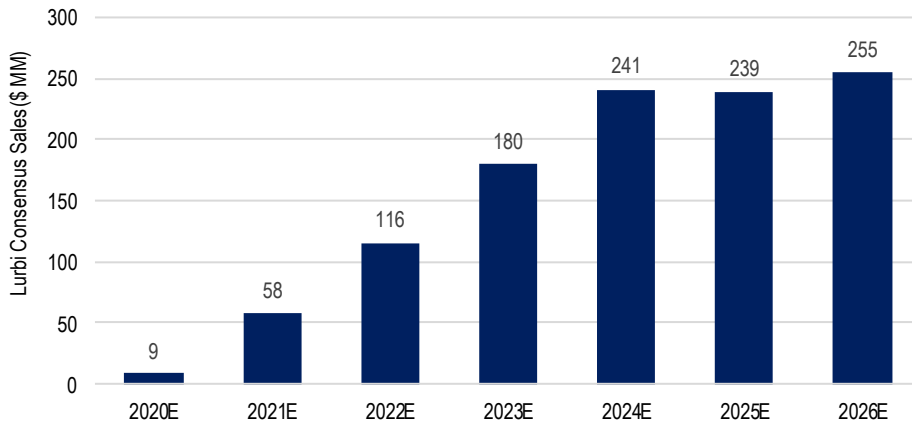
- up to \$250M upon the achievement of accelerated and/or full regulatory approval of lurbinectedin by FDA within certain timelines, and
- up to \$550M in potential commercial milestone payments

Source: Company filings

In our opinion, the setup for an approval/launch is pretty unusual: a) FDA approves the drug on Ph2 monotherapy data with a PDUFA on August 16 (n=105, ORR=35.2%) or b) Ph3 ATLANTIS combination trial (Lurbi + dox) data is successful with data due in 2H20. In our conversations with JAZZ management, JAZZ believes there is a path to FDA approval on monotherapy data even if ATLANTIS trial fails. This would include running a new monotherapy confirmatory trial.

Consensus is currently assuming U.S. peak sales in SCLC in the range of \$240MM-\$250MM. In the U.S., ~17,000 SCLC patients are treated annually (LS + ES SCLC). If we assume 60% penetration, 4 months of therapy and cost of \$20,000/month, we see a \$700MM+ sales opportunity (post royalties to Pharma Mar). This effectively implies consensus estimates are assuming a probability of success in the mid 30% range.

Exhibit 3. Lurbinectedin U.S. Consensus Sales for SCLC



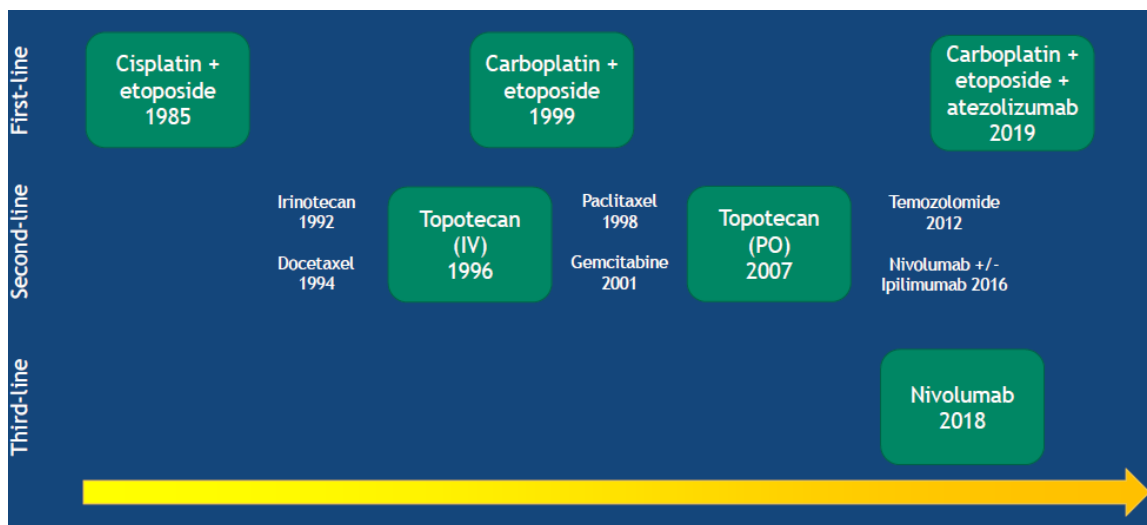
Source: Visible Alpha, Wells Fargo Securities, LLC

SCLC is an aggressive cancer that is generally diagnosed in an advanced stage. Five-year survival of limited-stage (LS) SCLC ranges from 20-40%, and five-year survival of extensive-stage (ES) SCLC is <5%. SCLC makes up ~14% of lung cancer diagnoses each year – the other 86% of diagnoses are non-small cell lung cancer (NSCLC). Compared to NSCLC, SCLC has a much higher doubling time (~86 days vs. ~166 days), a high growth fraction, and earlier development of widespread metastases. However, SCLC seems to have a much higher initial response to first-line chemotherapies and radiation, but most patients relapse regardless.

There are estimated to be ~30K patients diagnosed with SCLC (30% LS-SCLC, 70% ES-SCLC) in the U.S. Of these, ~27K will receive first-line treatment, ~17K will receive second-line treatment, and ~3K-5K will receive third or more-line treatment.

Currently, the treatment options available for SCLC are limited. The most recent major advancement was the approval of PD-L1 antagonists as a first-line therapy, but the majority of patients will relapse even when treated with these therapies. The most recent FDA approved second-line SCLC therapy was topotecan, which was released in 1996. While topotecan is still commonly used as a second-line therapy, it has a relatively low objective response rate (16.9%). For ES-SCLC, the only FDA approved first-line treatment regimen is platinum + etoposide + atezolizumab. The NCCN Guidelines prefer specifically carboplatin to be used for first-line ES-SCLC cases in combination with etoposide and atezolizumab or durvalumab (both of which are PD-L1 antagonists).

Exhibit 4. SCLC Standard of Care



Source: Anna Farago, MD, PhD, Harvard Medical School, 2019 ASCO Meeting

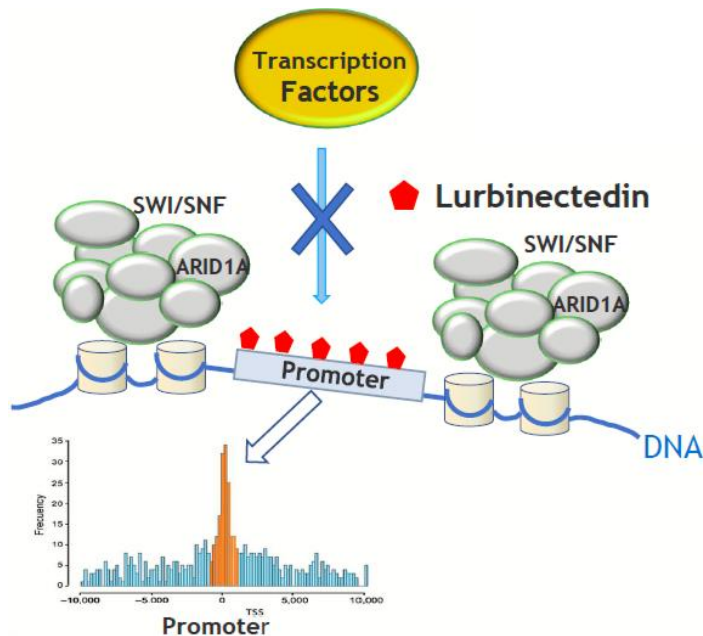
In second line treatment, Ipsen is also currently recruiting a Ph3 trial of Onivyde versus Topotecan in Patients with Small Cell Lung Cancer Who Have Progressed on or after Platinum-based First-Line Therapy.

According to clinicaltrials.gov, the study is currently recruiting with an estimated completion date of September 2022.

### Lurbinectedin – Mechanism of Action

Lurbinectedin (PM01183) is a selective inhibitor of oncogenic transcription. It inhibits active transcription of protein-coding genes by binding to promoters and irreversibly stalling elongating RNA polymerase II, which ultimately leads to double-stranded DNA breaks and eventually apoptosis (death) of tumor cells. Lurbinectedin specifically downregulates IL-6, IL-8, CCL2, and VEGF by inhibiting transcription in Tumor Associated Macrophages (TAMs). In doing so, it prevents the induction of tumor cell proliferation (mediated by IL-6 and IL-8), prevents the inhibition of immune response against tumor cells (mediated by IL-6 and CCL2), and prevents the induction of angiogenesis (mediated by VEGF and IL-8).

Exhibit 5. Lurbinectedin Mechanism of Action



Source: Company filings

Lurbinectedin is a second generation molecule for Pharma Mar – the prior generation was Trabectedin (Yondelis). The key differences are related to the max tolerated dose and how it is administered. On the former, per the Yondelis label, it is administered via a 24-hr IV through a central venous line.

Exhibit 6. Yondelis label

### **YONDELIS (trabectedin) for injection, for intravenous use**

**Initial U.S. Approval: 2015**

#### -----INDICATIONS AND USAGE-----

YONDELIS is an alkylating drug indicated for the treatment of patients with unresectable or metastatic liposarcoma or leiomyosarcoma who received a prior anthracycline-containing regimen (1)

#### -----DOSAGE AND ADMINISTRATION-----

- Administer at 1.5 mg/m<sup>2</sup> body surface area as a 24-hour intravenous infusion, every 3 weeks through a central venous line (2.1, 2.5)
- Premedication: dexamethasone 20 mg IV, 30 min before each infusion (2.2)

Source: FDA

Lurbinectedin in contrast is administered as a 1-hour IV infusion every 3 weeks, so significantly lower timeframe. Secondly, the max tolerated dose (MTD) for lurbinectedin is 5 mg/m<sup>2</sup> versus 1.1-1.8 mg/m<sup>2</sup> for Yondelis.

Exhibit 6. Maximum Tolerated Dose – Lurbi (PM01183) vs. Yondelis

**Results:** PM01183 was safely escalated over 200-fold, from 0.02 to 5.0 mg/m<sup>2</sup>. Dose doubling was utilized, requiring 15 patients and nine dose levels to identify DLT. The recommended dose was 4.0 mg/m<sup>2</sup>, with one of 15 patients having DLT (grade 4 thrombocytopenia). Clearance was independent of body surface area; thus, a flat dose of 7.0 mg was used during expansion. Myelosuppression, mostly grade 4 neutropenia, occurred in 40% of patients but was transient and manageable, and none was febrile. All other toxicity was mild and fatigue, nausea and vomiting were the most common at the recommended dose. Pharmacokinetic parameters showed high interindividual variation, though linearity was observed. At or above the recommended dose, the myelosuppressive effect was significantly associated with the area under the concentration-time curve from time zero to infinity (white blood cells, *P* = 0.0007; absolute neutrophil count, *P* = 0.016). A partial response was observed in one patient with pancreatic adenocarcinoma at the recommended dose.

Yondelis (ET-743) is a novel anticancer agent isolated from the marine ascidian Ecteinascidia turbinata. ET-743 possesses potent antitumour activity and a novel mechanism of action at the level of gene transcription. We conducted two sequential phase I dose escalation and pharmacokinetic studies of ET-743 given as a 1- or a 3-h intravenous (i.v.) infusion. Seventy-two adults with metastatic or advanced solid tumours received ET-743 in escalating doses between 50 and 1100 microg/m(2), initially as a 1-h infusion, and later at doses between 1000 and 1800 microg/m(2) as a 3-h infusion every 3 weeks. The maximum tolerated dose (MTD) of ET-743 was 1100 microg/m(2) for the 1-h infusion schedule and 1800 microg/m(2) when given as a 3-h infusion. Dose-limiting toxicities (DLTs) were fatigue, neutropenia and thrombocytopenia. Transient non-cumulative grade 3-4 increase in transaminases (not considered DLT) and grades 3-4 nausea and vomiting were frequently observed.

Source: AACR Journals, NIH

How Good is the Ph2 Monotherapy Data?

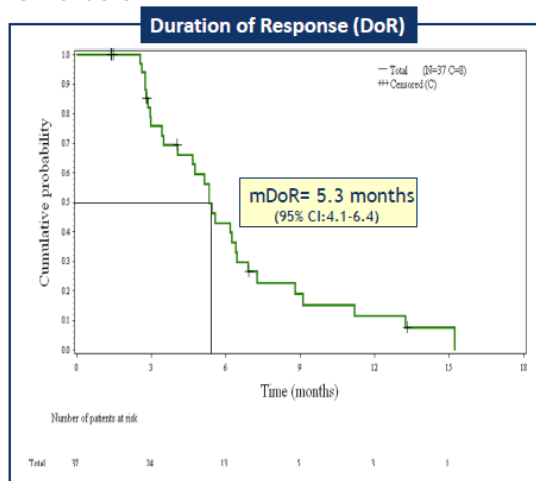
Jazz submitted NDA to the FDA (accepted for priority review) based on the Phase 2 monotherapy basket trial results, which were presented at the ASCO 2019 annual meeting. The data showed a 35.2% overall response rate for a large Ph2 trial (105 patients) which compares favorably to topotecan ORR of 16.9%.

Exhibit 7. Maximum Tolerated Dose – Lurbi (PM01183) vs. Yondelis

	Overall (n=105)
<b>ORR, % (95% CI)</b>	<b>35.2 (26.2-45.2)</b>
<b>Best response</b>	<b>n (%)</b>
- PR (confirmed)	37 (35.2) *
- SD	35 (33.3)
- PD	28 (26.7)
- NE* (non-evaluable)	5 (4.8)
<b>Disease Control Rate,% (95% CI)</b>	<b>68.6 (58.8-77.3)</b>

\* 5 of 8 patients who failed prior immunotherapy had confirmed response

\* Treatment discontinuation without any tumor assessment performed



Source: Dr. Luis Paz Ares, 2019 ASCO Meeting

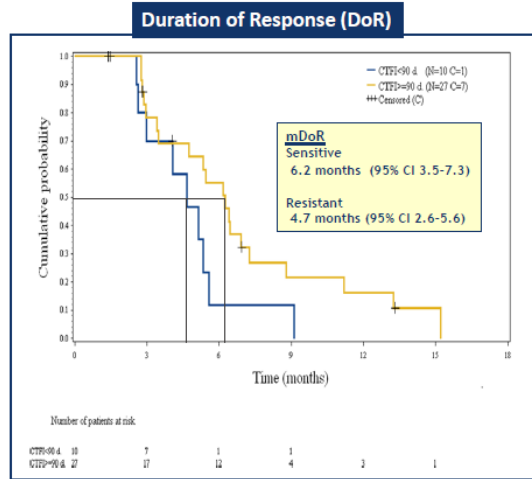
One potential sticking point for investors, in our view, could be a large difference in overall response rate for resistant and sensitive SCLC populations – ORR of 22% for resistant patients (n=45) versus ORR of 45% for sensitive patients (n=60). Sensitive patients had a chemo free interval period of >90 days.

Exhibit 8. ORR for Resistant and Sensitive SCLC Populations

	Resistant CTFI < 90 days (n=45)	Sensitive CTFI ≥ 90 days (n=60)
<b>ORR, % (95% CI)</b>	<b>22.2 (11.2-37.1)</b>	<b>45.0 (32.1-58.4)</b>
<b>Best response (confirmed)</b>	<b>n (%)</b>	<b>n (%)</b>
- PR	10 (22.2) #	27 (45.0) #
- SD	13 (28.9)	22 (36.7)
- PD	18 (40.0)	10 (16.7)
- NE* (non-evaluable)	4 (8.9)	1 (1.7)
<b>Disease Control Rate, % (95% CI)</b>	<b>51.1 (35.8-66.3)</b>	<b>81.7 (69.6-90.5)</b>

# 3 of 5 patients with resistant disease and 2 of 3 patients with sensitive disease who failed prior immunotherapy had confirmed response

\* Treatment discontinuation without any tumor assessment performed



PRESENTED AT: 2019 ASCO ANNUAL MEETING #ASCO19 Slides are the property of the author. permission required for reuse. PRESENTED BY: Dr. Luis Paz Ares

Source: Dr. Luis Paz Ares, 2019 ASCO Meeting

However, it is important to point out three of five patients with resistant disease who failed prior immunotherapy had a confirmed response. Further, if we look at the topotecan efficacy data, it also showed a much higher ORR for sensitive patients (CTFI >90 days).

Exhibit 9. Topotecan Efficacy Data in 2L SCLC

Select Efficacy Parameters

Efficacy	Overall (n=213)	Resistant CTFI < 90 days (n=93)	Sensitive CTFI ≥ 90 days (n=120)
ORR, %	16.9	9.4	23.1
OS months, median (95% CI)	7.8 (6.6-8.5)	5.7 (4.1-7.0)	9.9 (8.5-11.5)
PFS months, median (95% CI)	3.5 (2.9-4.2)	2.6 (1.8-3.3)	4.3 (3.8-5.4)

Source: Company filings

The data also looks comparable when looking at other historical studies.

Exhibit 10. Lurbi vs Historical Studies

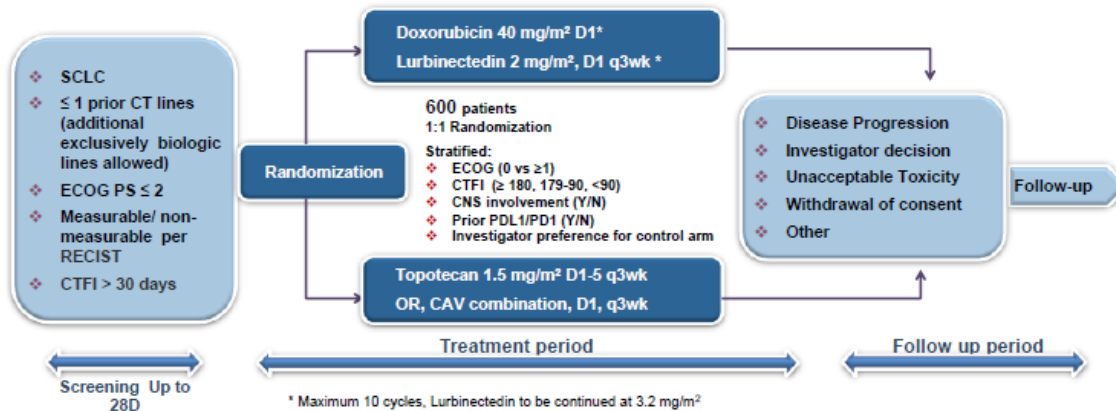
	Lurbinectedin (n=105)	Von Pawel 2014: Topotecan (n=213) <sup>1</sup>	Von Pawel 2014: Amrubicin (n=424) <sup>1</sup>	CheckMate 331: Chemotherapy (n=285) <sup>2</sup>	CheckMate 331: Nivolumab (n=284) <sup>2</sup>
<b>ORR (%)</b>	<b>35.2</b>	<b>16.9</b>	<b>31.1</b>	<b>16.5</b>	<b>13.7</b>
ORR sens (%)	45.0	23.1	40.9		
ORR res (%)	22.2	9.4	20.1		

Source: Company filings

### What about the Ph3 ATLANTIS combination trial?

Atlantis is a Phase 3 global randomized study in relapsed SCLC. The trial was initiated in August 2016 with 613 patients recruited across >150 centers. The trial reached enrollment in July 2018 and data is anticipated in 2H20 vs. "mid-2020" prior due to some pushouts in part related to COVID-19 – the last event happened in early Mar but they are in process of cleaning the data and the need to access hospitals is obviously difficult during COVID-19. The primary endpoint is overall survival (OS) with a time frame of every three months up to death or study termination.

Exhibit 11. Ph3 ATLANTIS Trial Design



Source: Anna Farago, MD, PhD, Harvard Medical School, 2019 ASCO Meeting

The Phase 2 trial for the combination shows good ORR, but it worries us why the data is inconsistent between Cohort A and Cohort B. For instance, the ORR for Cohort A was 67% vs. 37% for Cohort B.

Exhibit 12. Ph2 Data at 2017 ESMO

Response Evaluable patients	Lurbinectedin+DOX (q3wk)		Lurbinectedin +TAX (q3wk)	Lurbinectedin single-agent (q3wk)
	Cohort A L 3-5 mg FD D1 + DOX 50 mg/m² D1 (n=21)	Cohort B L 2 mg/m² D1 + DOX 40 mg/m² D1 (n=27)	L 2.2 mg/m² D1 + TAX 80 mg/m² D1 & D8 (n=7)	L 3.2 mg/m² D1 (n=36)
CR	2 (10%)	1 (4%)	1 (14%)	-
PR	12(57%)	9 (33%)	4 (57%)	13 (36%)
ORR	<b>14 (67%)</b>	<b>10 (37%)</b>	<b>5 (71%)</b>	<b>13 (36%)</b>
SD	3 (14%)	9 (33%)	-	14 (39%)
PD	4 (19%)	8 (30%)	2 (29%)	9(25%)
DCR	17 (81%)	19 (70%)	5 (71%)	27 (75%)
DOR (mo)	4.5	5.2	2.3	6.2+
PFS (mo) CTFI >30d*	4.7	5.3	3.9	3.1+
PFS (mo) Platinum-sensitive	5.8	6.2	3.9	4.6+

D, day; DCR, disease control rate; DOR, duration of response; FD, flat dose; mo, months; q3wk, every 3 weeks; CTFI, chemotherapy free interval.

Source: 2017 ESMO Presentation

Further, it is reasonable to question, even with COVID-19 why the data is delayed into 2H20 with the last event occurring prior to Mar 10.

## How are we thinking about approval based on mono + combo trials?

In our view, based on the cross-trial comparison of Ph2 monotherapy data vs. Topotecan and other historical studies, we believe it is reasonable to think the data could be good enough on its own for FDA approval. The Ph3 ATLANTIS trial is a higher bar in our opinion, and we believe our above concerns on variability of Cohort A vs B and length of time to data are valid. In our conversations with management teams of both Jazz and Pharma Mar, we understand the Ph3 ATLANTIS trial is a separate outcome and would be used to supplement the Ph2 monotherapy data. If we assume for a moment that this is true, we believe this is an attractive setup with potentially two shots on goal. Further, we believe expectations are relatively low with our conversations with investors not overly focused on this asset and consensus implying a ~35% probability of success.

## Peak Sales and NPV Analysis

Below is our peak sales analysis which assumes ~17K 2L patients are treated and ~65% penetration rate. We assume a duration of therapy of approximately 4 months, which is in line with the Ph2 trial. At a price point of \$20,000/month, and after deducting royalties to Pharma Mar, we believe this could be nearly a \$700MM peak sales opportunity for Jazz. On a NPV basis, it equates to >\$30/share after modelling out product sales to 2029, deducting OpEx, and discounting back. If we model a ~50% PoS, we see a NPV in the mid to upper teens.

### Exhibit 13. Peak Sales – US Only Lurbinectedin SCLC

Lurbinectedin-SCLC	US-only	Comments
2L Treated (LS + ES)	17,000	2L Treated of 30K diag; JAZZ Presentation
Penetration	65%	WFS assumption; limited competition
Duration of therapy (mo.)	4.0	Per trial design of Ph2 mono
Price per month	\$20,000	WFS assumption
Product Sales	\$884	in millions
Net Sales post royalty	\$663	Assumes mid-20s royalty

Source: Wells Fargo Securities, LLC estimates



## Price Target

Price Target: \$150 from NC

Our price target is based on a EV/EBITDA multiple of 6.5x our 2021 estimate. Risks to our thesis and target include: Jazz's heavy reliance on Xyrem revenue, upcoming patent cliff, potential increase in competition, and a more restrictive reimbursement and pricing environment.

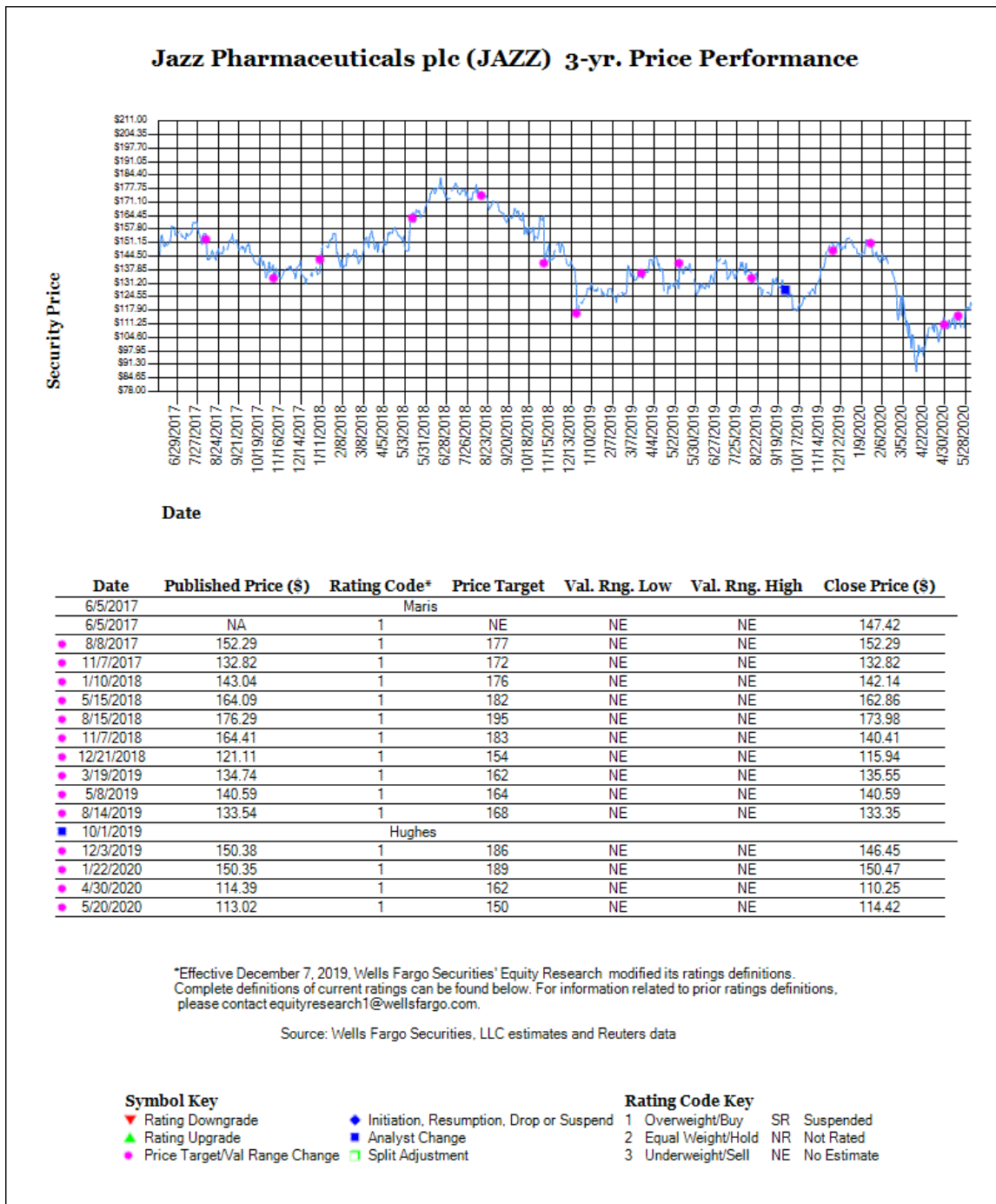
## Investment Thesis

We believe JAZZ shares are undervalued at current levels with investors under-appreciating Jazz's non-Xyrem related pipeline. We think continued strong revenue and earnings growth, expansion through business development, and progress on an unappreciated pipeline, have the potential to drive value further.

## Company Description

Jazz Pharmaceuticals, plc (JAZZ) is a commercial-stage specialty pharmacy company with a diverse set of specialized products in narcolepsy, hematology/oncology, psychiatry, and pain. Jazz is based in Dublin, Ireland, and engages in identifying, developing and commercializing branded pharmaceutical products in focused therapeutic areas of unmet medical need.

## Required Disclosures



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**JAZZ:** Risks to our thesis and target include: Jazz's heavy reliance on Xyrem revenue, upcoming patent cliff, potential increase in competition, and a more restrictive reimbursement and pricing environment.

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As of: June 8, 2020

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