

# **US** Biopharmaceuticals

# What caught our attention in SF (Day 1): TEVA, JAZZ, ALKS, EXEL, XENE, ROIV

**Price Objective Change** 

At a competitor healthcare conference we flag company updates that caught our attention (below). The note continues on page 2.

#### TEVA: foundations for growth pillars

Teva's (TEVA) presentation offered no '24E guidance but the company did reiterate its 2027 long-term financial targets. In our view, the most interesting points in the CEO's fireside related to spending and margins, notably OpEx is expected to grow in '24E thus OM's [~26% in 2023] might not grow "as quickly" in the near-term on the path to ~30% OM's by 2027. The CEO indicated OpEx will definitively grow (BofA forecast +1% Y/Y) but also caveated that the company will be disciplined on OpEx as a percentage of revenue [BofA: 27.7% in 2024 vs. 28.1% prior year]. In our view, Teva showing both top and bottom-line growth is key to investor sentiment. From a gross margin standpoint, the CEO indicated GM's should improve in '24 driven by mix (more Austedo; we model GM's 100 bps above '23 levels). On the pipeline, Teva noted its Ph2 TL1A IBD program will report topline data in 1H25 while in-house interim analysis completes in YE24. Otherwise, management offered consistent /bullish commentary around the trajectory of its two CNS growth brands (Austedo + Uzedy).

## JAZZ: zani Ph3 GEA tweaks, no impact on YE24 timing

Today, Jazz pre-announced 2023 company revenue is expected to fall within prior guidance ranges while the company did not offer '24E guide. However, Jazz did guide to top growth brands (c70% of '24 sales) growing low-DD (vs. our/Street +15%/+13%, respectively) and Xyrem AG royalties >\$200m vs. our \$225m. Overall, we view the color on key revenue line items as reassuring on near-term brand performance. Of note, Jazz appears to be highlighting extra efforts to boost Xywav-IH indication growth calling out more focused S&M investments to broaden the prescriber base and increase diagnosis rates (IH requires market build). The bulk of the fireside chat was focused on zani Ph3 GEA, which is Jazz's most high-profile program. While Jazz announced an increase in study size to boost study powering for the OS analysis, mgmt noted a) the decision involved consultation with the FDA and was not prompted by blinded assessment of event rates, and b) the PFS registrational endpoint readout won't be impacted by the sample size increase and is expected to readout by YE24. In our view, the GEA trial modifications make sense to us as they optimize time-to-market while increasing the odds of securing favorable OS data [overall survival; key to commercial adoption]. We see 1L mGEA as an \$800-900m indication, depending on strength of data. Otherwise, Jazz commentary around M&A was broadly in-line with past calls.

## ALKS: higher margin outlook (Invega) & orexin AEs

Alkermes (ALKS) issued an 8-K which most notably included an outlook to achieve ~30% EBITDA margins (in 2024) and some pipeline updates on Ph1 orexin (sleep) program. On margins, the ~30% target is above the Street's 22%. Previously, management had guided to 20% margins excluding US Invega royalties, thus upside to its own guide is a mix of re-inclusion of Invega and lower OpEx. On orexin, ALKS completed Ph1b in NT1 noting new AEs observed (elevated heart rate, nausea, lower appetite); **Cont'd on pg 2**.

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PO change: ALKS \$29 to \$30, see p. 2 and Exhibit 1 for summary of model changes

Acronyms: HRMY: Harmony OGN: Organon

OM: operating margin GM: gross margin

S&M: sales and marketing TL1A, FcRn: drug targets

IBD: inflammatory bowel disease FDA: US Food and Drug Administration

CNS: central nervous system

DD: double digit AG: authorized generics OS: overall survival

PFS: progression free survival

m: metastatic

GEA: gastroesophageal adenocarcinoma

L: line of therapy AE(s): adverse event(s)

NT1, NT2: narcolepsy type-1 / type-2

IH: idiopathy hypersomnia ASCO GU: medical meeting IP: intellectual property IND: investigational new drug

TBD: to be determined

**ALKS (continued from front page)**: we suspect increased investor focus on the elevated heart rate given Jazz recently paused its orexin program citing cardiovascular toxicity. ALKS plans to advance '2680 into Ph2 NT1 study (1H24) at doses ranging from 4mg, 6mg, 8mg. ALKS expects to disclose Ph1b data in NT2 and IH in 1H24. We see ALKS' own Ph2 data ('25E) as key de-risking event given Ph1 study in NT1 was limited to single-dose exposure. Reiterate Neutral: balanced risk/reward; PO to \$30 (from \$29) on lower OpEx given ALKS' revised '24 EBITDA guide.

## EXEL: soft '24 sales guide offset by cost cut, share repo

Exelixis' (EXEL) FY24 product sales guidance at midpoint came in -8% below cons offset by cost cutting and lower OpEx (-14% R&D, -19% SG&A). The sales guide at midpt (+4% Y/Y) was in-line with Cabo script averaging +1% Q/Q, though list price increase (+2% Y/Y) is less than prior years (+7-8%). We see Cabo providing steady cash flow to EXEL as the company looks to expand cabo label (prostate data at ASCO GU Jan 25<sup>th</sup>) and advance pipeline (zanza/XB002) to drive long-term sales growth. EXEL has planned up to \$450m additional buyback in '24. Reiterate Buy: upside potential from Cabo IP resolution. Model: 5-6% lower '24-26E topline offset by 6-7% lower OpEx; no impact to valuation (see Exhibit 1).

#### XENE: pivotal MDD design discussed + Nav1.7 in pain

The focus of the Xenon (XENE) management fireside was around XEN11011 development programs in epilepsy and depression. On epilepsy, we did not feel management disclosed anything new with Ph3 X-TOLE2 study topline data still estimated to come in 1H25 (6-8 months after last pt enrolled in 2H24). On '1101 for depression (MDD), management offered some outline on contours of Ph3 design which should resemble the Ph2 X-NOVA (sites, US-centric sites) while primary endpoint will likely to be HAMD-17 scale (based on Ph2 success) and leaning ("right now") to focusing on a single '1101 dose-level. One variable that continues to be debated internally at Xenon is having two vs. three Ph3 studies to mitigate placebo-risk (decision TBD). On the earlier stage pipeline, XENE mentioned IND-enabling studies will transpire in 2024-25 looking at Nav1.7 for pain, which comes after Vertex reported positive Ph2 for its Nav1.8 inhibitor in pain, with management is confident Nav1.7 is a more genetically validated target.

Acronyms: MDD: major depressive disorder; Nav1.7/8: sodium channel; HAMD-17: Hamilton Depression Rating Scale; pt: patient; XTOLE-2, X-NOVA: clinical trials; MADRS: Montgomery-hamilton depression rating scale.

# ROIV: no news on cap deployment; BD strategy unchanged

One key focus from Roivant's (ROIV) fireside chat was on capital deployment, where management reaffirmed prior messaging that they would take their time on business development (BD). Further on BD, management remains focused on opportunities with low upfront cost (vs \$17m average upfront in prior BDs), pursuing similar mix of early-and mid-/late-stage opportunities (roughly 50/50 in prior efforts), and agnostic to therapeutic area focus. We look to fireside tomorrow with subsidiary Immunovant (IMVT) for more in-dept discussions on its autoimmune FcRn franchise. Maintain Neutral on ROIV: balanced risk/reward.

#### **Exhibit 1: Summary of model changes**

We summarize estimate changes made with this report

Ticker	PC	) (\$)			Reveni	e (\$m)			EPS (\$)					
		Old		Current		Old		Current						
	Old	New	2023E	2024E	2025E	2023E	2024E	2025E	2023E	2024E	2025E	2023E	2024E	2025E
ALKS	29	30	1,674	1,538	1,550	1,674	1,538	1,550	1.59	2.28	2.28	1.59	2.57	2.43
EXEL	27	27	1,843	2,029	2,179	1,831	1,897	2,036	0.71	1.25	1.65	0.68	1.28	1.59

**Source:** BofA Global Research estimates



#### **Exhibit 1: Summary of model changes**

We summarize estimate changes made with this report

Ticker PO (\$) Revenue (\$m) EPS (\$)

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#### **Exhibit 2: Stocks mentioned in this report**

Ratings and stock prices of stock tickers mentioned in this report

Ticker	Company name	Rating	Stock price
ALKS	Alkermes PLC	B-2-9	29.60
EXEL	Exelixis Inc	B-1-9	22.54
JAZZ	Jazz Pharmaceuticals PLC	B-1-9	125.51
ROIV	Roivant Sciences Ltd	C-2-9	11.44
TEVA	Teva Pharmaceutical Industries	C-1-9	11.47
XENE	Xenon Pharmaceuticals Inc	C-1-9	47.88

Source: BofA Global research, Bloomberg

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## Price objective basis & risk

#### Alkermes (ALKS)

Our \$30 PO is based on a blended mix of DCF and 2025E P/E. We believe our DCF is based on reasonable assumptions, including: (1) discount rate of 9%, and (2) riskadjusted pipeline value for ALKS2680 in lieu of terminal value. Our assumption of 13x '25E EPS is within range of biopharma peers (7-17x) and comparable to 13x where ALKS trades at.

Upside risks: 1) better-than-expected product sales growth, 2) value accretive divestiture or partnership above our expectation.

Downside risks: 1) worse-than-expected product sales growth, 2) assets divested or partnered at values below our expectation.

#### **Exelixis (EXEL)**

Our \$27 price objective (PO) is based on DCF analysis. We assume the following: 1) Cabometyx US revenue climbs to \$1.8bn by '25E as the product maintains market leading position among approved TKIs, with modest 1L market share for RCC (we model 2L+ mCRPC at 55% likelihood of success adjustment), 2) exclusivity for Cabo though January 2030E, 3) 9.5% discount rate and no terminal value.

Downside risks to our PO: 1) clinical trial failure, 2) patent loss or settlement allowing generic entry prior to 2030 expiry of polymorph patent, 3) widening gross-to-net discount for Cabo with increase in Medicare Part D coverage gap.

#### Jazz Pharmaceuticals (JAZZ)

Our \$184 price objective (PO) is based on equally blended valuation based on 8x EV/EBITDA of our 2024E EBITDA. Our valuation multiple reflects our confidence in Jazz's ability to navigate patent cliff concerns, and company growth profile. Our EV/EBITDA multiple of 8x compares to the peer group that trades at 6-7x, which we think is appropriate based on JAZZ's growth outlook vs peers. We assume WACC of 9% and terminal growth rate of -3% in our DCF.

Downside risks to our PO are 1) slower-than-expected sales growth from Xywav or Zepzelca launch, 2) slower-than-expected sales growth of Epidiolex, and 3) competitive headwinds to sodium oxybate brand franchise.



Upside risks to our PO are 1) greater-than-expected sales growth from Xywav or Zepzelca launch, 2) less-than-expected generic erosion of Xyrem (eg. due to difficulty setting up a generic REMS), and 3) future business development transactions, which is a core element of the company's strategy.

#### Roivant (ROIV)

Our PO of \$12 assumes 1) a discount rate of 11% for hybrid biotech with mid-to-late stage pipeline and a commercial product, 2) POS of 95% for VTAMA atopic dermatitis, 3) risk-adjusted forecast for FcRn franchise, 4) loss of exclusivity of lead programs in 2038E+.

Downside risks to our PO: 1) clinical trial failure or clinical data come in below expectation, 2) product sales underperform our forecast, 3) dilutive capital raise

Upside risks to our PO: 1) clinical data come in above expectation, 2) product sales outperform our forecast, 3) acquisition at a premium

#### Teva Pharmaceuticals (TEVA)

Our \$13 price objective (PO) is based on a '24E EV/EBITDA multiple of 8x, which is slightly above the peer group avg of 6.7x reflecting key new product launches following resolution of opioid litigation. Our valuation factors in \$4.7bn in contingent legal liabilities related to opioid litigation resolution (\$3.2bn) and generic price fixing (\$1.5bn). The \$3.2bn estimate for present value of opioid resolution cost is based on \$4.35bn gross liability, with a 13-year payout.

Upside risks: 1) Ability to execute BD (business development) activity to drive mid-SD revenue growth in '23-27 timeframe, 2) surprise high value new generic product launch.

Downside risks: 1) annual opioid costs may limit BD activity thus hindering TEVA's aspiration of achieving mid-SD revenue growth in '23-27 timeframe, 2) increased price erosion to key spec pharma brands

#### Xenon Pharmaceuticals (XENE)

Our \$56 price objective (PO) is based on a risk-adjusted sum-of-the-parts analysis. 1) XEN1101 launches in 2025 and risk-adjusted FOS sales reach est. \$1.5bn by 2039, 2) 80% POS for lead FOS indication, 80% POS for PGTCS, and 65% POS for MDD, 4) No terminal value beyond 2040 LOE, 5) 10% discount rate.

Downside risks to our PO: 1) emerging retinal AE in ongoing FOS studies, 2) failure or disappointing results on confirmatory Ph3 FOS study, 3) failure or disappointing results on PGTCS and/or MDD studies.

Upside risks to our PO: 1) better-than-expected results from Ph3 PGTCS study, 2) better-than-expected results from MDD POC studies, 3) clinical success in FOS leading to better adoption and/or steeper market ramp.

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	bluebird bio	BLUE	BLUE US	Jason M. Gerberry
	Exelixis	EXEL	EXEL US	Jason M. Gerberry
	Immunovant, Inc.	IMVT	IMVT US	Jason M. Gerberry
	Intra-Cellular Therapies	ITCI	ITCI US	Jason M. Gerberry
	lonis	IONS	IONS US	Jason M. Gerberry
	Jazz Pharmaceuticals	JAZZ	JAZZ US	Jason M. Gerberry
	Lyra Therapeutics	LYRA	LYRA US	Jason M. Gerberry
	Oculis Holding AG	OCS	OCS US	Jason M. Gerberry
	Relay Therapeutics	RLAY	RLAY US	Jason M. Gerberry
	Tarsus Pharmaceuticals	TARS	TARS US	Jason M. Gerberry
	Teva Pharmaceuticals	TEVA	TEVA US	Jason M. Gerberry
	Vaxcyte Inc	PCVX	PCVX US	Jason M. Gerberry
	Xenon Pharmaceuticals	XENE	XENE US	Jason M. Gerberry
NEUTRAL				
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	Amphastar Pharmaceuticals	AMPH	AMPH US	Jason M. Gerberry
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	Galapagos	GLPG	GLPG US	Jason M. Gerberry
	ProKidney Corp	PROK	PROK US	Jason M. Gerberry
	Roivant	ROIV	ROIV US	Chi M. Fong
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	FibroGen Inc.	FGEN	FGEN US	Jason M. Gerberry
	Harmony Biosciences	HRMY	HRMY US	Jason M. Gerberry
	Organon	OGN	OGN US	Jason M. Gerberry
	Viatris Inc.	VTRS	VTRS US	Jason M. Gerberry

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Buy	234	60.94%	Buy	115	49.15%
Hold	80	20.83%	Hold	36	45.00%
Sell	70	18.23%	Sell	29	41.43%

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Coverage Universe	Count	Percent	Inv. Banking Relationships R1	Count	Percent
Buy	1895	53.62%	Buy	1083	57.15%
Hold	832	23.54%	Hold	454	54.57%
Sell	807	22 84%	Sell	383	47.46%

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 ≥ 0%
 ≤ 30%

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 ≥ 20%

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