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US Biopharmaceuticals

4Q23 Spec Pharma and SMID Biotech Preview

Price Objective Change

4Q matters for some; we flag top picks TEVA, ITCI, TARS

In this report, we preview 4Q EPS updates and FY24 guidance (where likely to be offered). Of note, 5/13 names in our coverage pre-announced or are unlikely to offer '24 guide, limiting the stock impact of their quarterly updates. Our analysis is based on 4Q pricing/volume trends and relevant company commentary on key products. Over the last 3-months, the group (stock) performance has been solid with 10 (77%) of 13 companies in this report outperforming the broader market and 5 (38%) beating the XBI biotech index in that period. Broader themes at play in the last 3-mo include: a) biotech 'own the [underappreciated] launch', b) CNS halo – given recent M&A activity in the space and some generalist interest in commercial names; c) value correction for some ultra-low multiple names that don't offer growth. In 4Q, we bucket our coverage into 3 groups: 1) new launches and/or '24 numbers focus: JAZZ, TEVA, HRMY, TARS; 2) mixed of commercial and pipeline stories: ITCI, ALKS, AXSM, 3) structural issues or future BD as key multiple lever: EXEL, ROIV, OGN, VTRS, BHC.

Alkermes (ALKS; Neutral) (FY24E revenue $1.52bn vs cons $1.52bn)

We expect a small cons revenue beat on higher R&D revenue but an in-line product revenue + royalties. The 4Q-focus remains on Lybalvi where we expect $56m 4Q sales (+61%) and >+50% sales growth in '24 (~$290m), both in-line with cons and imply some benefit from ongoing DTC marketing. Investor feedback suggests some concerns around ALKS growth profile with a '27 Vivitrol LOE, royalty discontinuations and Lybalvi competition (from muscarinics), thus we believe pipeline (Ph1 '2680 orexin for narcolepsy) will be key for the stock – 1H24 NT2 efficacy data at tolerable dose.

Amphastar (AMPH; Neutral) (FY24E revenue $794m vs consensus $796m)

We expect 4Q sales $163m below cons $174m, partially due to lower Baqsimi (1x accounting in asset transition). Ex-Baqsimi (recently acquired), we forecast the rest of the portfolio generating $140m (+4% Y/Y) on IQVIA trends and mgmt commentary on supply-disrupted product categories. In '24, we forecast $794m in total company sales which is in-line with cons. At the product-level, we expect Baqsimi end-user sales of $180m (+20% Y/Y), some continued Gx glucagon kit growth + pipeline offsetting modest erosion across other portfolio products. On the call, our focus will be on status of pipeline programs + supply dynamics in key product categories.

Continued page 3: BHC, BLUE, EXEL, HRMY, ITCI, JAZZ, OGN, ROIV, TEVA, VTRS

Tickers: ALKS = Alkermes; AMPH = Amphastar; AXSM = Axsome; BHC = Bausch; BLUE = bluebird bio; EXEL = Exelixis; HRMY = Harmony Biosciences; ITCI = Intra-Cellular; JAZZ = Jazz Pharmaceuticals; OGN = Organon; ROIV = Roivant; TARS = Tarsus Pharma; TEVA = Teva Pharmaceuticals; VTRS = Viatris Inc.

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PO changes:
VTRS: from $9/share to $10/share
TEVA: from $14/share to $15/share
TARS: from $42/share to $55/share

Acronyms:
1L: first-line
ASCO GU: medical meeting
BD: business development
BLCO: Bausch + Lomb
CNS: central nervous system
cons: consensus
DTC: direct to consumer
IH: idiopathic hypersomnia
LOE: loss of exclusivity
NT1, NT2: narcolepsy type-1/ type-2
OS: overall survival
PFS: progression free survival
MDD: major depressive disorder
ADHD: Attention-deficit/hyperactivity disorder
TDT: transfusion-dependent β thalassaemia
CALD: cerebral adrenoleukodystrophy
Ph1: Phase 1
CC: conference call
SD: single-digit
OM: operating margin
GEA: gastroesophageal adenocarcinoma
GTN: gross-to-net
XBI: S&P Biotech ETF

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Axsome (AXSM; Neutral) (FY24 Auvelitiy revenue $260m vs cons $255m)
Axsome recently preannounced 4Q sales and the company has not committed to offering '24E guidance. In the absence of any forward revenue guidance, we'd expect the focus of the call on: 1) Auvelity-MDD growth dynamics: we/cons forecast $260m/$255m or +100% Y/Y BofA growth (vs 34% Q/Q avg growth in 2H23), following a similar ramp a MDD comp Rexulti in year-2 post-launch. Recall, Axsome recently added +100 sales reps to promote Auvelity with an expectation the sales force comes fully online in 2H24; 2) multiple Ph3 readouts in '24: AXS-12 narcolepsy, Auvelity ADA and Sunosi ADHD.

Bausch (BHC; Underperform) (FY24E Pharma rev $4.61bn vs cons $4.64bn)
We forecast in-line 4Q Bausch sales and EBITDA which incorporates modest (+4% Y/Y) growth from top selling brand (Xifaxan). In 2024, we forecast flat topline growth with modest Xifaxan growth offset by declining diversified brands. As with prior quarterly updates, we expect a significant amount of focus on the progress/ timing for separating the Pharma and Eye Health businesses (BLCO), a process that has been running for over 3-years. Bausch still expects a decision in the Xifaxan patent appeal sometime in 1Q24, which could be an important variable to spin timing and other litigation matters.

Bluebird Bio (BLUE; Buy) (FY24E BofA $124m vs cons $124m)
We forecast 4Q sales modestly below cons ($15m vs $19m) and we assume ~6 patients treated with BLUE's gene therapies; we assume 5/1 patients on Zynteglo (TDT) and Skysona (CALD), respectively. We look to the progression of new patient starts vs the 22 starts (since BLUE launched both products). In 4Q, we estimate approximately 11 new starts are in-play for cell infusions (revenue recognition). We also look to Lyfgenia launch updates/metrics to inform feasibility of BofA/cons $124m '24 revenue respectively, which assumes ~50 pts treated vs last guide of 85-105 '24E new starts.

Exelixis (EXEL; Buy) (FY24E revenue $1.9bn vs cons $1.93bn)
We expect minimal 4Q surprises after EXEL pre-announced and guided on FY24. EXEL's Cabometyx (cancer drug) now faces tougher sales comps having launched the 1L renal indication in 1Q21, thus growth will likely be low-single digit going forward absent label expansion. We believe it is unlikely we get any material updates on the Cabometyx patent litigation where the presiding Judge is expected to issue a ruling in the Spring. Cabo Ph3 results for prostate cancer will likely be discussed after abstract data at ASCO GU showed a 35% risk reduction in PFS and 21% in OS (immature). Post December R&D Day, we doubt there will be any meaningful R&D pipeline updates on the 4Q call.

Harmony (HRMY; Underperform) (FY24E BofA $701m vs cons $714m)
The HRMY 4Q update could be uneventful after 4Q pre-announcement and FY24 guidance calling for Wakix '24 revenue of $700-720m (+22% Y/Y at mid-pt). We estimate Wakix should add ~210 patients/ quarter (vs ~280 avg qtr adds in 2023), which mainly reflects tougher comps. Our recent sleep survey suggests Wakix share amongst high prescribers should be flat to down in '24. On the conference call, we expect a focus on 1) nature of Ph1 Wakix life extension update in 1H24, 2) Zygel Ph3 enrollment updates. On Wakix patent litigation, we estimate a litigation event with Paragraph 4 challengers is 2025.

Intra-Cellular (ITCI; Buy) (FY24E BofA $662m vs cons $660m)
We expect 4Q Caplyta sales of $136m (+56% Y/Y) roughly in-line with cons and should put FY23 sales near the mid-point of management's guidance. In FY24, we expect Caplyta guidance to bracket our/cons $662m/$660m forecasts, respectively which reflect > 40% Y/Y growth. We expect investors to by hyper-focused on the pending 1Q24 Ph3 readout of Caplyta as adjunctive MDD treatment. We estimate MDD could add $770m in additional peak revenue and we model a 70% POS reflecting direct/indirect evidence for Caplyta in the MDD setting. Otherwise, we look for clarity on Ph2 starts (design, timelines) for deuterated lumateperone in various mental health disorders.

Jazz (JAZZ; Buy) (FY24E revenue $4.1bn vs cons $4.1bn)
We expect Jazz to report in-line 4Q sales while on FY24 sales guidance we/Street model Jazz achieving high-SD sales growth which seems feasible (to us) after Jazz guided to its top 3 growth driver products growing double digits. Also important in '24 is evolution of margins, where Street models lower adj. OM's versus Jazz Vision 2025 (45% vs 48%); 2024 is an important bridge year to '25 targets and near complete diversification away from legacy Xyrem. On pipeline, the focus will likely be on Ph3 zani 1L GEA study PFS readout by YE24 as the highest POS readout while Ph2b JZP-385 essential tremor remains high risk (not in our model).

Organon (OGN; Underperform) (FY24E revenue $6.5bn vs cons $6.4bn)
We forecast mid-SD top and bottom-line 4Q growth, both roughly in-line with cons. We believe OGN's recent '24E pre-announced sales and EBITDA likely eliminates the risk of positive or negative guidance-related surprise. On the call, we expect a focus on a) performance of key segments; b) pushes/pulls on margins.

Roivant (ROIV; Neutral) (FY3Q revenue $29m vs cons $30m)
On FY3Q call, we expect focus to be on management color (if any) on capital deployment and expectations for key updates related to subsidiary Immunovant's (IMVT) autoimmune FcRn franchise, notably competitor Biohaven's initial Ph1 data (1Q24) of first-gen IgG (Immunoglobulin G) degrader BHV-1300 and IMVT's own Ph2b data of batoclimab in CIDP (chronic inflammatory demyelinating polyneuropathy) in 1H. We are roughly in-line with cons on net sales of VTAMA (psoriasis) and do not see quarterly beat or miss on net pricing (gross-to-net; swing factor) to change the narrative of VTAMA launch in the absence of significant script trend inflection.

Tarsus (TARS; Buy) (FY24E revenue $76m vs cons $60m)
We forecast slightly above-cons Xdemvy (demodex blepharitis) sales of $7.6m vs $6.4m but we trimmed our estimate to reflect more conservative GTN pricing (first full qtr). We don't expect TARS to offer '24 Xdemvy sales guidance until reimbursement dynamics are better characterized. We increase our 2024 Xdemvy forecast to $73m (vs cons $60m) but we believe there are plausible scenarios wherein sales are closer to $90-100m (GTN being the biggest variable). While TARS' has been a strong YTD performer (+31% vs XBI -2%), we see valuation as undemanding at <1x peak sales and/or our $55/shr DCF.

Teva (TEVA; Buy) (FY24E revenue $15.9bn vs cons $15.6bn)
We forecast 4Q sales and EBITDA of $4.1bn (+5% Y/Y) and $1.4bn (+15% Y/Y) which is slightly higher/roughly in-line versus consensus of $4bn sales and $1.4bn EBITDA. Into 4Q, we believe investors are acutely focused on 1) margin progression given 1H volatility; 2) continued uptake of Austedo which is Teva's highest margin product and key to driving margin expansion and EBITDA growth. Looking to FY24 guide, we forecast sales and EBITDA of $15.9bn (+3% Y/Y) and $4.8bn (+4% Y/Y), respectively. We raise our PO to $15/share (from $14) on 8.25x EV/EBITDA (from 8x) on valuation multiple re-rate.

Viatris (VTRS; Underperform) (FY24E revenue $15.4bn vs cons $15.5bn)
We forecast 4Q sales of $3.9bn (flat Y/Y) and EBITDA $1.2bn roughly in-line with cons, respectively. We expect investor focus to be on 1) mechanics/specific details on capital deployment given pending divestitures; 2) organic pro forma growth – see report. Based on sector re-rating, we maintain Underperform and raise PO from $9/share to $10/share (raising our ev/ebitda to 5.5x from 5.25x); multiple reflects lack of growth and/or track record of accretive business development.

Exhibit 1: Summary of model changes
We summarize estimate changes made with this report

Ticker	PO ($)		Revenue ($m)						EPS ($)					
			Old			Current			Old			Current		
	Old	New	2023E	2024E	2025E	2023E	2024E	2025E	2023E	2024E	2025E	2023E	2024E	2025E
ALKS	30	30	1,674	1,538	1,550	1,665	1,524	1,541	1.59	2.57	2.43	1.54	2.52	2.34
AMPH	63	63	640	794	864	636	794	864	3.42	3.92	4.44	3.42	3.92	4.44
AXSM	96	96	270	406	824	270	362	767	(4.13)	(3.25)	1.68	(4.13)	(2.94)	1.54
BHC	6	6	8,647	8,780	7,662	8,642	8,912	7,683	3.53	3.65	2.07	3.53	3.78	2.09
BLUE	5	5	43	124	259	37	124	259	(2.03)	(1.65)	(1.52)	(2.26)	(1.66)	(1.52)
EXEL	27	27	1,831	1,897	2,036	1,831	1,897	2,041	0.68	1.28	1.59	0.68	1.28	1.60
HRMY	30	30	586	701	817	586	701	817	3.09	3.94	4.86	3.09	3.94	4.86
ITCI	82	82	469	662	1,218	469	662	1,218	(1.71)	(0.29)	3.80	(1.71)	(0.29)	3.80
JAZZ	184	184	3,855	4,116	4,325	3,855	4,116	4,325	18.60	19.94	20.89	18.60	19.94	20.89
OGN	12	12	6,242	6,486	6,584	6,212	6,477	6,582	3.78	4.31	4.50	3.93	4.30	4.49
ROIV	12	12	125	157	421	125	151	417	(1.30)	(0.84)	(0.66)	(1.30)	(0.85)	(0.67)
TARS	42	55	18	61	125	14	76	161	(4.42)	(4.02)	(2.05)	(4.53)	(3.82)	(1.88)
TEVA	14	15	15,455	15,879	16,483	15,455	15,879	16,483	2.38	2.45	2.74	2.38	2.45	2.74
VTRS	9	10	15,483	15,422	15,350	15,483	15,422	15,350	2.92	2.74	2.75	2.92	2.74	2.75

Source: BofA Global Research estimates

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ALKS: FY24E guidance + orexin updates

ALKS US – Rating: NEUTRAL (B-2-9) | PO: 30.00 USD | Price: 28.98 USD

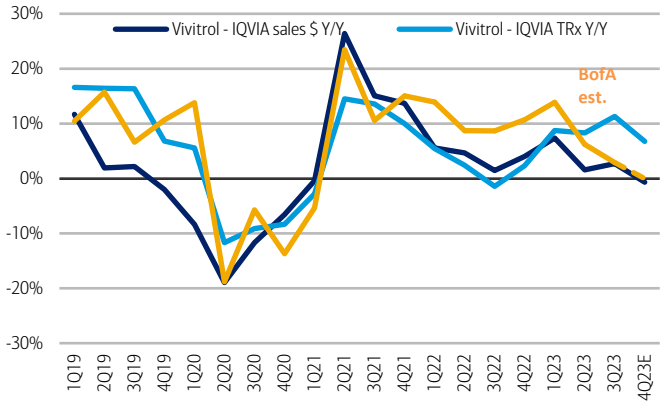
4Q23E TBD; Est. sales $379m, vs cons $368m Bloomberg / $372m visible alpha

We forecast 4Q topline of $379m (+24% Y/Y, -0.5% Q/Q) which assumes sequential sales growth in proprietary products (+4% Q/Q from Vivitrol, Aristada, Lybalvi combined) offset sequentially lower R&D revenue. By comparison, consensus is more conservative calling for 2-3% Q/Q revenue decline (driven by lower R&D revenue) despite forecasting growth in net sales from proprietary products (+6%). We don't see deviation in 4Q23 R&D revenue as stock impactful and expect investor focus on FY24E net product sales guidance including Lybalvi and any additional color on profitability (e.g. net margin, level of cost cuts to arrive at ~30% EBITDA margin provided in early January).

- **Vivitrol (addiction; $102m vs $102m cons)**: our 4Q forecast calls for flat Y/Y growth versus +3% Q/Q and factors in a blended average of sequential and Y/Y IQVIA script trends. In 4Q, Vivitrol TRx/units declined -1%/-2% Q/Q, whereas on Y/Y basis Vivitrol grew TRx/units +7%/ -1%, respectively. FY24E, we forecast $417m in Vivitrol sales (roughly in-line with cons $418m) with BofA/cons modelling a slight haircut to Y/Y growth vs 2023 level (+4% Y/Y FY24 vs +5% FY23).

- **Aristada (schizophrenia; $83m vs $86m cons)**: our 4Q forecast of $83m (+4% Y/Y) is below cons of $86m, as we factor in +1% Y/Y script growth and assume low single-digit net price tailwind (vs +3% list price). Our forecast calls for +1% Q/Q sales growth vs -1% Q/Q TRx in 4Q. FY24E, we forecast $354m (+8% Y/Y) in sales which calls for similar to high-SD growth expected in FY23. We are slightly below cons ($357m) on FY24E Aristada sales forecast.

Exhibit 2: Vivitrol IQVIA vs reported net sales Y/Y trends
Our 4Q forecast calls for flat Y/Y growth



Source: company reports; IQVIA National Prescription AuditTM and National Sales PerspectivesTM, Jan 2018 to Dec 2023, Copyright IQVIA. All rights reserved.
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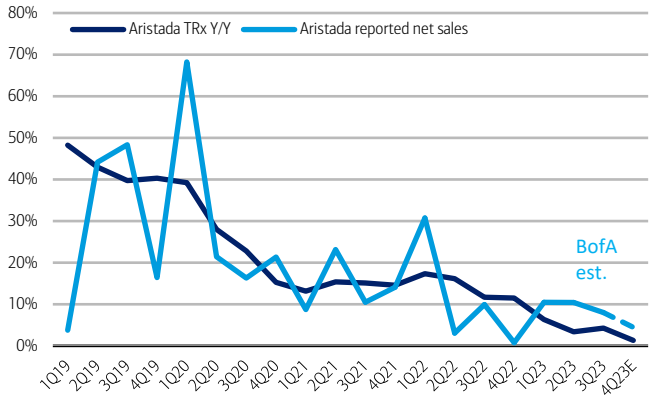
Exhibit 3: Aristada Y/Y trends: IQVIA vs reported net sales
Our 4Q forecast calls for +4% Y/Y growth



Source: company reports; IQVIA National Prescription AuditTM, April 2018 to Dec 2023, Copyright IQVIA. All rights reserved. Note: TRx - weekly data adjusted for script duration.
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- **Vumerity (multiple sclerosis; $35m vs cons $37m)**: we forecast $35m in 4Q royalty revenue (to ALKS), ~flat Q/Q, given sequential flattening of scripts in 4Q.

- **Lybalvi (mood disorders; $56m vs cons $58m):** We forecast $56m in 4Q sales (+61% Y/Y and +11% Q/Q, respectively) which factors TRx growth of +65% and +11% respectively; our estimate is a touch below cons. Our forecast factors in 46.5k scripts, assumes $4m inventory (vs $2-5m per quarter last 4 quarters), and assumes 26% GTN deduction off list price. Our FY24E forecast of $290m (vs cons $292m) calls for +51% in Y/Y sales and assumes +4% price tailwind (vs +4% list; assuming similar GTN level) and roughly +45% Y/Y volume/TRx growth (or 110-115 basis point w/w increase). We assume DTC will accelerate script trend vs +0.7% average w/w level observed over the last 26 weeks. ALKS expects GTN to be maintained at a similar level (26-27%) in 1H24E though expanded commercial contracting could increase GTN in 2H (presumably with the benefit of better volume growth).

Key focus on conference call

We highlight: 1) **orexin-2** – Alkermes plans to disclose Ph1 clinical data for its OX2R candidate ['2680] which will include full Ph1 data from the narcolepsy type 1 (NT1) group [last presented at World Sleep] and initial [new] Ph1 data in type 2 (NT2) and idiopathy hypersomnia (IH) sometime in 1H24. We also expect investors to focus on the read-across from competitor-Takeda's Ph2 orexin results (TAK-861) in NT1 and NT2 in 2H24E (based on primary completion est. of May 2024 on clinicaltrials.gov), and evolution of Merck's MK-6552 (mechanism undisclosed) in Ph1 assessment for NT1. In early Jan, Takeda noted the majority of Ph2 patients were rolling over to open label extension with no major safety red flags had been observed (to date) and no visual disturbance AE in ongoing blinded data (in NT1 trial). Further, Takeda plans to start a Ph3 trial in NT1 "at-risk" in mid 2024E ahead of Ph2 study completion. Lastly, Takeda expects to advance another oral orexin molecule TAK-360 ("quite distinct" vs TAK-861) into Ph1 in the "next couple of months" and framed TAK-861 data would help inform positioning for TAK-360; 2) **profitability** – in early January, ALKS guided to a ~30% EBITDA margin in FY24E vs prior guidance of ~20% where upside to its own guide appears to be a mix of re-inclusion of US Invega royalty and lower OpEx; 3) **Lybalvi** – our focus is on net product sales guidance range vs our/cons forecast of $290m/$292m (roughly +51% Y/Y) which implies mid-to-high 40% Y/Y volume growth and roughly 4% price tailwind. We will also look for color on any ramp/change in sales and marketing efforts (e.g. DTC) in 2024 vs 2023; 4) **capital allocation** – per ALKS from early January,

the company is considering possible capital return to shareholders (e.g. share repurchase) at the Board level and plans to provide an update later this year.

Acronyms: DTC: direct to consumer, GTN: gross-to-net deduction, CNS: central nervous system, TRx: total prescription, AE: adverse event.

AMPH: Competitor shortages persisting (for now), Baqsimi Y/Y growth

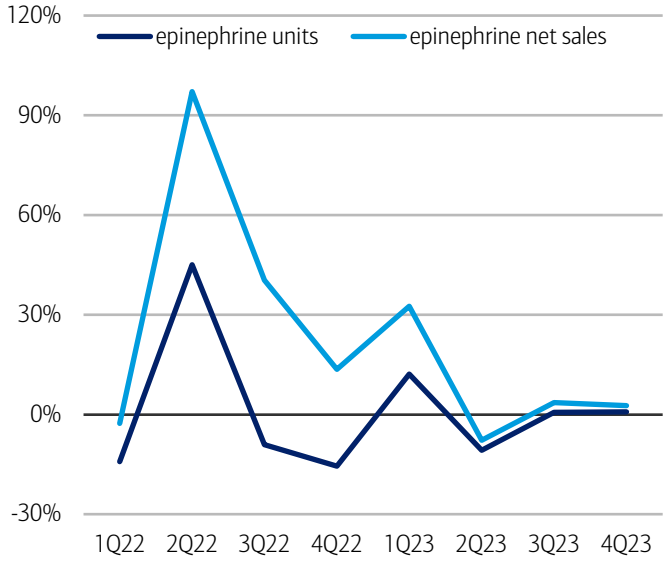
AMPH US – Rating: NEUTRAL (B-2-9) | PO: 63.00 USD | Price: 56.82 USD

4Q23E TBD; Estimated sales/EBIDTA $163m/$61m in-line with cons $174m/$67m

We forecast $163m sales and $61m EBITDA slightly below BBG cons of $174m and $67m, respectively. Key to AMPH's ability to retain its premium multiple is a) assuring investors Baqsimi can reach or beat mgmt's long-term product sales targets; b) base business durability and the durability of several products that benefited from 2022-23 competitor supply shortages [more below]; and c) pipeline execution. While AMPH has not historically offered forward year guidance, we expect 2024 sales and non-GAAP EPS of $794m (+26% Y/Y) and $3.92 (+15% Y/Y) vs cons +24% and +10%, respectively.

- **Base business performance likely to see continued benefit from competitor supply disruption:** Excluding the Baqsimi acquisition, ~two-thirds of AMPH 2021-23 sales growth was derived from three products (hospital epinephrine, Gx glucagon and lidocaine) while the remainder came from "other finished pharma products." Based on our review of 4Q IQVIA, none of the key competitors for these products re-emerged with supply in 4Q, notably Pfizer (epinephrine), Pfizer (lidocaine) and Lilly/Novo in generic glucagon kits. Per management 4Q commentary, the company was the only US supplier of dextrose, sodium bicarbonate, and hospital administered epinephrine (mentioned above) and the company expects the supply shortage for these 5 products to extend through 2Q24. On a combined basis, we estimate dextrose + sodium bicarbonate represent ~$40m IQVIA gross sales (est. $20m net sales) and have been growing +35% Y/Y and +20% Y/Y volumes, respectively, in 2H23; we think these could represent tailwinds to 2024 "other" revenue line and allow the company to offset base biz erosion and maintain relatively stable profile (-7% Y/Y). On other key products, in 2024 our forecasted growth compares to cons as follows: Gx glucagon +13% Y/Y vs +56% cons, epinephrine -15% Y/Y vs cons -11%, and lidocaine -18% Y/Y vs +10% cons.

Exhibit 4: Epinephrine tracking low-SD % Y/Y 4Q net sales growth
IQVIA data is a fairly accurate predictor of net sales for epinephrine (hospital)



Source: BofA Global Research, IQVIA

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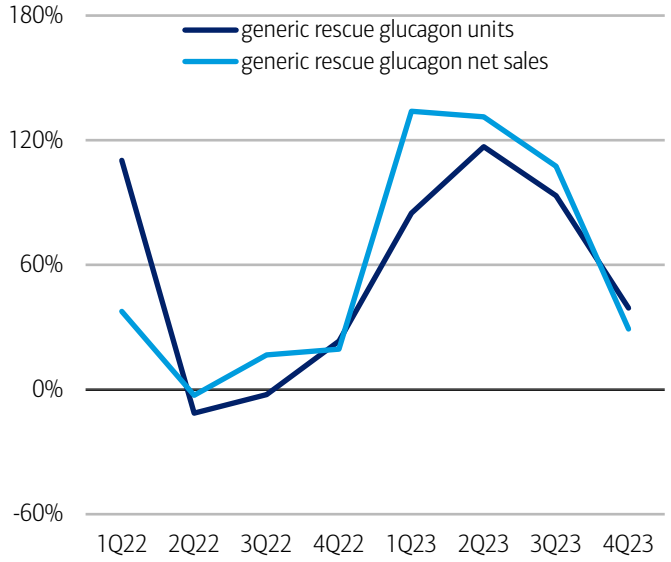
Exhibit 5: Gx rescue glucagon kit tracking ~30% Y/Y 4Q net sales
IQVIA data is a fairly accurate predictor of net sales for Gx rescue glucagon kit



Source: BofA Global Research, IQVIA

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- **BAQSIMI 4Q consensus forecast likely too high reflecting transition period accounting**—we lower our 4Q sales forecast to $29m (from $33m previously) reflecting added clarity around the company's 4Q23 (transition period) accounting of product-related operating profit (less COGS + OpEx). Per management, BAQSIMI total 4Q end-user revenue is likely to be $35-40m (towards high end of FY23E guidance) which is ultimately the more important measure as AMPH will start booking a clean revenue number sometime in 1Q24+. On Baqsimi volume trends, we note 4Q IQVIA units grew +7% Y/Y and -21% Q/Q), the Q/Q decline reflects seasonality.

Exhibit 6: We update our 4Q forecast of AMPH's Baqsimi contribution
Mgmt commentary suggests $29m AMPH Baqsimi 4Q revenue

	3Q23	4Q23	
COGS	9	8	
S&M	9	7	4Q selling expense will not be borne by LLY; this will be in AMPH's SG&A line item
R&D	2	2	
total expenses	20	17	"selling expense that they deduct will not be as high [as 3Q]"
Baqsimi - total sales	49	39	
Baqsimi - AMPH portion	**29**	**29**	

Source: BofA Global Research estimate, company reports

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- **Pipeline: near-term regulatory updates expected –** AMP-008 and generic Forteo have GDUFA goal dates of 2Q24 and 1Q24, respectively. On the call, we expect mgmt to address whether market conditions warrant launching several new products where the category has gotten increasingly "crowded" competitively, including: 1) g-Forteo: two approved ANDA generics and an AG now on the market and US brand net sales have meaningfully compressed to <$400m; 2) intranasal g-Naloxone – competitively crowded and TEVA OTC approval suggests channel shift. AMP-002 could be an interesting new product opportunity as management flags as the "first generic in the market niche >$600m [IQVIA gross sales]" but the product is beyond its initial GDUFA thus timing of approval is TBD.

Key focus on conference call

We highlight: 1) BAQSIMI growth trajectory – we look for management's outlook on the product's sales ramp to achieving out-year peak targets and how the company plans to market the brand; 2) base business performance – we are focused on any forward-looking commentary regarding supply disrupted markets and category pricing; 3) pipeline updates – we look for management updates regarding more prominent /late-stage pipeline programs as well as any commentary around the broader diabetes strategy (insulins and GLP1).

AXSM: focus on '24 Auvelity growth + pricing dynamics

AXSM US – Rating: NEUTRAL (C-2-9) | PO: 80.00 USD | Price: 90.43 USD

4Q23 pre-announced revenue $71m, Auvelity $49m

Given Axsome has pre-announced 4Q23 Auvelity-MDD sales, we expect investor focus to be on FY24 commentary/outlook. One investor debate remains whether Axsome's increased promotional support (+100 new sales people) will drive an inflection in Auvelity 2024 utilization (expectation is fully operational in 2H24). Auvelity is still tracking below MDD launch comp Rexulti (mid-teens % below) which we view as the best barometer of whether the drug can achieve sell-side cons out-year forecasts. Axsome has multiple Ph3 readouts in 2024 which will be discussed on the 4Q EPS call.

- **Auvelity-MDD metrics entering steady-state + impact from salesforce** – AXSM pre-announced revenue of $49m (30% Q/Q) which compares to TRx growth of 26% Q/Q; the results imply slightly better 4Q net pricing. Axsome has refrained from providing Auvelity sales guidance given the fluid nature of GTN net pricing but with the drug now >1-year into commercialization and ~70% of covered lives reimbursed (100% Medicare/48% commercial) we believe the company could be in a better position to guide either at the start of '24 or some point during the year. Our 2024 Auvelity sales forecasts of $260m (~+100% Y/Y) is slightly above cons $255m.

- **AXS-12 (reboxetine) narcolepsy data imminently in 1Q but niche peak sales limits stock upside -** the most near-term catalyst for AXSM is Ph3 topline data for AXS-12 in narcolepsy (1Q24). Given prior positive Ph2 results that included ~50% cataplexy reduction, we expect the Ph3 trial to be positive. However, given the AXS-12 study is limited to NT1 patients (30-50% of narcolepsy) and the availability of a generic alternative (venlafaxine or other antidepressants), we forecast peak sales of ~$400m and ~5-10% stock upside on data.

- **1H24 AXS-05 ADA topline most impactful stock catalyst** – in 1H24, Axsome plans to topline Ph3 ADVANCE-2 study results for Auvelity as a treatment for Alzheimer's agitation. We believe the ADA indication has the potential to be >$1.5bn in peak sales versus the company's $1.5-3bn peak target. Advance-2 safety follow-up data (2H24) is viewed as the gating item to an sNDA submission for the ADA indication. While not entirely clear if Advance-2 needs to hit on efficacy to enable approval (mgmt has not confirmed), we believe the prior (positive) Ph3 Advance-1 and ACCORD studies likely satisfy the company's efficacy requirement (thus we model 90% POS for indication). In our view, the main Advance-2 risks are inherent trial risks (patient heterogeneity, pbo-response) thus our focus (on the call) will be on trial progression, baseline characteristics and any company tactics to reduce placebo response (overlapping trial sites from Advance-1, etc).

Key focus of the conference call

We anticipate the main areas of focus of the conference call: 1) **Auvelity MDD guidance** – any quantitative guidance on 2024 Auvelity commercial metrics (GtN, payer

contracting); 2) **AXS-12 narcolepsy topline** – any color on trial progress and narrowing of timing for topline data (currently 1Q24); 3) AXS-05 Ph3 in Alzheimer's agitation – color on trial progress, including patient baseline characteristics, overlap in trial sites from Advance-1; 4) **Sunosi pipeline execution** – any progress on new Ph3 trials initiating for Sunosi (MDD, BED, SWD) and Ph3 ADHD topline in 2H24; we exclude MDD, BED, and SWSD in our model and model ~$350m in peak sales for ADHD.

Acronyms: MDD: major depressive disorder; EPS: earnings; TRx: prescription (scripts); Gtn: gross-to-net pricing; NT1: narcolepsy type 1; ADA: alzheimer's disease agitation; sNDA: supplemental new drug application; mgmt: management; POS: probability of success; BED: binge eating disorder; SWSD: shift work sleep disorder.

BHC: path to BLCO spin remains key focus

BHC US – Rating: UNDERPERFORM (C-3-9) | PO: 6.00 USD | Price: 8.18 USD

4Q23E TBD; Est. revenue/EBITDA $2.3bn/879m vs cons $2.3bn/874m

As with prior EPS calls, we believe investor focus remains on updates pertaining to the planned separation of the company's subsidiary, BLCO (Bausch & Lomb), as well as performance metrics (EBITDA, leverage). In FY24E, we forecast ~$4.6bn topline contribution from Bausch Pharma (ex-BLCO), ~flat Y/Y as we expect growth in Salix (driven by Xifaxan) to be offset by declines in legacy diversified brands; cons is modestly ahead of our forecast at $4.64bn topline for Bausch Pharma. On EBITDA, we forecast $2.3bn EBITDA contribution from Bausch Pharma which assumes similar margins as 2023 while consensus is spotty on pro forma EBITDA contribution from Bausch Pharma. Below, we frame Xifaxan script trends and other tracked pharma brands in 4Q:

- **Xifaxan**: Our 4Q forecast of $500m (~flat Q/Q, +4% Y/Y) is modestly above cons ($480m; +1% Y/Y). In 4Q, Xifaxan scripts grew +2% Q/Q and +4% Y/Y while we assume low-SD net price tailwind (vs +6% Y/Y list price). We model a discount to implied volume/price growth given 3Q23 sales benefited from inventory build-up. FY24E, we forecast $1.86bn (in-line with cons; +2% Y/Y) in net product sales vs +4% Y/Y sales growth in '23E assuming less net price tailwind; Xifaxan took +3% Y/Y list price increase in 2024 vs +6% Y/Y in 2023.

- **Other pharma brands**: outside of Xifaxan, among pharma products we track in IQVIA (~15% of PharmaCo revenue), we note 4Q script trends track roughly in-line with consensus.

Key focus on conference call

We highlight: 1) **Xifaxan IP dispute vs Norwich** – a 1Q24 oral hearing for the consolidated patent appeal occurred on Jan 8th. We will look for management commentary around expected timeline for a ruling (vs as early as 1Q24 prior); 2) **fraudulent conveyance matter** – before the US District Court of NJ is a case brought by Bausch investors in common shares and debt seek a declaratory judgment that argues transfer of B&L eye health represents a voidable transfer (e.g. alleges constitutes fraudulent transfer). The Court in this matter denied Bausch's motion to dismiss the lawsuit. Of note, the plaintiffs in the fraudulent conveyance case are also pursuing $3bn in damages for securities fraud, 3) **management** – BHC has yet to hire a CFO, though the company has indicated the interim CFO and accounting team could handle any BLCO equity offerings and/or company separation activities, 4) **amiselimod (S1P)** – in Dec'23, BHC toplined positive Ph2 data amiselimod for ulcerative colitis (UC) which met the primary endpoint. However, we view the data as undifferentiated vs four other S1P molecules, while we note the competitive bar is high to both compete and to warrant Ph3 investment. Currently, the market for S1P is dominated by large pharma (Bristol Myers and Pfizer) while UC is extremely competitive (other drug classes).

Acronyms: IP – intellectual property, NJ: New Jersey, FDA – US Food and Drug Administration, S1P – drug target, Ph – Phase.

BLUE: Lyfgenia launch in SCD

BLUE US – Rating: BUY (C-1-9) | PO: 5.00 USD | Price: 1.06 USD

4Q23 TBD: $16m BofA vs $18m/$19m cons (BBG/VA)

In 4Q23, we estimate $16m in total Bluebird product revenue which is below consensus ($19m) and assumes ~6 patients are treated with Zynteglo (TDT) and Skysona (CALD), both gene therapies. As of November 2023, Bluebird had confirmed a total of 22 patient starts, which we estimate ~11 patients are 'in-play' for 4Q revenue recognition (after backing out starts we assume got treatment). We expect most of the focus on BLUE's 4Q update to be around the recent Lyfgenia launch for Sickle Cell and any added color on payer contracting and phasing of new patient starts in 2024.

- **FY23 gene product sales offer conversion rate to revenue recognition** – in 4Q, we forecast BLUE's initial launch gene therapies, Zynteglo/Skysona, to generate ~$12m and ~$3m in revenue, respectively. Overall, we believe BLUE remains on the path of steady linear progression of new patient starts that translate to revenue recognition.

- **Lyfgenia launch & conversion of 85-105 total 2024 patient starts** – we expect a major focus of 4Q on the Lyfgenia launch where investors will likely be looking to ascertain whether there is upside on quicker market adoption (than Zynteglo) given QTC readiness upon launch. We look to updates on payer coverage (last update at 200mn lives) for comfort that Lyfgenia's $3m price tag won't be launch impediment and that Lyfgenia will be able to compete against VRTX's Casgevy's ($2m price). For Lyfgenia, we forecast ~50% of the 85-105 patient starts will get cell infusion in 2024. Our Lyfgenia sales are derived by backing out Skysona forecasts (maintain ~6 patient/year cadence) and Zynteglo (~20-22 patients) maintaining its linear growth trajectory.

Key focus on conference call

We highlight: 1) **Lyfgenia for sickle cell disease launch** – details regarding payer contracting, QTC activation and launch trajectory; 2) **gene therapy launch updates** - focus on new patient starts and time to revenue recognition for commercial progress; 3) **financing deal as a final bridging to profitability** – updates on plans to announce a non-dilutive financing deal to extend current 1Q25 cash runway, which BLUE views as the final piece to bridge the company to profitability.

Acronyms: SCD: sickle cell disease; TDT: transfusion dependent beta thalassemia; CALD: cerebral adrenoleukodystrophy; EPS: earnings; QTC: qualified treatment center.

EXEL: cabo prostate data near-term focus

EXEL US – Rating: BUY (B-1-9) | PO: 27.00 USD | Price: 22.12 USD

4Q23E TBD; Est. topline $481m, vs cons $482m

We expect minimal surprises from EXEL on its 4Q update given an early January pre-announcement of 4Q23 results and FY24E guidance. The company's sole commercial product, Cabometyx, remains subject to patent litigation (vs MSN) and the presiding district court judge is not expected to rule on the case until Spring 2024.

- **Cabo script growth moderating; label expansion key to growth outlook**: in 4Q, Cabo scripts grew +8% Y/Y and ~flat Q/Q while cabo TKI share was steady at 41% (same level [40-41%] as prior four quarters). The midpoint of EXEL's FY24E

net product sales guidance (+4% Y/Y) implies low single-digit volume (vs +1% Q/Q average last 4 quarters) and price tailwinds (+2% Y/Y on list price). While the R&D focus has shifted to zanza, we note main cabo label expansion opportunity lies in 2L+ mCRPC (prostate) where EXEL plans for a regulatory filing in 2024E.

Key focus on conference call

We highlight: 1) **cabo label expansion** – EXEL plans to submit cabo sNDA regulatory filings for both prostate and NET indications in 2024, with potential launch in late 2024 or early 2025 assuming approvals. In prostate, CONTACT-02 achieved a PFS HR of 0.65 (statistically significant) and an OS HR of 0.79 (immature; next OS analysis in '24). We expect debate to be on regulatory bar on OS benefit and sequencing of therapies among radiopharmaceuticals (Pluvicto), CONTACT-02, and chemo in 2L+ setting; 2) **pipeline updates** – we do not expect meaningful updates following's EXEL's recent corporate update from early January. On the question around new data updates for zanza and XB002 (TF-ADC), EXEL indicated it plans to present new data on these programs once the data have matured, citing zanza update at IKCS 2023 as an analog; 3) **cabo IP dispute** – last of post-trial briefs are due Feb 20th, and per EXEL the presiding Judge signaled Spring as likely timing for the trial ruling (vs EXEL's 1H24 estimate).

Acronyms: MSN: MSN Lab, IP: intellectual property, ASCO GU: American Society of Clinical Oncology Genitourinary Cancers, IKCS: International Kidney Cancer Symposium, NET: neuroendocrine tumors, OS: overall survival, TF-ADC: tissue factor antibody drug conjugate, HR: hazard ratio, PFS: progression free survival, sNDA: supplemental new drug application.

HRMY: pipeline updates pending post-January pre-announcement

HRMY US – Rating: UNDERPERFORM (C-3-9) | PO: 30.00 USD | Price: 31.08 USD

4Q23E TBD; pre-announced sales $172m

Harmony pre-announced 4Q results and guided to 2024 Wakix revenue of $700-720m, which could render the 4Q update a relative non-event. Based on our investor discussions, we expect the focus on R&D pipeline updates including: 1) Wakix life cycle extension program updates set for 1H24 – though we expect limited updates prior to the official program update; 2) Ph3 data for ZYN-002 Ph3 Fragile X syndrome topline which could occur in 2H24 or 2025 depending on pace of enrollment.

- **Pace of Wakix patient adds to slow in '24, given tougher comps:** Management's FY24E guidance of $700-720m and ~7000 avg patient target (from 6150 avg 4Q23) implies ~210 patient adds per quarter (vs ~280 avg patient adds/qtr in 2023). With the benefit of +5% Y/Y price increase, we forecast $701m FY24E sales. This continued growth at a lower pace is in-line with our assumption of ~220 avg patient adds per quarter and assumes HRMY can gain share by expanding the depth /breadth of the prescriber base (our recent survey suggested higher prescriber use flat to slightly down NTM).

- **Clinical-stage pipeline updates:** (1) we look for the status of patient enrollment in the Ph3 ZYN-002 Fragile X trial. Once enrollment is complete, the study incorporates an 18-week primary efficacy endpoint, thus we'd want to see enrollment complete around mid-year to get confidence in a '24 data readout. Given that the FXS study is focused on a patient population with full gene methylation, this selection criteria may slow the pace of enrollment; and (2) next-generation pitolisant formulation – the enhanced formulation appears aimed at increasing dose presumably without any meaningful tolerability trade-offs.

- **FDA Citizens Petition decision still pending:** FDA has yet ruled on a short-seller's Citizen's Petition to remove Wakix from the market. The CP was premised on omission of certain clinical data in the FDA registration and arguments around safety risk, which appear unfounded in our view (we expect the drug will remain on the market; see report). There is no timeline on the FDA to provide a CP response and a ruling could happen at any time.

Key focus on the conference call
We highlight: 1) pipeline updates – ZYN-002 Ph3 Fragile X syndrome enrollment updates and any added clarity on the value proposition of Wakix life cycle extension products; 2) FDA Citizen's Petition – we look for mgmt commentary regarding communication with FDA pending; 3) share buyback capacity and M&A appetite.

ITCI: Caplyta 2024 growth + adj MDD topline

ITCI US – Rating: BUY (C-1-9) | PO: 82.00 USD | Price: 67.37 USD

4Q23 TBD; est. revenue $136m, in-line with cons VA/BBG $136m/$137m
In 4Q23, we estimate in-line Caplyta revenue of $136m (+56% Y/Y) that reflects continued strong Y/Y script growth (+10% Q/Q and +56% Y/Y). Our FY23e sales forecasts remain unchanged at $467m, around the midpoint of management's guidance. On the 4Q update, we are focused on FY24 Caplyta revenue guidance and any added clarity around Caplyta Ph3 (study 501) MDD study readout.

- **Caplyta FY24 growth levers + potential guide** – Caplyta continues to demonstrate solid script growth exiting the year (4Q23) at +10% Q/Q. In 4Q, we saw reacceleration in Caplyta script trends with improved Q/Q metrics following a seasonally weak 3Q (included summer months). On Caplyta's gross-to-net, we assume ~low-30%s is likely to be maintained as steady state but management has flagged the potential for slight deviations depending on payer contracting.

- **1Q adj. MDD topline (Study 501) biggest near-term catalyst –** given proximity to data readout (est. 1Q24; PCD February), management may narrow its timeline. While we believe study 501 carries a high probability of success based on prior Caplyta efficacy on mood with the primary risk relating to high placebo response seen in some MDD trials. Beyond MDD, we look for more color on the regulatory path forward on the mixed features indication though that update seems more likely post-4Q call (meeting to occur sometime in 1Q). Interestingly, management has hinted that including the mixed features study in the MDD sNDA package is a possibility, which could enable a filing based on study 501 and the prior MF Ph3.

- **Pipeline updates; deuterated-luma Ph2 trial starts –** other pipeline updates outside of Caplyta could relate to the deuterated-lumateperone programs which are set to initiate in 1Q24 (imminently) in GAD, AD-agitation and AD-psychosis. We are curious about trial design, study size and time-to-data.

Key focus on conference call
We highlight: 1) **Caplyta commercial metrics** – we believe the focus is around net pricing, growth tailwinds, '24 guidance assumptions [at high and low end of range] and any 1Q phasing commentary; 2) **mixed features path forward** – Intra-Cellular is waiting to hear back on whether a single study (Study 403) is sufficient to file an sNDA for mixed features label expansion or whether the data will be packaged as part of an MDD filing; 3) **pipeline execution** – confirmation of trial starts for three Ph2's (GAD, ADA, ADP), and anticipated timeline for data readouts, and LAI formulation updates.

Acronyms: GtN: gross-to-net pricing; adj.: adjunctive; MDD: major depressive disorder; FDA: food and drug administration; PCD: primary completion date; MF: mixed features; sNDA: supplemental new drug application; conference call: conference call; GAD: generalized anxiety disorder; AD(A/P): alzheimer's disease agitation/psychosis; LAI: long-acting injectable

JAZZ: 4Q update & '24 guide offer bridge to Vision 2025

JAZZ US – Rating: BUY (B-1-9) | PO: 184.00 USD | Price: 122.54 USD

4Q23E TBD; Est. revs/EBITDA $1bn/$507m slightly above $1bn/$444m cons

We forecast Jazz reporting 4Q sales of ~$1bn and EBITDA of $507m versus cons $1bn and $444m, respectively. Our FY23 sales and non-GAAP EPS are at the high end and mid-points of Jazz's '23 guidance, respectively; in early January, Jazz affirmed '23 results will come within those ranges. On 2024 guidance, we are focused on the topline where we forecast total company sales +7% Y/Y (vs cons +4%) and +15% growth from the top 3 products (Xywav, Epidiolex and Rylaze; 70% of sales) vs Jazz guidance of DD %.

- **Sodium oxybate franchise erosion concerns:** Jazz's oxybate sleep franchise falls into multiple buckets including: 1) genericized Xyrem – we model Jazz receiving $225m in generic AG royalties vs guidance of >$200m while we expect net product sales from the Xyrem brand to decline over 50% Y/Y (in-line with our recent survey). Importantly, we model brand Xyrem contributing <10% of Jazz's total oxybate revenue by 4Q23 which is important as 2026 Xyrem multi-source generics will be forced to incur REMS cost and will only be interchangeable with a brand that has <$100m in forecasted sales; 2) branded Xywav – we forecast mid-SD growth from core narcolepsy indication driven by a mix of net price and volume while we model ~50% growth for the IH indication vs 105% growth in 2023. On an aggregate basis, we model Jazz oxybate-related sales flat on a Y/Y basis.

- **Epidiolex on-track for steady growth near-term:** we model +13% Y/Y growth in FY24 of $944m (in-line with cons $944m), with key sources of growth for the product from adult setting, rural, and ex-US expansion and some US net pricing benefit. Notably, management's commentary regarding FY24E revenue included Epidiolex (~20% of topline revenue).

- **OpEx step-ups leave some room for further operating margin improvement:** We estimate OpEx step-up of $115m assuming that SG&A slightly while R&D growth likely to be more meaningful. BofA operating margin estimate of 45% in 2024-25 is below management's 2025 guidance for 48% in FY25E. While management appears to indicate that R&D spend is not necessarily linear (could benefit FY25E margins), we think there is a show-me aspect to this and leave our estimates unchanged.

Key focus on conference call

We highlight: 1) 2024 financial guidance: key elements will be topline growth, sales mix and margin progression. Recently, Jazz management indicated future BD could be helpful the company reach its '25 OM target but did not offer more specific detail; 2) business development: management has been vocal about doing more deals but won't commit to buying an asset that provides $400-500m in 2025E revenue; 3) Epidiolex & Rylaze growth: our focus is on 4Q results and growth implied for each brand, based on segment level revenue guidance.

OGN: re-rate on 1x divi comments; pipeline diversification still lacking

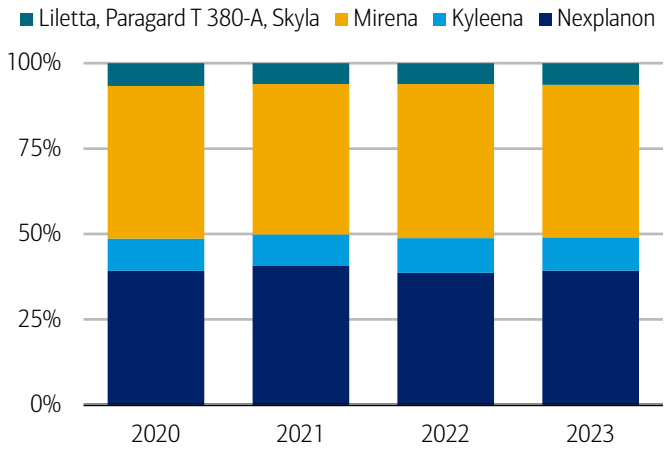
OGN US – Rating: UNDERPERFORM (B-3-7) | PO: 12.00 USD | Price: 16.73 USD

4Q23E TBD; Est. sales/EBITDA $1.5bn/$401m vs cons $1.5bn/$409m

We model 4Q sales and EBITDA of $1.5bn (+6% Y/Y; negligible FX impact) and $401m (+5% Y/Y), respectively which are in-line and slightly below consensus, respectively. In conjunction, we lower our OpEx spend estimates give management commentary around lower spend to defend EBITDA margins. While biosimilars currently make up a small % of total OGN revenues (~9%), we note OGN products maintained stable share in respective US markets. In '24, we forecast company revenue growth of +4% and EBITDA margin of 30.4% which compares to mgmt's initial outlook calling for low-SD growth and stable/improving EBITDA margins (vs '23 guidance mid-pt 31%); we estimate an Fx neutral environment for OGN in 2024.

- **Nexplanon 4Q performance:** management commentary last quarter indicated a "robust fourth quarter Nexplanon" that would set the product on a path to low-SD growth for the full-year (vs BofA's + 2% Y/Y). Based on IQVIA trend and lack of pricing benefit typically seen in 4Q, we lower our Nexplanon forecast to $250m (from $280m). In 2023, unlike previous years, the company will not benefit from a price increase (delayed to 2024), no Mexican tender, and discontinuation of voluntary discounts on federal 340b program. In 2024, we/Street forecast global Nexplanon sales of $903/$903m which include ~$60m of 1x tailwinds (+7%); Nexplanon share on long-acting reversible contraceptive market appears stable in the key US market (Exhibit 7, Exhibit 8).

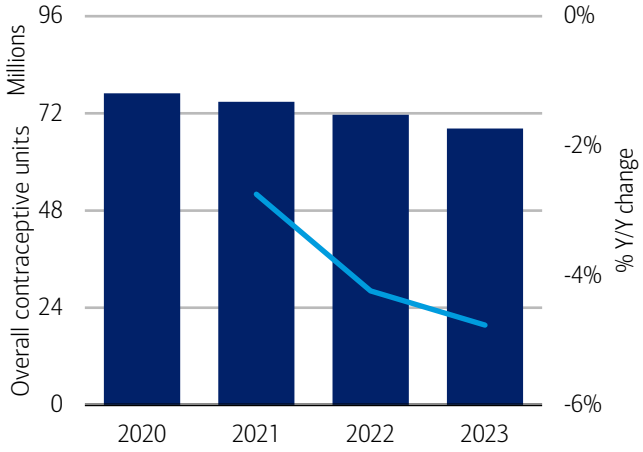
Exhibit 7: Nexplanon has maintained ~40% of LARC category
Nexplanon share fairly stable since 2020



Source: BofA Global Research, IQVIA

BofA GLOBAL RESEARCH

Exhibit 8: Contraceptives (aggregate) volume in decline since 2020
Aggregate includes LARC, oral, and other



Source: BofA Global Research, company reports

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- **Biosimilars 4Q mixed driven by category growth/decline (flat market share):** While US biosimilars remains a small revenue contributor (~9% of topline revenue), the segment remains strategically important to OGN. In 4Q, US biosimilar Remicade (biggest biosimilar) saw market share flat at 54% of the Infliximab volumes, while category growth drove unit (volume) + 20% Y/Y. US biosimilar Herceptin was also flat market share at 5%, though category decline drove b-Herceptin -5% Y/Y. So far, the newly launched Organon biosimilar Humira has captured ~5.1k units or 0.4% 4Q market share supporting our modest revenue ($7m US).

- **Benign macro environment: (1) Fx headwinds:** based on our OGN Fx model, we forecast small 4Q Fx headwinds of 1% or less while the the DXY (dollar index spot

currency) has only slightly (+1% Q/Q) increased in 4Q, indicating OGN's 76% of non-dollar denominated revenue will be less of a headwind; **(2) interest rate risk:** since 3Q, the SOFR [Secured Overnight Financing Rate] has increased 2% Q/Q indicating a relatively flat 4Q interest expense.

We highlight: 1) Nexplanon 2024 tailwinds – we look for management commentary as to plans for driving continued uptake beyond ~$60m Y/Y 1x-tailwinds mentioned above; 2) durability of established brands – we look for color around '24 growth outlook and commentary on key country-level markets; 3) US biosimilar Humira: prior commentary indicates a slow and steady launch. We look for commentary regarding Organon's ability to strike payer deals, like recent CVS-Cordavis, to be a preferred biosimilar supplier.

ROIV: bigger focus on corp updates, less on VTAMA quarterly sales

ROIV US – Rating: NEUTRAL (C-2-9) | PO: 12.00 USD | Price: 10.37 USD

FY3Q/CY4Q23E TBD; Est. topline $29m, vs cons $30m

We are roughly in-line with cons on topline and net sales of VTAMA (topical cream for psoriasis). With that said, we expect investor focus on the FY3Q call to be around management commentary on '24E corporate updates and capital deployment. ROIV completed its sale of Telvant to Roche in Dec'23 for net proceeds of ~$5.3bn which is not reflected in consensus P&L, though we note the cash proceeds are already priced into the stock thus we wouldn't expect any potential topline beat on accounting (revenue recognition on deal proceeds) to be stock moving.

- **VTAMA script tracking in-line FY3Q/CY4Q, but not needle moving for stock**: we forecast CY4Q net sales of $24m (+30% Q/Q), roughly in-line with cons $23m. Our estimate factors in ~59k scripts in CY4Q and assumes ~30% gross-to-net (GTN) yield, an improvement vs 28% GTN yield reported in CY3Q. Price (e.g. GTN yield) is a swing factor to the quarterly net sales results. However, we do not believe a quarterly beat/miss on GTN will change the narrative of VTAMA growth outlook in the absence of significant script trend inflection, considering consensus forecast remains very backloaded (>$600m in psoriasis, >$1.3bn psoriasis/atopic dermatitis combined at peak) vs CY3Q scripts annualizing at $160-165m in sales at best case assumption of 50% GTN yield. ROIV expects to file a supplemental NDA in 1Q for label expansion into atopic dermatitis (AD), which would position the company for a commercial launch of VTAMA in AD in 2025.

Key focus on conference call

We note: 1) **capital deployment** – in early January, ROIV indicated the company would continue to evaluate opportunities with low upfront costs similar to prior business development activities ($17m upfront on average), though ROIV has not provided any update on timeline; 2) **brepo in uveitis** – Ph2 open-label data of brepo in non-infectious uveitis is expected in 1Q. We believe data interpretation and thus de-risking value of the readout would be complicated by a) lack of a placebo control and b) small study (n=16 for high lose, n=8 low dose), c) background steroid use. ROIV framed no greater than 70% failure rate at week 24 as criteria for success based on a synthetic historical placebo rate of 80-90%, a range ROIV derived from historical clinical trial data and adjusted for "more aggressive" steroid tapering in the brepo study. By comparison, Ph3 trials of Humira (which incorporated mandatory taper scheduling) reported 42%-78% placebo rate through month 6 vs 35-50% rate from Humira (the lower the failure rate, the bigger the effect size). Further complicating any cross-trial comparison is small study size of brepo Ph2. At n=16 for the high dose arm, 1 patient would contribute to +/-6% failure rate.

Acronyms: NDA: new drug application.

TARS: Xdemvy scripts strong, focus on pricing & reimbursement

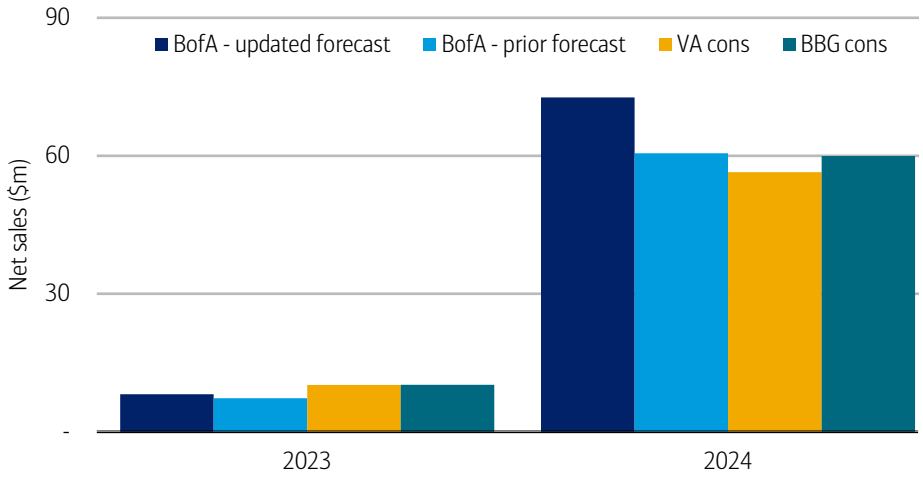
TARS US – Rating: BUY (C-1-9) | PO: 55.00 USD | Price: 25.80 USD

4Q23E TBD; Est. sales $7.6m slightly above cons $6.4m

We lower our 4Q Tarsus' Xdemvy (demodex blepharitis) forecast to ~$8m (from $11m), now more in-line with cons to reflect the most conservative net pricing assumptions (in early launch). However, we raise our 2024 Xdemvy forecast given strength of scripts (more below). We continue to see Tarsus as a solid biotech launch story where the market overly discounts the durability of the launch and the ability of Tarsus to get broad/favorable reimbursement. We see the first 4-5 quarters of the Xdemvy launch as an important stock catalyst. In 2024, TARS also offers some pipeline related upside with TP-05 Ph2 data (1Q24) for lyme disease and TP-04 Ph2 data for the treatment of Papulopustular Rosacea (also 1Q24).

- **Xdemvy IQVIA TRx trend supports '24 sales upside, keyed by pricing:** Our 4Q23 Xdemvy forecast of $7.6m sales is in-line with cons and assumes the following: 17.3K TRx and our 73% GTN deduction indicates a net price of $500/unit. In 2024, Xdemvy has been around 2K weekly TRx and growing, thus there are a range of scenarios wherein revenues could approach $90-100m depending on a) how quickly reimbursement and net pricing improves, and b) the ultimate accuracy of IQVIA script data. We forecast a base case $73m that assumes script over-capture (~2300 average scripts in '24) and a 67% GTN deduction which compares to Bloomberg cons $60m, whereas more favorable assumptions around GTN (60% deduction) or better script capture can push sales into $90-100m range. We view TARS' valuation and undemanding at <1x peak sales of $900m. In conjunction with our model refresh accounting for updated prescription trend (per data-tracking sources) we raise our PO to $55/share DCF (from $42/share).

Exhibit 9: We lower 4Q in-line with cons, but raise FY24E forecast
4Q impacted by seasonality, though run-rate indicates upside to cons FY24E



Source: BofA Global Research, Visible Alpha, Bloomberg

BofA GLOBAL RESEARCH

- **Ph2 TP-04 rosacea data; big but tough market**: TARS is evaluating TP-04 (topical lotilaner gel) for treatment of PPR (popular pustular rosacea) in a 30 patient Ph2 12-week study with two-arms (drug vs placebo) with a focus on safety and a number of exploratory efficacy endpoints. TP-04 is being advanced on the hypothesis that demodex mites are prevalent on the skin and may contribute to inflammatory response associated with disease. The rosacea market is potentially

large with 18-28% of 16m US prevalence suffering PPR disease type, but recent brand rosacea launches have been underwhelming. Soolantra (ivermectin; anti-parasitic) achieved $200m peak IQVIA gross sales and is now generic. Tarsus' hope is to develop TP-04 for rosacea with unique label claim differentiation vs Soolanta though we need to see Ph2 data before we can speculate on any unique and differentiable claims. TARS' has talked about finding a derm partner to promote TP-04 if successful in development.

- **Ph2 TP-05 lyme prevention – looking to validate partnership candidate**: Tarsus is evaluating TP-05 as an orally dosed lotilaner for prevention of lyme disease. In 1Q24, Tarsus plans to report initial Ph2 data from CARPO, a tick-killing study with various safety-focused primary efficacy endpoints such as changes from baseline in AEs, hematology lab tests, ECGs, QTC interval, and QRS interval. The Tarsus approach could in theory facilitate periodic monthly dosing of an oral agent during tick season in high-risk areas. The Tarsus approach differs from the vaccine approach (studied by Pfizer) though both likely share a similar Ph3 development pathway (Pfizer's Ph3 includes 9000 subjects 2.5 yr evaluation), thus Tarsus has long viewed the TP-05 lyme opportunity as a partnership opportunity once it gets beyond Ph2 tick killing or Ph2b de-risking events. Per mgmt, we look for high tick-kill rates in Ph2 along with a pristine safety profile.

Key focus on conference call

We highlight: 1) Xdemvy launch – reconciliation of "bottles dispensed" with IQVIA scripts and any commentary around re-instatement of Symphony tracking. We also look for updates regarding GTN deductions in 4Q and early 2024 and any progress updates regarding commercial covered lives; 2) Xdemvy Ph4 marketing study strategy to driver broader adoption in populations like contact lens wearing patients.

TEVA: pivot to growth meets key proof-point

TEVA US – Rating: BUY (C-1-9) | PO: 15.00 USD | Price: 11.91 USD

4Q23 Jan 31; Est. sales/EBITDA $4.1bn/$1.4bn vs cons $4bn/$1.4bn

We forecast 4Q sales and EBITDA of $4.1bn (+5% Y/Y) and $1.4bn (+15% Y/Y) which is slightly higher/roughly in-line versus consensus of $4bn sales and $1.4bn EBITDA. Into 4Q, we believe investors are acutely focused on 1) margin progression given 1H volatility; 2) continued uptake of Austedo which is Teva's highest margin product and key to driving margin expansion and EBITDA growth. Looking to FY24 guide, we forecast sales and EBITDA of $15.9bn (+3% Y/Y) and $4.8bn (+4% Y/Y), respectively. We expect Teva revenue guidance could range from $15.6-16.2bn to reflect some of the upside drivers (Humira, Korlym) in the portfolio while EBITDA could range $4.7-5.1bn. Importantly, Teva is in investment-mode to grow Austedo and has discussed increased OpEx in '24 on a Y/Y basis but disciplined on spend as a % of sales (28% est. in '23), which compares to our forecasted +2% OpEx growth and ~28% Opex as a % of revenue. We raise our PO to $15/share (from $14/share) on 8.25x EV/EBITDA (from 8x) on valuation multiple re-rate.

- **US generics – FY24 is shaping up as favorable year for new launches:** Heading into 2024, we have a line of site on several products which could offer favorable Y/Y tailwinds including g-Korlym, g-Sandostatin and g-Revlimid. We are less optimistic on g-Forteo which TEVA secured approval in 4Q23 but has yet to pickup meaningful share in the niche/crowded market. Also, Teva's biosimilar partner communicated favorable update post an FDA facility inspection which could pave the way for a March b-Humira launch as the only high concentrate interchangeable, though value capture is a show-me story given challenges faced by

other biosimilars picking up share (lead suppler has <1% volume share). We see Teva's generic Revlimid as a product (see our recent scenario analysis) that could generate ~$520m in revenue or +$100-125m tailwind vs 2023.

- **Key product metrics (Austedo, Ajovy, and Copaxone):** Austedo – we forecast 4Q Austedo sales at $444m (+29% Y/Y), above cons $416m. Austedo TRx (IQVIA) were +5% Q/Q and +28% Y/Y which generally support our growth outlook but we note that there is not an exact correlation between TRx and net sales. BofA sales forecast implies 4Q-wtd sales (35% of FY23E vs 36% in 4Q22). For FY24, we forecast Austedo growth of +19% Y/Y vs cons +21% Y/Y; 2) US Ajovy – we maintain our sales forecast from $78m (+3% Y/Y) roughly in-line with cons $75m on +9% Y/Y TRx growth. We see more Ajovy growth coming from ex-US markets; 3) Copaxone TRx (scripts) declined -30% Y/Y and we expect US net sales to decline by 45% given competitive Gx pressure.

- **Brand pipeline progress:** latest management commentary suggests that Olanzapine LAI trial has achieved 1200/3600 injections required to demonstrate more favorable safety profile vs Zyprexxa Relprevv which had lackluster uptake due to PDSS [post-injection delirium/sedation syndrome] concerns. On the call, we expect that management will disclose whether or not the company will provide some sort of go/no-go update on its Ph2 TL1A program in 2H24 or if investors will need to wait for 1H25 for a program data update. If the program progresses to Ph3, a $600m milestone payment will be due to TEVA.

Key focus on conference call

We highlight: 1) Biosimilars – recently TEVA's biosimilar partner reported a successful FDA manufacturing site inspection, meaning biosimilar Humira and Stelara could be on track for launches in 1Q24 and 1Q25, respectively. We expect investors to focus on whether TEVA can leverage the first high concentrate /interchangeable b-Humira and get meaningful US market share as a late-mover in the category. Furthermore, given the commercial challenges biosimilars have faced with PBM channel products (Humira), we look to better understand how Teva can successfully launch its b-Stelara; 2) Austedo growth outlook – we expect investors to look to TEVA's 2024 product-level sales guide for Austedo and how it bridges the company to its LT 2027 sales target for $2.5bn in revenue. We have been encouraged by the strength of Austedo 2H23 scripts and view increased S&M investment as a potential tailwind for revenue in 2024; 3) US generics – we are expecting generic Sandostatin and Korlym to be two of TEVA's better new product launches while the 2022 launch of generic Revlimid is expected to be a tailwind to '24 sales given the nature of the patent settlement with BMY. Overall, we believe US generics can grow low-SD in '24; 4) margins – given some of the '23 fluctuations in TEVA margins and company comments about increasing operational spend in '24E, we look for clarity around where TEVA is increasing investment vs deprioritizing investment (e.g. generics R&D) and how gross margins are expected to evolve in '24 with improving product mix; 5) pipeline – we look for management commentary as to whether a 2H24 update regarding go/no-go decision for TL1A program is likely.

VTRS: capital deployment + stabilization of generics business key to re-rate

VTRS US – Rating: UNDERPERFORM (B-3-7) | PO: 10.00 USD | Price: 11.93 USD

4Q23 TBD; Estimated sales/EBITDA $3.9bn/$1.2bn vs cons $4bn/$1.4bn

We forecast 4Q sales of $3.9bn (flat Y/Y) and EBITDA $1.2bn roughly in-line with cons $3.9bn and $1.2bn, respectively. We expect investors' focus to remain on capital deployment following the closing of business divestitures. Based on sector re-rating and improved visibility into planned divestitures, we maintain Underperform but raise PO from $9/share to $10/share (raising our ev/ebitda to 5.5x from 5.25x).

- **Stabilization of base business:** On the 4Q22 EPS call, the company (while not giving guidance) directionally indicated $4.6-5bn as a post-divestiture EBITDA range and the company subsequently retained OTC brands contributing ~$125m in EBITDA. Based on where we see 2023 financial results netting + anticipated contribution of the businesses that will be divested (est. ~$350m EBITDA), we forecast 2024 EBITDA coming in around $4.7bn and see some added downside risks including: 1) 2H23 gross margin pressure carrying over to 2024 – if 2H23 GM's carry into '24, that represents $140-200m drag to our/cons EBITDA; 2) if base business Y/Y erosion, ex-divestitures, trends similar to prior years this could represent an incremental $100-200m downside.

- **Key new product launches:** Potential 2024 new product opportunities include glatiramer acetate depot, generic Venofer (iron sucrose), Gx Victoza (liraglutide), and Gx Sandostatin LAR (octreotide acetate), Additional products that will continue to contribute new product revenue in 2024 include Breyna (g-Symbicort).

- **Inflation/Fx headwinds:** Last quarter, mgmt suggested that the company is managing inflationary headwinds to gross margins well. In 4Q, our BofA VTRS currency model forecasts Fx tailwinds flat Y/Y, or ~+$9m impact in 4Q. Looking ahead to 2024, our currency model indicates a benign Fx environment.

- **Capital deployment:** Net divestiture proceeds from other non-core assets are expected to be $2.55bn, with an estimated $2.3bn FCF in '24 excluding taxes and transaction costs, totaling $4.85bn cash available to deploy. Management plans to pay down ~$3bn debt in '24 per recent commentary at broker conference. The company's strategic plan allocates 50% FCF ($1.15bn) to be returned to capital in dividends and share repurchases; assuming a flat dividend (~$575m), there would be ~$575m firepower remaining for share repurchases.

Key focus on conference call

We highlight: 1) Pro forma EBITDA: we model $4.7bn in pro forma Viatris EBITDA in 2024 and look to mgmt's updated outlook [prior discussed in $4.6-5 range] given last update on divested OTC businesses is now stale (2022). Key elements in PF outlook: organically, Viatris and predecessor Mylan have declined EBITDA every year since 2015 excluding large M&A stub years for Upjohn (2020-21) and Abbott/Meda (2015-17). Viatris has talked about 1-2% revenue growth profile in the "future" versus first 9-months '23 adjusted operational flat growth and the company has communicated a $120m R&D step-up in '24; 2) Capital deployment – we look for added color on phasing of capital deployment. Recently, mgmt discussed being more "aggressive" on share buybacks in 2024-25 and we look for clarity around whether that includes expansion of the currently untapped authorization (~$750m remaining); 3) Spec brand buildout – progress of Oyster/Famycare acquired assets delivering $1bn in 2028 revenues versus est. $50m in '23 sales for Tyrvaya and Ph3 MR-148 for dry eye disease being framed as the most commercially attractive Famycare asset. We look for added clarity if future BD strategy will target assets similar to aforementioned deals.

Exhibit 10: Stocks mentioned
Prices and ratings for stocks mentioned in this report

BofA Ticker	Bloomberg ticker	Company name	Price	Rating
ALKS	ALKS US	Alkermes	US$ 27.74	B-2-9
AMPH	AMPH US	Amphastar	US$ 53.88	B-2-9
AXSM	AXSM US	Axsome	US$ 89.84	C-2-9
BHC	BHC US	Bausch	US$ 8.18	C-3-9
BLUE	BLUE US	bluebird bio	US$ 1.06	C-1-9
EXEL	EXEL US	Exelixis	US$ 22.12	B-1-9
HRMY	HRMY US	Harmony Biosciences	US$ 31.08	C-3-9
ITCI	ITCI US	Intra-Cellular	US$ 67.37	C-1-9
JAZZ	JAZZ US	Jazz Pharmaceuticals	US$ 122.54	B-1-9
OGN	OGN US	Organon	US$ 16.73	B-3-7
ROIV	ROIV US	Roivant	US$ 10.37	C-2-9
TARS	TARS US	Tarsus Pharma	US$ 25.8	C-1-9
TEVA	TEVA US	Teva Pharmaceuticals	US$ 11.91	C-1-9
VTRS	VTRS US	Viatris Inc.	US$ 11.93	B-3-7

Source: BofA Global Research

BofA GLOBAL RESEARCH

Note about IQVIA data in this report –

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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) risk-adjusted 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.

Amphastar Pharmaceuticals (AMPH)
Our $63 price objective is based on 12.5x EV/EBITDA multiple based on FY24E EBITDA outlook. We arrive out our 12.5x EV/EBITDA valuation multiple due to a more favorable gross margin and EBITDA margin profile relative to Spec Pharma peers, as well as lower net leverage ratio. As such, the valuation multiple is reflective of that seen with some large-cap pharma companies with comparable growth profiles trading in the 12-13x EV/EBITDA range.

Downside risks: (1) slower than expected commercial uptake of Baqsimi and (2) generics base business erosion

Upside risks: (1) better than expected commercial uptake of Baqsimi, (2) new generic product launches that drive upside to BofA/consensus revenue forecasts

Axsome Therapeutics (AXSM)
Our $96 price objective (PO) is based on a risk-adjusted SOTP analysis. Key assumptions: 1) total (nominal) product sales reach $1.7bn by 2027E, 2) no terminal value as we forecast sales through expected drug LOE, 3) 9.5% discount rate. For Sunosi - in EDS, we model $335m in peak sales (commercial, fully derisked) and in ADHD, we model $350m in nominal peak sales. Our AXS-05 (Auvelity) peak sales for depression are $1.3bn. For AXS-05 in Alzheimer's agitation, we model $1.5bn in risk-adjusted peak-sales. For migraine, we model $170m in risk-adjusted peak sales for AXS-07. We model AXS-12 narcolepsy risk-adj. peak-sales estimate at $400m. For AXS-14 in fibromyalgia, we model $240m in risk-adj. peak-sales.

Upside risks to our PO: 1) better-than-expected commercial uptake, 2) pipeline validation beyond our assumptions, 3) potential competitive setbacks.

Downside risks to our PO: 1) lower-than-expected commercial uptake of Auvelity in MDD, 2) competitive assets generating significantly better data vs AXSM, 3) potential setbacks on Axsome's execution on pipeline clinical development plan.

Bausch Health Cos Inc (BHC)
Our $6 price objective (PO) is based on a blended valuation, with 50% weighting to eventual spinoff valuation on SOTP basis (11x (peer multiple) of '23E Bausch & Lomb EBITDA), and 50% to blended company multiple that assumes spin delays lead to the market valuing the company as a single entity (6.3x of '23E EBITDA from total company assets based on diversified biopharma peers comp).

Upside risks to our PO: 1) outperformance of new product launches, 2) better-than-expected EBITDA growth, 3) strong performance of Bausch + Lomb segment combined with higher multiples assigned to eye care comps, including Cooper and Alcon

Downside risks to our PO: 1) underperforming revenue from key growth drivers, including eye care, Xifaxan or new pharma launch products, 2) margin compression - either due to greater than anticipated spend to support new brand launches or faster than expected erosion of diversified brands

bluebird bio (BLUE)
Our $5 PO is based on risk-adjusted discounted cash flow (DCF) analysis. Our DCF assumptions include (1) risk adjustment to programs dependent on their stage and strength of available data, including 100% combined probability of success (POS) for LentiGlobin-TDT, -SCD, and Lenti-D-CALD, (2) no value for earlier-stage programs that lack clinical data, (3) a 10% discount rate and -10% terminal growth value (end of loss of exclusivity period in 2034).

Downside risks to our PO: (1) cancer safety risk for LentiGlobin, (2) LentiGlobin launch

underperforming relative to our forecast, either due to limited demand or inability to adequately supply the market, (3) failure to show durable drug response in future data updates involving key assets, (4) competitor data showing efficacy/safety superior to that of company's lead programs, and (5) high cash burn and projected capital expenditure, which may require equity raises.

Upside risks to our PO: (1) clinical data shows superiority relative to competitor programs, and (2) LentiGlobin launch exceeds our expectations.

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.

Harmony Biosciences (HRMY)
Our $30 price objective is based on a sum-of-the-parts (SOTP) analysis. Key assumptions are that we forecast cash flow for each commercial and near-term pipeline asset through 2032E and a discount rate of 9%.

Downside risks are (1) slower-than-expected commercial uptake of Wakix and (2) IP litigation or settlement with generic Wakix manufacturers ahead of LOE.

Upside risks are (1) stronger-than-expected commercial update of Wakix and (2) FDA decision that we expect could maintain status quo on Wakix marketability in response to a recent Citizen's Petition.

Intra-Cellular Therapies (ITCI)
Our $82 price objective (PO) is based on a risk-adjusted sum-of-the-parts analysis. 1) Caplyta risk-adjusted sales climb to $2bn by 2027E, before loss-of-exclusivity (LOE) in 2034, 2) no terminal value, 3) operating margin reaching low-60s percentage, 4) 9% discount rate.

Downside risks to our PO: 1) lower-than-expected commercial uptake of Caplyta in schizophrenia, continued COVID disruption keeping a lid on script growth, 2) BPD commercial execution risk, 3) potential setbacks on ITCI's execution on pipeline clinical development plan, e.g. adjunctive MDD, mixed features.

Upside risks to our PO: 1) better-than-expected commercial uptake of Caplyta in schizophrenia, 2) bipolar depression launch significantly above our estimates, 3) further pipeline validation beyond our assumptions, for e.g. Caplyta in adjunctive MDD, mixed features

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.

Organon (OGN)
Our $14 PO for OGN is based on 6x EV/EBITDA multiple on our '24E EBITDA. We believe the multiple is justified vs peers trading at 6-10x given the potential growth outlook for Nexplanon and biosimilars.

Upside risks to our PO are: (1) higher-than-anticipated Nexplanon peak sales as it expands within the long-acting reversible contraceptive (LARC) category, (2) higher-than-expected operating leverage leading to higher EBITDA margin.

Downside risks to our PO are: (1) reduced uptake of Nexplanon in the LARC category or slow rebound by the LARC category due to C19 other factors and (2) steeper erosion of established brands than expected.

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

Tarsus Pharmaceuticals (TARS)
Our $55 price objective (PO) is based on a risk-adjusted DCF of TP-03 lead program. Key assumptions: 1) we forecast cash flows through 2038 patent life of TP-03. 2) 100% probability of success for TP-03 and 90% probability of achieving market expansion. 3) TP-03 generates $513m in 2030E risk-adjusted sales, 4) discount rate of 10% and no terminal value.

Downside risks to our PO are (1) failure of TP-03 to show desired results in clinical trials, (2) slower-than-expected commercial uptake of TP-03, (3) potential dilutive cash raises to commercialize the drug.

Upside risks to our PO are (1) better-than-expected clinical data and/or commercial uptake of TP-03, (2) acquisition at a premium price.

Teva Pharmaceuticals (TEVA)
Our $15 price objective (PO) is based on a '24E EV/EBITDA multiple of 8.25x, 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. We assign $800m equity value from TL1a deal proceeds.

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

Viatris Inc. (VTRS)
Our $10 price objective (PO) is based on 5.5x 2024E EV/EBITDA on our pro forma 2024 EBITDA estimate ($4.7bn), which is discounted to the peer group average of 6x. We conservatively incorporate a $1bn contingent liability related to the ongoing civil lawsuit pertaining to generic price fixing, even though we are not aware of any specific wrong-doing pertaining to the legal matter.

Upside risks to our PO: Pipeline opportunities adding sales/EBITDA above estimates, improvement in investor sentiment as new management executes on strategic priorities, higher synergy realization vs anticipated, dividend growth.

Downside risks to our PO: Failure to execute by new management, further decline in Upjohn China business, potential downside to cash flow generation, lackluster execution on business development plans (following the company's recently announced divestitures).

Analyst Certification

I, Jason M. Gerberry, hereby certify that the views expressed in this research report accurately reflect my personal views about the subject securities and issuers. I also certify that no part of my compensation was, is, or will be, directly or indirectly, related to the specific recommendations or view expressed in this research report.

US - Specialty Pharma & Biotechnology Coverage Cluster

Investment rating	Company	BofA Ticker	Bloomberg symbol	Analyst
BUY				
	Arcellx, Inc.	ACLX	ACLX US	Jason M. Gerberry
	Arrowhead Pharmaceuticals	ARWR	ARWR US	Jason M. Gerberry
	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
	Ionis	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				
	Alkermes	ALKS	ALKS US	Jason M. Gerberry
	Amphastar Pharmaceuticals	AMPH	AMPH US	Jason M. Gerberry
	Axsome Therapeutics	AXSM	AXSM US	Jason M. Gerberry
	Galapagos	GLPG	GLPG US	Jason M. Gerberry
	ProKidney Corp	PROK	PROK US	Jason M. Gerberry
	Roivant	ROIV	ROIV US	Chi M. Fong
UNDERPERFORM				
	Bausch Health Cos Inc	BHC	BHC US	Jason M. Gerberry
	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

Disclosures

Important Disclosures

Equity Investment Rating Distribution: Health Care Group (as of 31 Dec 2023)

Coverage Universe	Count	Percent	Inv. Banking Relationships [R1]	Count	Percent
Buy	234	60.94%	Buy	115	49.15%
Hold	80	20.83%	Hold	36	45.00%
Sell	70	18.23%	Sell	29	41.43%

Equity Investment Rating Distribution: Global Group (as of 31 Dec 2023)

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%

[R1] Issuers that were investment banking clients of BofA Securities or one of its affiliates within the past 12 months. For purposes of this Investment Rating Distribution, the coverage universe includes only stocks. A stock rated Neutral is included as a Hold, and a stock rated Underperform is included as a Sell.

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Investment rating	Total return expectation (within 12-month period of date of initial rating)	Ratings dispersion guidelines for coverage cluster[R2]
Buy	≥ 10%	≤ 70%
Neutral	≥ 0%	≤ 30%
Underperform	N/A	≥ 20%

[R2]Ratings dispersions may vary from time to time where BofA Global Research believes it better reflects the investment prospects of stocks in a Coverage Cluster.

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