BofA SECURITIES

US Biopharmaceuticals

Sleep survey: Xywav still standing, AXS12 interesting but niche + orexin TPP

Price Objective Change

Survey: Xywav minimal competitive impact in narco

We highlight takeaways from a 25-physician sleep medicine survey that include: 1) Jazz's Xywav narcolepsy share expected to remain stable through YE24 with high prescribers while oxybate competitor (Avadel's recently launched Lumryz) to grow category + brand Xyrem was seen as bigger share donor. We view survey as supportive of our durable Jazz Xyrem/Xywav outlook; 2) Axsome's AXS-12 for narcolepsy seen as niche + candidate for combo use; 3) mid-stage orexin receptor 2 class TPP framing (more below).

Lumryz growing, but fewer Xywav switches than reported

Physicians in our survey reported 10% Lumryz oxybate share at YE23 versus Avadel '23 sales guidance that implies 5-6% share. Respondents estimate Lumryz share growing to ~14% and 20% share in the next 6-mo and 1-year periods, respectively. Over the next year, respondents project ~two-thirds of Lumryz use coming from oxybate naïve or prior oxybate discontinuations with the next biggest source Xyrem switches (~25%). For Jazz, the Lumryz source of patients is important as brand Xywav is a long-tail growth product and we're encouraged survey feedback: a) Lumryz may be expanding the category; b) genericizing Xyrem is big share donor; c) aligns with Jazz feedback on Xywav growth.

Jazz: survey points to stable Xywav-narco share in '24

2024 is a key year for Jazz's Xywav to establish a tail through 2033 LOE. In '24, we forecast Xywav-narco growing +6% and Xywav-all indications growing +16% Y/Y. On projected use, respondents forecast Xywav narco share stable vs. YE23. We forecast low-SD volume for Xywav-narco assuming entrenched high prescribers hold volumes flat with some growth more broadly + low-SD price + gains coming from the IH indication; respondents expect Xyrem share to get cut roughly in half NTM (vs. BofA: -56% Y/Y) which is important as nearly all Jazz '25+ oxybate sales are Xywav and AG royalties.

Respondents see niche for AXS-12 in narcolepsy

Ahead of Axsome's Ph3 AXS-12 (antidepressant) narcolepsy data (in 1Q24), we probed respondents views on the market opportunity. The respondents indicated having 10-18 narcolepsy patients treated with anti-depressants or about 20-24% the size of their oxybate treated patients. Most of the respondents indicated AXS-12 replicating prior Ph2 efficacy profile would represent a clinically meaningful drug but saw only 20% of their narcolepsy patients as AXS-12 candidates. Most respondents saw AXS-12 as a candidate for combination therapy. We tweak our AXS-12 to reflect smaller nominal peak share + higher launch pricing (small impact to peak sales), new PO $96 (from $95).

Orexin target product profile: bigger focus on CV AE's

Ahead of 2024 clinical updates for development-stage orexin receptor-2 agonists (OX2R's; ALKS and Takeda), physicians framed a desire to see maintenance of stable sleep cycle, decrease in cataplexy, and decrease EDS with tolerability focused on cardiovascular AE's (biggest concern) followed by insomnia, urinary AE's and visual disturbances (least concerning). We flag physician flag AE concern (rank order) ahead of important 2024 data disclosures in class.

Refer to important disclosures on page 8 to 11. Analyst Certification on page 7. Price Objective Basis/Risk on page 6.
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PO changes

AXSM: PO to $96 (from $95)

Acronyms:

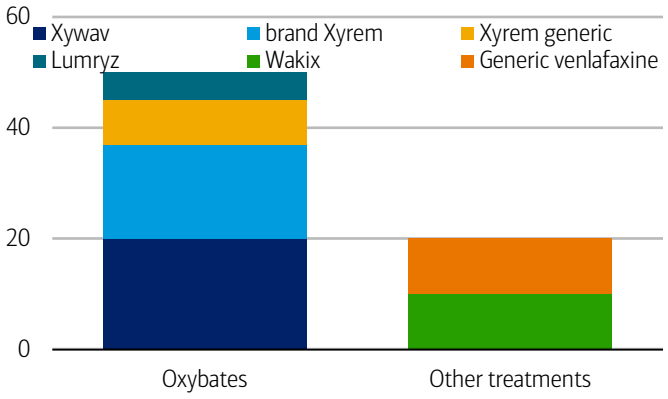
EDS: excessive daytime sleepiness
GTN: gross-to-net
SD: single-digit
DD: double-digit
IH: idiopathic hypersomnia
narco: narcolepsy
OX2R: orexin receptor 2 agonist
TPP: target product profile
NTM: next twelve months
LOE: loss of exclusivity
CV: cardiovascular
AE: adverse event
Ph2: phase 2

Survey in slides (n=25 respondents)

We surveyed 25 US-based physicians who we screened for a board certification in sleep medicine and having treated 25 or more (per annum) narcolepsy patients with an oxybate product (Xywav/Xyrem or Lumryz). Our survey goals were to: 1) better understand competitive dynamics with new, competing oxybate products; 2) gauge the potential market opportunity for Axsome's AXS-12 as a novel treatment for narcolepsy; 3) better understand key aspects of a target product profile for development stage orexin receptor 2 agonists.

Exhibit 1: Respondents currently treat a high volume of narcolepsy pts with an oxybate medication

On an annual basis (YE23), physician respondents treated a median 50 patients with an oxybate



Source: BofA Global Research

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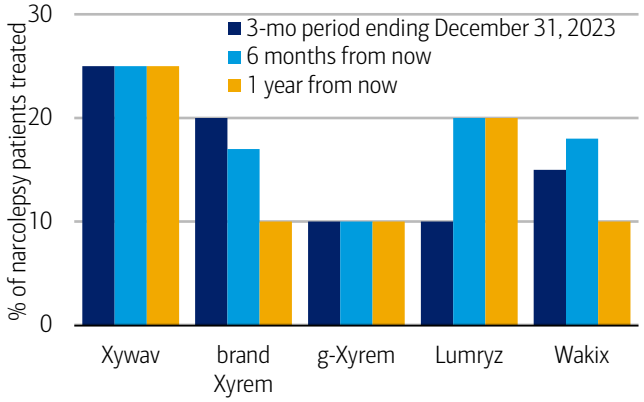
Exhibit 2: The recent launched Lumryz brand is not expected to take share from Jazz's brand Xywav and growth to come from other sources

Brand Xyrem remains share donor, giving up 50% share 1yr from now



Source: BofA Global Research. See appendix for detailed chart (Wakix only) showing mean, median, and mean ex-outliers.

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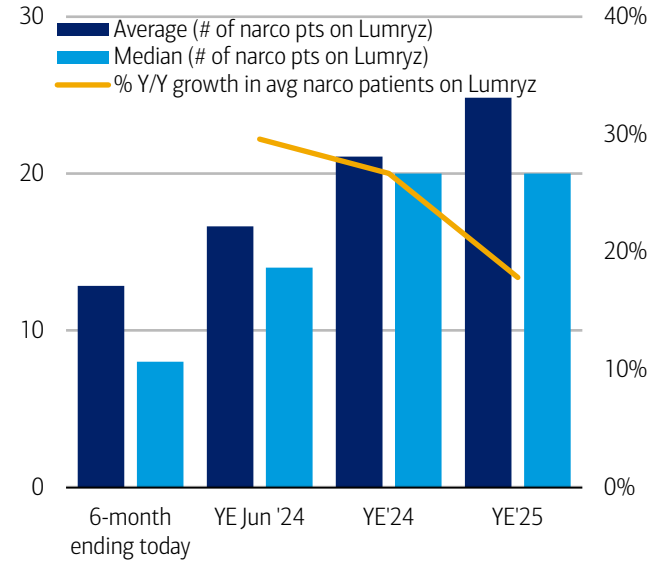
Exhibit 3: Lumryz market share is expected to double from YE23 to YE'25 focusing on median responses (ex-outliers)

Survey feedback is consistent with prior surveys indicating Lumryz as an option for roughly one-third of narco pts over time

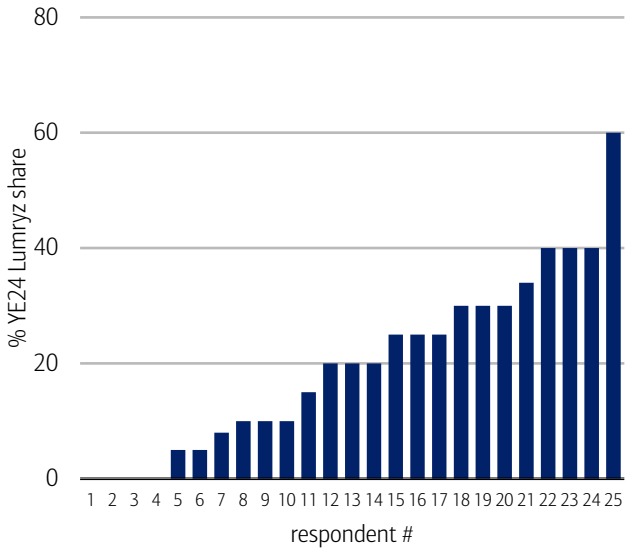


Source: BofA Global Research

BofA GLOBAL RESEARCH

Exhibit 4: Early Lumryz responses have some meaningful outliers on both high and low end of utilization

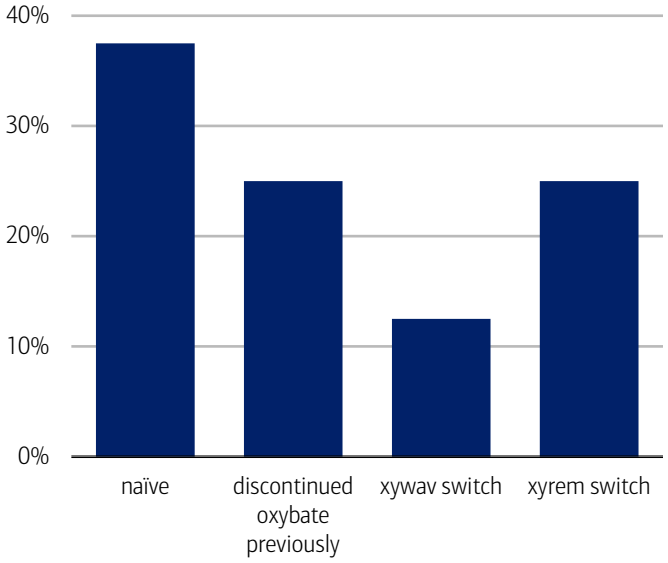
Given some of the 'noise' in 25 respondent survey, we view the median of responses as a better directional indicator of Lumryz uptake



Source: BofA Global Research

BofA GLOBAL RESEARCH

Exhibit 5: Lumryz may grow oxybate category as a significant % of future patients are not expected to be oxybate switches
Respondents expect most Lumryz pts to be oxybate naïve or discont. use



Source: BofA Global Research

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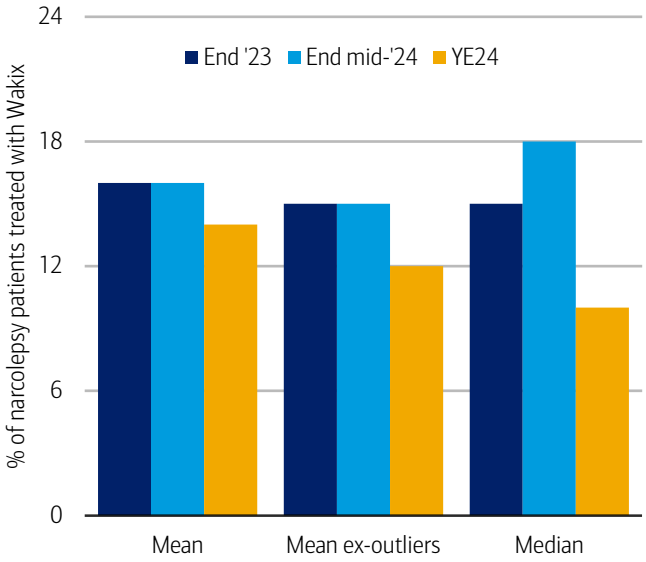
Exhibit 6: Harmony's Wakix % share gains may see a slow down
However, the small decline in projected share looks like noise given the sample size of our survey



Source: BofA Global Research

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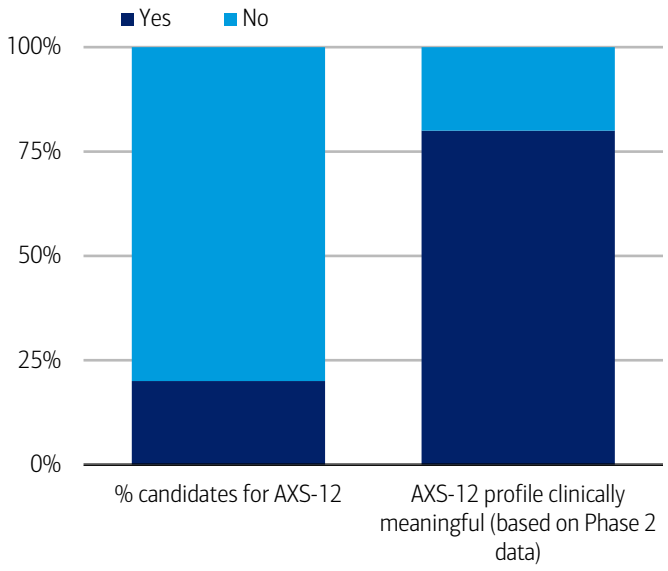
Exhibit 7: Axsome's AXS-12 prior Ph2 data viewed as clinically meaningful but only 20% of narco patients viewed as candidates
We asked respondents how they'd view AXS-12, assuming the drug replicated prior Ph2 data



Source: BofA Global Research

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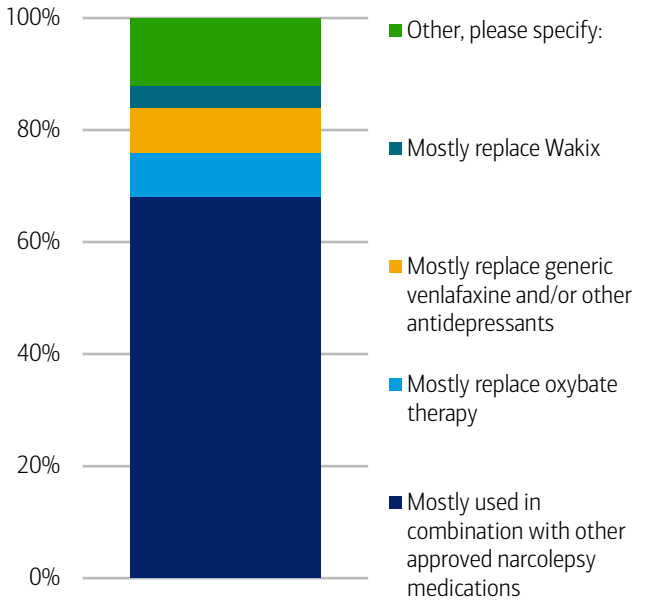
Exhibit 8: AXS-12 was viewed as a drug that would most commonly be used in combination with other approved narco therapies
Respondents in the survey did not see AXS-12 as drug that would cause meaningful disruption to approved treatments



Source: BofA Global Research

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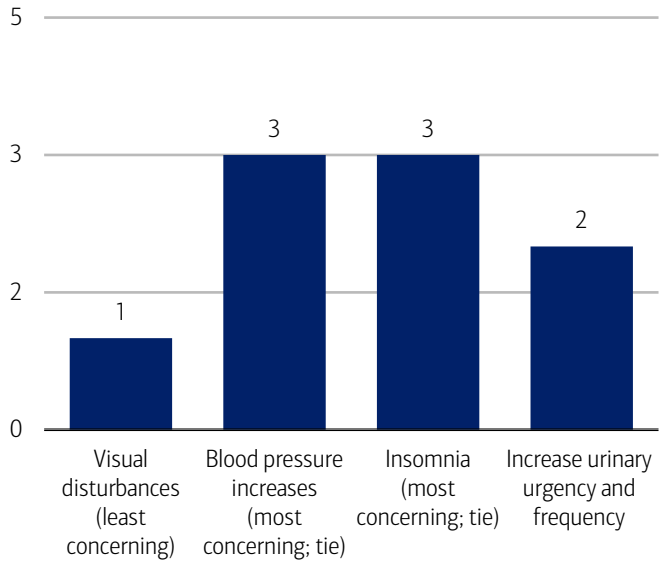
Exhibit 9: Clinical-stage orexins: CV + insomnia AE's trump concerns
Visual disturbances was ranked as the least concerning side effect; open-ended responses provided below



Source: BofA Global Research

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Appendix

Exhibit 10: Wakix share of new patient starts expected to slow down in 1yr
We depict mean, median, and trimmed mean (excl. 15% of top and bottom halves)

Wakix	3-mo period ending December 31, 2023	6 months from now	1 year from now
Mean	16	16	14
Median	15	18	10
Mean ex-outliers	15	15	12

Source: BofA Global Research

BofA GLOBAL RESEARCH

Exhibit 11: Open-ended responses: Rationale for Lumryz switch & OX2R key considerations
We include full-length responses for sodium oxybate and orexin related Qs

Respondent	If you plan to switch a patient to Lumryz from either Xyrem or Xywav, please explain why?	For orexin-receptor 2 agonist drugs to have a favorable risk-benefit and garner meaningful usage in the treatment of narcolepsy, what do you view as key product profile considerations assuming a development-stage product demonstrates adequate safety to secure FDA approval?
1	On request with a good rationale	Effect on insomnia
2	The efficacy is not optimal.	the side effects are to prominent.
3	More convenient dosing, expect better compliance and outcomes.	Effective for severe cases
4	mainly for the convenience of once a night dosing	improve awakeness and reduce cataplexy attacks
5	For some of my narcolepsy patients the once nightly is a a significant improvement. This is particularly true for narcolepsy 2 patients. All of these switches are from Xyrem. I do not plan to switch any Xywav patients over to Lumryz because of the sodium issue.	I am very familiar with the orexins in development and have some thoughts regarding safety which include, but are not limited, to those related to possible neurodegeneration. On the upside there is the potential for these agents to elegantly treat Narcolepsy Type 1 since narcolepsy Type 1 is cause by a deficiency of CNS orexin. Maybe, but only Narcolepsy Type 1 and not Narcolepsy Type 2 nor idiopathic hypersomnia. Why? Well, there is growing concern that orexin activity is part of the pathological cascade of Alzheimer's disease. Not to mention orexin is the basis of numerous motivation guided behaviors, feeding, hunting, mating. How much do we know whether these agents could cause impulse control disorders. And all of this assumes the other orexin agonists do not have the hepatic toxicity we say with Takeda's first agent. And remember most of these individuals are young. If this is a lingering concern are doctors going to be comfortable placing a teenager or young adult at higher risk of neurodegenerative disease? The evidence these companies are publishing suggests that there may in fact be a potentially toxic response. In particular, the MWT data is compared to other hypersomnia treatments. I read the MWT data as they are stimulating the system too much. Remember sleep-wakefulness is a balance. Too much in one direction and you have problems. Additionally, orexin activity in the brain can lead to more then just waking up. It promotes eating (the name comes from its discovery in young women with Anorexia), hunting, mating behaviors. What about the possibility that these agents will lead to impulse control problems with binge eating, violence, sex? . Could there be some scenario where my concerns are abated with the upcoming clinical trials. Its possible but ideally we would have longer term data. I suppose if results look really good, I could maybe Rx this to a patient with Narcolepsy Type 1 (where there is clear orexin deficiency) who has failed all other treatment options. I think the use of these agents in someone with normal orexin function (such as Narcolepsy Type 2 or Idiopathic Hypersomnia, or sleep deprivation) is unlikely to be appropriate until some of these other concerns are addressed.
6	has improved tolerability and dosing	long term efficacy and tolerability profile
7	Only if insurance does not cover it	Likely coming with a benign side effect profile plus convenience
8	The benefit of Lumryz in comparison xyrem is vast in terms of patient quality of life and patient buy-in, leading to better adherence and ultimately efficacy. This is due to the once nightly dosing, which is not as bad as it seems, but ends up being a huge barrier to initiating therapy. The difference between xywav and Lumryz is more nuanced. Mainly as a result of the potential cardiovascular benefits of Xywav, patients opting for Lumryz usually do this, when they cannot tolerate twice nightly dosing, or are appalled at the thought of twice nightly dosing. For my patients that are on Xywav, I would switch them if they have a low risk of cardiovascular events, and seem to struggle with the second dosing in the night.	The ability to safely reduce excessive daytime, sleepiness with minimal side effects and few drug interactions.
9	Better administration and tolerance	Feel is safe

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We include full-length responses for sodium oxybate and orexin related Qs

Respondent	If you plan to switch a patient to Lumryz from either Xyrem or Xywav, please explain why?	For orexin-receptor 2 agonist drugs to have a favorable risk-benefit and garner meaningful usage in the treatment of narcolepsy, what do you view as key product profile considerations assuming a development-stage product demonstrates adequate safety to secure FDA approval?
10	Tolerability and or efficiency	Neutral
11	Either low sodium or once a night makes sense not Xyrem	No cognitive impairment and better efficacy than what is presently available
12	Once daily convenience	Persistent benefits over at least 6 months
13	Patient preference for the once a night extended release version hopefully to improve adherence to treatment.	That it is beneficial for improvement with EDS and cataplexy in patients with narcolepsy with improvement in QOL/functional aspects.
14	better side effect profile, may be preferred agent on formularies	MOA, efficacy, safety
15	Dosing	Side effect profile
16	Expect improved efficacy from Lumryz	Superior side effect profile
17	Convenience for patients who can't wake up to take the second dose.	Extensive in reducing the frequency of cataplexy
18	Twice nightly dosing is a significant impediment to many patients, negatively impacting compliance with therapy and efficacy. Once nightly dosing offers significant advantages in this regard.	The magnitude of benefit on MWT outcomes and cataplexy reduction will be key factors. An optimal benefit-to-side-effect dose would need to be established.
19	No plans to switch	No toxicity
20	Convenience. Better compliance.	Less side effect and better tolerability
21	once dosing so patients do not have to wake up. I would like more experience in our institution before considering transition	significant improvement of daytime wakefulness (sleep latency, MWT) reduction in cataplexy rates low side effect profile least interaction with other medications
22	Once a night dosing	Efficacy compared to Xywav
23	better compliance since it is only once a night	efficacy in reducing daytime sleepiness
24	dosing schedule and efficacy profile	hepatic safety and need for monitoring requirements
25	The once nightly formulation means that patients will be more compliant with this medication, likely leading to improved patient outcomes.	The ability to maintain a stable sleep cycle, decrease episodes of cataplexy, and decrease excessive daytime sleepiness.

Source: BofA Global Research

BofA GLOBAL RESEARCH

Price objective basis & risk

Axsome Therapeutics (AXSM, C-2-9, $89.52)
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 $300m. 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.

Jazz Pharmaceuticals (JAZZ, B-1-9, $120.11)
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.

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.

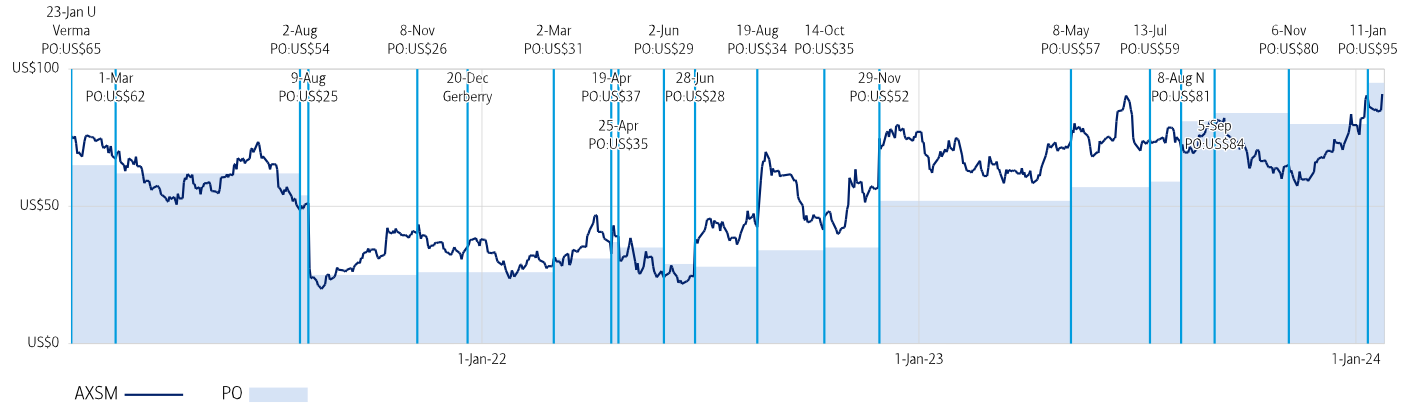
US - Specialty Pharma & Biotechnology Coverage Cluster

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

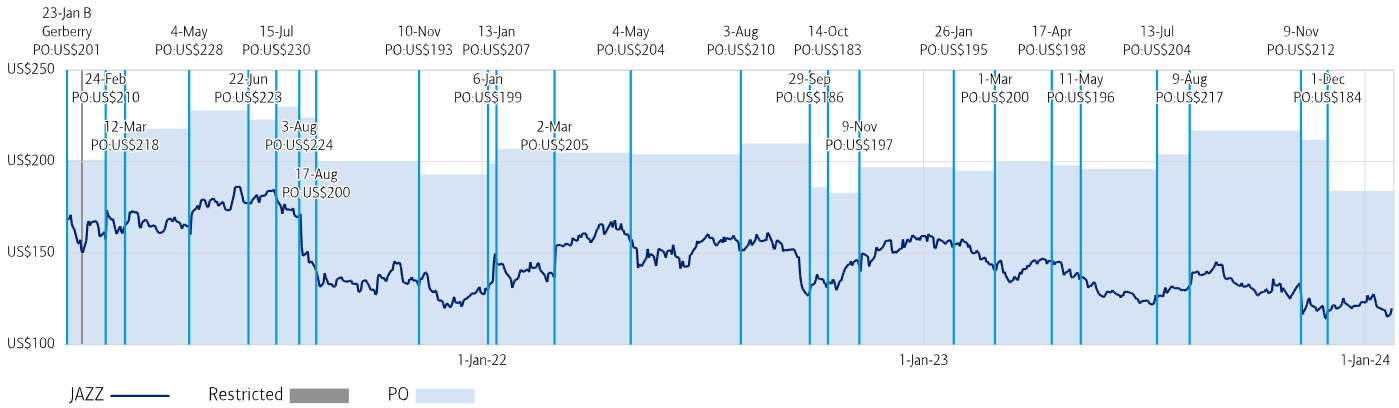
Axsome (AXSM) Price Chart



B: Buy, N: Neutral, U: Underperform, PO: Price Objective, NA: No longer valid, NR: No Rating

The Investment Opinion System is contained at the end of the report under the heading "Fundamental Equity Opinion Key". Dark grey shading indicates the security is restricted with the opinion suspended. Medium grey shading indicates the security is under review with the opinion withdrawn. Light grey shading indicates the security is not covered. Chart is current as of a date no more than one trading day prior to the date of the report.

Jazz Pharmaceuticals (JAZZ) Price Chart



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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.

INCOME RATINGS, indicators of potential cash dividends, are: 7 - same/higher (dividend considered to be secure), 8 - same/lower (dividend not considered to be secure) and 9 - pays no cash dividend. *Coverage Cluster* is comprised of stocks covered by a single analyst or two or more analysts sharing a common industry, sector, region or other classification(s). A stock's coverage cluster is included in the most recent BofA Global Research report referencing the stock.

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BofAS or an affiliate has received compensation for investment banking services from this issuer within the past 12 months: Jazz Pharmaceuticals.
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