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US Biopharmaceuticals

Neuropsych launch comps: favorable for adj. MDD but illustrates heavy-lift for ADA

Industry Overview

Emerging launch comps: faster validation for MDD vs. ADA

Within our CNS coverage, both AXSM and ITCI are nearing important pivotal neuropsych label expansion readouts in ADA (Alzheimer's agitation) and MDD (depression), respectively. Both programs account for meaningful risk-adjusted DCF contributions to our respective company valuations. Our review of two emerging launch comps, AbbVie's Vraylar for MDD and Otsuka/Lundbeck's Rexulti for ADA, highlights the challenges of launching into ADA vs. the established MDD market. While ADA and MDD are similarly sized markets in terms of prevalence (more below), we believe that the Vraylar MDD launch offers a more encouraging comp given greater psych-prescriber overlap, drug familiarity, and possibly better reimbursement. While ADA has limited treatment options and offers more of a white space category, the launch (so far) and feedback suggests that the market build will take time. For Buy-rated ITCI, we believe that Caplyta-MDD (if approved) should experience a much faster launch ramp, whereas Neutral-rated AXSM's Auvelity-ADA should launch more slowly; we slightly lower our AXSM estimates to reflect a slower ramp in Auvelity-ADA 2025-2029 peak sales.

ADA is white space opportunity, but commercial hurdles

Based on industry estimates, both US MDD (3L+) and ADA markets, respectively, have about 4 million US patients eligible for treatment, though Lundbeck (more conservatively) estimates that the number of US dementia patients living with agitation may be closer to ~1.5 million. In May 2023, Rexulti was the first FDA-approved drug to treat agitation symptoms associated with dementia due to Alzheimer's. Since launching Rexulti for ADA, total scripts in April-December 2023 were up +11% versus the prior period, though Lundbeck is more bullish, citing unique indication-level claims data. One clear challenge for Rexulti in ADA is the need to train physicians who have been taught not to prescribe antipsychotic medicine for frail/elderly patients. For Auvelity-ADA, we do not expect the sort of negative prescriber bias facing Rexulti (carries a boxed warning for mortality risk in elderly dementia), but we do expect an acclimation period before prescribers are comfortable prescribing. Less clear is the role of payer mix, with ADA predominantly reimbursed by government plans (Medicare/Medicaid), and physician feedback suggests that most ADA patients reside in nursing homes/assisted living, where reimbursement may be less favorable (heavy Medicaid) for expensive brand drugs (Exhibit 2).

MDD: Vraylar plug & play for psychiatrists

MDD is an established market with four approved atypical antipsychotics approved as adjunctive therapies (including Vraylar); commercial insurance is the predominant form of reimbursement in MDD (estimated 70%; same ballpark as BPD). Since AbbVie launched Vraylar for MDD, scripts have grown ~+30% versus the prior 45-week period and appear to be benefiting from physician psychiatrists familiar with atypical antipsychotics to treat mood disorders. Per AbbVie, Vraylar's "very strong access" is a key reason for the rapid inflection, while it is unclear (to us) to what extent some of the unique ADA payer mix dynamics have impeded the Rexulti-ADA ramp, though Lundbeck has downplayed payer reimbursement as an impediment to ADA adoption.

Continued

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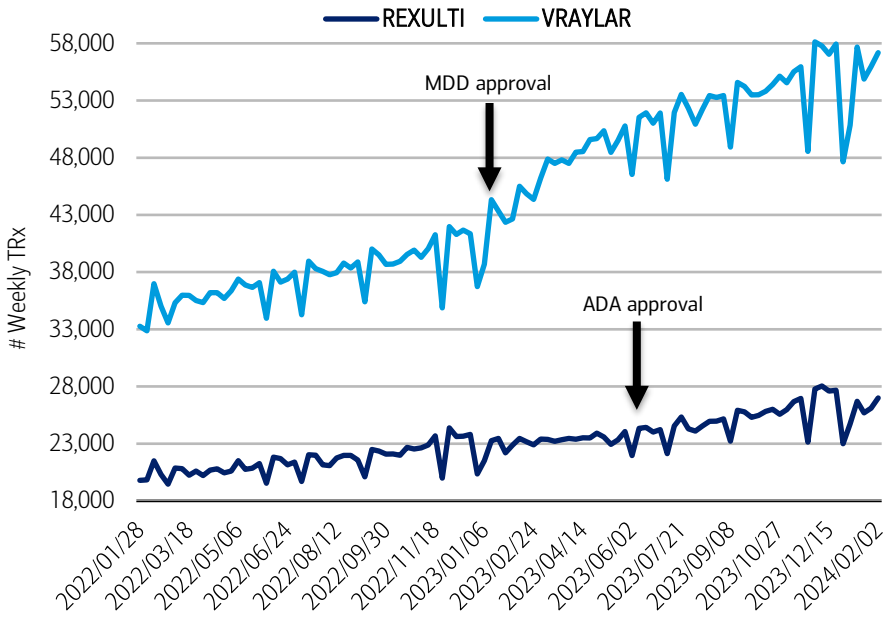
3L: third line
ABBV: AbbVie (covered by Geoff Meacham)
AD: Alzheimer's Disease
ADA: Alzheimer's Disease agitation
Adj: adjunctive
AE: adverse event
AXSM: Axsome
BPD: bipolar disorder
Comp: comparator
CNS: central nervous system
DCF: discounted cash flow
FDA: Food & Drug Administration
ITCI: Intra-Cellular
MDD: Major Depression Disorder
psychs: psychiatrists
Ph: phase
PO: price objective
POS: probability of success
sNDA: supplemental New Drug Application
TRx: prescriptions
vs.: versus

ITCI & AXSM: stock considerations

ITCI will report Ph3 MDD Caplyta data from two studies in 1H24. We forecast nominal peak Caplyta-MDD sales of $780 million, and we assume a 70% POS (~10% of our PO). In MDD, Caplyta would be the fifth atypical antipsychotic approved, and we believe that room remains for another atypical that can differentiate on safety (lack of akasthisia/ extrapyramidal AEs) and established benefit in patients with mixed features depression. Our peak sales estimates are in the ballpark of Rexulti and projected Vraylar (guidance) out-year US sales. Based on the rollout of Caplyta label expansion into BPD, we expect payer coverage for the new indication to be seamless and adoption to benefit from a high prescriber overlap in BPD and MDD indications. For Axsome, Auvelity Ph3 ADA data (ADVANCE-2) will read out efficacy data in 1H24 and long-term safety follow-up in 2H24 (gates sNDA submission), which could enable approval by 2H25. While our peak sales estimates for Auvelity-ADA are high ($1.7 billion) and contribute $28/share (risk-adjusted) to our AXSM PO (~30%), our review of comps suggests that the ADA indication may not start to materially contribute to franchise growth until 1H27.

Exhibit 1: Weekly script trends for Rexulti and Vraylar during label expansion period (MDD and ADA, respectively)

While Vraylar experienced a clear inflection in scripts upon MDD approval, Rexulti scripts experienced a slower acceleration in 3Q post ADA approval (arrows).



Source: IQVIA, BofA Research

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Exhibit 2: Estimated covered lives for ADA patients based on aggregate Alzheimer's costs

It is estimated that most ADA patients are on government insurance, while others either are on commercial/private and pay out of pocket

Payer type	% covered lives (est. ranges)	Comment
Medicare	50%	Per Alzheimer's Association (AA), Medicare accounts for 45% of aggregate Alzheimer's costs.
Medicaid	20-30%	State-level Medicaid programs vary on drug reimbursement. Per KOL's, some states offer fixed/capitated payments for drug cost in amount of a few hundred dollars for all drug costs/month. Per AA, Medicaid accounts for 19% of aggregate AD costs. In nursing homes, most of the coverage is Medicaid (~two-thirds per KFF). Medicaid plans can vary dramatically state-by-state
Commercial/ private	20-25%	Per AA, 25% of costs are incurred out of pocket. For patients with enough assets to disqualify them from Medicaid, they would fall into Memory Care/senior housing (private pay)

Source: Alzheimer's Association 2023; BofA Research

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Exhibit 3: Stocks mentioned
Prices and ratings for stocks mentioned in this report

BofA Ticker	Bloomberg ticker	Company name	Price	Rating
AXSM	AXSM US	Axsome	US$ 92.26	C-2-9
ITCI	ITCI US	Intra-Cellular	US$ 70.4	C-1-9

Source: BofA Global Research

BofA GLOBAL RESEARCH

Price objective basis & risk

Axsome Therapeutics (AXSM)
Our $96 price objective (PO) is based on a risk-adjusted sum-of-the-parts (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-adjusted peak-sales estimate at $400m. For AXS-14 in fibromyalgia, we model $240m in risk-adjusted 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.

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

Analyst Certification

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US - Specialty Pharma & Biotechnology Coverage Cluster

Investment rating	Company	BofA Ticker	Bloomberg symbol	Analyst
BUY				
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	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				
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	FibroGen Inc.	FGEN	FGEN US	Jason M. Gerberry
	Harmony Biosciences	HRMY	HRMY US	Jason M. Gerberry
	Organon	OGN	OGN US	Jason M. Gerberry
	Viatris Inc.	VTRS	VTRS US	Jason M. Gerberry

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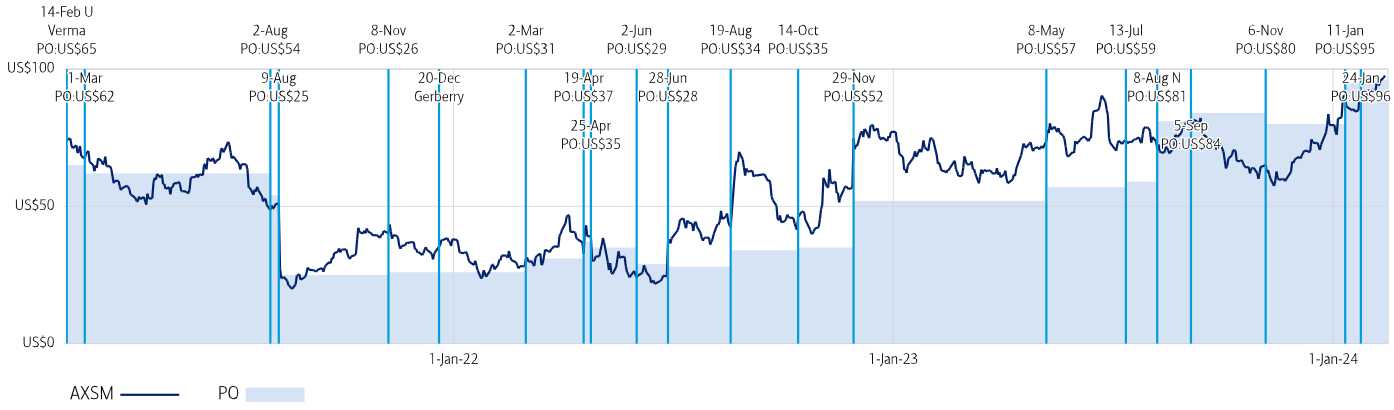
Important Disclosures

Axsome (AXSM) Price Chart



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

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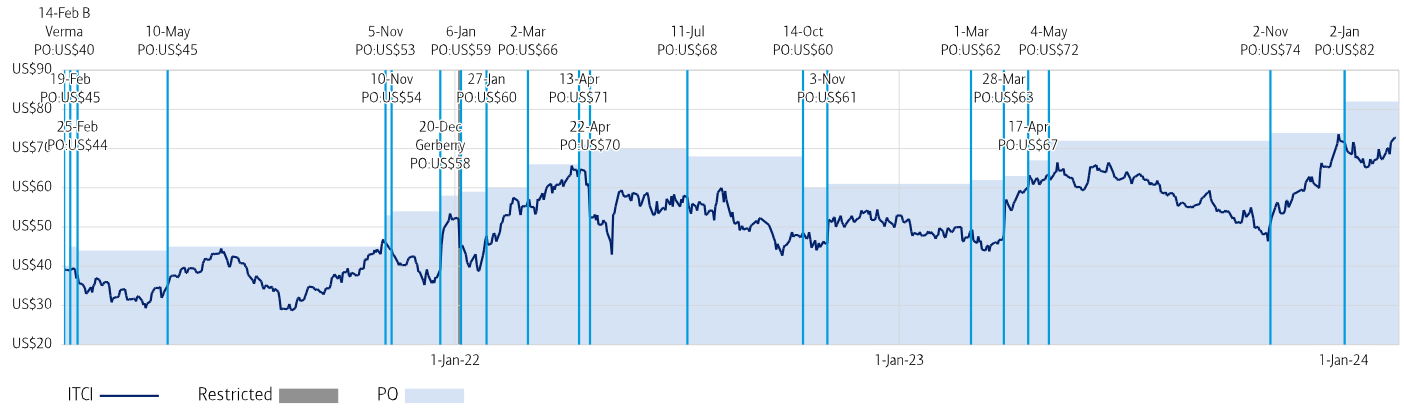
Intra-Cellular (ITCI) Price Chart



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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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