BofA SECURITIES

US Biopharmaceuticals

YA2024: Top questions for mgmt teams & thoughts on possible early Jan guidance

Industry Overview

Top company-level questions heading into 2024

In this report, we publish our top questions for company management teams ahead of upcoming January broker conferences. In this report, we focus on questions to elucidate understanding of the key commercial, regulatory and clinical catalysts for SMID biotechs and Spec Pharma in our coverage. Notably, fewer commercial-stage companies have been offering forward year financial guidance in early January, but a number of our companies pre-announce and refine timelines for pending clinical/regulatory milestone events. Below is a summary of companies covered in this report.

- **Commercial SMID biotech & Pharma**: ALKS, AMPH, AXSM, BHC, EXEL, HRMY, ITCI, JAZZ, OGN, ROIV, VTRS, TEVA
- **Pre-commercial SMID biotech**: ACLX, ARWR, GLPG, IMVT, IONS, RLAY, TARS, PCVX, XENE
- **Micro-cap biotechs:** BLUE, FGEN, LYRA, OCS, PROK

Who might guide to 2024 (or peak) in early January

Exelixis: the company typically offers preliminary 4Q/FY results, financial guidance and anticipated milestone events for the year ahead.

Who might discuss key product volume trends, margins or long-term targets:

- **JAZZ**: Last year communicated '22 revenues to fall within guide range, reiterated Vision 2025 targets but stopped giving volume growth outlook for its oxybate biz
- **OGN**: in prior years, the company has given "soft guidance" on EBITDA margins during its early year company presentation/fireside.

Unlikely candidates to guide in early January

We view these commercial stage companies as unlikely: 1) **typically wait for 4Q update**: ALKS, AMPH, BHC, JAZZ, TEVA, VTRS, OGN; 2) **no track record of guiding in January**: AXSM, BLUE, HRMY, ITCI though some SMID cap biotech peers do offer key product pre-announce and/or forward year guidance once reimbursement is established and the company has visibility on net pricing.

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ALKS: Alkermes
AMPH: Amphastar
AXSM: Axsome
BHC: Bausch Health
EXEL: Exelixis
HRMY: Harmony
ITCI: Intra Cellular Therapies
JAZZ: Jazz
OGN: Organon
ROIV: Roivant
VTRS: Viatris
TEVA: Teva
ACLX: Arcellx
ARWR: Arrowhead
GLPG: Galapagos
IMVT: Immunovant
IONS: Ionis
RLAY: Relay
TARS: Tarsus
PCVX: Vaxcyte
XENE: Xenon
BLUE: Bluebird
FGEN: Fibrogen
LYRA: Lyra
OCS: Oculis
PROK: Prokidney

Refer to important disclosures on page 46 to 49. Analyst Certification on page 45. Price Objective Basis/Risk on page 39.
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Alkermes: orexin de-risking dataflow in '24E

ALKS US – Rating: NEUTRAL (B-2-9) | PO: 29.00 USD | Price: 27.74 USD

Investment thesis

We are Neutral on ALKS on balanced risk/reward. We believe ALKS' product portfolio is relatively mature with minimal opportunities for upside to consensus: 1) '27 Vivitrol LOE limits the likelihood of a material stock re-rating, 2) we expect Lybalvi (key launch) to have an outsized contribution to ALKS growth, but we see limited upside to cons peak sale, 3) on orexin (key pipe), we believe our risk-adj. est. is priced into stock and key de-risking events (own Ph2 data) are likely to occur 2025+.

Key potential catalysts

Exhibit 1: ALKS catalyst tracker
We highlight upcoming potential catalysts events of ALKS

Drug/Event	Event	Timing
Category: Pipeline		
ALKS2680	Ph1 OX2R update(s) (NT1 and/or NT2)	2024E
ALKS2680	Ph2 initiation	2024E
TAK-861	Competitor Takeda's OX2R Ph2 topline in NT1 and NT2 (two studies)	Mid/2H-24E
Category: Regulatory, Corporate		
Corporate	FY24 guidance	FY23 call (Feb 2024)
Lybalvi	Commercial sales performance, direct-to-consumer campaign, gross-to-net	2024E

Source: BofA Global Research, company reports. Note: orexin-2 receptor agonist, NT: narcolepsy.

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Key questions for management

- Can you outline your '24 plans for disclosing new data for ALKS'2680 (orexin-2 receptor agonist), either full narcolepsy type 1 cohort or data in NT2 and IH cohorts?
- If visual disturbances post-OX2R therapy are more of an issue with healthy volunteers, would you expect that issue to carryover to NT2 and/or IH patients (who have more normal pre-existing orexin levels)?
- As we look ahead to Takeda's Ph2 OX2R data in NT1/NT2 patients (mid-'24E), what do you think is the threshold for acceptable liver-related AEs?
- Can you talk about how you plan to interrogate cardiovascular toxicity with OX2R?
- Can you talk about the impact you are seeing from the Lybalvi DTC ad campaign as it pertains to adoption trends? Are you seeing the bump in utilization you had hoped to see from that investment or is it still too early to evaluate?
- Where are you anticipating growth of Lybalvi coming in 2024 and beyond? Do you foresee any competitive headwinds from the muscarinics, which offer olanzapine-like efficacy without the weight gain?
- Do you see Lybalvi reaching full and optimal level of contracted reimbursement as you head into 2024 or will a meaningful percentage of patients need to go through the medical exceptions process to get coverage?
- Post the Mural spin, do you see the RemainCo CNS (neuro) business requiring greater OpEx relative to year prior? Do you plan to continue investing in Vivitrol given limited LOE (exclusivity) runway, or might you scale back that investment?

- Is the increasingly competitive LAI landscape having any impact on Aristada? Probe: Aristada scripts are flat Q/Q in 4Q23 (through 9-weeks).

- Does Alkermes see itself as an opportunistic deployer of capital, either for license or acquisition of new products? Or are the new product efforts still focused on OX2R?

Acronyms: OX2R: orexin-2 receptor agonist, NT1, NT2: narcolepsy type-1, type-2, IH: idiopathic hypersomnia, AE: adverse events, DTC: direct-to-consumer, LAI: long acting injectable.

Amphastar: focus on Baqsimi + base biz conditions

AMPH US – Rating: NEUTRAL (B-2-9) | PO: 63.00 USD | Price: 61.85 USD

Investment thesis

We rate AMPH Neutral on balanced risk-reward. We believe the bar for Amphastar to re-rate is high at current trading levels. From a risk/reward perspective, downside risks include 1) competitor supply dislocations that have been more recent tailwinds turn into headwinds, 2) pipeline visibility is low. Potential upside could come from the Baqsimi (glucagon rescue) launch which offers more predictable (and visible) growth driver that should help expand company margins in the out-years.

Key potential catalysts

Exhibit 2: AMPH catalyst tracker
We highlight upcoming potential catalysts events of AMPH

Drug	Event	Timing	Additional
intranasal naloxone	launch	4Q 2023	
AMP-008	approval	4Q 2023	ANDA product; inhalation; molecule undisclosed
AMP-002	approval	TBD	ANDA product; inhalation; molecule undisclosed (action date passed with no pending requests)
AMP-015 (teriparatide)	approval (GDUFA date)	1Q 2024	launch timing subject to confidential settlement agreement with product's innovator
AMP-007	Est. approval	2H24	
AMP-004	Est. approval	2024	

Source: BofA Global Research, company reports. Note: ANDA: generic drug application, GDUFA: FDA action date

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Key questions for management

- Can you talk about early observations overseeing the marketing of Baqsimi? Is there any synergy between having generic glucagon rescue kits and the top selling brand?

- How do you see your generic glucagon rescue kit business evolving if Baqsimi hits your out-year revenue targets?

- Can you talk about how much of Baqsimi growth is coming from volume, price and mix? Probe: on mix, is there a material benefit (to the overall market sales) from a shift from single generic rescue kits to Baqsimi sold with two intranasal cannisters per script?

- On Baqsimi, is the payer reimbursement landscape pretty settled? Probe: are you seeing parity coverage with other brands like Gvoke? Is there any step-edits with the generic kits?

- Can you speak to Baqsimi's relative gross and operating margin and if you reach your out-year targets could that dramatically change your margin profile?

- Can you elaborate on how you plan to market Baqsimi as a rescue glucagon?

- On your base business, are you seeing any headwinds from suppliers coming back in key product categories? Probe: Pfizer in lidocaine/epinephrine, Chartwell in lidocaine. Do you see those base biz products as headwind or tailwind in '24E?
- Do you still see generic Forteo as an attractive new product opportunity given the approval of two competitors + AG launch in 4Q23?
- Do either of the two undisclosed new product candidates (with action dates in 2024) have the potential to launch into exclusive or semi-exclusive market conditions?
- Do you foresee doing more Baqsimi-like BD deals in the near to medium term? If so, can you discuss the size and profile of the kind of assets you want to acquire?

Acronyms: AG: authorized generic, BD: business development.

Arcellx: pivotal ddBCMA + commercial readiness

ACLX US – Rating: BUY (C-1-9) | PO: 65.00 USD | Price: 55.50 USD

Investment thesis

We rate Arcellx Buy and like the company based on 1) encouraging Ph1 clinical data for anito-cel (ddBCMA) which looks competitive relative to more advanced players in the relapsed/refractory multiple myeloma CAR-T space, 2) 2024 data readouts are material catalysts with potential to de-risk anito-cel, and 3) upside optionality with SparX approach (we do not currently include SparX programs [early stage] in model).

Key potential catalysts

Exhibit 3: ACLX catalyst tracker
We highlight upcoming potential catalysts events of ACLX

Category: Pipeline		
Drug	Event	Timing
anito-cel (BCMA, d-domain)	Ph1 follow-up data, 5L+ MM	2024E
anito-cel (BCMA, d-domain)	Preliminary Ph2 pivotal data, 5L+ MM	2H24E
anito-cel (BCMA, d-domain)	Initiate iMMagine-2 trial, 2L+ or 3L+ MM	2024E
ACLX-001 (BCMA, ARC-SparX)	Initial Ph1 results, R/R M/M	2024E
Category: Regulatory, Corporate		
Drug	Event	Timing
Abecma (competitor)	FDA advisory committee, 3L+ MM (KarMMa-3)	1H24E
Carvykti (competitor)	FDA action date, 2L+ MM (Cartitude-4)	April 5 2024
anito-cel	BLA (regulatory) filing	2025E
anito-cel	FDA approval	2026E

Source: company reports, BofA Global Research estimates, MM: multiple myeloma, L: line of therapy, R/R: relapsed/refractory

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Key questions for management

- Do you plan on disclosing additional ddBCMA Ph1 data in refractory MM at ASCO or by year-end 2024? If so, please specify your thinking around data flow.
- If you plan to disclose more Ph1/2 data for ddBCMA, what aspects of the product profile are important to communicate (an update) to physicians in the field?

- Beyond executing the ddBCMA pivotal trial in RRMM, can you talk about where the company will be focusing its time and energy in 2024? Probe: advancing the earlier-stage pipeline or efforts to get ddBCMA commercial ready?
- Can you talk about how you see the supply /capacity of ddBCMA evolving over the first 1-3 years of the launch?
- Has Gilead/Arcellx committed to only securing product vector exclusively from Oxford or will the product be made in-house at Gilead's facility?
- Can you talk about where you see ddBCMA's vein-to-vein time settling versus the low 20-day number in Ph1 experience? Do you see vein-to-vein time as an important point of competitive differentiation?
- On delayed neurotox and parkinsonism, can you talk about the current strategies or recommendations to oncologists to mitigate those AE's?
- Post ASH 2023, how are you thinking about evaluating ddBCMA's performance in patients with EMD in order to establish this as a differentiated aspect of the product's profile?
- Where is Arcellx/Gilead with ArcSparx for RRMM? Can you share when you plan to update the street on this program and preview what you hope to see?
- Can you discuss the importance of showing OS in earlier line MM trials and how you think about trial design (e.g. mitigating cross-over risk)?

Acronyms: RR: relapsed/refractory, MM: multiple myeloma, ddBCMA: anito-cel, ASCO, ASH: medical meetings, EMD: extramedullary disease, OS: overall survival.

Arrowhead: pulmonary updates + APOC3 R&D updates

ARWR US – Rating: BUY (C-1-9) | PO: 37.00 USD | Price: 30.60 USD

Investment thesis

We rate ARWR a Buy. We expect ARWR to deliver P&L leverage driven by the rollout of new products that are either wholly owned or partnered (future royalty streams). Our thesis is based on favorable risk/reward in front of several key 2024 catalysts including 1) topline data from Ph3 ARO-APOC3 in FCS in 2Q24 - data could facilitate an NDA leading to ARWR's first approved product, 2) Ph1/2 biomarker data from respiratory assets.

Key potential catalysts

Exhibit 4: ARWR catalyst tracker
We highlight upcoming potential catalysts events of ARWR

Category: Pipeline

Drug	Event	Timing	Comment
ARO-ANG3 (HoFH)	EOP2 meeting, finalize Ph3 design	1H24	inform registrational trial
ARO-APOC3 (FCS)	Est. Ph3 Palisade readout in FCS	2Q/3Q24	TG lowering at 10-mo (primary)
Belcesiran	Est. Ph2 AATD ESTRELLA readout	4Q23/1H24	First AAT pt data (prior HV); Dicerna/Novo/Alynlam
ARO-RAGE	Est. Ph1/2a readout of high-dose in mild/mod asthma pts	1H24	Lung-targeted; safety and PK (sRAGE)
ARO-MUC5AC	NHP toxicology data	1H24	Toxicology data to characterize lack of off-target effect
ARO-MUC5AC (HV, asthma, COPD)	Ph1/2a data - part 1 HV, part 2 asthma + COPD pts	1H/2H24	includes COPD cohort
APOC3/ANG3	CVOT trial design and planned initiation	mid/2H24	strategy as of F4Q is to pursue ANG3
ARO-RAGE	Est. Ph1/2a readout in high-FeNo asthma pts	3Q24	Anti-inflammatory effect
ARO-RAGE	Initiate Ph2b	4Q24	Planned Ph2b trial after FeNO cohort data in 3Q24
Olezarsen (sHTG)	topline from Ph3 CORE studies	2H24/1H25	All-comers (TG>500); positive data would lead to sNDA

Exhibit 4: ARWR catalyst tracker
We highlight upcoming potential catalysts events of ARWR

Category: Pipeline

ARO-MMP7 (IPF)	Est. Ph1/2a readout in HV + IPF pts	2H24	target engagement, safety
Fazirsiran (ARO-AAT)	Est. ph3 AAT REDWOOD readout	2026/2027	Change in histologic fibrosis staging at week 106

Category: Regulatory/Other

Drug	Event	Timing	Comment
Olezarsen (IONS)	File NDA for FCS	2024	Met primary endpt of stat sig reduction in TG levels vs pbo
ARO-APOC3 (FCS)	File NDA	2H24	File NDA on positive Ph3 data (topline 2Q24)

Source: company reports; CT.gov; BofA Global Research

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Key questions for management

- Can you talk about what you want to see from plozasiran Ph3 FCS study to bolster the competitive positioning of that drug? Do you believe study results read-across to the drug's potential profile in the larger SHTG study?
- In Arrowhead's Ph3 FCS study, do you expect to see substantially more acute pancreatitis events (vs. Ionis Ph3 study) given longer duration of follow-up and any other study enrichment factors?
- When we see Ionis' Ph3 SHTG trial results, do you see that as an important validation of whether TG lowering strategies can reduce pancreatitis events in the broader SHTG population?
- Given ANG3 leads to a greater reduction in remnant cholesterol and APOB, why would that program not be advanced into a CVOT (over APOC3)? Probe: level of concern seen with Ionis' ANG3 program on liver fat.
- In the Ph3 SHASTA-3 and -4 studies for SHTG, do you planned to evaluate (prospectively) pooled data for patients at elevated risk of pancreatitis?
- Are you looking at GLP1 or other obesity related targeting strategies in your extra-hepatic delivery programs? If so, can you offer any details on the challenges and timeline for such an approach?
- Beyond seeing a 30% reduction in FeNo in your high FeNo asthma cohort (3Q24), can you talk about any other important data you expect to validate the impact of the drug in the inflammatory cascade of those patients? Can you speak to the variability of the FeNo measure and how comfortable you can get with the data in a relatively small data cut?
- For Muc5AC, do you expect to get anything more than target knockdown data in sick patients in 2024? Given FEV1 is a 'noisy' endpoint in small populations, is there any data you can generate to ascribe confidence in the clinical benefit of the approach?
- Where is Arrowhead in terms of shoring up its capital runway? Does management believe it has sufficient mid-stage assets to partner (that are non-core) that can bring in non-dilutive financing?
- On your cash burn, can you speak to some of the key trials you can delay to extend runway, if necessary?

Acronyms: P&L: profit & loss; NDA: new drug application; HoFH: heterozygous familial hypercholesterolemia; EOP2: end of phase 2; FCS: familial chylomicronemia syndrome; AAT(D): alpha-1 antitrypsin disease; TG: triglyceride; HV: healthy volunteer; COPD: chronic obstructive pulmonary disease; pts: patients; FeNo: exhaled nictric oxide; CVOT: cardiovascular outcomes trial; NHP: non human primates; IPF: idiopathic pulmonary fibrosis; sHTG: severe hypertriglyceridemia; GLP1: glucagon-like peptide 1; FEV1: forced exhaled volume; APOC3, RAGE, MUC5AC, APOC3, MMP7: drug targets.

Axsome: getting Auvelity over ADA goal-line

AXSM US – Rating: NEUTRAL (C-2-9) | PO: 80.00 USD | Price: 79.59 USD

Investment thesis

We are Neutral-rated on AXSM stock based on our view that there is a balanced risk/reward where Axsome's Auvelity launch as a treatment for MDD is tracking below consensus estimates and we see the company's primary care products are relatively undifferentiated (depression, narcolepsy, migraine). On the flip side, we see these negatives as being counter-balanced by likely positive Ph3 updates for AXS-12 (narcolepsy) and Auvelity third Alzheimer's agitation readout (1H24).

Key potential catalysts

Exhibit 5: AXSM Catalyst Tracker
We highlight upcoming potential catalyst events of AXSM

Category: Pipeline

Drug	Event	Timing	Comment
AXS-12	Ph3 data read-out for Narcolepsy (SYMPHONY)	1Q24	Timing per 3Q EPS; if data positive, NDA in 2024 (pending long term safety data)
Sunosi (solriamfetol)	Ph3 trial initiations (MDD, BED, SWD)	1Q24	Planned 3 Ph3 trial initiations
Lumateperone (ITCI)	Ph3 adjunct MDD trials topline	1H24	atypical antipsychotic; two Ph3s
AXS-05 (Auvelity)	Initiate pivotal Ph2/3 trial for smoking cessation	1Q24	Received positive pre-IND meeting guidance
AXS-05 (Auvelity)	Ph3 ADVANCE-2 AD agitation readout	1H24	NDA submission to follow; 1H24 readout as of 4QEPS due to fast enrollment
REL-1017 (Relmada)	Ph3 adjunctive MDD trial topline (Reliance II)	1H24	esmethadone. GluN1-GluN2D hyperactive NMDAR channel blocker. Separate Ph3s Reliance I (adjunct MDD) and Reliance III (monotherapy MDD) failed
BXCL-501 (BioXcel)	Ph3 ADA Tranquility III readout	1H24	Mod-to-severe AD pts in (long-term) residential care facilities. Ability to re-dose
BXCL-501 (BioXcel)	Ph3 at-home use agitation schizo BP1 and BP2	2H24	part 1 will readout in 2Q23 (see comment). primary endpoint PEC score at 2 hours. Approved Igalmi (same MOA from Bioxcel) in same indication but needs HCP supervision on risk of falls and syncope
Navacaprant (NMRA)	Ph3 monotherapy MDD	2H24	KOR antagonist. Trial: KOASTAL-1, part of 3 Ph3 MDD program
REL-1017 (Relmada)	Ph3 adjunctive MDD trial topline (Study 304)	2H24	Study 304 is new Ph3. Expected to initiate in mid-'23 with completion in 2H24
Sunosi (solriamfetol)	topline from Ph3 ADHD "FOCUS" study	2H24	Timing per Sunosi R&D Day

Category: Regulatory

Drug	Event	Timing	Comment
Auvelity (AXS-05)	Commercial launch metrics in MDD	2024+	GtN as of 3Q: high 50%s
Rexulti (Lundbeck/Otsuka)	Label expansion metrics in agitation	2024+	First approved drug for ADA
AXS-14	NDA submission for fibromyalgia	1Q24	Timing per 3QEPS
AXS-07	Planned NDA re-submission for migraine	1H24	per 2Q23 EPS, completed type A meeting with FDA. 6 month review based on expectation of class 2 NDA resubmission designation
AXS-12	NDA submission for narcolepsy	2H24	timing per 1Q23 EPS.

Source: Company reports; CT.gov; BofA Global Research

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Key questions for management

- Can you provide an update on where you are with adding +100 sales reps to market Auvelity and timing for anticipated commercial benefit from that investment?
- Where do you see the biggest opportunities or specific strategies to drive Auvelity MDD growth? Can you weight the relative importance of consumer activation vs. reaching a broader set of prescribers?
- Do you have a good data around Auvelity's typical duration of use in MDD for a typical patient and how that compares to other antidepressants? Directionally, are you getting good durability of use?

- On Ph3 Auvelity for ADA, can you talk about general trial risks in this setting and efforts you have taken to mitigate those risks?
- For ADA, is it possible to file your sNDA prior to 2H24 completion of long-term safety follow-up and package those data as part of a day 120 submission?
- A 50% steady-state gross to net deduction for Auvelity seems high relative to other recently launched CNS brands. Can you explain that and whether there is room for upside?
- Solriamfetol–Are you utilizing stimulant comps to drive your peak sales forecasts of $1bn for Solriamfetol in ADHD? Do you expect MDD to be larger opportunity? Are you expecting solriamfetol to work better in binge eating disorder patients who have MDD, by addressing a comorbidity?
- How do you envision AXS-12 for narcolepsy fitting into your commercial organization if successful in Ph3 and approved?
- Directionally, can you talk about your R&D outlay in '24E relative to '23. Do you expect a material step-up due to Ph3 trial initiations?
- On Auvelity IP litigation, when do you anticipate this case with Teva advancing to trial? Can you speak to your confidence this matter could be settled early? Probe: confirm no additional Paragraph IV filers have emerged post-Teva.

Acronyms: MDD: major depressive disorder; GtN: gross to net pricing; ADA: alzheimer's disease agitation; IND: investigational drug application; NDA: new drug application; MoA: mechanism of action; HCP: healthcare provider; PEC: syndrome excitatory component score; TAAR1: trace-amine associated receptor; BED: binge eating disorder; CNS: central nervous system; IP: intellectual property

Bausch: Xifaxan IP + interplay with eye health separation

BHC US – Rating: UNDERPERFORM (C-3-9) | PO: 6.00 USD | Price: 8.02 USD

Investment thesis

We rate BHC an Underperform as we see challenges to value creation in proposed separation of the B&L (eye health) and RemainCo (pharma): 1) RemainCo – key risk is multiple compression as a stand-alone business as the company is highly levered to Xifaxan, which is at risk of earlier than expected (2028) LOE and we see very limited equity value in a >5x levered RemainCo, 2) B&L spin - execution risk

Key potential catalysts

Exhibit 6: BHC catalyst tracker
We highlight upcoming potential catalysts events of BHC

Category: Pipeline		
Drug	**Event**	**Timing**
amiselimod	Ph2 data in mild to moderate UC (ulcerative colitis)	Early 2024E
Category: Regulatory, Corporate		
Drug or type of event	**Event**	**Timing**
Corporate	FY23 guidance	4Q call (Feb 2023)
Xifaxan	Appeal ruling on dispute with Norwich's generic	1Q24E
spin-off	Proposed spin-off of Bausch + Lomb	TBD
Debt maturities	~$2.8bn debt due	2025

Source: company reports, BofA Global Research estimates

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Key questions for management

- Can you provide the company's latest thinking regarding separation of the BLCO (Bausch + Lomb; B&L) eye health unit? Probe: timing and mechanism
- Does the company still expect an appellate ruling in Xifaxan patent litigation with Norwich sometime in early 2024?
- Can you talk about the importance of getting clarity on Xifaxan IP litigation as it pertains to the BLCO separation? Probe: interplay with D&O release, possible Canadian approval, solvency opinions, and/or fraudulent conveyance matter
- Now that a district court has dismissed Norwich's attempt to remove a lower court injunction, can you speak to whether that injunction is contingent on the appellate court's ruling?
- Can you speak to increased S&M investment behind Xifaxan growth and how that is impacting script trends? Is the business still evenly split between IBS and HE? Are you seeing benefit in any specific market channels?
- Can you speak to growth dynamics of Solta heading into 2024? What are the specific headwinds and tailwinds for that business?
- Where do you foresee EBITDA margins settling for RemainCo, post separation?
- Diversified brands declined an average mid-teens % in 1H23. Is that an appropriate rate of decline on a go-forward basis?
- As of today, do you plan on offering guidance in a similar format as 2023, assuming the separation has not yet occurred?
- Does Bausch (RemainCo) have any ability to invest in small bolt-on M&A deals to bolster its new product pipeline and leverage its commercial infrastructure?

Acronyms: IP: intellectual property, D&O: Directors and Officers, S&M: sales and marketing, IBS: irritable bowel syndrome, HE: hepatic encephalopathy, LOE: loss of exclusivity.

Bluebird: all about SCD gene therapy launch

BLUE US – Rating: BUY (C-1-9) | PO: 5.00 USD | Price: 1.38 USD

Investment thesis

We rate BLUE Buy. We like the peak sales potential for BLUE's Lyfgenia as a gene therapy for Sickle Cell, a large market for a curative treatment. We believe Lyfgenia's data are competitive with the only other marketed GT for SCD and we believe the company's prior launch of Zynteglo for beta thal has established commercial infrastructure that can be leveraged by Lyfgenia. We see Bluebird as funded to sustain operations to 2025 and we view upcoming quarterly results as key catalysts for the stock.

Key potential catalysts

Exhibit 7: BLUE catalyst tracker
We highlight upcoming potential catalysts events of BLUE

Category: Pipeline

Drug	Event	Timing	Comment
BEAM-101 (Beam for SCD)	Ph1/2 BEACON in SCD initial clinical data	2024	Increases fetal hb. timing per 1Q23 transcript. Base editing - uses CRISPR/ deaminase for single base edit
CTX001 (CRSP/VRTX for SCD, ages 2-11)	Ph3 SCD topline results in pediatrics	2H26	PC May 2026, trial started May 2022. Increases fetal hb
CTX001 (CRSP/VRTX for TDT, ages 2-11)	Ph3 TDT topline results in pediatrics	2H26	PC May 2026, trial started May 2022. Increases fetal hb

Category: Regulatory

Drug	Event	Timing	Comment
CTX001 (CRSP/VRTX for TDT)	US regulatory decision	Mar 30, 2024	Standard review announced June 2023

Source: company reports; BofA Global Research

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Key questions for management

- On BLUE's recently updated 2024 new patient start guidance, can you speak to contribution by product and whether the lion-share of new starts in 2024 comes from Sickle Cell?
- What do you see as the profile of the patient who is likely to be an early adopter of Lygenia? Do you think that is a common profile? Given Lyfgenia's product label and physician discretion to use broadly in SCD, do you expect use to be limited to more severe patients?
- Are you seeing QTC's and insurers providing access for both Casgevy and Lygenia, or have there been instances of where access is limited to only one product?
- You recently announced a value-based agreement (covering 100m patient lives) for Lygenia. Can you speak to likely net pricing versus $3m list price per patient treated?
- On your estimated 20K US severe patients with SCD, can you speak to % of those patients not actively under the care of someone your commercial sales force will call upon?
- Mindful your Lyfgenia boxed warning pertains to risks that are inherent to SCD patients getting busulfan conditioning regimen, what gives BLUE confidence some prescribers won't opt for a product (Casgevy) that lacks the boxed warning?
- Can you remind us – how Bluebird plans to follow patients' post-treatment and accumulate more data on long-term follow-up (safety and outcomes)?
- Following a recent dilutive capital raise, can you speak to your confidence the company's cash on hand can fund operations to profitability?
- On the PRV dispute, what are the arguments for why Lyfgenia should receive PRV grant given the API was the same as in prior approved Zynteglo approved for beta thal?
- How do you see Lyfgenia time from cell collection to infusion comparing to Zynteglo for beta thal?

Acronyms: SCD: sickle cell disease; TDT: transfusion-dependent beta thalassemia; QTC: qualified treatment center; PRV: priority review voucher; beta-thal: beta-thalassemia

Exelixis: Cabo IP and pipeline progression

EXEL US – Rating: BUY (B-1-9) | PO: 27.00 USD | Price: 23.99 USD

Investment thesis

We rate EXEL Buy as we believe the company provides favorable risk/reward on resolution of cabo IP dispute, continued progression of pipeline portfolio, and possible cabo label expansion opportunities. In 2024, we look to data updates on cabo prostate and mid-to-late-stage programs ie zanza and XB002 (TF-ADC).

Key potential catalysts

Exhibit 8: EXEL catalyst events
We highlight potential catalyst events of EXEL

Category: Pipeline		
Drug(s)	**Event**	**Timing**
Cabometyx + atezo	Ph3 readout in 2L+ mCRPC (CONTACT-02)	Early 2024E
Zanza	Potential program / clinical data update	2024E
XB002 (TF-ADC)	Potential program / clinical data update	2024E
Category: Regulatory, Corporate		
Drug(s)	**Event**	**Timing**
Corporate	FY24 guidance	Jan / Feb 2024
Cabometyx	Ruling on Cabo patent dispute vs MSN	1H24E

Source: company reports, BofA Global Research estimates

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- When in 2024 do you expect a trial ruling on Cabo IP? What is your LOE assumption for Cabo following conclusion of the second bench trial?
- Whether/how does your prior settlement with Teva on Cabo IP impact the calculus of any potential settlement discussion with MSN?
- Can you frame your expectations for cabo prostate (CONTACT-02) data in early 2024? Will the early'24 presentation include OS data, and when will the next OS analysis occur?
- Can you talk about the TAM for the CONTACT-02 patient population? Do you view OS benefit as necessary for regulatory approval and/or commercial uptake, in the context of PSMAfore data on Novartis' Pluvicto?
- What is your expectation on Cabo outlook in 2024 on net price tailwind, volume growth, and contribution between market share gain and longer duration of therapy? Will there be a benefit on net pricing due to IRA (limiting catastrophic costs + donut hole costs)?
- Do you expect to provide investors any data update(s) on zanza and XB002 in 2024? If so, can you discuss possible timing and nature/make of the data?
- BD activities on ADC were active in 2023, but investors have not given EXEL credit on its ADC pipeline. Can you discuss any differentiated attributes from your ADC platform that might have been underappreciated by the Street?
- What drives your enthusiasm for your USP1 program currently in early Ph1? Are there any learnings from competitor's data (Roche/KSQ) EXEL can leverage to expedite Ph1 development?
- What is your latest thinking on business development in terms of sense of urgency, size of BD, and type/stage of assets you would look for?

- As you advance your internal R&D pipeline and continue to assess potential BD, can you discuss your expectations for R&D spend in 2024 and over the next few years?

Acronyms: IP: intellectual property, MSN: MSN Lab, TF-ADC: tissue factor antibody drug conjugate, mCPRC: prostate cancer.

Fibrogen: pivot to oncology; pamrev Ph3 + FOR46 ph1 readouts

FGEN US – Rating: UNDERPERFORM (C-3-9) | PO: 0.50 USD | Price: 0.89 USD

Investment Thesis

We rate FGEN Underperform on tough stock setup due to lack of high conviction catalysts: 1) near-term pipeline catalysts are either high risk or too early stage to be accounted for our in our model and 2) risk of generic HIF entry in China pending ongoing litigation.

Key potential catalysts

Exhibit 9: FGEN catalyst tracker
We highlight potential catalyst events of FGEN

Drug	Event	Timing	Comment
Category: Pipeline			
Pamrevlumab-LAPC	Ph3 LAPIS topline OS data	1H24	locally advanced unresectable pancreatic cancer
FG-3246 (FOR46)	Ph1 mCRPC	1H24	lead to Ph2 initiation if positive
Category: Regulatory, Commercial			
Roxadustat-CKD	China launch metrics	2024	
FG-3246 (FOR46)	Initiate Ph2 trial in mCRPC	2H24	In-licensed
Category: Legal, Corporate			
Roxadustat	Composition of matter patent expiry, extension pending	2029-30E	Expires 2024-25, plus 5-yr patent term extension
Roxadustat	Polymorph crystalline patent	2033E	Subject to opposition proceedings in Europe; UK method of use patents ruled invalid Apr '20

Source: company reports; CT.gov; BofA Global Research

BofA GLOBAL RESEARCH

- Should we expect updates on roxadustat crystalline patent challenges in China in the near-term? What gives you confidence that the appeal will be granted? When do you expect to see generic impact in terms of pricing or market share?
- In China, what is your outlook for roxa's pricing and volume growth dynamics in 2024? Are there any specific segments of the Chinese market you see as tailwinds for growth?
- Can you talk about your strategy for pivoting to an oncology-focused company and how you decide where to allocate capital – are you focusing on FOR46 to determine which indications work best?
- Can you discuss the strength of data that supports the FOR46 asset – specifically, why this target? Why hasn't it been explored yet in mCPRC? What is the market opportunity in mCRPC?
- For pamrev in pancreatic cancer – what is the bar you need to meet for the OS read out in both trials?

Acronyms: HIF: hypoxia-inducible factor; OS: overall survival; mCRPC: metastatic castration-resistant prostate cancer

Galapagos: BD and progression of CAR-T programs

GLPG US – Rating: NEUTRAL (B-2-9) | PO: 44.00 USD | Price: 40.65 USD

Investment thesis

We rate GLPG Neutral on balanced risk reward: 1) potential upside from clinical catalysts readout next 12-18mo, 2) the Street may further discount cash in the absence of positive readouts from clinical catalysts.

Key potential catalysts

Exhibit 10: GLPG catalyst tracker
We highlight potential catalyst events of GLPG

Category: Clinical		
Drug	Event	Timing
GLPG 5201 (CD19 CAR-T)	Ph1 data update in r/r CLL and RT	2024E
GLPG 5201 (CD19 CAR-T)	IND clearance, pivotal trial initiation, manufacturing metrics	2024E
GLPG 5101 (CD19 CAR-T)	Ph1 data update in r/r NHL	2024E
GLPG5301 (BCMA CAR-T)	Initial Ph1 data in r/r multiple myeloma (trial initiated Dec'23)	TBD
GLPG 3667 (TYK2)	Ph2 topline in dermatomyositis	2025E
Category: Corporate		
Drug or type of event	Event	Timing
Corporate	FY24 guidance	FY23 call (Feb'24)
Oncology / immunology	Business development update	TBD

Source: company reports, BofA Global Research estimates. Note: r/r: relapsed/refractory, CLL: chronic lymphocytic leukemia, RT: Richter Transformation, NHL: non-Hodgkin's Lymphoma.

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- Based on Ph1 data of GLPG5201 in r/r CLL and RT, what is your current thinking on trial design and study population for the planned pivotal trial?
- Assuming IND clearance for GLPG5201 in early 2024, can you walk us through steps / timeline and clinical data needed prior to starting a pivotal trial? Do you anticipate a need to generate clinical data in US site(s) to support pivotal trial initiation?
- How many US and ex-US sites do you anticipate needing to setup for the pivotal trial (vs roughly a handful of EU sites currently in Ph1)? How might those numbers look on a commercial launch scenario?
- What metrics will you be tracking in 2024 as you look to demonstrate the decentralized mfg model is highly scalable with consistency as you expand your footprint of trial sites for GLPG5201?
- Can you discuss the current level of mfg automation for your CD19 CAR-Ts with respect to number of operators needed per run/per 50 runs/on site, and level of operators' attention required during the mfg process?
- Can you talk about mfg process optimization, given 3 out of 12 patients in Ph1 received a lower dose due to low level of CAR+ T-cells manufactured? What do you envision in-spec rate to be for GLPG5201 (and GLPG's broader CAR-T assets)?
- Where are you at with finalizing a product release spec? How do you ascertain your clinical spec will translate into commercial in-spec rate, given we have observed drop-off in spec rates (label to commercial) for approved CD19 and BCMA CAR-Ts?

- Where do you see a role for GLPG5101 given supply constraint is not an issue for CD19 CAR-Ts in NHL? As you continue to dose escalate '5201, can you talk about potential trade-off in safety and mfg in-spec rate (based on CAR+ T-cells)?
- Can you discuss cadence of clinical update expected for GLPG5301 (BCMA CAR-T)? What are learnings you can leverage from your CD19 CAR-T programs to '5301?
- Can you discuss your current thinking on business development (BD) in terms of sense of urgency, size of BD, and stage of assets?

Acronyms: r/r: relapsed/refractory, CLL: chronic lymphocytic leukemia, RT: Richter Transformation, NHL: non-Hodgkin's Lymphoma, CAR-T: cell therapy, CAR+ T-cells: modified T cells, CD19, BCMA: antigens.

Harmony: pipeline & CP updates to inform durability of business

HRMY US – Rating: UNDERPERFORM (C-3-9) | PO: 30.00 USD | Price: 32.30 USD

Investment thesis

We rate HRMY Underperform on lack of high impact catalysts and a challenging path to addressing a '29 Wakix LOE on balanced risk-reward. At this juncture we would have preferred to see the company more active on BD to diversify its product portfolio. Our model is highly sensitive to LOE assumption, assuming Wakix can exceed $1bn in '29+ revenue, though we do not believe it is prudent for investors to assign value to terminal polymorph patent (susceptible to non-infringing alternative polymorphs).

Key potential catalysts

Exhibit 11: HRMY catalyst tracker
We highlight potential catalyst events of HRMY

Category: Pipeline			
Drug	Event	Timing	Comment
TAK-861 (oral orexin / narcolepsy)	est Ph2 data (NT1, NT2 patients)	2H24	
Wakix	est Ph3 data - Prader-Willi Syndrome	TBD	initiate study in 4Q23
Category: Regulatory			
Drug	Event	Timing	Comment
Wakix	est FDA response to Citizen's Petition	TBD	180 days from submission (4/3) – no decision yet passed deadline
Wakix	est FDA approval pediatric narcolepsy	3Q24	submit pediatric narcolepsy sNDA in 4Q23
Category: Legal, Corporate			
Drug	Event	Timing	Comment
Wakix	Est. patent LOE (method of use patent)	2030	ODE: Oct. 2027; method patent: 9/26/29 + PTE + pediatric exclusivity, possible Sep '30E

Source: BofA Global Research, company reports. Note: NT: narcolepsy, LOE: loss of exclusivity, sNDA: supplemental new drug application., ODE: orphan drug exclusivity, PTE: patent term extension

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Key questions for management

- Can you confirm 2024 outlook previously conveyed regarding Wakix formulary coverage and net pricing still holds as we start the year?
- What do you see as the in-play market for Wakix in 2024+? Probe: oxybate non-responders or drop-outs vs. patients non-responsive to wake promoters?
- Do you expect to get to a steady-state net revenue per patient (on average) in 2024, as patient-assistance programs shrink as a % of total Wakix business?

- Can you outline the objectives heading into 1H24 data update for your next-generation pitolisant? Will you have data for both Formulation 1 and #2, or only Formulation 2 (abbreviated development program)?
- Has the management team had any FDA correspondence regarding the Citizen's Petition seeking to get Wakix removed from the market?
- What is your latest thinking regarding the timeline for Ph3 Zygel FragileX study readout? Probe: the deal has milestone payments the largest payment occurring if the data readout on or before Dec. 31, 2024. So, what is your confidence Ph3 can readout in 2024?
- Can you speak to supportive clinical data for cannabidiol as treatment for Fragile X beyond prior Ph2 data generated by Zynerba with Zygel?
- Can you frame key points from ACNP 2023 presentation of post-hoc data in subjects with 22q deletion and what gives you confidence you can generate positive Ph3 data for Zygel in FragileX?
- When do you plan to meet with FDA and be in a position to update the street on a pathway forward with Wakix for the IH indication?
- Capital deployment: can you speak to how you are prioritizing share repurchase versus acquisition of external assets?

Acronyms: ANCP: medical meeting, FDA: US Food and Drug Administration, IH: idiopathic hypersomnia.

Immunovant: key year for validating utility of deeper IgG reduction

IMVT US – Rating: BUY (C-1-9) | PO: 49.00 USD | Price: 41.21 USD

Investment thesis

We rate IMVT a Buy on upside potential for IMVT's clinical-stage FcRn portfolio. Catalysts include: 1) clinical data for TED and Graves', which are FcRn white spaces, 2) broad applicability in autoimmune diseases that provide further upside beyond crowded markets (MG, CIDP). Keys to the IMVT thesis: 1) broad FcRn commercial opportunity-set, 2) ability of IMVT to differentiate on dosing convenience and potential efficacy differentiation with next-gen drug possessing a favorable therapeutic index.

Key potential catalysts

Exhibit 12: IMVT Catalyst Tracker
We highlight potential catalyst events of IMVT

Category: Pipeline

Drug	Event	Timing	Comment
batoclimab	Data from Period 1 of Ph2b CIDP trial	1H24	Period 1: 12wk tx of 2 dose regimens; Period 2: randomized withdrawal of responders studied for ≤ 24wks. Efficacy analysis based on relapse (adj INCAT)
batoclimab	Est. topline from Ph3 MG study	2H24	PCD: April '24
nipocalimab (J&J)	Data from Stage B of Ph2/3 CIDP trial	2H24	Dependent on # of events
batoclimab	Est. topline from Ph2b CIDP study	2H24/1H25	Registrational package for CIDP may include 1 or 2 pivotal trials depending on variety of factors
batoclimab	Est. topline from Ph3 TED studies	2H25	Studies '3201 and '3202 both expected 1H25 (earliest PCD: Oct '24); OLE PCD May '25

Exhibit 12: IMVT Catalyst Tracker
We highlight potential catalyst events of IMVT

Category: Pipeline			
nipocalimab (J&J)	Est. topline from Ph2/3 CIDP	1H26	PCD May '26. Two part study - Stage A: open-label, responders enter double-blind Stage B + will receive IV q2w up to 1 yr; primary endpt is time to first relapse in Stage B

Source: Company reports; CT.gov; BofA Research

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Key questions for management

- Can you speak to what would be a meaningful efficacy dose-response in Period 1 of your '1401 CIDP study?
- If deeper IgG relationship to clinical efficacy does not play out in CIDP and MG studies, might this push you away from chasing other FcRn's in established indications and more to novel /first mover indications?
- Where is IMVT with getting its '1402 IND cleared?
- Can you provide an update on your TED program – where are you in terms of enrollment? How do you foresee FcRn based approaches competing with IGF1R approaches?
- Have 2023 TED market developments changed your outlook on '1401's value proposition?
- On IMVT's recent Ph2 Graves' data, can you discuss your next planned data update? Specifically, do you plan or need to dose all patients to inform the mid-'24 data update?
- Can you talk to how you balance your current capital position with need to invest heavily behind '1402 to maximize potential in FcRn related indications?
- Argenx's early-stage partner (Elekrofi) claims to be able to formulate 600mg/ml using their microparticle technology. Do you see that as a material risk to the '1402 value proposition?
- Given there is some time between now and presumably a mid-year FDA meeting (to discuss '1402 + '1401 GD data) that will drive broader development plans, are you planning some sort of 2H investor update?
- Competitor IgG degraders are being advanced on the hypothesis that deeper IgG reduction with FcRn inhibitors will lead to infection. What is Immunovant's assessment of data where FcRn's have pushed IgG reductions in 80% range?

Acronyms: TED: thyroid eye disease; FcRn: immune receptor; MG; myasthenia gravis; CIDP: chronic inflammatory demyelinating polyneuropathy; PCD: primary completion date; INCAT: inflammatory neuropathy cause and treatment scale; IGF1R: insulin growth like factor 1 receptor; IgG: immunoglobulin.

Intracellular: Caplyta Ph3 MDD data + BPD launch trajectory

ITCI US – Rating: BUY (C-1-9) | PO: 82.00 USD | Price: 71.62 USD

Investment thesis

We are Buy-rated on ITCI based on peak sales potential for Caplyta in approved and development-stage add-on indications. We believe the commercial opportunity for Caplyta in bipolar depression is substantial given limited approved therapies in this under-penetrated market. We are encouraged by recent MDD competitor launches and we view the 1H24 Ph3 updates for Caplyta in MDD as a meaningful upside opportunity.

Key potential catalysts

Exhibit 13: ITCI Catalyst Tracker
We highlight potential catalyst events of ITCI

Category: Pipeline

Drug	Event	Timing	Comment
Lumateperone LAI	Initiate Ph1 subq single-ascending study	1H24	Goal is treatment duration > 1 mo for schizophrenia
Caplyta (MDD)	Est. topline for Ph3 - Study 501	1Q24	As of 3Q EPS
Caplyta (MDD)	Est. topline for Ph3 - Study 502	2Q24	As of 3Q EPS
ITI-1284-ODT-SL	Ph2 trial initiation/readouts - GAD, ADA, ADP	2024	Ph2 trials initiated as of 3Q23 EPS; not yet on CT.gov (expected 1H24)
ITI-333 (pain, opioid disorder)	Results of Ph1 MAD safety study	2024	SAD data was reported in '23. Timing guideline as of 3Q EPS
Caplyta (MDD)	Est. topline for Ph3 - Study 505	2H24	Adj. to SOC ADT - Study 501 in 1Q24, Study 502 in 2Q24. Study 505 in 2H24. Study 505: open label long term fixed dose lead with safety & efficacy at 26 weeks
Caplyta (MDD)	sNDA submission for adj. MDD	2H24	Supported by data from Studies 501+502
ITI-1549 (non-hallucinogenic psych)	Initiate Ph1	2H24/1H25	advance to IND-enabling studies in 2024
ITI-214 (lenrispodun, PDE1 inh)	Topline from Ph2 trial	1H25	Ph2 initiated in 2023; evaluating motor symptoms, changes in cognition, inflammatory biomarkers

Category: Regulatory

Drug	Event	Timing	Comment
Caplyta (mixed features)	FDA discussions to determine reg path	1Q24	Including any potential for single Ph3 to support filing (vs our base case need for second Ph3)
Caplyta (MDD)	sNDA for adj. MDD	2H24	Supported by data from Studies 501+502

Source: company reports; CT.gov; BofA Research

BofA GLOBAL RESEARCH

Key questions for management

- Can you speak to where you see Caplyta-BPD in its growth cycle? What level of penetration are approved atypicals and what's your view on an appropriate analog for peak penetration? Probe: can atypicals get the same usage rate in BPD as MDD?
- Can you frame key Caplyta sales growth tailwinds in 2024?
- Can you provide an update on Caplyta payer contracting and gross-to-net dynamics heading into 2024?
- Has ITCI reached a steady-state level of S&M investment behind Caplyta for approved indications, or do you expect those investments to still scale with the topline growth?
- On Ph3 Caplyta adjunctive MDD readouts, do you focus on any specific metrics other than generating stat sig on the primary endpoint and replicating safety/tolerability seen with this drug? If so, please elaborate on important areas of focus?
- Do you believe the company can generate Caplyta revenue upside from mixed features if you had to leverage the data as a marketing study?

- What do you need to see from the Ph1 luma-LAI study to advance that forward in development? Is the focus achieving certain PK parameters that support once-monthly dosing?
- Have you started enrolling patients on your deuterated lumateperone trials? How long do you expect these trials will take to generate data and inform a potential pivotal trial? These trials were announced at JPM 2023 – can you talk about any factors that might have slowed patient enrollment of these studies?
- As you approach financial breakeven in 2024, how are you thinking about investing in the business? Does becoming profitable allow you to invest in the brand in ways you might not have prior?
- Do you have any concerns that deuterating lumateperone could negatively alter the pharmacokinetics of the drug? We've seen some compounds that get deuterated have unexpected negative outcomes such as Nuedexta.

Acronyms: BPD: bipolar disease; CNS: central nervous system; mo: month; MDD: major depressive disorder; (s)NDA: (supplemental) New Drug Application; GAD; generalized anxiety disorder; ADA: alzheimer's disease agitation; ADP: alzheimer's disease psychosis; CT.gov: clinical trials website; adj: adjunct; SOC: standard of care; ADT: anti-depressant; FDA: food and drug administration; S&M: sales and marketing; LAI: long acting injectible; PK: pharmacokinetic

Ionis: Helios-B read-across + updates on 3 key pipeline programs

IONS US – Rating: BUY (B-1-9) | PO: 62.00 USD | Price: 50.59 USD

Investment thesis

We rate IONS Buy on favorable stock setup ahead of catalyst-rich path in 2024-1H25. There will be multiple mid-/late-stage clinical readouts that can increase likelihood of success for four assets with $300m-1bn nominal peak revenue estimates (Wainua, donidalorsen, olezarsen, ION582). Approval of Wainua in polyneuropathy with a clean label indicates ION's improved antisense (ASO) platform can mitigate legacy safety issues, effectively validating the safety profile of IONS' broader pipeline.

Key potential catalysts

Exhibit 14: IONS catalyst tracker
We highlight potential catalyst events of IONS

Category: Pipeline		
Drug	**Event**	**Timing**
Vutrisian (TTR competitor)	Ph3 topline results of HELIOS B in CM	1H24E
Donidalorsen (PKK)	Ph3 data in HAE (placebo controlled)	1H24E
Donidalorsen (PKK)	Ph3 data in HAE (OASIS Plus - Switch)	Mid 2024E
ION582 / BIIB121 (UBE3A)	Ph1/2 data in Angelman syndrome (MAD + a cut of LTE)	Mid 2024E
ION541 / BIIB105 (ATXN2)	Ph1/2 data in ATXN2-repeats and broad ALS	Mid 2024E
IONIS-FB-LRx	Ph2 topline in geographic atrophy	2H24E
Olezarsen (APOC3)	Ph3 data in sHTG	1H25E
Eplontersen (TTR)	Ph3 results of CARDIO-TTRansform in CM	1H25E (earliest)
AKCEA-APO(a)-LRx / TQJ230	Ph3 outcomes trial readout (HORIZON study) in Lp(a) CV disease	2025E
Category: Regulatory, Corporate		
Drug	**Event**	**Timing**
IONS	FY24 guidance	4Q call (Feb 2024)
IONS	Commercial launch of eplontersen in PN	2024
Olezarsen (APOC3)	Olezarsen US approval decision	2H24E

Source: company reports, clinicaltrials.gov, BofA Global Research estimates. Note: CM: cardiomyopathy, HAE:hereditary angioedema, MAD: multi-ascending dose, LTE: long-term extension, ALS: amyotrophic lateral sclerosis, sHTG: severe hypertriglyceridemia, CV: cardiovascular, PN: polyneuropathy, TTR, PKK, UBE3A, ATXN2, APOC3, TTR: drug targets.

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Key questions for management

- Post approval of eplontersen for polyneuropathy, can you discuss any important factors for year-1 of the launch such as a) increased patient identification, b) expected product switch dynamics?

- For eplontersen in cardiomyopathy, what (if any) baseline level enrollment differences would you flag ahead of competitor HELIOS-B readout that might be important nuance to interpreting the read-across to your program? Alnylam had flagged several population enrichment factors so wondering how your study compares (directionally speaking)?

- For olezarsen in sHTG indication, assuming positive Ph3 data, do you see the potential for a premium pricing strategy in the high risk (>880mg/dl TG level) population versus the Street's presumed PCSK9 pricing assumption? Can you talk about some of the key data variables that could drive premium pricing, e.g. stat sig pancreatis event reduction (pooled data) or high % of at-risk patients getting to normal TG levels?

- On your geographic atrophy program (Ph2 GOLDEN data in '24E), while the benefits of dosing are clear (SQ > intravitreal injection), what gives you confidence you can achieve comparable therapeutic effect as intravitreal approaches by targeting systemic overactivity of complement pathway?

- For Angelman's, can you discuss your efforts to develop an assay to measure functional restoration of Ube3A protein levels? Given the challenges of measuring the fraction of Ube3A protein migrating from neurons into the CSF, do you expect investors will get any clarity on this important disease biomarker over the next 1-2 years?

- Can you talk about the competitive landscape for prophylactic HAE treatment and where you see donidalorsen fitting?

- Can you frame some of the important objectives with the donidalorsen switch study? Do you see this study as important to increasing physician willingness to move patients off therapies that generally have their disease under control?

- As we get closer to a 2025 outcome trial readout of pelacarsen (Lp(a)) for cardiovascular disease, can you flag any data points that investors can look to for increased confidence around Lp(a) targeting approaches and impact on event rates (Amgen's data is 2026)?

- Does Ionis have plans to resume activity against pulmonary targets, given competitor developments suggesting safe target knockdown is feasible? Or is Ionis waiting for further validation of pulmonary approaches?

- Last, Alnylam talked about obesity targets in adipose tissue. Does Ionis have any plans to move into this space given the increased focus on therapeutic intervention in obesity?

Acronyms: TG: triglyceride, SQ: subcutaneous, CSF: cerebrospinal fluid, HAE: hereditary angioedema, sHTG: severe hypertriglyceridemia, Ube3A, LP(a): drug targets.

Jazz: oxybate defense + pipeline readouts

JAZZ US – Rating: BUY (B-1-9) | PO: 184.00 USD | Price: 121.14 USD

Investment thesis

We rate JAZZ a Buy as the company is positioned to shed a long-lived "oxybate overhang" with the recent launch of a Xyrem authorized generic. In our view, strength in '23 numbers bridging to '25 targets is key to improving investor confidence in growth story and we're encouraged to see Epidiolex (seizures) performance uptick. Last, we believe Jazz's emerging pipeline (essential tremor, Zanidatimab programs) is essentially free at current valuation.

Key potential catalysts

Exhibit 15: JAZZ catalyst tracker

We highlight potential catalyst events of JAZZ

Category: Pipeline			
Drug	**Event**	**Timing**	**Comment**
JZP150	Ph2 readout for treatment of post-traumatic stress disorder (PTSD)	Jan-24	received fast-track designation in 4Q21
AXS-12 (Xyrem competitor)	Est. Ph3 data for narcolepsy	2H23	est. completion of enrollment in 3Q
JZP441 (orexin-2 receptor agonist)	Go/no-go decision on whether to progress clinical development	2H23	Ph1 SAD readout for safety, tolerability, PK/PD. Per mgmt update may not be in form of readout
JZP-385	Ph2b readout for treatment of essential tremor	1H24	
Zanidatamab	Ph3 1L GEA (pivotal)	2024	Zymeworks deal
JZP-385	Ph2 est readout for Parkinson's disease tremor	2H'24	PC: May 2024
JZP-541 (Oral cannabidiol)	Ph2 readout of treatment for autism (CASCADE trial)	TBD	PC: Feb 2025
Category: Legal, Corporate			
Drug or type of event	**Event**	**Timing**	**Comment**
JAZZ vs. Becerra et al. lawsuit		TBD	1:23-cv-01819-APM

Source: BofA Global Research, company reports

BofA GLOBAL RESEARCH

Key questions for management

- Have you observed any major competitive shifts in the oxybate market in late 2023? Do you expect Xywav to continue to grow volumes in both approved indications?
- Based on Avadel's comments about steady-state annual net pricing in oxybate space, do you agree with position that category has not spiraled into a pricing war to secure preferable formulary position?
- Can you talk about IH market build challenges and opportunities? What levers can Jazz pull to increase treatment rates?
- Can you expand upon the adverse events that led Jazz to pause its Orexin program? Do you believe the CV and visual disturbances are on- or off-target?
- On JZP-385 for essential tremor, are you committed to including objectively measured performance scale items in your primary composite endpoint? If so, can you talk about why you see that as prudent given competitor Praxis data and FDA feedback?
- For ET, do you believe treatment effect size differences ranging from 1.5 to 3-point placebo adjusted deltas are commercially important? Do you believe generating a result higher in that range is a big swing factor to the peak sales opportunity?
- For Zani, can you talk about the benefits of rolling out in the smaller BTC indication and how that might help with an eventual GEA launch?

- On Zani for GEA, can you confirm PDL1 positive and negative sub-groups will be evaluated as pre-specified sub-groups? Do you believe there are separate competitive bars with Toga for PDL1 -ve and KN811 for PDL1 +ve?

- In the context of future BD appetite, can you talk about what you see as an appropriate steady-state financial leverage ratio for Jazz? Probe: large pharma tend to operate around 2x while Jazz went to 5.5x to buy GW

- Is neuropsychiatry an area of M&A interest, particularly after the Ph2 PTSD study failure?

Acronyms: CV: cardiovascular, BD: business development, GEA: gastroesophageal adenocarcinoma. PDL1: biomarker, GW: GW pharma, PTSD: Post-Traumatic Stress Disorder, IH: idiopathic hypersomnia.

Lyra: Ph3 ENLIGHTEN-1 for LYR-210 in CRS

LYRA US – Rating: BUY (C-1-9) | PO: 12.00 USD | Price: 5.24 USD

Investment thesis

We are buy rated on LYRA for three reasons: 1) LYR-210, a steroid-eluting implant, has the potential to offer six-months of durable efficacy, 2) steroid incorporated in LYR-210 is a validated treatment for CRS, and 3) LYR-220 offers further expansion into the post-surgical CRS setting, 4) Lyra is attractively valued relative to massive addressable market.

Key potential catalysts

Exhibit 16: LYRA catalyst tracker
We highlight potential catalyst events of LYRA

Category: Pipeline

Drug	Event	Timing	Comment
LYR-220 (post-surgery)	Ph2 randomized data readout	Sep 2023	per 2Q23 PR, ct.gov primary completion June 2023
LYR-210 (pre-surgery)	Pivotal ENLIGHTEN-I Ph3 trial readout	1H24	per 2Q23 PR, ct.gov primary completion Aug 2023
LYR-210 (pre-surgery)	Pivotal ENLIGHTEN-II Ph3 trial readout	mid/2H25	per Jeff June 2023 broker conf

Source: BofA Global Research, company reports

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Key questions for management

- Can you help frame a positive result for Ph3 Enlighten-1, beyond hitting stat sig on 24-week primary endpoint? Is there a minimum magnitude of effect that you'd characterize as clinically meaningful?

- What are the key secondary endpoints in the Enlighten-1 trial? Probe: what is the labeling and/or commercial importance of each of those endpoints?

- Given the stat sig miss at week 4 of prior LYR-210 Ph2 study, can you speak to whether you'd expect the drug to show separation at week 4 on the modified endpoint in Enlighten-1?

- How confident is the management team that it can finish enrollment of Enlighten-2 by 2H24?

- Commercially, can you talk about steps to ensure LYR-210 is a more successful launch than (competitor) Sinuva? Probe: what are steps to ensure success other than generating a differentiated product profile.

- How should investors think about potential LYR-210 price range, with brand nasal spray cost on one end of the spectrum and biologic therapy on the higher end? Where do you see LYR-210 fitting in that range?
- Can you speak to the read-across LYR-210 provides for LYR-220, and vice versa?
- Post BEACON study results, where is Lyra with mapping out a regulatory path for LYR-220 in post-surgical CRS?
- Can you speak to how LYR-210 and LYR-220 would commercially co-exist? Do you see the two products as synergistic or cannibalistic with each other?
- Can you address your current thoughts for shoring up the balance sheet post Enlighten-1? What different levers would the company pursue and what would be the capital needs to fund Enlighten-2 and launch LYR-210?

Acronyms: CRS: chronic rhinosinusitis

Oculis: OCS-01 NDA + broader pipeline updates

OCS US – Rating: BUY (C-1-9) | PO: 21.00 USD | Price: 11.23 USD

Investment thesis

We rate Oculis Buy on key clinical-stage asset's potential to address unmet need in ophthalmology indications. Upcoming data readouts are expected to further de-risk novel pipeline assets, particularly OCS-01 for diabetic macular edema (full 52-wk data expected in 2H25) and post-ocular surgery related pain and/or inflammation (PC date: July 2024). While there is greater clinical risk associated with earlier stage Ph2 dry eye disease asset OCS-02, we believe there remains an unmet need.

Key potential catalysts

Exhibit 17: OCS catalyst tracker
We highlight potential catalyst events of OCS

Category: Pipeline			
Drug	Event	Timing	Comment
OCS-01	Ph2 POC readout - cystoid macular edema	4Q24	PC: October 2023
OCS--01	Ph3 readout - post- cataract surgery (OPTIMIZE-2)	2H24	PC: July 2024
OCS-02	Ph2b readout - dry eye disease	mid-2024	
OCS-02	Ph2b readout - uveitis	2H24	
OCS-05	Ph2 POC readout - acute optic neuritis	4Q24	PC: October 2023
OCS-01	Ph3 readout (stage 2) - diabetic macular edema	2H25	PC: June 2025. Stage 2: efficacy + safety of dosing
Category: Regulatory			
Drug	Event	Timing	Comment
OCS-01	Est FDA approval - inflammation and pain following ocular surgery	2025	late 2024 NDA filing
OCS-01	Est FDA approval - diabetic macular edema	2H26	BofA estimate
OCS-01	Est FDA approval - cystoid macular edema	2027	BofA estimate
OCS-02	Est FDA approval - dry eye disease	2027	BofA estimate
OCS-02	Est FDA approval - uveitis	2027	BofA estimate
OCS-05	Est FDA approval - acute optic neuritis	2027	BofA estimate. 1H23 IND meeting with FDA
Category: Legal, Corporate			
Drug	Event	Timing	Comment
na	Expiry of lockup period (180 days)	8/29/2023	New parent shares held by Oculis Shareholders
na	Expiry of lockup period (270 days)	11/27/2023	New parent shares held by sponsor (EBAC)

Source: BofA Global Research, company reports

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Key questions for management

- Can you talk about 2024 Ph2 pilot study readouts – which programs do you see as the most clinically de-risked and which programs have the most compelling commercial case (size and unmet need)?
- For the Ph2 proof-of-concept CME (cystoid macular edema; data late '24) – what are the key differences in the manifestation of disease between uveitic macular edema (UME), post-surgical macular edema (PSME), and diabetic macular edema (DME)? What would you characterize as a clinically meaningful improvement in efficacy on central subfield thickness and visual acuity at week 12?
- If you establish proof of concept in CME (UME and PSME), what's the path forward – would there need to conduct full Ph3 programs in each indication (similar to DME)? Probe: opportunities for running a single study sNDA.
- For the OCS-01 second pivotal Ph3 (OPTIMIZE-2) for post-op pain, are there any key differences between this study and prior (positive) Ph3? If you can launch OCS-01 for post-op pain, can you talk about the commercial overlap with your follow-on DME indication?
- What is the size and scope of sales force that you expect to deploy for OCS-01 in post-ocular surgery?
- Ahead of Ph2 OCS-02 data readout for dry eye disease, can you talk about the magnitude of benefit you'd need to see to pursue a biomarker selected indication vs. a broader all-comer indication?
- For dry eye disease, can you talk about recent product launches (the good and the bad) and whether you see this as an attractive market for new products?
- For DME Ph3 stage 2 study, it's largely focused on safety, so wanted to get your thoughts on what degree of AEs might be acceptable for patients looking for topical (eye drop) treatment for DME? Is the focus the impact of the drug on IOP (intraocular pressure)?
- Is the DME Ph3 stage 2 study on track to readout on time?
- Can you discuss the company's current cash runway and sequencing of financing-worthy catalyst events over the next 12-18 months?

Organon: '24 guide + path to diversification

OGN US – Rating: UNDERPERFORM (B-3-7) | PO: 12.00 USD | Price: 14.42 USD

Investment thesis

We rate OGN Underperform for 3 key reasons: 1) OGN's transformation via M&A has been slow to materialize and the company is relatively catalyst-light over next 12-18 mos. 2) while OGN's key growth brand, Nexplanon (long-acting reversible contraceptive) may be able to deliver on management's DD growth target, we don't foresee meaningful upward revisions relative to consensus forecasts for the product. 3) EBITDA trending to low-SD declines annually.

Key potential catalysts

Exhibit 18: OGN catalyst tracker
We highlight potential catalyst events of OGN

Category: Commercial, Clinical			
Drug	**Event**	**Timing**	**Comment**
Nexplanon	Results from Ph3 Nexplanon 5 yr duration study	2H24	PC: Jun 2024
6219 (endometriosis)	Results from Ph2 trial	late '24/1H25	endometriosis
7191 (polycystic ovary syndrome)	Results from Ph1 trial	mid-2026	polycystic ovary syndrome
Category: Regulatory			
Drug	**Event**	**Timing**	**Comment**
Hadlima (b-Humira)	Est. interchangeability approval	summer '24	
Category: Legal, Corporate			
Drug or type of event	**Event**	**Timing**	**Comment**
Nexplanon litigation	Jury trial begins as requested by Microspherix	10/16/2023	Jury trial requested, '402, '193, '401 and '835 patents
Nexplanon LOE	loss of exclusivity - US & EU, respectively	2027 (US); 2025 (EU)	

Source: company reports, BofA Global Research estimates

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Key questions for management

- For starters, can you discuss the evolution of your net debt leverage profile and the interplay with your business development efforts?
- Has the company considered moving outside the scope of women's health/women's health adjacencies to expand the scope of BD options.
- What is the company's appetite for transformational M&A in the near to medium term?
- On the recently acquired EU-Emgality commercial rights, can you talk about the margin contribution and how much you expect product sales to contribute to EBITDA? Probe: do you need to add S&M costs, or is this pure leverage with product added to existing commercial infrastructure?
- On US biosimilar Humira, are you seeing any encouraging signs that biosimilars can see an uptick in utilization?
- Can you speak to some of the puts/takes on OGN's gross margins? On the 3Q23 call, management had flagged Fx and inflationary pressures. Does Organon expect those GM pressures to carryover into 2024?
- On Nexplanon, can you talk about 2024 growth drivers for this key franchise?
- Ahead of Ph2 data for '6219 for treatment of endometriosis, what are you hoping to see from this drug to advance it forward in development? How big of a change in daily OPP score (primary endpoint) is clinically meaningful? How should investors think about the clinical benefit of '6219 relative to approved oral GnRh agents given the differences in endpoints?
- Can you speak to your current biosimilar arrangement with Samsung. When the deal term expires on respective products, can you talk about the factors that go into extending the partnership?
- What is Organon's latest thinking regarding payout of a dividend? Given the low multiple and investor desire to see more growth, has the company considered moving away from paying a dividend?

Acronyms: BD: business development, GnRh: drug target, OPP score: measurement of endometriosis-related pain

Prokidney: Ph2 bilateral dosing & read across to pivotal study

PROK US – Rating: NEUTRAL (C-2-9) | PO: 2.00 USD | Price: 1.78 USD

Investment thesis

We rate PROK Neutral based on a balanced risk/reward on lack of meaningful de-risking near-term catalysts. REACT's Ph2 bilateral dosing data in 2024 could offer insight on efficacy attributable to bilateral dosing (same dosing as registrational Ph3). However, we believe stock upside is limited by the uncertainty of key de-risking catalyst, REACT Ph3 topline in CKD patients, and 1H24 detailed data of GLP-1 on kidney function, which could begin to inform impact on REACT's market opportunity.

Key potential catalysts

Exhibit 19: PROK Catalyst Tracker
We highlight potential catalyst events of PROK

Category: Pipeline

Drug	Event	Timing	Comment
semaglutide (Novo)	Detailed data from FLOW (pts with T2D and CKD)	1H24	Interim data showed 20% improvement on composite endpt [5 measures]
REACT (adults, GFR 20-35)	Ph3 Proact 1 resume enrollment	1H24	Revised enrollment criteria + manuf audit
REACT (adults, GFR 20-50, bilateral)	Ph2 REGEN-007 open label, CKD T1/T2D interim data	1H24	Focus on GFR slope reduction and safety
REACT (adults, GFR 20-35)	Update on potential Ph3 proact 1(REGEN-006) RCT CKD T2D interim	2H24	Company will provide color on whether interim will occur
REACT (adults, GFR 20-50)	Ph2 RMCL-002 topline readout	early 2025	Focus on GFR at 24 months
REACT (adults, GFR 20-50, bilateral)	Ph2 REGEN-007 open label T1/T2D topline results	2H25	Focus on GFR slope reduction and safety
REACT (adults, GFR 20-50)	Ph2 RMCL-002 open label CKD T2D topline results	2H25	Focus on GFR at 24 months
Tirzepatide (LLY)	Est. topline from TREASURE-CKD (CKD pts with/without T2D)	1H26	focus on kidney hypoxia
REACT (adults, GFR 20-35, bilateral)	Ph3 REGEN-006 RCT CKD T2D topline results, registrational	2027	Focus on renal outcomes
REACT (adults, GFR 20-44, bilateral)	Ph3 REGEN-016 RCT CKD T2D topline results, registrational	2027	Focus on renal outcomes

Source: company reports; CT.gov; BofA Research

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- Since we know that GLP-1 have some sort of benefit on renal measures in type 2 diabetes patients, what could be the potential impact that GLP-1's on REACT's clinical development program and market opportunity?
- Can you talk about the interim data update from Ph2 -007 bilateral dosing – number of subjects treated and duration of treatment follow-up? Are you expecting a material change in eGFR slope in -007 study update?
- What is the magnitude of efficacy benefit you expect from bilateral dosing (007) compared to Ph2 single dose trial? Is there any reason that efficacy could be less than that of a single dose? Can we extrapolate that we'd expect a similar magnitude of efficacy in the Ph3?
- For proact-1 - when in 2024 will you be in a position to offer an update on enrollment progress and the potential for an interim analysis? What would an interim analysis look like now that it won't be events-based?
- For ex-US Ph3 (-016) study, besides getting the manufacturing process in compliance, are there any other gating factors to trial enrollment? Do you anticipate enrollment could go quicker for Proact-2 (than Proact-1) given the broader criteria for patient enrollment?
- Where is ProKidney in terms of implementing manufacturing and documentation improvements that led to a pause in Ph3?

Acronyms: T2D: type 2 diabetes; CKD: chronic kidney disease; RCT: randomized control trial; (e)GFR: (estimated) glomerular filtration rate; LLY: Eli Lilly (covered by Geoff Meacham)

Relay: PI3Ka data update in breast cancer

RLAY US – Rating: BUY (C-1-9) | PO: 27.00 USD | Price: 11.01 USD

Investment thesis

We rate RLAY Buy on the strength of RLAY's precision oncology pipeline. We like the upside opportunities tied to: 1) RLAY-2608 - a PIK3CAi being developed for metastatic breast cancer represents the largest peak sales opportunity. We will look to key '24 clinical data to de-risk the drug profile, 2) FGFR2i - a selective agent that can dial-out toxicities associated with first-gen agents thereby improving efficacy and mitigating toxicities that hinder the patient's ability to continuously dose.

Key potential catalysts

Exhibit 20: RLAY catalyst tracker
We highlight potential catalyst events of RLAY

Category: Pipeline		
Drug	Event	Timing
RLY-2608 (PIK3CA) + fulvestrant	Updated Ph1 dose expansion data in 2L+ HER2- mBC	Mid/2H24E
Lirafugratinib (FGFR2)	Ph2 pivotal data in CCC (bile duct cancer)	2024E
Lirafugratinib (FGFR2)	Clinical dose-expansion data update in non-CCC tumors	2024E
RLY-2608 (PIK3CA) + CDK4/6 + fulvestrant	Initial Ph1 data of triplet Ph1 in 2L+ HER2- mBC	TBD / 2025E
Category: Regulatory, Corporate		
Drug or type of event	Event	Timing
Lirafugratinib (FGFR2)	Update on regulatory path for tumor agnostic label	2024E
Corporate	Disclosure of new program(s)	2024E

Source: company reports, BofA Global Research estimates. Note: PIK3CA, FGFR2: drug targets, L: line of therapy, HER2: biomarker, mBC: breast cancer.

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- On RLY-2608 (PIK3CAi), can you discuss the timing and make of the Ph1 update in metastatic breast cancer (mBC) in 2024?
- What is your expectation for the Ph1 data update of RLY-2608/fulvestrant in 2L+ mBC? Do you expect '24 update to help inform differentiation vs other PIK3CA- and AKT-targeted agents (eg alpelisib, capivasertib, inavolisib)?
- How do you plan to convey durability of efficacy for RLY-2608 in the '24 update?
- Can you discuss read-through from Roche's positive Ph3 results of inavolisib/ribo/fulvestrant study in 1L mBC? Can you talk about room to improve on efficacy and safety vs 6% grade-3 hyperglycemia reported in Roche's Ph3?
- Can you talk about the primary objectives, study population, and expected data timeline for the triplet cohort (RLY-2608/ribo/fulvestrant) in Ph1?
- What is your strategy with your follow-on PIK3CAi, RLY-5836? What is the nature of the program update you expect to provide to investors in 2024?
- On lira (FGFR2i) dose expansion data update in non-CCC tumors, can you discuss timing, nature/make of the dataset, and your expectation for the update?
- Do you expect to provide investors an update on regulatory path for lira in 2024? Pending discussions with the FDA, what is your thinking on registration bar for a tumor- or alteration- agnostic label?

- Can you talk about timing and expectation for the Ph2/pivotal data of lira in CCC? How might the data add to your pursuit for a tumor-agnostic label for lira?

- Can you give us a flavor on new program(s) to be disclosed in 2024? Given your cash runway, do you expect to advance any new programs into the clinic in '24?

Acronyms: PI3Ka/PIK3CA, FGFR2: drug target, i: inhibitor, mBC: metastatic breast cancer, L: line of therapy, CCC: cholangiocarcinoma, FDA: Food and Drug Administration.

Roivant: capital deployment, FcRn updates

ROIV US – Rating: NEUTRAL (C-2-9) | PO: 12.00 USD | Price: 11.23 USD

Investment thesis

We rate ROIV Neutral on balanced risk/reward. We like IMVT's FcRn franchise and see upside potential from positive development updates, though upside magnitude to ROIV would be reduced by non-controlling interest (ROIV owns about 55% of IMVT). Conversely, ROIV is not yet profitable and continued cash outflow could lead to the Street's discounting ROIV's valuation on cash. We are below consensus on VTAMA sales forecast driven by our more cautious view on the topical psoriasis market opportunity.

Key potential catalysts

Exhibit 21: ROIV catalyst tracker
We highlight potential catalyst events of ROIV

Category: Pipeline			
Drug	Vant	Event	Timing
Batoclimab (FcRn)	Immunovant	Ph2b initial data in chronic inflammatory demyelinating polyneuropathy	1H24
Batoclimab (FcRn)	Immunovant	Ph3 topline in myasthenia gravis	2H24
Batoclimab (FcRn)	Immunovant	Ph3 topline in thyroid eye disease	1H25
Brepocitinib (TYK2/JAK1)	Priovant	Proof-of-concept topline data in non-infectious uveitis (open-label)	1Q24
RVT-2001	Hermavant	Data from Ph1/2 trial in lower-risk myelodysplastic syndrome	1Q24
Namilumab	Kinevant	Ph2 topline data in sarcoidosis	2H24
Category: Regulatory, Coporate			
Drug		Event	Timing
IMVT-1402 (FcRn)	Immunovant	Program updates (IND clearance, disease prioritization)	2024
VTAMA (tapinarof)	Dermavant	sNDA filing in atopic dermatitis	1Q24
VTAMA	Dermavant	Commercial sales in psoriasis	2024

Source: company reports, BofA Global Research estimates. Note: IND: investigational new drug, sNDA: supplemental new drug application.

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- Can you discuss plans and timeline for capital deployment? Can you talk about sense of urgency to return capital to investors and/or doing business development deals?

- What is your current thinking about size of business development and stage/type of assets you would look for?

- Can you discuss impact on ROIV's tax rate given evolving corporate tax policies from Bermuda and implementation of Pillar Two (which calls for 15% minimum corporate tax rate)?

- Can you speak to what would be a meaningful efficacy dose-response in Period 1 of your batoclimab CIDP study? If deeper IgG relationship to clinical efficacy does not play out in CIDP and MG studies, might this push you away from chasing other FcRn's in established indications and more to novel /first mover indications?

- Competitor IgG degraders are being advanced on the hypothesis that deeper IgG reduction with FcRn inhibitors will lead to infection. What is Immunovant's assessment of data where FcRn's have pushed IgG reductions in 80% range?
- Where is IMVT with getting its '1402 IND cleared? Given there is some time between now and presumably a mid-year FDA meeting that will drive broader development plans, are you planning some sort of 2H investor update?
- Argenx's early stage partner (Elekrofi) claims to be able to formulate 600mg/ml using their microparticle technology. Do you see that as a material risk to the '1402 value proposition?
- On VTAMA, can you talk about commercial outlook in 2024? What is the company's strategy to drive volume script in the psoriasis indication?
- What is your expectation for VTAMA's gross-to-net and pace of improvement throughout 2024? When do you expect gross-to-net to reach steady state level?
- Can you discuss any high conviction calls from your early pipeline outside of the FcRn franchise?

Acronyms: CIDP: chronic inflammatory demyelinating polyneuropathy, MG: myasthenia gravis, IND: investigational new drug, FDA: US Food and Drug Administration, IgG: immunoglobulin G, FcRn: drug target.

Tarsus: Xdemvy launch revenue conversion vs. strong TRx

TARS US – Rating: BUY (C-1-9) | PO: 42.00 USD | Price: 20.25 USD

Investment thesis

We rate TARS Buy on Xdemvy launch as the first FDA approved therapy for demodex blepharitis. We forecast peak sales >$900m given strength of Xdemvy profile, large TAM and lack of competitive alternatives. We view early prescription data as supportive of a favorable launch and look to upcoming quarterly results for validation that the launch uptake is durable and reimbursement is at favorable net pricing. TARS trades at <1x EV/peak sales, and we expect launch validation to drive a share re-rating.

Key potential catalysts

Exhibit 22: TARS catalyst tracker
We highlight potential catalyst events of TARS

Drug	Event	Timing	Comment
TP-05 (Lyme disease)	Ph2a topline data (in human tick kill data)	1Q24	timing per 3Q23 earnings call. Ph1b reported Dec 22 showed exploratory ex-vivo tick killing. Focus safety/tol + tick kill (2nd endp) day 30
TP-03 (Meibomian gland disease)	Ph2 topline data - matched placebo data	mid-2024	
TP-04 (Papulopustular Rosacea)	Ph2a topline data (in human tick kill data)	1H24	timing per PC Nov 23. focus on safety/tol at week 12. 2nd outcomes include inflam and global assessment scores
VLA15 (Lyme vaccine, Pfizer/Valneva)	Ph3 Lyme prevention trial readout	1H25	PC Dec 2024. feb 2023 PFE discontinued half of participants in Ph3 due to quality issues from third party operator unnamed. Not safety related rather study conduct (good clinical practice GCP standards)
TP-03 (China partnered)	Ph3 Libra in DB and MGD data	2025	

Source: BofA Global Research, company reports

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Key questions for management

- What is your latest assessment of the tracking quality of IQVIA and Symphony as it pertains to Xdemvy scripts?

- Do you see any early bolus activity occurring with Xdemvy for DB, or do you believe this uptake trend reflects natural demand?
- Is Xdemvy tracking in-line or ahead of your expectations at this stage of the launch?
- As you enter 2024, can you help frame the Xdemvy commercial reimbursement? Probe: what % of covered lives can get drug on a contracted basis vs. having to go through medical exceptions?
- Is Lamisil for onychomycosis a good launch comp for Xdemvy? Probe: Lamisil was a 90-day non-recurring script for a toenail fungus where the treatment decision was part medical and part aesthetic. Lamisil reached blockbuster status and there (similarly) was large epidemiology limiting risk of prevalence burn.
- Can you speak to the early launch experience with Xdemvy – describe the high prescribers and if you expect growth to occur by getting those docs to write more scripts vs. expanding the number of high prescribers?
- When do you expect to generate placebo only MGD data (pbo BID vs. pbo TID)? Given that you are looking at objective measures of MGD, can you frame the level of natural variability on key endpoints that you'd expect to confirm in those studies?
- If you went down the path of running a Ph4 MGD marketing study, can you speak to how readily identifiable are demodex blepharitis patients with comorbid MGD?
- In your Ph2 rosacea study, you have talked about trying to conduct study with the goal of generating a unique label claim vs. generic ivermectin. Can you speak to what we need to see in Ph2 to get more confidence in a differentiated label path?
- On Ph2 lyme tick-kill study, can you speak to what you need to see in terms of tick-kill rate to get highly confident TP-05 can be developed as a preventative for lyme disease?

Acronyms: IQVIA: prescription database, BID: twice daily, TID: 3x daily, MGD: meibomian gland disease

Teva: 'pivot to growth' is now reaching show-me time

TEVA US – Rating: BUY (C-1-9) | PO: 13.00 USD | Price: 10.06 USD

Investment thesis

We rate TEVA Buy as we see TEVA moving towards a phase of more predictable top and bottom-line growth. We see '24 financial performance as key for validating: 1) growth of high margin brands is outpacing LOE brands leading to improved margins, 2) stabilizing global gx business: the US segment should benefit from new launches while the ex-US business has been showing low to mid-SD organic growth over last 1-2 years. We also look to pipeline updates: Uzedy launch, olanzapine LAI Ph3, TL1A Ph2 data.

Key potential catalysts

Exhibit 23: TEVA catalyst tracker
We highlight potential catalyst events of TEVA

Category: Brand Pipeline			
Drug	**Event**	**Timing**	**Additional**
Biosimilar Humira	manufacturing facility inspection	TBD	reinspection of facility anticipated following pending resubmission of BLA (est. 6-mo review period --> new BsUFA date)
Biosimilar Stelara	Est. launch based on legal settlement	2/21/2025	2nd biosimilar (1-mo later) to launch per settlement agreement
Anti-TL1A (TEV-48574)	Ph2 interim analysis	2H24	

Exhibit 23: TEVA catalyst tracker
We highlight potential catalyst events of TEVA

Category: Brand Pipeline		
Anti-IL15 (TEV-53408)	Ph1 FIH SAD/MAD HV results	2H24
Olanzapine LAI (TEV-44749)	Adult Ph3 results	2H24
ICS/SABA (TEV-56248)	Ph3 results	2H26

Category: Legal, Corporate			
Drug or type of event	**Event**	**Timing**	**Additional**
copaxone charity foundation litigation matter	jury trial begins	TBD	Per 8/14 order, trial stayed pending resolution of TEVA's interlocutory appeal

Source: BofA Global Research, company reports

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Key questions for management

- Where is Teva in terms of increasing its promotional support behind Austedo, as outlined in the May 2023 Investor Day event? When should investors start to see the benefits on those initiatives in terms of better drug adherence and optimal dose, factors that should increase annual revenue per patient?
- Can you help frame Austedo 4Q23 dynamics given pronounced sequential growth seen with this product in 4Q22?
- On Ph3 olanzapine LAI - will investors get any safety updates around PDSS, which are monitored periodically on a blinded basis, prior to 2H24 topline data update?
- What are your thoughts on how the Uzedy LAI launch is progressing? Is it tracking in-line or better or worse than your pre-launch expectations? How do you see the progression of reimbursement in '24 altering the growth trajectory?
- How are you thinking about the upcoming Ph2 TL1A data readout in 4Q24? Specifically, what sort of data outcomes would you view as a major win vs. base case expectations?
- Are you and your partner Alvotech ready for 1Q24 biosimilar manufacturing site inspection? What are the key issues for resolution?
- Can you speak to the general pricing environment in your key generic country-markets? In the US, are manufacturing shortages creating any opportunities that offer tailwind to that business?
- How do you see 2024 gross margins evolving relative to 2023? In the past, management has flagged favorable mix shifts in 2024+ aided by bigger contribution from brands so it mainly mix benefit? Do you expect quarterly volatility seen in 2023 to repeat?
- On capital allocation, do you see an opportunity for some opportunistic and structured BD deals in 2024, or do you believe 2025+ is a more realistic timeframe to start thinking about Teva as being active in the M&A market?
- Can you remind us, are there any 2024 litigation events investors should be mindful in terms of trial events? Where is Teva in the Copaxone PAP litigation?

Acronyms: LAI: long acting injectable, TL1A: drug target, gx: generic, LOE: loss of exclusivity, PDSS: post-injection delirium sedation syndrome, PAP: patient assistance program

Vaxcyte: focus on VAX-31 Ph2 adult, pot'l category killer

PCVX US – Rating: BUY (C-1-9) | PO: 80.00 USD | Price: 62.80 USD

Investment thesis

We like PCVX for three key reasons: 1) Pneumococcal conjugate vaccine is the largest vaccine market with >$7bn global sales, where PCVX's VAX-24 has the potential to offer the broadest coverage against disease causing pathogens vs. key frontrunners in PCV pipeline, 2) Vaxcyte's novel technology may allow the company to overcome protein carrier immunosuppression, which is an issue for conventional approaches used by major players, 3) VAX-24's early clinical data support a best-in-class profile.

Key potential catalysts

Exhibit 24: PCVX catalyst tracker
We highlight potential catalyst events of PCVX

Category: Pipeline

Drug	Event	Timing	Comment
GSK/Affinivax (AFX3772)	Initiate Ph3 adult for 24 valent PCV	1H24	timing per 1Q23 transcript "beginning of next year"
VAX-31	Topline adult data	2H24	Ph1/2: ~1k adults 50+, 3 doses single injection. Ph1 evaluating safety in 64 adults, then progress to Ph2 (~936 adults)
GSK/Affinivax (AFX3772)	Topline Ph2 PCV24 pediatric readout	YE24	est based on ID day June 2023, 1Q23 transcript, paused infant program aim to restart asap
VAX-24	Topline Ph2 data for infants primary 3 dose series	2025	
VAX-24	Ph3 PCV topline NI data for adults	2025	

Category: Regulatory

Drug	Event	Timing	Comment
VAX-24	Regulatory interactions to inform CMC strategy	1Q24	

Source: company reports; CT.gov; BofA Research

BofA GLOBAL RESEARCH

Key questions for management

- Can you discuss the consistency and any notable differences you saw with VAX-31 in your rabbit model study versus VAX-24?
- Do you look at prior data generated with VAX-24 mixed dose as validation of limited protein carrier suppression or safety?
- Ahead of VAX-24 Ph2 adult, a lot of the focus was on showing non-inferiority on most shared strains with room for a couple misses on less pathogenic strains and a focus on achieving solid point estimates that could benefit from tighter confidence intervals in a larger Ph3. Should investors look at VAX-31 data similarly?
- Can you speak to your deal with Lonza to manufacture VAX-24 and possibly VAX-31. How much do you believe your behind-the-scenes efforts have de-risked your ability to manufacture vaccines at scale?
- Can you speak to Lonza deal in terms of how you preserved strategic flexibility, in the event larger pharma wanted to subsume Vaxcyte and do manufacturing differently? Probe: ability to seek out manufacturing redundancy
- Based on Vaxcyte's current manufacturing readiness efforts, how much of the pediatric market would you expect to be able to supply in years 1-2 post-launch?
- What are your observations of current market developments and how it reads onto your thesis for VAX-24? Are you surprised to see Merck's Vaxneuvance capture ~30% of the pediatric market so quickly?
- Do you expect the market to remain static in terms of ACIP's recommendations, meaning no preferential recommendation? Do you believe VAX-24 is enough of an increase in coverage to support a preferential recommendation?

- On VAX-24 trial execution, how are your Ph3 adult and Ph2 pediatric trials progressing in terms of enrollment and execution, to the extent you can speak to those considerations?

- In the past, you discussed potentially incorporating superiority measures in your Ph3 adult trial. Are you looking at showing superiority vs. PCV20 in your Ph3 trial?

Acronyms: PCV: pneumococcal vaccine; NI: non-inferiority; ACIP: advisory committee on immunization practices.

Viatris: pivot to specialty brand focus

VTRS US – Rating: UNDERPERFORM (B-3-7) | PO: 9.00 USD | Price: 10.83 USD

Investment thesis

We rate VTRS Underperform as VTRS embarks on a slow, multi-year transition phase pivoting to a specialty brand business. While VTRS will have >$2.5bn in divestiture proceeds, VTRS is committed to returning 50% of FCF to shareholders via dividends/buybacks, the size of M&A capacity may be constrained for some time. Some of our concerns near-term are around lack of visibility on pro forma (RemainCo) earnings power (EBITDA) and VTRS' ability to make value accretive M&A decisions (limited track record).

Key potential catalysts

Exhibit 25: VTRS catalyst tracker
We highlight potential catalyst events of VTRS

Category: Pipeline			
Drug	**Event**	**Timing**	**Additional**
MR-148 (dry eye disease)	Est topline data from first Ph3 trial	2024	
Category: Regulatory			
Drug	**Event**	**Timing**	**Additional**
Nyxol (Mydriasis, Presbyopia and Night Vision Disturbances)	Est approval - FDA target action date	9/28/2023	
GA Depot	Est approval - FDA target action date	3/8/2024	once-monthly injection for relapsing forms of multiple sclerosis
Glatiramer Once Monthly	Est launch	2024	
Meloxicam Fast Acting (opioid sparing)	Est launch	2025	
Xulane Low Dose	Est launch	2026	
Onabotulinumtoxin A (Botox)	Est launch	2026	
Effexor (generalized anxiety disorder)	Est launch	2027	
Category: Legal, Corporate, commercial			
Drug or type of event	**Event**	**Timing**	**Additional**
IPO	Biocon Biologics IPO in India	4Q23	IPO post-sale of Viatris' biosim business (12.9% stake in BBL)

Source: BofA Global Research, company reports

BofA GLOBAL RESEARCH

Key questions for management

- Does the company have any added clarity on when its divestiture transactions will close vs. prior stated 1H24?

- Can you talk about the prior communicated R&D step-up on a pre- and post-divestiture basis, which implies further R&D step-up in 2024. Is that still the plan?

- Can you speak to some of the elements that were expected to pressure 2H23 gross margins and how those have evolved heading into 2024? On the 3Q23 call, management indicated it was managing inflationary headwinds better than expected.

- On an ex-divestiture basis, can you highlight growth drivers in 2024-28 +3% sales growth CAGR outlook? How much of that growth outlook is predicated on the success of pipeline products?
- What do you foresee as important product-related catalysts in 2024? Probe: Ph3 MR148 dry eye data, GA-depot approval/launch, or other pipeline readouts?
- Can you discuss current market dynamics in China and whether stricter enforcement of VBP through the country's anti-corruption policy is having any residual impact on your business?
- Can you speak to the US generic market environment heading into 2024, both in terms of a) your new product offering, b) general pricing environment, and c) Viatris' ability to capture added value from competitor supply disruptions?
- Can you help investors think about M&A in 2024 in terms of 1) size, 2) profile of targets – development stage vs. commercial stage, 3) one large deal vs. multiple smaller deals?
- Is Viatris finished divesting non-core assets, or could the company foresee further divestitures to pivot the company to longer duration assets?
- As Viatris moves toward being a specialty brand player, does the company plan to provide product-level detail for new product launches (like peers) to provide visibility on the performance of those new branded products?

Acronyms: GA: Glatiramer Acetate

Xenon: early pipeline + pivotal MDD program start

XENE US – Rating: BUY (C-1-9) | PO: 56.00 USD | Price: 46.06 USD

Investment thesis

We rate XENE Buy and like the company based on 1) 1101's competitive product profile (strong early anti-seizure data + simplicity of dosing) positioning the drug as potential blockbuster ASM, 2) upside optionality with potential '1101 label expansion (PGTCS and/or MDD dual benefit), and 3) '1101 differentiated product profile including ease of dosing and lack of titration will help position its adoption in competitive epilepsy market.

Key potential catalysts

Exhibit 26: XENE Catalyst Tracker
We highlight potential catalyst events of XENE

Category: Pipeline			
Drug	**Event**	**Timing**	**Comment**
BHV-7000 (BHVN)	Initiation of pivotal FOS trials	1H24	ER version assessing 25/50/75mg Q1D
XEN1101	Mt. Sinai IST Ph2 in MDD data expected	1H24	IST trial expected to read out after X-NOVA
ETX-123 (ELYM)	Initiation of Ph1 in FOS	1H24	
XEN1101	Est. topline from Ph3 FOS X-TOLE2	1H/mid-25	est. enrollment completion 2H24; data 6-8mo post-last pt enrollment
XEN1101	Ph3 X-ACKT in PGTCS topline expected	1H/mid-25	Read-out determines filing (sNDA)
XEN1101	Est. topline from Ph3 FOS X-TOLE3	2H25	Not needed for NDA

Source: Company reports; BofA Research

BofA GLOBAL RESEARCH

Key questions for management

- What is management's latest thinking regarding XEN1101 development for MDD? Probe: thoughts on dosing, number of pivotal trials, and go-it-alone on development?

- Do you believe epilepsy and depression pricing and contracting are 'close enough' to market both indications considering and Medicaid best pricing considerations?
- Where would you see '1101 fitting into the MDD treatment landscape?
- Will the ongoing Ph2 '1101 study (Mt Sinai study) provide any read-across or impact your go-forward decision making with the MDD program?
- Do you see any overlap between the likely prescribers of '1101 in MDD vs. FOS epilepsy?
- Have you tested in market research the lift you'd foresee in epilepsy usage if '1101 was approved for MDD? Furthermore, would you foresee that being a competitive advantage (in FOS) having an established mood benefit relative to other Kv modulators?
- In 2024, do you expect to disclose any new clinical data for '1101 in MDD or offer any updated data/disclosures around earlier stage pipeline programs?
- Can you frame the in-play market for XEN1101 in FOS in terms of patient numbers and whether you see use concentrated in any particular line-of-therapy?
- Do you see ex-US markets as permissible to incremental innovation in epilepsy, or will penetration in those markets get more difficult? Probe: what country-markets are FOS brands able to derive most of their ex-US sales?
- Beyond Xenon's hatch-waxman regulatory exclusivity, does the company expect to have any later dated patents beyond the polymorph and method-of-use (food effect) patents?

Acronyms: ASM: anti-seizure medication; PGTCS: primary genberalized tonic clonic seizures; FOS: focal onset seizures; MDD: major depressive disorder; Kv: potassium channel; (s)NDA: (supplemental) New Drug Application;

Exhibit 27: Stocks mentioned in this report
Ratings and stock prices of stock tickers mentioned in this report

Ticker	Company name	Rating	Stock price	Ticker	Company name	Rating	Stock price
ACLX	Arcellx Inc	C-1-9	55.76	ITCI	Intra-Cellular Therapies Inc	C-1-9	71.81
ALKS	Alkermes PLC	B-2-9	27.76	JAZZ	Jazz Pharmaceuticals PLC	B-1-9	122.83
AMPH	Amphastar Pharmaceuticals Inc	B-2-9	61.93	LYRA	Lyra Therapeutics Inc	C-1-9	5.18
ARWR	Arrowhead Pharmaceuticals Inc	C-1-9	30.85	OCS	Oculis Holding AG	C-1-9	11.23
AXSM	Axsome Therapeutics Inc	C-2-9	79.61	OGN	Organon & Co	B-3-7	14.43
BHC	Bausch Health Cos Inc	C-3-9	8.08	PCVX	Vaxcyte Inc	C-1-9	63.15
BLUE	Bluebird Bio Inc	C-1-9	1.40	PROK	ProKidney Corp	C-2-9	1.77
EXEL	Exelixis Inc	B-1-9	24.14	RLAY	Relay Therapeutics Inc	C-1-9	11.10
FGEN	FibroGen Inc	C-3-9	0.90	ROIV	Roivant Sciences Ltd	C-2-9	11.20
GLPG	Galapagos NV	B-2-9	40.90	TARS	Tarsus Pharmaceuticals Inc	C-1-9	20.15
HRMY	Harmony Biosciences Holdings I	C-3-9	32.54	TEVA	Teva Pharmaceutical Industries	C-1-9	10.45
IMVT	Immunovant Inc	C-1-9	42.40	VTRS	Viatris Inc	B-3-7	10.85
IONS	Ionis Pharmaceuticals Inc	B-1-9	50.00	XENE	Xenon Pharmaceuticals Inc	C-1-9	46.00

Source: BofA Global research, Bloomberg

BofA GLOBAL RESEARCH

Investment Rationale

Alkermes

We are Neutral on ALKS on balanced risk/reward. We believe ALKS' product portfolio is relatively mature with minimal opportunities for upside to consensus: 1) '27 Vivitrol LOE

limits the likelihood of a material stock re-rating, 2) we expect Lybalvi (key launch) to have an outsized contribution to ALKS growth, but we see limited upside to cons peak sale, 3) on orexin (key pipe), we believe our risk-adj. est. is priced into stock and key de-risking events (own Ph2 data) are likely to occur 2025+.

Amphastar Pharmaceuticals

We rate AMPH Neutral on balanced risk-reward. We believe the bar for Amphastar to re-rate is high at current trading levels. From a risk/reward perspective, downside risks include 1) competitor supply dislocations that have been more recent tailwinds turn into headwinds, 2) pipeline visibility is low. Potential upside could come from the Baqsimi (glucagon rescue) launch which offers more predictable (and visible) growth driver that should help expand company margins in the out-years.

Arcellx, Inc.

We rate Arcellx Buy and like the company based on 1) encouraging Ph1 clinical data for anito-cel (ddBCMA) which looks competitive relative to more advanced players in the relapsed/refractory multiple myeloma CAR-T space, 2) 2024 data readouts are material catalysts with potential to de-risk anito-cel, and 3) upside optionality with SparX approach (we do not currently include SparX programs [early stage] in model).

Arrowhead Pharmaceuticals

We rate ARWR a Buy. We expect ARWR to deliver P&L leverage driven by the rollout of new products that are either wholly owned or partnered (future royalty streams). Our thesis is based on favorable risk/reward in front of several key 2024 catalysts including 1) topline data from Ph3 ARO-APOC3 in FCS in 2Q24 - data could facilitate an NDA leading to ARWR's first approved product, 2) Ph1/2 biomarker data from respiratory assets

Axsome Therapeutics

We are Neutral-rated on AXSM stock based on our view that there is a balanced risk/reward where Axsome's Auvelity launch as a treatment for MDD is tracking below consensus estimates and we see the company's primary care products are relatively undifferentiated (depression, narcolepsy, migraine). On the flip side, we see these negatives as being counter-balanced by likely positive Ph3 updates for AXS-12 (narcolepsy) and Auvelity third Alzheimer's agitation readout (1H24).

Bausch Health Cos Inc

We rate BHC an Underperform as we see challenges to value creation in proposed separation of the B&L (eye health) and RemainCo (pharma): 1) RemainCo - key risk is multiple compression as a stand-alone business as the company is highly levered to Xifaxan, which is at risk of earlier than expected (2028) LOE and we see very limited equity value in a >5x levered RemainCo, 2) B&L spin - execution risk

bluebird bio

We rate BLUE Buy. We like the peak sales potential for BLUE's Lyfgenia as a gene therapy for Sickle Cell, a large market for a curative treatment. We believe Lyfgenia's data are competitive with the only other marketed GT for SCD and we believe the company's prior launch of Zynteglo for beta thal has established commercial infrastructure that can be leveraged by Lyfgenia. We see Bluebird as funded to sustain operations to 2025 and we view upcoming quarterly results as key catalysts for the stock

Exelixis
We rate EXEL Buy as we believe the company provides favorable risk/reward on resolution of cabo IP dispute, continued progression of pipeline portfolio, and possible cabo label expansion opportunities. In 2024, we look to data updates on cabo prostate and mid-to-late-stage programs ie zanza and XB002 (TF-ADC).

Harmony Biosciences
We rate HRMY Underperform on lack of high impact catalysts and a challenging path to addressing a '29 Wakix LOE on balanced risk-reward. At this juncture we would have preferred to see the company more active on BD to diversify its product portfolio. Our model is highly sensitive to LOE assumption, assuming Wakix can exceed $1bn in '29+ revenue, though we do not believe it is prudent for investors to assign value to terminal polymorph patent (susceptible to non-infringing alternative polymorphs)

Immunovant, Inc.
We rate IMVT a Buy on upside potential for IMVT's clinical-stage FcRn portfolio. Catalysts include: 1) clinical data for TED and Graves', which are FcRn white spaces, 2) broad applicability in autoimmune diseases that provide further upside beyond crowded markets (MG, CIDP). Keys to the IMVT thesis: 1) broad FcRn commercial opportunity-set, 2) ability of IMVT to differentiate on dosing convenience and potential efficacy differentiation with next-gen drug possessing a favorable therapeutic index.

Intra-Cellular Therapies
We are Buy-rated on ITCI based on peak sales potential for Caplyta in approved and development-stage add-on indications. We believe the commercial opportunity for Caplyta in bipolar depression is substantial given limited approved therapies in this under-penetrated market. We are encouraged by recent MDD competitor launches and we view the 1H24 Ph3 updates for Caplyta in MDD as a meaningful upside opportunity.

Ionis
We rate IONS Buy on favorable stock setup ahead of catalyst-rich path in 2024-1H25. There will be multiple mid-/late-stage clinical readouts that can increase likelihood of success for four assets with $300m-1bn nominal peak revenue estimates (Wainua, donidalorsen, olezarsen, ION582). Approval of Wainua in polyneuropathy with a clean label indicates ION's improved antisense (ASO) platform can mitigate legacy safety issues, effectively validating the safety profile of IONS' broader pipeline.

Jazz Pharmaceuticals
We rate JAZZ a Buy as the company is positioned to shed a long-lived "oxybate overhang" with the recent launch of a Xyrem authorized generic. In our view, strength in '23 numbers bridging to '25 targets is key to improving investor confidence in growth story and we're encouraged to see Epidiolex (seizures) performance uptick. Last, we believe Jazz's emerging pipeline (essential tremor, Zanidatimab programs) is essentially free at current valuation.

Lyra Therapeutics
We are buy rated on LYRA for three reasons: 1) LYR-210, a steroid-eluting implant, has the potential to offer six-months of durable efficacy, 2) steroid incorporated in LYR-210 is a validated treatment for CRS, and 3) LYR-220 offers further expansion into the post-surgical CRS setting, 4) Lyra is attractively valued relative to massive addressable market.

Oculis Holding AG
We rate Oculis Buy on key clinical-stage asset's potential to address unmet need in ophthalmology indications. Upcoming data readouts are expected to further de-risk novel pipeline assets, particularly OCS-01 for diabetic macular edema (full 52-wk data expected in 2H25) and post-ocular surgery related pain and/or inflammation (PC date: July 2024). While there is greater clinical risk associated with earlier stage Ph2 dry eye disease asset OCS-02, we believe there remains an unmet need.

Organon
We rate OGN Underperform for 3 key reasons: 1) OGN's transformation via M&A has been slow to materialize and the company is relatively catalyst-light over next 12-18 mos. 2) while OGN's key growth brand, Nexplanon (long-acting reversible contraceptive) may be able to deliver on management's DD growth target, we don't foresee meaningful upward revisions relative to consensus forecasts for the product. 3) EBITDA trending to low-SD declines annually.

ProKidney Corp
We rate PROK Neutral based on a balanced risk/reward on lack of meaningful de-risking near-term catalysts. REACT's Ph2 bilateral dosing data in 2024 could offer insight on efficacy attributable to bilateral dosing (same dosing as registrational Ph3). However, we believe stock upside is limited by the uncertainty of key de-risking catalyst, REACT Ph3 topline in CKD patients, and 1H24 detailed data of GLP-1 on kidney function, which could begin to inform impact on REACT's market opportunity.

Relay Therapeutics
We rate RLAY Buy on the strength of RLAY's precision oncology pipeline. We like the upside opportunities tied to: 1) RLAY-2608 - a PIK3CAi being developed for metastatic breast cancer represents the largest peak sales opportunity. We will look to key '24 clinical data to de-risk the drug profile, 2) FGFR2i - a selective agent that can dial-out toxicities associated with first-gen agents thereby improving efficacy and mitigating toxicities that hinder the patient's ability to continuously dose.

Roivant
We rate ROIV Neutral on balanced risk/reward. We like IMVT's FcRn franchise and see upside potential from positive development updates, though upside magnitude to ROIV would be reduced by non-controlling interest (ROIV owns about 55% of IMVT). Conversely, ROIV is not yet profitable and continued cash outflow could lead to the Street's discounting ROIV's valuation on cash. We are below consensus on VTAMA sales forecast driven by our more cautious view on the topical psoriasis market opportunity.

Tarsus Pharmaceuticals
We rate TARS Buy on Xdemvy launch as the first FDA approved therapy for demodex blepharitis. We forecast peak sales >$900m given strength of Xdemvy profile, large TAM and lack of competitive alternatives. We view early prescription data as supportive of a favorable launch and look to upcoming quarterly results for validation that the launch uptake is durable and reimbursement is at favorable net pricing. TARS trades at <1x EV/peak sales, and we expect launch validation to drive a share re-rating

Teva Pharmaceuticals
We rate TEVA Buy as we see TEVA moving towards a phase of more predictable top and bottom-line growth. We see '24 financial performance as key for validating: 1) growth of high margin brands is outpacing LOE brands leading to improved margins, 2) stabilizing global gx business: the US segment should benefit from new launches while the ex-US business has been showing low to mid-SD organic growth over last 1-2 years. We also look to pipeline updates: Uzedy launch, olanzapine LAI Ph3, TL1A Ph2 data

Viatris Inc.
We rate VTRS Underperform as VTRS embarks on a slow, multi-year transition phase pivoting to a specialty brand business. While VTRS will have >$2.5bn in divestiture proceeds, VTRS is committed to returning 50% of FCF to shareholders via dividends/buybacks, the size of M&A capacity may be constrained for some time. Some of our concerns near-term are around lack of visibility on pro forma (RemainCo) earnings power (EBITDA), VTRS' ability to make value accretive M&A decisions (limited track record)

Price objective basis & risk

Alkermes (ALKS)
Our $29 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 Vivitrol or Aristada 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

Arcellx, Inc. (ACLX)
Our $65 per share price objective is based on a risk-adjusted, sum-of-the-parts DCF. We assume 1) a discount rate of 10% for a pivotal clinical-stage company, 2) a Probability of Success of 80% for ddBCMA program given that it will soon enter pivotal testing. 3) terminal value with terminal growth rate of 0% to reflect a durable market position for ddBCMA given high capital barriers to competitor entry

Downside risks: 1) ddBCMA trial failure, 2) worse-than-expected ddBCMA clinical data

Upside risks: 1) better-than-expected ddBCMA clinical data and 2) acquisition at a premium.

Arrowhead Pharmaceuticals (ARWR)
Our $37 price objective (PO) is based on a risk-adjusted DCF analysis which assumes 1) risk-adjustment to pipeline programs based on abundance and strength of clinical data with <30% POS assigned to early-stage programs vs >50% POS for mid-to-late stage assets, 2) the biggest value drivers in our DCF valuation are ARO-APOC3 for FCS and sHTG (48%), ARO-AAT (31%) and pipeline programs (59%), 3) we assume 10% discount rate.

Downside risks to our PO: 1) failure of wholly-owned late stage clinical trials, 2) competitor clinical data outperform vs our expectation, 3) failure to partner programs for financing requirements.

Upside potential to our PO: 1) delay to regulatory approval of competitors products, 2) failure of competitors' clinical trials, 3) better-than-expected performance of wholly-owned and/or pipeline assets.

Axsome Therapeutics (AXSM)
Our $80 price objective (PO) is based on a risk-adjusted SOTP analysis. Key assumptions: 1) risk-adjusted sales climb to $1.4bn by 2027E, 2) no terminal value as we forecast sales through the expected drug LOE, 3) 9.5% discount rate. For Sunosi in EDS, we model $335m in peak sales (commercial, fully derisked). Our AXS-05 (Auvelity) peak sales for depression are $1.2bn. For AXS-05 in Alzheimer's agitation, we model $1.7bn 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 $210m. For AXS-14 in fibromyalgia, we model $180m 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 $2.5bn by '25E as the product maintains a market leading position in 2L RCC and HCC segments, with modest 1L market share for RCC (we model 2L+ mCRPC at 55% likelihood of success adjustment), 2) EXEL's operating margin expands meaningfully from '19 to '25E and beyond, as the company gradually

comes out of heavy investment phase on Cabo franchise in out-years (we assume operating margin expands to c56% by '25E), 3) exclusivity for Cabo though January 2030E, 4) 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.

FibroGen Inc. (FGEN)
Our $0.50 PO is based on risk-adj DCF. We assume: (1) risk-adjustment (% POS) to roxa programs include approx. blended 98% for CKD (ex-US) and 45% for CIA (chemotherapy). (2) 11% discount rate, consistent with our other SMID Biotech coverage, and no terminal value as we forecast through the end of roxa patent life (2033). We risk-adjust roxa cashflows starting in 2026 based on ongoing patent litigation and potential generic entry in 2026-2028 timeframe.

Upside risks to our PO: (1) Roxa CKD wins appeals and LOE to 30+ (2) roxa labeling for cardiovascular risk/cancer is better than our expectations, (3) competitor data readouts show weaker efficacy/safety profile relative to roxa.

Downside risks to our PO: (1) Roxa ex-US launch underperforms vs. our projections due to low demand and/or lower net pricing, (2) competitor data is superior to roxa on efficacy/safety.

Galapagos (GLPG)
Our $44 price objective (PO) is based on a risk-adjusted DCF analysis. We assume the following: (1) Jyseleca forecast for approved indications in the form of royalties, (2) modest pipeline contribution, (3) 9.5% discount rate and 0% terminal growth rate.

Downside risk to our PO: (1) failure of clinical trials, (2) worse-than-expected filgotinib safety profile and/or label.

Upside risks to our PO: (1) acquisition at a premium, (2) higher-than-expected filgotinib sales

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.

Immunovant, Inc. (IMVT)
Our $51 price objective (PO) is based on a risk-adjusted sum-of-the-parts analysis. 1) batoclimab launches in 2025 and total FcRn nominal sales reach $4.5bn by 2035e, 2) 75% POS for Myasthenia Gravis and Thyroid Eye Disease indications, 2) 65% POS for CIDP, 3) 50% POS for Graves' Disease, 4) no terminal value beyond batoclimab's 2040 LOE and 1402's 2043 LOE, 5) 11% discount rate.

Downside risks to our PO: 1) inability for batoclimab/1401 to adequately mitigate LDL safety signal in clinical trials, 2) less competitive 1402 product profile, and 3) failure to demonstrate efficacy in future clinical trials.

Upside risks to our PO:1) better than expected outcomes in MG, CIDP, and TED clinical trials, 2) clinical success in trials leading to a steeper market ramp and/or penetration.

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

Ionis (IONS)
Our $62 price objective (PO) is based on a risk-adjusted DCF analysis, in which we assume: (1) risk-adjustment to pipeline programs based on abundance and strength of supportive clinical data, with <30% POS generally assigned to early-stage programs vs. >50% POS for mid-to-late stage assets, (2) the biggest value drivers in our DCF valuation are Wainua, Olezarsen, and Spinraza, (3) we assign marginal value to more speculative, early-stage program, (4) we assume 9.5% discount rate and 0% terminal growth rate.

Downside risks to our PO: 1) key product sales underperform relative to our forecast, 2) failure of key clinical trials, 3) competitor clinical data outperform vs. our expectation.

Upside risks to our PO: 1) delay to regulatory approval of competitors' drug products, 2) failure of competitors' clinical trials, 3) better than expected clinical data readouts

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.

Lyra Therapeutics (LYRA)
Our $12 price objective (PO) is based on a risk-adjusted sum-of-the-parts NPV model of LYR-210 and LYR-220. Key assumptions: 1) we forecast cash flows through 2037 patent life of LYR-210, 2) 70% likelihood to market for LYR-210 and 70% for LYR-220, 3) LYR-

210 and LYR-220 to generate $160m and $30m in 2029E risk-adjusted sales, respectively, 4) discount rate of 12% and no terminal value.

Downside risks to our PO are: (1) failure of LYR-210 or LYR-220 to show desired results in clinical trials, (2) slower-than-expected commercial uptake of LYR-210 or LYR-220, (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 LYR-210 or LYR-220, (2) acquisition at a premium price.

Oculis Holding AG (OCS)
Our $21 price objective is based on sum of the parts (SOTP) analysis. Key assumptions: 1) we forecast cash flow for each near-term pipeline asset through 2035E and 2) discount rate of 9%.

Downside risks are: 1) clinical-stage assets fail to demonstrate stat sig benefit on primary endpoints, 2) slower-than-expected uptake of OCS-01 in post-ocular surgery and/or DME (diabetic macular edema) and OCS-02 in DED (dry eye disease), and 3) higher than expected R&D expenses (impacting cash runway).

Upside drivers are: 1) 2H25 DME Ph3 stage 2 demonstrates that loading dose confers improved efficacy profile, 2) 3Q23 Ph3 data readout of OCS-01 in post-ocular surgery pain/inflammation clears path to est 2025 launch, and 3) positive proof of concept data for OCS-01 Ph2 CME (cystoid macular edema) and OCS-05 Ph2 AON (acute optic neuritis)

Organon (OGN)
Our $12 PO for OGN is based on 5.75x 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.

ProKidney Corp (PROK)
Our $2-per-share price objective (PO) is based on a risk-adjusted DCF. We assume (1) a discount rate of 12%, consistent with the rate we use for biotech peers with early clinical data and ongoing late-stage clinical testing, (2) value contribution of $2/share and $0/share for REACT and cash, respectively, (3) a POS of 45% for the REACT program given availability of open label interim clinical proof-of-concept data and currently in Ph3 registrational development, (4) REACT contribution through 2040 - we model a biologic-like product life cycle, although we concede that conventional generics are unlikely and the bigger threat to tail value comes from innovative cell therapy competitor approaches, (5) a terminal value (TV) growth rate of 0%, reflecting long-term value generation of a cell therapy company without the expectation for conventional generics given complex nature of modality.

Downside risks: 1) REACT Ph3 trial failure, 2) REACT fails to demonstrate improved renal function and renal outcomes to justify the high price associated with cell therapy, 3) procedural safety events, or theoretical cell therapy related safety events occurring at unacceptable levels in subsequent data readouts

Upside risks: 1) better-than-expected REACT Ph3 CKD data in early 2025, 2) better-than-expected Ph2 data in the 2023-2024 time frame, 3) potential acquisition at a premium.

Relay Therapeutics (RLAY)
Our PO of $27 is based on a risk-adjusted, SOTP DCF. We assume: 1) a discount rate of 12% for a Ph2 clinical-stage company, 2) likelihood of success (POS) of 5-65% for the FGFR2 program across multiple tumor types, 3) POS of 30% for the PIK3CA program in HER2- breast cancer, 4) 10% POS for platform pipeline, 5) loss of exclusivities of lead programs in the 2040-41E timeframe.

Downside risks: 1) clinical trial failure, 2) FGFR2i or PIK3CAi fails to show differentiated clinical profile vs existing therapies, 3) dilutive equity raise

Upside risks: 1) clinical advancement of FGFR2i or PIK3CAi program, 2) FGFR2i or PIK3CAi finds utility in additional tumor indications, 3) acquisition at a premium

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 $42 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 $13 price objective (PO) is based on a '24E EV/EBITDA multiple of 8x, which is slightly above the peer group avg of 6.7x reflecting key new product launches following resolution of opioid litigation. Our valuation factors in $4.7bn in contingent legal liabilities related to opioid litigation resolution ($3.2bn) and generic price fixing ($1.5bn). The $3.2bn estimate for present value of opioid resolution cost is based on $4.35bn gross liability, with a 13-year payout.

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

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

Vaxcyte Inc (PCVX)
Our $80 price objective (PO) is based on a risk-adjusted DCF analysis. Key assumptions: 1) we forecast cash flows through 2034, with VAX-24 launching in 2026E, 2) we see 55% likelihood to market for VAX-24, 3) we expect VAX-24 to generate $4bn in nominal sales by 2034E, 4) we apply a discount rate of 11.5% and +1% terminal growth rate.
Downside risks to our PO are (1) failure of VAX-24 to show desired results in clinical trials, (2) slower-than-expected commercial uptake, (3) potential dilutive cash raises to develop and commercialize the drug.
Upside risks to our PO are (1) better-than-expected clinical data and/or commercial uptake of VAX-24, (2) acquisition at a premium price.

Viatris Inc. (VTRS)
Our $9 price objective (PO) is based on 5.25x 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).

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

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

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

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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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