BofA SECURITIES

US Biopharmaceuticals

Upcoming launches in the spotlight: 4Q23 SMid Biotech Preview

Price Objective Change

08 February 2024

Equity
United States
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Greg Harrison, CFA
Research Analyst
BofAS
+1 646 855 1476
gregory.harrison@bofa.com

Mary Kate Davis
Research Analyst
BofAS
+1 646 855 1778
mary.k.davis@bofa.com

Focused on clinical development and regulatory timelines

Regulatory and late-stage updates from companies in our coverage remain top of mind going into 4Q23 earnings. As we discussed in our Year Ahead 2024 (see report), we anticipate outperformance from companies making the transition from clinical to commercial stage as well as those with transformational regulatory events. With key regulatory events on deck for Travere (Filspari sNDA filing 1Q24), Liquidia (Yutrepia launch approaching), Rocket (KRESLADI PDUFA March 31), and BridgeBio (acoramidis PDUFA November 29), we look for discussion of clinical and commercial strategy to set expectations for these opportunities. We maintain all ratings; PO changes in Exhibit 1.

Travere: Looking to hit regulatory milestones

Along with a Filspari launch update (see our preannouncement note), we expect focus to be on key regulatory events for the sparsentan IgAN program in the update, including the anticipated sNDA filing (1Q24) and the CHMP decision (1Q24). We also look for details on the ongoing phase 3 pegtibatinase trial (data 2026). Maintain Buy, PO $23.

Liquidia: Regulatory clarity for Yutrepia launch in focus

As we wait for the final FDA decision regarding the approval of Yutrepia in PH-ILD (see report) and the Tyvaso loss of exclusivity in PH-ILD (March 31), we look for Liquidia to review the path to the launch of Yutrepia in PAH and discuss potential launch plans. We think the company remains in a strong place to launch Yutrepia upon full approval and look for the lifting of the injunction to allow for a PAH launch. We also expect the company to give an update on the L606 program after recent encouraging data (see report). Maintain Buy, PO $15.

Rocket: Ready for commercial transition

Ahead of Rocket's first PDUFA for the approval of Kresladi in LAD-1 (March 31), we look for the 4Q23 release to give a detailed overview of ongoing late-stage clinical development of the company's gene therapy pipeline and plans for the initial commercial launch. Focus remains on the ongoing Danon program, and we look for a potential enrollment update and expect interim data in 2024. We also expect status updates from additional clinical programs including PKD (phase 2 initiation upcoming) and FA (BLA filing 1H24), along with the earlier stage programs. Maintain Buy PO $37.

BridgeBio: NDA acceptance puts eyes on Nov. 29 PDUFA

We look for BridgeBio's 4Q23 release to give a detailed overview of the company's broad pipeline and a financial update. After the recent NDA acceptance (see report) and in anticipation of Alnylam's HELIOS-B update, we expect focus to remain on the ATTR-CM acoramidis anticipated approval and launch (Nov. 29 PDUFA). While we look for the future launch of silencers to evaluate the impact on the ATTR-CM market, we think the HELIOS-B readout is important to the space and see room for multiple treatment strategies in the ATTR market. Beyond acoramidis, we also expect the 4Q23 update to detail anticipated clinical development progress including achondroplasia phase 3 enrollment completion (1H24). Maintain Buy, PO $52.

See our expectations for our coverage and catalyst calendar (Exhibit 2) below:

Exhibit 1: Coverage PO changes
We detail our PO changes beginning on page 2 for IgM Bio, Tyra, and BioXcel.

Company	Old PO	New PO
IGMS	$9.50	$15
TYRA	$15	$20
UTHR	$178	$180
BTAI	$9	$8

Source: BofA Global Research

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IgAN: IgA nephropathy
CHMP: Committee for Medicinal Products for Human Use
PH-ILD: pulmonary hypertension and interstitial lung disease
PAH: pulmonary arterial hypertension
PDUFA: Prescription Drug User Fee Act
FA: Fanconi anemia
PKD: pyruvate kinase deficiency
NDA: New Drug Application
BLA: Biologics License Application
LAD-1: leukocyte adhesion deficiency type 1
ATTR-CM: transthyretin amyloidosis cardiomyopathy

Refer to important disclosures on page 12 to 14. Analyst Certification on page 10. Price Objective Basis/Risk on page 7.
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4Q23 Earnings Preview

Agios: ENERGIZE-T data set to support label expansion

AGIO US – Rating: BUY (C-1-9) | PO: 49.00 USD | Price: 23.73 USD

We expect Agios to give a launch update for Pyrukynd in PKD (4Q23 BofA $7.8M vs. $7.9M cons.) though the focus will likely be on the ongoing pivotal programs which are designed to support label expansion into larger indications, thalassemia and sickle cell disease. After positive ENERGIZE data in non-transfusion dependent thalassemia (see report), we also look for management to discuss the upcoming ENERGIZE-T data readout (mid-24) which is evaluating mitapivat in transfusion dependent thalassemia (TDT). If data from ENERGIZE-T is supportive as anticipated, Agios plans to file for the approval of mitapivat in thalassemia by YE24. We currently model risk-adj. peak sales of $776M (75% PoS) for thalassemia. Similar to the company's recent conference update (see report), we also expect management to discuss other clinical programs ongoing including the phase 3 RISE-UP trials in SCD and phase 1 study of the PAH stabilizer in PKU (dosing 1H24). Building upon phase 2a data of AG-946 in MDS (see report), we look for dosing of the first patient in the phase 2b study of AG-946 in LR-MDS in mid-24. Maintain Buy, PO $49.

Agios is hosting a call to discuss 4Q23 earnings on February 15 at 8:00 AM EST.

Alector: INVOKE-2 readout top of mind in 2024

ALEC US – Rating: NEUTRAL (C-2-9) | PO: 9.00 USD | Price: 5.99 USD

Alector will likely give a 4Q23 update containing a detailed overview of ongoing clinical development of both PRGN and TREM2 portfolios along with a financial update. After encouraging R&D days (see report), we expect focus to remain on the phase 2 update from the INVOKE-2 trial evaluating AL002 in early AD. As the 4Q24 update approaches, we look for continued details surrounding expectations for the readout with the primary endpoint of the trial set as disease progression as measured by CDR-SB. Beyond the AL002 program, we expect the update to detail the ongoing INFRONT-3 phase 3 trial evaluating latozinemab in FTD-GRN but we note updates from additional programs remain far off with data from the INFRONT-3 trial expected in 2025. We update our model for the recent public offering of common stock (~$75M). Given the ongoing clinical programs which are progressing towards additional derisking data, we maintain Neutral, PO $9.

BridgeBio: NDA acceptance puts launch plans in motion

BBIO US – Rating: BUY (C-1-9) | PO: 52.00 USD | Price: 33.63 USD

Building upon the recent NDA acceptance of the acoramidis NDA (see report), we expect BridgeBio to focus on the anticipated acoramidis approval in ATTR-CM while providing a broad clinical update in the 4Q23 release. With a PDUFA set at November 29, we anticipate the company to continue reviewing the launch plans and potential market as discussed during the recent conference update (see report). Beyond acoramidis, we expect the earnings release to include a detailed overview of the company's broad pipeline. With the recent trial alignment for a pivotal achondroplasia program (see report), we look for enrollment progress and completion by 1H24 and study completion in 2025. We update our model for clinical development timeline changes including moving the modeled launch of encaleret in ADH1 to 2026 from 2025 with a phase 3 readout expected in early 2025. We also look for a status update on the LGMD2i program (enrollment completion 2025), CAH gene therapy program (3Q24 readout) and the BBO-8520 program (IND 2024). Maintain Buy, PO $52.

Beam: BEACON readout to shine light on clinical base editing application in SCD

BEAM US – Rating: NEUTRAL (C-2-9) | PO: 35.00 USD | Price: 25.93 USD

DR5: death receptor 5
IND: Investigational New Drug application
CRC: colorectal cancer
SCD: sickle cell disease
PKU: phenylketonuria
LR-MDS: low risk myelodysplastic syndrome
PRGN: progranulin
CDR-SB: Clinical Dementia Rating scale Sum of Boxes
AD: Alzheimer's disease
FTD-GRN: GRN frontotemporal dementia
ADH1: autosomal dominant hypocalcemia type 1
AATD: alpha-1 antitrypsin deficiency
CAH: congenital adrenal hyperplasia
GSD1a: glycogen storage disease type 1a
S/BP: schizophrenia and bipolar disorder
PVRI: Pulmonary Vascular Research Institute conference
ASH: American Society of Hematology conference
CKD: chronic kidney disease
HAE: hereditary angioedema
sNDA: supplemental New Drug Application

We expect Beam's release to give a detailed overview of ongoing pipeline development and early stage research, with a focus on the ongoing BEACON study evaluating BEAM-101 in sickle cell disease. We look for updates surrounding additional dosing of BEAM-101 as the company is expected to initiate the expansion cohort of the BEACON study in 1H24. With enrollment ongoing we look for data in 2H24. Beyond the SCD program, we also look for clinical progress from the broader pipeline including trial design details and dosing schedules of the BEAM-302 trial in AATD (trial initiation 1H24) and the status of the anticipated filing of BEAM-301 in GSD1a (1H24). After the recent conference update (see report), we look for successful and timely execution of clinical development plans to bring the company closer towards derisking data. Maintain Neutral, $35 PO.

BioXcel: Focus on phase 3 trials to support label expansion

BTAI US – Rating: BUY (C-1-9) | PO: 8.00 USD | Price: 3.71 USD

BioXcel will likely focus on the anticipated phase 3 clinical trials to support Igalmi label expansion into the at-home settings in AD (TRANQUILITY) and S/BP (SERENITY III). While our expectations remain low for the hospital based Igalmi program, we also expect a commercial Igalmi update, and we are in line with consensus at $1.5M for FY23. After the recent R&D day (see report), we also expect the company to discuss early stage programs from the AI driven portfolio and we wait for future derisking data to add to our model. Looking at the TRANQUILITY and SERENITY III programs, we look for details surrounding the timing and enrollment of the 2 planned phase 3 trials, highlighting that management expects the trials to run quickly. We tweak our model to increase our OpEx assumptions due to the upcoming phase 3 trials resulting in a new PO of $8 (from $9). As we discussed in the recent patent allowance announcement (see report), we expect investor focus to remain on execution of the two planned phase 3 trials to support Igalmi label expansion. Maintain Buy, PO $8 (from $9).

Editas: Multiple data updates in 2024 set to derisk '301

EDIT US – Rating: NEUTRAL (C-2-9) | PO: 15.00 USD | Price: 7.08 USD

We expect Editas to focus on the ongoing RUBY and EDITHAL trials evaluating EDIT-301 in SCD and thalassemia during the 4Q23 update. With clinical updates expected from both RUBY and EDITHAL in mid-24 and YE24, we look for maintained responses across patients as follow up times increase and signs of hemoglobin normalization, which if sustained could be potentially differentiating. As the company discussed at a recent conference (see report), Editas is also focusing on early stage research of in vivo editing and we look for future detail on targets and potential indications for the research. After the recent licensing agreement with Vertex for the usage of Cas9, we look for details from the 4Q23 update along with future quarters for expectations for the revenue to be expected from the agreement. As we look for continued clinical data and progress on early stage research, we maintain Neutral, PO $15.

Keros: Enrollment ongoing to build encouraging datasets

KROS US – Rating: BUY (C-1-9) | PO: 66.00 USD | Price: 51.41 USD

We look for Keros' 4Q23 release to include a review of the ongoing clinical development pipeline and a financial update. With enrollment updates expected from the TROPOS trial and phase 2 transfusion dependent MDS trial in 1H24, we look for the company to review the programs in the earnings release. We also look for details surrounding the anticipated mid-year data update for KER-050. After the recent incremental presentations at the PVRI conference (see report) and encouraging data at ASH (see report), we look for Keros to continue to make clinical progress in 2024. We update our model for the upsized public offering of stock ($151.3M). Maintain Buy, PO $66.

Liquidia: Ready for Yutrepia launch upon full approval

LQDA US – Rating: BUY (C-1-9) | PO: 15.00 USD | Price: 14.58 USD

With the FDA requiring additional time to review the NDA package to approve Yutrepia in PH-ILD (see report), we expect the 4Q23 update to revolve around the path to

approval and launch of Yutrepia in PAH and PH-ILD. With a clear path to approval in PAH (see report), we continue to model a launch of Yutrepia in PAH upon the lifting of the injunction to launch in PAH. While we look for the final decision from the FDA to update our expectations for a launch in PH-ILD, we note the FDA review delay does not necessarily affect the potential launch timeline, as United Therapeutics has exclusivity for Tyvaso in PH-ILD until March 31. Strengthened by the recent corporate update (see report), we think Liquidia is prepared to launch Yutrepia when possible, and we look for legal and regulatory updates to allow for a launch in 2024. We update our model for the recent $126M in financings and our Yutrepia price assumptions. Maintain Buy, PO $15.

Mineralys: Pivotal progress set to support filing

MLYS US – Rating: BUY (C-1-9) | PO: 36.00 USD | Price: 12.47 USD

We expect the Mineralys 4Q23 update to discuss the ongoing pivotal programs (Advance-HTN and Launch-HTN) evaluating lorundrostat in resistant and uncontrolled hypertension (rHTN/uHTN). With the company highlighting continued clinical progress (see report), we also look for management to discuss the initial data updates expected from the Advance-HTN trial in 2H24. As an aldosterone synthase inhibitor, we think lorundrostat could find a niche treating obese HTN patients and we look for the clinical updates from Advance-HTN (2H24) and Launch-HTN (2H25) to support approval (model launch 2027). Beyond HTN, we also look for a status update on the CKD profiling trial Explore-CKD, which is evaluating lorundrostat in patients with CKD and expected to have an initial readout in 4Q24. Maintain Buy, PO $36.

IgM Bio: Looking for derisking data in autoimmune studies

IGMS US – Rating: NEUTRAL (C-2-9) | PO: 15.00 USD | Price: 11.95 USD

IgM Bio should have a straightforward 4Q23 update, as the company continues to execute on clinical trials from both T cell engagers (imvotamab) in autoimmune diseases and DR5 agonists (aplitabart) in colorectal cancer. With recent conference updates (see report), we look for an enrollment update form the aplitabart trial in CRC as the company plans to enroll 110 patients by 1Q24. We also think the company will provide an overview of the ongoing imvotamab studies in autoimmune indications, but don't expect data updates in the near term. We also look for details surrounding the IGM-2644 program including progress towards an IND filing which is expected in 2024 in autoimmune indications. We update our model to remove our 1-year cash discounting from our valuation, resulting in a new PO of $15 (from $9.50) and we reiterate our Neutral rating.

Intellia: Gene editing validation on deck with late stage development

NTLA US – Rating: BUY (C-1-9) | PO: 80.00 USD | Price: 26.07 USD

With the recent conference update giving an overview of 2024 priorities (see report), we look for Intellia's 4Q23 call to review the late stage clinical progress expected along with providing a financial update. While we do not expect new data in the update, we look for details on dosing progress (initial dosing 1Q24) from the phase 3 MAGNITUDE trial evaluating '2001 in ATTR-CM and timing details surrounding the phase 1/2 updates expected from both '2001 and '2002 programs, which we expect to build upon previous positive data (see report). With plans to initiate a global pivotal phase 3 trial evaluating NTLA-2001 in HAE in 2H24 and to initiate dosing of the phase 1 trial evaluating NTLA-3001 in AATD lung disease in 2024, we anticipate Intellia to provide a detailed overview of all clinical programs during the 4Q call. We look for the company to continue to execute on the outlined corporate development plans (see report) and maintained positive clinical data in updates later this year. Maintain Buy, PO $80.

Rocket: Commercial transition on deck with March PDUFA

RCKT US – Rating: BUY (C-1-9) | PO: 37.00 USD | Price: 28.91 USD

Rocket will likely provide a detailed overview of all clinical programs in the company's 4Q23 release, and we expect an emphasis on anticipated commercial launch of the LAD-1 program (PDUFA March 31) and the ongoing pivotal Danon trial. As we expect an interim update later from the Danon program this year, we look for any updates on trial status or enrollment progress in the release. Beyond Danon, Rocket will likely review the FA program, where filing is anticipated in 1H24, and the PKD programs, where we look for timeline updates on the pivotal trial initiation. After the recent conference update (see report), we also expect the company to review early stage programs. We update our launch timing for the FA gene therapy program into 2025 based on the anticipated filing timeline. Maintain Buy, PO $37.

Travere: Focus on full approval of sparsentan in IgAN

TVTX US – Rating: BUY (C-1-9) | PO: 23.00 USD | Price: 8.28 USD

We expect Travere to give a commercial update of the Filspari launch along with an overview of anticipated regulatory and clinical events. With the recent preannouncement (see report), 4Q23 product sales of Filspari were strong at $15M. We update our model for the Filspari price increase in IgAN. We look for details regarding the anticipated sNDA filing (1Q24) and CHMP opinion (1Q24) for Filspari, and for the company to discuss the recent licensing agreement with Renalys Pharma for the development of sparsentan in Japan and other countries in Asia. We also expect management to discuss details surrounding the Filspari launch strategy and a discussion of the ongoing trial in pegtibatinase (data 2026). Maintain Buy, PO $23.

Tyra: Achon. program approaches clinic with 2H IND

TYRA US – Rating: NEUTRAL (C-2-9) | PO: 20.00 USD | Price: 18.00 USD

We anticipate Tyra's 4Q23 update to include a detailed overview of the clinical pipeline including both ongoing and planned trials. After the recent clinical status updates (see report), we look for continued dosing and enrollment progress from both SURF201 and SURF301 (dose escalation ongoing). With an IND submission expected in 2H24 for TYRA-300 in achondroplasia, we also look for the release to include details on the anticipated phase 2 program. With the TYRA-300 program recently receiving rare pediatric disease designation for the treatment of achondroplasia, we increase our pipeline value for Tyra in our model, resulting in a new PO of $20 (from $15). We also update our model for the recent $200M PIPE, which the company plans to use to advance the clinical development of TYRA-300, TYRA-200, and its preclinical programs and for drug discovery, working capital and new drug candidates. We are encouraged by the ongoing clinical progress though the need for derisking data readouts keeps us Neutral on the name. New PO $20 (from $15).

United Therapeutics: Upcoming competition approvals threaten strong position in PAH space

UTHR US – Rating: UNDERPERFORM (B-3-9) | PO: 180.00 USD | Price: 210.76 USD

After the recent conference update (see report), we look for United Therapeutics' 4Q23 report and call to provide an overview of PAH products with a focus on Tyvaso. With the recent acquisition of Miromatrix Medical, we also expect the discussion to include details surrounding its organ manufacturing programs. We remain below consensus for our 4Q23 estimates for Orenitram ($82.7M cons; $76M BofA) and Tyvaso ($322.1M cons; $313.1M BofA), and we are relatively in line for our 4Q23 estimates for Remodulin ($120.2M cons; $118.1M BofA), Adcirca ($7M cons.; $5.8M BofA), and Unituxin ($46.2M cons. $45.5M BofA). We update our revenue builds in our model including our PAH/PH-ILD market model and revenue build for Orenitram and Tyvaso, resulting in a new PO of $180 (from $178). While we expect Tyvaso DPI to continue to drive revenue growth for United, with the anticipated launch of Yutrepia and Merck's sotatercept approaching, we expect additional competition in the PAH and potentially PH-ILD space if Yutrepia is

approved in both indications to add pressure to United's strength in the space. Maintain Underperform, PO $180 (from $178).

Exhibit 2: Catalyst Calendar

BridgeBio recently announced the PDUFA for the approval of acoramidis in ATTR-CM is November 29, 2024.

Company	Asset	Indication	Event	Timing	Importance
Agios	Mitapivat	SCD	Phase 3 data	2025	High
Agios	AG-946	LR-MDS	Initiate phase 2b	mid-2024	Low
Agios	Mitapivat	TDT	Phase 3 ENERGIZE-T data	mid-2024	High
Agios	Mitapivat	Pediatric PKD	Data from ACTIVATEkids-T	YE24	High
Agios	Mitapivat	Pediatric PKD	Data from ACTIVATEkids	2025	High
Agios	PAH stabilizer	PKU	Initiate dosing	1H24	Low
Agios	Mitapivat	Thalassemia	File for regulatory approval	YE24	High
Alector	AL001	FTD	INFRONT-3 data	2025	High
Alector	AL002	Alzheimer's disease	AbbVie opt-in decision	early 2025	High
Alector	AL002	Alzheimer's disease	Topline phase 2 data	4Q24	High
Beam	BEAM-101	SCD	BEACON trial readout	2H24	High
Beam	BEAM-101	SCD	Expansion cohort initiation	1H24	Moderate
Beam	BEAM-201	T-ALL/T-LL	Initial data	2H24	High
Beam	BEAM-301	GSD1a	Regulatory filing	1H24	Low
Beam	BEAM-302	AATD	Trial initiation	1H24	Moderate
BioXcel	Igalmi	Alzheimer's disease	Phase 3 trial initiation	2024	Low
BioXcel	Igalmi	Schizophrenia/ Bipolar disorder	Phase 3 trial initiation	2024	Low
BioXcel	Igalmi	Alzheimer's disease	TRANQUILITY At-Home readout	1Q25	High
BridgeBio	Acoramidis	ATTR-CM	Global marketing authorization applications	2024	Moderate
BridgeBio	Acoramidis	ATTR-CM	PDUFA	29-Nov	High
BridgeBio	low-dose infigratinib	Achon.	Last patient enrolled	1H24	Moderate
BridgeBio	low-dose infigratinib	Achon.	Study completion	2025	High
BridgeBio	low-dose infigratinib	hypochondroplasia	Clinical program initiation	2024	High
BridgeBio	BBP-418	LGMD2i	Complete enrollment	2024	Moderate
BridgeBio	Encaleret	ADH1	Phase 3 readout	early 2025	Moderate
BridgeBio	Gene therapy	CAH	Phase 2 data readout	3Q24	High
BridgeBio	BBP-418	LGMD2i	FORTIFY topline data	1H25	High
BridgeBio	BBO-8520	Oncology	IND filing	2024	Low
Editas	reni-cel	SCD/thal	Clinical update	mid-24	High
Editas	reni-cel	SCD/thal	Clinical update	YE24	High
IgM Bio	IGM-8444	CRC	Initial data of '8444 + FOLFIRI + bev	YE24	High
IgM Bio	IGM-8444	CRC	Enroll 110 patients	1Q24	Low
IgM Bio	IGM-2644	autoimmune indications	IND filing	2024	Low
Intellia	NTLA-2001	ATTR-CM	Dose patient in phase 3 trial	1Q24	Moderate
Intellia	NTLA-2001	ATTR	Present updated phase 1 data	2024	High
Intellia	NTLA-2002	HAE	Initiate a global pivotal phase 3 trial	2H24	Moderate
Intellia	NTLA-2002	HAE	Present phase 1/2 data	2024	High
Intellia	NTLA-3001	AATD lung disease	Dose patient in phase 1 trial	2024	Low
Keros	KER-050	MDS	Complete phase 2 TD enrollment	1H24	Low
Keros	KER-012	Chronic heart failure	Initial data from phase 2 trial	2H24	High
Keros	KER-012	PAH	Update on enrollment of TROPOS	1H24	Moderate
Keros	KER-050	MDS	Additional data from Ph2 part 2 MDS trial	2Q and 4Q24	High
Keros	KER-050	MF	Additional data from Ph2 MF trial	2Q and 4Q24	High
Keros	KER-065	Obesity/ neuromuscular	Phase 1 proof of concept data	1Q25	High
Liquidia	Yutrepia	PAH	Anticipated launch	2024	High
Liquidia	L606	PH-ILD	Initiate PH-ILD trial	late 2024	Low
Mineralys	MLS-101	HTN	Topline data from phase 2 pivotal trial	2H24	High
Mineralys	MLS-101	CKD	Topline data from CKD profiling trial	4Q24/1Q25	High
Mineralys	MLS-101	HTN	Topline data from phase 3 pivotal trial	2H25	High
Rocket	RP-L201	LAD-1	PDUFA	31-Mar-24	High
Rocket	RP-L301	PKD	Pivotal phase 2 trial initiation	2024	Low
Rocket	RP-A501	Danon disease	Pivotal trial interim update	2024	High
Rocket	RP-L102	Fanconi anemia	BLA-MAA filing	1H24	High
Rocket	BAG3-association DCM	BAG3-DCM	IND filing	2024	Low
Travere	Sparsentan	IgAN	CHMP opinion	1Q24	High
Travere	Sparsentan	IgAN	Potential EMA decision	2Q24	High
Travere	Sparsentan	IgAN	sNDA filing	1Q24	High
Travere	Sparsentan	IgAN	Filspari + SGLT2i combo data and first line Filspari data	2024	Moderate
Travere	pegtibatinase	HCU	HARMONY topline data	2026	High
Tyra	TYRA-300	Achondroplasia	IND submission for phase 2 study	2H24	Low
United	Ralinepag	PAH	ADVANCE OUTCOMES study data	2025	High

Exhibit 2: Catalyst Calendar
BridgeBio recently announced the PDUFA for the approval of acoramidis in ATTR-CM is November 29, 2024.

Company	Asset	Indication	Event	Timing	Importance
United	Tyvaso	IPF	TETON 1 and 2 enrollment completion	YE24	Moderate
United	Tyvaso	IPF	TETON data	2025	High

Source: BofA Global Research, company reports

BofA GLOBAL RESEARCH

Stocks mentioned

Prices and ratings for stocks mentioned in this report

BofA Ticker	Bloomberg ticker	Company name	Price	Rating
AGIO	AGIO US	Agios	US$ 23.69	C-1-9
ALEC	ALEC US	Alector	US$ 6.4	C-2-9
BEAM	BEAM US	Beam Therapeutics	US$ 27.57	C-2-9
BTAI	BTAI US	BioXcel	US$ 3.78	C-1-9
BBIO	BBIO US	BridgeBio Pharma	US$ 33.77	C-1-9
EDIT	EDIT US	Editas	US$ 7.11	C-2-9
IGMS	IGMS US	IGM Biosciences	US$ 10.98	C-2-9
NTLA	NTLA US	Intellia	US$ 26.07	C-1-9
KROS	KROS US	Keros	US$ 51.41	C-1-9
LQDA	LQDA US	Liquidia Corporation	US$ 14.58	C-1-9
MLYS	MLYS US	Mineralys	US$ 12.47	C-1-9
RCKT	RCKT US	Rocket Pharma	US$ 28.91	C-1-9
TVTX	TVTX US	Travere Therapeutics	US$ 8.28	C-1-9
TYRA	TYRA US	Tyra Biosciences	US$ 18	C-2-9
UTHR	UTHR US	United Therapeutics	US$ 210.76	B-3-9

Price objective basis & risk

Agios Pharmaceuticals (AGIO)
Our $49/share price objective is based on a probability-adjusted (40-100%) net present value (NPV) analysis of 1 commercial program and 2 programs under development. We use a weighted-average cost of capital (WACC) of 13%, similar to other commercial companies in our coverage universe and a -25% terminal growth rate. Given these assumptions, we estimate a value of $6/share for PKD, $18/share for thalassemia, $4/share for SCD, $7/share for Pyrukynd ex-US royalties, and $14/share for net cash.

Downside risks: 1) soft market uptake, 2) dangerous safety signals, 3) superior competitor data.

Alector, Inc (ALEC)
Our sum-of-the-parts NPV PO of $9 for Alector includes $1/sh for AL001 in FTD, $2/sh for AL002 in AD. The remaining value in our PO comes from cash. We use a 15% WACC and assume a -5% terminal growth rate.

Upside risks are 1) positive data from clinical-stage programs in FTD and AD, 2) potential accelerated path to approval from the FDA, and 3) positive data from early stage assets.

Downside risks are 1) failure to show benefits in target indications in clinical studies, 2) slower-than-expected enrollment for its pivotal studies, and 3) visibility need on pricing assumptions.

Beam Therapeutics (BEAM)

Our $35/share price objective is based on a probability adjusted (30%) NPV analysis of its primary program under development. We use a WACC of 15%, similar to other early-stage companies in our coverage universe and a -2% terminal growth rate.

Downside risks: 1) failure of early clinical trials, 2) dangerous safety signals, 3) superior competitor data, 4) soft market uptake.

BioXcel Therapeutics (BTAI)
Our $8 PO is based on a sum-of-the-parts valuation. We assume a 13% discount rate for each of the programs and a likelihood of success (PoS) of 100% for BXCL501 for both of the schizophrenia (approved) and bipolar disorder (approved) indications, and 25% for dementia (phase 3). Given this, we ascribe $5/share for BXCL501 and net cash of $3/share.

Downside risks: 1) failure of clinical trials, 2) limited commercial uptake, 3) limited formulary access due to pricing.

BridgeBio Pharma (BBIO)
Our net present value (NPV) sum-of-the-parts valuation gives a price objective of $52/share for BridgeBio, which includes $32/share for acoramidis, $3/share for ribitol in LGMD2i, $11/share for infigratinib in achondroplasia, $6/share for encaleret, $5/share for CAH gene therapy, and -$4/share in net cash. We assume a weighted-average cost of capital (WACC) of 15% and terminal growth rates ranging from -50% to 0%.

Downside risks to our price objective are 1) clinical trial failures, 2) inability to raise capital to fund development programs, and 3) superior data from competitors.

Upside risks to our price objective are 1) stronger-than-expected uptake in infigratinib, 2) unexpected de-risking data for early programs, and 3) clinical trial failures from competing companies.

Editas Medicine (EDIT)
Our $15 share price objective is based on a probability adjusted (50%) net present value (NPV) analysis of, EDIT-301 in SCD/TDT ($6/share), $1/sh on royalties, $2/share in platform value, and net cash ($6/share). We use a weighted-average cost of capital (WACC) of 15%, similar to other early-stage companies in our coverage universe and a -2% terminal growth rate.

Upside risks: higher-than-anticipated uptake of approved products, better-than-expected clinical trial results.

Downside risks: unexplained safety signals, clinical trial failures, and strong data from competitors.

IGM Biosciences (IGMS)
Our price objective of $15 is based on a probability adjusted (10-20%) NPV analysis of IGM-2323 in SLE/RA ($6/sh), IGM-8444 in mCRC ($4/sh), and discounted net cash ($5/sh). We use a WACC of 15% similar to other early-stage companies in our coverage universe and a -2% terminal growth rate.

Upside risks are better than expected data in clinical programs including better efficacy or safety in IGM-2323 compared to other companies, which could lead to higher than expected usage if approved. Also positive clinical trial results in clinical and preclinical programs.

Downside risks are unexpected safety signals, clinical trial failures, and competitors releasing stronger data.

Intellia Therapeutics (NTLA)
Our $80 share price objective is based on a probability adjusted (60-75%) net present value (NPV) analysis of NTLA-2001 in ATTR ($50/share), NTLA-2002 in HAE ($12/share), platform value ($8/share) and net cash ($10/share). We use a weighted average cost of capital (WACC) of 15% similar to other clinical-stage companies in our coverage universe and a -2% terminal growth rate.

Downside risks: unexpected safety signals, clinical trial failures, and strong data from competitors.

Keros (KROS)
Our $66/share price objective is based on a probability adjusted (20%-50%) net present value (NPV) analysis of its program under development. We use a weighted-average cost of capital (WACC) of 15%, similar to other early-stage companies in our coverage universe, and a terminal growth rate of -5%. Given these assumptions we estimate a value of $38/sh for KER-050 in MDS, $3/sh for KER-050 in MF, $6/sh in KER-050 royalties, $10/sh in KER-012, and $9/sh in net cash.

Upside risks are better than expect data in clinical trials including MDS/MF patients treated with KER-050 which could lead to higher than anticipated usage if approved.

Downside risks are unexpected safety signals, clinical trial failures, and competitors releasing stronger data.

Liquidia Corporation (LQDA)
Our $15/share price objective is based on an net present value (NPV) analysis of Yutrepia ($12/share), collaboration revenues ($2/share), and net cash ($1/share). We use a weighted average cost of capital (WACC) of 13%, in line with similar companies in our coverage universe and a -50% terminal growth rate.

Downside risks: 1) additional competition in the market, 2) delayed full approval of Yutrepia.

Upside risk: 1) higher-than-expected uptake of Yutrepia once approved

Mineralys Therapeutics (MLYS)
Our $36/share price objective is based on a probability adjusted (50%) net present value (NPV) analysis of its programs under development. We use a weighted-average cost of capital (WACC) of 15%, similar to other early-stage companies in our coverage universe, and a terminal growth rate of -50%. Given these assumptions we estimate a value of $30/share for lorundrostat in HTN and $6/share in net cash.

Upside risks are better than expected data in clinical programs which could lead to higher than anticipated usage if approved.

Downside risks are unexpected safety signals, clinical trial failures, and competitors releasing stronger data.

Rocket Pharmaceuticals, Inc. (RCKT)
Our $37/share price objective is based on a probability-adjusted (35%-90%) net present value (NPV) analysis of its four programs under development. We use a weighted-average cost of capital (WACC) of 15%, similar to other early-stage companies in our coverage universe, and terminal growth rate of -2%. Given these assumptions, we estimate a value of $9/share for RP-L102 (Fanconi anemia), $21/share for RP-A501 (Danon disease), $2/share for RP-L201 (LAD-1), $1/share for RP-L301 (PKD), and $4/share in net cash.

Risks: 1) failure of early clinical trials, 2) emergence of unacceptable safety signals, 3) shorter efficacy duration than expected, and 4) commercialization failures.

Travere Therapeutics Inc (TVTX)
Our $23 PO is based on a sum-of-the-parts NPV analysis. Using a 13% WACC, we model $2/share in bile acid portfolio milestones, $3/share for Thiola, $13/share for sparsentan, $1/share for pegtibatinase, and $3/share net cash.
Risks are 1) regulatory risk, 2) competitive entrants, 3) lower-than-expected sparsentan uptake, 4) insurance or pricing concerns

Tyra Biosciences (TYRA)
Our $20/share price objective is based on a probability-adjusted adjusted SOTP NPV of TYRA-300 ($1/sh), TYRA-200 ($2/sh), RET inhibitor program ($3/sh), and potential for contribution from additional pipeline programs including achondroplasia and FGFR4 ($8/sh), with net cash contributing $6/sh. We apply a WACC of 15% for each program, and terminal growth rate of -40%, reflecting the programs' early stages in development and potential for genericization after patent expiration.

Downside risks: 1) initial clinical data for pipeline programs fail to demonstrate a meaningful benefit in patients, 2) pipeline therapies fail to differentiate from similar competing products, 3) regulatory/reimbursement environment weighs on commercial economics, 4) unexpected safety concerns.

United Therapeutics Corporation (UTHR)
Our 12-month price objective for United of $180/share is based on our net present value (NPV) analysis. We forecast sales for each of the approved products, Remodulin, Tyvaso, Orenitram, Adcirca, and Unituxin. We assume a WACC of 13%, in line with peer commercial companies of similar size and risk and varying terminal values for each asset based on its characteristics and patent life. Given these assumptions, we estimate a value of $18/share for Remodulin, $59/share for Tyvaso, $11/share for Orenitram, $8/share Unituxin, $1/share for the pipeline, and $83/share for net cash.

Upside risks: 1) better-than-expected PAH sales despite generic and branded competition, 2) successful launch of next-generation Remodulin and Tyvaso delivery devices near-term that meaningfully improves growth, 3) robust uptake of Orenitram following the updated FREEDOM-EV label, 4) stabilizing or improving gross to net adjustments, and 5) success of a number of pipeline programs, resulting in accelerated approval, development, and commercialization.

Downside risks: 1) faster-than-expected erosion of sales across the commercial portfolio due to generics or branded competition, with similarly increasing gross-to-net adjustments, 2) efforts to launch a next-generation drug delivery device may experience further setbacks, delaying their launches, and 3) other development programs, including those evaluating the portfolio in other categories of PH, may experience limited success.

Analyst Certification

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

US - Biopharmaceuticals Coverage Cluster

Investment rating	Company	BofA Ticker	Bloomberg symbol	Analyst
BUY				
	89bio, Inc	ETNB	ETNB US	Geoff Meacham
	Acumen Pharma	ABOS	ABOS US	Geoff Meacham
	Agios Pharmaceuticals	AGIO	AGIO US	Greg Harrison, CFA
	Amylyx Pharmaceuticals	AMLX	AMLX US	Geoff Meacham
	BioMarin	BMRN	BMRN US	Geoff Meacham
	BioXcel Therapeutics	BTAI	BTAI US	Greg Harrison, CFA
	BridgeBio Pharma	BBIO	BBIO US	Greg Harrison, CFA
	Caribou	CRBU	CRBU US	Geoff Meacham
	CRISPR Therapeutics	CRSP	CRSP US	Geoff Meacham
	Eli Lilly and Company	LLY	LLY US	Geoff Meacham
	Gilead Sciences Inc.	GILD	GILD US	Geoff Meacham
	HUTCHMED	HCM	HCM US	Alec W. Stranahan
	Immatics	IMTX	IMTX US	Alec W. Stranahan
	Insmed Incorporated	INSM	INSM US	Jason Zemansky
	Intellia Therapeutics	NTLA	NTLA US	Greg Harrison, CFA
	Janux Therapeutics	JANX	JANX US	Geoff Meacham
	Keros	KROS	KROS US	Greg Harrison, CFA
	Kiniksa Pharmaceuticals, Ltd.	KNSA	KNSA US	Geoff Meacham
	Krystal Biotech	KRYS	KRYS US	Alec W. Stranahan
	Kura Oncology	KURA	KURA US	Jason Zemansky
	Liquidia Corporation	LQDA	LQDA US	Greg Harrison, CFA
	Lyell Immunopharma	LYEL	LYEL US	Geoff Meacham
	MeiraGTx	MGTX	MGTX US	Alec W. Stranahan
	Merck & Co.	MRK	MRK US	Geoff Meacham
	Mineralys Therapeutics	MLYS	MLYS US	Greg Harrison, CFA
	Neumora Therapeutics	NMRA	NMRA US	Geoff Meacham
	Rani Therapeutics	RANI	RANI US	Geoff Meacham
	Regenxbio, Inc.	RGNX	RGNX US	Alec W. Stranahan
	Revolution Medicines	RVMD	RVMD US	Alec W. Stranahan
	Rocket Pharmaceuticals, Inc.	RCKT	RCKT US	Greg Harrison, CFA
	Royalty Pharma	RPRX	RPRX US	Geoff Meacham
	Sana Biotechnology	SANA	SANA US	Geoff Meacham
	SpringWorks	SWTX	SWTX US	Alec W. Stranahan
	Syndax Pharmaceuticals	SNDX	SNDX US	Jason Zemansky
	Travere Therapeutics Inc	TVTX	TVTX US	Greg Harrison, CFA
	Turnstone Biologics	TSBX	TSBX US	Geoff Meacham
	Vertex Pharmaceuticals Inc.	VRTX	VRTX US	Geoff Meacham
	Werewolf Therapeutics	HOWL	HOWL US	Jason Zemansky
	Xencor	XNCR	XNCR US	Alec W. Stranahan
NEUTRAL				
	AbbVie	ABBV	ABBV US	Geoff Meacham
	Alector, Inc	ALEC	ALEC US	Greg Harrison, CFA
	Amgen Inc.	AMGN	AMGN US	Geoff Meacham
	Arcus Biosciences	RCUS	RCUS US	Jason Zemansky
	Beam Therapeutics	BEAM	BEAM US	Greg Harrison, CFA
	Biogen Inc.	BIIB	BIIB US	Geoff Meacham
	Bristol-Myers Squibb	BMY	BMY US	Geoff Meacham
	Cytokinetics, Incorporated	CYTK	CYTK US	Jason Zemansky
	Editas Medicine	EDIT	EDIT US	Greg Harrison, CFA
	Erasca	ERAS	ERAS US	Alec W. Stranahan
	Esperion	ESPR	ESPR US	Jason Zemansky
	Exscientia	EXAI	EXAI US	Alec W. Stranahan
	IGM Biosciences	IGMS	IGMS US	Greg Harrison, CFA
	Johnson & Johnson	JNJ	JNJ US	Geoff Meacham
	Kymera Therapeutics	KYMR	KYMR US	Geoff Meacham
	Moderna	MRNA	MRNA US	Geoff Meacham
	Pfizer	PFE	PFE US	Geoff Meacham
	Recursion Pharmaceuticals, Inc.	RXRX	RXRX US	Alec W. Stranahan
	Tyra Biosciences	TYRA	TYRA US	Greg Harrison, CFA
	Vir	VIR	VIR US	Geoff Meacham
	Y-mAbs Therapeutics, Inc	YMAB	YMAB US	Alec W. Stranahan
UNDERPERFORM				
	AlloVir, Inc.	ALVR	ALVR US	Jason Zemansky

US - Biopharmaceuticals Coverage Cluster

Investment rating	Company	BofA Ticker	Bloomberg symbol	Analyst
	CureVac	CVAC	CVAC US	Geoff Meacham
	Day One Biopharmaceuticals	DAWN	DAWN US	Alec W. Stranahan
	LianBio	LIAN	LIAN US	Geoff Meacham
	Novavax	NVAX	NVAX US	Alec W. Stranahan
	Regeneron Pharmaceuticals Inc.	REGN	REGN US	Geoff Meacham
	Reneo Pharmaceuticals	RPHM	RPHM US	Jason Zemansky
	TG Therapeutics	TGTX	TGTX US	Alec W. Stranahan
	United Therapeutics Corporation	UTHR	UTHR US	Greg Harrison, CFA

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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