BofA SECURITIES

Biotechnology

Takeaways from Day 2 of the SF Healthcare Conference

Price Objective Change

NBIX: NDA for crinecerfont in CAH in 2024

Neurocrine (NBIX, Buy, $154 PO) provided a strategic outlook for the company and highlighted several expected readouts in 2024. Management reiterated the guidance for 2023 Ingrezza sales of $1.82-1.84bn and highlighted the company's focus in expanding into neurology, neuroendocrinology and neuropsychiatry. Management also outlined long-term goals including moving 2 gene therapy programs into the clinic in 2025. The company noted the high unmet need in congenital adrenal hyperplasia (CAH) and the potential market opportunity for crinecerfont following 2 positive phase 3 readouts in adult and pediatric patients. Management commented they expect to file a new drug application in 2024 and expect a potential US approval in 2025. They commented they are focusing on building the commercial infrastructure to support the potential launch. They noted that while significant physician and patient education is needed as there have been no new approved therapies in over 50 years, they are confident in crinecerfont's differentiated profile over current standard of care and the commercial opportunity. Additionally, management highlighted the neuropsychiatry pipeline, particularly the broad portfolio of muscarinic targeting assets including M4 selective agonists, M1/M4 dual agonists, M1-/M4- preferring compounds and M4 antagonists. The company highlighted the validated mechanism of action for these compounds and the large potential for muscarinic-targeting agents in several indications, and highlighted the phase 2 readout of NBI-1117568 (M4 agonist) in schizophrenia in 2H. We view the muscarinic portfolio as an attractive commercial opportunity for the company given extensive clinical validation for this pathway. We are encouraged by the continued strong commercial performance of Ingrezza and the potential to expand the commercial portfolio, and will look for additional color on FY24 guidance at the next earnings call. We reiterate our Buy with new $154 PO (prev. $135).

Additional data readouts in 2024 include: 1) phase 2 data for NBI-1065845 in inadequate response in major depressive disorder in 1H, 2) phase 2 data for luvadaxistat in cognitive impairment associated with schizophrenia in 2H, and 3) phase 2 data for Efmody in adrenal insufficiency and CAH in 1H. In our DCF-based model, we roll the quarter and increase our pipeline value to $3bn (prev. $1bn) as we see the large muscarinic portfolio as an attractive commercial opportunity. These changes result in our new $154 PO.

See inside for details on Acadia Pharmaceuticals (ACAD), BioNTech (BNTX) and Denali Therapeutics (DNLI).

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Exhibit 1: Summary of PO changes
PO changes from our covered names

Ticker	Previous	Current
NBIX	$135	$154

Source: BofA Global Research

BofA GLOBAL RESEARCH

ACAD: Commercial guidance expected at 4Q23 earnings

Acadia Pharmaceuticals (ACAD, Neutral, $33 PO) provided an overview of their commercial and pipeline franchises as well as presented a 2024 strategic outlook. Management reiterated 4Q23 Daybue revenue guidance of $80-87.5mn, which we think the company is likely to beat based on positive feedback from our KOLs on current usage trends (see our Daybue usage survey). As such, we currently model 4Q23 Daybue revenue of $93mn slightly above the upper range of guidance. However, we note long-term opportunity still needs de-risking with ACAD providing an updated look at discontinuations noting that the current 6-month real world persistency is 76% (4-month: 81%). While we are encouraged by the real-world persistency trending higher than the open label LILAC study (4-month: 65%; 6-month: 58%), we look for clarity on steady-state discontinuation rates to better understand long-term Daybue opportunity as a chronic Rett syndrome (RS) therapy. On Nuplazid, the company highlighted the program continues to be cash flow positive and notes prioritization to continue leveraging the bottom-line by minimizing SG&A spend to ensure program profitability. Additionally, we highlight the company recently received a favorable court ruling on Nuplazid composition of matter (COM) patent (expires in 2030; see our takes note). We view the positive ruling as an important de-risking event for the Nuplazid franchise but note color is still needed on long-term Nuplazid growth opportunities especially given management commentary on reducing SG&A spend. We maintain our Neutral rating with $33 PO ahead of 4Q23/FY23 earnings where the company expects to provide color on key commercial growth drivers in 2024 as well as Nuplazid (FY24) and Daybue (1Q24) revenue guidance.

Management also provided a status update on pipeline programs: 1) topline results for the phase 3 ADVANCE-2 trial evaluating pimavanserin for negative symptoms of schizophrenia (NSOS) on track to readout in 1Q24, 2) phase 3 trial evaluating ACP-101 in Prader-Willi syndrome is ongoing (initiated in November), 3) seamless phase 2/3 trial evaluating ACP-204 in Alzheimer's disease psychosis is ongoing (initiated in November), and 4) Daybue global expansion work planned for 2024. Management guides to a New Drug Submission (NDS) filing in Canada in 1Q24 (~600-900 RS patients), Marketing Authorization Application (MAA) filing in Europe in 1H25 (~9K-14K RS patients) and engaging with Japanese regulators on a filing path in 2024 (~1K-2K RS patients).

BNTX: Strategic focus on expanding oncology franchise

BioNTech (BNTX, Buy, $159 PO) provided FY24 COVID revenue guidance of €3bn and a strategic outlook for the company in 2024. Management reiterated their focus on expanding the vaccine business to other respiratory viruses and highlighted they see the COVID combination vaccines with other respiratory viruses as a major long-term driver of uptake. Management commented they maintained COVID vaccine market leadership in 2023 and expect to continue the shift to commercialization model in major markets in 2024. Additionally, the company emphasized their focus on expanding the oncology platform with several pivotal trials ongoing and expected to initiate in 2024. They noted their portfolio strategy is focusing on immunomodulators, targeted therapies and personalized mRNA vaccines. Their goal is to demonstrate initial single agent activity for different assets to then focus on developing combination therapies with synergistic mechanisms of action. Management noted their goal to start building a global commercial infrastructure in oncology to support multiple oncology launches starting in 2026. We are encouraged by the long-term opportunity of the COVID franchise driven by next generation and combination vaccines, and the large potential commercial opportunity from the maturing oncology pipeline. We currently model €2.5bn in COVID revenues in 2024. We maintain our Buy with $159 PO.

Key data catalysts in 2024 include: 1) phase 2 data for BNT311 (anti-PD-L1/4-1BB bispecific) +/- pembrolizumab in relapsed refractory metastatic non-small cell lung cancer, 2) phase 1/2 expansion cohort data for BNT312 (anti-CD40/4-1BB bispecific), BNT316 (anti-CTLA-4) and BNT323 (anti-HER2) in multiple solid tumors, 3) phase 1/2

data for BNT325 (anti-TROP2) in multiple solid tumors, 4) phase 2 data for BNT327 (anti-PD-L1/VEGF bispecific) in multiple solid tumors. The company highlighted phase 2 data for BNT327 in combination with nab-paclitaxel in 1L triple negative breast cancer showing 78.6% objective response rate, 5) phase 2/3 data for Omicron XBB.1.5 monovalent vaccine, and 6) an update on the phase 1 trial of BNT167 (Shingles vaccine). Management commented that an update on the ongoing trial of BNT122 (iNeST) in colorectal cancer is expected in 2025.

DNLI: Phase 2 topline data in ALS expected in 2024

Denali Therapeutics (DNLI, Buy, $29 PO) provided a strategic outlook for 2024. Management highlighted their focus on advancing the current programs in the clinic and their transport-vehicle (TV) platform for efficient brain delivery with potential in several neurodegenerative diseases including Alzheimer's and Parkinson's disease. On DNL310 in Hunter syndrome, the company highlighted they anticipate to complete enrollment of the phase 2/3 COMPASS trial in 2024, and expect to provide updates on the phase 1/2 study at WORLDSymposium (Feb 4-9) and Society for the Study of Inborn Errors of Metabolism (SSIEM) (Sep 3-6), which will include longer follow-up safety and biomarker data. Management commented that while they continue to engage with regulators on the potential for accelerated approval based on heparan sulfate reduction, their base case is to file after the full COMPASS readout. The company also announced they expet to initiate a phase 1/2 trial in Sanfilippo syndrome type A in early-24 and present initial biomarker and safety data by YE24. Additionally, topline phase 2 data from the HIMALAYA study (led by partner Sanofi) evaluating SAR443820/DNL788 in amyotrophic lateral sclerosis (ALS) is expected to readout in 1H. Sanofi continues to run phase 2 studies for DNL788 in multiple sclerosis and DNL758 in ulcerative colitis. The company also expects to complete enrollment of the phase 2/3 HEALEY study evaluating DNL343 in ALS in 2024. Management also highlighted the next wave of TV-enabled assets, OTV-MAPT in AD and OTV-SNCA in PD, which aim to deliver therapeutic antisense oligos via intravenous delivery, are entering IND-enabling studies. We are encouraged by DNLI's differentiated brain delivery platform with potential in several neurodegenerative disorders and await data updates in 2024 to provide further clinical validation. We maintain our Buy with $29 PO.

Exhibit 2: Companies mentioned in this report
Summary of tickers mentioned in this report

Ticker	Company name	Rating	Price	Price Obj.
ACAD	Acadia Pharmaceuticals	C29	$30.66	$33
BNTX	BioNTech	C19	$108.70	$159
DNLI	Denali Therapeutics	C19	$19.74	$29
NBIX	Neurocrine Biosciences	B19	$133.71	$154

Source: BofA Global Research, Bloomberg

BofA GLOBAL RESEARCH

Price objective basis & risk

Acadia Pharmaceuticals (ACAD)

Our DCF-derived PO of $33 encompasses commercial drug Nuplazid in PDP at $14/share. Daybue in Rett represents $18/share to our PO. The remainder of our net present value (NPV) comes from pipeline and cash. We use a weighted-average cost of capital (WACC) of 9% for PDP and Rett, consistent with how we value other drugs in similar stages of development in our coverage universe. We assume a 21% tax rate for ACAD and zero terminal value.

Downside risks to our PO are 1) slower-than-expected commercialization of Nuplazid and Daybue, 2) stronger-than-expected competition from other 5HT2A compounds and

other drugs in development for the same indications as Nuplazid and Daybue, and 3) negative results in pipeline indications.

Upside risks are 1) faster-than-expected Nuplazid and Daybue uptake in the US, 2) potential for partnerships or transactions with larger pharma companies, and 3) advances of early-stage pipeline assets in pain and central nervous system (CNS) disorders.

BioNTech (BNTX)

Our DCF-derived PO of $159 for BNTX consists of $18/share for FixVac over four indications (melanoma, H&N, prostate) and $5/share for iNeST over four indications (solid tumors). We assign $76/share to the Comirnaty COVID vaccine and -$15/share to BNTX's early-stage pipeline assets including intratumoral immunotherapy, RiboMabs, RiboCytokines and engineered cell therapy and antibody platforms, as well as future potential infectious disease indications. The remaining value in our PO comes from cash. We use 12-14% WACC for FixVac, 12-13% WACC for iNeST, and 8% for BNT162 (COVID vaccine). We also assume 1.5% terminal growth for FixVac and iNeST.

Upside risks to our price objective are 1) approval of COVID vaccine boosters in a broad population, 2) positive data from clinical-stage programs (FixVac and iNeST) in oncology including melanoma and other solid tumors, 3) potential to reach earlier line patient populations based on combination therapies, and 4) positive data from early stage assets from other platforms including cell therapies, antibodies and small molecule immunomodulators.

Downside risks are 1) failure to show benefit in clinical studies, 2) failure to reach optimized turnaround time for iNeST, 3) visibility needed on regulatory path forward for iNeST, 4) competition from other companies pursuing the same therapeutic modalities, and 5) challenges in scaling up to commercial manufacturing capacity.

Denali Therapeutics (DNLI)

Our PO of $29 for DNLI consists of $16/sh for DNL343 in amyotrophic lateral sclerosis (ALS), $4/sh for DNL310 in Hunter syndrome, and $1/sh for DNL151 in Parkinson's disease. $8/sh is contributed from our pipeline assumptions and net cash. We apply a WACC of 11-12% for modeled programs and 14% for pipeline.

Upside risks to our PO are 1) better than expected uptake of modeled programs, 2) positive results from DNL343, DNL310 and DNL151 programs, 3) early-stage pipeline advancing into late-stage development, and 4) positive results from partnered programs.

Downside risks to our PO are 1) slower than expected uptake of modeled programs, 2) unexpected adverse safety issues from the company's transport vehicle (TV) platform technology, 3) clinical trial failures of key pipeline programs, and 4) higher than expected expenses

Neurocrine Biosciences (NBIX)

Our DCF-derived PO of $154 consists of $124/share for Ingrezza for tardive dyskinesia, $6/share for chorea and $8/share for CAH. Royalties from Orilissa for endometriosis and Oriahnn for uterine fibroids represent another $3/share. The rest of the valuation is attributed to cash, corporate expense and pipeline assets. We use a 9% weighted-average cost of capital (WACC) for commercial assets and assume no terminal value, consistent with other companies under coverage that have commercial products, and 13% WACC for pipeline.

Downside risks to our price objective and estimates are Ingrezza not approved for chorea in Huntington's patients, pipeline setbacks, higher-than-expected operating expenses, greater-than-expected competition from other drugs, earlier-than-expected

generic competition to NBIX's products, potential for future dilutive cash raises, potential for the US drug pricing environment to worsen and any unexpected management changes.

Analyst Certification

I, Tazeen Ahmad, 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.

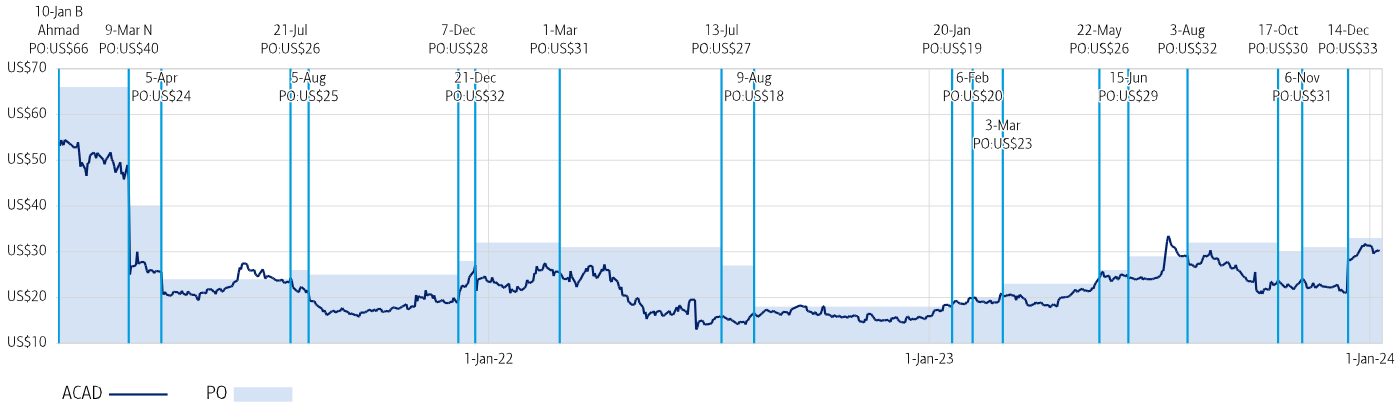
US - Biotechnology Coverage Cluster

Investment rating	Company	BofA Ticker	Bloomberg symbol	Analyst
BUY				
	4D Molecular Therapeutics, Inc.	FDMT	FDMT US	Tazeen Ahmad
	Alnylam Pharmaceuticals	ALNY	ALNY US	Tazeen Ahmad
	Amicus Therapeutics	FOLD	FOLD US	Tazeen Ahmad
	Annexon Biosciences	ANNX	ANNX US	Tazeen Ahmad
	Apellis Pharmaceuticals	APLS	APLS US	Tazeen Ahmad
	Argenx SE	ARGX	ARGX US	Tazeen Ahmad
	Arvinas	ARVN	ARVN US	Tazeen Ahmad
	Ascendis Pharma	ASND	ASND US	Tazeen Ahmad
	Biocryst Pharmaceuticals Inc	BCRX	BCRX US	Tazeen Ahmad
	BioNTech	BNTX	BNTX US	Tazeen Ahmad
	Denali Therapeutics	DNLI	DNLI US	Tazeen Ahmad
	Inozyme Pharma, Inc.	INZY	INZY US	Tazeen Ahmad
	Merus	MRUS	MRUS US	Tazeen Ahmad
	Neurocrine Biosciences	NBIX	NBIX US	Tazeen Ahmad
	PepGen Inc	PEPG	PEPG US	Tazeen Ahmad
	Prothena Corporation	PRTA	PRTA US	Tazeen Ahmad
	Rhythm Pharmaceuticals	RYTM	RYTM US	Tazeen Ahmad
	Sarepta Therapeutics	SRPT	SRPT US	Tazeen Ahmad
	Ultragenyx Pharmaceuticals	RARE	RARE US	Tazeen Ahmad
NEUTRAL				
	Acadia Pharmaceuticals	ACAD	ACAD US	Tazeen Ahmad
	Incyte Corporation	INCY	INCY US	Tazeen Ahmad
	SAGE Therapeutics	SAGE	SAGE US	Tazeen Ahmad
UNDERPERFORM				
	Achilles Therapeutics	ACHL	ACHL US	Tazeen Ahmad
	Fate Therapeutics	FATE	FATE US	Tazeen Ahmad
	Fulcrum Therapeutics	FULC	FULC US	Tazeen Ahmad
	Pharvaris	PHVS	PHVS US	Tazeen Ahmad
	PTC Therapeutics	PTCT	PTCT US	Tazeen Ahmad

Disclosures

Important Disclosures

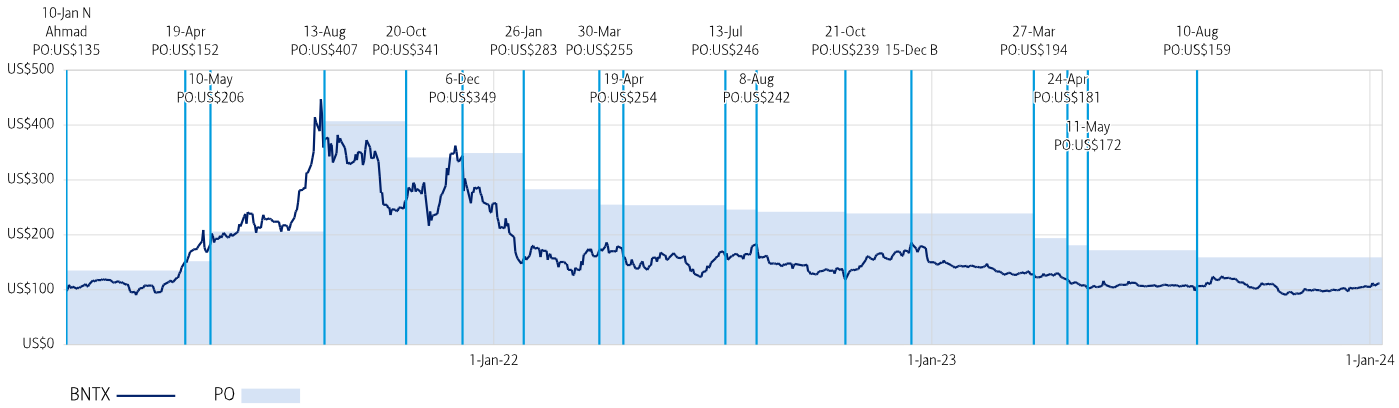
Acadia Ph (ACAD) Price Chart



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

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

BioNTech (BNTX) Price Chart



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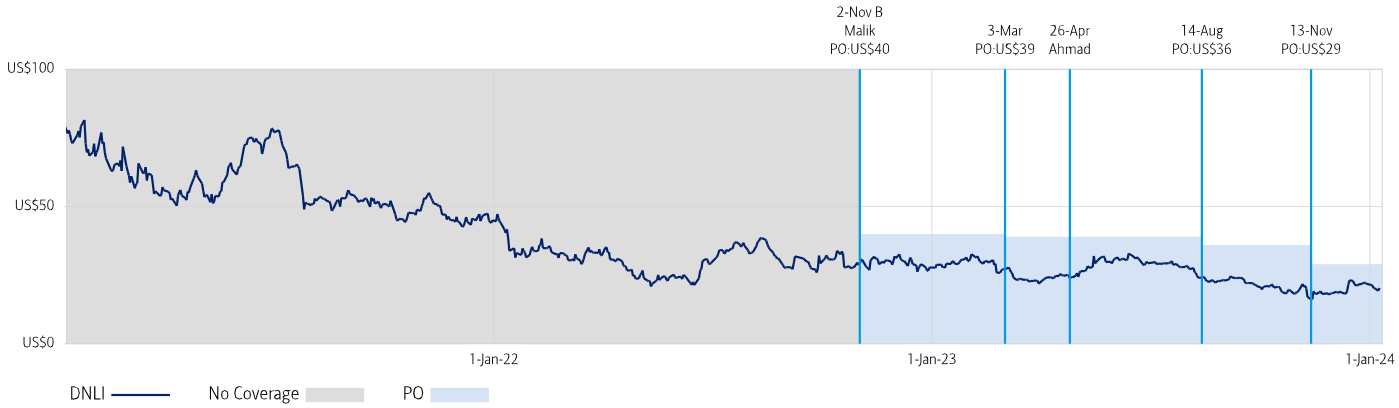
Denali (DNLI) Price Chart



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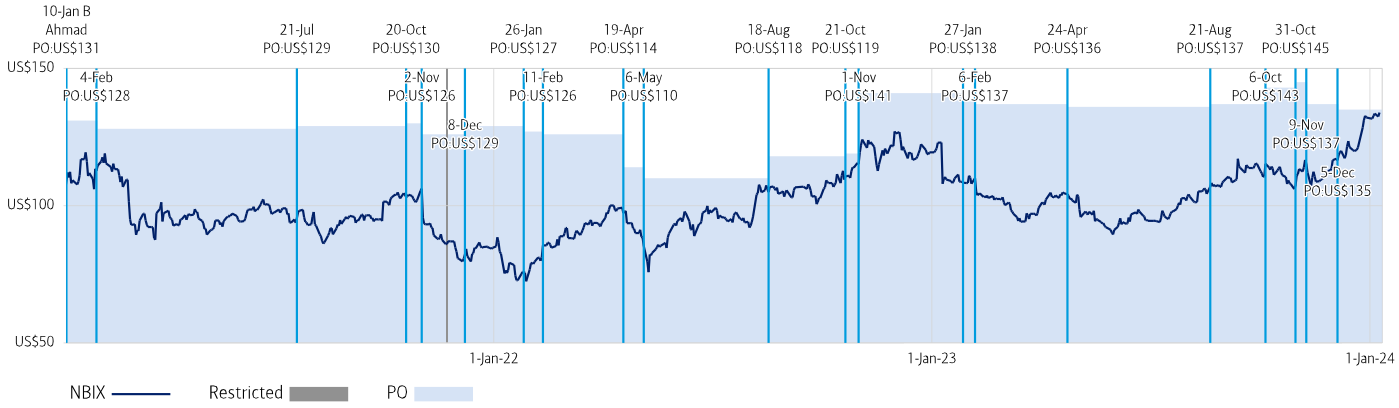
Neurocrine (NBIX) Price Chart



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

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

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

Coverage Universe	Count	Percent	Inv. Banking Relationships [R1]	Count	Percent
Buy	1895	53.62%	Buy	1083	57.15%
Hold	832	23.54%	Hold	454	54.57%
Sell	807	22.84%	Sell	383	47.46%

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

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Investment rating	Total return expectation (within 12-month period of date of initial rating)	Ratings dispersion guidelines for coverage cluster[R2]
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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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