

US Biopharmaceuticals

4Q23 Earnings Wrap-up: DAWN NVAX
RXRX RVMD HCM RGNX YMAB

Price Objective Change

High level thoughts from 4Q23 earnings

Companies within our coverage reported their 2023 earnings this week, we summarize key takes, debates and what we are hearing in investor conversations for our universe. We roll over our 2023 models from estimates to actual and make adjustments to our earnings models for all companies. We raise our PO for YMAB. See inside for details.

Day One Biopharmaceuticals (DAWN): PDUFA (April 30th 2024, 3-month delay seems to be FDA norm especially if no AdCom) remains the most significant binary for the stock. While the company has started building out sales force (18 reps hired), we still see regulatory pressure ahead given multiple overhangs (single-arm study, risk of stunted growth, misalignment in endpoint etc.). Reiterate Underperform and \$10 PO.

Novavax (NVAX): Nuvaxovid sales hit guidance for 2023 (~\$537M, -67% YoY) but the drop from 2022 nevertheless reveals the shrinking C-19 market. While cost-cutting is underway and moderately effective, next clinical catalyst (combo vaccine) still 1-2 years away, and the company continues to lack a game-changing catalyst near-term. Reiterate Underperform and \$4 PO.

Recursion (RXRX): We continue to see technological progress of the company to be impressive, but we do note only clinical data can validate the AI platform. Upcoming data in multiple programs this year in our view is a great first step but scope of data likely still too early to definitively gauge platform value. Reiterate Neutral and \$14 PO.

Revolution Medicines (RVMD): While 2024 is quieter on the data front as compared to the previous year, addition of EQRx deal bolsters cash to \$1.85B, which in our view will carry the company over multiple catalysts over coming years including **1)** RMC-6236-001 efficacy/safety data in 2Q/3Q24e, **2)** RMC 6291-101 efficacy/safety data in 2H24e and **3)** RMC 9805-001 efficacy/safety data in 2H24e. Reiterate Buy and \$34 PO.

HUTCHMED (HCM): \$15M Fruzaqla sales in just two months of commercialization exceeded our expectations (BofA est: ~\$9M 2023e). With the company reporting 97% growth of revenue to \$838M in 2023, with net income of \$101M, we continue to believe in the Chinese biotech and see recent share pullback as largely driven by non-fundamental factors. Reiterate Buy and \$29 PO.

Regenxbio (RGNX): Imminent data readout from RGX-202 (March 5th 2024) can add further confidence to shares especially after positive readout from both '314 (subretinal and suprachoroidal) and '121 programs. The company's goal of introducing two commercialized assets by 2025 certainly seems more likely. Reiterate Buy and \$35 PO.

Y-mAbs Therapeutics (YMAB): Danyelza sales in 4Q23 exceeded our expectations (~\$23M; BofA est: ~\$20M), but we need to see a few more quarters of momentum before we become more positive. With SADA still in its early stages, we reiterate Neutral and raise PO to \$21 (\$18 prior) to reflect stronger than expected sales.

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Refer to important disclosures on page 12 to 14. Analyst Certification on page 10. Price Objective Basis/Risk on page 8.

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Abbreviations:

ESMO: European society of molecular oncology
AdCom: Advisory committee
NDA: New drug application
FDA: Food and drugs administration
KOL: Key opinion leader
NSCLC: Non-small cell lung cancer
ORR: Overall response rate
KRAS: Kirsten rat sarcoma viral vector
PDUFA: Prescription drug user free act
DMD: Duchene muscular dystrophy
MPS: mucopolysaccharidoses
NBI: Nasdaq biotech index
CRC: Colorectal cancer
MALT1: Mucosa-associated lymphoid tissue lymphoma translocation protein 1
IND: Investigational New Drug
GD2-SADA: Self-assembling and de-assembling
CD38: Cluster of differentiate 38
FDA: Food and drug administration
IND: Investigational new drug
DLT: Dose limiting toxicities
PK: Pharmacokinetics
ICANS: Immune effector Cell Associated Neurotoxicity
ORR: Overall response rates
NBI: Nasdaq biotech index
EMA: European medicine association

DAWN (Underperform, \$10 PO): PDUFA binary for shares

DAWN stock continues to trade up this year (YTD: 16%; NBI: flat) with April 30th PDUFA continuing to be key priority for the company. We see the company remaining confident as they already place their vision on commercialization, mentioning that the sales team (hiring of 18 sales reps completed in 4Q23) is already in place to commercialize tovorafenib once approved (PDUFA April 30th 2024). We do note that the potential for PDUFA delay is still likely (given 3-month delay has been common recently) especially if no AdCom is scheduled. That said, we continue to rehash our concerns given regulatory endpoint misalignment (RANO-LGG vs HGG), open-label study design without a comparator arm (drug benefits not accurately quantifiable), lowered ORR when using RANO-LGG (MR not likely to be included on the label according to antecedent cases in D/T), and hampered growth in children which raises questions on true risk/benefit for tovorafenib. Reiterate Underperform, \$10 PO.

RXXRX (Neutral, \$14 PO): 2024 data still too early

RXXRX stock trading down on earnings (-10%; NBI: -1.2%). While we continue to applaud impressive progress for the company especially on the technological front including **1)** deeper collaborative relationship with NVIDIA, **2)** LOWE drug discovery software utilization, and **3)** causal AI modelling and additional dataset, we believe concrete evidence in the form of clinical data is still needed to validate the AI platform. That said, we do see upcoming data catalysts to include a preliminary look at the platform's performance in the clinic including **1)** REC-994 (CCM) phase 2 data (exploratory efficacy) in 3Q24e, **2)** REC-2282 (NF2) phase 2 safety and preliminary efficacy data in 4Q24e, **3)** REC-4881 (FAP) phase 2 safety and preliminary efficacy data in 1H25e, **4)** REC-4881 (AXIN1/APC mutant cancers) safety and preliminary efficacy data in 1H25e, and **5)** REC-3964 (C. difficile) initiation of phase 2 study in 2024. While we have not heard from management just how deep will the upcoming efficacy data be, we speculate that the phase 2 data will likely still be too early for investors to gauge definitely on the AI platform capabilities. Reiterate Neutral and \$14 PO.

NVAX (Underperform, \$4 PO): going concern still lingers

NVAX stock has traded down this year (-2%; NBI: flat) after achieving revenues in 4Q23 of \$291M and full year 2023 of \$1.0B (Nuvaxovid sales: ~\$531M, -67% YoY), we see the shrinking C-19 market and diminishing demand further weighing on the stock with product sales hitting lower end of the guidance. That said, we do note that given the delayed FDA authorizations and CDC recommendations as compared to its peers, 1Q24 sales could fill the hole with regulatory hurdles mostly in the rearview mirror. However, the lingering going concern language is not yet eliminated, and now, in our view, is mostly due to two factors: **1)** continued uncertainty around the revenue piece (expenses continue to be reined in and B/S is getting cleaned up), and **2)** time needed to prove profit stability. With cost-cutting measures well underway (2023 full-year OpEx reduced by \$1.1 billion (-41% YoY)), we do see promise for the biotech to reverse negative sentiment especially with company guiding to a reasonable range for revenue (\$800M-\$1B) and an even more lean corporate structure (\$700M-\$800M R&D/SG&A) in 2024. That said, factors both within (BLA approval, prefilled syringe, relationships with pharmacies, etc.) and outside (C-19 demand dynamic, competing CIC therapies) the company's control can affect the company's fate in the coming years. Reiterate Underperform and \$4 PO.

RVMD (Buy, \$34 PO): RMC-6236 phase 3 core focus

RVMD stock reacted minimally to earnings (last 5 days: +2%; NBI: -0.51%) with most investors likely still focused on pipeline validation and robust clinical data following de-risking data from ESMO/Triple for 6236/6291 ([see our thoughts from ESMO, Triple meeting](#)). Company highlighted that the goal for 2024 is to allocate capital (company cash position bolstered through acquisition of EQRx, [see our thoughts here](#)) to **1)** expand reach of RMC-6236 by clinically assessing opportunities (1L, types, mutations), **2)** qualify

mutant-selective inhibitors led by 6291/9805 for late-stage development, **3)** advancing 6236 into phase 3 pivotal trials (aiming to initiate 2024). Upcoming catalysts include **1)** RMC-6236-001 efficacy/safety data in 2Q/3Q24e, **2)** RMC 6291-101 efficacy/safety data in 2H24e and **3)** RMC 9805-001 efficacy/safety data in 2H24e. With comfortable year-end cash balance up to \$1.85B, we see the biotech as well-funded to carry over multiple value inflection points in the near-future. Reiterate Buy and \$34 PO.

HCM (Buy, \$29 PO): Fruzaqla add significantly to topline

HCM stock trading down (YTD: -13%; NBI: flat) which in our view is not reflective of the company's strong fundamentals, especially with the company reporting 97% growth of revenue to \$838M in 2023, with net income of \$101M. In our view, newly approved Fruzaqla is already showing potential, doing \$15.1M in sales (just as we speculated from our Takeda's earnings) after being in market for merely 2 months. With US representing an immediate ~27k+ addressable patient and ~\$300M peak revenue opportunity for HUTCHMED and Takeda, with additional upside from label expansions (GC, NSCLC) and approvals in EU and Japan (filings currently under review), combined with Takeda's already-existing expertise in oncology drug commercialization, we see little hurdles ahead for Fruzaqla. The company continues to be eligible to receive royalties on net ex-China product sales, which we estimate could be close to 20% based on transactions for other assets at a similar stage of development ([see our thoughts on the deal](#)). Potential upcoming clinical and regulatory milestones include **1)** Fruquintinib: topline results from phase 2/3 registration trial in clear cell RCC 2024 year end, **2)** savoltinib: engagement with US FDA regarding possible NDA filing on SAVANNAH. Reiterate Buy and \$29 PO.

RGNX (Buy, \$35 PO): pipeline value realization in 2024/25

With positive updates from both '314 ([see our thoughts on the data here](#)), '202 ([see our report here](#)), and '121 ([see our key takeaways](#)), we see 2024 shaping up to be a promising year for the biotech. We summarize our key takes from earnings: **1)** ABBV-RGX-314 subretinal wAMD enrollment is on track for pivotal trials and are expected to support global regulatory submissions with the FDA and EMA in 4Q25/1H26e. **2)** Phase 2 '314 AAVIATE (subretinal) trial data update in mid-2024, **3)** Phase 2 '314 ALTITUDE (suprachoroidal) trial data updates in 2Q24e, **4)** '202 DUCHENNE trial new updates at Muscular Dystrophy Association Clinical and Scientific Meeting (Mar. 3rd – 6th), **5)** '202 pivotal dose determination in mid-2024, with initial strength and functional assessment data and initiation of pivotal program in 2H24e, **6)** company plans to use RGX-202 microdystrophin expression as a surrogate endpoint to support a BLA filing using the accelerated approval pathway, **7)** RGX-121 also on track to file a BLA in 2024 using the accelerated approval pathway (we note approval of the planned BLA could result in receipt of a Priority Review Voucher in 2025). Reiterate Buy and \$35 PO.

YMAB (Neutral, \$21 PO): Danyelza sales beat expectations

As we mentioned in our earnings preview ([see our preview report here](#)), and 4Q23 Danyelza did manage to beat the plateau and exceeded our expectations (4Q23: ~\$23M, BofA est: ~\$20M) which beat our estimates by 15%. Ex-US Danyelza expansion/label expansion into 1L pediatric neuroblastoma/osteosarcoma can also be a potential upside to market opportunity. In our view, the recent surge in YMAB stock (YTD: +143%; NBI: flat) is more likely to be growing interest from investors on SADA, which in our view can bring long-term value but still early (GD2-SADA phase 1 progressing, CD38-SADA IND cleared). We therefore reiterate Neutral and raise our PO to \$21 (\$18 prior) to reflect stronger-than-expected sales, as we wait for more actionable data-driven events before making a definitive call on the stock based on fundamentals.



Model Changes

Exhibit 1: DAWN Model Changes

Minor adjustments to OpEx

	2024E		2025E		2026E	
\$ in thousands	Prior	Current	Prior	Current	Prior	Current
Product revenue	7	7	31	31	131	131
License revenue	0	0	0	0	0	0
Total Revenues	7	7	31	31	131	131
COGS	1	1	6	6	26	26
R&D	141	144	148	151	156	158
SG&A	90	94	108	113	130	136
Total Operating Expenses	233	239	263	270	312	321
Operating Income	(226)	(233)	(232)	(239)	(181)	(189)
Interest income	3	15	2	13	2	12
Interest expense	(0)	(0)	(0)	(0)	(0)	(0)
Pretax Income	(229)	(247)	(234)	(252)	(183)	(201)
Net income to common (GAAP)	(224)	(218)	(230)	(226)	(152)	(149)
Earnings per share (non-GAAP)	(2.59)	(2.68)	(2.64)	(2.77)	(1.74)	(1.81)
Shares outstanding diluted	86,469	81,380	86,901	81,787	87,335	82,196

Source: Company guidance, BofA Global Research estimates

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Exhibit 2: HCM Model Changes

Adjustments made based on guidance and historical trends

	2024E		2025E		2026E	
\$ in thousands	Prior	Current	Prior	Current	Prior	Current
Other Ventures	317,704	346,509	349,474	381,160	384,421	419,276
Oncology/Immunology R&D	143,220	143,220	245,381	245,381	297,650	297,650
Oncology/Immunology Products	230,893	230,893	317,053	317,053	512,630	450,822
Savolitinib	54,906	54,906	79,657	79,657	121,913	121,913
Fruquintinib	96,115	96,115	123,899	123,899	242,603	180,795
Surufatinib	79,872	79,872	113,497	113,497	148,114	148,114
Amdizalisib	0	0	1,203	1,203	5,795	5,795
Sovleplenib	3,077	0	8,816	8,816	33,308	33,308
Total Revenues	691,817	720,622	911,908	943,594	1,194,702	1,167,748
COGS	(276,727)	(288,249)	(182,382)	(188,719)	(179,205)	(175,162)
R&D (adjusted)	(357,489)	(317,101)	(364,639)	(323,443)	(448,887)	(330,559)
Selling & Administrative Expenses	(158,700)	(141,167)	(166,635)	(148,225)	(171,785)	(155,636)
Non-GAAP Operating Income	(101,099)	(25,894)	198,253	283,208	394,824	506,391
Other (expense) income	(2,784)	40,332	(2,812)	40,736	(2,840)	41,143
Pretax Income	(103,883)	14,438	195,442	323,943	391,984	547,534
Provision for Taxes	1,039	(144)	(1,954)	(3,239)	(3,920)	(5,475)
Non-GAAP Net Income	(53,311)	61,369	243,086	367,845	437,710	589,246
Non-GAAP EPS	(\$0.26)	\$0.33	\$1.22	\$1.88	\$2.24	\$2.95
Diluted Shares Out Non-GAAP	191,446	184,480	203,164	195,771	207,227	199,687

Source: Company guidance, BofA Global Research estimates

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Exhibit 3: RVM Model Changes

Minor adjustments to OpEx to reflect start of pivotal trials

	2024E		2025E		2026E	
\$ in thousands	Prior	Current	Prior	Current	Prior	Current
Product revenue	0	0	12	0	12	26
Collab revenue	47	13	51	14	51	15
Total Revenues	47	13	63	14	63	42
COGS	0	0	1	0	1	3
R&D	342	457	366	489	366	528
SG&A	58	87	65	97	65	107
Total Operating Expenses	400	544	432	586	432	638
Operating Income	(353)	(531)	(369)	(572)	(369)	(596)
Interest income	10	55	11	63	11	72
Interest expense	0	(0)	0	(0)	0	(0)
Pretax Income	(363)	(586)	(380)	(635)	(380)	(668)
Net income to common (GAAP)	(343)	(477)	(358)	(510)	(358)	(524)
Earnings per share (non-GAAP)	(3.51)	(3.34)	(3.71)	(3.54)	(3.74)	(3.60)
Shares outstanding diluted	110,120	142,596	111,221	144,022	111,221	145,462

Source: Company guidance, BofA Global Research estimates

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Exhibit 4: RGNX Model Changes

Minor adjustments to revenue and OpEx

	2024E		2025E		2026E	
\$ in thousands	Prior	Current	Prior	Current	Prior	Current
Partnered royalties	114,405	102,365	132,742	109,324	149,861	105,811
License revenue	6,483	5,908	4,538	4,135	3,177	2,895
Total Revenues	170,888	158,273	394,935	371,114	485,797	441,465
COGS	49,636	48,377	61,797	60,229	67,976	66,252
R&D	232,464	236,911	263,149	268,184	298,937	304,657
SG&A	97,425	90,264	107,168	99,290	117,884	109,219
Total Operating Expenses	380,193	375,949	432,781	428,100	485,466	480,525
Operating Income	(209,304)	(217,677)	(37,847)	(56,986)	331	(39,060)
Interest income from licensing	215	26	226	28	238	29
Investment income	3,042	1,885	2,270	979	3,611	2,345
Pretax Income	(213,372)	(222,971)	(43,041)	(63,545)	(3,896)	(44,629)
Net income to common (GAAP)	(202,593)	(211,450)	(31,724)	(51,448)	7,988	(31,928)
Earnings per share (non-GAAP)	1.17	(4.89)	0.71	(1.15)	(1.62)	(0.70)
Shares outstanding diluted	43,302	43,302	44,602	44,602	45,902	45,902

Source: Company guidance, BofA Global Research estimates

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Exhibit 5: NVAX Model Changes

Minor modifications to OpEx due to cost cutting, aligned our 2024+ estimates with guidance

\$ in millions	2024E		2025E		2026E	
	Prior	Current	Prior	Current	Prior	Current
Product revenue	661	788	745	771	923	923
Grants revenue	0	0	0	0	0	0
Other revenue	24	21	25	21	25	22
Total Revenues	686	809	770	792	948	945
COGS	99	118	149	154	138	138
R&D	371	369	374	372	378	376
SG&A	352	375	380	405	407	434
Total Operating Expenses	822	862	903	932	923	948
Operating Income	(136)	(53)	(134)	(139)	25	(3)
Investment Income	0	0	0	0	0	0
Interest expense	8	10	5	8	4	5
Other income/expense	(6)	(15)	(2)	(6)	(1)	(2)
Pretax Income	(138)	(48)	(137)	(141)	22	(6)
Tax expense/(benefit)	4	2	(7)	(7)	2	(0)
Net income to common (GAAP)	(142)	(50)	(130)	(134)	21	(6)
Earnings per share (non-GAAP)	(1.03)	(0.28)	(0.69)	(0.59)	0.10	(0.02)
Shares outstanding diluted (thousands)	138,643	178,006	188,820	226,870	211,896	245,981

Source: Company guidance, BofA Global Research estimates

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Exhibit 6: YMAB Model Changes

Adjustment made to OpEx based on company guidance

\$ in thousands	2024E		2025E		2026E	
	Prior	Current	Prior	Current	Prior	Current
Omburtamab	0	0	0	0	0	0
Naxitamab	96,207	96,207	126,760	126,760	163,678	163,678
Early Pipeline	0	0	0	0	1,280	1,280
License Revenue	0	0	0	0	0	0
Total revenue	96,207	96,207	126,760	126,760	164,958	164,958
Operating expenses:						
R&D GAAP	61,317	60,749	64,996	64,394	70,195	69,545
SG&A GAAP	46,070	45,631	48,373	47,913	51,760	51,267
Total expenses	121,817	119,849	132,383	131,321	146,699	145,556
Operating income (loss)	(25,611)	(23,642)	(5,623)	(4,560)	18,260	19,403
Other (expense) income, net	454	454	477	477	501	501
Pretax income (loss)	(25,157)	(23,188)	(5,146)	(4,083)	18,761	19,903
Foreign currency translation	(38)	(38)	(40)	(40)	(42)	(42)
Net income (loss)	(25,194)	(23,226)	(5,031)	(4,001)	17,406	18,469
Net income (loss) to common stockholders	(25,157)	(23,188)	(5,146)	(4,083)	18,761	19,903
EPS to common stockholders (GAAP)	-\$0.54	-\$0.49	-\$0.10	-\$0.08	\$0.32	\$0.34
Diluted shares outstanding	46,851	46,852	52,901	53,103	58,951	59,354

Source: Company guidance, BofA Global Research estimates

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Exhibit 7: RXRX Model Changes

Minor adjustments to OpEx

\$ in thousands	2024E		2025E		2026E	
	Prior	Current	Prior	Current	Prior	Current
REC-994 (CCM)	0	0	22	22	79	79
REC-2282 (NF2)	0	0	25	25	90	90
REC-4881 (FAP)	0	0	0	0	0	0
REC-3964 (C. diff)	0	0	33	33	107	107
REC-3599 (GM2)	0	0	0	0	0	0
Product revenue	0	0	80	80	276	276
Grant/Collaboration revenue	70	70	175	175	150	150
Total Revenue	70	70	335	335	701	701
Cost of revenue/good sold	64	50	159	124	136	106
Research and development	269	277	296	305	310	321
General and administrative	121	122	139	140	167	168
Operating Income (loss)	(383)	(379)	(259)	(235)	88	106
Interest income (expense)	0	0	0	0	0	0
Other income (expense)	7	23	7	30	7	39
Consolidated net income	(390)	(402)	(266)	(265)	81	67
Net income (loss) per share	(1.97)	(1.49)	(1.50)	(1.12)	(0.78)	(0.51)
Shares outstanding, diluted ('000)	191,407	239,284	221,702	254,932	239,108	265,842

Source: Company guidance, BofA Global Research estimates

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Exhibit 8: Stocks mentioned

Prices and ratings for stocks mentioned in this report

BofA Ticker	Bloomberg ticker	Company name	Price	Rating
DAWN	DAWN US	Day One	US\$ 16.73	C-3-9
HCM	HCM US	Hutchmed China Ltd	US\$ 15.11	C-1-9
NVAX	NVAX US	Novavax	US\$ 4.94	C-3-9
RXR	RXR US	Recursion	US\$ 13.46	C-2-9
RGX	RGX US	Regenxbio	US\$ 17.44	C-1-9
RVMD	RVMD US	Revolution Medicines	US\$ 29.48	C-1-9
YMAB	YMAB US	Y-mAbs	US\$ 16.7	C-2-9

Source: BofA Global Research

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Price objective basis & risk**Day One Biopharmaceuticals (DAWN)**

Our \$10/share price objective is based on a probability adjusted NPV for tovorafenib in r/r pLGG (\$2/sh), tovorafenib for 1L pLGG (\$1/sh), tovorafenib for RAF-driven solid tumors (\$1/sh), pimasertib/tovorafenib combo for RAF-driven solid tumors (\$1/sh), and cash (\$5/sh). We apply a WACC of 10-12% and 1% (tovorafenib) to 3% (pima/tovo combo) terminal growth rate.

Downside risks to our PO are: 1) FDA red flags FIREFLY-1 trial design and delays tovorafenib approval, 2) lack of urgency for FDA to approve tovorafenib given high survival rate for current pLGG patients, 3) new RANO-LGG endpoint can result in lower ORR than previously reported, 4) D+T combo presents as further competition with randomized trial design setting a bar hard for tovorafenib to reach, 5) lack of platform innovation with all assets acquired could mean potential for future lacking, 6) small end market size can affect topline contribution even with approval, 7) rapidly expiring patents for pimasertib can give room for biosimilars to erode market share

Upside risks to our PO are: 1) FDA approves tovorafenib with no delays given unmet need and compelling data package, 2) BRAF-driven solid tumors substudy trial continues to readout positively, 3) FIREFLY-2 phase 3 pivotal for 1L pLGG reads out positively and earlier than expected, 4) clear pipeline strategy and potential for future synergy in combos starting with pimasertib/tovorafenib, which opens up larger market in solid tumors.

HUTCHMED (HCM)

Our PO of \$29 is derived from a probability-adjusted net present value (NPV) analysis, including \$7/share for savolitinib, \$10/share for fruquintinib, \$4/share for surufatinib, \$1/share for amdzalisib, \$1/share for sovepleinib, -\$2/share for other pipeline assets, \$3/share for the commercial platform and \$5/share for net cash. We use a weighted-average cost of capital (WACC) value ranging from 7% (commercial platform) to 11% (future pipeline) and terminal value ranging from -5% (legacy business) to 2% (future pipeline).

Downside risks to our price objective are 1) unfavorable efficacy and/or safety data for savolitinib, fruquintinib and surufatinib in clinical trials, 2) weaker-than-expected revenue for commercial platform, and 3) earlier-than-expected or more-than-expected competition for the above-mentioned three leading clinical assets.

Novavax (NVAX)

Our \$4/sh price objective is based on probability-adjusted net present value (NPV) of lead assets Nuvaxovid (\$-3/share), NanoFlu (\$2/share), ResVax (\$0/share), other pipeline (\$-1/share), and cash (\$6/share). We use a weighted-average cost of capital (WACC) of 10-13% and terminal values ranging from -12% (COVID-19) to 2% (other pipeline). We apply probabilities of success including 100% for Nuvaxovid in EU/ROW, 64% for NanoFlu, 7% for ResVax, and 4% for other pipeline.

Upside risks: 1) Nuvaxovid use could be stronger than expected, 2) assets in flu, RSV, and malaria may find a path to regulatory approval, 3) additional pipeline candidates may be nominated for novel disease areas, 4) competing therapies may show worse-than-expected efficacy/safety.

Downside risks: 1) omicron efficacy and heterologous boost benefit could wane, 2) Nuvaxovid revenue durability may miss consensus' high expectations, 3) sustained operating expense may erode profits, 4) regulatory path unclear for RSV/flu, 5) competition across pipeline disease areas could continue to intensify, 6) lack of early pipeline could leave a profitability gap 2023-2027.

Recursion Pharmaceuticals, Inc. (RXX)

Our \$14 PO is based on a probability-adjusted NPV of Recursion's lead pipeline assets, including REC-4881 (\$5/sh), REC-2282 (\$3/sh), REC-994 (\$2/sh), REC-3964 (\$3/sh), and REC-3599 (\$0/sh). We also assign value to platform and collaborations (\$10/sh), as well as expenses for platform buildout (-\$11/sh). We apply a 14% WACC (we project revenues out through 2038), in-line with other biotech companies of similar size and stage of clinical development. Current cash and equivalents contributes \$2/share to our valuation.

Upside risks would come from pipeline updates or further external validation of the platform.

Downside risks to our PO are: 1) clinical trial failures, 2) better than expected data from competitors, 3) dilution from cash raises.

Regenxbio, Inc. (RGNX)

Our \$35/share price objective is based on a probability-adjusted net present value (NPV) analysis of its four internal clinical programs, as well as royalties from partnered programs. We use a weighted-average cost of capital (WACC) of 10-12% and no terminal value (we project revenues through 2038), similar to other early-stage companies in our coverage universe. We ascribe \$7 for RGX-314 in wAMD, \$6 for RGX-202 in DMD, \$0/\$0 for MPS I/II, \$13 for partnered programs, and approximately \$9 for cash.

Downside risks: 1) failure of ongoing clinical trials, 2) emergence of untoward safety signals, 3) failure of partnered programs which reduces economics owed to Regenxbio, 4) difficulties in commercializing gene therapies, 5) manufacturing issues as capabilities are brought in house, 6) litigation risk that could jeopardize the NAV platform IP estate or cause undue legal/court fees.

Revolution Medicines (RVMD)

Our \$34/share price objective is based on a probability adjusted sum of the parts (SOTP) net present value (NPV) of RevMed's pipeline therapies targeting RAS (\$24/share), SHP2/ SOS1 (\$0/share), mTORC1/4EBP1 (\$3/share), the early pipeline, which includes other KRAS targets (i.e., G12R, G12V, G13D, Q61X, etc.) (\$0/share), and cash (\$7/share, 44%). We apply a weighted-average cost of capital (WACC) of 10-13%, -5% to 2% terminal growth rate, and probabilities of success ranging from 16% (RAS) to 6% (early pipeline).

Upside risks: 1) RMC-4630 (SHP2) shows meaningfully better activity in combination, 2) additional responses are demonstrated for RMC-5552 (mTORC1) in subsequent data updates, 3) RAS(ON) studies recruit faster than anticipated or find an accelerated path to market, 4) competing therapies show worse-than-expected efficacy/safety.

Downside risks: 1) lackluster SHP2 monotherapy data could expand to company's other pipeline assets, 2) RAS(ON) assets experience delays in clinical development slowing their path to market, 3) data from competing therapies is better than expected, 4) unexpected safety issues for mTORC1, SHP2, or RAS narrows the therapeutic window, 5) regulatory outlook worsens, slowing path to market (i.e. accelerated approval).



Y-mAbs Therapeutics, Inc (YMAB)

Our \$21 price objective is based on a probability-adjusted net present value (NPV) of lead assets omburtamab (\$0/share) and naxitamab (\$6/share), early pipeline, including GD2xCD3 and SADA platform (\$13/share), and cash approximately (\$2/share). We apply probability of approvals from 6%-16% (early platform) to 55% (Danyelza in 1L Neuroblastoma), a weighted average cost of capital (WACC) of 10-13%, and terminal growth rate of -1% to -3%.

Upside risks: 1) Danyelza sales outperform projections, 2) Danyelza label expansion successful, 3) SADA platform encouraging clinical data

Downside risks: 1) failure of late-stage clinical trials, 2) emergence of safety signals, 3) slow clinical adoption, and 4) commercialization failures.

Analyst Certification

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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
	Insmmed Incorporated	INSM	INSM US	Jason Zemansky
	Intellia Therapeutics	NTLA	NTLA US	Greg Harrison, CFA
	Janux Therapeutics	JANX	JANX US	Alec W. Stranahan
	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
	Traverse 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	BMJ	BMJ 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
	Kymira Therapeutics	KYMR	KYMR US	Geoff Meacham
	Moderna	MRNA	MRNA US	Geoff Meacham
	Pfizer	PFE	PFE US	Geoff Meacham
	Recursion Pharmaceuticals, Inc.	RXR	RXR US	Alec W. Stranahan
	Tyra Biosciences	TYRA	TYRA US	Greg Harrison, CFA
	Vir	VIR	VIR US	Alec W. Stranahan
	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
	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%

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