BofA SECURITIES

US Biopharmaceuticals

4Q23 SMid Biotech Preview: New drugs main driver for stock, sales in focus

Price Objective Change

High level thoughts heading into 4Q23 earnings reports

While data/regulatory catalysts should dominate news flow in our coverage for the rest of 2024 (see our 2024YA report), the focus into 4Q earnings reports remains both new (SWTX. HCM, KRYS, TGTX) and ongoing (YMAB, NVAX) drug launches. We outline our expectations into the print for each of these companies below.

Krystal Biotech (KRYS): With first commercial sale occurring at the end of August (284 new starts from the three months of 3Q23), we still see room for Krystal to beat our expectation for FY23 even after a narrow sales miss in 3Q23 ($8.6M actual vs $9.3M cons; 2023 sales: BofAe: $29M, cons: $36M). Our focus for the full-year print will remain on Vyjuvek sales/guidance on projected sales in 2024. Reiterate Buy and $140 PO.

TG Therapeutics (TGTX): While TG's announcement of ~$40M sales for Briumvi in 4Q23 is likely to be viewed positively numbers ($40M sales in 4Q23e cons: $35.5M, prior BofAe: ~$36M), we see the results as hitting but not exceeding expectations. With Ocrevus being the market leader in US/EU with 24% market and higher retention rates as compared to other MS medicines as emphasized by Roche's management, affirmed by our KOL survey (see our KOL survey here), we will focus on TG's commentary to validate their position in a market dominated by Ocrevus. Reiterate Underperform and $7 PO.

SpringWorks (SWTX): With our KOL confirming that prescription of Ogsiveo has been happening as early as one-week into approval (see our KOL call here), we remain optimistic on the Ogsiveo launch but note the key caveat that full-year earnings results will only consist of one to two months of sales, which is not enough to declare a definitive success/flop. That said, our model projects ~$2M in 2023e (cons: $2.2M) although we expect more weight will be placed on 2024 commentary from the company. Reiterate Buy and raise PO to $56 ($50 prior) give increased projected sales.

HUTCHMED (HCM): We continue to believe that Fruzaqla can become a "monster drug" despite the recent share pullback. With Takeda dropping clues from earnings guiding to approximately JPY2.4Bn ($15M) in 4Q23e, we see the guide as exceeding our expectations (BofAe: ~$9M 2023e) and therefore reiterate our Buy rating and $29 PO.

Novavax (NVAX): We will be looking for inventory write-downs as an indicator of pharmacies delaying/electing not to stock the vaccine. With mRNA-based vaccines already off to a shaky start, we expect an uptick in 4Q23 product sales could lead to sharp declines in 1H24 if vaccine demand is low. Reiterate Underperform and $4 PO.

Y-mAbs Therapeutics (YMAB): The Danyelza campaign will likely invigorate sales, but its effects (breaking plateau) are unlikely to be realized in 4Q23 earnings. Reiterate Neutral and raise PO to $18 ($10 prior) to reflect increased likelihood of success of SADA with value-unlocking catalysts expected in 2024.

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Abbreviations:
FY: Fiscal year
KOL: Key opinion leader
MS: Multiple sclerosis
RNA: Ribonucleic acid

See additional abbreviation definitions associated with each individual section of the report.

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2024 Coverage Catalysts

Exhibit 1: Coverage Catalysts
Summary of important catalysts in 2024 for our coverage companies

Company	Ticker	Asset	Indication	Catalyst	Timing	Importance
Day One Biopharmaceuticals	**DAWN**	Tovorafenib	r/r pLGG	Estimated PDUFA	April 30th 2024	**HIGH**
		Tovorafenib	1L pLGG	FIREFLY-2 pivotal	2024e/2025e	**MODERATE**
		Pimasertib/Tovo combo	MAPK-altered solid tumors	Combo with tovorafenib data readout	2025e	**MODERATE**
Erasca	**ERAS**	naporafenib	RAS Q61 solid tumors	SEACRAFT-1 Phase 1b combo signal-seeking efficacy data	2Q24e/4Q24e	**HIGH**
		naporafenib	NRASm Melanoma	SEACRAFT-2 Phase 3 pivotal study first patient dose	1H24e	**MODERATE**
		ERAS-007	EC-naïve BRAFm CRC	HERKULES-3 Phase 1b combo dose expansion data	1H24e	**MODERATE**
		ERAS-801	glioblastoma multiforme	THUNDERBOLT-1 phase 1 monotherapy escalation data	2024e	**MODERATE**
HUTCHMED	**HCM**	Amdizalisib	3L FL/2L MZL	Phase 2 study readout for potential NDA submission	2024e	**HIGH**
		Savolitinib/Tagrisso	EGFR TKI ref. Met+NSCLC	SAVANNAH global study readout, NDA aimed for 2025	2024e	**LOW**
Immatics	**IMTX**	IMA203 (PRAME)	Solid tumors	Program updates	2024e	**HIGH**
		IMA203CD8 (PRAME) 2nd gen	Solid tumors	Interim date readout	2024e	**HIGH**
		IMA401 (MAGEA4/8)	Solid tumors	Program updates	2024e	**LOW**
		IMA402 (PRAME)	Solid tumors	Program updates	2024e	**LOW**
Krystal Biotech	**KRYS**	Vyjuvek	DEB	2023 full-year earnings update	1Q24e	**HIGH**
		KB407	Cystic Fibrosis	Program updates	2024e	**MODERATE**
		KB301	Wrinkling/Acne (collagen type III)	Initial phase 1 data	2024e	**LOW**
MeiraGTx	**MGTX**	botaretigene sparoparvovec (AAV-RPGR)	XLRP	Phase 3 Lumeos study readout	2024e	**HIGH**
		AAV-AQP1	xerostomia	Phase 3 start	2024e	**MODERATE**
		AAV-GAD	Parkinson's Disease	IND opening study readout	2024e	**MODERATE**
		Riboswitch platform	Salivary gland	First phase 1 gene regulation study readout	2024e	**MODERATE**
		AAV-RPE65	RPE65-associated retinal dystrophy	Phase 3 pivotal study readout	2024e	**MODERATE**
		AAV-CNGA3/B3	achromatopsia	Late-stage study readout	2024e	**MODERATE**

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Novavax	**NVAX**	Nuvaxovid	COVID-19	2023 full-year earnings	1Q24e	**MODERATE**
Regenxbio	**RGNX**	RGX-202	DMD	Pivotal trial initiation	2H24e	**HIGH**
		RGX-121	MPS II	BLA filing in 2024/25	2024e	**MODERATE**
		RGX-314	wAMD	Phase 3 study enrollment (vs Lucentis and Eylea)	2025e	**MODERATE**
		RGX-314	Diabetic retinopathy	Phase 2 suprachoroidal further readout	2025e	**MODERATE**
Revolution Medicine	**RVMD**	RMC-6236	Multi	Phase 1/1b monotherapy interim update	2024e	**HIGH**
		RMC-6291	G12C	Phase 1/1b monotherapy interim update	2024e	**HIGH**
		RMC-4630	SHP2	Global phase 2 topline update	2024e	**LOW**
		RMC-5552	mTORC1-4EBP1	Additional evidence of monotherapy activity	2024e	**MODERATE**
SpringWorks Therapeutics	**SWTX**	Mirdametinib	NF1-PN	NDA submission	2024e	**HIGH**
		Nirogacestat/Blenrep	Multiple Myeloma	Data readout for Blenrep combo	2024e	**HIGH**
TG Therapeutics	**TGTX**	Briumvi	RMS	2023 Full-year earnings update	1Q24e	**HIGH**
Y-mAbs Therapeutics	**YMAB**	GD2-SADA	Solid tumors	Interim phase 1 data	2024e	**MODERATE**
		GD2-CD38 Bispecific	Liquid tumors	Early phase 1 data	2024e	**MODERATE**
		Danyelza	osteosarcoma	Phase 2 data and pivotal phase 3 study start	2H24e	**LOW**
		Danyelza	1L Neuroblastoma	Phase 2 interim readout	1H24e	**LOW**
		Naxitamab	NB	BCC study phase 2 readout	2024e	**LOW**

Source: Company reports, BofA Global Research

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KRYS (Buy, $140 PO): commercial picture to be clearer

KRYS stock price has declined since the beginning of 2024 (YTD: -10%, NBI: -2.19%), likely due to expected early launch variability in 4Q as inferred from our conversation with management (growing cadence of conversion to drug, seasonal effects on new starts, j-code coming online), which could impact shares in the near term. That said, we continue to like the commercial setup looking to the balance of 2024, with the true shape of the launch curve likely beginning to come into focus only in 2H24e. Additional upside levers include approvals in EU/JP and FDA guidance about label expansion studies for ocular manifestations in DEB (roughly 50% of DEB patients) over the course of 2024. Reiterate Buy and $140 PO.

Our focus for the FY23 print: hit or miss on revenue can drive stock

With first commercial sale occurring at the end of August (284 new starts from three months in 3Q23), we still see room for Krystal to beat our expectations for FY23 even after the narrow sales miss in 3Q23 ($8.6M actual vs $9.3M cons, see our 3Q23 earnings takeaways report), we project 177 patients on therapy by the end of 2023; BofAe: $29M 2023 sales, cons: $36M). Assuming roughly four to six weeks for new start forms to convert to paid drug and an 85% conversion rate, the majority of new starts reported in 3Q should be given at least one commercial dose of Vyjuvek by the end of the year. At the current rate, ~$40-45M for 2023 is not out of reach (284*500k pricing*85% G/N*90% compliance*0.4 median duration of therapy); therefore our adjusted model estimates $182M for 2024 Vyjuvek sales (cons $192M), $344M for 2025 (cons: $371M) and $487M for 2026 (cons: $496M). And while peak sales for Vyjuvek are likely the biggest swing factor for valuation, in our view, directional commentary from the company on patient receptivity could also begin to help inform timing/magnitude of peak sales over the next quarter or two beyond the full-year earnings.

TGTX (Underperform, $7 PO): not exceeding expectations

TGTX shares have been trading down in 2024 (YTD: -17%; NBI: -2.19%), especially after presentation from an investor conference (see our thoughts from the conference here). While we applaud that the company was able to realize $40M of Briumvi sales in 4Q23e (prior cons: $35.5M, prior BofAe: ~$36M), while also guiding to positively viewed 1Q24 revenue guidance at $41M-$46M (cons: $45M, our model projects the lower-end of guidance at $41M), and $220M-$260M in 2024e (cons: $217M; BofAe: $236M), we note that the 2024 outlook is in line with consensus and the relatively small increase from 4Q23e-1Q24e sales/est. is suspect to pull-forward/year-end stocking on sales (seasonality could be the driver). We adjust our estimates to $344M for 2025 (cons: $352M) $510M for 2026 (cons: $521M) to reflect marginally higher mid-term sales expectations. That said, based on our recent KOL survey analysis (see our survey here), where we observed (1) a growing consensus from prescribers to choose Ocrevus over Briumvi; (2) Briumvi prescribers are generally from smaller clinics treating smaller patient population; and (3) most prescribers still unwilling to switch therapy for current patients nor would introduce Briumvi as a first choice, we continue to see difficulty for the stock to exceed our current expectations. Reiterate Underperform and $7 PO.

Our for the FY23 print: comp commentary to be expected

With management having more or less already provided 4Q23 sales results ($40M sales in 4Q23e prior cons: $35.5M, prior BofAe: ~$36M), and guidance as well, we therefore turn our attention to updates since the last guidance and potentially future color on stocking/pull-over effects, which we believe have been an investor concern contributing to share price weakness. Moreover, we listened in on Roche's FY23 earnings and noted that the large pharma remains nonchalant about Briumvi's potential for competition. With Ocrevus continuing to be the market leader in US/EU with 24% market share (300k patients being treated globally) and higher retention rates as compared to other MS medicines as emphasized by Roche's management, not to mention the imminent Ocrevus subq approval this year, we are especially interested to see what TG will say on their earnings call to validate their position in a market dominated by Ocrevus.

DEB: dystrophic epidermolysis bullosa

HSV: herpes simplex virus

IL-2/12: interleukin 2/12

G/N: gross-to-net

CF: cystic fibrosis

AATD: alpha-1 antitrypsin deficiency

RMS: Relapsing multiple sclerosis

Subq: subcutaneous

IV: intravenous

BTK: Burton's Tyrosine Kinase

SWTX (Buy, raise PO to $56): first look at Ogsiveo sales

SWTX has been trading up in 2024 (YTD: +24%; NBI:-2.19%) with confidence increasing given a clear commercialization gameplan and the company reaping the "benefits" of the regulatory delay. We see potential for Ogsiveo to capture a lucrative market (1.6k newly diagnosed patients per year, 7k actively getting treatment, 20k+ not getting treatment). From our conversation with management, company is ready with ~35 sales reps to cover the country, and given (1) management reiterated that 90%+ of prescribers said they would switch to niro if approved; (2) new QoL, pain assessments data can become key differentiator for patients (most of whom are experiencing mild to severe symptoms) to drive more market share according to management; and (3) positive feedback from payors in terms of cost-benefit given lack of treatment in DT and sizeable market. Reiterate Buy and raise PO to $56 ($50 prior) to reflect increasing confidence heading into FY23 earnings.

Our focus for the FY23 print: Ogsiveo sales will only be 1-2 mo

While we see the market becoming gradually more excited to see the first report of Ogsiveo sales numbers (our KOLs have indicated that prescriptions were already being written as soon as one-week into approval, see our KOL insights call here), we do note cautiously that the sales data to be presented will only cover one to two months, which is unlikely to be an indicative signal of success. That said, with our KOL conversation highlighting unmet need in DT (surgery not the ideal solution), efficacy much better than SOC, and AEs not being a concern to preclude prescription, we see hurdles ahead as effectively addressed due to the drug's superior clinical profile. Our adjusted model is mostly in line with consensus and currently projects $2M in sales for 2023 (two months since Nov. 27th approval, cons: $2.2M), $54M in 2024 (cons $59.8M), $161M in 2025 (cons: $158.7M), and $293M in 2026 (cons: $289.9M), which could, in our view, conservatively represent the market opportunity for Ogsiveo.

HCM (Buy, $29 PO): Takeda earnings dropping clues

HCM stock has been trading down (YTD: -23%; NBI: -2.19%), which in our view does not reflect the company's strong fundamentals. In our view, newly approved Fruzaqla can become a "monster drug" and 2024 is the year to prove it. With US representing an immediate ~27k+ addressable patients and a ~$300M peak revenue opportunity for HUTCHMED and Takeda, with additional upside from label expansions (GC, NSCLC) and approvals in the EU and Japan (filings currently under review), combined with Takeda's already-existing expertise in oncology drug commercialization, we see few hurdles ahead for Fruzaqla. US approval triggered a $35M milestone to HUTCHMED ($1.13B total milestones under the deal, including $400M upfront earlier this year). The company is also 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). We also expect a WAC price in the range of $10-12k per month would put it roughly in line with competing oral therapies approved for mCRC. That said, early quarters of 2024 are especially important to gauge launch trajectory, on which we will continue to focus. Reiterate Buy and $29 PO.

Our focus on for the FY23 print: Fruzaqla did JPY2.4Bn ($15M) in 4Q23

We listened in on Takeda's earnings call and the large pharma dropped some clues regarding how well Fruzaqla did in one quarter of commercialization. Takeda reported in their "others" category on their 10-K and we inferred that Fruzaqla was able to secure $15M in sales in its first quarter of commercialization in the US (our model projected only $245K in sales in the US 2023e). To put this number in perspective, Fruzaqla China sales were $42M in 1H23 after being approved in China for five years. We therefore have reasons to believe that Fruzaqla can indeed become a blockbuster drug and will continue to focus on the numbers reported during the FY23 print.

PDUFA: Prescription drug user free act

ORR: Overall response rate

FDA: Food and drugs administration

NF1-PN: neurofibromatosis type 1

ORR: Overall response rate

PRO: patient-reported outcomes

BICR: blinded-independent central review

DT: Desmoid tumors

NDA: new drug application

Gr3: Grade 3

QoL: quality of life

GC: Gastric cancer

mCRC: metastatic Colorectal cancer

NSCLC: non-small cell lung cancer

WAC: wholesale acquisition cost

BTK1: Bruton tyrosine kinase

IDH1/2: isocitrate dehydrogenases types 1 and 2

AACR: American Association of Cancer Research

ITP: immune thrombocytopenic purpura

NVAX (Underperform, $4 PO): grim outlook continues

NVAX stock continues to trade down (YTD: -19% NBI:-2.19%) due to a narrowing window for the company to rebound in a shrinking C-19 market. We see the path as now clear (outside of disadvantage of a multi-dose format) for the company with execution being key to meet the company's 2023 guidance and near-term sales aspirations. And while we expect small initial orders to be placed to stock the vaccine, which should be reflected in 4Q revenues, subsequent orders through the remainder of the 2023-2024 COVID-19 season will likely be demand-driven. While management sees the 2023 story reversing as the US transition from pandemic to endemic for C-19, slow uptake does not bode well for the endemic market when NVAX is up against large pharmaceutical companies (see our 2023 YA report), especially with the mRNA vaccine producers also taking their foot off the C-19 pedal (as evident from the YoY step-down in sales for Moderna's mRNA vaccines: 2022: ~$18.4B; 2023: ~$6B; 2024 guidance: ~$4B), we remain reserved about a near-term rebound for shares. Reiterate Underperform and $4 PO.

Our focus for the FY23 print: Execution is everything

What we will focus on for the full-year print is whether the company will indeed execute and reach the previous numbers guided both in cost-cuts and revenue. As a reminder: the cost-cutting plan will reduce 12% of the company's global workforce, costing $4M-$7M to implement with 85% of the benefit expected this year. We see this as well-telegraphed already, with the company already guiding to lower 2023 OpEx (~$1.15B-$1.25B; prior: $1.3B-$1.4B) and 2024 OpEx (~$750M) through multiple cost-cutting efforts. Novavax's ability to execute on the guided ~$0.96-1.14B product sales in 2023 is key to reverse negativity. Furthermore, we see this season's commercial uptake as further complicated by the multi-dose format of a Novavax vaccine, with each carton containing 10 doses (two vials in total) totaling ~$1,300 WAC price, with unused doses discarded if not used within 12 hours after first puncture. Therefore, in a scenario where demand is low, we could see pharmacies delaying or electing not to stock the vaccine in subsequent months. We will be looking for inventory write-downs as an indicator of this in the company's 4Q23 earnings. Either way, with mRNA-based vaccines already off to a shaky start, we expect an uptick in 4Q23 product sales could lead to sharp declines in 1H24 if vaccine demand remains low. Our model currently projects numbers meaningfully below consensus: $686M for 2024 (cons: $981M), $770M for 2025 (cons: $1072M), and $948M (cons: $1168M) as we remain bearish on the stock.

YMAB (Neutral, raise PO to $18): SADA derisking ahead

YMAB shares have been trading up meaningfully in 2024 (YTD: +132%; NBI: -2.19%), especially after a positive presentation at an investor conference in January (see our thoughts from the investor conference here), where (1) management's announcement of a new 4Q23 Danyelza campaign invigorated dormant investors; and (2) SADA programs impressing many, with growing confidence in the platform ahead of key derisking catalysts in 2024e. Y-mAbs goal for 2024 is also clear: (1) continue to push Danyelza market uptake and growth; and (2) unlock value from SADA through a combination of clinical data updates and potential partnerships. And while we see opportunity for the company to execute on both fronts (our thoughts following 3Q23 earnings), recent sales/scripts for Danyelza appear to be plateauing (stabilizing at ~$20M in quarterly sales) and SADA programs are still early (GD2-SADA phase 1 progressing, CD38-SADA IND cleared).That said, we note ex-US Danyelza expansion into 1L pediatric neuroblastoma/osteosarcoma as potential upside to the market opportunity, and if we continue to see strong sales from the company's lead asset in the full-year print, we do see opportunities for current strength in shares to continue. Reiterate Neutral and raise PO to $18 ($10 prior) to account for increasing confidence in SADA as reflected in the increase of probability of success in our model.

What we will focus on for the FY23 print: Can Danyelza overcome the plateau

Mediocre Danyelza sales in 3Q23 (~$20M), and with sales growth has stalling in recent quarters, declining -3.8% q/q in 3Q, do not bode well for the biotech heading into full-

FDA: Food and drug administration

CDC: Center of disease control

C-19: Covid 19

EUA: Emergency use approval

SADA: Self-assembling and de-assembling

1L: Front line

r/r: relapse/refractory

2L: Second line

GD2: disialoganglioside

NB: Neuroblastoma

PK: pharmacokinetics

FDA: Food and Drug Administration

CRL: complete response letter

BD: business development

year earnings. While company has not changed its guidance of $80-$85M for 2023, Danyelza would have to at least perform on-par with 3Q23 (~$20M) to hit the lower end of that guidance range (our model projects $20.3M in 4Q23e (cons: $21.2M) in order to hit ~$81M for 2023e (cons: $78.4M)). We expect the company also to provide guidance for 2024, and depending on the number given, we should have a good picture of management's expectations. With our model projections for 2024e/25e/26e remaining mostly in line with consensus with $96M (cons: $99M), $126M (cons: $120M), and $163M (cons: $143M), respectively, we see high possibility of the company guiding in line with current consensus, with any guidance above that threshold considered to be a bullish indicator, in our opinion. We therefore see the outcome of the full-year earnings to be quite binary: either a hit or a miss on guidance could be directionally bipolar.

Exhibit 2: TGTX Model Changes
Adjusted revenue projections based on company guidance

	2024E		2025E		2026E	
$ in thousands	**Prior**	**Current**	**Prior**	**Current**	**Prior**	**Current**
Product revenue	174,229	236,183	260,825	343,729	391,820	510,189
License revenue	89,100	89,100	79,200	79,200	69,300	69,300
Total Revenues	**263,329**	**325,283**	**340,025**	**422,929**	**453,948**	**579,489**
COGS	26,134	47,237	39,124	51,559	58,773	76,528
R&D	69,946	76,715	66,449	72,880	64,456	70,693
SG&A	138,614	163,816	152,475	180,198	164,673	194,614
Total Operating Expenses	**234,695**	**287,768**	**258,048**	**304,637**	**287,902**	**341,835**
Operating Income	**28,634**	**37,515**	**81,977**	**118,292**	**173,218**	**237,653**
Interest income	(5,587)	(5,587)	(5,028)	(5,028)	(4,526)	(4,526)
Interest expense	15,134	15,134	13,620	13,620	12,258	12,258
Pretax Income	**19,088**	**27,968**	**73,385**	**109,700**	**165,486**	**229,921**
Net income to common (GAAP)	**19,374**	**28,343**	**75,844**	**113,249**	**174,147**	**241,803**
Earnings per share (non-GAAP)	**0.12**	**0.17**	**0.47**	**0.70**	**1.08**	**1.50**
Shares outstanding diluted	162,276	162,276	161,992	161,992	161,708	161,708

Source: BofA Global Research estimates

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Exhibit 3: SWTX Model Changes
We adjust our revenue estimates for Ogsiveo based on consensus

	2024E		2025E		2026E	
$ in thousands	Prior	Current	Prior	Current	Prior	Current
Desmoid Tumors - Adult, total revenue ($M)	46	54	109	161	201	293
NF1-Associated PN, total revenue ($M)	0	0	12	12	85	85
BGB-3245 (RAF Mutant Solid Tumors), total revenue ($M)	0	0	0	0	0	0
Product Revenues	**46**	**54**	**120**	**173**	**297**	**388**
Other Revenue (licensing/collaboration)	0	0	0	0	0	0
Total Revenues	**46**	**54**	**120**	**173**	**297**	**388**
Costs of goods sold	9	11	24	35	25	78
Research and development	174	174	200	200	230	230
General and administrative	220	258	264	310	303	356
Operating income (loss)	**(356)**	**(388)**	**(367)**	**(371)**	**(367)**	**(275)**
Interest and other income, net	3	19	3	17	3	15
Interest expense	(0)	(0)	(1)	(1)	(1)	(1)
Unrealized gain (loss) on available-for-sale securities	(3)	(3)	(4)	(4)	(4)	(4)
Consolidated net income (loss)	**(357)**	**(373)**	**(369)**	**(359)**	**(254)**	**(224)**
Net income (loss) per share	**(4.93)**	**(5.16)**	**(4.49)**	**(4.37)**	**(2.82)**	**(2.49)**
Shares outstanding, diluted ('000)	72,351	72,351	82,076	82,076	90,113	90,113

Source: BofA Global Research estimates

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Exhibit 4: NVAX Model Changes
Adjusted revenue projections for Nuvaxovid due to diminishing COVID-19 market

	2024E		2025E		2026E	
$ in millions	**Prior**	**Current**	**Prior**	**Current**	**Prior**	**Current**
Product revenue	1,083	661	1,361	745	1,051	923
Grants revenue	291	0	247	0	255	0
Other revenue	47	24	48	25	29	25
Total Revenues	**1,422**	**686**	**1,656**	**770**	**1,336**	**948**
COGS	163	99	204	149	158	138
R&D	986	371	995	374	764	378
SG&A	449	352	494	380	559	407
Total Operating Expenses	**1,597**	**822**	**1,693**	**903**	**1,481**	**923**
Operating Income	**(175)**	**(136)**	**(38)**	**(134)**	**(145)**	**25**
Investment Income	0	0	0	0	0	0
Interest expense	8	8	5	5	4	4
Other income/expense	(2)	(6)	(1)	(2)	(3)	(1)
Pretax Income	**(182)**	**(138)**	**(42)**	**(137)**	**(145)**	**22**
Tax expense/(benefit)	**(5)**	**4**	**(2)**	**(7)**	**10**	**2**
Net income to common (GAAP)	**(177)**	**(142)**	**(41)**	**(130)**	**(155)**	**21**
Earnings per share (non-GAAP)	**(1.98)**	**(1.26)**	**(0.44)**	**(0.95)**	**0.84**	**0.13**
Shares outstanding diluted (thousands)	89,320	112,669	92,478	136,872	159,948	159,948

Source: BofA Global Research estimates

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Exhibit 5: HCM Model Changes
Adjusted revenue based on current projections

	2024E		2025E		2026E	
$ in thousands	Prior	Current	Prior	Current	Prior	Current
Other Ventures	**317,704**	**323,480**	**349,474**	**355,828**	**384,421**	**391,411**
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**	**697,593**	**911,908**	**918,263**	**1,194,702**	**1,139,883**
COGS	(276,727)	(279,037)	(182,382)	(183,653)	(179,205)	(170,982)
R&D (adjusted)	(357,489)	(357,489)	(364,639)	(364,639)	(448,887)	(372,661)
Selling & Administrative Expenses	(158,700)	(158,700)	(166,635)	(166,635)	(171,785)	(174,966)
Non-GAAP Operating Income	**(101,099)**	**(97,633)**	**198,253**	**203,337**	**394,824**	**421,273**
Other (expense) income	(2,784)	(2,784)	(2,812)	(2,812)	(2,840)	(2,840)
Pretax Income	**(103,883)**	**(100,417)**	**195,442**	**200,525**	**391,984**	**418,433**
Provision for Taxes	1,039	1,004	(1,954)	(2,005)	(3,920)	**(4,184)**
Non-GAAP Net Income	**(53,311)**	**(49,880)**	**243,086**	**248,119**	**437,710**	**463,894**
Non-GAAP EPS	($0.28)	($0.26)	$1.20	$1.22	$3.80	$2.24
Diluted Shares Out Non-GAAP	191,446	191,446	203,164	203,164	207,227	207,227

Source: BofA Global Research estimates

BofA GLOBAL RESEARCH

Exhibit 6: YMAB Model Changes
Adjusted revenue projections from SADA, raise PO to $16 ($10 prior)

	2024E		2025E		2026E	
$ in thousands	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	58,478	61,317	61,987	64,996	66,945	70,195
SG&A GAAP	45,192	46,070	47,452	48,373	50,774	51,760
Total expenses	118,101	121,817	128,453	132,383	142,463	146,699
Operating income (loss)	**(21,895)**	**(25,611)**	**(1,692)**	**(5,623)**	**22,496**	**18,260**
Other (expense) income, net	454	454	477	477	501	501
Pretax income (loss)	(21,440)	(25,157)	(1,215)	(5,146)	22,996	18,761
Foreign currency translation	(38)	(38)	(40)	(40)	(42)	(42)
Net income (loss)	**(21,478)**	**(25,194)**	**(1,219)**	**(5,031)**	**21,345**	**17,406**
Net income (loss) to common stockholders	**(21,440)**	**(25,157)**	**(1,215)**	**(5,146)**	**22,996**	**18,761**
EPS to common stockholders (GAAP)	**-$0.46**	**-$0.54**	**-$0.02**	**-$0.10**	**$0.39**	**$0.32**
Diluted shares outstanding	46,851	46,851	52,901	52,901	58,951	58,951

Source: BofA Global Research estimates

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Exhibit 7: KRYS Model Changes
Adjusted B-VEC projected revenues based on revised guidance

	2024E		2025E		2026E	
$ in thousands	Prior	Current	Prior	Current	Prior	Current
B-VEC	152	182	290	344	515	487
KB301	0	0	3	3	20	20
KB407	0	0	6	6	33	33
KB408	0	0	0	0	5	5
Total other pipeline/platform	0	0	0	0	0	0
Total Revenues	**155**	**185**	**319**	**373**	**636**	**608**
Costs of goods sold	15	18	32	37	32	30
Research and development	62	62	74	74	85	85
General and administrative	155	155	194	194	223	223
Operating income (loss)	**(78)**	**(51)**	**19**	**67**	**296**	**269**
Interest and other income, net	16	16	14	14	13	13
Interest expense	0	0	0	0	0	0
Unrealized gain (loss) on available-for-sale securities	0	0	0	0	0	0
Income tax benefit (expense)	0	0	0	0	(44)	(40)
Consolidated net income (loss)	**(62)**	**(35)**	**33**	**81**	**264**	**242**
Net income (loss) per share	**(2.15)**	**(1.21)**	**1.07**	**2.67**	**8.30**	**7.59**
Shares outstanding, diluted ('000)	28,971	28,971	30,410	30,410	31,832	31,832

Source: BofA Global Research estimates

BofA GLOBAL RESEARCH

Exhibit 8: Stocks mentioned
Prices and ratings for stocks mentioned in this report

BofA Ticker	Bloomberg ticker	Company name	Price	Rating
HCM	HCM US	Hutchmed China Ltd	US$ 13.53	C-1-9
KRYS	KRYS US	Krystal	US$ 110.13	C-1-9
NVAX	NVAX US	Novavax	US$ 4.1	C-3-9
SWTX	SWTX US	SpringWorks	US$ 46.53	C-1-9
TGTX	TGTX US	TG Therapeutics	US$ 14.19	C-3-9
YMAB	YMAB US	Y-mAbs	US$ 15.2	C-2-9

Source: BofA Global Research

BofA GLOBAL RESEARCH

Price objective basis & risk

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 amdizalisib, $1/share for sovleplenib, -$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.

Krystal Biotech (KRYS)

Our $140/share price objective is based on a probability-adjusted net present value (NPV) for rare dermatology ($107/share), respiratory, including cystic fibrosis (CF) and AATD ($9/share), aesthetics through the Jeune subsidiary ($6/share), the discovery pipeline ($4/share), and cash ($14/share). We apply probabilities of success from 9% (aesthetics) to 100% (Vyjuvek), a weighted-average cost of capital (WACC) of 10-13%, and -3% (rare derm) to 2% (early pipeline) terminal growth rate.

Downside risks: 1) Vyjuvek launch uptake slower than anticipated, 2) HSV-1 technology fails to yield compelling data in expanded chronic indications, 3) competitors produce more convincing data for competing therapies, 4) regulatory and/or reimbursement landscape changes unfavorably for gene therapies, and 5) funding is insufficient to move forward pipeline aspirations or further commercial/manufacturing build out.

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.

SpringWorks (SWTX)
Our $56/share price objective is based on a probability-adjusted net present value (NPV) for nirogacestat mono ($26/share), nirogacestat combo ($3/share), mirdametinib ($16/share), BGB-3245 ($2/share), TEAD inhibitor program ($1/share), EGFR inhibitor program ($1/share), and cash ($7/share). We apply probabilities of success from 3% (EGFR, TEAD) to 100% (nirogacestat), a weighted-average cost of capital (WACC) of 10-13%, and -4% (nirogacestat) to -1% (early pipeline) terminal growth rate.

Downside risks are: 1) nirogacestat regulatory review experiences setbacks or final label is more limited than expected, 2) nirogacestat launch delayed or uptake slower than anticipated, 3) nirogacestat fails to yield compelling data in combination with BCMA therapies, 4) competitors produce more convincing data for competing therapies, 5) regulatory and/or reimbursement landscape changes unfavorably, and 6) funding is insufficient to move forward pipeline aspirations or further commercial/manufacturing build out.

TG Therapeutics (TGTX)
Our $7/share price objective is based on a probability adjusted NPV for ublituximab ($6/sh), TG1801 ($0/sh), and cash ($1/sh). We apply a WACC of 10-13% and -3% (ublituximab) to -5% (TG1801) terminal growth rate.

Downside risks are: 1) ublituximab efficacy data not promising in comparison with control arm, 2) hour-long infusion time not a sufficient convenience differentiator, 3) vaccine tolerance and infection rate still a concern for anti-CD20s, 4) switch from current anti-CD20 unlikely, 5) discounted pricing feasibility diminishing, 6) lack of early pipeline value leaves uncertainty for 2023-2026 , 7) complete oncology pipeline disbandment may induce further concerns.

Upside risks are: 1) ublituximab launch could be stronger than expected, 2) ublituximab approval could induce more-than-expected strength in shares, 3) pipeline synergy means possibility for combos, 4) cost reduction/synergies with deleted oncology pipeline might yield positives.

Y-mAbs Therapeutics, Inc (YMAB)
Our $18 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 ($10/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

I, Alec W. Stranahan, 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
	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
	CureVac	CVAC	CVAC US	Geoff Meacham

US - Biopharmaceuticals Coverage Cluster

Investment rating	Company	BofA Ticker	Bloomberg symbol	Analyst
	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
RSTR				
	Gilead Sciences Inc.	GILD	GILD US	Geoff Meacham

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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