

Insmed Incorporated

Quiet update with company on track for transformative 2Q; thoughts post 4Q23

Reiterate Rating: BUY | PO: 37.00 USD | Price: 27.56 USD

Few surprises after pre-announce as focus turns to 2Q

While admittedly absent major updates, we thought there was still a lot to like about Insmed's 4Q as it heads into a potential transformative year—with, in our view, management's optimistic messaging and tone offering further support of our positive outlook. In terms of financial updates, while Insmed had pre-announced (see <u>our takes on the update</u>), GAAP EPS was slightly below (-\$0.13) due to higher R&D spend. The team also reiterated FY24 Arikayce guidance (\$340-\$360M), which despite +15% y/y at the midpoint, still looks conservative to us given abating C-19 related headwinds, growing OUS opportunities, and buzz from ARISE (our <u>final takes on the data</u>).

That said, we suspect there was more focus on the clinical updates. Regarding the latter, Insmed continues to await feedback from FDA regarding ENCORE's statistical design, with the trial progressing after the third DSM meeting. While PDMA confirmed ARISE would not be sufficient by itself for 1L label expansion due to the lack of Japanese participants and <12 mos treatment duration, we wouldn't be surprised if FDA allows a filing for accelerated approval given the strength of the data. Management also reiterated timing for brensocatib's pivotal ASPEN readout in NCFB (late 2Q; see below) and TPIP's topline in PH-ILD (2Q ahead of ASPEN). Despite positive, albeit early, clinical signals and bullish management feedback, we think investors are underappreciating each. On the latter, Insmed noted enrollment exceeded expectations—not a surprise to us given likely advantages over treprostinil—and we continue to see potential for a rerating on positive updates. The team also intends to share blended, blinded data from ~40 PAH patients during the readout, where they believe a PVR reduction >30% would likely position the molecule as BIC. Insmed has forecasted peak potential >\$2B for TPIP (2030e unadj BofAe: \$1.0B vs. cons. \$846M), and with, we think, few similarly including much contribution from brenso (Insmed: >\$5B peak) and Arikayce (>\$1B), we continue to like the overall risk/ reward for shares, especially at current levels. Maintain Buy, \$37 PO.

Despite questions over oppty, team bullish on ASPEN

Unsurprisingly, much of the call was focused on expectations for ASPEN. While we don't dispute there are reasons to be cautious given prior class failures (few candidates have progressed past phase 2), and hurdles conducting trials in NCFB (see <u>our NCFB deepdive</u>)—we think investors are overlooking key differentiating factors, including 1) greater DPP-1 inhibition, and 2) ASPEN's well-thought out/ powered design.

Model Updates

Following the 4Q report, we have updated our model and now forecast 2024e EPS of (\$4.93) vs. (\$4.70) prior. See page 3 for further details.

Estimates (Dec) (US\$)	2022A	2023A	2024E	2025E	2026E
EPS	(3.91)	(5.34)	(4.93)	(3.78)	(1.10)
EPS Change (YoY)	-0.8%	-36.6%	7.7%	23.3%	70.9%
Consensus EPS (Bloomberg)			(4.52)	(3.56)	(1.78)
DPS	0	0	0	0	0
Valuation (Dec)					
Free Cash Flow Yield*	-10.4%	-13.9%	-15.0%	-12.9%	-4.6%
* For full definitions of <i>iQ</i> method ^{≤M} measures, see page 6.					

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Refer to important disclosures on page 7 to 9. Analyst Certification on page 4. Price
Objective Basis/Risk on page 4.

22 February 2024

Equity

Key Changes		
(US\$)	Previous	Current
2024E Rev (m)	377.2	377.3
2025E Rev (m)	684.4	684.5
2026E Rev (m)	1,460.2	1,379.0
2024E EPS	-4.70	-4.93
2025E EPS	-3.48	-3.78
2026E EPS	-0.58	-1.10

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Stock Data

Price	27.56 USD
Price Objective	37.00 USD
Date Established	5-Sep-2023
Investment Opinion	C-1-9
52-Week Range	16.04 USD - 32.00 USD
Mrkt Val (mn) / Shares Out	3,943 USD / 143.1
(mn)	
Free Float	98.5%
Average Daily Value (mn)	46.46 USD
BofA Ticker / Exchange	INSM / NAS
Bloomberg / Reuters	INSM US / INSM.OQ
ROE (2024E)	NA
Net Dbt to Eqty (Dec-2023A)	NA
ESGMeter™	Medium

ESGMeter is not indicative of a company's future stock price performance and is not an investment recommendation or rating. ESGMeter is independent of BofA Global Research's equity investment rating, volatility risk rating, income rating, and price objective for that company. For full details, refer to "BofA ESGMeter Methodology".

For a list of abbreviations, please see page 3...

iQprofile[™] Insmed Incorporated

iQmethod SM − Bus Performance*					
(US\$ Millions)	2022A	2023A	2024E	2025E	2026
Return on Capital Employed	-32.0%	-49.7%	-67.5%	-77.3%	-25.0%
Return on Equity	-193.2%	NM	NM	NM	NM
Operating Margin	-186.4%	-232.5%	-199.2%	-90.0%	-10.4%
Free Cash Flow	(410)	(550)	(593)	(507)	(182)
<i>iQ</i> method [™] – Quality of Earnings*					
(US\$ Millions)	2022A	2023A	2024E	2025E	2026E
Cash Realization Ratio	NM	NM	NM	NM	NM
Asset Replacement Ratio	1.9x	2.4x	1.0x	1.1x	1.1x
Tax Rate	NM	NM	NM	NM	NM
Net Debt-to-Equity Ratio	58.2%	NM	NM	NM	NM
Interest Cover	-20.0x	-19.0x	-17.0x	-12.7x	-2.7x
Income Statement Data (Dec)					
(US\$ Millions)	2022A	2023A	2024E	2025E	2026
Sales	245	305	377	684	1,379
% Change	30.2%	24.4%	23.6%	81.4%	101.5%
Gross Profit	190	240	294	520	1,062
% Change	31.8%	26.0%	22.8%	76.8%	104.1%
EBITDA	(447)	(699)	(735)	(599)	(125)
% Change	-23.9%	-56.4%	-5.2%	18.5%	79.1%
Net Interest & Other Income	(23)	(37)	(44)	(49)	(53)
Net Income (Adjusted) % Change	(482) -10.8%	(750) -55.7%	(796) -6.2%	(665) 16.4%	(197) 70.4%
- 6 LT D. (D.)					
Free Cash Flow Data (Dec) (US\$ Millions)	2022A	2023A	2024E	2025E	2026E
Net Income from Cont Operations (GAAP)	(482)	(750)	(796)	(665)	(197)
Depreciation & Amortization	10	11	16	17	18
Change in Working Capital	7	(39)	(67)	(132)	(297)
Deferred Taxation Charge	NA	NA	NA	NA	NA
Other Adjustments, Net	64	242	265	286	308
Capital Expenditure	(10)	(13)	(11)	(13)	(14)
Free Cash Flow	-410	-550	-593	-507	-182
% Change	-10.7%	-33.9%	-7.9%	14.6%	64.1%
Share / Issue Repurchase	312	171	469	170	21
Cost of Dividends Paid	0	0	0	0	0
Change in Debt	0	(1)	0	0	0
Balance Sheet Data (Dec)					
(US\$ Millions)	2022A	2023A	2024E	2025E	2026E
Cash & Equivalents	1,074	482	508	170	9
Trade Receivables	30	41	38	62	99
Other Current Assets	170	406	256	337	503
Property, Plant & Equipment	56	65	67	69	73
Other Non-Current Assets	327	335	333	370	498
Total Assets	1,656	1,330	1,201	1,008	1,182
Short-Term Debt	0	0	0	0	0
Other Current Liabilities	190	226	301	473	685
Long-Term Debt	1,125	1,155	1,166	1,180	1,197
Other Non-Current Liabilities	253 1 569	281	310	339	369
Total Liabilities	1,568	1,662	1,777	1,992	2,250
Total Equity	1 656	(332)	(576)	(984)	(1,069)
Total Equity & Liabilities	1,656	1,330	1,201	1,008	1,182

Company Sector

Biotechnology

Company Description

Insmed Incorporated is a commercial stage biopharmaceutical company focused on rare diseases. The company is addressing areas of high unmet need, fueled by its four pillars: Arikayce, Brensocatib, TPIP, and translational medicine. With Arikayce already on the market, we see commercial synergies and established physician relationships putting Insmed in a good position for commercialization of the clinical stage pipeline.

Investment Rationale

In our view, Arikayce sales should support near-term revenues, bolstered by potential for growth in Brensocatib and TPIP, where we see good clinical efficacy and tolerability. We recognize a number of commercial challenges, but ultimately view a favorable risk/ reward profile given KOL feedback, promising clinical/preclinical data, and under penetration in these markets with high unmet need, supportive of our Buy rating.

Stock Data

Average Daily Volume

Quarterly Earnings Estimates

	2023	2024
Q1	-1.17A	-1.31E
Q2	-1.78A	-1.12E
Q3	-1.11A	-1.01E
04	-1 28A	-1 49F

1,685,749

* For full definitions of \emph{IQ} method $^{\text{SM}}$ measures, see page 6.

Model Updates

We've updated our Insmed model to reflect the 4Q print (see Exhibit 1 below).

Exhibit 1: INSM Model Changes for 2024E and 2025E

We've provided our model changes for 2024e and 2025e below

	2024E		2025E	
\$ in millions (ex. per share items)	Prior	Current	Prior	Current
\$	377 \$	377 \$	684 \$	684
Total Revenue	\$ 377	\$ 377	\$ 684	\$ 684

	202	24E	202	:5E
\$ in millions (ex. per share items)	Prior	Current	Prior	Current
Revenue	377	377	684	684
COGS	83	83	164	164
Gross Profit	294	294	520	520
R&D	625	622	675	666
SG&A	389	389	424	436
Operating Income	(743)	(751)	(602)	(616)
Other income, net	(5)	2	(6)	2
Taxes	-	=	-	=
GAAP Net Income	(777)	(796)	(640)	(665)
GAAP EPS	(4.70)	(4.93)	(3.48)	(3.78)
Shares Outstanding - Diluted	166	161	184	176

Source: BofA Global Research

BofA GLOBAL RESEARCH

Abbreviations:

1L: frontline

FDA: Food and Drug Administration

OUS: outside of the US

NCFB: non-cystic fibrosis bronchiectasis

MoA: mechanism of action

TPIP: treprostinil palmitil inhalation powder

PAH: pulmonary arterial hypertension

PH-ILD: pulmonary hypertension associated with interstitial lung disease

DPP-1: dipeptidyl peptidase-1 **DSM:** Data Safety Monitoring **PVR:** pulmonary vascular resistance

BIC: best in class



Price objective basis & risk

Insmed Incorporated (INSM)

Our 12-month PO is based on our NPV analysis of revenue forecasts assumptions. We model sales of Arikayce for refractory NTM-PD and frontline expansion (modified by a LOS of 80%). We assume a collective value for the pipeline: Brensocatib in NCFB (LOS: 65%), with potential expansion into CF (LOS: 20%), CRSsNP, and HS (LOS: 15%) and TPIP for PAH and PH-ILD (LOS: 50%). Given a WACC of 15%, in line with peers of similar size and risk, and a terminal growth rate of -10%, -40%, we estimate a value of \$12/sh for Arikayce, \$18/sh for Brensocatib, \$8/sh for TPIP, \$0.62/sh for the early pipeline, and \$-2/sh for net cash, resulting in \$37/sh.

Upside risks: 1) Arikayce full approval, 2) validation of Brensocatib in phase 3, with strong clinical efficacy and no safety concerns, 3) robust efficacy/ safety profile for TPIP in PAH and PH-ILD, 4) growth of translational medicine pipeline, including on-track IND-approvals, and 5) indications of strong commercial support from payers/ community-based providers.

Downside risks: 1) failure to achieve full approval/ commercial expansion of Arikayce in the EU and Japan, 2) failure to meet safety/ efficacy profile in Brensocatib (phase 3), especially due to meaningful infection risk, 3) marginal tolerability improvements, diminished efficacy, and/ or lack of differentiation of TPIP, 4) competition from disease modifying PAH agents, 5) failure of translational medicine pillar, 6) regulatory delays, and 7) commercial pushback from payers/providers.

Analyst Certification

I, Jason Zemansky, 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
•	Company	DOIA TICKET	bloomberg symbol	Analyst
BUY				
	89bio, Inc	ETNB	ETNB US	Geoff Meacham
	Acumen Pharma	ABOS	ABOS US	Geoff Meacham
	Agios Pharmaceuticals	AGIO	AGIO US	Greg Harrison, CFA
	Amylyx Pharmaceuticals	AMLX	AMLX US	Geoff Meacham
	BioMarin	BMRN	BMRN US	Geoff Meacham
	BioXcel Therapeutics	BTAI	BTAI US	Greg Harrison, CFA
	BridgeBio Pharma	BBIO	BBIO US	Greg Harrison, CFA
	Caribou	CRBU	CRBU US	Geoff Meacham
	CRISPR Therapeutics	CRSP	CRSP US	Geoff Meacham
	Eli Lilly and Company	LLY	LLY US	Geoff Meacham
	Gilead Sciences Inc.	GILD	GILD US	Geoff Meacham
	HUTCHMED	HCM	HCM US	Alec W. Stranahan
	Immatics	IMTX	IMTX US	Alec W. Stranahan
	Insmed Incorporated	INSM	INSM US	Jason Zemansky
	Intellia Therapeutics	NTLA	NTLA US	Greg Harrison, CFA
	Janux Therapeutics	JANX	JANX US	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



US - Biopharmaceuticals Coverage Cluster

Investment rating	Company	BofA Ticker	Bloomberg symbol	Analyst
	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
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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	Alec W. Stranahan
	Y-mAbs Therapeutics, Inc	YMAB	YMAB US	Alec W. Stranahan
UNDERPERFORM	•			
UNDERPERFURM	All Mr. I	ALLVE	ALVELIC	
	AlloVir, Inc.	ALVR	ALVR US	Jason Zemansky
	CureVac	CVAC	CVACUS	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



*IQ*method[™] Measures Definitions

Business Performance	Numerator	Denominator
Return On Capital Employed	NOPAT = (EBIT + Interest Income) \times (1 - Tax Rate) + Goodwill Amortization	Total Assets — Current Liabilities + ST Debt + Accumulated Goodwill
		Amortization
Return On Equity	Net Income	Shareholders' Equity
Operating Margin	Operating Profit	Sales
Earnings Growth	Expected 5 Year CAGR From Latest Actual	N/A
Free Cash Flow	Cash Flow From Operations – Total Capex	N/A
Quality of Earnings	Numerator	Denominator
Cash Realization Ratio	Cash Flow From Operations	Net Income
Asset Replacement Ratio	Capex	Depreciation
Tax Rate	Tax Charge	Pre-Tax Income
Net Debt-To-Equity Ratio	Net Debt = Total Debt — Cash & Equivalents	Total Equity
Interest Cover	EBIT	Interest Expense
Valuation Toolkit	Numerator	Denominator
Price / Earnings Ratio	Current Share Price	Diluted Earnings Per Share (Basis As Specified)
Price / Book Value	Current Share Price	Shareholders' Equity / Current Basic Shares
Dividend Yield	Annualised Declared Cash Dividend	Current Share Price
Free Cash Flow Yield	Cash Flow From Operations — Total Capex	Market Cap = Current Share Price × Current Basic Shares
Enterprise Value / Sales	EV = Current Share Price × Current Shares + Minority Equity + Net Debt +	Sales
ze.pse raide / Sales	Other LT Liabilities	

EV / EBITDA Enterprise Value Basic EBIT + Depreciation + Amortization

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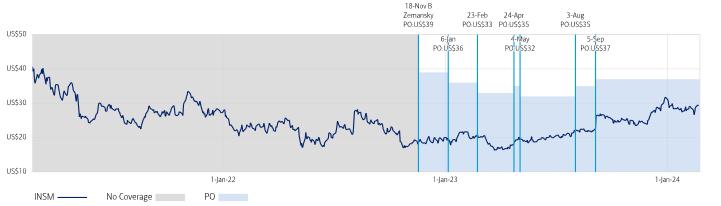
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Disclosures

Important Disclosures

Insmed (INSM) 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.

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%

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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%
Inderperform	N/A	> 20%

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