

Insmmed Incorporated

Arikayce guidance looks conservative and poised to anchor pivotal '24

Reiterate Rating: BUY | PO: 37.00 USD | Price: 29.13 USD

Arikayce looks solid despite somewhat conservative guide

INSM shares are trading flat this morning after the company provided FY24 guidance for Arikayce that although up an impressive +15% y/y at the midpoint, was still at the lower end of consensus—while also reaffirming timing for key readouts (see below). 2023 revenues were pre-announced at \$305.2M (in-line), with 2024 sales projected to be \$340-360M vs. cons \$361M and our more optimistic \$386M. That said, we note Street forecasts had been trending downwards recently, and with the company historically guiding conservatively, we wouldn't be surprised if investors frame today's numbers as such. Indeed, we'd argue guidance looks beatable, even under non-heroic estimates, especially as global COVID-related and OUS pricing/ reimbursement headwinds improve and awareness/ support increases following the robust 1L expansion data (see [our takes on ARISE](#))—supporting our positive, near-term outlook. As a result of today's updates, we are lowering our 2024 Arikayce forecasts to \$377M but continue to see favorable risk/ reward to shares on the basis of potential Arikayce near-term outperformance and a favorable catalyst-rich '24 setup (see [our YA24 guide](#)). Maintain Buy and \$37 PO.

ENCORE enrollment continues, pending updates from FDA

While we still see the NTM-PD refractory setting as under-penetrated, easily the greater opportunity is 1L (2030e BofA: \$1.2B vs. cons \$1.1B; see [our 1L preview](#)). Updates on label expansion efforts were understandably limited following the relatively recent ARISE readout, but given the strength of the data, we remain optimistic for a nearer-term approval (see [our ARISE takes](#)). While the company plans to meet with FDA near-term following “encouraging” written feedback, enrollment in ENCORE is continuing past the 250 target (topline reaffirmed 2025)—a potential signal, in our view, the company may be able to use ARISE for accelerated approval, with the latter used as a confirmatory.

Firing on all pillars, setting up possibly transformative '24

Other pipeline updates were similarly positive, albeit incremental. Notably, the timing of brensocatib's—easily the biggest source of investor debate given the opportunity—pivotal ASPEN topline was narrowed to the “latter part” of 2Q24 (2Q prior), enabling a possible US launch mid-25, followed by the EU/ Japan 1H26. Among other encouraging updates, in Nov, the DSMC recommended ASPEN continue, with the company also providing guidance for phase 2b BIRCh readout for CRSsNP (2025) with another phase 2 in HS planned to initiate 2H24. In addition, data from the phase 2 of TPIP in PH-ILD was reiterated for 2Q24, the study exceeding its enrollment goals (39 vs 32) with the phase 2 PAH continuing (topline 2025). (For a recent discussion, [click here for our YA24 guide](#)).

Estimates (Dec) (US\$)	2021A	2022A	2023E	2024E	2025E
EPS	(3.88)	(3.91)	(5.20)	(4.70)	(3.48)
EPS Change (YoY)	-28.9%	-0.8%	-33.0%	9.6%	26.0%
Consensus EPS (Bloomberg)			(5.16)	(4.50)	(3.51)
DPS	0	0	0	0	0
Valuation (Dec)					
Free Cash Flow Yield*	-8.9%	-9.8%	-15.5%	-16.5%	-15.2%

* For full definitions of *IQmethod*SM measures, see page 6.

05 January 2024

Equity

Key Changes

(US\$)	Previous	Current
2023E Rev (m)	309.5	305.1
2024E Rev (m)	386.3	377.2
2025E Rev (m)	821.2	684.4
2023E EPS	-5.17	-5.20
2024E EPS	-5.25	-4.70
2025E EPS	-3.58	-3.48

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Stock Data

Price	29.13 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
Mkt Val (mn) / Shares Out (mn)	4,167 USD / 143.1
Free Float	98.6%
Average Daily Value (mn)	47.23 USD
BofA Ticker / Exchange	INSM / NAS
Bloomberg / Reuters	INSM US / INSM.OQ
ROE (2023E)	NA
Net Dbt to Eqty (Dec-2022A)	58.2%
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"](#).

Please see page 3 for a list of abbreviations

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iQprofileSM Insmed Incorporated

iQmethodSM – Bus Performance*

(US\$ Millions)	2021A	2022A	2023E	2024E	2025E
Return on Capital Employed	-37.8%	-32.0%	-54.6%	-89.4%	-86.6%
Return on Equity	-126.7%	-193.2%	NM	NM	NM
Operating Margin	-199.0%	-186.4%	-230.3%	-196.8%	-87.9%
Free Cash Flow	(371)	(410)	(646)	(686)	(635)

iQmethodSM – Quality of Earnings*

(US\$ Millions)	2021A	2022A	2023E	2024E	2025E
Cash Realization Ratio	NM	NM	NM	NM	NM
Asset Replacement Ratio	0.8x	1.9x	1.0x	1.0x	1.1x
Tax Rate	0.4%	NM	NM	NM	NM
Net Debt-to-Equity Ratio	-36.6%	58.2%	NM	NM	NM
Interest Cover	-6.1x	-20.0x	-29.5x	-21.3x	-15.7x

Income Statement Data (Dec)

(US\$ Millions)	2021A	2022A	2023E	2024E	2025E
Sales	188	245	305	377	684
% Change	14.6%	30.2%	24.4%	23.6%	81.4%
Gross Profit	144	190	242	294	520
% Change	15.9%	31.8%	27.1%	21.7%	76.8%
EBITDA	(361)	(447)	(687)	(726)	(585)
% Change	-43.7%	-23.9%	-53.7%	-5.7%	19.5%
Net Interest & Other Income	(61)	(23)	(24)	(35)	(38)
Net Income (Adjusted)	(435)	(482)	(728)	(777)	(640)
% Change	-47.8%	-10.8%	-51.2%	-6.8%	17.6%

Free Cash Flow Data (Dec)

(US\$ Millions)	2021A	2022A	2023E	2024E	2025E
Net Income from Cont Operations (GAAP)	(435)	(482)	(728)	(777)	(640)
Depreciation & Amortization	14	10	16	16	17
Change in Working Capital	(59)	7	(38)	(40)	(134)
Deferred Taxation Charge	NA	NA	NA	NA	NA
Other Adjustments, Net	116	64	115	126	134
Capital Expenditure	(7)	(10)	(10)	(11)	(13)
Free Cash Flow	-371	-410	-646	-686	-635
% Change	-64.3%	-10.7%	-57.4%	-6.3%	7.4%
Share / Issue Repurchase	292	312	20	472	493
Cost of Dividends Paid	0	0	0	0	0
Change in Debt	337	0	0	0	0

Balance Sheet Data (Dec)

(US\$ Millions)	2021A	2022A	2023E	2024E	2025E
Cash & Equivalents	717	1,074	404	159	15
Trade Receivables	24	30	34	38	62
Other Current Assets	96	170	246	256	337
Property, Plant & Equipment	53	56	57	58	60
Other Non-Current Assets	354	327	292	323	358
Total Assets	1,244	1,656	1,032	834	832
Short-Term Debt	0	0	0	0	0
Other Current Liabilities	135	190	182	189	226
Long-Term Debt	567	1,125	1,133	1,143	1,157
Other Non-Current Liabilities	131	253	270	288	306
Total Liabilities	833	1,568	1,585	1,620	1,689
Total Equity	410	88	(553)	(786)	(857)
Total Equity & Liabilities	1,244	1,656	1,032	834	832

* For full definitions of iQmethodSM measures, see page 6.

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 1,621,267

Quarterly Earnings Estimates

	2022	2023
Q1	-0.80A	-1.17A
Q2	-0.80A	-1.78A
Q3	-1.09A	-1.11A
Q4	-1.21A	-1.16E

Abbreviations:

NTM-PD: nontuberculous mycobacterial pulmonary disease

OUS: outside of the US

1L: frontline

CRSsNP: chronic rhinosinusitis without nasal polyps

HS: hidradenitis suppurativa

TPIP: treprostinil palmitil inhalation powder

PH-ILD: pulmonary hypertension associated with interstitial lung disease

PAH: pulmonary arterial hypertension

DSMC: Data Safety Monitoring Committee

Price objective basis & risk

Insmmed 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
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	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

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
	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
	Kymera 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	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
	Day One Biopharmaceuticals	DAWN	DAWN US	Alec W. Stranahan
	LianBio	LIAN	LIAN US	Geoff Meacham
	Novavax	NVAX	NVAX US	Alec W. Stranahan
	Regeneron Pharmaceuticals Inc.	REGN	REGN US	Geoff Meacham
	Reneo Pharmaceuticals	RPHM	RPHM US	Jason Zemansky
	TG Therapeutics	TGTX	TGTX US	Alec W. Stranahan
	United Therapeutics Corporation	UTHR	UTHR US	Greg Harrison, CFA

iQmethodSM Measures Definitions

Business Performance

Return On Capital Employed

Return On Equity
Operating Margin
Earnings Growth
Free Cash Flow

Numerator

NOPAT = (EBIT + Interest Income) × (1 – Tax Rate) + Goodwill Amortization
Net Income
Operating Profit
Expected 5 Year CAGR From Latest Actual
Cash Flow From Operations – Total Capex

Denominator

Total Assets – Current Liabilities + ST Debt + Accumulated Goodwill
Amortization
Shareholders' Equity
Sales
N/A
N/A

Quality of Earnings

Cash Realization Ratio
Asset Replacement Ratio
Tax Rate
Net Debt-To-Equity Ratio
Interest Cover

Numerator

Cash Flow From Operations
Capex
Tax Charge
Net Debt = Total Debt – Cash & Equivalents
EBIT

Denominator

Net Income
Depreciation
Pre-Tax Income
Total Equity
Interest Expense

Valuation Toolkit

Price / Earnings Ratio
Price / Book Value
Dividend Yield
Free Cash Flow Yield
Enterprise Value / Sales

Numerator

Current Share Price
Current Share Price
Annualised Declared Cash Dividend
Cash Flow From Operations – Total Capex
EV = Current Share Price × Current Shares + Minority Equity + Net Debt +
Other LT Liabilities
Enterprise Value

Denominator

Diluted Earnings Per Share (Basis As Specified)
Shareholders' Equity / Current Basic Shares
Current Share Price
Market Cap = Current Share Price × Current Basic Shares
Sales

Basic EBIT + Depreciation + Amortization

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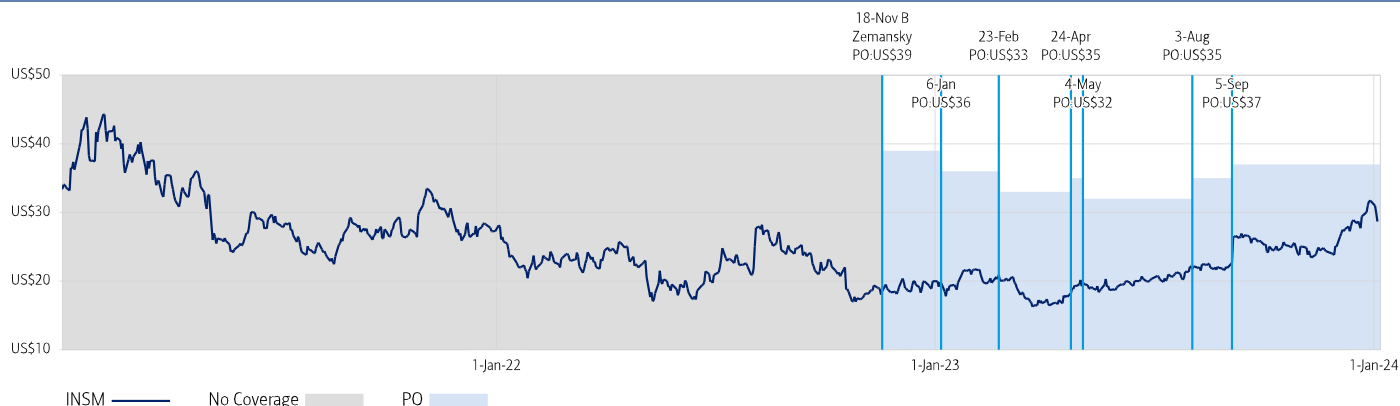
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Disclosures

Important Disclosures

Insmcd (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%

^{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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