

Insmmed Incorporated

Investors can breathe easy now as a path towards 1L expansion ARISEs...

Reiterate Rating: BUY | PO: 35.00 USD | Price: 22.64 USD

Breaking News

- We look for INSM shares to trade up this morning after encouraging ARISE data set the stage for a positive ENCORE
- Arikayce treatment improved PROs, as measured by the QoL-B, and resulted in positive culture conversion rates
- Indeed, we continue to see Arikayce well poised for success with validated PROs paving the way to 1L approval

ARISE data look solid, removing PRO-related overhang

This morning Insmmed announced positive data from ARISE, their phase 3b for Arikayce in frontline NTM-PD, with clear, positive trends towards significance on the respiratory PRO (QoL-B) supported by the PGI-S. Recall ARISE was not statistically powered, but rather designed to look for directional trends in patient reported outcomes the FDA said would be necessary to support an eventual filing. We think this represents a best-case scenario given widespread skepticism neither the respiratory nor fatigue (PROMIS F-SF) PRO would be able to capture an improvement in symptoms, representing a near-term overhang on sentiment. That said we, along with our KOLs, have long been bullish on a positive outcome (see our [ARISE preview](#)). With additional positive efficacy outcomes—notably culture conversion rates—today's update should help allay concerns over expansion into the frontline setting, helping shift focus to other late-stage pipeline candidates—namely brensocatic and TPPI—where we see potentially greater value creation. Maintain Buy and a PO of \$35. **Insmmed is hosting an investor call at 8:30am today**

Efficacy signals similarly trending positive

Preliminary efficacy signals were also generally positive. To be fair, the data just missed significance at month 6 (80.6% vs. 63.9%, $p=0.0712$) but not month 7 (78.8% vs. 47.1%, $p=0.0010$), which may raise some concerns among bears. That said, beyond the small study size of ARISE (N=99) and the relatively short duration of therapy (6 mos of treatment, one month off), 78.8% of patients receiving Arikayce vs. 47.1% on the comparator culture-converted—implying the liposomal antibiotic was effective at eradicating the bacteria. Ultimately, given the long-standing, well established efficacy of amikacin, we remain encouraged over a positive, stat sig benefit in the registrational ENCORE—followed by global approvals.

Significant symptom and functional improvements

In terms of QoL-B, 43.8% of Arikayce-treated patients experienced improvements, (vs. 33.3% control; $p=0.1073$) above the 14.8-point meaningful threshold for improvement. Arikayce treatment also resulted in significant improvements in culture conversion rates (79% vs. 47% control; $p=0.0010$), with more patients converting earlier (i.e., within 1 mos). In contrast, trends were less significant in terms of the fatigue PRO, PROMIS F-SF, with 35.5% of those Arikayce patients achieving a meaningful 4-unit decrease vs. 29.4% on the comparator arm. Still, we don't see this as likely to weigh on regulators—or potentially, prescribers.

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Timestamp: 05 September 2023 08:25AM EDT

05 September 2023

Equity

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Stock Data

Price	22.64 USD
Price Objective	35.00 USD
Date Established	3-Aug-2023
Investment Opinion	C-1-9
52-Week Range	16.04 USD - 25.48 USD
Mkt Val (mn) / Shares Out (mn)	3,089 USD / 136.4
Average Daily Value (mn)	27.90 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

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Abbreviations:

- PROs:** patient reported outcomes
- PGI-S:** Patient Global Impression of Severity
- QoL-B:** Quality of Life Questionnaire-
Bronchiectasis
- PROMIS F-SF:** Patient reported Outcome
Measurement Information System Fatigue-
Short Form
- NTM-PD:** non-tuberculous mycobacterial
pulmonary disease
- NT:** near-term
- KOLs:** key opinion leaders
- 1L:** frontline

Price objective basis & risk

Insmid 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 75%). 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 \$10/sh for Arikayce, \$18/sh for Brensocatib, \$8/sh for TPIP, \$0.59/sh for the early pipeline, and \$-2/sh for net cash, resulting in \$35/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.

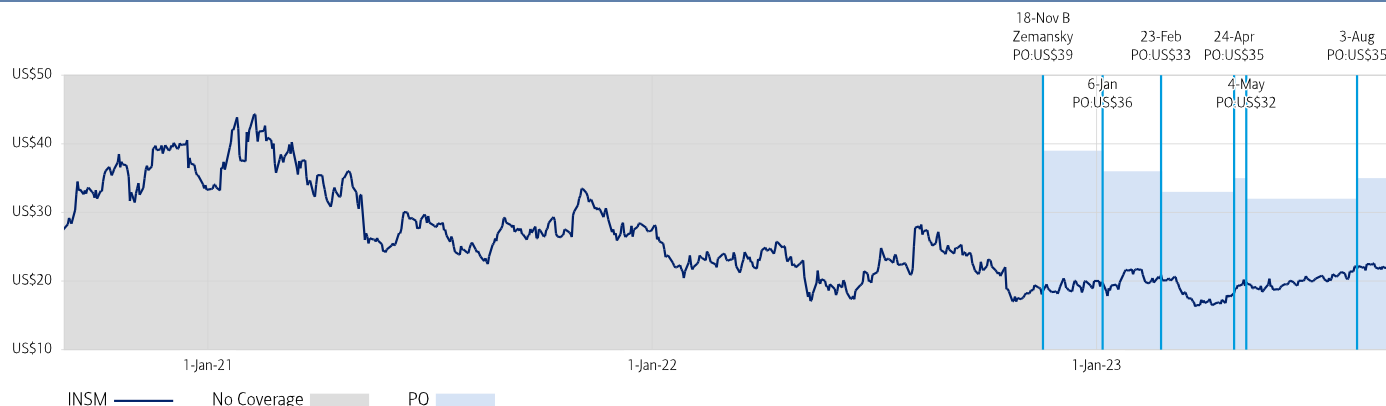
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Important Disclosures

Insmcd (INSM) Price Chart



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

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Coverage Universe	Count	Percent	Inv. Banking Relationships ^{R1}	Count	Percent
Buy	236	57.84%	Buy	105	44.49%
Hold	87	21.32%	Hold	38	43.68%
Sell	85	20.83%	Sell	22	25.88%

Equity Investment Rating Distribution: Global Group (as of 30 Jun 2023)

Coverage Universe	Count	Percent	Inv. Banking Relationships ^{R1}	Count	Percent
Buy	1877	53.28%	Buy	1040	55.41%
Hold	815	23.13%	Hold	464	56.93%
Sell	831	23.59%	Sell	385	46.33%

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