

89bio, Inc

# Madrigal garners the first MASH approval setting the stage for differentiated assets

Maintain Rating: BUY | PO: 30.00 USD | Price: 12.61 USD

## Breaking News

- FDA approved Madrigal's Rezdiffra for adults with MASH with moderate to advanced liver fibrosis (fibrosis stage F2-F3)
- Given Rezdiffra's clean label, with no biopsy requirement for diagnosis, we view the label as a win for the MASH space
- We expect ETNB shares to trade with strength as Rezdiffra's label sets a positive precedent for differentiated MASH entrants

## First MASH drug approved with a clean label

FDA has approved Madrigal's Rezdiffra (resmetirom), a thyroid beta agonist, for patients with metabolic dysfunction-associated steatohepatitis (MASH) with F2-F3 stage fibrosis. Today's update is particularly notable as it's the first FDA approval of a MASH therapeutic. Importantly, FDA did not require a biopsy to diagnose MASH patients which had been an investor concern as a biopsy requirement could severely limit prescriber + patient uptake as it's a costly, invasive procedure. Moreover, there was no guidance on patient monitoring, which sets a positive precedent for prescriber use and differentiated MASH assets, in our view.

Given the clean label, we expect ETNB to trade with strength as the rising MASH tide could lift all ships, particularly given the past regulatory challenges in MASH have made investors cautious on the commercial opportunity (e.g., CRL for Intercept's obeticholic acid last year). That said, from a commercial perspective, we'd argue there's still a lot of wood-to-chop given open questions around 1) sequencing of liver directed therapies + GLP-1s, 2) payer access + reimbursement, and 3) patient monitoring to determine treatment progress (e.g., how to identify a treatment failure). However, we suspect that 89Bio will benefit from Madrigal's commercial investments in the space, including prescriber education and identifying MASH patients, which is still a debate based on our prescriber discussions. Indeed, we expect Madrigal's commercial investment should set up 89Bio well given the competitive efficacy + tolerability profile for its Fibroblast growth factor 2 (FGF21) analogue, pegozafermin (see [our thoughts on pegozafermin's ENLIVEN results here](#)). We maintain Buy and our \$30 PO as we see today's approval of Madrigal's Rezdiffra as a win for the entire MASH space.

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## Stock Data

Price	12.61 USD
Price Objective	30.00 USD
Date Established	8-Mar-2024
Investment Opinion	C-1-9
52-Week Range	6.58 USD - 22.93 USD
Mkt Val (mn) / Shares Out (mn)	1,032 USD / 81.8
Free Float	83.7%
Average Daily Value (mn)	19.82 USD
BofA Ticker / Exchange	ETNB / NAS
Bloomberg / Reuters	ETNB US / ETNB.OQ
ROE (2024E)	-53.2%
Net Dbt to Eqty (Dec-2023A)	-54.3%
ESGMeter™	Low

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## Abbreviations:

FDA: Food and Drug Administration  
GLP-1: glucagon like peptide 1  
FGF21: fibroblast growth factor 2  
CRL: complete response letter

## Price objective basis & risk

### 89bio, Inc (ETNB)

Our \$30 PO is based on a probability-adjusted NPV, including a \$12/share for pegozafermin in MASH, a \$11/share for pegozafermin in MASH cirrhosis and \$0/share for pegozafermin in SHTG. The remaining value in our PO comes from cash. We use a 14% WACC in MASH and SHTG and a terminal growth of -40% (we project revenues out through 2035), in-line with other biotech companies of similar size and stage of clinical development.

Upside risks to our price objective are 1) additional positive clinical results in MASH showing potential dosing superiority, 2) positive clinical data in SHTG showing differentiation against standard of care, and 3) higher than expected prevalence/diagnosis rate in MASH/SHTG leading to high market penetration.

Downside risks are 1) failure of pivotal studies in MASH/ MASH cirrhosis, 2) subpar efficacy/lack of dosing advantage of pegozafermin in MASH compared to other FGF21 analogs, 3) low penetration/poor uptake in the MASH/SHTG market for pegozafermin and 4) failure to show clinical benefits in SHTG in the pivotal trial.

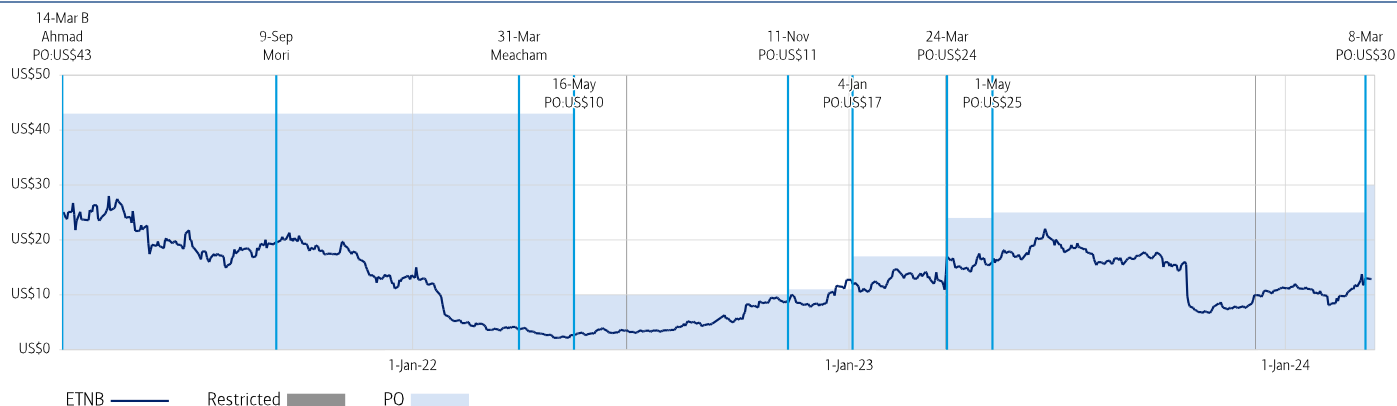
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### 89bio, Inc (ETNB) Price Chart



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Coverage Universe	Count	Percent	Inv. Banking Relationships <sup>R1</sup>	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%

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Hold	832	23.54%	Hold	454	54.57%
Sell	807	22.84%	Sell	383	47.46%

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Neutral	≥ 0%	≤ 30%
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