

## Traverse Therapeutics Inc

## Filspari sales beat consensus ahead of sNDA filing

Maintain Rating: BUY | PO: 23.00 USD | Price: 8.64 USD

## Full Filspari approval comes closer with upcoming sNDA

Traverse gave a positive corporate update today highlighting plans 2024 including the on track submission of an sNDA for the full approval of Filspari in IgAN (1Q24) along with announcing preliminary net product sales of \$15M for Filspari in 4Q23 (vs. \$13.5M cons.) and \$30M FY23 (vs. \$28M consensus). With 459 new patient forms in 4Q23, we think Traverse is well-positioned to continue the Filspari launch into 2024 and with a CHMP opinion for approval of Filspari in IgAN in the EU expected 1Q24, we think the company could see encouraging growth with the help of partner, Vifor Pharma. [As one of our top picks for 2024 \(see report\)](#), we think Traverse is positioned for a catalyst-rich year including continued launch updates and we model \$105M 2024 Filspari sales (vs. \$96M cons.) and \$197M 2024 in net product sales. For pegtibatase, the pivotal HARMONY study is underway evaluating pegtibatase in classical HCU, which is designed to provide topline results in 2026. Given the encouraging Filspari launch and ongoing clinical development of pegtibatase in HCU, we maintain Buy, PO \$23.

## Filspari launch continues to build

Traverse highlighted the sNDA filing remains on track for 1Q24 to support the conversion of Filspari in IgAN to full approval, and we look for the filing and acceptance of the sNDA in early 2024. Traverse is also looking to move Filspari in additional geographies and we look for the review opinion by CHMP for the potential approval of Filspari in IgAN in 1Q24 which would lead to a CMA. The company also expects to present additional data from the combination of Filspari and SGLT2i in 2024 and data from the ongoing SPARTAN study evaluating Filspari as a first-line therapy in IgAN. Beyond IgAN, Traverse is also considering pathways forward for sparsentan in FSGS (not included in our model).

## Pegtibatase phase 3 moving towards 2026 data

Traverse is evaluating pegtibatase in the phase 3 HARMONY study enrolling approximately 70 patients with the primary endpoint of the relative geometric mean change in plasma tHcy levels from baseline compared to W6-W12. Beyond the HARMONY study, Traverse also plans to initiate the phase 3b, open-label, long-term extension ENSEMBLE study to evaluating ongoing efficacy and long-term safety of pegtibatase in patients who have completed either COMPOSE or HARMONY studies. The ENSEMBLE study will also include an optional protein tolerance sub-study to support dietary protein intake increases while receiving pegtibatase.

## 4Q23 preliminary announcement

Traverse announced preliminary 4Q23 guidance, including preliminary net product sales for Filspari (\$15M 4Q23 and \$30M since launch in February 2023). The company also expects \$40 in net product sales from continuing operations (ex-bile acids) vs. \$40M cons. and \$128M for FY23. Traverse ended 2023 with approximately \$567M in cash and cash equivalents.

See our catalyst calendar below (Exhibit 1):

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## Equity

**Greg Harrison, CFA**  
Research Analyst  
BofAS  
+1 646 855 1476  
[gregory.harrison@bofa.com](mailto:gregory.harrison@bofa.com)

**Mary Kate Davis**  
Research Analyst  
BofAS  
+1 646 855 1778  
[mary.k.davis@bofa.com](mailto:mary.k.davis@bofa.com)

## Stock Data

Price	8.64 USD
Price Objective	23.00 USD
Date Established	7-Nov-2023
Investment Opinion	C-1-9
52-Week Range	5.25 USD - 23.18 USD
Mkt Val (mn) / Shares Out (mn)	648 USD / 75.0
Free Float	98.7%
Average Daily Value (mn)	14.02 USD
BofA Ticker / Exchange	TVTX / NAS
Bloomberg / Reuters	TVTX US / TVTX OQ
ROE (2023E)	-309.6%
Net Dbt to Eqty (Dec-2022A)	NA
ESGMeter™	Low

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CHMP: Committee for Medicinal Products for Human Use

HCU: homocystinuria

IgAN: IgA nephropathy

CMA: conditional marketing authorization

sNDA: supplemental new drug application

SGLT2i: SGLT2 inhibitor

**Exhibit 1: Travere catalyst calendar**

Travere remains on track to file for the full approval of Filspari in IgAN in 1Q24.

Company	Asset	Indication	Event	Timing	Importance
Travere	Sparsentan	IgAN	EMA review decision	1Q24	High
Travere	Sparsentan	IgAN	sNDA filing	1Q24	High
Travere	pegibatinase	HCU	HARMONY topline data	2026	High

**Source:** BofA Global Research, company reports

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## Price objective basis & risk

### Travere Therapeutics Inc (TVTX)

Our \$23 PO is based on a sum-of-the-parts NPV analysis. Using a 13% WACC, we model \$2/share in bile acid portfolio milestones, \$3/share for Thiola, \$13/share for sparsentan, \$1/share for pegibatinase, and \$3/share net cash.

Risks are 1) regulatory risk, 2) competitive entrants, 3) lower-than-expected sparsentan uptake, 4) insurance or pricing concerns

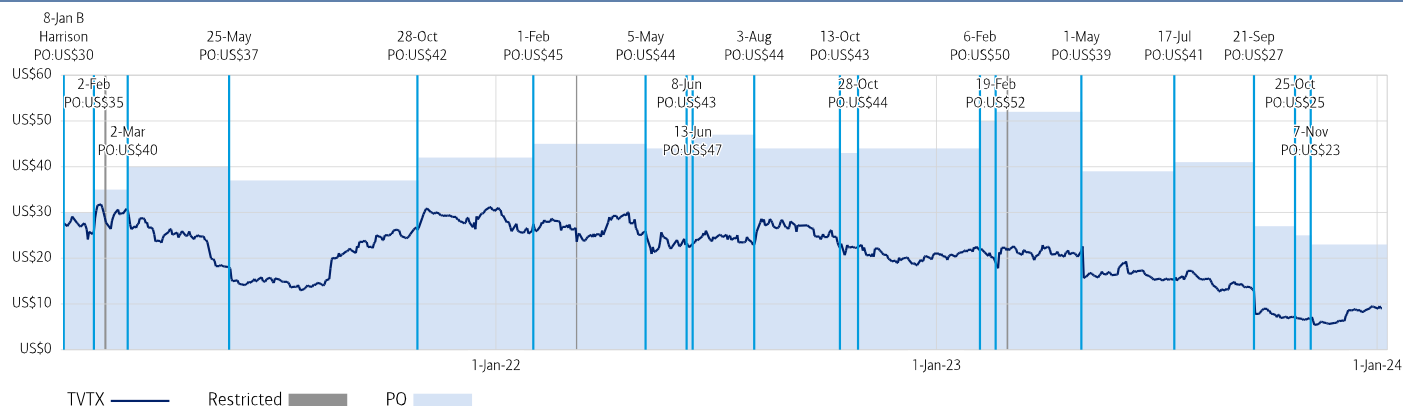
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### Travere Therapeutics (TVTX) Price Chart



TVTX — Restricted PO

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 <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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Sell	807	22.84%	Sell	383	47.46%

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Neutral	≥ 0%	≤ 30%
Underperform	N/A	≥ 20%

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