

## Turnstone Biologics

## Read-through from lifileucel / Amtagvi approval

Maintain Rating: BUY | PO: 15.00 USD | Price: 2.42 USD

## FDA approval of lifileucel helps lift overhang on TIL's

Late last Friday, the Food and Drug Administration (FDA) approved the first adaptive cell therapy treatment for advanced, metastatic melanoma, lovance's (not covered) lifileucel, now known as Amtagvi, a tumor infiltrating lymphocyte (TIL) product. Despite the initial delay to timing of FDA approval, there were a number of positive indicators, including: no major review issues or need for an AdComm, and completion of CMC (Chemistry, Manufacturing, and Controls) inspections. We view approval of lifileucel as having positive read-through for TIL products broadly and TSBX shares traded with strength. With lovance's initial approval, we are incrementally more confident that Turnstone will be successful in pursuing a similar accelerated approval process for TIDAL-01. Maintain Buy on TSBX, \$15 PO.

## Amtagvi paves path for TIL commercialization

One uncertainty of the regulatory process was whether the FDA would accept lovance's quality control metrics for evaluating the cells, which was a matrix approach that looks at multiple different (undisclosed) attributes of the cells. That said, given lifileucel is not made up of genetically modified cells and targets unspecified antigens, we think gauging cell potency would be less challenging for next-generation TIL assets, like Turnstone's TIDAL-01. Further, with lovance able to secure approval for the lovance Cell Therapy Center (iCTC), which is the first regulated, scalable manufacturing facility for TIL's and has capacity to generate TIL therapies for thousands of patients, we think the path for commercial manufacturing has now been proven. There are also 30 approved treatment centers prepared to collect and ship tumor tissues from patients to Amtagvi, which should lay the commercial foundation for uptake and broader exposure of TIL's.

## Next catalyst is proof-of-concept data mid-2024

From a clinical standpoint, we also think that approval of lifileucel further solidifies clinical benchmarks for TIDAL-01. As a reminder, lifileucel led to an overall response rate (ORR) of 31.4% with a 5.2% complete response (CR) rate and 26.1% partial response (PR) rate. Further, median duration of response (DOR) was not reached at 36.5 months with 42% of responses lasting  $\geq 24$  months. We would view Turnstone-01 data in melanoma patients showing  $\geq 40\%$  ORR,  $\geq 30\%$  PR, and  $\geq 10\%$  CR as compelling. First-in-human data in both melanoma and other solids tumors (mostly colorectal cancer) is expected by mid-2024.

20 February 2024

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## Stock Data

Price	2.42 USD
Price Objective	15.00 USD
Date Established	17-Nov-2023
Investment Opinion	C-1-9
52-Week Range	1.63 USD - 13.20 USD
Mrkt Val (mn) / Shares Out (mn)	56 USD / 23.1
Free Float	45.2%
Average Daily Value (mn)	0.39 USD
BofA Ticker / Exchange	TSBX / NAS
Bloomberg / Reuters	TSBX US / TSBX.OQ
ROE (2023E)	-71.7%
Net Dbt to Eqty (Dec-2022A)	-49.3%

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Timestamp: 20 February 2024 07:46AM EST

## Price objective basis & risk

### Turnstone Biologics (TSBX)

Our 12-month PO of \$15 is based on a probability adjusted SOTP NPV of TIDAL-01 in melanoma (42% of our valuation) and other solid tumors, primarily breast / CRC / uveal melanoma (3% of our valuation). We assign a valuation of \$1/share valuation to TIDAL-02 (3% of our valuation), given its stage of development. We apply a midpoint WACC of 15% (13-17%) and -10% terminal growth rate, which is comparable to our valuation methodology for other biotech companies of similar size and stage of clinical development. The remaining \$3/sh comes from net cash.

Upside risks to our PO: 1) Lifileucel enjoys a broad label following approval, supporting robust coverage and uptake with positive read-through to the TIL space, 2) TIDAL-01 phase 1 trials enroll faster than expected and data readout comes prior to mid-2024, 3) breakthrough in TIDAL-02 or other pipeline programs, 4) business development contributes non-dilutive funding, 5) improvements in manufacturing bring down costs sooner, and 6) clinical data from the phase 1 TIDAL-01 trials are better than expected.

Downside risks to our PO: 1) Failure of lifileucel to receive accelerated approval in advanced refractory melanoma, 2) delays in TIDAL-01 clinical development, 3) cash balance is insufficient to fund TIDAL-01 clinical development through initial data mid-2024, 4) manufacturing and/or supply chain issues prevent production of selected TIL products, and 5) phase 1 TIDAL-01 clinical trials do not support continued development.

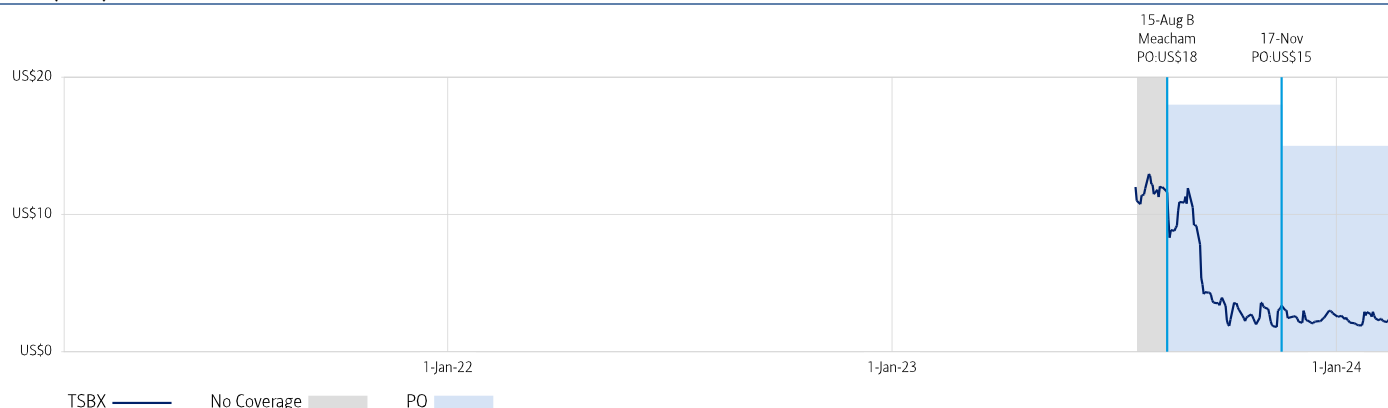
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### Turnstone (TSBX) Price Chart



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 <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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