BofA SECURITIES

Vertex Pharmaceuticals Inc.

Another VX-548 win highlights pain could be Vertex's encore to Cystic fibrosis

Maintain Rating: BUY | PO: 540.00 USD | Price: 435.82 USD

Pivotal VX-548 results in acute pain support approval

Following VX-548's impressive phase 2 results in diabetic peripheral neuropathy (DPN) late last year (see our thoughts on the results here), expectations were high for VX-548's three pivotal trials in acute pain. That said, VX-548's acute pain results, presented today, hit expectations, in our view, though we could see a 'sell the news' phenomenon as a strong result was already factored into shares, though numerically better results versus opioids in abdominoplasty was an upside surprise. With the clinical results in hand to support a broad label for moderate-to-severe acute pain, we expect Vertex to submit VX-548 for regulatory approval by mid-2024 and looking forward, we now expect the story to transition to the commercial opportunity. While we suspect the commercial opportunity in acute to be more muted than in neuropathic pain, based on the hospital business case, today's results add to the favorable body of evidence for VX-548's safety profile, which following the phase 2 results for DPN, was the most meaningful event for the program, in our view. Indeed, today's results bolsters Vertex's best-in-class growth profile with additional shots on goal with 1) VX-548 in neuropathic pain, 2) Casgevy for SCD/ TDT, 3) vanzacaftor in CF, and 4) an earlier pipeline that Vertex doesn't get much credit for. We maintain Buy and our $540 PO.

Abdominoplasty numerically superior to opioids

Recall, to support a broad label in acute pain, Vertex initiated three phase 3 trials for VX-548 for patients undergoing 1) bunionectomy (n=1,073), 2) abdominoplasty (n=1,118), and 3) general acute pain (n=258). The LS mean difference in the SPID48 between the VX-548 group and the placebo group was 48.4 (95% CI, (33.6, 63.1)) in the abdominoplasty trial and was numerically improved compared to hydrocodone bitartrate/acetaminophen (HB/APAP) with the LS mean difference 6.6 (95% CI: -5.4, 18.7; P=0.2781). For the bunionectomy trial, the LS mean difference in the SPID48 between VX-548 and placebo was 29.3 (95% CI, 14.0 to 44.6) and was numerically inferior compared to HB/APAP with the LS mean difference -20.2 (95% CI: -32.7, -7.7; P=0.0016)). Safety was in-line with expectations, with a lower number of AEs in the placebo arm than the VX-548 arm. Overall, while some investors may have hoped for superiority versus HB/APAP, VX-548 hit the bar for clinically meaningfulness, in our view, showing >20 points on SPID48; moreover, Vertex and our KOLs have stressed that a differentiated safety + efficacy profile would be enough for approval.

We expect commercial hurdles for VX-548 in acute pain

While the unmet need is high in both acute and neuropathic pain, we continue to think that commercial hurdles for acute pain will be a higher hurdle than in acute. Indeed, we suspect the opportunity for acute pain could be more levered to access / pricing reimbursement given broad availability of cheap opioids and the challenges of launching in hospital settings, based on our channel checks. We remain below the Street's 2025-2027 forecasts of $192M, $401M and $653M in acute pain, but we're meaningfully above the Street's 2027-2030 forecasts in acute pain of $198M, $349M, $566M as neuropathic pain is uncomplicated by the same challenges as acute.

30 January 2024

Equity

Geoff Meacham
Research Analyst
BofAS
+1 646 855 1004
geoff.meacham@bofa.com

Alexandria Hammond
Research Analyst
BofAS
+1 646 855 1654
alexandria.hammond@bofa.com

Charlie Yang
Research Analyst
BofAS
charlie.yang@bofa.com

Susan Chor
Research Analyst
BofAS
susan.chor@bofa.com

John Joy
Research Analyst
BofAS
john.joy@bofa.com

Stock Data

Price	435.82 USD
Price Objective	540.00 USD
Date Established	26-Jan-2024
Investment Opinion	B-1-9
52-Week Range	283.60 USD - 443.82 USD
Mrkt Val (mn) / Shares Out (mn)	113,575 USD / 260.6
Free Float	99.8%
Average Daily Value (mn)	671.55 USD
BofA Ticker / Exchange	VRTX / NAS
Bloomberg / Reuters	VRTX US / VRTX.OQ
ROE (2023E)	24.5%
Net Dbt to Eqty (Dec-2022A)	-77.5%
ESGMeter™	High

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Abbreviations:
HC: healthcare
SCD: Sickle cell disease
TDT: Transfusion-dependent beta-thalassemia
CF: Cystic fibrosis
AE: adverse events
KOL: key opinion leader
SPID48: Sum of Pain Intensity Difference over first 48hours of treatment
LS: least-squares

CI: confidence interval

Price objective basis & risk

Vertex Pharmaceuticals Inc. (VRTX)
Our 12-month price objective for Vertex of $540/share is based on our net present value (NPV) analysis. We forecast sales for each of the approved products, Kalydeco, Orkambi, Symdeko, and Trikafta through 2030. We assume a weighted-average cost of capital (WACC) of 9%, in line with peer companies of similar size and risk and varying terminal growth rates for each asset based on its characteristics and patent life (-50% to 2%). Given these assumptions, we estimate a value of $3/share for Kalydeco, $1/share for Orkambi, $0/share for Symdeko, $399/share for Trikafta, $18/share for Casgevy, $8/share for VX-548, $57/sh for vanzacaftor, $46/share in net cash, and $8/share for the pipeline.

Risks to our price objective are 1) payer pushback on pricing, 2) difficulty in securing reimbursement agreements, particularly in the EU, 3) clinical trial failures, and 4) new competitors in cystic fibrosis.

Analyst Certification

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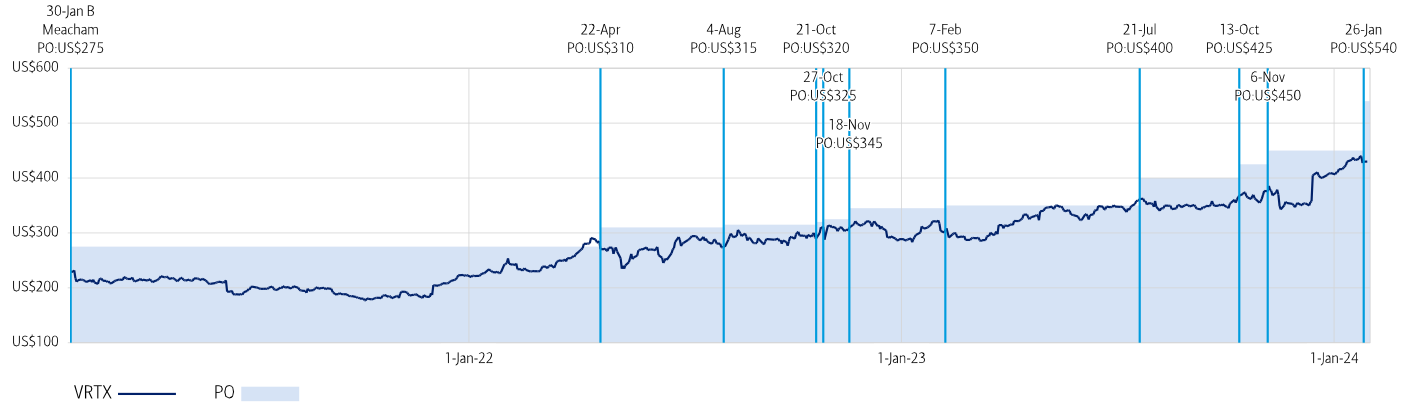
Vertex Pharmaceutica (VRTX) Price Chart



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	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
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