Vertex Pharmaceuticals, Inc. (Nasdaq: VRTX)

Rating: Buy

Price Target: $550.00
Share Price: $493.64

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Company Data	
Average Daily Volume (M)	1.05
52-Week Range	341.90-510.64
Shares Outstanding (M)	258.00
Market Cap (B)	127.21
Enterprise Value (B)	124.00
Total Cash (B), mrq	6.52
Total Debt (B)	1.70
Total Debt to Cap	10.89%

GAAP Estimates				
FYE: Dec		2023A	2024E	2025E
EPS	Q1	2.69	4.21	3.86
	Q2	3.52	(13.92)	3.90
	Q3	3.97	4.01	3.96
	Q4	3.71	4.00	4.06
	FY	13.89	(1.57)	15.79
P/E		35.6x	NM	31.3x
Rev	Q1	2,374.8	2,690.6	2,750.0
	Q2	2,493.2	2,645.6	2,790.0
	Q3	2,483.5	2,771.9	2,845.0
	Q4	2,517.7	2,775.0	2,920.0
	FY	9,869.2	10,883.1	11,305.0
EV/Sales		12.6x	11.4x	11..0x

One-Year Performance Chart

As of November 6, 2024. Source: E*Trade.

November 7, 2024

Vertex Pharmaceuticals Reports Third Quarter 2024 Earnings

Vertex Continues Strong Performance, Increases FY 2024 Revenue Guidance; Reiterate BUY Rating

Summary

- On November 4, 2024, Vertex reported consolidated financial results for the third quarter ended September 30, 2024, and updated its full year 2024 guidance. Product revenue of $2,771.9 million exceeded Kingswood Capital estimates of $2,690.0 million by 3%. GAAP EPS of $4.01 reflected stronger than anticipated operating results and higher interest income, outperforming our $3.79 EPS estimate.

- We raise our FY 2024 earnings estimate from $(1.78) to $(1.57) to account for the stronger than anticipated third quarter results and a slight increase in our fourth quarter 2024 revenue projections. FY 2024 earnings are affected by Vertex's second quarter EPS of $(13.92), due to its $5.0 billion acquisition of Alpine Immune Sciences.

- Vertex continues to progress multiple product development programs toward commercialization, expecting two new product launches in early 2025 and advancing three additional programs into Phase 3 testing during the third quarter of 2024.

- Sustained execution has helped Vertex achieve strong operating margins and cash position, allowing continued, significant investments in its pipeline and commercial capabilities.

Q3 2024 Financial Results

- Product revenue was $2,771.9 million, a 12% increase compared to Q3 2023, primarily driven by the strong performance of TRIKAFTA/KAFTRIO. Revenue growth rates were 10% in the U.S. (to $1.71 billion) and 14% outside the U.S. (to $1.06 billion), compared to the third quarter of 2023.

- Combined GAAP R&D and SG&A expenses were $1,247.7 million, compared to $1,073.8 million in the third quarter of 2023, due to costs associated with global product launches and continued R&D investments in support of clinical development programs that have advanced to Phase 3.

- Acquired in progress R&D (AIPR&D) expenses were $15.0 million, compared to $51.7 million in the third quarter of 2023.

- GAAP net income was $1,045.4 million, essentially unchanged from the third quarter of 2023, as increased Q3 2024 product revenue was partially offset by increased Q3 2024 R&D and SG&A expenses.

- GAAP EPS was $4.01 on 261.0 million shares outstanding, compared to $3.97 on 260.6 million shares outstanding in the third quarter of 2023.

- Vertex ended the quarter with $6,524.5 million in cash, cash equivalents, and marketable securities, compared to $11,218.3 million as of 12/31/23. The decrease is primarily due to the $5.0 billion cash consideration paid to acquire Alpine Immune Sciences in the second quarter of 2024, partially offset by positive cash flow from other operations.

FY 2024 Guidance

- Vertex raised its FY 2024 revenue guidance to $10.80 to 10.9 billion, from $10.65 to $10.85 billion previously, reflecting expectations for continued growth of its cystic fibrosis products through new approvals and reimbursement for the treatment of younger patients, as well as contributions to revenue from sales of CASGEVY in approved indications and geographies.

- FY 2024 combined R&D and SG&A guidance remained unchanged in a range of $5.0 to $5.2 billion due to the inclusion of Alpine operating expenses for the remainder of 2024.

Commercial and Clinical Highlights

Cystic Fibrosis (CF)

- Vertex anticipates continued growth in cystic fibrosis through new approvals and reimbursement for the treatment of younger patients. As of the third quarter of 2024, its best-selling CF drug KAFTRIO is now reimbursed in all 27 countries of the European Union (EU).

- Vertex's vanzacaftor triple combination therapy for cystic fibrosis in patients six years and older received FDA Priority Review designation and was assigned a Prescription Drug User Fee Act (PDUFA) target action date of January 2, 2025.

- Regulatory submissions for vanzacaftor triple are under review in the U.S., EU, United Kingdom, Australia, New Zealand, and Switzerland.

Sickle Cell Disease (SCD) and Transfusion-Dependent Beta-Thalassemia (TDT)

- Vertex received regulatory approvals for CASGEVY for the treatment of patients 12 years and older with SCD or TDT in Switzerland and Canada. In addition to these two countries, the gene therapy is approved in the U.S., Great Britain, the EU, the Kingdom of Saudi Arabia, the Kingdom of Bahrain, and launches are ongoing in all approved geographies.

- As of mid-October, Vertex has activated 45 authorized treatment centers globally and increasing numbers of patients across all regions have initiated cell collection.

Moderate to Severe Acute Pain

- Vertex's suzetrigine (VX-548) for the treatment of moderate-to-severe acute pain received FDA Priority Review designation and was assigned a PDUFA target action date of January 30, 2025.

- Suzetrigine advanced to Phase 3 pivotal trials in patients with painful diabetic peripheral neuropathy (DPN), a type of chronic peripheral neuropathic pain (PNP) that accounts for approximately 20% of patients suffering from PNP. The FDA has granted suzetrigine Breakthrough Therapy Designation in DPN.

Other Programs

- Povetacicept advanced to Phase 3 testing in Immunoglobulin A Nephropathy (IgAN), a disease of the kidney and the immune system in which the glomeruli of the kidney are inflamed. The povetacicept Phase 3 study, RAINIER, is a global pivotal trial of povetacicept 80mg versus placebo on top of standard of care in approximately 480 patients with IgAN. A pre-planned interim analysis will be conducted after a certain number of patients reach 36 weeks of treatment, evaluating the change from baseline in the urine protein creatinine ratio for the povetacicept arm versus the placebo arm. If positive, the interim analysis may serve as the basis for accelerated approval in the U.S. Final analysis will occur at two years of treatment, with a primary endpoint of total estimated glomerular filtration rate slope through Week 104.

- VX-880 advanced to Phase 3 testing in type 1 diabetes. The therapy is being developed as a potential one-time functional cure for type 1 diabetes and entails delivering stem-cell-derived, fully differentiated islet cells in combination with standard immunosuppression. Vertex reached agreement with regulatory agencies in the U.S. and Europe to convert its ongoing Phase 1/2 study to a Phase 1/2/3 study, in which a total of 50 patients will be infused with a single target dose of VX-880. The primary endpoint is the proportion of patients with insulin independence and absence of severe hypoglycemic episodes.

Company Description

Founded in 1989, and headquartered in Boston, MA, and London, U.K., Vertex Pharmaceuticals, Inc., is a global biotechnology company focused on discovering, developing, manufacturing, and commercializing small molecule treatments for chronic and genetic diseases, for which there is acute medical need.

The firm's initial focus, and subject of ongoing research and development, is cystic fibrosis (CF), a genetic disease affecting the lungs and other organs. The Vertex portfolio of marketed CF medicines includes KALYDECO, ORKAMBI, SYMDEKO, and TRIKAFTA, which improve lung function and reduce hospitalizations in CF patients.

The company has also received regulatory approval for CASGEVY™, the first CRISPR/Cas9 gene editing therapy that treats the underlying causes of two chronic, life-shortening diseases: sickle cell disease and transfusion-dependent beta thalassemia.

Vertex has a robust clinical pipeline of investigational therapies for other debilitating diseases and conditions, including non-opioid treatment of acute and chronic pain, Type 1 diabetes, alpha-1 antitrypsin deficiency, kidney disease, Duchenne muscular dystrophy, and myotonic dystrophy type 1.

The company has research and development sites and commercial offices in the United States, Canada, Latin America, the Middle East, Japan, Australia, and several European countries.

Valuation

As an established company in the cystic fibrosis space, Vertex leads its competitors across a spectrum of solvency, valuation, and profitability metrics, including having a 2023 P/E of 34.2x versus the competitor group median of 17.0x. The firm's 2023 enterprise value (EV)/Revenue was 11.1x versus its competitor group median of 6.6x. Vertex's 2023 EV/EBIT was 25.4x, versus its competitor group median of 15.6x. The company's 2023 gross margin was 87.2%, contrasted with its competitor group median of 74.2%, and its 2023 net margin was 36.7% against the competitor group median of 19.0%.

Combined with the above metrics, Vertex’s rich valuation is, in our opinion, justified by its formidable cash resources, deep and broadening pipeline, historical successes in clinical trials, and the marketing of its drugs in key strategic regions.

We believe that additional shareholder value will be unlocked as Vertex’s portfolio of approved products broadens. One example is the company's global launch of and reimbursement coverage for CASGEVY™, its gene therapy for SCD and beta thalassemia. Another near-term product launch opportunity is the vanzacaftor/tezacaftor/deutivacaftor triple oral small molecule combination for cystic fibrosis, which employs a similar mechanism of action as Vertex’s blockbuster drug TRIKAFTA.

Vertex’s non-opioid treatment for moderate to severe acute pain, Suzetrigine (VX-548), completed Phase 3 clinical trials in December 2023. It is now in regulatory review by the U.S. FDA. Non-opioid pain

management is a significant, unmet medical need worldwide. It is possible that Suzetrigine could be approved within one calendar year, and capture a significant first mover share of the $80-90 billion global pain management market.

Based on our analysis of available clinical data, we expect regulatory approvals of the vanzacaftor triple combination and Suzetrigine in 2025, followed by accelerating revenue and EPS growth in 2026. We recommend investors begin accumulating shares of Vertex during the next 12-18 months. Our 12-month price target of $550.00 is based on next-twelve-months (NTM) projected earnings, not including one-time acquisition charges, of $15.50 and a P/E multiple of 35.5x.

Vertex Pharmaceuticals Financial Forecast											
	FY 23 A	MAR 24 A	JUN 24 A	SEP 24 A	DEC 24 E	FY 24 E	MAR 25 E	JUN 25 E	SEP 25 E	DEC 25 E	FY 25 E
Revenue	9,869.2	2,690.6	2,645.6	2,771.9	2,775.0	10,883.1	2,750.0	2,790.0	2,845.0	2,920.0	11,305.0
Cost of Sales	1,262.2	342.6	371.9	392.6	395.5	1,502.6	337.5	345.6	355.6	365.0	1,403.7
Gross Profit	**8,607.0**	**2,348.0**	**2,273.7**	**2,379.3**	**2,379.5**	**9,380.5**	**2,412.5**	**2,444.4**	**2,489.4**	**2,555.0**	**9,901.3**
Operating Expenses:											
R&D	3,162.9	789.1	966.6	875.9	888.0	3,519.6	935.0	948.6	967.3	992.8	3,843.7
Acquired in-process R&D	527.1	76.8	4,449.1	15.0	30.0	4,570.9	30.0	30.0	30.0	30.0	120.0
SG&A	1,136.6	342.7	372.2	371.8	374.6	1,461.3	357.5	362.7	369.9	379.6	1,469.7
Change in Fair Value of Contingent Consideration	-51.6	-0.1	0.5	0.3	0.5	1.2	-15.0	-15.0	-15.0	-15.0	-60.0
Total Operating Expenses	**4,775.0**	**1,208.5**	**5,788.4**	**1,263.0**	**1,293.1**	**9,553.0**	**1,307.5**	**1,326.3**	**1,352.2**	**1,387.4**	**5,373.4**
Operating Income	**3,832.0**	**1,139.5**	**-3,514.7**	**1,116.3**	**1,086.4**	**-172.5**	**1,105.0**	**1,118.1**	**1,137.3**	**1,167.6**	**4,528.0**
Interest Expense/Income, net	570.6	170.8	146.6	124.7	135.0	577.1	88.0	89.0	90.0	91.0	358.0
Other Income/Expense, net	-22.8	-31.2	-23.1	-16.9	-	-71.2	-	-	-	-	-
Earnings Before Tax	**4,379.8**	**1,279.1**	**-3,391.2**	**1,224.1**	**1,221.4**	**333.4**	**1,193.0**	**1,207.1**	**1,227.3**	**1,258.6**	**4,886.0**
Income Tax Expense	760.2	179.5	202.4	178.7	178.3	738.9	179.0	181.1	184.1	188.8	732.9
Net Income	**3,619.6**	**1,099.6**	**-3,593.6**	**1,045.4**	**1,043.1**	**-405.5**	**1,014.1**	**1,026.0**	**1,043.2**	**1,069.8**	**4,153.1**
Weighted Average Basic Shares Outstanding	257.7	258.2	258.1	258.0	257.9	258.0	259.8	260.0	260.4	260.7	260.2
Weighted Average Diluted Shares Outstanding	260.5	261.1	258.1	261.0	260.9	259.0	262.9	263.0	263.2	263.6	263.1
Net Income per Share, GAAP, Basic	$14.05	$4.26	-$13.92	$4.05	$4.04	-$1.57	$3.90	$3.95	$4.01	$4.10	$15.96
Net Income per Share, GAAP, Diluted	$13.89	$4.21	-$13.92	$4.01	$4.00	-$1.57	$3.86	$3.90	$3.96	$4.06	$15.79
All figures in millions of U.S. Dollar except per share items.											

Sources: Capital IQ, Kingswood Capital Partners Estimates.

Risks to Our Price Target

Clinical trial setbacks: The success of Vertex's drug development pipeline depends on the outcomes of clinical trials, which are subject to risks and uncertainties, including unexpected safety issues, serious side effects, or lack of efficacy.

Regulatory: Vertex may face delays caused by, or rejections from regulatory agencies of its applications for regulatory clearance and marketing authorizations, which in turn would delay or prevent commercialization.

Pricing and reimbursement: Payers such as medical insurers or government-underwritten health systems may limit patient access, or decline to reimburse Vertex's therapies if Vertex's prices are deemed too high, or the efficacy of its therapies are deemed insufficient.

Dependence on a few key products: Vertex's revenue is heavily dependent on its cystic fibrosis products, and any setbacks or competition in this area could have a significant impact on the company's financial performance.

Intellectual property challenges: Vertex's patents may be challenged by competitors, declared invalid by the Patent Trial and Appeal Board, or in court, which could lead to loss of intellectual property or formulary exclusivity, and increased competition.

Competition: Vertex operates in a highly competitive industry, and its competitors may develop equivalent or superior therapies, thereby eroding its market share and revenue.

Supply chain disruptions: Vertex relies on a complex global supply chain to manufacture its therapies, and disruptions or quality issues could impact production, sales, as well as clinical trial timelines.

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BUY	3	75.00	1	33.33
HOLD	0	0.00	0	0.00
SELL	0	0.00	0	0.00
NOT RATED	1	25.00	1	100.00

As of November 2024.

Vertex Pharmaceuticals Rating History as of August 2, 2024

Source: E-Trade.

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