Vertex Pharmaceuticals, Inc. (Nasdaq: VRTX)

Rating: Buy

Price Target: $550.00
Share Price: $494.46

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Company Data	
Average Daily Volume (M)	1.19
52-Week Range	340.68-510.64
Shares Outstanding (M)	158.05
Market Cap (B)	127.60
Enterprise Value (B)	122.73
Total Cash (B), mrq	5.80
Total Debt (M)	933.40
Total Debt to Cap	5.94%

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	3.79	3.96
	Q4	3.71	3.99	4.06
	FY	13.89	(1.78)	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	2,690.0	2,845.0
	Q4	2,517.7	2,730.0	2,920.0
	FY	9,869.2	10,756.2	11,305.0
EV/Sales		12.4x	11.4x	10.9x

One-Year Performance Chart

As of August 2, 2024. Source: E*Trade.

August 5, 2024

Vertex Pharmaceuticals Reports Second Quarter 2024 Earnings

Biotech Powerhouse Continues Strong Performance, Bolsters Pipeline with Strategic Acquisition; Reiterate BUY Rating

Summary

- On August 1, 2024, Vertex Pharmaceuticals reported consolidated financial results for the second quarter ended June 30, 2024, and updated its full year 2024 guidance. Product revenue of $2,645.6 million was in line with Kingswood Capital estimates of $2,660.0 million. GAAP EPS of $(13.92) reflected the $5.0 billion acquisition of Alpine Immune Sciences.

- We update our FY 2024 earnings estimate to $(1.78) to account for the impact of the Alpine acquisition on FY 2024 EPS.

- Vertex continues to exhibit strong momentum behind its multiple product development programs, anticipating two potential new product launches during 2025.

- Vertex sustained its strong operating margins and maintains a healthy cash position post-acquisition, allowing for significant investments in its pipeline and commercial capabilities.

Q2 2024 Financial Results

- Product revenue was $2,645.6 million, a 6% increase compared to Q2 2023, primarily driven by the strong performance of TRIKAFTA/KAFTIRO, including in younger age groups, which accounted for $2,449.2 million (92.6%) of total

revenue. Revenue growth rates were 7% in the U.S. (to $1.61 billion) and 5% outside the U.S. (to $1.03 billion), compared to the second quarter of 2023.

- Combined GAAP R&D and SG&A expenses were $1.3 billion, compared to $1.0 billion in the second quarter of 2023, due to costs associated with global product launches and continued R&D investments in mid-to-late-stage clinical development programs.

- Acquired in-progress R&D (AIPR&D) expenses were $4.4 billion, compared to $111 million in the second quarter of 2023, due to Vertex's acquisition of Alpine Immune Sciences for approximately $5.0 billion in cash, resulting in a $4.4 billion charge to AIPR&D.

- GAAP net losses were $(3,593.6) million, compared to net income of $915.7 million in the second quarter of 2023, reflecting the one-time, non-tax deductible AIPR&D charge of $4.4 billion.

- GAAP EPS was $(13.92) on 258.1 million shares outstanding, compared to $3.52 on 260.4 million shares outstanding in Q2 2023.

- Vertex ended the quarter with $5,795.5 million in cash, cash equivalents, and marketable securities, compared to $11,218.3 million as of 12/31/23, primarily driven by the $5.0 billion cash consideration paid to acquire Alpine Immune Sciences, partially offset by positive cash flow from other operations.

FY 2024 Guidance

- Vertex raised its FY 2024 revenue guidance to $10.65 to 10.85 billion, from $10.55 to $10.75 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. Our FY 2024 revenue estimate of $10.76 billion is in line with company guidance.

- Vertex also raised its FY 2024 combined R&D and SG&A guidance from $4.8 to $5.0 billion to $5.0 to $5.2 billion due to the inclusion of Alpine operating expenses for the remainder of 2024.

Clinical Highlights

- Vertex anticipates continued growth as it is advancing its clinical pipeline, with multiple milestones expected during the second half of 2024. The company's focus for the remainder of the year will remain on commercial execution in cystic fibrosis and the global launch of CASGEVY, Vertex's gene therapy for sickle cell anemia and beta thalassemia. CASGEVY launches are ongoing in the U.S., Great Britain, the EU, the Kingdom of Saudi Arabia, and the Kingdom of Bahrain. Regulatory decisions for CASGEVY are pending in Switzerland and Canada.

- The FDA accepted NDA applications for Vertex's vanzacaftor triple combination therapy for cystic fibrosis in patients six years and older and suzetrigine (VX-548) for moderate-to-severe acute pain. Both therapies received Priority Review designations and were assigned Prescription Drug User Fee Act (PDUFA) target action dates of January 2 and 30, 2025, respectively.

- Vertex also received validation of its vanzacaftor triple Marketing Authorization Application (MAA) submissions from the European Medicines Agency (EMA) in the EU and the Medicines and Healthcare products Regulatory Agency (MHRA) in the U.K. Vertex has completed regulatory submissions for its vanzacaftor triple therapy in Canada, Australia, New Zealand, and Switzerland.

- Vanzacaftor triple and suzetrigine represent potential near-term product launch opportunities.

- Vertex is on track to initiate its Phase 3 pivotal program of suzetrigine in patients with painful diabetic neuropathy (DPN) this quarter. Primary endpoint is the change from baseline in the weekly average of daily pain intensity at week 12 compared to placebo. The study also includes an active comparator arm of pregabalin (Lyrica)–an anticonvulsant analgesic used to treat epilepsy, neuropathic pain, fibromyalgia, restless leg syndrome, opioid withdrawal, and generalized anxiety disorder–to assess non-inferiority on change from baseline to week 12 versus pregabalin.

- Expanding suzetrigine's potential market to include chronic pain indications would be an important label expansion and significant amplification of Vertex's commercial opportunity in the pain treatment space.

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 E	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	2,690.0	2,730.0	10,756.2	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	336.3	342.5	1,393.3	337.5	345.6	355.6	365.0	1,403.7
Gross Profit	8,607.0	**2,348.0**	**2,273.7**	**2,353.7**	**2,387.5**	9,362.9	**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	860.8	873.6	3,490.1	935.0	948.6	967.3	992.8	3,843.7
Acquired in-process R&D	527.1	76.8	4,449.1	100.0	30.0	4,655.9	30.0	30.0	30.0	30.0	120.0
SG&A	1,136.6	342.7	372.2	349.7	354.9	1,419.5	357.5	362.7	369.9	379.6	1,469.7
Change in Fair Value of Contingent Consideration	-51.6	-0.1	0.5	-30.0	-12.9	-42.5	-15.0	-15.0	-15.0	-15.0	-60.0
Total Operating Expenses	**4,775.0**	**1,208.5**	**5,788.4**	**1,280.5**	**1,245.6**	**9,523.0**	**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**	**1,073.2**	**1,141.9**	**-160.1**	**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	86.0	87.0	490.4	88.0	89.0	90.0	91.0	358.0
Other Income/Expense, net	-22.8	-31.2	-23.1	-	-	-54.3	-	-	-	-	-
Earnings Before Tax	**4,379.8**	**1,279.1**	**-3,391.2**	**1,159.2**	**1,228.9**	**276.0**	**1,193.0**	**1,207.1**	**1,227.3**	**1,258.6**	**4,886.0**
Income Tax Expense	760.2	179.5	202.4	173.9	184.3	740.1	179.0	181.1	184.1	188.8	732.9
Net Income	**3,619.6**	**1,099.6**	**-3,593.6**	**985.3**	**1,044.6**	**-464.1**	**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	259.3	259.5	258.8	259.8	260.0	260.4	260.7	260.2
Weighted Average Diluted Shares Outstanding	260.5	261.1	258.1	260.0	261.5	260.2	262.9	263.0	263.2	263.6	263.1
Net Income per Share, GAAP, Basic	$14.05	$4.26	-$13.92	$3.80	$4.03	-$1.79	$3.90	$3.95	$4.01	$4.10	$15.96
Net Income per Share, GAAP, Diluted	$13.89	$4.21	-$13.92	$3.79	$3.99	-$1.78	$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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			Investment Banking Services/Past 12 Months	
Rating	**Count**	**Percent**	**Count**	**Percent**
BUY	3	75.00	2	66.67
HOLD	0	0.00	0	0.00
SELL	0	0.00	0	0.00
NOT RATED	1	25.00	1	100.00

As of August 2024.

Vertex Pharmaceuticals Rating History as of August 2, 2024

Source: E-Trade.

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