

Vertex Pharmaceuticals (VRTX)

\$215.69 (As of 03/19/20)

Price Target (6-12 Months): **\$238.00**

Long Term: 6-12 Months

Zacks Recommendation:
Neutral

(Since: 12/20/19)

Prior Recommendation: Outperform

Short Term: 1-3 Months

Zacks Rank: (1-5)

2-Buy

Zacks Style Scores:

VGM:C

Value: C

Growth: B

Momentum: D

Summary

We like Vertex's dominance in the cystic fibrosis (CF) market. While consistent label expansion of CF drugs drove sales growth in 2019, in 2020, sales are expected to be primarily driven by the uptake of Trikafta as well as higher international revenues due to additional ex-U.S. reimbursement arrangements in key countries like England and France. Trikafta's early approval and launch was a key milestone for Vertex. Trikafta is crucial for Vertex's long-term growth as it has the potential to treat up to 90% of CF patients. Meanwhile, Vertex's non-CF pipeline is progressing rapidly with data in multiple diseases expected in 2020. However, competitive pressure is rising in the CF market. Also, Vertex's dependence on just the CF franchise for growth is a concern. Stock has outperformed the industry in the past one year.

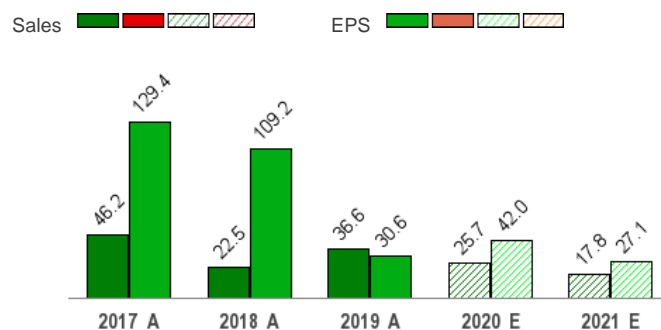
Price, Consensus & Surprise



Data Overview

52 Week High-Low	\$249.85 - \$163.68
20 Day Average Volume (sh)	2,368,485
Market Cap	\$55.9 B
YTD Price Change	-1.5%
Beta	1.32
Dividend / Div Yld	\$0.00 / 0.0%
Industry	Medical - Biomedical and Genetics
Zacks Industry Rank	Top 28% (72 out of 254)

Sales and EPS Growth Rates (Y/Y %)



Last EPS Surprise	40.5%
Last Sales Surprise	41.4%
EPS F1 Est- 4 week change	0.0%
Expected Report Date	05/05/2020
Earnings ESP	0.0%
P/E TTM	40.5
P/E F1	28.5
PEG F1	1.0
P/S TTM	13.4

Sales Estimates (millions of \$)

	Q1	Q2	Q3	Q4	Annual*
2021	1,501 E	1,543 E	1,574 E	1,608 E	6,161 E
2020	1,254 E	1,308 E	1,328 E	1,386 E	5,232 E
2019	858 A	941 A	950 A	1,413 A	4,163 A

EPS Estimates

	Q1	Q2	Q3	Q4	Annual*
2021	\$2.25 E	\$2.24 E	\$2.30 E	\$2.37 E	\$9.62 E
2020	\$1.77 E	\$1.81 E	\$1.92 E	\$2.03 E	\$7.57 E
2019	\$1.14 A	\$1.26 A	\$1.23 A	\$1.70 A	\$5.33 A

*Quarterly figures may not add up to annual.

The data in the charts and tables, including the Zacks Consensus EPS and Sales estimates, is as of 03/19/2020. The reports text is as of 03/20/2020.

Overview

Boston, MA-based Vertex Pharmaceuticals Incorporated is focused on the discovery, development, and commercialization of small molecule drugs targeting serious diseases. The company's main area of focus is cystic fibrosis (CF).

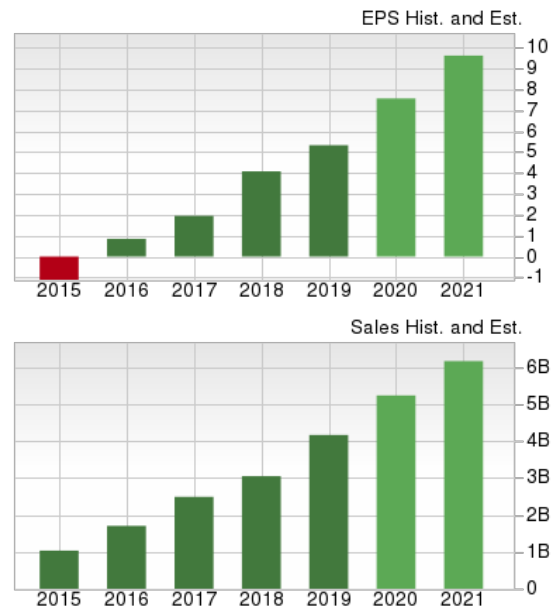
The company's lead marketed products are Trikafta (elexacaftor/tezacaftor/ivacaftor and ivacaftor), Symdeko/Symkevi (tezacaftor in combination with ivacaftor), Orkambi (lumacaftor in combination with ivacaftor) and Kalydeco (ivacaftor), which are collectively approved to treat around 60% of the 75,000 CF patients in North America, Europe and Australia. Trikafta, Vertex's triple combination regimen, was approved by the FDA in October 2019 for the treatment of CF in people aged 12 years and older who have at least one F508del mutation. It is under review in Europe and is also being evaluated in younger patients in the United States. With approval of Trikafta, Vertex can address a significantly larger CF patient population — almost 90% of patients with CF — in the future.

Symdeko was approved by the FDA in February 2018 to treat CF patients homozygous for the F508del mutation or with at least one mutation that is responsive to tezacaftor/ivacaftor. Symkevi (brand name of Symdeko in EU) was approved in the European Union in November 2018.

While CF remains the main area of focus, Vertex is also developing treatments for sickle cell disease, thalassemia and pain management.

Pimodivir/VX-787, for the treatment of influenza, was out-licensed to Janssen in 2014 while oncology candidates VX-970, VX-984 and VX-803 were divested to Merck KGaA in 2017.

The company recorded total revenues of \$4.16 billion in 2019, up 37%. Orkambi accounted for 29.4% of the company's total product revenues, Kalydeco accounted for 24.7%, Symdeko accounted for 35.4% and Trikafta comprised 10.5% of the same.



Reasons To Buy:

▲ **Shares Outperforming Industry:** In the past one year, Vertex's shares have risen 18.2% against a decrease of 17.7% for the industry.

▲ **Consistent Rise in CF Product Sales:** Consistent positive regulatory approvals have led to an increase in the eligible patient population for Vertex's approved medicines in the past 2-3 years. In 2019 alone, Vertex received nine new regulatory approvals or label expansions for its CF medicines globally. Also, in 2019, Vertex reached a number of key reimbursement agreements in important ex-U.S. countries like England and France, which expanded access to its CF medicines. With consistent expansion in patient population, Vertex's CF product revenues rose 29% in 2017, 40% in 2018 and 32% in 2019. With the approval of Trikafta, approximately 45,000 patients worldwide are now eligible to be treated with one of Vertex's four CF medicines. Vertex believes that revenue growth in 2020 will be primarily driven by the uptake of Trikafta as well as higher international revenues due to additional ex-U.S. reimbursement arrangements.

▲ **Strong CF Portfolio:** The CF market represents huge commercial potential. It is a rare, life-threatening disease estimated to affect about 75,000 people in North America, Europe and Australia. Vertex enjoys a strong position in this market, being the first company to successfully develop a drug (Kalydeco) that treats the underlying cause of CF.

Symdeko, in a very short time, became a primary driver of CF revenues and generated sales of \$1.4 billion in 2019. In June 2019, Vertex gained FDA approval for Symdeko in eligible patients as young as six years of age. This label expansion coupled with launch of Symkevi in additional European countries further boosted sales.

Trikafta's early approval and launch was the most significant milestone for Vertex and the drug generated \$420 million in sales in just around two months on the market. In the EU, a regulatory application for Trikafta is under review with approval expected in 2020. Meanwhile, phase III studies are also ongoing to evaluate Trikafta in children aged 6 through 11. A sNDA seeking approval for the pediatric patient population is expected to be filed in 2020. A potential approval of Trikafta in EU and for the pediatric patients in the United States could bring additional Trikafta revenues in 2020. Trikafta is crucial for Vertex's long-term growth as it has the potential to treat up to 90% of CF patients.

In 2017, Vertex bought Concert Pharmaceuticals' CF pipeline candidate, VX-561 (previously CTP-656). A phase II dose ranging study is ongoing to evaluate VX-561 to support potential phase III development of VX-561 in a once-daily triple combination regimen. Vertex has initiated another phase II study evaluating the next-generation corrector, VX-121, in triple combination with VX-561 and tezacaftor as a potential once-daily triple combination regimen.

▲ **Upside Potential from Non-CF Pipeline:** While Vertex's main focus is on the development and strengthening of its CF franchise, the company also has a rapidly advancing early-stage portfolio in five other specialty disease areas like pain, alpha-1 antitrypsin deficiency (AAT), sickle cell disease, beta-thalassemia and APOL1-mediated kidney diseases.

Vertex is co-developing a gene editing treatment, CTX001 in partnership with CRISPR Therapeutics in two devastating diseases — sickle cell disease and thalassemia. Phase I/II studies of CTX001 in adult transfusion-dependent b-thalassemia in Europe and sickle cell disease in the United States are ongoing. First safety and efficacy data from the studies were positive. In June 2019, Vertex announced expansion of its collaboration with CRISPR Therapeutics and acquisition of privately held Exonics Therapeutics to boost its gene editing capabilities to develop novel therapies for Duchenne muscular dystrophy ("DMD") and Myotonic dystrophy type 1 (DM1).

Also, Vertex's first oral small molecule corrector, VX-814, is being evaluated in a phase II study for the treatment of AAT while a second small molecule corrector, VX-864 is in a phase I study. Both VX-814 and VX-864 have received Fast-Track Designation from the FDA. Vertex has completed a phase I study on VX-147, its first oral small molecule medicine for APOL1-mediated focal segmental glomerulosclerosis (FSGS). A phase II study to evaluate the reduction in protein levels in urine is expected to be initiated in 2020.

In pain, Vertex demonstrated proof-of-concept across multiple phase II studies of Nav1.8 inhibitor, VX-150, in acute, neuropathic and musculoskeletal pain conditions. It plans to advance an additional molecule in pain into phase I development in the first-half of 2020.

Vertex is also looking for early stage companies and products or intellectual property acquisitions that could help it broaden its pipeline beyond CF.

▲ **Collaborations Broadening Pipeline:** Vertex's success in CF has given it the financial strength to invest in both internal and external innovation. Vertex has entered into multiple agreements in the past couple of years to provide it with access to new external scientific technologies, programs and expertise in multiple diseases to complement its internal pipeline. It has such collaborations with CRISPR Therapeutics, Arbor Biotechnologies, Moderna Therapeutics, Kymera Therapeutics, Merck KGaA, Genomics Plc and X-Chem. Vertex also owns equity investments in CRISPR and Moderna. Vertex plans to pursue more business development transactions to bolster its pipeline for serious diseases with multiple modalities and technologies. In October 2019, Vertex acquired Semma Therapeutics to develop a cellular therapy that both alone and in combination with an implantable device has the potential to cure type I diabetes. In 2019, Vertex invested approximately \$1.6 billion in cash in external innovation through new acquisitions and collaborations.

The rapid approval of Vertex's triple combo CF pill, Trikafta, was a big boost. Reimbursement approval in England for its CF drugs removed a key overhang.

Reasons To Sell:

- ▼ **Trikafta Launch May Cannibalize Sales of Other Drugs:** On third/fourth quarter conference call, management said that a large proportion of patients currently on Kalydeco, Orkambi or Symdeko will switch to Trikafta over time. We expect that once Trikafta is fully launched in the United States and EU and gains necessary reimbursement approvals in EU, there will be a rapid erosion of existing combinations.

Also, even if Trikafta is eventually approved in EU in 2020, Vertex would need to seek government reimbursement on a country-by-country basis, in most European markets, which is a time consuming process and may limit ex-U.S. revenues of the drug.

Vertex's dependence on just the CF franchise for growth is concerning. Moreover, several other companies are working on bringing their CF products to market.

- ▼ **Competing Therapies in Development:** Several companies like AbbVie, Eloxx Pharmaceuticals, Translate Bio and Proteostasis Therapeutics are developing medicines to treat CF. Even though Vertex enjoys a strong position in this market, the entry of additional competition would cut into revenues.
- ▼ **Banking on CF Franchise:** Although we are positive on Vertex's decision to focus on the CF franchise, we remain concerned about the company's dependence on just this franchise for growth. While the company does have other pipeline candidates targeting other therapeutic areas, it is too early to get excited about them.
- ▼ **Pipeline/Regulatory Setbacks:** Vertex has several studies ongoing with its CF product candidates and any negative development on the pipeline/regulatory front will have an adverse impact on shares. In October 2017, Vertex announced that it will not file regulatory applications for VX-661 - ivacaftor combination in CF patients with one copy of the F508del mutation and one copy of a gating mutation, as a phase III study evaluating VX-661 — ivacaftor use in such patients failed to meet the primary endpoint.

In October 2018, Vertex discontinued development of VX-210 (acute cervical spinal cord injuries) due to futility.

Last Earnings Report

Vertex Q4 Earnings & Sales Beat

Vertex's fourth-quarter 2019 earnings per share of \$1.70 beat the Zacks Consensus Estimate of \$1.14. Moreover, earnings rose 31% year over year driven by higher product sales, which made up for higher costs and taxes.

Revenues of \$1.4 billion rose 63% year over year and also surpassed the Zacks Consensus Estimate of \$1 billion. Total revenues included \$155.8 million of sales from Orkambi distributed through the early access program in France during the fourth quarter. Excluding this impact, the company's sales surged 45% year over year to \$1.26 billion, driven by the early launch of Trikafta in the United States and the global uptake of Symdeko/Symkevi.

Quarter Ending **12/2019**

Report Date	Jan 30, 2020
Sales Surprise	41.36%
EPS Surprise	40.50%
Quarterly EPS	1.70
Annual EPS (TTM)	5.33

CF Franchise Sales Strong

Vertex's fourth-quarter revenues comprised only CF product revenues. The company did not record any collaborative and royalty revenues during the reported quarter.

Newly launched Trikafta was off to a strong start and generated sales of \$420 million. Fourth-quarter revenues included launch-related stocking of approximately \$100 million, which is not expected to repeat in 2020.

Symdeko/Symkevi registered sales of \$322 million in the fourth quarter, reflecting a rise of 12.9% year over year. Kalydeco recorded sales of \$236 million in the quarter, down 8.8% year over year. Orkambi generated sales of \$270 million in the reported quarter, down 14.3% year over year. Sales of Kalydeco and Orkambi may have been hurt by patient switching to Trikafta.

On fourth-quarter conference call, management stated that a large proportion of patients currently on Kalydeco, Orkambi or Symdeko who are eligible for Trikafta will switch to Trikafta over time.

Costs Rise

Adjusted operating income rose 70% to \$593 million in the quarter driven by higher revenues and disciplined spending.

Adjusted research and development (R&D) expenses rose 22.5% to \$337 million in the fourth quarter due to expansion of CF and non-CF pipeline. Adjusted selling, general and administrative (SG&A) expenses increased 27.2% to \$159 million in the reported quarter due to investments made in supporting CF patients' treatment, globally.

Full-Year Results

For 2019, Vertex generated revenues of \$4.2 billion, reflecting 37% growth year over year.

For the same period, the company reported earnings of \$5.33 per share, up 31% year over year.

2020 Outlook

The company expects total revenues for CF products in the range of \$5.1-\$5.3 billion in 2020 which at the midpoint, reflects approximately 30% growth over 2019.

During fourth-quarter conference call, management stated that strong uptake of Trikafta and the recent reimbursement approvals in key countries like England and France for its CF drugs should lead to revenue growth in 2020

Moreover, combined adjusted R&D and SG&A expenses for 2020 are anticipated in the band of \$1.95-\$2 billion which is higher than 2019 due to Trikafta launch-related costs and the expansion of the R&D pipeline. Adjusted tax rate is expected in the range of 21%-22%.

Recent News

Coronavirus Has No Impact on Vertex' Supply Chain – Mar 9

Vertex announced that the coronavirus outbreak has had no impact on its supply chain and it will be able to continue to supply its medicines. The company retained its 2020 guidance provided in January.

Amendment to Reimbursement Deal in Ireland – Dec 13

Vertex announced that it has negotiated an agreement with the Republic of Ireland to expand the existing long-term CF reimbursement agreement to include the triple combination regimen (elexacaftor, tezacaftor and ivacaftor). The triple combo regimen is under review and pending approval by the European Medicines Agency.

Kalydeco Gets EU Approval in Infants – Dec 10

Vertex announced that the European Commission has granted marketing authorization to Kalydeco for expanded use in infants aged from six to less than 12 months with at least one of specified nine mutations in the CFTR gene. The approval was based on data from an ongoing open-label phase III study, ARRIVAL, which evaluated children aged less than 24 months with a CFTR gating mutation.

Valuation

Vertex's shares are down 1.5% in the year-to-date period but up 18.2% over the trailing 12-month period. Stocks in the Zacks sub-industry and sector are down 13.4% and 19.9%, respectively in the sector. Over the past year, the Zacks sub-industry and sector are down 17.7% and 21.2%, respectively.

The S&P 500 Index is down 25.3% in the year-to-date period and 16.7% in the past year.

The stock is currently trading at 13.58X trailing 12-month sales per share, which compares to 2.44X for the Zacks sub-industry, 2.65X for the Zacks sector and 2.6X for the S&P 500 Index.

Over the past five years, the stock has traded as high as 53.78X and as low as 10.86X, with a 5-year median of 16.04X. Our Neutral recommendation indicates that the stock will perform in-line with the market. Our \$238.0 price target reflects 15.0X trailing 12-month sales per share.

The table below shows summary valuation data for VRTX

Valuation Multiples - VRTX					
		Stock	Sub-Industry	Sector	S&P 500
P/S TTM	Current	13.58	2.44	2.65	2.6
	5-Year High	53.78	5.04	4.16	3.68
	5-Year Low	10.86	2.17	2.65	2.55
	5-Year Median	16.04	2.65	3.28	3.17
P/B TTM	Current	9.12	3.34	3.67	3.23
	5-Year High	32.77	5.8	5.04	4.54
	5-Year Low	8.45	2.47	3.49	2.9
	5-Year Median	18.21	3.29	4.33	3.64

As of 3/19/2020

Industry Analysis Zacks Industry Rank: Top 28% (72 out of 254)



Top Peers

Pfizer Inc. (PFE)	Outperform
AbbVie Inc. (ABBV)	Neutral
Senesco Technologies Inc. (ELOX)	Neutral
Merck & Co., Inc. (MRK)	Neutral
Novartis AG (NVS)	Neutral
ProQR Therapeutics N.V. (PRQR)	Neutral
Proteostasis Therapeutics, Inc. (PTI)	Neutral
Translate Bio, Inc. (TBIO)	Neutral

Industry Comparison Industry: Medical - Biomedical And Genetics				Industry Peers		
	VRTX Neutral	X Industry	S&P 500	ABBV Neutral	PRQR Neutral	PTI Neutral
VGM Score	C	-	-	A	F	F
Market Cap	55.92 B	141.09 M	16.45 B	105.11 B	276.95 M	72.49 M
# of Analysts	12	3	13	2	1	3
Dividend Yield	0.00%	0.00%	2.67%	6.64%	0.00%	0.00%
Value Score	C	-	-	B	F	F
Cash/Price	0.07	0.29	0.06	0.32	0.43	1.36
EV/EBITDA	33.74	-1.87	10.36	10.72	-3.89	-0.26
PEG Ratio	0.99	1.57	1.49	1.50	NA	NA
Price/Book (P/B)	9.11	2.54	2.16	NA	2.64	1.14
Price/Cash Flow (P/CF)	45.26	10.61	8.92	6.88	NA	NA
P/E (F1)	28.49	25.02	13.12	6.75	NA	NA
Price/Sales (P/S)	13.43	10.27	1.72	3.16	NA	NA
Earnings Yield	3.51%	-23.00%	7.54%	14.80%	-32.09%	-74.10%
Debt/Equity	0.09	0.02	0.70	-7.71	0.14	0.19
Cash Flow (\$/share)	4.77	-1.05	7.01	10.33	-1.24	-1.15
Growth Score	B	-	-	B	F	D
Hist. EPS Growth (3-5 yrs)	216.65%	18.12%	10.85%	21.82%	NA	NA
Proj. EPS Growth (F1/F0)	42.01%	5.68%	4.90%	17.73%	-16.13%	10.92%
Curr. Cash Flow Growth	52.02%	13.92%	6.03%	8.78%	43.79%	-3.01%
Hist. Cash Flow Growth (3-5 yrs)	31.70%	7.66%	8.55%	19.92%	NA	NA
Current Ratio	3.61	4.64	1.23	3.18	10.43	6.88
Debt/Capital	8.13%	4.11%	42.57%	NA	11.93%	16.18%
Net Margin	28.27%	-230.92%	11.57%	23.69%	NA	NA
Return on Equity	20.97%	-66.62%	16.74%	-162.54%	-73.94%	-74.97%
Sales/Assets	0.57	0.20	0.54	0.51	NA	NA
Proj. Sales Growth (F1/F0)	25.68%	11.12%	3.13%	43.93%	31.92%	10.00%
Momentum Score	D	-	-	B	F	B
Daily Price Chg	1.27%	5.75%	1.03%	0.04%	1.45%	8.59%
1 Week Price Chg	-5.41%	-21.39%	-11.01%	-3.88%	-26.16%	-36.36%
4 Week Price Chg	-12.00%	-35.19%	-33.45%	-24.59%	-38.49%	-29.80%
12 Week Price Chg	-2.07%	-29.95%	-30.67%	-20.90%	-42.34%	-43.03%
52 Week Price Chg	18.15%	-41.69%	-23.69%	-12.53%	-62.68%	-67.67%
20 Day Average Volume	2,368,485	253,809	3,981,936	15,174,074	227,282	1,504,265
(F1) EPS Est 1 week change	0.00%	0.00%	-0.01%	0.00%	0.00%	0.00%
(F1) EPS Est 4 week change	0.00%	0.00%	-0.85%	1.20%	-12.27%	19.48%
(F1) EPS Est 12 week change	9.57%	-0.47%	-1.70%	11.91%	-12.27%	24.02%
(Q1) EPS Est Mthly Chg	0.00%	0.00%	-0.88%	0.75%	NA	34.29%

Zacks Style Scores

The Zacks Style Score is as a complementary indicator to the Zacks rating system, giving investors a way to focus on the highest rated stocks that best fit their own stock picking preferences.

Academic research has proven that stocks with the best Value, Growth and Momentum characteristics outperform the market. The Zacks Style Scores rate stocks on each of these individual styles and assigns a rating of A, B, C, D and F. We also produce the VGM Score (V for Value, G for Growth and M for Momentum), which combines the weighted average of the individual Style Scores into one score. This is perfectly suited for those who want their stocks to have the best scores across the board.

Value Score	C
Growth Score	B
Momentum Score	D
VGM Score	C

As an investor, you want to buy stocks with the highest probability of success. That means buying stocks with a Zacks Recommendation of Outperform, which also has a Style Score of an A or a B.

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