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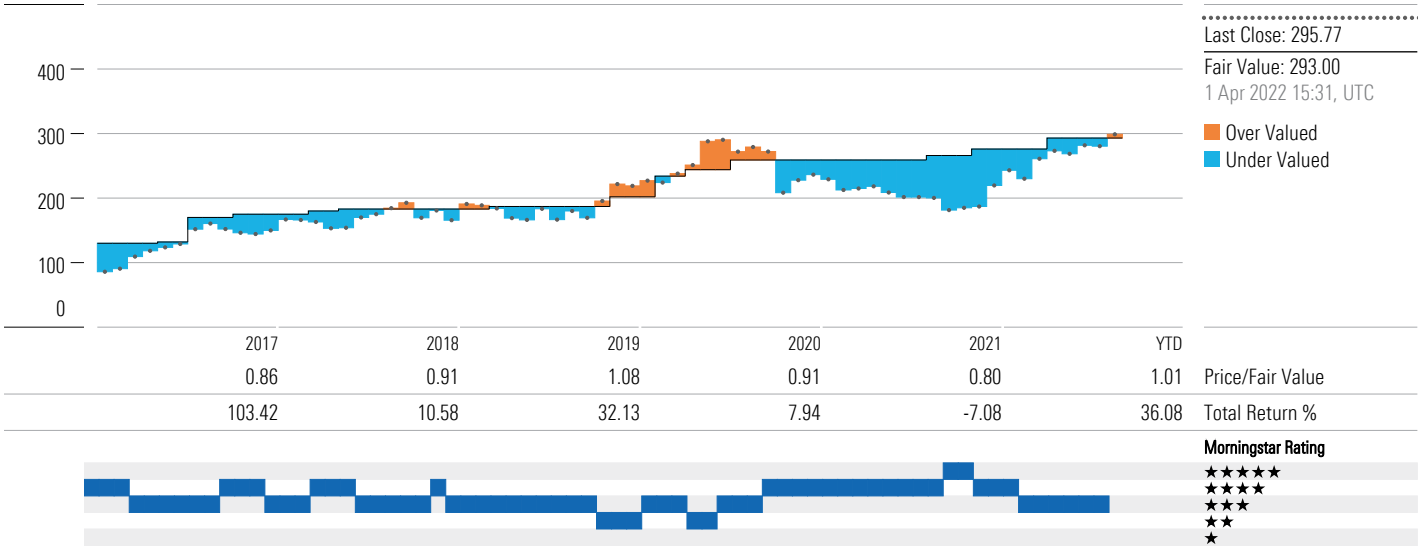
Vertex Pharmaceuticals Inc VRTX ★★★ 9 Aug 2022 21:16, UTC

Last Price	Fair Value Estimate	Price/FVE	Market Cap	Economic Moat™	Moat Trend™	Uncertainty	Capital Allocation	ESG Risk Rating Assessment[1]
295.77 USD	293.00 USD	1.01	76.64 USD Bil	Narrow	Positive	High	Standard	
10 Aug 2022	1 Apr 2022 15:31, UTC		9 Aug 2022					3 Aug 2022 05:00, UTC

Price vs. Fair Value



	2017	2018	2019	2020	2021	YTD
Price/Fair Value	0.86	0.91	1.08	0.91	0.80	1.01
Total Return %	103.42	10.58	32.13	7.94	-7.08	36.08

Total Return % as of 9 Aug 2022. Last Close as of 10 Aug 2022. Fair Value as of 1 Apr 2022 15:31, UTC.

Contents

Important Disclosure

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The primary analyst covering this company does not own its stock.

[1]The ESG Risk Rating Assessment is a representation of Sustainalytics' ESG Risk Rating.

Narrow-Moat Vertex Reports Solid Q2 Results; Maintaining $293 FVE, Shares Fairly Valued

Analyst Note Rachel Elfman, Equity Analyst, 10 Aug 2022

Vertex reported solid second-quarter results highlighted by nearly $2.2 billion in revenue, representing a 22% increase from the prior-year period. Management raised its 2022 revenue guidance by about 2% at the midpoint thanks to strong demand for key cystic fibrosis triple combination therapy Trikafta/Kaftrio. Vertex's pipeline candidates continue to make progress and are tracking our expectations. After slightly adjusting our near-term forecasts to account for stronger Trikafta sales, we forecast Vertex will achieve $8.7 billion in cystic fibrosis revenue this year, and we maintain our fair value estimate of $293 per share as our long-term outlook remains unchanged. We view shares as fairly valued, currently trading in 3-star territory. We maintain our narrow economic moat and positive trend ratings, which are supported by Vertex's intangible assets and diverse pipeline.

We continue to have a strong outlook for Vertex's gene-editing pipeline candidate, exa-cel (formerly known as CTX001), which is being developed in partnership with CRISPR Therapeutics for transfusion-dependent beta thalassemia and sickle cell disease. Exa-cel remains on track to submit regulatory filings in Europe and the U.K. by the end of 2022, and discussions with the FDA are ongoing. Vertex and CRISPR presented positive phase 3 data for exa-cel demonstrating that the drug has the potential to be a durable, one-time functional cure. We like that two additional phase 3 studies have been initiated to evaluate exa-cel in pediatric patients, which would broaden the addressable patient population if approved. We assign a 45% probability of approval to exa-cel and anticipate it could reach the market

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Sector Healthcare

Industry Biotechnology

Business Description

Vertex Pharmaceuticals is a global biotechnology company that discovers and develops small-molecule drugs for the treatment of serious diseases. Its key drugs are Kalydeco, Orkambi, Symdeko, and Trikafta/Kaftrio for cystic fibrosis, where Vertex therapies remain the standard of care globally. In addition to its focus on cystic fibrosis, Vertex is diversifying its pipeline through gene-editing therapies such as CTX001 for beta-thalassemia and sickle-cell disease, small-molecule inhibitors targeting acute and chronic pain using non-opioid treatments, and small-molecule inhibitors of APOL1-mediated kidney diseases. Vertex is also investigating cell therapies to deliver a potential functional cure for type 1 diabetes.

as early as 2023. By 2031, we forecast Vertex could receive $2.7 billion in probability-weighted revenue from exa-cel.

Business Strategy & Outlook Rachel Elfman, Equity Analyst, 8 Nov 2021

Vertex was once known for discovering Incivek, a blockbuster hepatitis C drug now overshadowed by a robust cystic fibrosis franchise with megablockbuster potential. The company's approved cystic fibrosis drugs are Kalydeco, Orkambi, Symdeko, and Trikafta, which will make Vertex eligible to treat about 90% of the CF population, assuming international and pediatric approvals. We expect Vertex to maintain its dominant position in CF, given the strong efficacy of its therapies, lengthy patents, and lack of competition, while developing pipeline candidates in other rare indications to spur growth.

Cystic fibrosis is a rare indication characterized by a progressive and deadly decline in lung function, affecting approximately 83,000 people worldwide. Since its 2012 launch, Kalydeco has captured most of its target patient population (less than 10% of CF patients with specific genetic mutations) and has become the backbone of combination therapies, including Orkambi, Symdeko, and Trikafta. Orkambi's launch in 2015 expanded the eligible patient population by adding CF patients with homozygous F508del mutations, but its uptake was slower because of its safety profile. Symdeko's 2018 launch didn't come with any worries over safety and contributed over $700 million in revenue in its first year, targeting the same population as Orkambi plus some additional patients. Trikafta, a triple-combination therapy, has had a strong launch since its U.S. approval in 2019, significantly expanding the company's addressable patient population to heterozygous patients.

Vertex's comprehensive approach has already shaped the treatment of CF and earned it a dominant position worldwide. The chronic nature of therapy and limited competition on the horizon heighten the CF market's attractiveness. Given these positive market dynamics, we think Vertex's CF program could grow to over $11 billion within our forecast period.

Vertex's pipeline spans several rare diseases, including CTX001 for beta-thalassemia and sickle-cell disease, VX-147 for APOL1-mediated kidney disease, and small-molecule inhibitors for pain. We think the CF franchise will provide ample cash for the development of these candidates.

Bulls Say Rachel Elfman, Equity Analyst, 7 Jun 2022

- The firm's cystic fibrosis therapies are poised to dominate the lucrative market for the foreseeable future, based on the disease-modifying potential of the drugs, chronic use by patients, and limited competition.
- Vertex's leading drug candidates were mostly discovered in-house, lending credibility to its drug-discovery technology and potential to generate additional pipeline candidates.
- Vertex's combination therapies have lengthy patents, protecting the profitable cystic fibrosis portfolio

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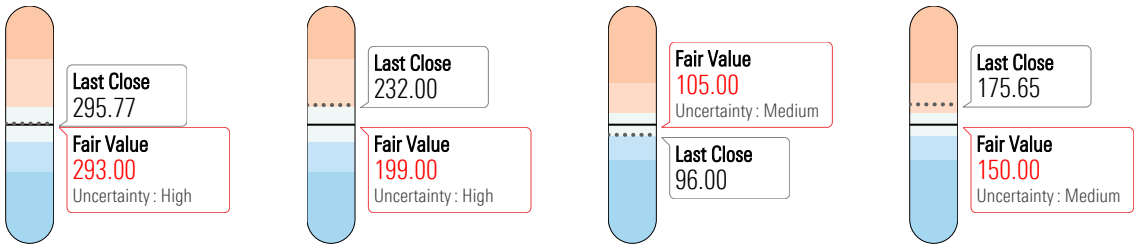
Competitors



	Vertex Pharmaceuticals Inc VRTX	Alnylam Pharmaceuticals Inc ALNY	Biomarin Pharmaceutical Inc BMRN	Seagen Inc Ordinary Shares SGEN
Economic Moat	Narrow	Narrow	Narrow	Narrow
Moat Trend	Positive	Positive	Positive	Positive
Currency	USD	USD	USD	USD
Fair Value	293.00 1 Apr 2022 15:31, UTC	199.00 4 Aug 2022 06:55, UTC	105.00 19 Nov 2021 20:13, UTC	150.00 15 Nov 2021 20:35, UTC
1-Star Price	454.15	308.45	141.75	202.50
5-Star Price	175.80	119.40	73.50	105.00
Assessment	Fairly Valued 9 Aug 2022	Fairly Valued 9 Aug 2022	Under Valued 9 Aug 2022	Over Valued 9 Aug 2022
Morningstar Rating	★★★9 Aug 2022 21:16, UTC	★★★9 Aug 2022 21:16, UTC	★★★★9 Aug 2022 21:16, UTC	★★9 Aug 2022 21:16, UTC
Analyst	Rachel Elfman, Equity Analyst	Rachel Elfman, Equity Analyst	Karen Andersen, Sector Strategist	Rachel Elfman, Equity Analyst
Capital Allocation	Standard	Standard	Standard	Standard
Price/Fair Value	1.01	1.17	0.91	1.17
Price/Sales	9.24	30.33	9.30	18.10
Price/Book	6.42	152.30	3.94	11.04
Price/Earning	24.20	—	341.79	—
Dividend Yield	—	—	—	—
Market Cap	76.64 Bil	26.81 Bil	17.75 Bil	32.39 Bil
52-Week Range	176.36—301.73	117.58—231.53	70.73—97.76	105.43—192.79
Investment Style	Large Growth	Mid Growth	Mid Core	Mid Growth

from generics.

Bears Say Rachel Elfman, Equity Analyst, 7 Jun 2022

- Vertex is highly dependent on the success of its cystic fibrosis franchise, and it could fail to diversify if its other pipeline candidates are not successful.
- Pricing pressure could erode returns, given the high price tag of Vertex's therapies.
- Gene-editing programs could disrupt Vertex's hold in the cystic fibrosis market.

Economic Moat Rachel Elfman, Equity Analyst, 8 Nov 2021

Vertex's portfolio of patent-protected cystic fibrosis drugs forms the basis of our narrow economic moat rating. The company is well supported by lengthy patent protections extending as far as 2037 and first-mover status in the lucrative cystic fibrosis market. Additionally, Vertex holds significant patient share as nearly 50% of patients worldwide are currently treated for cystic fibrosis using its medicines. More than 30,0000 additional patients worldwide who are currently untreated will be able to seek treatment using

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Vertex's recently approved triple combination regimen, Trikafta/Kaftrio. Vertex's marketed drugs Kalydeco, Orkambi, Symdeko, and Trikafta/Kaftrio are the only disease-modifying cystic fibrosis drugs on the market that restore cystic fibrosis transmembrane conductance regulator, or CFTR. They restore proper function to the CFTR protein or correct its production process so that a normal protein is made. Vertex's portfolio makes up the backbone of cystic fibrosis therapy and supports strong pricing power.

Cystic fibrosis is a genetic disorder affecting roughly 83,000 people worldwide that causes a progressive and deadly decline in the function of the lungs and digestive system. While the number of patients is small, the six-figure pricing for Vertex's disease-modifying drugs creates megablockbuster sales. Vertex's cystic fibrosis portfolio has experienced a pretty welcoming commercial and regulatory environment due to the rarity of cystic fibrosis and the lack of disease-modifying treatments. The market's attractiveness is heightened by the chronic nature of therapy and limited competition due to the complexity of developing efficient drugs to treat the disease.

Intangible assets are the key moat source for Vertex, as the company benefits from lengthy patent protections for each of its four cystic fibrosis therapies currently on the market. Vertex has been able to build upon its intellectual property, developing better drug combinations that increasingly capture a greater number of patients with various cystic fibrosis mutations. Kalydeco, approved in 2012 for patients with one copy of the G551D mutation, quickly picked up label expansions in additional mutations and age groups, which expanded the eligible patient population from about 1,000 patients in the U.S. when first approved to over 4,000 by 2015. Orkambi was approved in 2015 for patients with two copies of the common F508del mutation. Orkambi expanded the eligible patient population significantly, to over 30,000 globally by the end of 2016. Symdeko, approved in 2018, didn't significantly expand the addressable population as it targets the same patient population as Orkambi, but it helped capture some additional patients due to its better efficacy.

Trikafta was approved in the United States in 2019, and it was approved in the European Union in 2020 under the name Kaftrio. Trikafta/Kaftrio is a triple combination regimen that further expands the eligible patient population by an additional 30,000 patients worldwide. Just since the beginning of 2021, Trikafta/Kaftrio has been approved and reimbursed/accessible in 12 countries outside the U.S., including Denmark, Germany, Ireland, Israel, Switzerland, the United Kingdom, and Australia. Vertex is awaiting the potential approval of Trikafta in many other countries and in pediatric patients not yet approved for the drug, but we think the eligible patient population for Vertex's four therapies will reach about 75,000 people, or roughly 90% of all cystic fibrosis patients. Only 10% of cystic fibrosis patients have a genetic mutation that is not currently able to be treated with any of Vertex's four drugs on the market.

Vertex's strategy has been to use its intangible assets and expertise to build upon its first cystic fibrosis drug, Kalydeco. Symdeko and Orkambi are doublet combinations that add a CFTR corrector to Kalydeco,

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a CFTR potentiator. Vertex's most recent drugs to receive approval, Trikafta/Kaftrio, which are triple combination regimens, build on molecules in Symdeko and Kalydeco while layering in a new CFTR corrector, elexacaftor. The complexity and unique mechanism of these drugs results in a new, efficacious therapy that serves as a competitive advantage for Vertex. Many competitors study their own drug pipeline candidates in combination with one or more of Vertex's molecules, illustrating Vertex's position as the backbone of treatment options.

Vertex commands strong pricing power because cystic fibrosis is a rare, chronic condition and there are no alternative disease-modifying treatment options currently on the market. Many patients start treatment for cystic fibrosis in early childhood and continue throughout their lifetime. Trikafta's U.S. list price at launch reached $311,000, exhibiting the company's strong pricing power. We estimate that Kalydeco, Orkambi, and Symdeko all command pricing upward of $230,000-$250,0000 a year for their therapies. With strong efficacy and pricing power, Vertex's cystic fibrosis portfolio has the potential to contribute over $11 billion in 2030 sales compared with just over $6 billion in 2020.

We believe Vertex does not face significant competition in the cystic fibrosis market. Galapagos (in partnership with AbbVie) was previously its closest competitor, but in 2018 it reported lackluster phase 2 results for its lead candidates, illustrating the high bar of efficacy from Vertex's portfolio. AbbVie initially stepped away from further trials, but then it entered into an agreement to license a cystic fibrosis asset from the Cystic Fibrosis Foundation in October 2019. AbbVie is in the process of two phase 2 studies conducted with the Therapeutics Development Network. We don't see this as a viable threat to Vertex since phase 2 trials are still very early in the drug-development process and it would be years away from potentially reaching the market.

We don't think Vertex's pipeline outside of cystic fibrosis contributes to its narrow moat, as many of its assets are in the early stages of development. However, with Vertex's substantial cash flow, we think the company is well positioned to continue the research and development of drugs for several rare diseases over the next decade. Further, the pipeline's focus on rare indications with few or no approved treatment options will likely support pricing power. Therefore, we believe it is more likely than not that Vertex will be able to earn excess returns over the next 10 years and warrants a narrow economic moat rating.

Fair Value and Profit Drivers Rachel Elfman, Equity Analyst, 7 Jun 2022

We're maintaining our fair value estimate at $293 per share.

Our valuation remains heavily dependent on the cystic fibrosis portfolio, including its latest drug, Trikafta/Kaftrio. This new triple-combination drug is poised to continue generating strong sales throughout our explicit forecast period.

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We model nearly $8.5 billion in cystic fibrosis sales in 2022, driven by Trikafta/Kaftrio, which treats both F508del homozygous and heterozygous patients. Vertex's portfolio of cystic fibrosis therapies allows it to reach 90% of cystic fibrosis patients globally, assuming international and pediatric approvals.

While we give the company's pipeline candidates fairly low probabilities of approval due to their early stages in development, Vertex is targeting several blockbuster opportunities, which we forecast will contribute roughly $2.4 billion in 2027 pipeline sales. Key opportunities include CTX001 (gene-editing candidate in partnership with CRISPR Therapeutics) for beta-thalassemia and sickle-cell disease as well as next-generation CFTR correctors for cystic fibrosis. CTX001 is co-developed and will be co-commercialized, if approved, with net profits split under a 60/40 agreement with 60% allocated to Vertex and 40% to CRISPR Therapeutics. Management targets regulatory submissions in late 2022, and we anticipate CTX001 could reach the market by 2023.

We also expect the company will continue funding research in cystic fibrosis to develop next-generation therapies for CF, including small-molecule correctors and gene-editing technology. We've assigned as 25% base-case probability of approval for Vertex's next-generation cystic fibrosis therapy, VX-121/tezacaftor/VX-561. Phase 3 clinical trials are now underway to evaluate this new once-daily triple-combination regimen that has the potential for superior performance to existing drugs, including Trikafta/Kaftrio, which is taken twice daily.

We assume that selling, general, and administrative expenses as a percentage of sales is in the low-double digits to high-single digits throughout our forecast period. Robust product sales should expand the 2031 operating margin to about 54%.

Risk and Uncertainty Rachel Elfman, Equity Analyst, 8 Nov 2021

We assign Vertex a high uncertainty rating. Chronic therapies for rare diseases are often priced above cost-effective levels, and Vertex's cystic fibrosis therapies are priced at least three times the level that cost-effectiveness watchdog ICER would deem cost-effective. We expect Vertex could see reduced exposure to potential pricing pressure with time, particularly if the firm makes headway with gene editing (CTX-001 for rare blood disorders) and cell therapy (VX-880 for type 1 diabetes). Gene and cell therapies have the potential to provide cost-effective, one-time therapies, as shown by recent reviews for approved therapies like Gilead's Yescarta and Novartis' Zolgensma.

Less cost-effective drugs like Vertex's Trikafta/Kaftrio could face U.S. pricing pressure from potential disruptive drug pricing reforms, and our high uncertainty rating accounts for potential pricing pressure from payers or regulators that may depress returns. Also, Vertex's sales from the U.S. are relatively high as compared with its biopharma peer group, which gives more weight to U.S. pricing decisions.

That said, Vertex's concentration in cystic fibrosis is offset by its dominant position and lack of

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competition. We think the lack of close competition and strong cash generation in the medium term provide a solid cushion, which should allow Vertex to continue diversifying and expanding its pipeline. Vertex's therapies are disease-modifying, but they do not correct the underlying genetic mutation, which leaves room for improvement. While Vertex has a next-generation pipeline in CF correctors and gene editing, competition in gene editing could disrupt the company's successful franchise.

Product governance is also an ESG risk, as failure to adhere to extensive regulations and quality management standards can lead to expensive recalls, increased regulatory scrutiny, compliance costs, and lawsuits from affected customers.

Capital Allocation Rachel Elfman, Equity Analyst, 27 Jan 2022

We assign Vertex a Standard capital allocation rating. Our analysis evaluates what we determine to be the three key facets of management decision-making from the perspective of shareholders: balance sheet strength, investment efficacy, and distributions. Our Standard rating results from a sound balance sheet, fair investment strategy, and an assessment of shareholder distributions as appropriate.

Vertex's balance sheet is sound, with revenue cyclicality and operating leverage each possessing a medium rating. The company is in strong financial health, thanks to its robust cash flow generation and low debt. As of year-end 2021, Vertex held about $7.5 billion in cash and investments.

We view Vertex's investment decisions as fair, with economic profit increasing throughout our explicit forecast period. In 2019, management wisely allocated capital toward diversifying the pipeline, which included two acquisitions of private biotechnology companies, each presenting a unique market opportunity. Vertex bought Exonics Therapeutics (gene editing in Duchenne muscular dystrophy) for $266 million up front (plus milestones) and Semma Therapeutics (human-derived stem cell islets to cure type 1 diabetes) for $937 million. While these assets remain in early stages of development, we like management's focus on diversifying Vertex's pipeline to ensure future growth, well before any patent expirations or serious competition related to its CF drugs. The company is also investing in gene-editing technology in order to create even more innovative and effective cystic fibrosis drugs. We expect Vertex will continue investing in a more diversified rare-disease portfolio as it looks beyond the cystic fibrosis market.

Finally, we assess overall shareholder distributions as appropriate. Even though the company does not currently pay a dividend, we view this as appropriate since Vertex is growing quickly and reinvesting in R&D helps build its value and support its narrow moat.

Dr. Jeffrey Leiden became CEO and chairman in 2012. His experience includes a role as managing director at Clarus Ventures, which specializes in life sciences capital, as well as president and chief operating officer at Abbott. His experience in Big Pharma shone through as he brought Vertex from the

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cash-burning stage of an emerging biotech to a large, leading biotech firm with an expansive franchise in cystic fibrosis therapies. He has since stepped down from the CEO role and serves as executive chair of the board.

Former chief medical officer Dr. Reshma Kewalramani took on the CEO role in April 2020. Before joining Vertex in 2017, Kewalramani spent over a decade at Amgen. We believe she is well suited to lead Vertex as it expands outside cystic fibrosis.

The rest of the management team is composed of other Big Pharma veterans, with adequate levels of experience, in our view. Previous CFO Ian Smith was abruptly terminated in early 2019 because of personal behavior. While no details were disclosed, we have no reason to believe that this significantly weighs on the company's stewardship.

Historical controversies related to compensation and other practices don't affect our stewardship rating for the current team. We think management compensation has been historically high, although recent measures spurred by a shareholder vote have curtailed the amounts going forward. In 2014, Leiden's total compensation was $36.6 million, and several senior managers had compensation packages above $10 million. In 2015, Leiden's total compensation dropped to $28 million in response to shareholder disapproval, and in 2020, it dropped to about $16.5 million. The company has also been probed by the Securities and Exchange Commission for a series of large insider stock sales on positive clinical news in past years.

Analyst Notes Archive

Drug Pricing Policy in the Inflation Reduction Act a Moderate But Manageable Negative to Biopharma Karen Andersen, CFA, Sector Strategist, 1 Aug 2022

The likelihood of drug-pricing policy changes in the United States changed dramatically over the course of July, and we are now assessing the impact of the various measures included in the Inflation Reduction Act of 2022 in our Big Biopharma valuation models. Assuming the bill is eligible to pass via reconciliation (the Senate parliamentarian is reviewing the bill), we think Democrats will be able to pass the Senate bill, paving the way for it to be signed into law. Overall, we don't expect major changes to our fair value estimates or moat ratings, as the changes net out to a moderate negative that we believe is manageable, likely through a combination of cost-cutting, agreements with generic firms for limited authorized generic launches (to avoid the list for negotiated drugs), and higher launch prices (to counter pressure on price increases and earlier declines due to negotiation).

From the perspective of patients, the bill reduces potential out-of-pocket costs in Medicare, making it widely popular. While government savings are highly driven by Medicare drug price negotiation and inflation caps (roughly $100 billion in savings from each measure, according to Congressional Budget

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Office estimates), we see three key impacts to drug firm revenue streams from the bill: shifting Medicare Part D cost-sharing to biopharma firms with more expensive drugs; penalizing biopharma firms that raise Medicare prices by more than the rate of inflation annually; and mandatory price cuts on the top-selling Medicare drugs that have extended patent protection. We had previously included potential modest U.S. drug policy changes in our Big Biopharma valuation models related to Part D redesign and inflation caps, but these didn't result in any significant fair value estimate changes.

Our New Capsule System Tackles Biopharma ESG Risk Tied to U.S. Drug Pricing and Cost-Effectiveness Karen Andersen, CFA, Sector Strategist, 13 Jun 2022

Morningstar now directly incorporates cost-effectiveness analysis into our biopharmaceutical ratings through what we're calling our capsule system. Given the lack of regulatory oversight on whether U.S. drug launch prices or price increases are justified, an independent, private organization—the Institute for Clinical and Economic Review, or ICER—has gained prominence and authority assessing cost-effectiveness. Drugs that are priced above ICER's cost-effectiveness thresholds or that record high unsupported price increases contribute to Morningstar's ESG Risk Rating Assessment and equity research methodology for incorporating environmental, social, and governance risk into our fair value estimates and moat and uncertainty ratings.

Using our capsule system, we think that AbbVie, Amgen, Biogen, Johnson & Johnson, and Vertex Pharmaceuticals have the largest excessive deviations from cost-effective pricing for a significant portion of their branded drug portfolios. We have raised our uncertainty ratings for AbbVie, Amgen, and Vertex to high from medium because of their lower capsule number and high reliance on branded drug sales in the United States.

Looking at the intersection of ESG risk and valuation, BioMarin Pharmaceutical and Sanofi appear well positioned. Conversely, firms such as AbbVie, Amgen, and J&J are more exposed to ESG risk and appear either fairly valued or overvalued.

Narrow-Moat Vertex Reports Strong Q1 Results; Maintaining $293 FVE, Shares Undervalued Rachel Elfman, Equity Analyst, 8 May 2022

Vertex reported strong first-quarter results highlighted by nearly $2.1 billion in product revenue, representing a 22% increase from the prior year period. We've updated our valuation model, and we maintain our fair value estimate of $293 per share and continue to view shares as undervalued. The stock is currently trading in 4-star territory about 14% below our fair value estimate. We maintain our narrow economic moat and positive trend ratings, which are supported by intangible assets and its diversified pipeline spanning six disease areas.

Vertex's sales were primarily driven by Trikafta/Kaftrio, its highly effective triple combination therapy for

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cystic fibrosis, thanks to the drug's rapid uptake in the U.S. and strong performance in Europe. Trikafta/Kaftrio accounted for 84% of the first quarter's revenue, up from 69% year over year. We anticipate Vertex will reach over $8.5 billion in cystic fibrosis sales this year.

We think the market doesn't fully appreciate Vertex's expansive cystic fibrosis portfolio and the potential blockbuster opportunities in its diverse pipeline, contributing to our positive trend rating. Vertex has dominance within the cystic fibrosis market, and the company is well supported by lengthy patent protections extending as far as 2037.

In addition to the macroeconomic headwinds felt broadly across the stock market, the FDA recently issued a clinical hold on Vertex's stem cell-derived islet candidate for the treatment of Type 1 Diabetes, VX-880. This pipeline candidate is in a phase 1/2 study, and the first two patients dosed established proof-of-concept. In addition, the drug has been well tolerated with no serious adverse events. Vertex is working with the FDA to address their questions related to dose escalation of the product. We maintain our 15% probability of approval for VX-880, and we forecast the earliest it could reach the market is 2025.

Vertex's Gene-Editing Candidate Drives Additional Growth; Raising FVE to $293, Shares Undervalued

Rachel Elfman, Equity Analyst, 1 Apr 2022

We've updated our forecasts for Vertex Pharmaceuticals to reflect a more robust outlook for its gene-editing pipeline candidate, CTX001, in partnership with CRISPR Therapeutics for two blood diseases – transfusion-dependent beta thalassemia (TDT) and sickle cell disease (SCD). We've raised our fair value estimate to $293 per share from $276 and maintain our narrow moat and positive trend ratings. We view Vertex as an attractive opportunity trading at an 11% discount to our $293 fair value estimate.

CTX001 is a CRISPR/Cas9-based gene-editing candidate that's currently in phase 3 trials, and regulatory submissions are expected to be filed in late 2022. Based on positive data from CTX001's trials, we've increased our probability of approval to 45% from 35% previously. CTX001 is co-developed and will be co-commercialized, if approved, with net profits split under a 60/40 agreement with 60% allocated to Vertex and 40% to CRISPR Therapeutics. We anticipate CTX001 could reach the market by 2023.

Due to the high unmet medical needs for patients with TDT and SCD, we anticipate this could lead to pricing power and a blockbuster opportunity for CTX001. We forecast Vertex's share of probability-weighted sales for CTX001 reaching over $2.7 billion in 2031.

Vertex's lengthy patent protections extending as far as year 2037 and first-mover status in the lucrative cystic fibrosis (CF) market support its narrow economic moat rating. We believe Vertex benefits from a positive moat trend based on its CF drug approvals, lack of near-term competition within the CF market,

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Vertex Pharmaceuticals Inc VRTX ★★★ 9 Aug 2022 21:16, UTC

Last Price	Fair Value Estimate	Price/FVE	Market Cap	Economic Moat™	Moat Trend™	Uncertainty	Capital Allocation	ESG Risk Rating Assessment[1]
295.77 USD 10 Aug 2022	293.00 USD 1 Apr 2022 15:31, UTC	1.01	76.64 USD Bil 9 Aug 2022	Narrow	Positive	High	Standard	3 Aug 2022 05:00, UTC

and its leading partnership with CRISPR Therapeutics.

We think Vertex's cystic fibrosis portfolio will continue to provide ample cash for the development of its pipeline drugs. We like that Vertex is investing in a diversified pipeline, including treatments for kidney disease, type 1 diabetes, and pain, and its pipeline spans multiple drug classes.

Vertex Reports Solid Q4 and Strong Momentum for 2022; Maintaining $276 FVE, Shares Undervalued Rachel Elfman, Equity Analyst, 27 Jan 2022

Vertex reported strong fourth-quarter results driven by continued robust performance of its cystic fibrosis drugs (CF). Fourth-quarter revenue was just over $2 billion, and fiscal 2021 revenue was over $7.5 billion, representing a 22% increase from the previous year. After updating our valuation model, we maintain our fair value estimate of $276 per share and continue to view shares as very undervalued. Vertex's lengthy patent protections extending as far as year 2037 and first-mover status in the lucrative cystic fibrosis market support its narrow economic moat rating.

Vertex's sales were primarily driven by Trikafta/Kaftrio, its triple combination therapy for CF, thanks to the drug's rapid uptake in the U.S. and strong performance in Europe. Trikafta/Kaftrio accounted for 75% of 2021's revenue, up from 62% in 2020. Management's CF revenue guidance for 2022 was largely within our expectations, and we anticipate over $8.5 billion in CF sales for the year.

We like that Vertex is investing in a diversified pipeline, including treatments for kidney disease, type 1 diabetes, pain, and alpha-1 antitrypsin (AAT) deficiency and its pipeline spans multiple drug classes. Vertex is focused on rare indications with few or no approved treatment options, which will likely support pricing power once the drugs are approved. We think Vertex's CF portfolio will continue to provide ample cash for the development of its pipeline drugs. The company has strong momentum entering this year as it works to advance its pipeline candidates, and clinical data is expected for multiple trials in 2022.

We believe Vertex benefits from a positive moat trend based on its CF drug approvals, lack of near-term competition within the CF market, and its leading partnership with CRISPR Therapeutics using gene editing technology for two blood diseases--sickle cell disease and beta-thalassemia, which are both in phase 3 trials.

Raising Vertex's FVE to $276 on Strong Outlook Thanks to CF Franchise; Shares Remain Undervalued Rachel Elfman, Equity Analyst, 8 Nov 2021

Vertex reported healthy third-quarter results driven by continued robust performance of its cystic fibrosis drugs. We've raised our fair value estimate to $276 per share from $266 to reflect an improved 2021 outlook based on stronger-than-expected Trikafta/Kaftrio sales. We continue to view shares as undervalued, trading in 4-star territory. We maintain our narrow economic moat rating thanks to lengthy

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Vertex Pharmaceuticals Inc VRTX ★★★ 9 Aug 2022 21:16, UTC

Last Price	Fair Value Estimate	Price/FVE	Market Cap	Economic Moat™	Moat Trend™	Uncertainty	Capital Allocation	ESG Risk Rating Assessment[1]
295.77 USD 10 Aug 2022	293.00 USD 1 Apr 2022 15:31, UTC	1.01	76.64 USD Bil 9 Aug 2022	Narrow	Positive	High	Standard	3 Aug 2022 05:00, UTC

patent protections extending as far as 2037 and first-mover status in the lucrative cystic fibrosis market.

Third-quarter revenue was just under $2 billion, representing a 29% increase from the previous year, primarily driven by Trikafta/Kaftrio, Vertex's triple-combination therapy for cystic fibrosis, and the drug's rapid uptake in the U.S. and strong launch in Europe. Trikafta/Kaftrio accounted for 78% of the third quarter's total revenue, up from 70% in the prior quarter.

Trikafta/Kaftrio is now approved and reimbursed or accessible in more than 20 countries outside the U.S., up from 15 in the second quarter of 2021. Vertex will reach more patients in 2021 than previously forecast because of its additional approvals, and management has raised its 2021 revenue guidance to $7.4 billion-$7.5 billion, up from $7.2 billion-$7.4 billion. We've increased our revenue forecast to $7.5 billion from $7.3 billion after raising our Trikafta/Kaftrio forecast.

We've also increased our base-case probability of approval to 25% from 10% for Vertex's next-generation cystic fibrosis therapy, VX-121/tezacaftor/VX-561. Phase 3 clinical trials are underway to evaluate this new once-daily triple combination regimen that has the potential for superior performance to existing drugs, including Trikafta/Kaftrio, which is taken twice daily.

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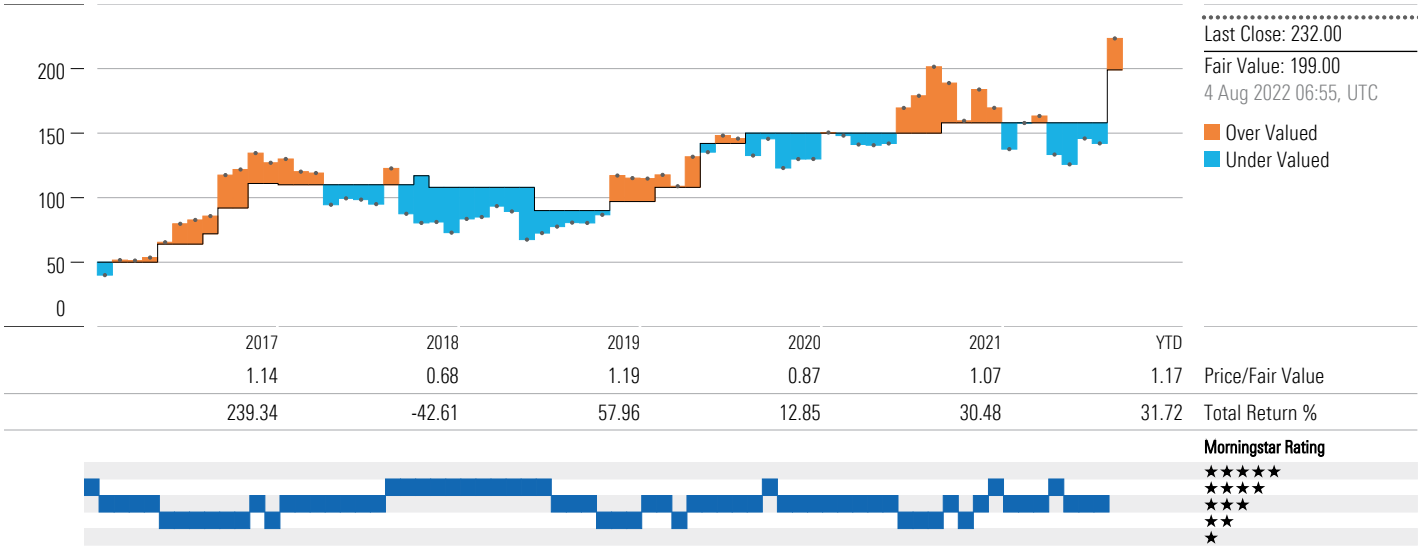
Vertex Pharmaceuticals Inc VRTX ★★★ 9 Aug 2022 21:16, UTC

Competitors Price vs. Fair Value

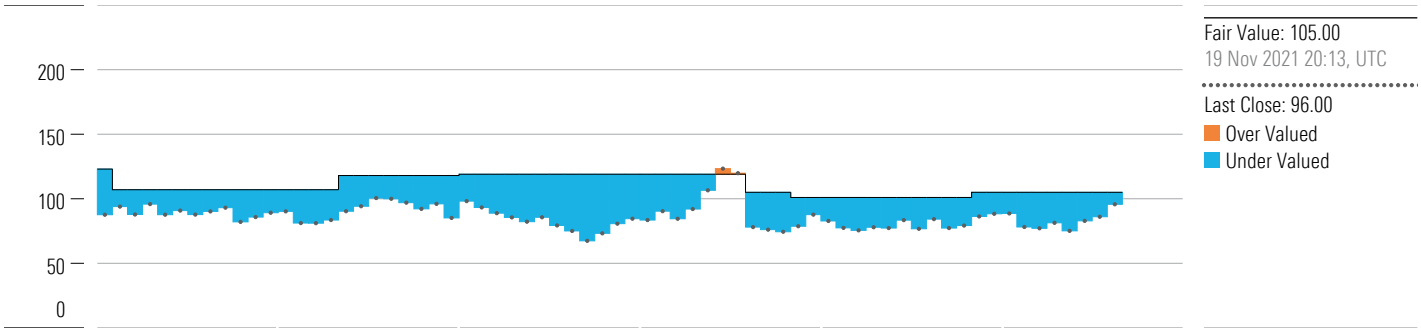
Alnylam Pharmaceuticals Inc ALNY



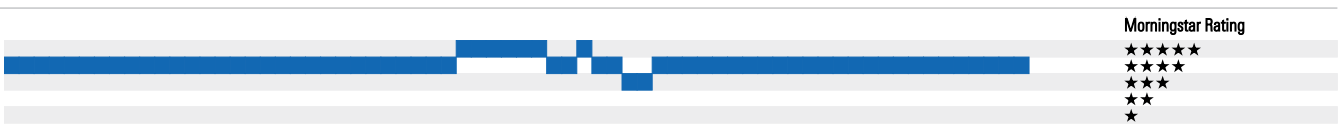
	2017	2018	2019	2020	2021	YTD	
	1.14	0.68	1.19	0.87	1.07	1.17	Price/Fair Value
	239.34	-42.61	57.96	12.85	30.48	31.72	Total Return %

Total Return % as of 9 Aug 2022. Last Close as of 10 Aug 2022. Fair Value as of 4 Aug 2022 06:55, UTC.

Biomarin Pharmaceutical Inc BMRN



	2017	2018	2019	2020	2021	YTD	
	0.83	0.72	0.71	0.87	0.84	0.91	Price/Fair Value
	7.64	-4.51	-0.70	3.71	0.75	8.32	Total Return %



Total Return % as of 9 Aug 2022. Last Close as of 10 Aug 2022. Fair Value as of 19 Nov 2021 20:13, UTC.

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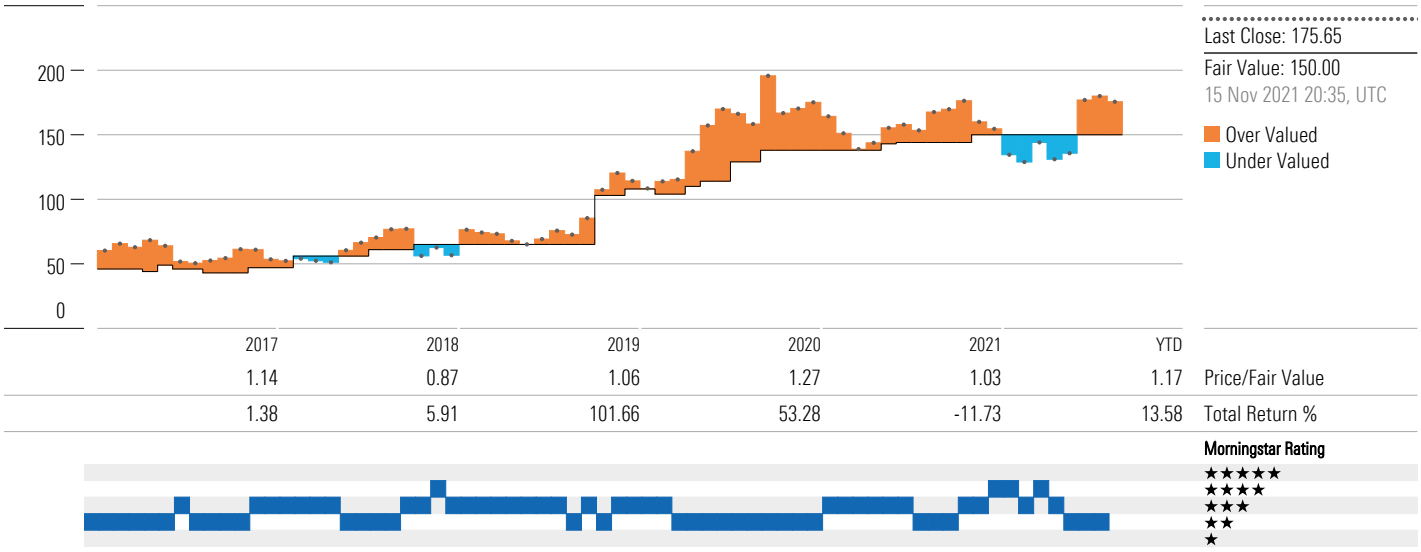
Vertex Pharmaceuticals Inc VRTX ★★★ 9 Aug 2022 21:16, UTC

Seagen Inc Ordinary Shares SGEN



	2017	2018	2019	2020	2021	YTD	
	1.14	0.87	1.06	1.27	1.03	1.17	Price/Fair Value
	1.38	5.91	101.66	53.28	-11.73	13.58	Total Return %

Total Return % as of 9 Aug 2022. Last Close as of 10 Aug 2022. Fair Value as of 15 Nov 2021 20:35, UTC.

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Vertex Pharmaceuticals Inc VRTX ★★★ 9 Aug 2022 21:16, UTC

Last Price	Fair Value Estimate	Price/FVE	Market Cap	Economic Moat™	Moat Trend™	Uncertainty	Capital Allocation	ESG Risk Rating Assessment[1]
295.77 USD	293.00 USD	1.01	76.64 USD Bil	Narrow	Positive	High	Standard	
10 Aug 2022	1 Apr 2022 15:31, UTC		9 Aug 2022					3 Aug 2022 05:00, UTC

Morningstar Historical Summary

Financials as of 30 Jun 2022

Fiscal Year, ends 31 Dec	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	YTD	TTM
Revenue (USD Mil)	1,527	1,212	580	1,032	1,702	2,489	3,048	4,163	6,206	7,574	4,294	8,350
Revenue Growth %	8.3	-20.6	-52.1	77.9	64.9	46.2	22.5	36.6	49.1	22.1	22.1	24.9
EBITDA (USD Mil)	85	-555	-599	-411	75	115	745	1,560	3,285	2,918	2,082	4,131
EBITDA Margin %	5.6	-45.8	-103	-39.8	4.4	4.6	24.5	37.5	52.9	38.5	48.5	49.5
Operating Income (USD Mil)	49	-157	-641	-465	11	393	664	1,202	2,869	2,779	2,154	3,126
Operating Margin %	3.2	-12.9	-110	-45.0	0.7	15.8	21.8	28.9	46.2	36.7	50.2	37.4
Net Income (USD Mil)	-107	-445	-739	-556	-112	263	2,097	1,177	2,712	2,342	1,573	3,195
Net Margin %	-7.0	-36.7	-127	-53.9	-6.6	10.6	68.8	28.3	43.7	30.9	36.6	38.3
Diluted Shares Outstanding (Mil)	215	225	235	241	245	253	259	261	263	260	258	258
Diluted Earnings Per Share (USD)	-0.50	-1.98	-3.14	-2.31	-0.46	1.04	8.09	4.51	10.29	9.01	6.09	12.35
Dividends Per Share (USD)	—	—	—	—	—	—	—	—	—	—	—	—

Valuation as of 29 Jul 2022

	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	Recent Qtr	TTM
Price/Sales	5.8	13.7	35.2	39.8	10.8	16.3	15.1	15.7	10.4	8.0	9.2	9.1
Price/Earnings	-84.0	-29.2	-53.8	-45.9	-82.0	196.1	66.2	26.5	23.1	26.3	29.8	29.6
Price/Cash Flow	33.1	-416.7	-76.3	-64.1	149.3	49.3	36.2	39.7	19.4	26.8	27.2	27.1
Dividend Yield %	—	—	—	—	—	—	—	—	—	—	—	—
Price/Book	9.1	13.7	24.9	33.6	17.9	21.2	14.6	10.8	7.6	5.9	6.6	6.6
EV/EBITDA	99.8	-29.5	-46.9	-75.0	239.5	318.9	53.4	34.2	17.0	17.1	0.0	0.0

Operating Performance / Profitability as of 30 Jun 2022

Fiscal Year, ends 31 Dec	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	YTD	TTM
ROA %	-4.3	-17.5	-31.7	-23.0	-4.2	8.2	42.8	16.2	27.0	18.6	10.8	23.0
ROE %	-12.0	-37.8	-60.8	-55.2	-10.7	16.5	64.9	22.4	36.7	24.9	14.3	30.2
ROIC %	-6.6	-24.0	-36.7	-27.6	-3.4	12.9	55.4	19.9	33.5	23.2	13.4	28.3
Asset Turnover	0.6	0.5	0.2	0.4	0.6	0.8	0.6	0.6	0.6	0.6	0.3	0.6

Financial Leverage

Fiscal Year, ends 31 Dec	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	Recent Qtr	TTM
Debt/Capital %	40.6	26.5	42.4	44.0	31.1	22.4	11.6	9.3	9.3	8.1	6.6	—
Equity/Assets %	36.2	58.5	46.0	37.6	39.9	57.2	71.0	73.2	73.9	75.2	76.6	—
Total Debt/EBITDA	8.2	-0.9	-1.4	-2.0	11.1	5.3	0.8	0.4	0.3	0.3	0.4	—
EBITDA/Interest Expense	5.7	-24.2	-8.2	-4.9	0.9	1.7	10.3	26.7	56.4	47.4	70.6	69.1

Morningstar Analyst Historical/Forecast Summary as of 07 Jun 2022

Financials

			Estimates		
Fiscal Year, ends 31 Dec	2020	2021	2022	2023	2024
Revenue (USD)	6.21	7.57	8.55	9.67	10.93
Revenue Growth %	49.1	22.1	12.9	13.1	13.0
EBITDA (USD Mil)	2,966	2,908	4,321	5,417	6,307
EBITDA Margin %	47.8	38.4	50.6	56.0	57.7
Operating Income (USD Mil)	2,856	2,782	4,108	5,175	6,034
Operating Margin %	46.0	36.7	48.1	53.5	55.2
Net Income (USD Mil)	2,719	3,384	3,715	4,587	5,273
Net Margin %	43.8	44.7	43.5	47.5	48.3
Diluted Shares Outstanding (Mil)	263	260	256	255	254
Diluted Earnings Per Share(USD)	10.32	13.02	14.49	17.99	20.77
Dividends Per Share(USD)	0.00	0.00	0.00	0.00	0.00

Forward Valuation

			Estimates		
	2020	2021	2022	2023	2024
Price/Sales	9.9	7.4	9.0	7.9	7.0
Price/Earnings	22.9	16.9	20.6	16.6	14.4
Price/Cash Flow	20.5	23.2	21.5	17.5	15.3
Dividend Yield %	—	—	—	—	—
Price/Book	—	—	—	—	—
EV/EBITDA	18.8	17.1	15.8	12.6	10.8

MORNINGSTAR®

Research Methodology for Valuing Companies

Overview

At the heart of our valuation system is a detailed projection of a company's future cash flows, resulting from our analysts' research. Analysts create custom industry and company assumptions to feed income statement, balance sheet, and capital investment assumptions into our globally standardized, proprietary discounted cash flow, or DCF, modeling templates. We use scenario analysis, indepth competitive advantage analysis, and a variety of other analytical tools to augment this process. Moreover, we think analyzing valuation through discounted cash flows presents a better lens for viewing cyclical companies, high-growth firms, businesses with finite lives (e.g., mines), or companies expected to generate negative earnings over the next few years. That said, we don't dismiss multiples altogether but rather use them as supporting cross-checks for our DCF-based fair value estimates. We also acknowledge that DCF models offer their own challenges (including a potential proliferation of estimated inputs and the possibility that the method may miss shortterm market-price movements), but we believe these negatives are mitigated by deep analysis and our longterm approach.

Morningstar's equity research group ("we," "our") believes that a company's intrinsic worth results from the future cash flows it can generate. The Morningstar Rating for stocks identifies stocks trading at a discount or premium to their intrinsic worth—or fair value estimate, in Morningstar terminology. Five-star stocks sell for the biggest risk adjusted discount to their fair values, whereas 1-star stocks trade at premiums to their intrinsic worth.

Four key components drive the Morningstar rating: (1) our assessment of the firm's economic moat, (2) our estimate of the stock's fair value, (3) our uncertainty around that fair value estimate and (4) the current market price. This process ultimately culminates in our singlepoint star rating.

1. Economic Moat

The concept of an economic moat plays a vital role not only in our qualitative assessment of a firm's long-term investment potential, but also in the actual calculation of our fair value estimates. An economic moat is a structural feature that allows a firm to sustain excess profits over a long period of time. We define economic profits as returns on invested capital (or ROIC) over and above our estimate of a firm's cost of capital, or weighted average cost of capital (or WACC). Without a moat, profits are more susceptible to competition. We have identified five sources of economic moats: intangible assets, switching costs, network effect, cost advantage, and efficient scale.

Companies with a narrow moat are those we believe are more likely than not to achieve normalized excess returns for at least the next 10 years. Wide-moat companies are those in which we have very high confidence that excess returns will remain for 10 years, with excess returns more likely than not to remain for at least 20 years. The longer a firm generates economic profits, the higher its intrinsic value. We believe low-quality, no-moat companies will see their normalized returns gravitate toward the firm's cost of capital more quickly than companies with moats.

When considering a company's moat, we also assess whether there is a substantial threat of value destruction, stemming from risks related to ESG, industry disruption, financial health, or other idiosyncratic issues. In this context, a risk is considered potentially value destructive if its occurrence would eliminate a firm's economic profit on a cumulative or midcycle basis. If we deem the probability of occurrence sufficiently high, we would not characterize the company as possessing an economic moat.

To assess the sustainability of excess profits, analysts perform ongoing assessments of the moat trend. A firm's moat trend is positive in cases where we think its sources of competitive advantage are growing stronger; stable where we don't anticipate changes to competitive advantages over the next several years; or negative when we see signs of deterioration.

2. Estimated Fair Value

Combining our analysts' financial forecasts with the firm's economic moat helps us assess how long returns on invested capital are likely to exceed the firm's cost of capital. Returns of firms with a wide economic moat rating are assumed to fade to the perpetuity period over a longer period of time than the returns of narrow-moat firms, and both will fade slower than no-moat firms, increasing our estimate of their intrinsic value.

Our model is divided into three distinct stages:

Stage I: Explicit Forecast

In this stage, which can last five to 10 years, analysts make full financial statement forecasts, including items such as revenue, profit margins, tax rates, changes in workingcapital accounts, and capital spending. Based on these projections, we calculate earnings before interest, after taxes (EBI) and the net new investment (NNI) to derive our annual free cash flow forecast.

Stage II: Fade

The second stage of our model is the period it will take the company's return on new invested capital—the return on capital of the next dollar invested ("RONIC")—to decline (or rise) to its cost of capital. During the Stage II period, we use a formula to approximate cash flows in lieu of explicitly modeling the income statement, balance sheet, and cash flow statement as we do in Stage I. The length of the second stage depends on the strength of the company's economic moat. We forecast this period to last anywhere from one year (for companies with no economic moat) to 10–15 years or more (for wide-moat companies). During this period, cash flows are forecast using four assumptions: an average growth rate for EBI over the period, a normalized investment rate, average return on new invested capital (RONIC), and the number of years until perpetuity, when excess returns cease. The investment rate and return on new invested capital decline until a perpetuity value is calculated. In the case of firms that do not earn their cost of capital, we assume marginal ROICs rise to the firm's cost of capital (usually attributable to less reinvestment), and we may truncate the second stage.

Stage III: Perpetuity

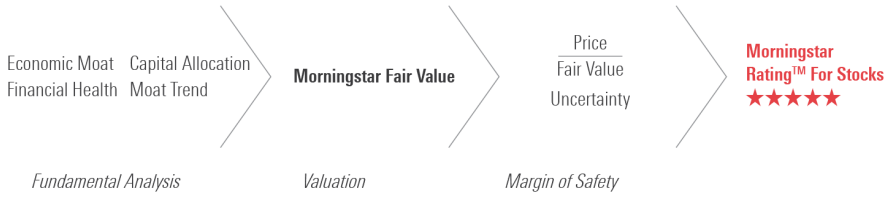
Once a company's marginal ROIC hits its cost of capital, we calculate a continuing value, using a standard perpetuity formula. At perpetuity, we assume that any growth or decline or investment in the business neither creates nor destroys value and that any new investment provides a return in line with estimated WACC.

Because a dollar earned today is worth more than a dollar earned tomorrow, we discount our projections of cash flows in stages I, II, and III to arrive at a total present value of expected future cash flows. Because we are modeling free cash flow to the firm—representing cash available to provide a return to all capital providers—we discount future cash flows using the WACC, which is a weighted average of the costs of equity, debt, and preferred stock (and any other funding sources), using expected future proportionate long-term, market-value weights.

3. Uncertainty Around That Fair Value Estimate

Morningstar's Uncertainty Rating captures a range of likely potential intrinsic values for a company and uses it to assign the margin of safety required before investing, which in turn explicitly drives our stock star rating system. The Uncertainty Rating represents the analysts' ability to

Morningstar Equity Research Star Rating Methodology



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Research Methodology for Valuing Companies

bound the estimated value of the shares in a company around the Fair Value Estimate, based on the characteristics of the business underlying the stock, including operating and financial leverage, sales sensitivity to the overall economy, product concentration, pricing power, exposure to material ESG risks, and other company-specific factors.

Analysts consider at least two scenarios in addition to their base case: a bull case and a bear case. Assumptions are chosen such that the analyst believes there is a 25% probability that the company will perform better than the bull case, and a 25% probability that the company will perform worse than the bear case. The distance between the bull and bear cases is an important indicator of the uncertainty underlying the fair value estimate. In cases where there is less than a 25% probability of an event, but where the event could result in a material decline in value, analysts may adjust the uncertainty rating to reflect the increased risk. Analysts may also make a fair value adjustment to reflect the impact of this event.

Our recommended margin of safety widens as our uncertainty of the estimated value of the equity increases. The more uncertain we are about the estimated value of the equity, the greater the discount we require relative to our estimate of the value of the firm before we would recommend the purchase of the shares. In addition, the uncertainty rating provides guidance in portfolio construction based on risk tolerance.

Our uncertainty ratings for our qualitative analysis are low, medium, high, very high, and extreme.

	Margin of Safety	
Qualitative Analysis Uncertainty Ratings	★★★★★Rating	★Rating
Low	20% Discount	25% Premium
Medium	30% Discount	35% Premium
High	40% Discount	55% Premium
Very High	50% Discount	75% Premium
Extreme	75% Discount	300% Premium

4. Market Price

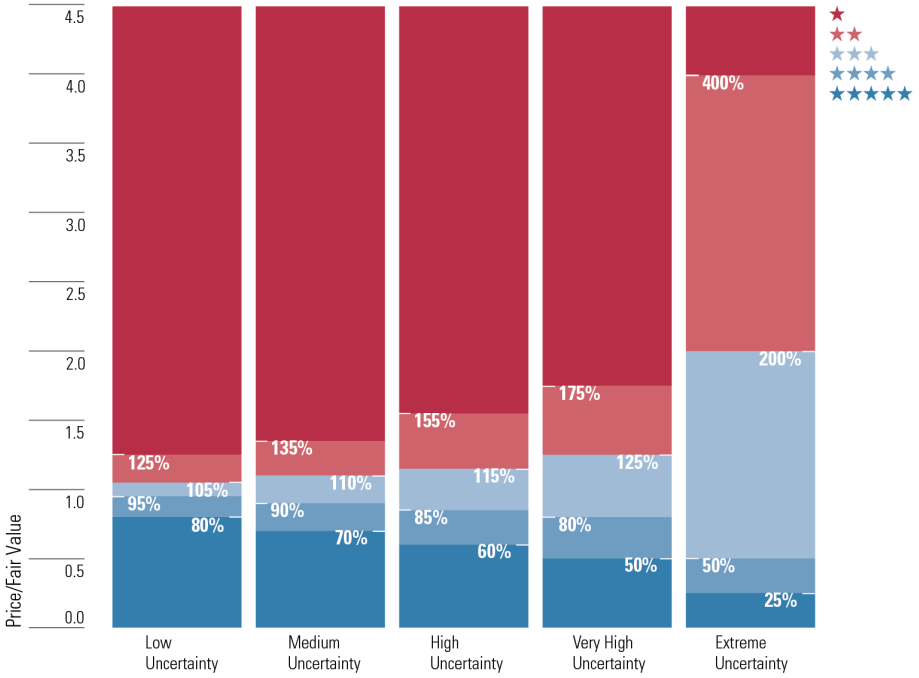
The market prices used in this analysis and noted in the report come from exchange on which the stock is listed which we believe is a reliable source.

For more details about our methodology, please go to https://shareholders.morningstar.com.

Morningstar Star Rating for Stocks

Once we determine the fair value estimate of a stock, we compare it with the stock's current market price on a daily basis, and the star rating is automatically re-calculated at the market close on every day the market on which the stock is listed is open. Our analysts keep close

Morningstar Equity Research Star Rating Methodology



tabs on the companies they follow, and, based on thorough and ongoing analysis, raise or lower their fair value estimates as warranted.

Please note, there is no predefined distribution of stars. That is, the percentage of stocks that earn 5 stars can fluctuate daily, so the star ratings, in the aggregate, can serve as a gauge of the broader market's valuation. When there are many 5-star stocks, the stock market as a whole is more undervalued, in our opinion, than when very few companies garner our highest rating.

We expect that if our base-case assumptions are true the market price will converge on our fair value estimate over time generally within three years (although it is impossible to predict the exact time frame in which market prices may adjust).

Our star ratings are guideposts to a broad audience and individuals must consider their own specific investment goals, risk tolerance, tax situation, time horizon, income needs, and complete investment portfolio, among other factors.

The Morningstar Star Ratings for stocks are defined below:

★★★★★ We believe appreciation beyond a fair risk adjusted return is highly likely over a multiyear time frame. Scenario analysis developed by our analysts indicates that the current market price represents an excessively pessimistic outlook, limiting downside risk and maximizing upside potential.

★★★★ We believe appreciation beyond a fair risk-adjusted return is likely.

★★★ Indicates our belief that investors are likely to receive a fair risk-adjusted return (approximately cost of equity).

★★ We believe investors are likely to receive a less than fair risk-adjusted return.

★ Indicates a high probability of undesirable risk-adjusted returns from the current market price over a multiyear time frame, based on our analysis. Scenario analysis by our analysts indicates that the market is pricing in an excessively optimistic outlook, limiting upside potential and leaving the investor exposed to Capital loss.

Other Definitions

Last Price: Price of the stock as of the close of the market of the last trading day before date of the report.

Capital Allocation Rating: Our Capital Allocation (or Stewardship) Rating represents our assessment of the quality of management's capital allocation, with particular emphasis on the firm's balance sheet, investments, and shareholder distributions. Analysts consider companies' investment strategy and valuation, balance sheet management, and dividend and share buyback policies. Corporate governance factors are only considered if they are likely to materially impact shareholder value, though either the balance sheet, investment, or shareholder distributions. Analysts assign one of three ratings: "Exem-

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plary", "Standard", or "Poor". Analysts judge Capital Allocation from an equity holder's perspective. Ratings are determined on a forward looking and absolute basis. The Standard rating is most common as most managers will exhibit neither exceptionally strong nor poor capital allocation.

Capital Allocation (or Stewardship) analysis published prior to Dec. 9, 2020, was determined using a different process. Beyond investment strategy, financial leverage, and dividend and share buyback policies, analysts also considered execution, compensation, related party transactions, and accounting practices in the rating.

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