Momentum: C



# AstraZeneca plc (AZN) \$51.33 (As of 01/17/20) Price Target (6-12 Months): \$54.00 Long Term: 6-12 Months (Since: 10/23/19) Prior Recommendation: Outperform Short Term: 1-3 Months Zacks Rank: (1-5) Zacks Style Scores: VGM:C

## **Summary**

AstraZeneca's core products like Nexium, Crestor and Seroquel are facing generic competition, which is hurting sales. The diabetes franchise is also facing stiff competition while pricing pressure is hurting sales in the respiratory unit. Nonetheless, AstraZeneca returned to product sales growth in 2018 with the momentum continuing in 2019 mainly on the back of its cancer medicines, Lynparza, Tagrisso and Imfinzi, which should keep driving revenues. Several launches are underway across each of the therapeutic areas, Oncology, CV metabolism and Respiratory. AstraZeneca also has a promising late-stage pipeline. Its shares have outperformed the industry in the past one year. The company has a positive record of earnings surprises in the recent quarters. Estimates have gone up slightly ahead of Q4 earnings release.

# Price, Consensus & Surprise



Value: C

Growth: C

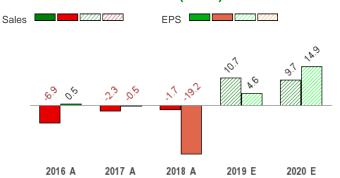
## **Data Overview**

P/S TTM

52 Week High-Low	\$51.55 - \$35.30
20 Day Average Volume (sh)	1,979,181
Market Cap	\$134.7 B
YTD Price Change	3.0%
Beta	0.46
Dividend / Div Yld	\$0.88 / 1.7%
Industry	Large Cap Pharmaceuticals
Zacks Industry Rank	Top 21% (54 out of 254)

Last EPS Surprise	11.1%
Last Sales Surprise	4.3%
EPS F1 Est- 4 week change	-0.2%
Expected Report Date	02/14/2020
Earnings ESP	3.3%
P/E TTM	17.7
P/E F1	24.7
PEG F1	1.4

## Sales and EPS Growth Rates (Y/Y %)



## Sales Estimates (millions of \$)

	Q1	Q2	Q3	Q4	Annual*
2020					26,822 E
2019	5,491 A	5,823 A	6,406 A	6,713 E	24,460 E
2018	5,178 A	5,155 A	5,340 A	6,417 A	22,090 A

## **EPS Estimates**

	Q1	Q2	Q3	Q4	Annual*
2020					\$2.08 E
2019	\$0.45 A	\$0.37 A	\$0.50 A	\$0.50 E	\$1.81 E
2018	\$0.24 A	\$0.35 A	\$0.36 A	\$0.79 A	\$1.73 A
*Quarterl	y figures may no	t add up to anni	ual.		

The data in the charts and tables, including the Zacks Consensus EPS and Sales estimates, is as of 01/17/2020. The reports text is as of 01/21/2020.

5.6

#### Overview

AstraZeneca plc, headquartered in London, UK, is one of the largest biopharmaceutical companies in the world. AstraZeneca was formed on Apr 6, 1999, through the merger of Sweden's Astra AB and UK's Zeneca Group plc. AstraZeneca's business can be broken down into separate lines based on therapeutic classes. These include metabolic diseases, cardiovascular, respiratory, oncology, neuroscience, infection and other.

In order to bolster its respiratory portfolio, AstraZeneca acquired rights to Allergan's branded respiratory business in the U.S. and Canada in Mar 2015. The company also acquired Takeda's core respiratory business in May 2016.

In Jun 2007, AstraZeneca acquired biotechnology company MedImmune for \$15.6 billion, which strengthened its product portfolio. In Aug 2011, AstraZeneca sold its Astra Tech business to DENTSPLY for about \$1.8 billion in cash. In a bid to add late-stage candidates to its pipeline, AstraZeneca entered into a number of deals (Almirall's respiratory franchise, Bristol-Myers' diabetes portfolio, Pearl Therapeutics and Omthera Pharmaceuticals) and struck agreements with companies such as FibroGen, Inc. In Dec 2015, AstraZeneca acquired biotech company, ZS Pharma, for about \$2.7 billion to boost its cardiovascular and metabolic disease pipeline. In Feb 2016, AstraZeneca bought a majority equity stake in privately owned biotech company, Acerta Pharma, to enhance its oncology pipeline.





In 2018, total sales declined 2% (CER) to \$22.1 billion.



## **Reasons To Buy:**

- ▲ Shares Outperforming Industry: AstraZeneca's share price has risen 41.6% in the past one year against an increase of 15.1% for the industry.-
- ▲ Strong Diversified Portfolio; New Drugs Supporting Sales:

AstraZeneca has a strong product portfolio. Newer drugs like Brilinta (cardiovascular), Lynparza (ovarian cancer), Farxiga/Forxiga (type II diabetes) and Tagrisso (lung cancer) are driving top-line growth, with AstraZeneca launching them in more markets and in an increased number of indications. Tagrisso became AstraZeneca's biggest medicine in 2019. Brilinta and Farxiga achieved blockbuster status in 2017, exceeding \$1 billion in sales. In fact,

AstraZeneca has a strong diversified portfolio, an expanding presence in emerging markets, ongoing cost-cutting initiatives and a robust pipeline.

AstraZeneca expects Imfinzi and Lynparza to achieve blockbuster status by 2019. This means five of its newer medicines (Tagrisso, Brilinta, Farxiga, Imfinzi and Lynparza) will have blockbuster status by the end of 2019. In 2018, AstraZeneca gained approval for Lokelma (hyperkalemia) in both United States and EU. AstraZeneca is looking for further label expansions for all these drugs.

AstraZeneca returned to product sales growth in the second half of 2018 with the momentum continuing in 2019 on the back of its newer drugs. Patent expirations had been hurting its product sales growth since 2010. Sales of AstraZeneca's newer medicines rose 81% in 2018 and 72% in the first nine months of 2019 as almost every new product it has launched in recent years has done well. The company is confident of seeing sustained growth for several years driven by sales growth of its new medicines, Tagrisso, Imfinzi, Lynparza, Farxiga and Fasenra.

- ▲ Emerging Markets A Focus Area: AstraZeneca, which operates in multiple countries across the globe, is focusing on emerging markets. Emerging markets represents its largest market by product sales and accounted for 33% of its total product sales in 2018 and 35% in 2019 so far. Revenues from emerging markets climbed 8% in 2017, 12% in 2018 and 26% in the first nine months of 2019, supported by strong growth in China. Emerging markets represent significant commercial opportunity, given factors like pricing pressure in the EU and intensifying generic competition affecting sales in large pharmaceutical markets. In late 2015, AstraZeneca struck a deal with WuXi AppTec, an operating subsidiary of China-based WuXi PharmaTech Inc., to develop innovative biologics targeting therapeutics areas such as respiratory, inflammation and autoimmunity among others. The company is looking to make additional investments in China. In-fact, in Emerging Markets, countries outside China are also starting to contribute more, with sales in ex-China markets rising 12% in first nine months of 2019. AstraZeneca's operations in emerging markets should place it well, going forward.
- ▲ Cost Cutting Initiatives and Divestures: AstraZeneca has consistently made significant efforts to restructure and reshape its business to improve its long-term competitiveness. AstraZeneca is working to reduce the impact of genericization on its key products by trimming its cost structure to drive operational efficiency. Its latest restructuring efforts include centralization of global R&D footprint into three strategic centers, transformation of the IT organization, closure of a number of manufacturing facilities and other activities to simplify and streamline the organization. These restructuring initiatives are expected to be completed in 2021 and generate annualized benefits of \$1.2 billion. Streamlining of operations and focus on R&D will benefit the company in the long run.

In 2018, AstraZeneca divested several non-core products as it streamlines its portfolio to focus on its core areas of Oncology, Cardiovascular, Renal & Metabolism and Respiratory.

Acquisitions & Deals to Boost Growth: AstraZeneca is working on bolstering its pipeline and is looking at suitable acquisitions and deals. In order to strengthen its respiratory portfolio, AstraZeneca acquired rights to Allergan's branded respiratory business in the U.S. and Canada in Mar 2015. AstraZeneca had also acquired Almirall's respiratory franchise in Oct 2014. In May 2016, AstraZeneca acquired Takeda's core respiratory business, thereby gaining global rights to Daliresp/Daxas.

In February 2014, AstraZeneca boosted its diabetes portfolio by acquiring Bristol-Myers' global diabetes business for an upfront payment of \$2.7 billion and capitalized on its strong presence in emerging markets to promote its diabetes franchise.

In December 2015, AstraZeneca acquired biotech company, ZS Pharma, for about \$2.7 billion, to boost its cardiovascular and metabolic disease pipeline. In Feb 2016, AstraZeneca also acquired a majority equity stake in privately owned biotech company, Acerta Pharma, to boost its oncology pipeline.

Meanwhile, the June 2012 acquisition of Ardea added Zurampic to AstraZeneca's gout portfolio. The Pearl Therapeutics takeover added Bevespi to AstraZeneca's respiratory portfolio. Other acquisitions include Omthera and AlphaCore, both boosting the company's cardiovascular pipeline.

In addition to acquisitions, the company is pursuing co-development deals with companies like Ionis, Merck and Bausch Health to boost its pipeline. We believe that the company will continue to pursue such accretive deals and acquisitions.

▲ Focus on Oncology: AstraZeneca is working on strengthening its oncology product portfolio and has several candidates in its pipeline. Oncology sales now comprise around 37% of total product sales for AstraZeneca and rose 50% in 2018 and 54% in the first nine months of 2019. The company's target is to launch at least six new oncology medicines between 2014 and 2020, with five - Lynparza, Tagrisso, Imfinzi, Lumoxiti and Calquence - already launched. The immuno-oncology therapeutic area is presently attracting a lot of interest and represents huge commercial potential. An interesting candidate in the company's immuno-oncology pipeline is Imfinzi (durvalumab).

Imfinzi was launched in the United States for the first indication — second line advanced bladder cancer — in May 2017. Imfinzi was approved and immediately launched for the second indication in the United States — early stage lung cancer (NSCLC) — in February 2018, which drove sales significantly in 2018 and in the first nine months of 2019. Imfinzi is also being evaluated for multiple cancers, either alone or in combination with other regimens, including phase III trials in combination with tremelimumab in hepatocellular carcinoma (HCC, liver cancer), in earlier settings in NSCLC, small cell lung cancer, metastatic urothelial cancer and head and neck squamous cell carcinoma (HNSCC) among others. In November 2017, another cancer drug Calquence (acalabrutinib) gained FDA approval for previously treated mantle cell lymphoma (MCL), the first for AstraZeneca for a type of blood cancer. In November 2019, Calquence was approved by the FDA

for the larger chronic lymphocytic leukemia indication (in frontline as well as relapsed/recurrent disease setting), which will significantly expand the drug eligible patient population.

Other important oncology candidates in AstraZeneca's pipeline include selumetinib (pediatric neurofibromatosis type 1 - under review in the United States (PDUFA date: second quarter of 2020)) and savolitinib (NSCLC - phase III). In April 2019, AstraZeneca acquired joint development and commercialization rights to an innovative antibody drug conjugate (ADC), trastuzumab deruxtecan from Japan's Daiichi Sankyo. Trastuzumab deruxtecan was approved by the FDA in metastatic breast cancer in December 2019 under the brand name of Enhertu.

Lynparza, presently marketed for advanced ovarian cancer and breast cancer, is also in different studies for a range of tumor types including prostate, pancreatic and gastric cancers as well as earlier-line settings for ovarian cancer and breast cancer. Lynparza was approved for the first-line maintenance setting in the United States and EU in late 2018 and mid-2019, respectively, becoming the first PARP inhibitor to be approved as a first-line maintenance therapy for BRCA-mutated advanced ovarian cancer. Tagrisso is also being evaluated in earlier-line settings for lung cancer. AstraZeneca gained approval for Tagrisso in first-line EGFR-mutated NSCLC in the U.S. in April 2018 and in the EU in June 2018. These label expansions drove sales of these important cancer drugs higher in the second half of 2018 and continue to do so in 2019. A regulatory application seeking approval for use of Lynparza tablets in BRCA-mutated pancreatic cancer was approved by the FDA in December 2019 with a similar decision in the EU expected in the first half of 2020.

▲ Pipeline Progress: The company had 16 new molecular entities in pivotal development or under regulatory review at the end of September 2019. Its R&D focus is on three main therapy areas — Oncology; Cardiovascular, Renal and Metabolism; and Respiratory. AstraZeneca has been making significant progress with its non-oncology pipeline as well.

Promising pipeline candidates include tezepelumab (asthma – phase III), Breztri/PT010 (COPD – under review in the EU, second NDA to be filed in United States soon), anifrolumab (systemic lupus erythematosus – phase III) and roxadustat (anemia in patients with chronic kidney disease – NDA to be filed soon). AstraZeneca expects to launch four respiratory medicines between 2017 and 2020 with Fasenra (benralizumab) and Bavespi already launched. Fasenra is also being evaluated in a late-stage study for nasal polyposis.

#### **Reasons To Sell:**

Generics Eroding Revenues: AstraZeneca's core products like Nexium, Seroquel XR and Crestor are facing generic competition, which are hurting earnings growth. Atacand, Toprol-XL and Merrem are also facing generic competition in the United States. The genericization of key products makes it challenging for the company to drive its top line.

Sales of products which lost exclusivity declined by more than \$13 billion between 2011 and 2018.

AstraZeneca core products are facing generic competition. The diabetes franchise also faces stiff competition while pricing pressure hurts sales of the Respiratory franchise.

▼ Intense Competition: In addition to generic threats, AstraZeneca's products already face intense competition in the market from both large pharma companies as well as small and mid-sized companies. One of AstraZeneca's key focus areas, the diabetes market, is heavily crowded with a number of products present in the market. AstraZeneca's Farxiga/Forxiga belongs to the same class (SGLT2) as Johnson & Johnson's Invokana. Bydureon, a GLP-1 receptor agonist with a once weekly dosing is facing competition from Glaxo's Tanzeum and Lilly's Trulicity. The diabetes franchise is facing increased pricing pressure. Products targeting other areas, such as oncology and respiratory among others, are also facing stiff competition.

Although AstraZeneca is among the major players in immunotherapy, there are several other companies, big as well as small, looking to develop and bring immunotherapy treatments to market. Rising competition in the immuno-oncology market is a significant concern.

Loss of market share due to intense competition will severely impact AstraZeneca's top line.

- ▼ Declining Sales of Symbicort: Sales of another important drug, Symbicort are declining due to challenges in both the United States and Europe. In the United States, Symbicort sales are declining due to significant pricing pressure on the ICS/LABA class from managed care as well as competition from outside the class, especially in COPD. Sales are declining in Europe due to continued pressure from both analogue competitors and branded competitors. Sales of Symbicort, which accounts for 12% of AstraZeneca's product sales, declined 6% in 2017, 9% in 2018 and 4% in the first nine months of 2019.
- Pipeline Setbacks: Although AstraZeneca has several candidates in its pipeline in different stages of development, the company has had its share of pipeline setbacks. Pipeline setbacks include the discontinuation of the development of candidates like zibotentan (prostate cancer), TC-5214 (major depressive disorder), sifalimumab (lupus) and selumetinib (uveal melanoma, NSCLC, thyroid cancer).
  ZS-9 received a complete response letter (CRL) from the FDA twice, thus delaying the drug's entry to the market. In Jul 2017, a pivotal phase III study (MYSTIC) on Imfinzi in the 1st line NSCLC patient population failed to meet the primary endpoint of progression-free-survival. The same study failed to meet the second primary endpoint of showing statistical improvement in overall survival in the patients in November 2018. In June 2018, AstraZeneca discontinued two late-stage studies on Alzheimer's disease candidate, lanabecestat as the independent data monitoring committee (IDMC) felt they were unlikely to meet their primary endpoint.

Given the generic competition being faced by the company, the pipeline needs to deliver.

▼ Issues Regarding Diabetes Drugs: In early Apr 2016, AstraZeneca received a communication from the FDA on proposed label changes related to a potential risk for an increase in heart failure in the SAVOR (Saxagliptin Assessment of Vascular Outcomes Recorded in Patients with Diabetes Mellitus) outcomes study on Onglyza. The post-marketing study was conducted to evaluate cardiovascular (CV) effects of Onglyza when added to type II diabetes therapy in adult diabetics at a risk of a CV disease. Consequently, AstraZeneca updated Onglyza's label. Onglyza sales were adversely impacted due to the label update.

In addition, the FDA raised concerns regarding DPP-4 inhibitors (including the company's Onglyza and Kombiglyze XR) and warned patients in Aug 2015 of severe and disabling joint pain associated with its use. Moreover, the FDA, along with the European Medicines Agency, has raised concerns regarding SGLT2 inhibitors (including the company's Forxiga/Forxiga) and warned patients of ketoacidosis – a serious condition where the body produces high levels of blood acids called ketones.

## **Last Earnings Report**

#### Q3 Earnings & Sales Beat

AstraZeneca beat the Zacks Consensus Estimate for both earnings and sales in the third quarter of 2019.

Third-quarter 2019 core earnings of 50 cents per American depositary share beat the Zacks Consensus Estimate of 45 cents. Core earnings per share of 99 cents increased 36% year over year at constant exchange rates ("CER"), benefiting from higher revenues.

Total revenues were up 20% (22% at CER) to \$6.4 billion in the reported quarter driven by higher product sales. Revenues also beat the Zacks Consensus Estimate of \$6.14 billion.

All growth rates mentioned below are on a year-over-year basis and at CER.

09/2019		
Oct 24, 2019		
4.33%		
11.11%		
0.50		
2.11		

#### **Product Sales Rise**

Product sales rose 18% at CER in the quarter to \$6.13 billion. Higher sales of newer medicines, particularly cancer drugs, and higher sales in every sales region, offset lower sales of many other legacy medicines and drove product sales growth.

However, product sales in the quarter benefited from favorable inventory and gross-to-net movements, which are not expected to benefit in the fourth quarter.

AstraZeneca's newer medicines recorded sales of \$2.71 billion in the third quarter, up 64%. Sales of newer medicines in emerging markets were \$539 million, up 90% year over year.

Collaboration revenues (formerly Externalization revenues) were \$274 million compared with \$74 million in the year-ago period.

Among AstraZeneca's various therapeutic areas, Oncology was up 48%, New Cardiovascular, Renal and Metabolism was up 11% and Respiratory rose 18%. However, other medicines declined 7%.

#### **Newer Products**

Among the newer medicines, Lynparza sales rose 96% year over year and 15.5% sequentially to \$327 million on the back of expanded use in ovarian and breast cancer.

Tagrisso recorded sales of \$891 million, up 78% year over year driven by continued underlying demand growth and strong uptake in the first-line setting. Sales increased 17% sequentially in the U.S. market.

Imfinzi generated sales of \$412 million in the quarter, up 21.9% sequentially mainly driven by strong demand in lung cancer patients. Like previous quarters, the vast majority of Imfinzi's sales came from the United States and the lung cancer indication

Calquence, which was launched in the United States in October 2017, generated sales of \$44 million in the third quarter compared with \$35 million in the previous quarter.

Brilinta/Brilique sales were \$416 million in the reported quarter, up 27% year over year driven by continued patient uptake in acute coronary syndrome and high-risk post-myocardial infarction indications.

New hyperkalemia drug, Lokelma recorded sales of \$4 million in the quarter, predominantly in the United States, where it was launched last quarter. The drug is expected to be launched in other markets soon.

Farxiga recorded sales of \$398 million in the quarter, up 14% mainly driven by growth in emerging markets and Europe. U.S. sales declined 18% due to increased competition and formulary plan changes for competitors' drugs. Sales in Europe were up 26%. Emerging market sales increased 59%.

Fasenra recorded sales of \$202 million in the quarter compared with \$167 million in the previous quarter. AstraZeneca said Fasenra enjoys leadership position among novel biologic asthma medicines in some key markets.

Bevespi, a LAMA/LABA in a pressurized metered dose inhaler, recorded sales of \$10 million in the quarter, similar to the previous two quarters, amid slower-than-anticipated growth in LAMA/LABA class.

Breztri, which was approved in Japan in June, recorded sales of \$1 million in the third quarter.

Among other medicines, Iressa sales were down 29% to \$91 million. Bydureon sales declined 16% to \$127 million and Onglyza sales declined 7% to \$127 million. Byetta sales declined 18% to \$28 million and Movantik/Moventig recorded sales of \$25 million in the quarter, down 23%.

## **Older Products**

Crestor sales declined 2% to \$337 million. U.S. and Europe sales were weak as multiple generic versions of the drug entered the market.

Symbicort sales were up 1% in the quarter to \$613 million due to stronger sales in Japan and the emerging markets. U.S. sales were hurt by pricing pressure and the impact of managed-market rebates. Pulmicort sales rose 31% to \$337 million as higher sales in the emerging and U.S. markets made up for weaker performance in Europe.

Nexium recorded sales of \$374 million, down 10% due to lower sales in the United States and Europe. Sales of other legacy drugs including Zoladex, Arimdex, Casodex Seloken and Daliresp/Daxas grew in the quarter while sales of others like Faslodex, Synagis, Duaklir and Atacand declined.

#### **Regional Performance**

In the United States, product sales were up 17% to \$2 billion on the back of higher sales of newer products. Sales in European markets grew 4% in the third quarter to \$1.14 billion. Revenues from Emerging Markets were up 29% to \$2.12 billion, primarily on the back of strong growth in China (up 40% to \$1.28 billion). In Emerging Markets, AstraZeneca said that countries outside China are starting to contribute more, with sales rising 15% in ex-China markets. In Established ROW market (comprising Japan, Canada and other markets), sales were up 19% to \$845 million.

#### **Profit Discussion**

AstraZeneca's core gross margin declined 1 percentage point (at CER) at 79.4%. Core selling, general and administrative (SG&A) expenses rose 9% to \$2.21 billion.

In the quarter, core research and development (R&D) expenses rose 9% to \$1.32 billion. Core operating profit rose 41% to \$1.88 billion in the quarter. Operating margin increased 4 percentage points to 29.3% in the quarter.

#### 2019 Outlook

AstraZeneca upgraded its product sales guidance. The company expects product sales to grow by a low to mid-teens percentage versus prior expectation of a low double-digit percentage.

AstraZeneca however maintained core EPS guidance for 2019 in the range of \$3.50 to \$3.70 at CER. Core operating profit is expected to increase ahead of product sales in 2019 versus prior expectation of growth in a mid-teens range. The sum of total collaboration revenues and other income/expenses is expected to decline.

Currency movements are expected to unfavorably impact product sales and core earnings per share by a low single-digit percentage.

Adjusted tax rate is expected to be in the range of 20%-22%.

#### **Recent News**

#### FDA's Priority Review to Lynparza sNDA in mCRPC — Jan 20

AstraZeneca and Merck announced that the FDA granted priority review to a supplemental new drug application (sNDA), seeking approval of Lynparza in men with metastatic castration-resistant prostate cancer (mCRPC) who have a mutation in their homologous recombination repair (HRRm) genes. The disease of these men had progressed on prior treatment with new hormonal agent (NHA) treatments like Zytiga and Xtandi, making it difficult to treat. The FDA's decision is expected in the second quarter of 2020. The designation was granted based on results from the phase III PROfound study.

#### FDA Grants Orphan Drug Status to Imfinzi for HCC - Jan 20

AstraZeneca announced that the FDA has granted Orphan Drug designation to Imfinzi plus tremelimumab for the treatment of hepatocellular carcinoma (HCC), the most common type of liver cancer. A phase III HIMALAYA study is presently testing Imfinzi monotherapy and Imfinzi plus tremelimumab in first-line advanced HCC setting.

#### Discontinues Heart Risk Study on Epanova - Jan 13

AstraZeneca announced that it will discontinue the phase III STRENGTH outcomes study on its fish-oil pill, Epanova. The study was evaluating cholesterol medicine Epanova to reduce the risk of cardiovascular disease in patients with mixed dyslipidaemia (MDL) or high triglyceride (TG) levels. The decision to stop the STRENGTH study was taken based on the recommendation of an independent Data Monitoring Committee as it was unlikely to demonstrate a benefit to patients

#### FDA's Priority Review to Lynparza sNDA in Ovarian Cancer— Jan 13

AstraZeneca and Merck announced that the FDA has granted priority review to a sNDA seeking approval for Lynparza as a first-line maintenance treatment for advanced ovarian cancer regardless of patients' biomarker status or surgical outcome. The sNDA is based on data from the PAOLA-1 study. With the FDA granting priority review, approval is expected in the second quarter of 2020.

#### Lokelma approved in China - Jan 6

AstraZeneca announced that Lokelma has been approved in China for the treatment of adult patients with hyperkalaemia. Lokelma is already approved in the United States, the EU and Canada for hyperkalaemia

#### Farxiga sNDA Gets FDA's Priority Review Status - Jan 6

AstraZeneca announced that the FDA accepted a sNDA for Farxiga and granted priority review to the same. The sNDA was seeking approval of the drug to reduce the risk of cardiovascular (CV) death or the worsening of heart failure (HF) patients with reduced ejection fraction, with and without type-II diabetes (T2D). With the FDA granting priority review to the sNDA, a decision is expected in the second quarter of 2020. The sNDA was based on positive results from the DAPA-HF study on Farxiga.

### FDA Approves Lynparza for First-Line Pancreatic Cancer — Dec 30

AstraZeneca/Merck announced that the FDA has granted approval to Lynparza as a first-line maintenance treatment in germline BRCA-mutated metastatic pancreatic cancer. With this approval, Lynparza becomes the first PARP inhibitor to be approved for treating biomarker-selected patients with advanced pancreatic cancer. The decision was expected as the FDA Oncologic Drugs Advisory Committee had recommended the approval earlier this month. The drug is under review in Europe for a similar indication, with a decision expected in the first half of 2020. The sNDA was based on data from the phase III POLO study.

## Triple-Combo COPD Inhaler Gets Approval in China - Dec 23

AstraZeneca announced that its triple combination therapy, a combination of budesonide, glycopyrronium and formoterol fumarate, has been approved by the National Medical Products Administration of China as maintenance treatment for chronic obstructive pulmonary disease ("COPD"). The therapy had been approved in Japan in June with the trade name of Breztri Aerosphere for a similar indication. The medicine is also under regulatory review in the United States and EU, under the name PT010. The COPD therapy, which is known as PT010 outside China, is under review in the United States and Europe.

The approval is based on positive data from the KRONOS study, which compared PT010 to dual combination therapies — Bevespi Aerosphere and PT009 — in COPD.

## FDA Nod for Enhertu/trastuzumab deruxtecan - Dec 23

AstraZeneca and its Japan-based partner Daiichi Sankyo Company announced that the FDA has granted accelerated approval to their antibody drug conjugate candidate, trastuzumab deruxtecan for metatstaic breast cancer. The drug will be available as monotherapy for unresectable or metastatic HER2-positive breast cancer in patients who have received two or more prior anti-HER2 based regimens in the metastatic setting. The drug will be marketed by the trade name of Enhertu.

The approval to Enhertu came much earlier than expected. It is the first approval for the antibody drug conjugate in any indication. In October, the FDA had granted priority review to the biologics license application seeking approval for Enhertu. A decision is expected in the second quarter of 2020.

#### To Sell Rights to Arimidex/Casodex in Some Countries - Dec 20

AstraZeneca announced that it has agreed to sell the commercial rights to Arimidex and Casodex, which are used primarily to treat breast and

prostate cancers in a number of European, African and other countries to Juvisé Pharmaceuticals. The sale, made for an upfront payment of \$181 million, is in line with AstraZeneca's strategy of focusing on pipeline of new medicines. Meanwhile, AstraZeneca will also be entitled to future sales-contingent payments of up to \$17 million.

## **Valuation**

AstraZeneca's shares are up 41.6% in the trailing 12-month period. Stocks in the Zacks sub-industry and sector are up 15.1% and 5.5%, respectively, over the past year. The S&P 500 Index is up 25.6% in the past year.

The stock is currently trading at 24.42X forward 12-month earnings per share, which compares to 15.71X for the Zacks sub-industry, 21.78X for the Zacks sector and 19.19X for the S&P 500 Index.

Over the past five years, the stock has traded as high as 27.92X and as low as 11.1X, with a 5-year median of 17.91X. Our Neutral recommendation indicates that the stock will perform in-line with the market. Our \$54 price target reflects 25.7X forward 12-month earnings per share.

The table below shows summary valuation data for AZN.

		Stock	Sub-Industry	Sector	S&P 500
	Current	24.42	15.71	21.78	19.19
P/E F12M	5-Year High	27.92	18.1	21.78	19.34
	5-Year Low	11.1	13.94	15.85	15.17
	5-Year Median	17.91	15.56	18.91	17.44
	Current	4.99	4.82	2.88	3.57
P/S F12M	5-Year High	5.46	4.84	3.82	3.57
	5-Year Low	2.99	3.93	2.43	2.54
	5-Year Median	3.8	4.43	2.94	3
	Current	9.85	6.98	4.61	4.55
P/B TTM	5-Year High	9.85	7.26	5.03	4.55
	5-Year Low	3.82	3.78	3.43	2.85
	5-Year Median	5.41	5.16	4.29	3.61

As of 1/20/2020

# Industry Analysis Zacks Industry Rank: Top 21% (54 out of 254)

#### ■ Industry Price 220 - Industry ■ Price ₩-50

# **Top Peers**

Pfizer Inc. (PFE)	Outperform
Amgen Inc. (AMGN)	Neutral
Bristol-Myers Squibb Company (BMY)	Neutral
GlaxoSmithKline plc (GSK)	Neutral
Johnson & Johnson (JNJ)	Neutral
Merck & Co., Inc. (MRK)	Neutral
Novartis AG (NVS)	Neutral
Roche Holding AG (RHHBY)	Neutral

Industry Comparison Ind	Comparison Industry: Large Cap Pharmaceuticals			Industry Peers			
	AZN Neutral	X Industry	S&P 500	NVS Neutral	PFE Outperform	RHHBY Neutra	
VGM Score	С	-	-	В	D	Α	
Market Cap	134.68 B	134.35 B	24.65 B	219.85 B	224.19 B	290.51 B	
# of Analysts	5	3	13	5	6	4	
Dividend Yield	1.71%	2.58%	1.73%	1.92%	3.55%	1.60%	
Value Score	С	-	-	В	С	C	
Cash/Price	0.04	0.04	0.04	0.04	0.04	NA NA	
EV/EBITDA	20.58	15.22	14.11	10.75	13.75	NA	
PEG Ratio	1.36	1.98	2.08	1.98	4.24	2.45	
Price/Book (P/B)	9.85	5.74	3.39	4.18	3.43	NA	
Price/Cash Flow (P/CF)	15.98	12.73	13.81	11.78	9.62	14.78	
P/E (F1)	24.68	16.22	19.19	16.92	15.46	16.01	
Price/Sales (P/S)	5.58	4.50	2.69	4.55	4.23	NA	
Earnings Yield	4.05%	6.17%	5.21%	5.91%	6.47%	6.25%	
Debt/Equity	1.29	0.68	0.72	0.42	0.55	NA	
Cash Flow (\$/share)	3.21	4.30	6.94	8.15	4.21	2.87	
Growth Score	С	-	-	С	F	Α	
Hist. EPS Growth (3-5 yrs)	-2.47%	8.42%	10.56%	0.15%	8.42%	NA	
Proj. EPS Growth (F1/F0)	14.57%	6.62%	7.57%	8.41%	-11.59%	3.82%	
Curr. Cash Flow Growth	-3.77%	10.96%	14.73%	6.18%	8.89%	13.00%	
Hist. Cash Flow Growth (3-5 yrs)	-5.68%	4.99%	9.00%	2.20%	2.30%	7.35%	
Current Ratio	0.92	1.17	1.24	0.95	0.90	NA	
Debt/Capital	56.26%	40.27%	42.99%	29.33%	35.53%	NA	
Net Margin	8.42%	20.26%	11.14%	24.43%	30.57%	NA	
Return on Equity	38.63%	38.63%	17.16%	20.86%	28.10%	NA	
Sales/Assets	0.40	0.53	0.55	0.37	0.33	NA	
Proj. Sales Growth (F1/F0)	9.66%	5.12%	4.16%	2.86%	-11.59%	1.92%	
Momentum Score	C	-	-	С	A	C	
Daily Price Chg	1.62%	0.05%	0.27%	0.87%	-0.25%	1.60%	
1 Week Price Chg	-0.48%	1.19%	0.39%	-0.98%	1.44%	0.93%	
4 Week Price Chg	2.72%	3.34%	2.95%	1.76%	3.95%	7.72%	
12 Week Price Chg	8.63%	12.59%	7.76%	9.96%	11.32%	15.59%	
52 Week Price Chg	41.44%	18.73%	22.29%	8.24%	-4.62%	30.85%	
20 Day Average Volume	1,979,181	1,878,471	1,536,375	1,073,944	15,693,486	1,197,123	
(F1) EPS Est 1 week change	-0.19%	0.00%	0.00%	0.00%	1.29%	0.00%	
(F1) EPS Est 4 week change	-0.19%	0.00%	0.00%	-0.11%	1.29%	0.47%	
(F1) EPS Est 12 week change	0.78%	0.63%	-0.40%	-1.60%	4.18%	2.91%	
(Q1) EPS Est Mthly Chg	NA%	0.00%	0.00%	NA	NA	NA	

## **Zacks Stock Rating System**

We offer two rating systems that take into account investors' holding horizons: Zacks Rank and Zacks Recommendation. Each provides valuable insights into the future profitability of the stock and can be used separately or in combination with each other depending on your investment style.

#### **Zacks Recommendation**

The Zacks Recommendation aims to predict performance over the next 6 to 12 months. The foundation for the quantitatively determined Zacks Recommendation is trends in the company's estimate revisions and earnings outlook. The Zacks Recommendation is broken down into 3 Levels; Outperform, Neutral and Underperform. Unlike many Wall Street firms, we have an excellent balance between the number of Outperform and Neutral recommendations. Our team of 70 analysts are fully versed in the benefits of earnings estimate revisions and how that is harnessed through the Zacks quantitative rating system. But we have given our analysts the ability to override the Zacks Recommendation for the 1200 stocks that they follow. The reason for the analyst over-rides is that there are often factors such as valuation, industry conditions and management effectiveness that a trained investment professional can spot better than a quantitative model.

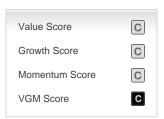
#### **Zacks Rank**

The Zacks Rank is our short-term rating system that is most effective over the one- to three-month holding horizon. The underlying driver for the quantitatively-determined Zacks Rank is the same as the Zacks Recommendation, and reflects trends in earnings estimate revisions.

## **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.



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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