

Eli Lilly & Company (LLY)

\$157.30 (As of 04/28/20)

Price Target (6-12 Months): **\$181.00**

Long Term: 6-12 Months

Zacks Recommendation:

Outperform

(Since: 03/31/20)

Prior Recommendation: Neutral

Short Term: 1-3 Months

Zacks Rank: (1-5)

1-Strong Buy

Zacks Style Scores:

VGM:C

Value: B

Growth: C

Momentum: D

Summary

Lilly beat estimates for earnings and sales in Q1. However, Lilly expects coronavirus-related benefits seen in the first quarter to reverse over the course of 2020, with the most significant impact in the second quarter. Nonetheless, Lilly still expects revenue growth to be driven by higher demand for its growth drugs like Trulicity, Taltz, and others and from product launches. Lilly is making significant pipeline progress with several positive late-stage data readouts scheduled for 2020. Lilly is regularly adding promising new pipeline assets through business development deals. However, generic competition for several drugs, rising pricing pressure in the United States, and price cuts in some international markets like China, Japan and Europe are some top-line headwinds expected in 2020. The stock has outperformed the industry this year so far.

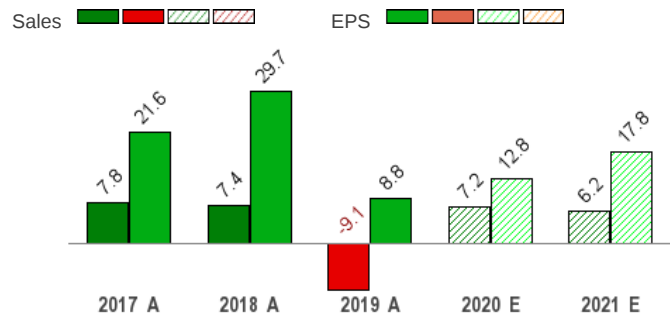
Price, Consensus & Surprise



Data Overview

52 Week High-Low	\$164.90 - \$101.36
20 Day Average Volume (sh)	3,607,761
Market Cap	\$150.5 B
YTD Price Change	19.7%
Beta	0.16
Dividend / Div Yld	\$2.96 / 1.9%
Industry	Large Cap Pharmaceuticals
Zacks Industry Rank	Top 8% (20 out of 253)

Sales and EPS Growth Rates (Y/Y %)



Last EPS Surprise	12.9%
Last Sales Surprise	6.3%
EPS F1 Est- 4 week change	0.6%
Expected Report Date	08/04/2020
Earnings ESP	0.0%
P/E TTM	24.4
P/E F1	23.1
PEG F1	2.2
P/S TTM	6.5

Sales Estimates (millions of \$)

	Q1	Q2	Q3	Q4	Annual*
2021					25,424 E
2020	5,860 A	5,808 E	5,816 E	6,577 E	23,934 E
2019	5,092 A	5,637 A	5,477 A	6,114 A	22,320 A

EPS Estimates

	Q1	Q2	Q3	Q4	Annual*
2021					\$8.02 E
2020	\$1.75 A	\$1.60 E	\$1.76 E	\$1.75 E	\$6.81 E
2019	\$1.33 A	\$1.50 A	\$1.48 A	\$1.73 A	\$6.04 A

*Quarterly figures may not add up to annual.

The data in the charts and tables, including the Zacks Consensus EPS and Sales estimates, is as of 04/28/2020. The reports text is as of 04/29/2020.

Overview

Indianapolis, IN based Eli Lilly and Company, one of the world's largest pharmaceutical companies, boasts a diversified product profile including a solid lineup of new successful drugs. It also has a dependable pipeline as it navigates through challenges like patent expirations of several drugs and rising pricing pressure on its U.S. diabetes franchise.

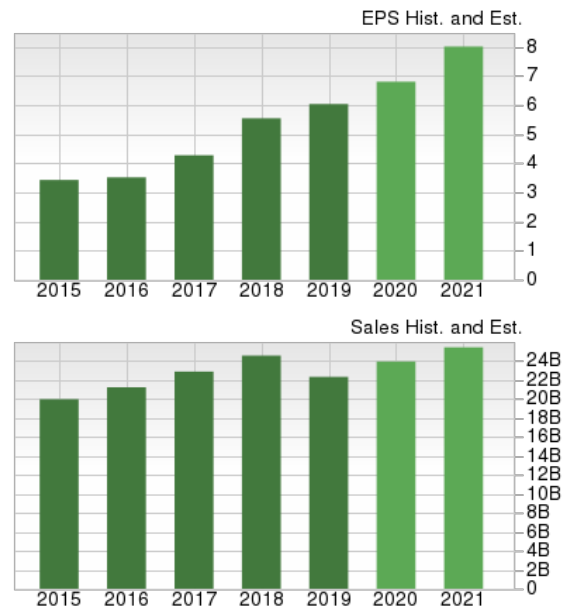
Its pharmaceutical product categories are neuroscience (Zyprexa, Cymbalta, Emgality), diabetes (Humalog, Humulin, Trulicity and others), oncology (Alimta, Cyramza, Verzenio), immunology (Taltz and Olumiant) and others (Cialis).

Over the past few years, Lilly has been actively seeking acquisitions and in-licensing deals to boost its product portfolio and pipeline. The \$6.5 billion purchase of ImClone Systems in November 2008 brought with it blockbuster cancer compound, Erbitux. The January 2007 acquisition of ICOS Corporation gave Lilly full control over erectile dysfunction drug, Cialis. Its other acquisitions include Hypnion, Inc. (a neuroscience drug discovery company focused on sleep disorders), CoLucid Pharmaceuticals (which added lasmiditan for acute migraine) and Loxo Oncology (added selpercatinib for RET-altered lung and thyroid cancers).

Lilly has collaboration agreements with several companies including Pfizer (tanezumab), Incyte (Olumiant), Boehringer Ingelheim (diabetes), among others.

Lilly divested its Elanco animal health unit as an independent publicly traded company - Elanco Animal Health Incorporated - via an initial public offering (IPO) of a minority stake in 2018. Elanco Animal Health started trading with the ticker symbol ELAN on NYSE from Sep 20. Lilly divested the remaining 80.2% stake in the new company through a "tax-efficient transaction" in March 2019.

Lilly's 2019 revenues increased 4% to \$22.3 billion. Among the key drugs, Trulicity accounted for 18% of Lilly's 2019 revenues, Humalog accounted for around 13%, Alimta accounted for 9% and Taltz accounted for 6% of the top line.



Reasons To Buy:

▲ **Shares Outperforming Industry:** Lilly's share price has risen 19.6% this year so far, outperforming the industry's increase of 0.9%.

▲ **Key Products Target a Wide Range of Therapeutic Areas:** Lilly boasts of a wide range of products that serve a vast number of therapeutic areas. The company focuses primarily on central nervous system disorders, metabolic diseases, autoimmune diseases, cardiovascular diseases and cancer, which are all high growth areas and represent significant commercial potential.

▲ **Successful Diabetes Business:** Lilly has a strong portfolio of medicines to treat diabetes that includes drugs like Tradjenta, Jardiance, Trulicity, Synjardy, Synjardy XR, Glyxambi (a fixed dose combination of Jardiance/metformin), Basalgar and Humalog U-200 KwikPen. Trulicity, its highest revenue generating product, recorded sales of \$4.1 billion in 2019. With the inclusion of the cardiovascular indication in Jardiance's label in 2017, there has been a surge in the drug's sales. Lilly is also developing an automated insulin delivery system (phase II) to automate insulin dosing in type I diabetes in order to make diabetes management easier. It also launched Insulin Lispro, a lower priced version of Humalog in the United States in May 2019 and lower-priced versions of Humalog Mix75/25 and KwikPen and Humalog Junior KwikPen in April.

▲ **Working on Building Its Pipeline:** Lilly has been working on building its pipeline and has a wide range of compounds in different stages of development. Lilly believes it has the potential to launch 20 new products in a 10-year time frame from 2014 through 2023. The company is also looking to launch an average of two new indications or line extensions for approved products every year during this time period.

Lilly's key areas of focus are diabetes, oncology, immunology and neurodegeneration. Notable pipeline agents include tanezumab (osteoarthritis pain – under review in United States and Europe), mirikizumab (psoriasis – phase III, ulcerative colitis – phase III and Crohn's disease – phase III), Lyumjev/Ultra-rapid Lispro/ultra-rapid acting insulin (type I and type II diabetes – under review in the U.S. and approved in EU), an oral RET inhibitor, selpercatinib (RET-altered lung and thyroid cancers - under review in United States (PDUFA Date in Q3) and Europe; naive RET fusion-positive NSCLC and RET-mutant medullary thyroid cancer - phase III) and lebrikizumab (atopic dermatitis – phase III). A novel diabetes candidate in Lilly's pipeline is tirzepatide, a dual GIP and GLP-1 receptor agonist (GIP/GLP-1 RA), which showed impressive blood sugar reductions and weight loss in type II diabetes patients in October. Phase III studies began in late 2018. The company also plans to initiate a cardiovascular outcome study for tirzepatide in 2020. Tirzepatide is also in phase III studies for obesity and phase II in NASH.

New drugs, Olumiant (in Europe) for rheumatoid arthritis, Verzenio (abemaciclib) for metastatic breast cancer, and Emgality (galcanezumab), its CGRP antibody, for the preventive treatment of migraine are off to strong starts. In July 2019, Lilly gained FDA approval for Baqsim, its glucagon nasal powder to treat severe hypoglycemia in diabetes patients. Baqsim is the first and only nasally administered glucagon to be approved by the FDA. In October 2019, the FDA granted approval to Lilly's Reyvow (lasmiditan) oral tablets to treat acute migraine, thus boosting its portfolio of pain medicines. In 2020, Lilly expects to launch two medicines, selpercatinib and Lyumjev/Ultra-rapid Lispro.

Meanwhile, relatively newer drugs are also being evaluated for additional indications/label expansions. These include Taltz (ixekizumab) (approved for axial spondyloarthritis in August 2019 and launched for psoriatic arthritis in 2017/2018), Cyramza (under review in United States for first-line EGFR mutation positive NSCLC), and Verzenio (phase III for adjuvant breast cancer). Meanwhile, two phase III EMPEROR studies (outcomes studies) of Jardiance for chronic heart failure and a phase III study for chronic kidney disease are also ongoing. Olumiant is under review in Europe and Japan for atopic dermatitis and will be filed for the same in the United States later in 2020. It is also being studied in phase III studies for systemic lupus erythematosus.

▲ **Committed to Dividend and Cost Savings:** Even though quite a few of Lilly's drugs are facing generic competition, the company returned to annual dividend hikes in December 2016 and regularly returns excess cash through share repurchases. Cash distribution to shareholders, through dividends and share buybacks, was around \$2.6 billion in 2017, \$1.7 billion in 2018 and \$7 billion in 2019.

Lilly is actively pursuing in-licensing deals and acquisitions to drive near-to-medium term growth. The company is also resorting to cost cutting and headcount reduction to drive the bottom line. Lilly is regularly investing the savings in new drugs and overall growth of the company.

▲ **Emerging Markets and Japan to Drive Long-Term Growth:** Lilly is looking toward Japan and emerging markets to drive growth in the coming years. Cyramza and Verzenio are bringing in robust sales in Japan given high unmet need. The company also launched Trulicity, Taltz, Jardiance and Olumiant in Japan, which are driving sales growth in the country.

In 2020, Lilly's sales should be driven by higher demand for newer drugs including Trulicity, Taltz, Basaglar, Emgality and also newly launched Baqsimi and Reyvow.

Risks

- **Generic Threat to Key Products:** We are concerned about the patent expiration faced by several products in Lilly's portfolio. Products like Zyprexa, Cymbalta, Evista, and Gemzar are all facing declining sales due to generic competition. In 2017, Lilly lost patent protection for key drugs like Strattera, Axiron and Effient in the United States, which resulted in generic competition and consequent loss of sales. Lilly lost exclusivity for Cialis in September 2018 and generic versions entered the market in the same month resulting in rapid erosion of sales. Lilly lost exclusivity for Forteo in August 2019, making way for generic competition. Alimta sales outside the United States are being hurt due to loss of exclusivity in several countries. The drug's U.S. sales are also being affected by the entry of immuno-oncology agents in the market. The compound patent for Alimta expired in the United States in January 2017 and in major European countries and Japan in December 2015. Many generic manufacturers are looking for approval of generic versions of Alimta prior to the expiration of the vitamin regimen patent (expiring in June 2021 in Japan and European countries and in the United States in May 2022). Generic competition for Alimta following the loss of effective patent protection will cause a rapid decline in revenues from the product.
- **Pipeline Setbacks:** Lilly has had its share of development and regulatory setbacks. In October 2015, Lilly announced the termination of the development of its late-stage CETP inhibitor, evacetrapib. Lilly's decision was based on the recommendation of an independent data monitoring committee, which suggested that chances of meeting the primary endpoint were low.

In November 2016, Lilly's key candidate solanezumab failed to meet the primary endpoint in a late-stage study that was conducted in patients with mild dementia due to AD. Lilly decided to drop the development of solanezumab. In June 2018, Lilly discontinued two late-stage studies on Alzheimer's disease lanabecestat on recommendation of the independent data monitoring committee (IDMC).

In early 2018, Lartruvo, which had won conditional approval in 2016, failed to improve survival in patients with advanced soft tissue sarcoma in a late-stage confirmatory study, ANNOUNCE. With ANNOUNCE failing to confirm clinical benefit, Lilly stopped promoting Lartruvo, which sharply hurt sales of the drug in 2019.

- **Intense Competition:** In addition to generic threats, Lilly's products already face intense competition in the market from both large pharma companies as well as small and mid-sized companies. Competition for Lilly's diabetes care products has increased with the entry of Novo Nordisk's Victoza. Novo Nordisk's Ozempic/semaglutide, which was launched in 2018, is posing strong competition to Lilly's key growth driver, Trulicity. In fact, Lilly is seeing pricing pressure across all its diabetes products, which creates uncertainty around the franchise's long-term growth prospects. A number of competitors are entering the diabetes space. For example, with the approval of Merck/Pfizer's, Steglatro and its combinations, competition in the SGLT2 inhibitors class has increased.

Meanwhile, cancer drugs like Alimta and Cyramza are being impacted by competition from immuno-oncology agents in the United States. Meanwhile, Sanofi's biosimilar version of Humalog - Admelog – can create pricing pressure on Lilly's branded drug and erode its market share. Admelog was launched in 2018.

Last Earnings Report

Lilly Q1 Earnings Beat, Coronavirus May Mar Profits

Lilly reported first-quarter 2020 adjusted earnings per share of \$1.75, which comprehensively beat the Zacks Consensus Estimate of \$1.55. Earnings rose 32% year over year as higher R&D costs were offset by higher revenues.

Revenues in Detail

Revenues of \$5.86 billion beat the Zacks Consensus Estimate of \$5.51 billion. Sales grew 15% year over year (16% in constant currency), backed by strong volume trends, which offset the impact of lower realized prices.

Lower realized prices had a negative impact of 6% on sales. Volumes rose 22%, gaining from strong underlying demand trends for key growth products, augmented by higher patient and supply chain purchasing as people stocked medicines amid coronavirus-led lockdown. The coronavirus-related stockpiling mainly of Lilly's diabetes medicine, Trulicity and psoriasis medicine, Taltz increased Lilly's worldwide revenues by approximately \$250 million. Higher volumes of key growth products, namely Trulicity, Taltz, Jardiance, Basaglar, Emgality, and Verzenio compensated for lower sales of older products like Cialis and Forteo due to loss of exclusivity.

Foreign exchange had a modest negative impact on revenue growth this quarter.

Key growth products (products launched since 2014) drove 19% of revenue growth and represented nearly 51% total revenues, up from 46% in the previous quarter.

U.S. revenues rose 15% to \$3.33 billion while ex-U.S. revenues rose 15% to \$2.53 billion.

Among the established products, Forteo sales declined 13% to \$272.4 million. Humalog sales dropped 5% to \$695.8 million. Humulin sales rose 6% to \$315.7 million. Alimta sales rose 12% to \$560.1 million.

Among the growth products, Trulicity generated revenues of \$1.23 billion, up 40% year over year driven by higher volumes in the United States as well as ex-U.S. markets, which offset the impact of lower realized prices. COVID-19 related increased customer buying patterns and patient prescription trends benefited U.S. Trulicity sales by approximately \$30 million to \$40 million in the quarter.

Cyramza revenues were \$239.0 million, up 21% year over year driven by higher volumes in both U.S. and international markets.

Jardiance sales rose 31% to \$267.5 million, driven by increased demand trends within the SGLT2 class of diabetes medicines in the United States and increased volume outside the United States.

Basaglar recorded revenues of \$303.7 million, up 21% year over year driven by higher volumes in both U.S. and international markets.

Taltz brought in sales of \$443.5 million, up 76% year over year as U.S. sales gained from higher demand and higher realized prices due to changes in estimates for rebates and discounts. Ex-U.S. sales were driven by increased volume, which offset the impact of lower realized prices. U.S. revenues for Taltz were favorably impacted by approximately \$20 million to \$25 million due to COVID-19.

Olumiant generated sales of \$139.7 million in the quarter compared with \$127.8 million in the previous quarter, backed by increased demand in international markets. Revenues outside the United States were \$128.4 million compared with \$114.9 million in the previous quarter. In the United States, Olumiant recorded sales of \$11.3 million compared with \$13.0 million in the previous quarter.

Verzenio generated sales of \$188.0 million in the quarter, up from \$179.1 million in the previous quarter driven by increased volume.

Emgality generated revenues of \$74.0 million in the quarter compared with \$66.3 million in the previous quarter. In the United States, Emgality sales were \$67.3 million compared with \$63.1 million in the previous quarter. Ex U.S. sales were \$6.7 million in the first quarter.

Lilly's newly launched product, Baqsimi, which is a glucagon nasal powder to treat severe hypoglycemia in diabetes patients, generated sales of \$17.8 million in the quarter.

Gross Margin & Operating Income

Adjusted gross margin was 80.3% in the quarter, up 10 basis points driven by favorable product mix and manufacturing efficiencies, which were partially offset by price and increased costs associated with COVID-19.

Operating income rose 32% year over year to \$1.76 billion. Operating margin was 30.1% in the quarter, up 390 bps year over year, gaining from impact of COVID-19 buying patterns.

Total operating expenses (including research and development and marketing, selling and administrative expenses) rose 7% in the quarter. Marketing, selling and administrative expenses rose 2% to \$1.55 billion due to cost control, partially offset by increased investment behind recent launches. R&D expense rose 13% to \$1.39 in the quarter due to higher development expenses for late-stage assets.

Adjusted effective tax rate was 13.6%, higher than 12.9% in the year-ago quarter.

2020 Guidance

However, despite the solid first-quarter results, the company maintained its full-year revenue guidance as it expects the coronavirus-related

Quarter Ending 03/2020

Report Date	Apr 23, 2020
Sales Surprise	6.32%
EPS Surprise	12.90%
Quarterly EPS	1.75
Annual EPS (TTM)	6.46

benefits seen in the first quarter to reverse over the course of 2020.

Importantly, Lilly warned that the economic consequences of the pandemic are uncertain and could hurt its profits in the future quarters of 2020 and potentially in 2021. In fact, reduced non-COVID healthcare activities due to business disruptions and global economic challenges emanating from the pandemic may hurt its profits, going forward. Lilly expects reduction in new prescription trends (as fewer patients visit a doctor) to be most significant in the second quarter in the United States and most European countries. The company expects headwinds from destocking as supply chains normalize from the recent demand surge and potential changes in segment mix in the United States due to rising unemployment in 2020.

Lilly upped the higher end of its 2020 adjusted earnings guidance from a range of \$6.70-\$6.80 per share to \$6.70 - \$6.90 to reflect the uncertainty of the impact of COVID-19 for the rest of the year. This indicates year-over-year growth in the range of 11% to 14%. However, the 2020 revenue guidance was maintained in the range of \$23.7 billion-\$24.2 billion. Gross margin guidance was maintained at approximately 81%. Adjusted tax rate is expected to be approximately 15%. Adjusted operating margin is expected to be 31% in 2020 (maintained).

The other expense guidance was lowered from a range of 100 million-250 million to \$0-150 million.

Marketing, selling and administrative expense guidance was maintained in the range of \$6.2 to \$6.4 billion. Research and development expense is still expected to be in the range of \$5.6 billion to \$5.9 billion.

Nonetheless, Lilly still expects revenue growth to be driven by higher demand for its growth drugs including Trulicity, Taltz, Basaglar, Jardiance, Verzenio, Cyramza, Olumiant, Emgality, Baqsimi as well as potential revenues from new product launches. However, generic competition for several drugs, rising pricing pressure in the United States due to rebates and legislated increases in Medicare Part D cost sharing, price reductions from increased utilization of patient affordability programs, and price cuts in some international markets like China, Japan and Europe are some top-line headwinds expected in 2020. In the United States, prices are still expected to decline in a low-single digit range.

Coronavirus Related Research Efforts

Earlier in April, Lilly announced that the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH), will evaluate Olumiant (baricitinib), as a potential treatment for hospitalized patients diagnosed with COVID-19. The drug will be evaluated in one of the arms of NIAID's Adaptive COVID-19 Treatment study. The study will first begin in April in the United States and then expand to additional sites in Europe and Asia. Data from the studies are expected in two months' time.

Alongside, Lilly has begun a phase II study on LY3127804, its monoclonal antibody that inhibits Angiotensin 2 (Ang2), in pneumonia patients hospitalized with COVID-19 who are at a higher risk of progressing to acute respiratory distress syndrome. The phase II study is already enrolling patients in the United States and data from the study is expected in the coming months.

In March, Lilly signed a deal with private biotech, AbCellera to co-develop antibody therapies to treat and prevent COVID-19. Lilly is working with AbCellera, NIH and academic partners to characterize virus-neutralizing antibodies isolated from the blood sample of a U.S. COVID-19 patient who recovered from the disease. The most advanced antibody in this program has now entered GMP manufacturing. Lilly plans to submit an IND to the FDA by the end of May to allow start of clinical testing in patients

Last month, Lilly halted enrollment in most ongoing studies and said that it will delay new study starts in order to allow doctors and healthcare facilities to focus on efforts to combat COVID-19. Along with the earnings release, Lilly clarified that enrollment in ongoing studies and new clinical study starts will resume in the second half of the year.

Recent News

Launches Cheaper Versions of Humalog KwikPen Insulins — Apr 16

Lilly announced that lower-priced versions of two of its insulin products, Humalog Mix75/25 KwikPen and Humalog Junior KwikPen are now available for order by U.S. pharmacies. The list price of these low-priced insulin injections is 50% lower than the current list price of the branded options. The lower-priced version of Humalog Mix75/25 are known as Insulin Lispro Protamine and Insulin Lispro Injectible Suspension Mix75/25 KwikPen (100 units/mL) while that of Humalog Junior KwikPen is known as Insulin Lispro Injection Junior KwikPen. The cheaper KwikPens pack of five will cost \$265.20.

Olumiant to Be Studied for Severe Coronavirus – Apr 10

Lilly announced that the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH), will evaluate its JAK inhibitor, Olumiant (baricitinib), as a potential treatment for hospitalized patients diagnosed with COVID-19. The drug will be evaluated in one of the arms of NIAID's Adaptive COVID-19 Treatment study, which will evaluate Olumiant, now marketed for rheumatoid arthritis, as a potential treatment for hospitalized patients diagnosed with COVID-19. The study will first begin this month in the United States and then expand to additional sites in Europe and Asia. Data from the studies are expected in two months' time.

Alongside, Lilly announced that it will advance LY3127804, its monoclonal antibody that inhibits Angiopoietin 2 (Ang2), to phase II studies in pneumonia patients hospitalized with COVID-19 who are at a higher risk of progressing to acute respiratory distress syndrome (ARDS). The phase II studies will begin later in April. Ang2 is found in high levels in ARDS patients and the study will test if LY3127804 can inhibit the effects of Ang2 and reduce the progression to ARDS or the need for mechanical ventilation in COVID-19 patients

Medical Service Volunteer Programs – Apr 1

Lilly, along with other Pfizer and Merck announced medical service volunteer programs. The programs will enable their employees who are licensed medical professionals to offer their services in the fight against COVID-19 for a longer period of time than normally allowed.

Collaboration with Sitryx – Mar 31

Lilly announced collaboration with small biotech, Sitryx to study up to four novel preclinical targets, identified by the latter, which can be developed into new medicines for autoimmune diseases. For the research and license collaboration, Lilly will make an upfront payment of \$50 million to Sitryx while also investing \$10 million in its stock. Lilly will also be entitled to pay potential development milestones up to \$820 million to Sitryx, as well as commercialization milestones and royalty payments on potential sales in the mid- to high-single digit range

FDA Approves Taltz for Pediatric Patients – Mar 30

Lilly announced that the FDA has approved a supplemental biologics license application (sBLA) for its psoriasis drug Taltz (ixekizumab). Taltz injection (80 mg/mL) is now approved for the treatment of pediatric patients (aged from six to below 18 years) with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy. Following this nod, Taltz became the first and the only IL-17A antagonist to be approved to treat the given patient population.

Halts Enrollment in Ongoing Studies; Delays New Study Starts – Mar 23

Lilly announced that it is halting enrollment in most ongoing studies and will delay new study starts in order to allow doctors and healthcare facilities to focus on efforts to combat the coronavirus disease, COVID-19. However, ongoing studies where patients are already enrolled will continue.

The coronavirus pandemic has compelled healthcare systems to prioritize caring for the COVID-19 patients while limiting other activities. Along the same lines, Lilly laboratories have diverted resources to conduct diagnostic testing for COVID-19 patients and are researching potential treatments for the disease.

Meanwhile, Lilly said it is keeping its previously issued 2020 financial guidance intact. The drugmaker expects no delay in the timeline of the ongoing late-stage studies, except those on mirikizumab for gastrointestinal (GI) indications

CRL for Jardiance in Type I Diabetes Indication – Mar 20

Lilly announced that the FDA has issued a complete response letter ("CRL") for its supplemental new drug application (sNDA) seeking label expansion of Jardiance (empagliflozin) 2.5 mg for type I diabetes. Please note that Jardiance is already marketed for treating type II diabetes.

The sNDA filed by Lilly and partner Boehringer Ingelheim sought approval for empagliflozin as an adjunct to insulin for treating type I diabetes patients, under a separate brand name. The FDA stated in its CRL that it was unable to approve empagliflozin's sNDA in its current form.

The FDA's Endocrinologic and Metabolic Drugs Advisory had voted against the label expansion in November last year, suggesting that the benefits of Jardiance 2.5 mg do not outweigh the risks to support approval for the indication.

The sNDA included data from two phase III studies under the EASE program. Data from the EASE studies have shown that empagliflozin 2.5 mg plus insulin led to a statistically significant reduction in A1C versus plus placebo. Meanwhile, empagliflozin treatment led to reduction in weight and decrease in systolic blood pressure, which were the secondary endpoints.

Valuation

Lilly's shares are up 19.6% in the year-to-date period and 34.4% over the trailing 12-month period. While stocks in the Zacks sub-industry are up 0.9%, that in the sector are down 2.1% in the year-to-date period. Over the past year, stocks in the sub-industry and sector are up 12.4% and 2.5%, respectively.

The S&P 500 Index is down 10.9% in the year-to-date period and 2.7% in the past year.

The stock is currently trading at 21.9X forward 12-month earnings per share which compares to 15.18X for the Zacks sub-industry, 22.05X for the Zacks sector and 20.2X for the S&P 500 Index.

Over the past five years, the stock has traded as high as 26.2X and as low as 14.92X, with a 5-year median of 19.47X. Our Outperform recommendation indicates that the stock will perform better than the market. Our \$181 price target reflects 25.2X forward 12-month earnings per share.

The table below shows summary valuation data for LLY.

Valuation Multiples - LLY					
		Stock	Sub-Industry	Sector	S&P 500
P/E F12M	Current	21.9	15.18	22.05	20.2
	5-Year High	26.2	18.12	22.05	20.2
	5-Year Low	14.92	13.04	15.81	15.19
	5-Year Median	19.47	15.38	18.81	17.45
P/S F12M	Current	6.21	4.74	2.78	3.22
	5-Year High	6.43	4.83	3.84	3.44
	5-Year Low	3.41	3.92	2.25	2.54
	5-Year Median	4.21	4.39	2.96	3.01
P/B TTM	Current	55.78	5.4	3.8	3.81
	5-Year High	57.96	7.19	5.04	4.54
	5-Year Low	4.79	3.8	3.02	2.9
	5-Year Median	6.43	5.21	4.29	3.65

As of 4/28/2020

Industry Analysis Zacks Industry Rank: Top 8% (20 out of 253)



Top Peers

Company (Ticker)	Rec	Rank
Sanofi (SNY)	Outperform	3
AbbVie Inc. (ABBV)	Neutral	3
AstraZeneca PLC (AZN)	Neutral	3
Bristol-Myers Squibb Company (BMY)	Neutral	2
GlaxoSmithKline plc (GSK)	Neutral	3
Merck & Co., Inc. (MRK)	Neutral	2
Novo Nordisk A/S (NVO)	Neutral	3
Novartis AG (NVS)	Neutral	3

Industry Comparison Industry: Large Cap Pharmaceuticals				Industry Peers		
	LLY	X Industry	S&P 500	AZN	BMY	NVO
Zacks Recommendation (Long Term)	Outperform	-	-	Neutral	Neutral	Neutral
Zacks Rank (Short Term)	1	-	-	3	2	3
VGM Score	C	-	-	C	B	C
Market Cap	150.54 B	140.28 B	20.14 B	133.76 B	140.28 B	152.95 B
# of Analysts	6	2.5	14	5	5	3
Dividend Yield	1.88%	2.51%	2.13%	3.65%	2.90%	1.74%
Value Score	B	-	-	C	B	C
Cash/Price	0.02	0.06	0.06	0.05	0.11	0.02
EV/EBITDA	24.99	13.63	12.15	21.32	25.04	17.31
PEG Ratio	2.18	2.02	2.43	1.60	1.19	2.27
Price/Book (P/B)	55.96	4.24	2.68	9.16	2.68	17.72
Price/Cash Flow (P/CF)	22.21	11.28	10.78	16.09	14.15	22.87
P/E (F1)	23.10	14.66	19.06	25.36	10.18	24.01
Price/Sales (P/S)	6.52	4.22	2.12	5.49	5.37	8.36
Earnings Yield	4.33%	6.82%	5.11%	3.94%	9.82%	4.16%
Debt/Equity	5.30	0.57	0.72	1.11	0.84	0.05
Cash Flow (\$/share)	7.08	4.33	7.01	3.17	4.39	2.82
Growth Score	C	-	-	D	B	C
Hist. EPS Growth (3-5 yrs)	16.98%	8.34%	10.88%	-2.79%	20.53%	8.20%
Proj. EPS Growth (F1/F0)	12.72%	4.77%	-6.33%	14.86%	30.15%	9.35%
Curr. Cash Flow Growth	-7.51%	4.27%	5.92%	2.12%	36.74%	-0.50%
Hist. Cash Flow Growth (3-5 yrs)	9.27%	7.62%	8.55%	-0.86%	22.46%	7.63%
Current Ratio	1.16	1.26	1.23	0.86	1.60	1.06
Debt/Capital	84.13%	39.95%	43.90%	52.63%	45.63%	4.97%
Net Margin	23.97%	22.40%	11.13%	5.38%	13.15%	31.95%
Return on Equity	197.26%	32.05%	16.47%	32.24%	31.85%	73.70%
Sales/Assets	0.60	0.48	0.55	0.40	0.38	1.02
Proj. Sales Growth (F1/F0)	7.23%	5.31%	-1.35%	7.66%	58.09%	6.61%
Momentum Score	D	-	-	A	D	B
Daily Price Chg	-2.47%	-1.10%	1.10%	-0.99%	-0.67%	-0.84%
1 Week Price Chg	3.59%	1.87%	-1.74%	2.30%	2.72%	2.92%
4 Week Price Chg	13.39%	13.39%	11.80%	14.13%	11.48%	7.29%
12 Week Price Chg	9.66%	-1.90%	-17.28%	4.53%	-3.34%	4.87%
52 Week Price Chg	34.40%	7.07%	-10.69%	35.34%	33.84%	31.79%
20 Day Average Volume	3,607,761	3,607,761	2,660,864	3,981,195	14,128,653	2,450,848
(F1) EPS Est 1 week change	0.54%	0.00%	0.00%	0.00%	0.00%	0.12%
(F1) EPS Est 4 week change	0.57%	-1.44%	-6.46%	0.10%	-0.43%	-3.35%
(F1) EPS Est 12 week change	0.63%	-1.86%	-12.81%	-3.83%	0.89%	-4.72%
(Q1) EPS Est Mthly Chg	-6.63%	-5.35%	-10.84%	-4.00%	-3.29%	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.

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

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

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