

Exelixis, Inc.(EXEL)

\$24.79 (As of 07/21/20)

Price Target (6-12 Months): **\$27.00**

Long Term: 6-12 Months

Zacks Recommendation:

Neutral

(Since: 10/03/19)

Prior Recommendation: Outperform

Short Term: 1-3 Months

Zacks Rank: (1-5)

3-Hold

Zacks Style Scores:

VGM:C

Value: B

Growth: D

Momentum: A

Summary

Exelixis' lead drug, Cabometyx, continues to gain traction in both indications — RCC and HCC. While demand for the RCC indication has been strong, the initial traction for the HCC indication in second and third-line settings was encouraging. The company is on track to expand cabozantinib's label and the drug is already being evaluated in various studies with Tecentriq and Opdivo. Successful outcomes from these ongoing studies should boost growth prospects further. Exelixis has collaborations with several leading pharmaceuticals, such as Bristol-Myers, which bode well. However, the company is heavily dependent on Cabometyx for growth. Competition has stiffened with the approval of Opdivo + Yervoy in first-line RCC and other treatments and will affect sales. Shares have outperformed the industry in the past year.

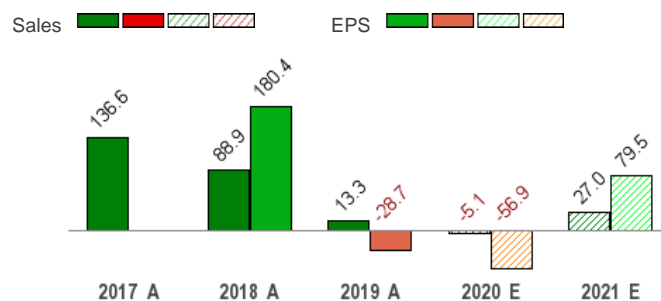
Price, Consensus & Surprise



Data Overview

52 Week High-Low	\$27.80 - \$13.67
20 Day Average Volume (sh)	2,231,851
Market Cap	\$7.9 B
YTD Price Change	45.3%
Beta	1.54
Dividend / Div Yld	\$0.00 / 0.0%
Industry	Medical - Biomedical and Genetics
Zacks Industry Rank	Top 37% (93 out of 252)

Sales and EPS Growth Rates (Y/Y %)



Last EPS Surprise	15.4%
Last Sales Surprise	6.8%
EPS F1 Est- 4 week change	0.0%
Expected Report Date	07/29/2020
Earnings ESP	0.8%
P/E TTM	27.5
P/E F1	56.3
PEG F1	1.2
P/S TTM	8.0

Sales Estimates (millions of \$)

	Q1	Q2	Q3	Q4	Annual*
2021	254 E	277 E	298 E	318 E	1,167 E
2020	227 A	232 E	230 E	241 E	919 E
2019	215 A	240 A	272 A	240 A	968 A

EPS Estimates

	Q1	Q2	Q3	Q4	Annual*
2021	\$0.13 E	\$0.15 E	\$0.19 E	\$0.22 E	\$0.79 E
2020	\$0.15 A	\$0.12 E	\$0.10 E	\$0.09 E	\$0.44 E
2019	\$0.27 A	\$0.25 A	\$0.31 A	\$0.22 A	\$1.02 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 07/21/2020. The reports text is as of 07/21/2020.

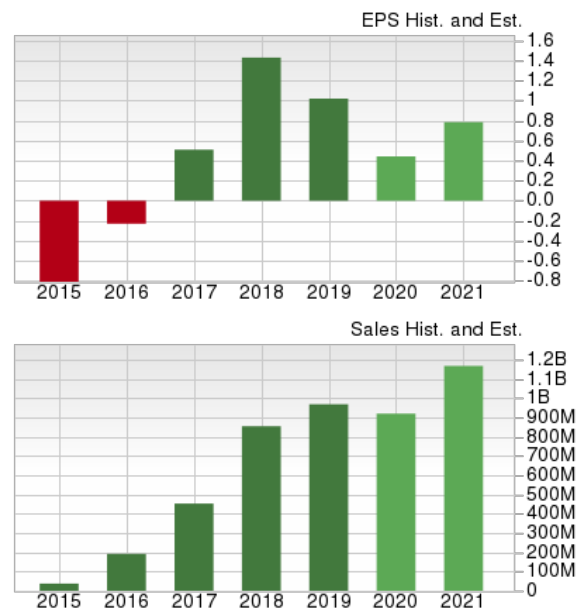
Overview

San Francisco, CA-based Exelixis, Inc. is an oncology-focused biotechnology company, which primarily focuses on the discovery, development and commercialization of new drugs for the treatment of difficult cancers.

The company has four approved drugs in its portfolio. Of these, two are derived from cabozantinib, the company's flagship molecule, which an inhibitor of multiple tyrosine kinases, including MET, AXL, VEGF receptors and RET. The approved drugs are Cabometyx (cabozantinib) tablets approved for advanced renal cell carcinoma (RCC) and previously treated hepatocellular carcinoma (HCC); Cometriq (cabozantinib) capsules approved for progressive, metastatic medullary thyroid cancer (MTC); Cotellic (cobimetinib), an inhibitor of MEK approved as part of a combination regimen to treat advanced melanoma, marketed under a collaboration with Genentech, Inc. (a member of the Roche Group) (Genentech); and Minnebro (esaxerenone), an oral, non-steroidal, selective blocker of the mineralocorticoid receptor (MR) approved for the treatment of hypertension in Japan and licensed to Daiichi Sankyo Company, Limited (Daiichi Sankyo).

Exelixis has a licensing agreement with Ipsen, under which the latter has exclusive commercialization rights for current and potential future indications of cabozantinib outside the United States, Canada and Japan. The company also has collaborations with other leading pharmaceutical and biotechnology companies such as Bristol-Myers, Sanofi, Merck and Daiichi Sankyo for various compounds and programs in its portfolio.

The company earns revenues through milestones and royalty payments from these collaborations. Revenues in 2019 came in at \$967.8 million, up from \$853.8 million in 2018.



Reasons To Buy:

▲ **Share Price Performance:** Exelixis' stock has outperformed the industry in the past year.

▲ **Cabometyx Performance Impressive:** The uptake of Cabometyx, a tablet formulation of cabozantinib, for the treatment of patients with advanced RCC who have received prior anti-angiogenic therapy since its approval (April 2016), has been strong. The drug's label was further expanded to include previously-untreated, advanced RCC patients, which has boosted demand. Kidney cancer is among the top ten most commonly diagnosed forms of cancer among both men and women in the United States and RCC is the most common form of kidney cancer in adults. Since the drug is now approved for first-line RCC as well, Exelixis can now target the entire patient population suffering from the disease in the United States. Meanwhile, Exelixis' European partner, Ipsen, also obtained approval for the drug in the region for the first-line treatment of adults with intermediate- or poor-risk advanced RCC. In October 2019, Ipsen announced Health Canada's approval of Cabometyx for the first-line treatment of adults with advanced RCC. The approval has broadened the geographic reach of the drug and targeted patient population.

The approval of Cabometyx for RCC is a great boost for the company. The company's efforts to develop cabozantinib for various other indications are also encouraging.

The drug is also approved as a monotherapy for HCC in adults in Europe who have previously been treated with Bayer's Nexavar. The FDA also approved Cabometyx for HCC. Sales should get a boost from this label expansion, given the market potential. In November 2019, it was approved in Canada for HCC.

▲ **Developing Cabozantinib for Additional Indications:** Exelixis is working on expanding cabozantinib's label further. The candidate is being evaluated in a broad development program comprising more than 85 clinical studies across multiple indications both as single agent and in combination with other drugs. The successful development of the drug for additional indications will propel sales further. CheckMate -9ER, a phase III study evaluating Opdivo in combination with Cabometyx compared to Sutent in previously untreated advanced or metastatic RCC met its primary endpoint of progression-free survival (PFS) at final analysis, as well as the secondary endpoints of OS at a pre-specified interim analysis, and objective response rate (ORR).

▲ **Collaborations with Leading Companies:** Exelixis has collaborations with several leading pharmaceuticals such as Bristol-Myers Squibb, Merck and Daiichi Sankyo Company for various compounds and programs in its portfolio. These collaborations allow Exelixis to earn milestone payments and royalties that boost its top line. Exelixis also has an exclusive licensing agreement with Ipsen for the commercialization and further development of cabozantinib. Per the terms of the agreement, Ipsen enjoys exclusive commercialization rights for all current and potential future indications of the drug outside the United States, and Japan. The companies will jointly work on the development of cabozantinib for current and potential future indications. Exelixis, on the other hand, will retain rights to commercialize the drug in the United States. This agreement was recently amended and Ipsen was granted rights in Canada also. Daiichi Sankyo launched Minnebro tablets as a treatment for patients with hypertension in Japan. Consequently, Exelixis received an associated \$20-million milestone payment from Daiichi Sankyo with the first commercial sale of Minnebro. In 2017, Exelixis signed collaboration agreements with Bristol-Myers Squibb and Roche to evaluate cabozantinib in combination with immunotherapy agents.

Exelixis has also collaborated with Roche to evaluate Cabometyx in combination with the latter's PD-L1 immune checkpoint inhibitor, Tecentriq, in patients with advanced non-small cell lung cancer (NSCLC), castration-resistant prostate cancer (CRPC) and renal cell carcinoma (RCC). All three studies have been initiated.

In July, Exelixis announced an exclusive collaboration, option and license agreement with Aurigene, an India-based biotechnology company focused on oncology and inflammatory disorders, to in-license as many as six programs. Per the agreement, Exelixis made an upfront payment of \$10.0 million for exclusive options to license three pre-existing programs from Aurigene. The companies selected three additional Aurigene-led drug discovery programs on mutually agreed upon targets, in exchange for supplemental option payments totaling \$7.5 million.

In October 2019, Exelixis expanded its collaboration with Invenra to include the development of novel binders against six additional targets. Under the terms of the expanded collaboration agreement, Exelixis will have the opportunity to use these binders to generate multispecific antibodies based on Invenra's B-Body technology platform, or with other platforms and formats, at Exelixis' option.

Reasons To Sell:

▼ **Heavily Dependent on the success of Cabometyx for RCC:** The company is heavily dependent on Cabometyx for growth now and the drug might not be able to capture market share, given the competition. Additionally, given the market potential, most pharma/biotech bigwigs are scurrying to grab a larger chunk of this pie. Evidently, the focus is on better and effective treatments. The focus, of late, has shifted to checkpoint inhibitor-containing regimens in combination with a TKI as the first-line option for RCC patients. Merck's PD-L1 inhibitor, Keytruda, is approved in combination with Pfizer's Inlyta for the first-line treatment of advanced RCC. In May, the FDA approved the combination regimen of Bavencio (avelumab) and Inlyta for the first-line treatment of patients with advanced RCC. In particular, competition has stiffened with the approval of Opdivo and Yervoy for the treatment of poor and intermediate risk first-line RCC.

▼ **Pipeline Setbacks:** Exelixis is not new to pipeline setbacks. The company suffered a setback in 2014 when two phase III studies (COMET-1 and COMET-2) on Cometriq for the treatment of metastatic castration-resistant prostate cancer failed to meet its primary endpoint of an increase in overall survival. Meanwhile, the phase III trial, IMblaze370, evaluating the combination of Cotellic and Tecentriq did not meet its primary endpoint. The trial evaluated the combination in patients with difficult-to-treat, locally advanced or metastatic colorectal cancer (CRC) whose disease had progressed or who were intolerant to at least two systemic chemotherapy regimens. Any further setback in the label expansion of Cometriq will adversely impact the company's growth prospects.

The company is heavily dependent on Cabometyx for growth and failure of the drug to capture additional market share amid increasing competition will be detrimental.

Last Earnings Report

Exelixis Q1 Earnings and Revenues Surpass Estimates

Exelixis reported earnings of 15 cents per share, beating the Zacks Consensus Estimate of 13 cents. The bottom-line figure, however, declined from the year-ago quarter's 24 cents per share due to higher R&D expenses.

Net revenues came in at \$226.9 million, increasing from the \$215.5 million reported in the year-ago quarter. Revenues also beat the Zacks Consensus Estimate of \$212.5 million.

Quarter Ending **03/2020**

Report Date	May 05, 2020
Sales Surprise	6.79%
EPS Surprise	15.38%
Quarterly EPS	0.15
Annual EPS (TTM)	0.93

Quarter in Detail

Net product revenues came in at \$193.9 million, up 7.9% from the year-ago quarter due to an increase in the average net selling price and sales volume.

Lead drug, Cabometyx, is approved in the United States for the treatment of advanced renal cell carcinoma (RCC). The drug was also approved for the treatment of patients with hepatocellular carcinoma, who have been previously treated with sorafenib, in January 2019. The label expansion of the drug into this indication in the United States also boosted product sales.

Cabometyx generated \$189.2 million of revenues. Cometriq (cabozantinib capsules) for the treatment of medullary thyroid cancer generated \$4.7 million in net product revenues. Exelixis earned \$17.9 million in royalty revenues on the basis of cabozantinib-related revenues generated by its partner Ipsen in the first quarter of 2020.

Total collaboration revenues were \$33 million, down from the \$35.9 million recorded in the year-ago quarter.

In the reported quarter, research and development expenses increased significantly to \$101.9 million from the \$63.3 million due to a rise in clinical trial costs and personnel expenses. Selling, general and administrative (SG&A) expenses were \$62.9 million, up from \$60.1 million in the year-ago quarter.

Pipeline Update

In January 2020, Exelixis announced plans to further expand an existing metastatic castration-resistant prostate cancer (mCRPC) cohort (Cohort 6) of COSMIC-021, the phase Ib trial of cabozantinib in combination with Roche's Tecentriq in patients with locally advanced or metastatic solid tumors.

Last month, Exelixis and Bristol-Myers announced that CheckMate -9ER, the phase III study evaluating Opdivo in combination with Cabometyx compared to Sutent in previously untreated advanced or metastatic RCC, met its primary endpoint of progression-free survival at the final analysis as well as the secondary endpoints of overall survival at a pre-specified interim analysis and objective response rate. This preliminary analysis of data showed a favorable safety profile for the combination of a 40 mg dose of cabozantinib with nivolumab, with a low frequency of treatment discontinuations due to adverse events.

2020 Guidance Reiterated

Revenues are projected at \$850-\$900 million, while product revenues are estimated in the range of \$725-\$775 million for 2020. Per the company, the COVID-19 pandemic has had a relatively modest impact on Exelixis' business operations, particularly on the clinical studies and drug discovery activities.

Recent News

Initiates CONTACT-03 – July 20

Exelixis initiated CONTACT-03, a global phase III study of Cabometyx in combination with Tecentriq in patients with inoperable, locally advanced or metastatic renal cell carcinoma (RCC) who progressed during or following treatment with an immune checkpoint inhibitor as the immediate preceding therapy. The study is being conducted as part of a collaboration between Exelixis and Roche.

Initiates CONTACT-02 – Jun 30

Exelixis initiated CONTACT-02, a global phase III study of Cabometyx in combination with Tecentriq in patients with metastatic castration-resistant prostate cancer (CRPC) who have been previously treated with one novel hormonal therapy.

Initiated Cabozantinib, Tecentriq Study – Jun 11

Exelixis initiated phase III study, CONTACT-01, on Cabometyx in combination with Tecentriq in patients with metastatic non-small cell lung cancer (NSCLC) who have been previously treated with an immune checkpoint inhibitor (ICI) and platinum-containing chemotherapy. Two additional phase III pivotal studies in metastatic castration-resistant prostate cancer (CRPC; CONTACT-02) and renal cell carcinoma (RCC; CONTACT-03) are planned as part of the clinical trial collaboration between Exelixis and Roche.

Results From COSMIC-021 Study – May 13

Exelixis announced phase Ib clinical study results for the combination of Cabometyx and Tecentriq in patients with locally advanced or metastatic solid tumors. The data from three expansion cohorts of the COSMIC-021 trial will be presented during the 2020 American Society of Clinical Oncology Virtual Scientific Program (ASCO20). In the study, 27% objective response rate was seen in immune checkpoint inhibitor-pretreated non-small cell lung cancer cohort 7.

Valuation

Exelixis' shares are up 41.3% in the year-to-date period and 15.9% over the trailing 12-month period. Stocks in the Zacks sub-industry and the Zacks Medical sector are up 11.8% in the year-to-date period and 2.3% respectively. Over the past year, the Zacks sub-industry is up 9.8% and the Zacks Medical sector is up 8.9%.

The S&P 500 index is up 1.3% in the year-to-date period and 9.8% in the past year.

The stock is currently trading at 7.46X trailing 12-month sales per share, which compares to 2.59X for the Zacks sub-industry, 2.89X for the Zacks sector and 3.61X for the S&P 500 index.

Over the past five years, the stock has traded as high as 24.16X and as low as 4.45X, with a 5-year median of 8.44X. Our Neutral recommendation indicates that the stock will perform in-line with the market. Our \$27 price target reflects 7.87X trailing 12-month sales per share.

The table below shows summary valuation data for EXEL

Valuation Multiples - EXEL					
		Stock	Sub-Industry	Sector	S&P 500
P/S F12M	Current	7.46	2.59	2.89	3.61
	5-Year High	24.16	3.23	3.74	3.61
	5-Year Low	4.45	1.93	2.22	2.53
	5-Year Median	8.44	2.73	2.9	3.02
P/B TTM	Current	4.49	3.13	4.48	4.46
	5-Year High	131.3	6.39	5.07	4.56
	5-Year Low	N/A	2.06	2.94	2.83
	5-Year Median	4.81	3.88	4.3	3.71

As of 07/20/2020

Industry Analysis Zacks Industry Rank: Top 37% (93 out of 252)



Top Peers

Company (Ticker)	Rec	Rank
Bayer Aktiengesellschaft (BAYRY)	Outperform	1
Bristol Myers Squibb Company (BMY)	Outperform	2
Eli Lilly and Company (LLY)	Neutral	3
MerckCo., Inc. (MRK)	Neutral	3
Novartis AG (NVS)	Neutral	3
Pfizer Inc. (PFE)	Neutral	3
Roche Holding AG (RHHBY)	Neutral	2
AVEO Pharmaceuticals, Inc. (AVEO)	Underperform	5

Industry Comparison Industry: Medical - Biomedical And Genetics				Industry Peers		
	EXEL	X Industry	S&P 500	BMY	NVS	PFE
Zacks Recommendation (Long Term)	Neutral	-	-	Outperform	Neutral	Neutral
Zacks Rank (Short Term)	3	-	-	2	3	3
VGM Score	C	-	-	A	A	A
Market Cap	7.85 B	248.39 M	22.29 B	134.54 B	201.43 B	202.75 B
# of Analysts	4	3	14	5	5	4
Dividend Yield	0.00%	0.00%	1.85%	3.03%	2.28%	4.16%
Value Score	B	-	-	A	B	B
Cash/Price	0.13	0.21	0.06	0.13	0.02	0.05
EV/EBITDA	16.97	-4.19	13.06	23.67	14.25	9.65
PEG Ratio	1.22	1.79	2.98	1.14	1.94	2.95
Price/Book (P/B)	4.49	4.41	3.12	2.69	3.95	3.10
Price/Cash Flow (P/CF)	23.62	17.32	12.03	13.54	11.15	8.88
P/E (F1)	56.34	25.59	22.15	9.64	15.58	12.67
Price/Sales (P/S)	8.02	17.82	2.35	4.34	4.14	4.00
Earnings Yield	1.72%	-12.49%	4.30%	10.38%	6.42%	7.89%
Debt/Equity	0.00	0.02	0.75	0.86	0.50	0.56
Cash Flow (\$/share)	1.08	-1.08	6.94	4.39	7.90	4.11
Growth Score	D	-	-	A	B	B
Hist. EPS Growth (3-5 yrs)	126.28%	17.18%	10.82%	21.90%	1.77%	8.07%
Proj. EPS Growth (F1/F0)	-56.62%	12.06%	-9.08%	31.56%	7.79%	-2.37%
Curr. Cash Flow Growth	-26.95%	15.05%	5.51%	36.74%	4.27%	-6.57%
Hist. Cash Flow Growth (3-5 yrs)	27.52%	7.73%	8.55%	22.46%	7.11%	2.54%
Current Ratio	8.09	5.57	1.30	1.66	0.74	1.02
Debt/Capital	0.00%	4.23%	44.41%	46.16%	33.33%	35.70%
Net Margin	30.01%	-203.22%	10.54%	3.08%	24.97%	31.17%
Return on Equity	18.01%	-61.83%	15.74%	30.06%	24.39%	25.76%
Sales/Assets	0.54	0.19	0.54	0.33	0.41	0.31
Proj. Sales Growth (F1/F0)	-5.02%	4.85%	-2.36%	59.38%	5.03%	-10.61%
Momentum Score	A	-	-	A	A	B
Daily Price Chg	4.07%	0.96%	-0.77%	-1.54%	-0.18%	0.69%
1 Week Price Chg	-1.36%	1.32%	3.82%	5.15%	1.33%	7.15%
4 Week Price Chg	5.92%	0.00%	2.71%	3.30%	-2.88%	10.24%
12 Week Price Chg	-6.47%	15.49%	9.79%	-4.96%	-1.76%	-4.77%
52 Week Price Chg	19.13%	11.36%	-3.79%	39.02%	-6.41%	-14.76%
20 Day Average Volume	2,231,851	372,253	2,095,914	11,069,774	1,207,292	29,504,660
(F1) EPS Est 1 week change	0.00%	0.00%	0.00%	0.14%	0.07%	0.00%
(F1) EPS Est 4 week change	0.00%	0.00%	0.09%	0.41%	0.04%	0.00%
(F1) EPS Est 12 week change	6.63%	1.07%	-4.60%	0.90%	-0.91%	6.75%
(Q1) EPS Est Mthly Chg	15.15%	0.00%	0.00%	1.09%	-2.84%	-0.46%

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	D
Momentum Score	A
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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