Clovis Oncology, Inc. (CLVS)

$6.14 (As of 08/03/20)

Price Target (6-12 Months): **$6.50**

Long Term: 6-12 Months	**Zacks Recommendation:** (Since: 04/01/19) Prior Recommendation: Underperform	**Neutral**
Short Term: 1-3 Months	**Zacks Rank:** (1-5)	**2-Buy**
	Zacks Style Scores:	VGM:F
	Value: F | Growth: C | Momentum: D	

Summary

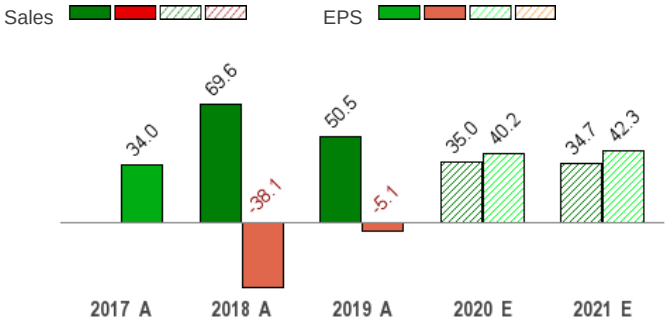
Market share of Clovis' Rubraca in the ovarian cancer PARP inhibitor market improved in 2019. Approval in second-line maintenance setting for ovarian cancer irrespective of the BRCA-mutation is boosting revenues. Successful development of Rubraca in several ongoing studies, targeting different types of ovarian cancer patients and potential approval for prostate cancer indication are likely to boost the drug's prospects. However, Rubraca faces strong competition from other PARP inhibitors in the market, Lynparza and Zejula. Moreover, competition is likely to increase with several others under development. Shares have underperformed the industry so far this year. Loss estimates have narrowed ahead of Q2 earnings. The company has a mixed record of earnings surprises in the recent quarters.

Price, Consensus & Surprise

Data Overview

52 Week High-Low	**$17.37 - $2.93**
20 Day Average Volume (sh)	**3,506,020**
Market Cap	**$472.2 M**
YTD Price Change	**-41.1%**
Beta	**2.39**
Dividend / Div Yld	**$0.00 / 0.0%**
Industry	**Medical - Biomedical and Genetics**
Zacks Industry Rank	**Top 43% (109 out of 254)**
Last EPS Surprise	**0.8%**
Last Sales Surprise	**1.8%**
EPS F1 Est- 4 week change	**2.3%**
Expected Report Date	**08/06/2020**
Earnings ESP	**-16.1%**
P/E TTM	**NA**
P/E F1	**NA**
PEG F1	**NA**
P/S TTM	**3.1**

Sales and EPS Growth Rates (Y/Y %)



Sales Estimates (millions of $)

	Q1	Q2	Q3	Q4	Annual*
2021	59 E	62 E	65 E	74 E	260 E
2020	43 A	45 E	50 E	56 E	193 E
2019	33 A	33 A	38 A	39 A	143 A

EPS Estimates

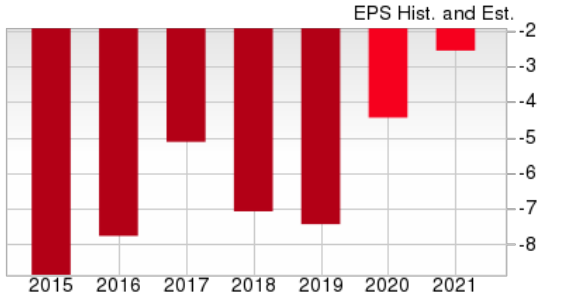
	Q1	Q2	Q3	Q4	Annual*
2021	-$0.89 E	-$0.84 E	-$0.83 E	-$0.73 E	-$2.56 E
2020	-$1.28 A	-$1.02 E	-$1.02 E	-$0.99 E	-$4.44 E
2019	-$1.63 A	-$2.27 A	-$1.89 A	-$1.81 A	-$7.43 A

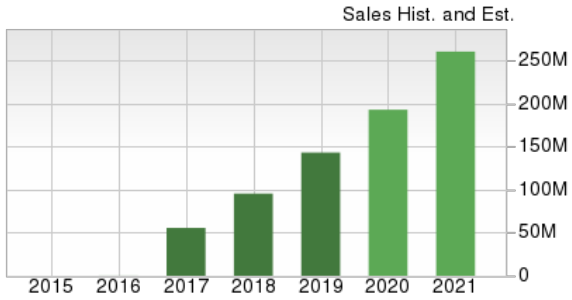
*Quarterly figures may not add up to annual.

The data in the charts and tables, including the Zacks Consensus EPS and Sales estimates, is as of 08/03/2020. The reports text is as of 08/04/2020.

Overview

Boulder, CO-based Clovis Oncology, Inc. has only one marketed drug in its portfolio, Rubraca. Rubraca is approved as a maintenance treatment in recurrent ovarian cancer patients who have received one prior platinum-based chemotherapy (second-line setting), irrespective of BRCA-mutation. The drug is also approved as monotherapy for the treatment of deleterious BRCA mutation (germline and/or somatic)-associated advanced ovarian cancer in patients who have been treated with two or more chemotherapies (third or later line setting), and selected for therapy based on an FDA-approved companion diagnostic for Rubraca. The drug is also approved in the United States as monotherapy for treating BRCA-mutant metastatic castrate-resistant prostate cancer (mCRPC).





A broad development program on Rubraca is currently underway across a variety of solid tumors. Clovis is looking to expand Rubraca's label into additional cancer types like prostrate, breast and gastroesophageal cancers, among others. Meanwhile, Clovis holds global development and commercialization rights to Rubraca. Clovis in-licensed Rubraca from Pfizer in 2011.

In addition, the company has another product candidate, lucitanib (FGFR, VEGFR and PDGFR inhibitor) in its pipeline. In the second quarter of 2019, the company terminated development of rociletinib (EGFR inhibitor).

Currently, Clovis is seeking to license/acquire additional oncology assets for further development. Clovis generated product revenues of $143 million in 2019, representing a growth of 49.9% from the year-ago period.

Reasons To Buy:

- **Rubraca Holds Potential in Ovarian Cancer:** Rubraca is the sole marketed product in Clovis' portfolio and has bright prospects, given the immense commercial potential in the target market and the tremendous demand for PARP inhibitors. Rubraca's label was expanded in second-line maintenance setting based on data from the ARIEL-3 study in the United States in April 2018 and in Europe in January 2019. With the expanded label, the commercial uptake of the drug is improving. Moreover, the company is conducting patient-focused awareness programs for Rubraca as well as PARP inhibitors. These programs helped the company to increase the penetration of PARP inhibitors and improve market share of the PARP inhibitor ovarian cancer market, boosting Rubraca's sales.

> Rubraca's approval for advanced ovarian cancer is a major boost for Clovis. Its prospects are pretty bright given the tremendous demand for PARP inhibitors.

Clovis is evaluating Rubraca in several label expansion studies. A phase III confirmatory study - ARIEL4 is evaluating Rubraca versus chemotherapy in patients who have failed two prior lines of therapy. A phase III study – ATHENA – is evaluating Rubraca as monotherapy and in combination with Bristol-Myers' Opdivo in advanced ovarian cancer as first-line maintenance treatment. The company expects to complete enrollment in the ATHENA study by the end of June 2020.

- **Rubraca's Potential in Other Cancers:** Clovis is looking to expand Rubraca's label into additional cancer types like prostrate, breast and gastroesophageal cancers, among others. A phase III TRITON 3 study is evaluating Rubraca in mCRPC patients with tumor with BRCA mutations and ATM mutations. In May 2020, the FDA approved Rubraca as monotherapy for BRCA-mutant recurrent mCRPC. A decision is expected by May 15, 2020. The company is also developing the drug as monotherapy or in combination with other therapies for lung, bladder, breast, pancreatic, gastric cancer and recurrent solid tumors with deleterious homologous recombination repair (HRR) gene mutations. Enrollment in ongoing in the phase II LODESTAR study evaluating Rubraca in HRR patients. The company may file for approval in 2021 based on the data from this study.

  Clovis has a collaboration agreement with Merck and Bristol-Myers to develop Rubraca in combination with their PD-1/ PDL1 inhibitors for treating several cancer indications. Separate phase II studies are evaluating the same combination in prostate and advanced gastric cancer.

- **Encouraging Pipeline Candidate:** Apart from Rubraca, the company is also developing lucitanib for treating breast and lung cancer. The company is currently evaluating lucitanib in early-stage clinical studies in combination with Rubraca in ovarian cancer or Bristol-Myers' PD-1 inhibitor, Opdivo, in advanced gynecologic cancers and other solid tumors. Initial data from these clinical studies are expected later in 2020.

- **Potential in the Target Market:** According to the American Cancer Society, ovarian cancer ranks fifth in cancer deaths among women, accounting for more deaths than any other cancer of the female reproductive system. It is estimated that more than 21,570 cases of ovarian cancer will be diagnosed in the United States in 2020. Per GLOBOCAN 2018, 68,000 women are diagnosed with ovarian cancer every year in Europe. With standard-of-care treatments for ovarian cancer including surgery, radiation, chemotherapy, targeted and hormone therapies, the five-year relative survival rate for all types of ovarian cancer is 45%. There is huge unmet need for new treatment options, given that one in four women with ovarian cancer have a germline or somatic BRCA mutation. Therefore, Rubraca has bright prospects given the immense commercial potential of the target market and the tremendous demand for PARP inhibitors. Moreover, there will be 191,930 and 80,470 newly diagnosed prostate and bladder cancer patients, respectively, in the United Stated in 2020, per the American Cancer Society. There will be 43,000 patients diagnosed with mCRPC in the United States in 2020. Per GLOBOCAN, 450,000 men in Europe were diagnosed with prostate cancer in 2018.

Reasons To Sell:

- **Rubraca Sales Disappoint:** Although the company is progressing well with label expansion of Rubraca, sales are not improving in tandem. Moreover, the adoption of drugs belonging to the PARP inhibitor class, to which Rubraca belongs, remained slow in the U.S. market in 2019. Rubraca sales growth in Europe was also weak. Hence, we prefer to keep a wait and see approach. Although Clovis is developing the drug for several indications beyond ovarian cancer, it will face competition upon successful development and launch in those indications too.

> With just one approved product in the portfolio, Clovis is heavily dependent on Rubraca for growth.

- **Pipeline Setbacks:** In April 2019, Clovis discontinued phase II ATLAS study evaluating Rubraca monotherapy for metastatic bladder cancer as preliminary data suggested that it was unlikely to provide a meaningful clinical benefit to patients. In 2016, the company discontinued all developmental activities related to rociletinib following the issuance of a CRL by the FDA and the in-licensing deal with Celgene was terminated. Additionally, Clovis withdrew its regulatory application for rociletinib that was previously filed with European regulatory authorities.

- **Fierce Competition in Target Market:** While the ovarian cancer market provides immense commercial potential, we note that Rubraca is facing intense competition from currently marketed PARP inhibitors as well as other approved therapies. Approved PARP inhibitors for ovarian cancer include Merck/AstraZeneca's Lynparza and Glaxo's Zejula, which were approved in early 2017. Moreover, Lynparza and Pfizer's Talzenna have received approval for metastatic breast cancer. Lynparza is also approved for treating pancreatic cancer. Moreover, these big pharma companies have strong cash resources to promote their drugs, which can push Clovis on the back foot.

  Meanwhile, there are a number of PARP inhibitors in clinical development including AbbVie's veliparib. Meanwhile, the oncology market is attracting a lot of attention with several companies inking deals and working on bringing their candidates to this high-revenue potential market.

- **Unfavorable Debt Profile:** Clovis has an unfavorable debt profile. As of Mar 31, 2020, the company's total debt (current and long-term debt) was approximately $610 million. The company's cash, cash equivalents, and marketable securities were approximately $228 million, as of the end of March 2020. Although the company has enough resources to pay off its short-term debt ($5 million), the company's total debts exceeds its total assets, which may lead to bankruptcy in case of insolvency. However, the company's debt to capital of 123.6% as of March end demonstrates a decline from 132.3% at December end.

Last Earnings Report

Clovis Q1 Earnings and Revenues Surpass Estimates

Quarter Ending	03/2020
Report Date	**May 05, 2020**
Sales Surprise	**1.84%**
EPS Surprise	**0.78%**
Quarterly EPS	**-1.28**
Annual EPS (TTM)	**-7.25**

Clovis incurred loss of $1.28 per share for the first quarter of 2020, narrower than the Zacks Consensus Estimate of a loss of $1.29 and the year-ago loss of $1.63 per share.

Net revenues, entirely from Rubraca, were up almost 28.5% year over year to $42.6 million in the quarter, beating the Zacks Consensus Estimate of $41.8 million. Sales were up 8.4% sequentially.

Quarter in Details

Sales of Rubracain the United States were $39.3 million, compared with$31.9 million in the first quarter of 2019. Ex-U.S. market sales were $3.3 million in the first quarter compared with $3.2 million the fourth quarter of 2019.

In the first quarter, research & development expenses increased 10% year over year to $68.2 million, mainly due to higher costs related to Rubraca label expansion studies. Selling, general and administrative expenses declined 10.9% year over year to $42.6 million primarily driven by lower commercialization expenses for Rubraca in the U.S. and Europe

Clovis ended the quarter with $228.4 million of cash equivalents and available-for-sale securities compared with $296.7 million as of Dec 31, 2019.

The company expects its cash resources to be enough to support its operations in the second half of 2021.

Recent News

Completes Enrollment in ATHENA Study – Jun 10

Clovis announced that it has reached the patient enrollment target in the phase III study — ATHENA — evaluating its sole marketed drug, Rubraca, as a treatment for advanced ovarian cancer.

New Recommendations for Rubraca – May 28

Clovis announced that the National Comprehensive Cancer Network (NCCN) updated its Clinical Practice Guidelines in Oncology for Prostate Cancer to include new recommendations for Rubraca. The drug is now recommended in the NCCN Guidelines for the treatment of BRCA-mutant patients with mCRPC under second-line treatment and subsequent therapy as a Category 2A recommendation.

Rubraca Gets FDA Approval for Prostate Cancer – May 15

Clovis announced that the FDA has granted accelerated approval to label expansion of Rubraca as a monotherapy for BRCA-mutant recurrent, mCRPC in patients treated with androgen receptor-directed therapy and a taxane-based chemotherapy.

Valuation

Clovis' shares are down 41.1% in the year-to-date period and 30.7% over the trailing 12-month period. Stocks in the Zacks sub-industry are up 3.7% while stocks in the Zacks sector are up 0.1% in the year-to-date period. Over the past year, stocks in the sub-industry and the sector are up 20.1% and 9.9%, respectively.

The S&P 500 Index is up 1.7% in the year-to-date period and 15.5% in the past year.

The stock is currently trading at 2.89X trailing 12-month sales per share which compares to 3.4X for the Zacks sub-industry, 3.07X for the Zacks sector and 4.07X for the S&P 500 Index.

Over the past five years, the stock has traded as low as 1.22X, with a 5-year median of 17.51X. Our Neutral recommendation indicates that the stock will perform in line with the market. Our $6.50 price target reflects 3.06X trailing 12-month sales per share.

Industry Analysis **Zacks Industry Rank:** Top 43% (109 out of 254)

Top Peers

Company (Ticker)	Rec	Rank
AbbVie Inc. **(ABBV)**	Neutral	3
AstraZeneca PLC **(AZN)**	Neutral	3
BeiGene, Ltd. **(BGNE)**	Neutral	2
Constellation Pharmaceuticals, Inc. **(CNST)**	Neutral	3
GlaxoSmithKline plc **(GSK)**	Neutral	2
JohnsonJohnson **(JNJ)**	Neutral	3
Pfizer Inc. **(PFE)**	Neutral	3
Roche Holding AG **(RHHBY)**	Neutral	2

Industry Comparison Industry: Medical - Biomedical And Genetics

	CLVS	X Industry	S&P 500	AZN	GSK	PFE
Zacks Recommendation (Long Term)	Neutral	-	-	Neutral	Neutral	Neutral
Zacks Rank (Short Term)	2	-	-	3	2	3
VGM Score	F	-	-	B	B	B
Market Cap	472.17 M	263.17 M	22.67 B	149.12 B	103.58 B	213.03 B
# of Analysts	4	3	13.5	5	6	4
Dividend Yield	0.00%	0.00%	1.77%	3.27%	4.52%	3.96%
Value Score	F	-	-	B	A	B
Cash/Price	0.51	0.23	0.07	0.04	0.11	0.05
EV/EBITDA	-2.29	-3.82	13.08	23.53	10.32	10.09
PEG Ratio	NA	1.92	2.94	1.68	3.07	3.09
Price/Book (P/B)	NA	4.09	3.10	10.92	4.15	3.26
Price/Cash Flow (P/CF)	NA	15.94	12.34	17.94	9.53	9.33
P/E (F1)	NA	31.51	21.71	27.91	13.96	13.24
Price/Sales (P/S)	3.10	15.76	2.46	5.80	2.35	4.33
Earnings Yield	-72.31%	-13.35%	4.38%	3.59%	7.17%	7.56%
Debt/Equity	-4.76	0.02	0.75	1.14	1.28	0.56
Cash Flow ($/share)	-7.29	-1.07	6.94	3.17	4.33	4.11
Growth Score	C	-	-	B	C	B
Hist. EPS Growth (3-5 yrs)	NA%	17.80%	10.46%	-2.71%	7.30%	7.38%
Proj. EPS Growth (F1/F0)	40.24%	12.92%	-7.08%	16.34%	-6.68%	-1.78%
Curr. Cash Flow Growth	11.25%	15.03%	5.47%	2.12%	4.83%	-6.57%
Hist. Cash Flow Growth (3-5 yrs)	NA%	7.73%	8.55%	-0.86%	1.08%	2.54%
Current Ratio	2.47	5.57	1.32	0.82	0.96	1.02
Debt/Capital	NA%	4.19%	44.21%	53.34%	56.09%	35.70%
Net Margin	-271.13%	-203.22%	10.25%	8.36%	19.03%	28.80%
Return on Equity	NA%	-61.45%	14.72%	37.72%	31.21%	25.10%
Sales/Assets	0.23	0.19	0.52	0.43	0.42	0.29
Proj. Sales Growth (F1/F0)	34.78%	5.41%	-1.79%	9.35%	2.20%	-10.10%
Momentum Score	D	-	-	D	D	D
Daily Price Chg	6.04%	2.71%	0.27%	1.86%	2.41%	-0.34%
1 Week Price Chg	-5.85%	-2.85%	0.14%	-0.04%	0.07%	2.18%
4 Week Price Chg	-5.90%	-1.64%	2.96%	5.03%	0.68%	11.13%
12 Week Price Chg	-33.55%	3.38%	10.90%	5.32%	-1.85%	0.66%
52 Week Price Chg	-30.70%	11.55%	2.35%	30.44%	2.30%	3.76%
20 Day Average Volume	3,506,020	338,499	2,043,624	11,147,011	3,394,974	33,644,288
(F1) EPS Est 1 week change	0.00%	0.00%	0.00%	0.10%	2.99%	0.70%
(F1) EPS Est 4 week change	2.32%	0.00%	0.82%	0.39%	3.10%	0.61%
(F1) EPS Est 12 week change	5.93%	1.21%	0.59%	0.17%	1.59%	1.67%
(Q1) EPS Est Mthly Chg	4.68%	0.00%	0.25%	-0.95%	-0.61%	-4.13%

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	F
Growth Score	C
Momentum Score	D
VGM Score	F

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.

Disclosures

This report contains independent commentary to be used for informational purposes only. The analysts contributing to this report do not hold any shares of this stock. The analysts contributing to this report do not serve on the board of the company that issued this stock.The EPS and revenue forecasts are the Zacks Consensus estimates, unless indicated otherwise on the reports first page. Additionally, the analysts contributing to this report certify that the views expressed herein accurately reflect the analysts personal views as to the subject securities and issuers. ZIR certifies that no part of the analysts compensation was, is, or will be, directly or indirectly, related to the specific recommendation or views expressed by the analyst in the report.

Additional information on the securities mentioned in this report is available upon request. This report is based on data obtained from sources we believe to be reliable, but is not guaranteed as to accuracy and does not purport to be complete. Any opinions expressed herein are subject to change.

ZIR is not an investment advisor and the report should not be construed as advice designed to meet the particular investment needs of any investor. Prior to making any investment decision, you are advised to consult with your broker, investment advisor, or other appropriate tax or financial professional to determine the suitability of any investment.This report and others like it are published regularly and not in response to episodic market activity or events affecting the securities industry.

This report is not to be construed as an offer or the solicitation of an offer to buy or sell the securities herein mentioned. ZIR or its officers, employees or customers may have a position long or short in the securities mentioned and buy or sell the securities from time to time.ZIR is not a broker-dealer.ZIR may enter into arms-length agreements with broker-dealers to provide this research to their clients.Zacks and its staff are not involved in investment banking activities for the stock issuer covered in this report.

ZIR uses the following rating system for the securities it covers. **Outperform-** ZIR expects that the subject company will outperform the broader U.S. equities markets over the next six to twelve months. **Neutral-** ZIR expects that the company will perform in line with the broader U.S. equities markets over the next six to twelve months. **Underperform-** ZIR expects the company will underperform the broader U.S. equities markets over the next six to twelve months.