Clovis Oncology, Inc. (CLVS)

$9.91 (As of 01/03/20)

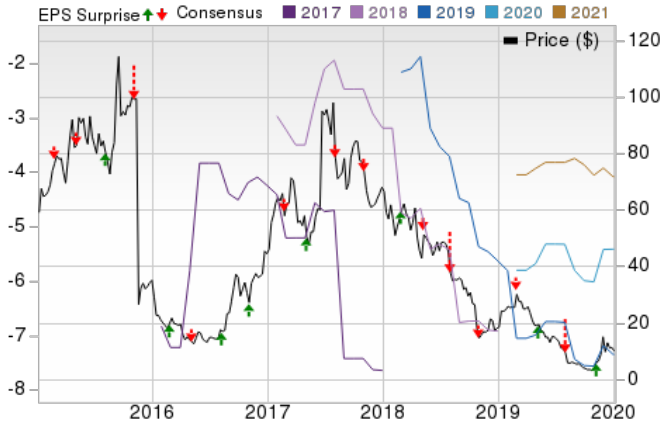
Price Target (6-12 Months): **$11.00**

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: F | Momentum: B	

Summary

Market share of Clovis' Rubraca in the ovarian cancer PARP inhibitor market improved in the first half. Approval in second-line maintenance setting for ovarian cancer irrespective of the BRCA-mutation is a positive. Successful development of Rubraca in several ongoing studies, targeting different types of ovarian cancer patients, is likely to boost the drug's prospects. The company is actively working on expanding the label of Rubraca as monotherapy or combination therapy in and beyond ovarian cancer. 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.

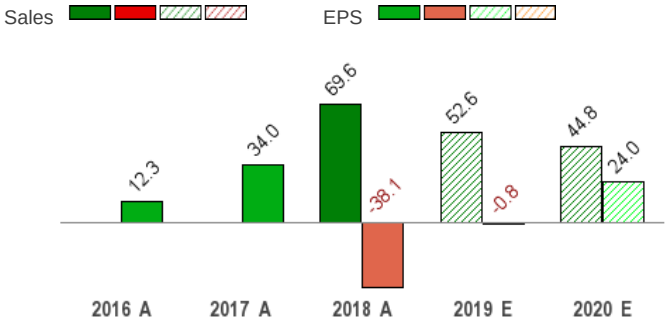
Price, Consensus & Surprise



Data Overview

52 Week High-Low	**$32.05 - $2.93**
20 Day Average Volume (sh)	**7,391,998**
Market Cap	**$543.2 M**
YTD Price Change	**-4.9%**
Beta	**3.13**
Dividend / Div Yld	**$0.00 / 0.0%**
Industry	**Medical - Biomedical and Genetics**
Zacks Industry Rank	**Top 23% (57 out of 252)**
Last EPS Surprise	**1.6%**
Last Sales Surprise	**3.6%**
EPS F1 Est- 4 week change	**0.0%**
Expected Report Date	**02/25/2020**
Earnings ESP	**0.0%**
P/E TTM	**NA**
P/E F1	**NA**
PEG F1	**NA**
P/S TTM	**4.1**

Sales and EPS Growth Rates (Y/Y %)



Sales Estimates (millions of $)

	Q1	Q2	Q3	Q4	Annual*
2020	41 E	44 E	50 E	59 E	210 E
2019	33 A	33 A	38 A	41 E	145 E
2018	19 A	24 A	23 A	30 A	95 A

EPS Estimates

	Q1	Q2	Q3	Q4	Annual*
2020	-$1.56 E	-$1.47 E	-$1.40 E	-$1.35 E	-$5.42 E
2019	-$1.63 A	-$2.27 A	-$1.89 A	-$1.58 E	-$7.13 E
2018	-$1.30 A	-$1.94 A	-$1.71 A	-$1.88 A	-$7.07 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 01/03/2020. The reports text is as of 01/06/2020.

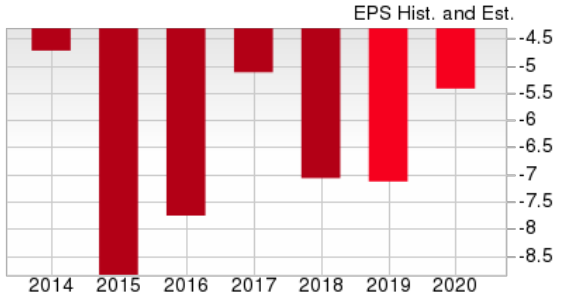
Overview

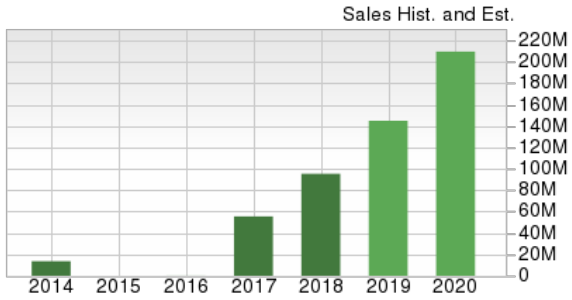
Boulder, CO-based Clovis Oncology, Inc. is a biopharmaceutical company focused on the development and commercialization of treatments targeting specific subsets of cancer population. The company has only one marketed drug in its portfolio, Rubraca. Rubraca is approved as a maintenance treatment in recurrent 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.

A broad development program on Rubraca is currently underway across a variety of solid tumors. 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 $95.4 million in 2018, up 71.8% from 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 gain 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 in combination with Bristol-Myers' Opdivo in advanced ovarian cancer as first-line maintenance treatment.

▲ **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 II TRITON2 study and a phase III TRITON 3 study are evaluating Rubraca in metastatic castrate-resistant prostate cancer (mCRPC) patients with tumor with BRCA mutations and ATM mutations. The FDA granted orphan drug status to the drug for this indication in October 2018. The company plans to file for label expansion of Rubraca in prostate cancer in the fourth quarter of 2019. The company is also developing the drug as monotherapy or in combination with other therapies for lung, bladder, breast, pancreatic and gastric cancer.

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. A phase II study is evaluating the same combination in prostate cancer.

▲ **Encouraging Pipeline Candidate:** Apart from Rubraca, the company is also developing lucitanib for treating breast and lung cancer. In the fourth quarter of 2018, the company expanded its agreement with Bristol-Myers to include combination studies of lucitanib. The company is currently evaluating lucitanib in early-stage clinical studies in combination with Rubraca in ovarian cancer or PD-1 inhibitor, Opdivo, in advanced gynecologic cancers and other solid tumors.

▲ **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 22,530 cases of ovarian cancer will be diagnosed in the United States in 2019. 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 174,650 newly diagnosed prostate cancer patients in the United Stated in 2019, per the American Cancer Society. According to the National Cancer Institute, 80,470 patients will be diagnosed with bladder cancer in 2019.

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 remained slow in the U.S. market. . The slower adoption of this class of drugs may impact Rubraca's sales going forward. 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 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 has successfully completed a late-stage study targeting 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.

Last Earnings Report

Clovis Q3 Earnings & Sales Beat Estimates

Quarter Ending	09/2019
Report Date	**Nov 07, 2019**
Sales Surprise	**3.56%**
EPS Surprise	**1.56%**
Quarterly EPS	**-1.89**
Annual EPS (TTM)	**-7.67**

Clovis incurred adjusted loss of $1.89 per share in the third quarter of 2019, narrower than the Zacks Consensus Estimate of a loss of $1.92 but wider than the year-ago loss of $1.71 per share. Adjusted loss excludes expense related to acquired in-process research and development, and a gain on extinguishment of debt. Including these items, the company incurred a loss of $1.72 in the quarter.

Net revenues, entirely from Rubraca, were up almost 65% year over year to $37.6 million in the quarter, beating the Zacks Consensus Estimate of $36.31 million. Sales were up 14% sequentially. The company had recorded total revenues of $22.8 million, entirely from Rubraca sales in the United States, in the year-ago quarter.

Quarter in Details

Rubraca sales in the United States were up 12% sequentially to $36.5 million during the quarter. Ex-U.S. market sales were $1.1 million in the third quarter compared with $0.3 million in the second quarter of 2019. The growth was driven by progress in new patient starts and higher duration of use.

In October, the company launched the drug in England with reimbursement provided through the Cancer Drugs Fund.

In the third quarter, research & development expenses increased 21.9% year over year to $77.9 million, primarily due to increased expenses for clinical studies on Rubraca. Selling, general and administrative (SG&A) expenses declined 1.6% year over year to $41.8 million, reflecting the impact of cost-savings initiatives.

The company expects R&D expenses to decline in 2020 as the largest of the Clovis-sponsored clinical trials near completion and spending related to clinical programs reduce.

Cash used in operating activities in the quarter was $57 million, lower than $72.5 million in the year-ago quarter. The decline was expected as Clovis guided lower cash utilization for operating activities in the second half of 2019 on its second-quarter earnings call.

Clovis ended the quarter with $354.1 million of cash equivalents and available-for-sale securities compared with $315.9 million as of Jun 30, 2018.

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

2019 Guidance

Clovis raised the lower end of its full-year guidance for product revenues. The company expects Rubraca to generate sales in the range of $141 million to $147 million, compared to the previously provided range of $137 million to $147 million.

Recent News

Announces Reimbursement for Rubraca in Italy – Nov 13

Clovis announced that the Italian Medicines Agency has approved Rubraca for reimbursement. The company will soon launch the drug in Italy as monotherapy maintenance treatment for patients with elapsed, platinum-sensitive ovarian cancer in second-line setting.

Gains Rights to Pre-Clinical Cancer Program – Sep 23

Clovis entered into a global licensing and collaboration agreement with privately-held, Germany-based biotech 3B Pharmaceuticals GmbH. The deal grants Clovis U.S. and global rights (excluding Europe) to fibroblast activation protein alpha (FAP)-targeted radiopharmaceutical program. 3B Pharmaceuticals retains rights in Europe related to the FAP program.

Under the collaboration agreement, the initial focus will be on developing a peptide-targeted radionuclide therapy and imaging agent targeting FAP. Clovis will conduct global clinical studies and will solely bear the expenses during pre-clinical stage of development. Clovis expects to file an Investigational New Drug application for FAP-targeted radiopharmaceutical therapy in the second half of 2020.

Per the terms of the deal, Clovis will pay $12 million in upfront payment to 3B Pharmaceuticals. Clovis is also liable to pay certain development and regulatory milestone payments and commercial royalties on any potential future sales related to products developed under the program.

Meanwhile, Clovis and 3B Pharmaceuticals intend to collaborate on a discovery program for three additional targets for radionuclide therapy. 3B Pharmaceuticals will be responsible for discovery activities and Clovis will be responsible for IND-enabling studies.

Valuation

Clovis' shares are down 54.4% over the trailing 12-month period. Over the past year, the Zacks sub-industry remained flat while the sector is up 7.2%.

The S&P 500 Index is up 25.6% in the past year.

The stock is currently trading at 2.58X forward 12-month sales per share, which compares to 2.46X for the Zacks sub-industry, 2.83X for the Zacks sector and 3.47X for the S&P 500 index.

Over the past five years, the stock has traded as high as 270.37X and as low as 0.82X, with a 5-year median of 15.53X. Our Neutral recommendation indicates that the stock will in-line with the market. Our $11.00 price target reflects 2.86X forward 12-month sales per share.

Industry Analysis **Zacks Industry Rank:** Top 23% (57 out of 252)

Top Peers

Pfizer Inc. **(PFE)**	Outperform
AbbVie Inc. **(ABBV)**	Neutral
AstraZeneca PLC **(AZN)**	Neutral
BeiGene, Ltd. **(BGNE)**	Neutral
Constellation Pharmaceuticals, Inc. **(CNST)**	Neutral
GlaxoSmithKline plc **(GSK)**	Neutral
Johnson & Johnson **(JNJ)**	Neutral
Roche Holding AG **(RHHBY)**	Neutral

Industry Comparison Industry: Medical - Biomedical And Genetics

Industry Peers

	CLVS Neutral	X Industry	S&P 500	AZN Neutral	GSK Neutral	PFE Outperform
VGM Score	F	-	-	C	A	D
Market Cap	543.22 M	189.56 M	23.66 B	131.42 B	115.93 B	215.44 B
# of Analysts	5	2.5	13	5	5	4
Dividend Yield	0.00%	0.00%	1.79%	1.76%	4.14%	3.70%
Value Score	F	-	-	C	B	C
Cash/Price	0.58	0.24	0.04	0.04	0.05	0.04
EV/EBITDA	-2.55	-3.51	13.88	20.13	14.12	13.27
PEG Ratio	NA	1.66	1.99	1.49	3.07	3.96
Price/Book (P/B)	NA	3.69	3.36	9.61	5.21	3.29
Price/Cash Flow (P/CF)	NA	11.65	13.62	15.59	11.18	9.24
P/E (F1)	NA	25.18	18.74	24.06	14.94	15.05
Price/Sales (P/S)	4.05	12.18	2.67	5.44	2.75	4.06
Earnings Yield	-54.69%	-15.99%	5.32%	4.15%	6.69%	6.65%
Debt/Equity	-7.91	0.02	0.72	1.29	1.38	0.55
Cash Flow ($/share)	-6.83	-1.07	6.94	3.21	4.16	4.21
Growth Score	F	-	-	C	C	F
Hist. EPS Growth (3-5 yrs)	NA%	17.09%	10.56%	-2.47%	5.16%	8.42%
Proj. EPS Growth (F1/F0)	24.00%	7.35%	7.41%	15.41%	-4.25%	-12.69%
Curr. Cash Flow Growth	51.99%	19.98%	14.83%	-3.77%	8.35%	8.89%
Hist. Cash Flow Growth (3-5 yrs)	NA%	8.69%	9.00%	-5.68%	-0.78%	2.30%
Current Ratio	3.76	5.15	1.23	0.92	0.82	0.90
Debt/Capital	NA%	3.95%	42.92%	56.26%	57.90%	35.53%
Net Margin	-298.53%	-196.01%	11.08%	8.42%	13.76%	30.57%
Return on Equity	-1,576.32%	-63.46%	17.10%	38.63%	92.73%	28.10%
Sales/Assets	0.18	0.21	0.55	0.40	0.49	0.33
Proj. Sales Growth (F1/F0)	44.66%	15.19%	4.20%	9.99%	4.85%	-11.59%
Momentum Score	B	-	-	B	A	B
Daily Price Chg	-3.32%	-0.69%	-0.61%	-0.60%	-0.94%	-0.54%
1 Week Price Chg	1.55%	0.83%	0.13%	-0.04%	-0.06%	0.23%
4 Week Price Chg	11.85%	2.47%	2.60%	5.19%	2.81%	2.37%
12 Week Price Chg	212.62%	13.88%	8.87%	14.88%	10.01%	8.77%
52 Week Price Chg	-43.88%	-0.58%	29.34%	30.68%	22.87%	-7.40%
20 Day Average Volume	7,391,998	221,436	1,603,615	2,424,171	2,021,953	16,184,152
(F1) EPS Est 1 week change	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
(F1) EPS Est 4 week change	0.00%	0.00%	0.00%	0.10%	0.59%	0.00%
(F1) EPS Est 12 week change	9.64%	0.82%	-0.57%	-0.50%	3.19%	1.50%
(Q1) EPS Est Mthly Chg	0.00%	0.00%	0.00%	-2.04%	0.00%	0.00%

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	F
Momentum Score	B
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

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