# Clovis Oncology, Inc. (CLVS)

**$6.79** (As of 04/07/20)

Price Target (6-12 Months): **$7.50**

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

## Summary

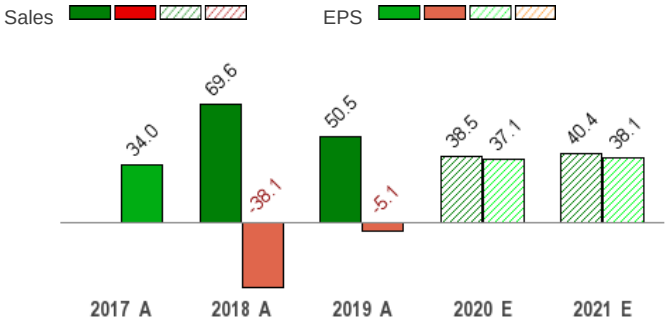
Clovis reported mixed fourth-quarter results, wherein earnings missed estimates but revenues beat the same. Market share of Clovis' Rubraca in the ovarian cancer PARP inhibitor market improved in 2019. Approval in second-line maintenance setting for ovarian cancer irrespective of the BRCA-mutation is 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. The company is actively working on expanding the label of Rubraca. 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 in the past year.

## Price, Consensus & Surprise


## Data Overview

| | |
|---|---|
| 52 Week High-Low | **$25.29 - $2.93** |
| 20 Day Average Volume (sh) | **7,250,671** |
| Market Cap | **$498.7 M** |
| YTD Price Change | **-34.9%** |
| Beta | **2.81** |
| Dividend / Div Yld | **$0.00 / 0.0%** |
| Industry | **Medical - Biomedical and Genetics** |
| Zacks Industry Rank | **Top 10% (25 out of 253)** |
| Last EPS Surprise | **-12.4%** |
| Last Sales Surprise | **1.4%** |
| EPS F1 Est- 4 week change | **0.0%** |
| Expected Report Date | **05/05/2020** |
| Earnings ESP | **0.0%** |
| P/E TTM | **NA** |
| P/E F1 | **NA** |
| PEG F1 | **NA** |
| P/S TTM | **3.5** |

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




## Sales Estimates (millions of $)

| | Q1 | Q2 | Q3 | Q4 | Annual* |
|---|---|---|---|---|---|
| 2021 | 59 E | 62 E | 65 E | 73 E | 278 E |
| 2020 | 43 E | 46 E | 52 E | 57 E | 198 E |
| 2019 | 33 A | 33 A | 38 A | 39 A | 143 A |

## EPS Estimates

| | Q1 | Q2 | Q3 | Q4 | Annual* |
|---|---|---|---|---|---|
| 2021 | -$0.92 E | -$0.88 E | -$0.86 E | -$0.80 E | -$2.89 E |
| 2020 | -$1.27 E | -$1.16 E | -$1.16 E | -$1.15 E | -$4.67 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 04/07/2020. The reports text is as of 04/08/2020.

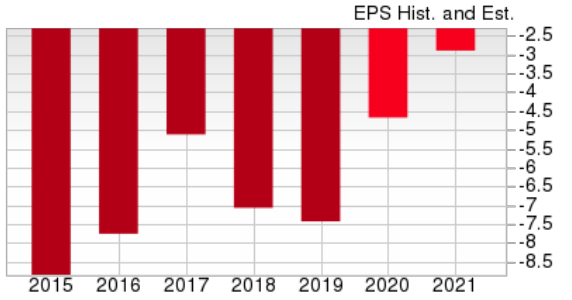
## Overview

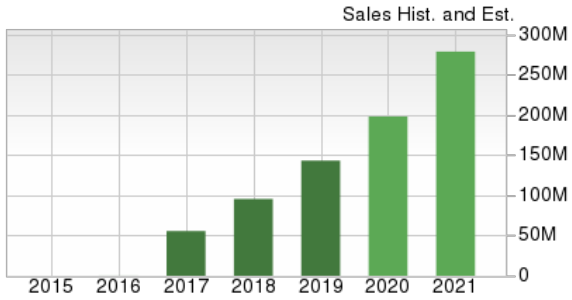
Boulder, CO-based Clovis Oncology, Inc. has only one marketed drug in its portfolio, Rubraca. Rubraca is approved as a maintenance treatment in recurrent ovarian cancer patients who have received one prior platinum-based chemotherapy (second-line setting), irrespective of BRCA-mutation. The drug is also 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 under review in the United States as monotherapy for treating metastatic castrate-resistant prostate cancer (mCRPC).

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 $143 million in 2019, up 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.

- **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. A regulatory application seeking label expansion of Rubraca as monotherapy for mCRPC is under review with the FDA. 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.

  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 remained slow in the U.S. market in 2019. 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 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.

## Last Earnings Report

**Clovis Q4 Earnings & Sales Miss Estimates**

| Quarter Ending | 12/2019 |
|---|---|
| Report Date | **Feb 24, 2020** |
| Sales Surprise | **1.35%** |
| EPS Surprise | **-12.42%** |
| Quarterly EPS | **-1.81** |
| Annual EPS (TTM) | **-7.60** |

Clovis incurred loss of $1.81 per share in the fourth quarter of 2019, wider than the Zacks Consensus Estimate of a loss of $1.61. However, the loss was narrower than the year-ago loss of $1.88 per share.

Net revenues, entirely from Clovis' only marketed drug, Rubraca, were up almost 29.5% year over year to $39.3 million in the quarter, slightly beating the Zacks Consensus Estimate of $38.79 million. Sales were up 4.5% sequentially.

**Quarter in Details**

Sales of Rubracain the United States were $36.1 million, a slight decline from $36.5 million in the third quarter of 2019. Ex-U.S. market sales were $3.2 million in the fourth quarter compared with $2.1 million in the third quarter of 2019 driven by higher sales in Germany and launches in England and Italy during the fourth quarter.

During the fourth quarter, the company gained reimbursement agreements for Rubraca in England and Italy. Subsequently, in February, the company successfully negotiated reimbursement agreement for the drug in France.

In the fourth quarter, research & development expenses increased 1.8% year over year to $72.5 million. Selling, general and administrative expenses declined 8.1% year over year to $45.2 million.

Clovis ended the quarter with $296.7 million of cash equivalents and available-for-sale securities compared with $354.1 million as of Sep 30, 2019.

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

**Full-Year Results**

Clovis reported total revenues of $143 million, up almost 50% year over year. The company incurred an adjusted loss of $7.40 per share, wider than the year-ago adjusted loss of $6.68. Adjusted loss excludes expense related to acquired in-process research and development, and a gain on extinguishment of debt. Including these items, the company had incurred a loss of $7.43 in 2019.

## Recent News

**Announces Reimbursement for Rubraca in Spain – Mar 2**

Clovis announced that Rubraca is now available and reimbursed in Spain. The drug is approved in Spain as monotherapy maintenance treatment for patients with elapsed, platinum-sensitive ovarian cancer in second-line setting.

**Announces Reimbursement for Rubraca in France – Feb 3**

Clovis announced that Rubraca is now available and reimbursed in France. The drug is approved as monotherapy maintenance treatment for patients with elapsed, platinum-sensitive ovarian cancer in second-line setting.

**Rubraca sNDA for Prostate Cancer Gets Priority Review – Jan 15**

Clovis announced that the FDA has accepted and granted priority review to the supplemental new drug application (sNDA) for Rubraca. The company submitted the sNDA in November last year, seeking approval for the label expansion of Rubraca as monotherapy for BRCA-mutant recurrent, metastatic castrate-resistant prostate cancer (mCRPC). A decision from the FDA is expected by May 15, 2020.

**Announces Fourth Quarter Preliminary Results – Jan 7**

Clovis announced fourth-quarter preliminary results. The company estimates its fourth-quarter Rubraca sales in the range of $38.3M - $39.3 million and full-year sales between $142.0 million and $143.0 million. Full-year sales projection indicates growth of approximately 50%.

## Valuation

Clovis' shares are down 34.8% in the year-to-date period and 72.1% over the trailing 12-month period. Stocks in the Zacks sub-industry and sector are down 9.6% and 13.6% in the year-to-date period. Over the past year, stocks in the sub-industry and the sector both are down 12.3%.

The S&P 500 Index is down 17.3% in the year-to-date period and 7.7% in the past year.

The stock is currently trading at 2.6X trailing 12-month sales per share which compares to 2.91X for the Zacks sub-industry, 2.71X for the Zacks sector and 2.88X 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 24.51X. Our Neutral recommendation indicates that the stock will perform in line with the market. Our $7.50 price target reflects 2.87X trailing 12-month sales per share.

## Industry Analysis **Zacks Industry Rank:** Top 10% (25 out of 253)


## Top Peers

| | |
|---|---|
| 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 |
| Pfizer Inc. **(PFE)** | 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 Neutral |
|---|---|---|---|---|---|---|
| **VGM Score** | F | - | - | C | B | D |
| Market Cap | 498.71 M | 152.64 M | 18.38 B | 113.11 B | 93.65 B | 186.46 B |
| # of Analysts | 5 | 3 | 13 | 5 | 6 | 4 |
| Dividend Yield | 0.00% | 0.00% | 2.31% | 4.32% | 6.31% | 4.52% |
| **Value Score** | F | - | - | C | B | B |
| Cash/Price | 0.66 | 0.31 | 0.06 | 0.05 | 0.07 | 0.05 |
| EV/EBITDA | -2.46 | -1.94 | 11.23 | 18.25 | 9.69 | 8.97 |
| PEG Ratio | NA | 1.62 | 1.91 | 1.32 | 6.89 | 2.72 |
| Price/Book (P/B) | NA | 2.85 | 2.45 | 7.75 | 3.99 | 2.93 |
| Price/Cash Flow (P/CF) | NA | 13.43 | 9.63 | 13.61 | 8.66 | 8.18 |
| P/E (F1) | NA | 26.05 | 15.92 | 21.34 | 12.43 | 12.06 |
| Price/Sales (P/S) | 3.49 | 11.73 | 1.94 | 4.64 | 2.18 | 3.60 |
| Earnings Yield | -68.78% | -20.51% | 6.15% | 4.69% | 8.05% | 8.30% |
| Debt/Equity | -4.07 | 0.02 | 0.70 | 1.11 | 1.29 | 0.57 |
| Cash Flow ($/share) | -7.29 | -1.03 | 7.01 | 3.17 | 4.33 | 4.11 |
| **Growth Score** | F | - | - | D | C | F |
| Hist. EPS Growth (3-5 yrs) | NA% | 18.12% | 10.92% | -2.79% | 6.31% | 8.48% |
| Proj. EPS Growth (F1/F0) | 37.12% | 5.73% | -0.12% | 15.43% | -4.79% | -5.51% |
| Curr. Cash Flow Growth | 11.25% | 13.26% | 5.93% | 2.12% | 4.83% | -6.57% |
| Hist. Cash Flow Growth (3-5 yrs) | NA% | 8.18% | 8.55% | -0.86% | 1.08% | 2.54% |
| Current Ratio | 2.75 | 4.82 | 1.24 | 0.86 | 0.81 | 0.88 |
| Debt/Capital | NA% | 4.33% | 42.36% | 52.63% | 56.24% | 36.17% |
| Net Margin | -280.01% | -229.34% | 11.64% | 5.38% | 13.72% | 31.44% |
| Return on Equity | -1,576.32% | -65.95% | 16.74% | 32.24% | 57.93% | 27.01% |
| Sales/Assets | 0.20 | 0.20 | 0.54 | 0.40 | 0.47 | 0.32 |
| Proj. Sales Growth (F1/F0) | 38.33% | 8.56% | 0.85% | 9.61% | 4.54% | -11.39% |
| **Momentum Score** | B | - | - | A | B | D |
| Daily Price Chg | -0.15% | -1.17% | 0.69% | -2.73% | -1.00% | -2.78% |
| 1 Week Price Chg | -14.45% | -3.64% | -4.40% | 3.51% | 1.92% | 8.87% |
| 4 Week Price Chg | 8.29% | -12.95% | -10.67% | -8.10% | -8.51% | -2.83% |
| 12 Week Price Chg | -23.71% | -27.12% | -23.70% | -14.11% | -20.22% | -16.12% |
| 52 Week Price Chg | -72.10% | -36.66% | -15.92% | 5.92% | -9.54% | -21.55% |
| 20 Day Average Volume | 7,250,671 | 256,188 | 4,068,329 | 6,706,005 | 6,572,225 | 41,956,936 |
| (F1) EPS Est 1 week change | 0.00% | 0.00% | 0.00% | 0.10% | 0.00% | -0.36% |
| (F1) EPS Est 4 week change | 0.00% | 0.00% | -5.24% | 0.10% | -0.60% | -0.36% |
| (F1) EPS Est 12 week change | 4.94% | -1.84% | -6.86% | -2.88% | -4.26% | 7.76% |
| (Q1) EPS Est Mthly Chg | 0.00% | 0.00% | -8.25% | 0.00% | 0.00% | -4.38% |

## 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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