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# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION

**Washington, D.C. 20549**

# FORM 10-K

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934.**

**For the fiscal year ended December 31, 2019.**

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934.**

**For the transition period from to .**

**Commission file number: 001-35347**

## Clovis Oncology, Inc.

**(Exact name of Registrant as specified in its charter)**

| **Delaware** | **90-0475355** |
|---|---|
| **(State or other jurisdiction of incorporation or organization)** | **(I.R.S. Employer Identification No.)** |
| **5500 Flatiron Parkway, Suite 100 Boulder, Colorado** | **80301** |
| **(Address of principal executive offices)** | **(Zip Code)** |

**(303) 625-5000**
**(Registrant's telephone number, including area code)**

**Not Applicable**
**(Former name, former address and former fiscal year, if changed since last report)**

Securities registered pursuant to Section 12(b) of the Act

| Title of Each Class | Trading Symbol(s) | Name of each exchange on which registered |
|---|---|---|
| Common Stock par Value $0.001 per share | CLVS | The NASDAQ Global Select Market |

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405) of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company, and "emerging growth company" in Rule 12b-2 of the Exchange Act.

| | | | |
|---|---|---|---|
| Large accelerated filer | ☒ | Accelerated filer | ☐ |
| Non-accelerated filer | ☐ | Smaller reporting company | ☐ |
| | | Emerging growth company | ☐ |

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The aggregate market value of the registrant's common stock, par value $0.001 per share, held by non-affiliates of the registrant on June 30, 2019, the last business day of the registrant's most recently completed second quarter, was $756,187,813 based on the closing price of the registrant's common stock on the NASDAQ Global Market on that date of $14.87 per share.

The number of outstanding shares of the registrant's common stock, par value $0.001 per share, as of February 15, 2020 was 73,448,619.

**DOCUMENTS INCORPORATED BY REFERENCE** Portions of the registrant's definitive proxy statement to be filed with the Securities and Exchange Commission pursuant to Regulation 14A in connection with the registrant's 2020 Annual Meeting of Stockholders, which is to be filed within 120 days after the end of the registrant's fiscal year ended December 31, 2019, are incorporated by reference into Part III of this Annual Report on Form 10-K to the extent stated therein.

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## PART I

*This Annual Report filed on Form 10-K and the information incorporated herein by reference includes statements that are, or may be deemed, "forward-looking statements." In some cases, these forward-looking statements can be identified by the use of forward-looking terminology, including the terms "believes," "estimates," "anticipates," "expects," "plans," "intends," "may," "could," "might," "will," "should," "approximately" or, in each case, their negative or other variations thereon or comparable terminology, although not all forward-looking statements contain these words. They appear in a number of places throughout this Annual Report on Form 10-K and include statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things, the market acceptance and commercial viability of our approved product, the development of our sales and marketing capabilities, the performance of our clinical trial partners, third party manufacturers and our diagnostic partners, our ongoing and planned non-clinical studies and clinical trials, the timing of and our ability to make regulatory filings and obtain and maintain regulatory approvals for our product candidates, including our ability to confirm the clinical benefit of our approved product through confirmatory trials and other post-marketing requirements, the degree of clinical utility of our products, particularly in specific patient populations, expectations regarding clinical trial data, expectations regarding sales of our products, our results of operations, financial condition, liquidity, prospects, growth and strategies, the industry in which we operate, including our competition and the trends that may affect the industry or us.*

*By their nature, forward-looking statements involve risks and uncertainties because they relate to events, competitive dynamics and industry change and depend on the economic circumstances that may or may not occur in the future or may occur on longer or shorter timelines than anticipated. We caution you that forward-looking statements are not guarantees of future performance and that our actual results of operations, financial condition and liquidity and the development of the industry in which we operate may differ materially from the forward-looking statements contained herein.*

*Any forward-looking statements that we make in this Annual Report on Form 10-K speak only as of the date of such statement, and we undertake no obligation to update such statements to reflect events or circumstances after the date of this Annual Report on Form 10-K or to reflect the occurrence of unanticipated events.*

*You should also read carefully the factors described in the "Risk Factors" section of this Annual Report on Form 10-K to better understand the risks and uncertainties inherent in our business and underlying any forward-looking statements. You are advised, however, to consult any further disclosures we make on related subjects in our Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and our website.*

*Clovis Oncology®, the Clovis logo and Rubraca® are trademarks of Clovis Oncology, Inc. in the United States and in other selected countries. All other brand names or trademarks appearing in this report are the property of their respective holders. Unless the context requires otherwise, references in this report to "Clovis," the "Company," "we," "us" and "our" refer to Clovis Oncology, Inc., together with its consolidated subsidiaries.*

### ITEM 1. BUSINESS

#### Overview

We are a biopharmaceutical company focused on acquiring, developing and commercializing innovative anti-cancer agents in the United States, Europe and additional international markets. We target our development programs for the treatment of specific subsets of cancer populations, and simultaneously develop, with partners, for those indications that require them, diagnostic tools intended to direct a compound in development to the population that is most likely to benefit from its use.

Our marketed product Rubraca® (rucaparib), an oral small molecule inhibitor of poly ADP-ribose polymerase ("PARP"), is marketed in the United States for two indications specific to recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer. The initial indication received approval from the United States Food and Drug Administration ("FDA") in December 2016 and covers the treatment of adult patients with deleterious BRCA (human genes associated with the repair of damaged DNA) mutation (germline and/or somatic)-associated epithelial ovarian, fallopian tube, or primary peritoneal cancer who have been treated with two or more chemotherapies and selected for therapy based on an FDA-approved companion diagnostic for Rubraca. In April 2018, the FDA also approved Rubraca for the maintenance

treatment of adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy. The approval in this second, broader and earlier-line indication on a priority review timeline was based on positive data from the phase 3 ARIEL3 clinical trial. Diagnostic testing is not required for patients to be prescribed Rubraca in this maintenance treatment indication.

In May 2018, the European Commission granted a conditional marketing authorization for Rubraca as monotherapy treatment of adult patients with platinum-sensitive, relapsed or progressive, BRCA mutated (germline and/or somatic), high-grade epithelial ovarian, fallopian tube, or primary peritoneal cancer, who have been treated with two or more prior lines of platinum-based chemotherapy, and who are unable to tolerate further platinum-based chemotherapy. This conditional approval requires the completion of certain confirmatory post marketing commitments. In January 2019, the European Commission granted a variation to the marketing authorization to include the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy. With this approval, Rubraca is now authorized in the European Union ("EU") for certain patients in the recurrent ovarian cancer maintenance setting regardless of their BRCA mutation status. Following successful reimbursement negotiations in each country, commercial launches of Rubraca are underway in each of Germany, England, Italy and France and planned in Spain shortly.

Additional 2019 Rubraca key regulatory and clinical developments include the following:

- In November 2019, we submitted the supplemental New Drug Application ("sNDA") for Rubraca as a monotherapy treatment of adult patients with BRCA1/2-mutant recurrent, metastatic castrate-resistant prostate cancer. On January 15, 2020, we announced that the FDA accepted the sNDA and granted priority review status to the application with a Prescription Drug User Fee Act ("PDUFA") date of May 15, 2020. We are actively preparing for the launch of Rubraca in prostate cancer in the U.S., which we will commence upon receipt of FDA approval.
- We initiated the Phase 2 LODESTAR study in December 2019 to evaluate Rubraca in homologous recombination repair genes across tumor types. The study will evaluate rucaparib as monotherapy treatment in patients with recurrent solid tumors associated with a deleterious mutation in homologous recombination repair ("HRR") genes. Based on our interactions with the FDA, this study may be registration-enabling for a targeted gene- and tumor-agnostic label, if data from the trial support an accelerated approval.

Beyond our initial labeled indication, we have a clinical development program underway to further evaluate Rubraca in a variety of solid tumor types, either as monotherapy or in combination with other agents, including several studies as part of our ongoing clinical collaboration with Bristol-Myers Squibb Company ("BMS") to evaluate its immunotherapy OPDIVO® (nivolumab) in combination with Rubraca. We hold worldwide rights for Rubraca.

In addition to Rubraca, we have a second product candidate currently in clinical development. Lucitanib is an investigational, oral, potent inhibitor of the tyrosine kinase activity of vascular endothelial growth factor receptors 1 through 3 ("VEGFR1-3"), platelet-derived growth factor receptors alpha and beta ("PDGFR α/β") and fibroblast growth factor receptors 1 through 3 ("FGFR1-3"). We believe that data for a drug similar to lucitanib that inhibits these same pathways – when combined with a PD-1 inhibitor – represent a scientific rationale for development of lucitanib in combination with a PD-1 inhibitor, and in February 2019, lucitanib was added to our clinical collaboration with BMS. Encouraging data of VEGF and PARP inhibitors in combination also supports the evaluation of lucitanib combined with Rubraca. Thus, currently enrolling Phase 1b/2 combination studies involving lucitanib consist of the Clovis-sponsored LIO-1 study of lucitanib in combination with nivolumab in advanced gynecologic cancers and other solid tumors and an arm of the Clovis-sponsored SEASTAR study evaluating lucitanib in combination with Rubraca in advanced solid tumors. In addition to the LIO-1 study, the BMS-sponsored Phase 1/2 study CheckMate 79X is planned to initiate in early 2020 to evaluate multiple combinations of nivolumab with other therapies, including an arm with lucitanib in patients with second-line non-small cell lung cancer. We hold the global (excluding China) development and commercialization rights for lucitanib.

In September 2019, we entered into a license and collaboration agreement with 3B Pharmaceuticals GmbH ("3BP") to develop a peptide-targeted radionuclide therapy ("PTRT") and imaging agent targeting fibroblast-activating protein alpha ("FAP").

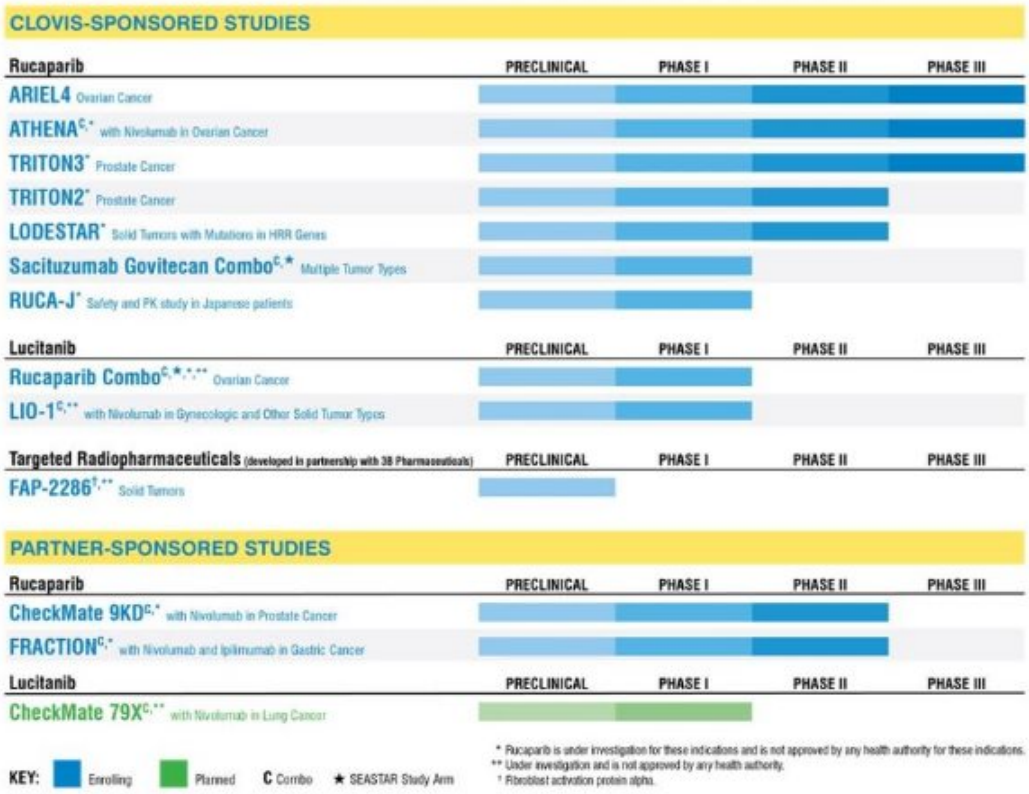
Following completion of preclinical work to support an investigational new drug application ("IND") for the lead candidate under our license and collaboration agreement, designated internally as FAP-2286, we plan to conduct global

clinical trials. We anticipate submitting the IND in the second half of 2020 to support an initial Phase 1 study to determine the dose and tolerability of FAP-2286 as a therapeutic agent. We hold U.S. and global rights to FAP-2286, excluding Europe (inclusive of Russia, Turkey and Israel), where 3BP retains rights. We also have agreed with 3BP to collaborate on a discovery program directed to up to three additional, undisclosed targets for peptide-targeted radionuclide therapy, to which we would obtain global rights for any resulting product candidates.

Clovis was founded in 2009. We have built our organization to support innovative oncology drug development for the treatment of specific subsets of cancer populations. To implement our strategy, we have assembled an experienced team with core competencies in global clinical and non-clinical development, regulatory operations and commercialization in oncology, as well as establishing collaborative relationships with companies specializing in companion diagnostic development.

**Clinical Development Pipeline**

We continue to evaluate the use of Rubraca for selected patient populations and, where appropriate, collaborate with partners for companion diagnostic development. We have focused our development strategy for Rubraca on indications where we believe patient populations exhibit higher frequencies of mutant BRCA tumors or tumors with other homologous recombination deficiencies ("HRD"), where PARP inhibitors have demonstrated clinical or pre-clinical activity in tumors. We are also developing lucitanib in combinations, including with Rubraca, based on encouraging data in clinical studies of other similar oncology compounds. FAP-2286 is currently the subject of IND-enabling preclinical studies and we plan to submit the IND in the second half of 2020. The following table summarizes the ongoing or planned Clovis- or partner-sponsored studies:




In certain of these trials, we or our partners may have access to interim data on a periodic or continuing basis that will not be made available publicly on the same timeframe as such data becomes available to us, or at all.

**Rubraca – a PARP Inhibitor**

*Overview*

Rubraca (rucaparib) is an oral, small molecule inhibitor of PARP1, PARP2 and PARP3. We in-licensed Rubraca from Pfizer, Inc. in June 2011 and hold exclusive worldwide rights. Rubraca has received regulatory approvals in the United States and the EU for patients with recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer.

In the United States, Rubraca is approved by the FDA for the treatment of adult patients with deleterious BRCA mutation (germline and/or somatic)-associated epithelial ovarian, fallopian tube, or primary peritoneal cancer who have been treated with two or more chemotherapies and selected for therapy based on an FDA-approved companion diagnostic for Rubraca. BRCA mutations are believed to occur in approximately 25 percent of women with ovarian cancer. In April 2018, the FDA granted a second approval for Rubraca for the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy, a broader and earlier-line indication. Diagnostic testing is not required for patients to be prescribed Rubraca in this maintenance treatment indication.

In the EU, the EMA granted a conditional marketing authorization for Rubraca in May 2018 as monotherapy treatment of adult patients with platinum-sensitive, relapsed or progressive, BRCA mutated (germline and/or somatic), high-grade epithelial ovarian, fallopian tube, or primary peritoneal cancer, who have been treated with two or more prior lines of platinum-based chemotherapy, and who are unable to tolerate further platinum-based chemotherapy. This conditional approval requires the completion of certain confirmatory post marketing commitments. In January 2019, the European Commission granted a variation to the marketing authorization to include the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy. With this approval, Rubraca is now authorized in the EU for certain patients in the recurrent ovarian cancer maintenance setting regardless of their BRCA mutation status. Following successful reimbursement negotiations in each country, commercial launches of Rubraca are underway in each of Germany, England, Italy and France and planned in Spain shortly.

*The Role of PARP Inhibition in Cancer Therapy*

Cells in the human body are under constant attack from agents that can cause damage to DNA, including sunlight and other forms of radiation, as well as DNA-binding chemicals that can cause changes in the composition of DNA. Cells have evolved multiple mechanisms to enable such DNA repair, and these mechanisms are complementary to each other, each driving repair of specific types of DNA damage. If a cell's DNA damage repair system is overwhelmed, then the cell will die undergoing a form of suicide termed apoptosis. A fundamental principle of cancer therapy is to damage cells profoundly with radiation or DNA-binding drugs, such as alkylating agents or platinums, to induce apoptosis and, subsequently, cancer cell death. Multiple DNA repair mechanisms active in the cell may reduce the activity of these anti-cancer therapies.

The PARP family comprises 17 structurally related proteins that have been identified on the basis of sequence similarity. PARP1, PARP2, and PARP3 play a central role in DNA repair. They are rapidly recruited to the sites of DNA damage and catalyze the recruitment of additional proteins that initiate the repair of damaged DNA. The breast cancer 1 (BRCA1) and breast cancer 2 (BRCA2) genes also have important roles in DNA repair pathways such as homologous recombination. According to the National Cancer Institute, BRCA1 and BRCA2 mutations are associated with an increased risk of ovarian, breast, prostate, and pancreatic cancers.

Rubraca is an inhibitor of PARP enzymes, including PARP1, PARP2, and PARP3. PARP inhibitors have shown activity in BRCA1/2 mutant and homologous recombination ("HR") repair deficient cancer cell lines through a mechanism known as synthetic lethality in which the loss of two genes/pathways is required for cell death. The inhibition/inactivation of repair pathways by administration of a PARP inhibitor in the context of an underlying genetic defect such as a BRCA mutation results in tumor cell death through accumulation of unrepaired DNA damage.

Alterations in DNA repair genes other than BRCA1/2 have been observed in, and contribute to the hereditary risk of, ovarian, breast, prostate and pancreatic cancers. PARP inhibitors have shown evidence of nonclinical and clinical activity in tumors with alterations in non-BRCA HR genes. DNA repair deficiencies resulting from genetic and

epigenetic alterations can result in a "BRCA-like" phenotype that may also render tumor cells sensitive to PARP inhibitors. One approach to identify patients with DNA repair deficiencies due to mechanisms other than a mutation in BRCA or other non-BRCA HR genes is to assess loss of heterozygosity ("LOH"), or the loss of one normal copy of a gene, which arises from error-prone DNA repair pathways when HR is compromised.

On the basis of these scientific observations, we initially developed Rubraca in ovarian cancer patients with tumors having BRCA mutations or other HRD. These molecular markers also may be used to select patients with other tumors for treatment with Rubraca. Thus, in addition to ovarian trials, studies open for enrollment or under consideration to further evaluate Rubraca, either alone or in combination with other agents, include prostate, breast, pancreatic, bladder and gastroesophageal cancers.

*Ovarian cancer*

According to the American Cancer Society, an estimated more than 22,000 women will be diagnosed with ovarian cancer in the United States in 2020, and according to GLOBOCAN in 2018, an estimated 68,000 women in Europe are diagnosed each year with ovarian cancer, and ovarian cancer is among those cancers with the highest rate of deaths. Approximately 80 to 85 percent of ovarian cancer cases are not diagnosed, and therefore remain untreated, until the disease has spread to other parts of the body. Most women with ovarian cancer will relapse after surgery and/or chemotherapy.

Rubraca's approvals in the U.S. and the EU in the recurrent BRCA mutant ovarian cancer treatment setting were based on data from two multicenter, single-arm, open-label clinical trials, Study 10 (NCT01482715) and ARIEL2 (NCT01891344), in women with advanced BRCA-mutant ovarian cancer who had progressed after two or more prior chemotherapies. All patients received Rubraca orally 600 mg twice daily as monotherapy. Treatment continued until disease progression or unacceptable toxicity. The primary efficacy outcome measure of both studies was objective response rate (ORR) as assessed by the investigator according to Response Evaluation Criteria in Solid Tumors (RECIST) version 1.1. Results from a blinded independent radiology review ("BICR") were consistent.

The efficacy of Rubraca in the ovarian cancer maintenance treatment setting was investigated in ARIEL3 (NCT01968213), a double-blind, multicenter clinical trial in which 564 patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who were in response to platinum-based chemotherapy were randomized (2:1) to receive Rubraca tablets 600 mg orally twice daily (n=375) or placebo (n=189). Treatment was continued until disease progression or unacceptable toxicity. All patients had achieved a response (complete or partial) to their most recent platinum-based chemotherapy. Randomization was stratified by best response to last platinum (complete or partial), time to progression following the penultimate platinum therapy (6 to < 12 months and ≥ 12 months), and tumor biomarker status. The major efficacy outcome was investigator-assessed progression-free survival ("PFS") evaluated according to RECISTv1.1.

The primary efficacy analysis evaluated three prospectively defined molecular sub-groups in a step-down manner: 1) tumor BRCA mutant ("tBRCAmut") patients, inclusive of germline and somatic BRCA mutations (n=196); 2) HRD patients, including tBRCAmut patients and BRCA wild-type with high LOH (n=354), and, finally, 3) the intent-to-treat population, or all patients treated in ARIEL3 (n=564). ARIEL3 demonstrated a statistically significant improvement in PFS for patients randomized to Rubraca as compared with placebo in all patients, and in the HRD and tBRCAmut subgroups. Median PFS in the tBRCAmut patients was 16.6 months (95% CI: 13.4–22.9) in the Rubraca group (n=130) versus 5.4 months (95% CI: 3.4–6.7) in the placebo group (n=66) (Hazard Ratio, or HR: 0.23 [95% CI: 0.16–0.34]; p<0.0001). Median PFS in the HRD patients was 13.6 months (95% CI: 10.9–16.2) in the Rubraca group (n=236) versus 5.4 months (95% CI: 5.1–5.6) in the placebo group (n=118) (HR: 0.32 [95% CI: 0.24–0.42]; p<0·0001). Median PFS in the intent-to-treat population was 10.8 months (95% CI: 8.3–11.4) in the Rubraca group (n=375) versus 5.4 months (95% CI: 5.3–5.5) in the placebo group (n=189) (HR: 0.36 [95% CI: 0.30–0.45]; p<0·0001).

BICR results were consistent. In a pre-specified analysis of the key stand-alone secondary endpoint of progression-free survival assessed by BICR, PFS was also improved in the Rubraca group compared with placebo in all three populations. Median PFS in the tBRCAmut patients was 26.8 months (95% CI: 19.2 to not reached) in the Rubraca group versus 5.4 months (95% CI: 4.9–8.1) in the placebo group (HR: 0.20 [95% CI: 0.13–0.32]; p<0.0001). Median PFS in the HRD patients was 22.9 months (95% CI: 16.2 to not reported) in the Rubraca group versus 5.5 months (95% CI: 5.1–7.4) in the placebo group (HR: 0.34 [95% CI: 0.24–0.47]; p<0.0001). Median PFS in the intent-to-treat

population was 13.7 months (95% CI: 11.0–19.1) versus 5.4 months (95% CI: 5.1–5.5) in the placebo group (HR: 0.35 [0.28–0.45]; p<0.0001).

Enrollment in ARIEL3 included one-third of patients who had achieved a complete response to their prior platinum-based therapy, and two-thirds of patients who had achieved a partial response to their prior platinum-based therapy. Of those with a partial response, 37% had measurable disease at the time of enrollment and were therefore evaluable for response. The confirmed overall response rate by investigator-assessed RECISTv1.1 in the tBRCAmut group treated with Rubraca was 37.5% (15/40), of these, 17.5% (7/40) were complete responses. This compared with 9% (2/23) in the placebo group (p=0.0055). No complete responses were seen in the tBRCAmut placebo group. RECIST responses were also observed in BRCA wild-type HRD-positive and BRCA wild-type HRD-negative subgroups. In a subsequent post hoc exploratory analysis of ARIEL3 data, a higher response rate was also seen in patients without measurable disease in both the tBRCAmut group and the intent to treat population (inclusive of BRCAmut patients) as compared to placebo. RECIST responses were not assessed by independent blinded review.

Safety data from ARIEL3 demonstrated consistency with prior Rubraca studies. Treatment emergent adverse events ("TEAEs") in the ARIEL3 Rubraca group were generally managed with dose modifications and not associated with increased mortality or morbidity compared with the placebo group. The most common (occurring in ≥5% of patients) TEAEs of grade ≥3 reported in patients treated with Rubraca in the ARIEL3 study were anemia/decreased hemoglobin (21%), increase in ALT/AST (10%), neutropenia (7%), asthenia/fatigue (7%) and thrombocytopenia (5%). The discontinuation rate for TEAEs (excluding disease progression) was 15% for Rubraca-treated patients and 2% for the placebo arm. In ARIEL3, the rate of treatment-emergent myelodysplastic syndrome ("MDS")/acute myeloid leukemia ("AML") in the Rubraca arm was <1% (3/372), and no patients on the placebo arm experienced treatment-emergent MDS/AML. In approximately 1,100 patients treated with Rubraca, MDS/AML occurred in 10 patients (0.9%), including those in long term follow-up. Of these, 5 occurred during treatment or during the 28-day safety follow-up (0.5%). The duration of Rubraca treatment prior to the diagnosis of MDS/AML ranged from 1 month to approximately 28 months. The cases were typical of secondary MDS/cancer therapy-related AML; in all cases, patients had received previous platinum containing chemotherapy regimens and/or other DNA damaging agents.

At the time of the analysis of PFS, overall survival (OS) data were not mature (with 22% of events). The comprehensive dataset for ARIEL3 was presented at the 2017 European Society of Medical Oncology ("ESMO") Congress in early September 2017 and subsequently published in *The Lancet*. The ARIEL3 dataset formed the basis for sNDA filed with the FDA as well as the marketing authorization variation filed with the EMA supporting the approval of Rubraca in the US in April 2018 and the EU in January 2019 respectively, as maintenance treatment in adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy.

The ARIEL4 confirmatory study (NCT 02855944) is a Phase 3 multicenter, randomized study of Rubraca versus chemotherapy enrolling relapsed ovarian cancer patients with BRCA mutations (inclusive of germline and/or somatic) who have failed two prior lines of therapy. The primary endpoint of the study is PFS. This study represents a post marketing commitment to support the conditional approval granted for the treatment indication in the EU, including ensuring that sufficient partially platinum-sensitive patients are enrolled in the trial. This may require enrollment of additional patients into the study, increasing its overall size and extending the time for enrollment.

The Phase 1 RUCA-J study has identified the recommended 600 mg BID dose of rucaparib in Japanese patients, which will enable development of a bridging strategy and potential inclusion of Japanese sites in planned or ongoing global studies. Enrollment is complete for this study.

*Prostate cancer*

The American Cancer Society estimates that approximately 192,000 men in the United States will be diagnosed with prostate cancer in 2020, and the GLOBOCAN Cancer Fact Sheets estimated that approximately 450,000 men in Europe were diagnosed with prostate cancer in 2018. Castrate-resistant prostate cancer has a high likelihood of developing metastases. Metastatic castrate-resistant prostate cancer ("mCRPC") is an incurable disease, usually associated with poor prognosis. Approximately 43,000 men in the U.S. are expected to be diagnosed with mCRPC in 2020. According to the American Cancer Society, the five-year survival rate for mCRPC is approximately 30%. A number of publications have reported germline or somatic mutations in BRCA1 or BRCA2 are approximately 12 percent in mCRPC according to an

article published in JCO Precision Oncology in 2017. These molecular markers may be used to select patients for treatment with a PARP inhibitor.

The TRITON (Trial of Rucaparib in Prostate Indications) program in prostate cancer initiated in the second half of 2016, and currently includes two Clovis-sponsored potential registration studies. Enrollment is complete for TRITON2; TRITON3 continues to enroll patients.

The TRITON2 study (NCT02952534) is a Phase 2 single-arm study of Rubraca in men with mCRPC that enrolled patients with BRCA mutations (inclusive of germline and/or somatic) or other deleterious mutations in other homologous recombination repair genes. Patients in the TRITON2 study have received prior treatment with at least one androgen receptor ("AR")-directed therapy and one previous line of taxane-based chemotherapy and were screened for a deleterious germline or somatic mutation in BRCA1, BRCA2 or one of 13 other pre-specified homologous recombination ("HR") genes. Study participants are allocated into three cohorts based on the type of gene mutation and disease status, which is determined by genomic sequencing and RECIST criteria, respectively. Each cohort receives 600 mg Rubraca twice daily and are grouped based on the following criteria: A) mutation in either BRCA1, BRCA2 or ATM genes, with tumors that can be measured with visceral and/or nodal disease; B) mutation in either BRCA1, BRCA2 or ATM genes, with tumors that cannot be measured with visceral and/or nodal disease, or C) mutation in another HR gene associated with sensitivity to PARP inhibition, with or without measurable disease. The primary study endpoints include confirmed ORR per RECIST/PCWG3 in patients with measurable disease at baseline by independent review and PSA response in patients with no measurable disease at baseline. Secondary endpoints include overall survival ("OS"), clinical benefit rate, and safety and tolerability.

In November 2019, we submitted the sNDA for Rubraca as a monotherapy treatment of adult patients with BRCA1/2-mutant recurrent, metastatic castrate-resistant prostate cancer. On January 15, 2020, we announced that the FDA accepted the sNDA and granted priority review status to the application with a PDUFA date of May 15, 2020.

Rubraca was granted Breakthrough Therapy designation ("BTD") for its development as a monotherapy treatment of adult patients with BRCA1/2-mutated mCRPC who have received at least one prior androgen receptor (AR)-directed therapy and taxane-based chemotherapy on October 1, 2018 by the FDA.

The TRITON3 study (NCT02975934), a Phase 3 comparative study in men with mCRPC enrolling BRCA mutant and ATM (both inclusive of germline and/or somatic) patients who have progressed on AR-targeted therapy and who have not yet received chemotherapy in the castrate-resistant setting. TRITON3 will compare Rubraca to physician's choice of AR-targeted therapy or chemotherapy in these patients. The planned primary endpoint of the study is radiologic PFS. TRITON3 initiated during the first quarter of 2017, and this earlier-line comparative study could potentially serve as a confirmatory study in the advanced prostate setting should the sNDA currently under review for BRCA1/2-mutant recurrent mCRPC support an accelerated approval.

*LODESTAR tumor-agnostic study*

The LODESTAR clinical study (NCT04171700) is a Phase 2 study evaluating rucaparib as monotherapy treatment in patients with recurrent solid tumors associated with a deleterious HRR gene mutation across a variety of tumor types. These gene mutations included in the primary cohort include BRCA1, BRCA2, PALB2, RAD51C, RAD51D, as well as several additional genes in an exploratory cohort. We anticipate that this study may potentially be registration-enabling for a targeted gene- and tumor-agnostic label. The study initiated in late 2019.

*Combination trials*

Our ongoing collaboration with BMS involves the evaluation of the combination of Rubraca with BMS's immunotherapy Opdivo® (nivolumab) in multiple tumor types.

We believe that a preclinical rationale supports the conduct of clinical trials of the combination of our PARP inhibitor Rubraca with immune checkpoint inhibitors such as the PD-1 inhibitor Opdivo. BRCA1 and BRCA2 and other HRD mutations are associated with increased tumor mutational burden, which may create additional tumor-specific antigens or "neoepitopes." Increased tumor mutation burden has been shown to correlate with increased benefit from immune checkpoint blockade. In addition, cell death that is induced by a PARP inhibitor is considered immunogenic and stimulates a "STING-like" pathway due to fragmented DNA release into cytosol. In mice studies, rucaparib and an anti-

PD-1 antibody demonstrated anti-tumor activity in BRCA1 mutant ovarian tumors. The combination of rucaparib and either an anti-PD-L1 or anti-CTLA-4 antibody were equally compelling in preclinical studies.

Three combination trials of Rubraca and Opdivo are currently underway sponsored by Clovis or BMS, and in February 2019, lucitanib was added to the clinical collaboration in combinations with Opdivo.

ATHENA is the Clovis-sponsored four-arm first-line maintenance treatment study (NCT03522246) to evaluate Rubraca and Opdivo, Rubraca, Opdivo and placebo in an estimated 1,000 newly diagnosed patients with stage III/IV high-grade ovarian, fallopian tube, or primary peritoneal cancer who have completed platinum-based chemotherapy. The primary objectives are first, to determine if Rubraca extends PFS versus placebo, and second, to determine if the combination of Rubraca and Opdivo meaningfully extends PFS versus Rubraca monotherapy, or versus placebo. The ATHENA study, which initiated in 2018, is expected to complete enrollment in the second quarter of 2020, and evaluate Rubraca in terms of two key outcomes in a step-down manner: monotherapy versus placebo in the first-line maintenance setting in the HRD population, inclusive of BRCA, and in the all comers (intent-to-treat) population, and later, any potential advantage for the combination of Rubraca and Opdivo in the same patient populations. ATHENA is the first front-line switch maintenance study to evaluate a PARP inhibitor as monotherapy and in combination with an anti-PD-1 in one study design. We anticipate the results of the Rubraca monotherapy arm versus placebo in all study populations in the second half of 2021, and then a year or more later, the results of Rubraca plus Opdivo versus Rubraca in all study populations. Each of the analyses will first evaluate outcomes in the HRD population, inclusive of BRCA, and then step down to the entire intent-to-treat population.

BMS is sponsoring CheckMate 9KD (NCT03338790), a Phase 2 three-arm study in mCRPC, evaluating Opdivo + Rubraca, Opdivo + docetaxel + prednisone, and Opdivo + enzalutamide, with the objective of determining how the combinations affects objective response rate and PSA response. The study is enrolling patients with biomarker negative or positive disease, and tumor tissue samples are being used to determine biomarker status. BMS initiated the study in the fourth quarter of 2017.

BMS is also sponsoring FRACTION-GC (NCT02935634), a Phase 2 multi-arm study evaluating Opdivo in combination with other therapies in advanced gastric cancer. The trial includes, among other combinations, an evaluation of Opdivo + Rubraca, Yervoy + Rubraca and the triplet combination of Opdivo + Yervoy + Rubraca. This is the first sponsored study to explore this triplet combination, and it is now enrolling patients into the safety lead-in part of the Rubraca-containing portion of the study.

Beyond the BMS clinical collaboration, the Clovis-sponsored SEASTAR Phase 1b/2 study (NCT03992131) is comprised of multiple single-arm rucaparib combination studies, including:

- Rubraca with lucitanib, our investigational inhibitor of multiple tyrosine kinases including VEGFR, for the treatment of advanced solid tumors in the Phase 1b portion. This study is currently enrolling patients in the dose-finding portion of the study.
- As part of a clinical collaboration with Immunomedics, Rubraca with sacituzumab govitecan, Immunomedics' lead antibody-drug conjugate product candidate. The safety cohort is currently enrolling patients, and decisions on any expansion cohorts will be made following review of safety data.

*Pancreatic cancer*

Interim results from an investigator-initiated Phase 2 trial of Rubraca as first-line maintenance therapy in platinum-sensitive patients with advanced pancreatic cancer reported at the American Association for Cancer Research ("AACR") annual meeting in April 2019 suggest that first-line maintenance therapy with Rubraca following induction with platinum-based chemotherapy provides disease control with no new safety signals among patients with a pathogenic mutation in BRCA1, BRCA2 or PALB2. Based on these data as well as the earlier Clovis-sponsored RUCAPANC study, we plan to enroll patients with pancreatic cancer and selected genetic mutations in the LODESTAR pan-tumor study of rucaparib that initiated in late 2019.

*Bladder cancer*

In April 2019, we discontinued our Clovis-sponsored ATLAS Phase 2 open-label monotherapy clinical trial evaluating rucaparib in recurrent, metastatic bladder cancer. The decision was based on recommendations by an independent data monitoring committee ("DMC") following its review of preliminary efficacy data for 62 patients

enrolled and treated in the study, which demonstrated that the objective response rate in the intent-to-treat population did not meet the protocol-defined continuance criteria, and suggested that monotherapy treatment may not provide a meaningful clinical benefit in the all-comer patient population enrolled in the trial. Following the DMC's recommendation to stop enrollment in the study, we terminated the ATLAS study early. We plan to enroll patients with advanced bladder cancer and selected genetic mutations in the LODESTAR pan-tumor study of rucaparib that initiated in late 2019.

*Companion Diagnostics*

Two FDA-approved companion diagnostic tests are commercially available to select ovarian cancer patients for treatment with Rubraca.

Foundation Medicine, Inc. ("Foundation") markets its comprehensive companion diagnostic test for solid tumors, FoundationOne®CDx ("F1CDx"), a next generation sequencing-based in vitro diagnostic device for detection of substitutions, insertion and deletion alterations, and copy number alterations in 324 genes (including BRCA1/2), select gene rearrangements, as well as genomic signatures, including LOH, microsatellite instability and tumor mutational burden using tumor tissue specimens. F1CDx is approved as a companion diagnostic to select ovarian cancer patients with BRCA1/2 mutations for treatment with Rubraca.

BRACAnalysis™CDx, is a blood-based assay for the qualitative detection and classification of germline mutations in BRCA1/2 genes commercialized by Myriad Genetics Laboratories, Inc. BRACAnalysis CDx is approved as a companion diagnostic to select ovarian cancer patients with BRCA1/2 mutations for treatment with Rubraca.

In July 2019, we entered into an agreement with Foundation to collaborate on the development of a plasma-based companion diagnostic assay to select patients with deleterious BRCA1/2 mutations for treatment with Rubraca based on Foundation's liquid biopsy platform, FoundationOne®Liquid.

***Lucitanib – a VEGFR, PDGFR and FGFR Inhibitor***

Lucitanib is an investigational, oral, potent inhibitor of the tyrosine kinase activity of vascular endothelial growth factor receptors 1 through 3 ("VEGFR1-3"), platelet-derived growth factor receptors alpha and beta ("PDGFR α/β") and fibroblast growth factor receptors 1 through 3 ("FGFR1-3"). We believe that data for a drug similar to lucitanib that inhibits these same pathways – when combined with a PD-1 inhibitor – represent a scientific rationale for development of lucitanib in combination with a PD-1 inhibitor, and in February 2019, lucitanib was added to our clinical collaboration with BMS. Encouraging data of VEGF and PARP inhibitors in combination also supports the evaluation of lucitanib combined with Rubraca. Thus, currently enrolling Phase 1b/2 combination studies involving lucitanib consist of the Clovis-sponsored LIO-1 study (NCT04042116) of lucitanib in combination with nivolumab in advanced gynecologic cancers and other solid tumors and an arm of the Clovis-sponsored SEASTAR study evaluating lucitanib in combination with Rubraca in advanced solid tumors. We anticipate initial data from these studies to be presented at medical meetings in 2020. In addition to the LIO-1 study, the BMS-sponsored Phase 1/2 study CheckMate 79X is planned to initiate in early 2020 to evaluate multiple combinations with nivolumab, including an arm with lucitanib in patients with second-line non-small cell lung cancer.

The composition of matter patent for lucitanib expires in 2030 in the U.S. and 2028 in Europe, with up to five years patent term extension available. We hold the global (excluding China) development and commercialization rights for lucitanib.

*VEGF, PDGF and FGF: The Role of these Tyrosine Kinase Inhibitors in Cancer*

The VEGFs are a family of related extracellular proteins that normally regulate blood and lymphatic vessel development in humans. They act by binding to and activating VEGF receptors, which are cell surface proteins that transmit growth signals to specific cells that are involved in the development of new blood vessels. Certain VEGFs promote growth of multiple solid tumors by stimulating the formation of new blood vessels to feed the tumor and allow it to grow and metastasize. Tumors produce an excessive amount of VEGF. This results in excess VEGFR signaling and the formation of new blood vessels within the tumor. The VEGF ligands that induce angiogenesis are often present in a wide range of cancer indications, including a type of kidney cancer called renal cell carcinoma, a type of liver cancer called hepatocellular carcinoma, gastric cancer, head and neck cancers and other solid tumors.

The PDGF family consists of five different isoforms of PDGF ligand that bind to and activate cellular responses through two different receptors (PDGFRα/ß). In tumors, PDGF signaling plays a diverse role in many aspects of tumor development promoting cell proliferation, invasion, migration and angiogenesis. Amplification and/or mutation of the gene encoding the PDGFRα receptor is observed in a wide range of cancers, including lung cancer, an aggressive form of brain cancer called glioblastoma and a cancer of the gastrointestinal tract known as gastrointestinal stromal tumors. Amplification of the PDGFRα gene results in excess production, or the over-expression, of PDGFRα protein on the surface of the tumor cell. The over-expression of PDGFRα on the tumor cell surface leads to an increased receptor signaling, which stimulates uncontrolled proliferation of some types of tumor cells.

The FGFs are a family of related extracellular proteins that normally regulate cell proliferation and survival in humans. The FGF family consists of 22 ligands that exert their physiological effect on cells by binding to four FGFRs (FGFR1- 4). As with the PDGF family, some cancers display FGF/FGFR gene amplification/mutation resulting in continual activation of the FGFR signaling pathway leading to uncontrolled cell division. Tumors with a relatively high incidence of FGF aberrations, which include amplification of the FGFR1 gene and amplification of a region of chromosome 11q that contains several FGF ligands, include breast and lung cancers. In addition, FGFR gene amplification/mutation is also observed in a wide range of cancer indications including sarcoma, ovarian cancer, adenocarcinoma of the lung, bladder cancer, colorectal cancer and endometrial cancer.

As an inhibitor of VEGFR1-3, PDGFRα/ß and FGFR1-3 and given the role that each of these receptor kinases plays in tumor progression and metastasis formation, lucitanib has the potential benefit of targeting three relevant pro-angiogenic growth factors in targeted patient populations identified by molecular markers. Data from earlier studies suggest that lucitanib's VEGF inhibition may be the primary driver of its activity, and both preclinical and clinical data provide a scientific rationale for further development on lucitanib in combination with other agents.

Targeting angiogenesis and immune checkpoint pathways may have a synergistic effect on antitumor activity. Angiogenesis has been shown to be immunosuppressive within the tumor microenvironment, dampening anti-tumor immune responses, according to Nature Reviews in Clinical Oncology (Fukumara 2018). Immune effects of angiogenesis include modulation of T-cell infiltration into the tumor, inhibition of dendritic cell maturation, and the modulation of cell adhesion molecules and immune cell populations. Inhibition of angiogenesis by small molecule RTK inhibitors or monoclonal antibodies may reverse immunosuppression. These data suggest the clinical activity of PD-(L)1 inhibitors may be enhanced through the inhibition of angiogenesis by lucitanib. Clovis preclinical studies of multiple syngeneic tumor models have shown that lucitanib in combination with a PD-1 inhibitor delivers superior activity. In addition to the Clovis- and BMS-sponsored studies underway, multiple additional Phase 1-3 studies are examining the combination of angiogenesis and PD-(L)1 inhibitors in different indications.

Preclinical and clinical data support the potential activity of combining angiogenesis and PARP inhibition. According to Cancer Research (Bindra 2005, Chan 2008, Chan 2010) and Molecular and Cellular Biology (Bindra 2004), there is a link between PARP inhibition and suppression of angiogenesis: chronic hypoxia induces down-regulation of BRCA1 and RAD51 and decreases homologous recombination in cancer cells. Clovis preclinical data in an ovarian tumor BRCA1mut syngeneic model showed the combination of lucitanib and rucaparib is more active than monotherapy than either lucitanib or rucaparib as a single agent and showed similar anti-tumor activity to rucaparib in combination with another oral VEGFR inhibitor. Published clinical data for the combination of another oral VEGFR inhibitor and PARP inhibitor in development further demonstrate the potential activity of the combination.

***FAP-2286 and Peptide-Targeted Radiopharmaceutical Therapy Discovery Program***

FAP-2286 is a preclinical candidate discovered by 3BP under investigation as a peptide-targeted radionuclide therapy ("PTRT") and imaging agent targeting fibroblast activation protein alpha ("FAP"). In September 2019, we acquired U.S. and global rights to FAP-2286, excluding Europe (inclusive of Russia, Turkey and Israel), where 3BP retains rights. We plan to file an IND application for FAP-2286 in the second half of 2020 to support a Phase 1 study to determine the dose and tolerability of FAP-2286 as a therapeutic agent, with expansion cohorts planned in multiple tumor types as part of a global development program.

Patent applications are pending that claim FAP-2286 generically and specifically (including with respect to composition of matter) that, if issued, would have expiration dates in 2040.

We also have agreed with 3BP to collaborate on a discovery program directed to up to three additional, undisclosed targets for peptide-targeted radionuclide therapy, to which we would obtain global rights for any resulting product candidates.

*The Role of Fibroblast Activation Protein Alpha as a Radiopharmaceutical Target*

FAP is highly expressed in cancer-associated fibroblasts ("CAFs") which are found in the majority of cancer types, potentially making it a suitable target across a wide array of solid tumors. FAP is highly expressed in many epithelial cancers, including more than 90 percent of breast, lung, colorectal and pancreatic carcinomas. CAFs are highly prevalent in the tumor microenvironment of many cancers and persist through all malignant stages of a tumor, from primary tumor to metastasis. FAP has limited expression on normal fibroblasts, reducing the potential for effects in normal tissue.

PTRT is an emerging class of drugs and it involves the injection of a small amount of radioactive material – a radionuclide – that is combined with a cancer-targeting peptide for use as a targeted pharmaceutical. The targeting peptide is able to recognize and bind to specific receptors on the cancel cells, and the intended result is to deliver a high dose of radiation to the tumor while sparing normal tissue because of its rapid systemic clearance. In order for the targeted radiopharmaceutical to be safe and efficacious, it must rapidly attach to cancer cells or in close vicinity to the cancer cells, be retained in or at the tumor site for a sufficient period of time that the radionuclide can have activity on the cancer cells, have minimal attachment to non-cancer cells, and then be rapidly cleared from the body.

Clinical studies of small molecule imaging agents targeting FAP have validated this target in a diverse number of cancer indications and support the further evaluation of peptide-targeted radionuclide therapy. FAP-targeted radiopharmaceuticals have at least two potential modes of anti-tumor activity: radiation crossfire, in which tumor cells are irradiated due to their close proximity to CAFs; and depletion of CAFs, disrupting the communication between the tumor cells and the tumor stroma. In addition, in certain tumor types, such as sarcoma and mesothelioma, FAP is expressed on the tumor cells themselves, and in those tumors, FAP-targeted radiopharmaceuticals may have a direct antitumor effect.

In addition, an evident biological rationale supports the combination of targeted radionuclide therapy with cancer therapies including PARP inhibitors and anti-PD-1/PDL-1 agents. While our initial development focus will be on monotherapy with FAP-2286, we may explore these types of combinations pre-clinically and clinically as well.

*First Clinical Experience Reported from FAP-2286 Named Patient Use*

Physicians in Germany and certain other countries may treat patients suffering from life-threatening diseases or disease leading to severe disability with experimental drugs if no other appropriate options are available under named-patient or similar programs. A physician may initiate treatment for specific patients until there is commercial product available and patients are encouraged to enroll in clinical trials where possible. Named patient programs are not clinical trials and the treating physician is solely responsible for, and makes all decisions independently, including dose and assessment of efficacy and safety, and the drug sponsor has no role in decisions.

In December 2019, Professor Dr. Richard P. Baum reported his initial independent clinical experience with FAP-2286 in named-patient use in ten patients at the International Centers for Precision Oncology ("ICPO") Foundation Symposium in Bad Berka, Germany. At Prof. Dr. Baum's clinic, FAP-2286 was linked to Gallium-68 as a tumor-imaging compound using PET/CT scanning and to Lutetium-177 as a therapeutic agent. While we were not provided the data behind his results and have not verified those results, we were encouraged by his presentation, and believe that his reported experience supports our pre-clinical and development plans.

As the early named patient use in Germany suggests, significant interest already exists within the academic community to explore the potential of FAP as an imaging and treatment target. We are evaluating opportunities to support investigator-initiated research proposals that could generate imaging data for FAP-2286 prior to the availability of any clinical data. Information from these independent projects could be useful to provide additional experience with FAP-2286 and better understand the characteristics of FAP expression in multiple tumor types.

**Competition**

The development and commercialization of new drugs is intensely competitive, and we face competition from major pharmaceutical companies, biotechnology companies, universities and other research institutions worldwide. Our competitors may develop or market products or other novel technologies that are more effective, safer or less costly than any that have been or will be commercialized by us, or may obtain regulatory approval for their products more rapidly than we may obtain approval for ours.

The acquisition or licensing of pharmaceutical products is also very competitive. More established companies, which have acknowledged strategies to license or acquire products, may have competitive advantages over us, as may other emerging companies that take similar or different approaches to product acquisitions. Many of our competitors have substantially greater financial, technical and human resources than we have. Our competitors also compete with us in recruiting and retaining qualified scientific, management and commercial personnel as well as in establishing clinical trial sites and patient enrollment for clinical trials.

Additional mergers and acquisitions in the pharmaceutical industry may result in even more resources being concentrated in our competitors. Competition may increase further because of advances made in the commercial applicability of technologies and greater availability of capital for investment in these fields. Our success will be based in part on our ability to build and actively manage a portfolio of drugs that addresses unmet medical needs and creates value in patient therapy.

***Rubraca Competition***

Lynparza®/olaparib (AstraZeneca UK Limited) was the first PARP inhibitor to market and has been approved in the US in the following indications:

- for the maintenance treatment of adult patients with deleterious or suspected deleterious germline or somatic BRCA-mutated ("gBRCAm" or "sBRCAm") advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy;
- for the treatment of adult patients who have deleterious or suspected deleterious gBRCAm advanced ovarian cancer who have been treated with three or more prior lines of chemotherapy;
- for the maintenance treatment of adult patients with recurrent epithelial, fallopian tube or primary peritoneal cancer, who are in a complete or partial response to platinum-based chemotherapy;
- in patients with deleterious or suspected deleterious gBRCAm, human epidermal growth factor receptor 2 ("HER2")-negative metastatic breast cancer who have been treated with chemotherapy in the neoadjuvant, adjuvant, or metastatic setting; and
- for the maintenance treatment of adult patients with deleterious or suspected deleterious gBRCAm metastatic pancreatic adenocarcinoma whose disease has not progressed on at least 16 weeks of a first-line platinum-based chemotherapy regimen.

Lynparza is approved in the EU as monotherapy for the:

- maintenance treatment of adult patients with advanced (FIGO stages III and IV) BRCA1/2-mutated (germline and/or somatic) high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer who are in response (complete or partial) following completion of first-line platinum-based chemotherapy;
- maintenance treatment of adult patients with platinum-sensitive relapsed high-grade epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in response (complete or partial) to platinum-based chemotherapy; and
- treatment of adult patients with germline BRCA1/2-mutations, who have HER2 negative locally advanced or metastatic breast cancer. Patients should have previously been treated with an anthracycline and a taxane in the (neo)adjuvant or metastatic setting unless patients were not suitable for these treatments. Patients with hormone receptor-positive breast cancer should also have progressed on or after prior endocrine therapy, or be considered unsuitable for endocrine therapy.

AstraZeneca and Merck & Co., Inc. have a global strategic oncology collaboration to co-develop and co-commercialize Lynparza for multiple cancer types. Lynparza is being investigated, alone and in combination with other agents, in multiple indications across several tumor types, including breast, prostate, and pancreatic cancers.

AstraZeneca has filed an sNDA for Lynparza in combination with bevacizumab, which has been granted priority review in the United States, for the maintenance treatment of patients with advanced ovarian cancer who are in complete or partial response to 1st-line platinum-based chemotherapy with bevacizumab. A PDUFA date is set for the second quarter of 2020.

In October 2019, the results of the PROFOUND Phase 3 trial were reported in men with metastatic castration-resistant prostate cancer ("mCRPC") who have a homologous recombination repair gene mutation and have progressed on prior treatments with new hormonal anticancer treatments. Results from the trial showed a statistically-significant and clinically-meaningful improvement in the primary endpoint of radiographic progression-free survival ("rPFS") with Lynparza vs. enzalutamide or abiraterone in men with mCRPC selected for BRCA1/2 or ATM gene mutations, a subpopulation of HRR gene mutations. AstraZeneca has filed an sNDA for second line mCRPC with HRR mutations based on data from the PROFOUND trial, and has been granted priority review, with a PDUFA date set for Q2 2020.

Zejula®/niraparib (GlaxoSmithKline plc) was the first PARP inhibitor approved for maintenance in the recurrent setting and is approved in the United States in the following indications:

- for the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy.
- for the treatment of adult patients with advanced ovarian, fallopian tube, or primary peritoneal cancer who have been treated with three or more prior chemotherapy regimens and whose cancer is associated with homologous recombination deficiency ("HRD") positive status defined by either:
    - a deleterious or suspected deleterious BRCA mutation, or
    - genomic instability and who have progressed more than six months after response to the last platinum-based chemotherapy.

In February 2020, GlaxoSmithKline announced acceptance of an sNDA with the FDA for first line maintenance treatment for women with platinum-responsive advanced ovarian cancer. The sNDA filing is based on data from the PRIMA trial. The sNDA is being reviewed under the Real-Time Oncology Review pilot program.

Zejula is approved in the EU as monotherapy for the maintenance treatment of adult patients with platinum-sensitive relapsed high grade serous epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in response (complete or partial) to platinum-based chemotherapy.

Additional clinical investigations of Zejula in ovarian, breast and lung cancers are ongoing or planned. Janssen Pharmaceuticals has licensed rights to develop and commercialize niraparib specifically for patients with prostate cancer worldwide, except in Japan. Preliminary results announced in February and September 2019 for Janssen's Phase 2 GALAHAD study evaluating niraparib in patients with mCRPC and DNA-repair pathway defects showed that approximately 40 percent of patients with a BRCA1/2 mutation demonstrated a RECIST response.

TALZENNA™/talazoparib (Pfizer Inc.) is approved in the US and EU for the treatment of adult patients with deleterious or suspected deleterious germline BRCA-mutated (gBRCAm) HER2-negative locally advanced or metastatic breast cancer.

There are several PARP inhibitors in clinical development including AbbVie Inc.'s veliparib and ABT-767, BeiGene, Ltd.'s pamiparib, Checkpoint Therapeutics Inc.'s CK-102, and Oncology Venture A/S's 2X-121. While most PARP inhibitor development focuses on ovarian, breast and prostate cancers, additional efforts are aimed toward bladder, lung, and pancreatic cancers as well.

In addition, combination approaches that include PARP inhibitors, including Lynparza and Zejula, with other anticancer agents are in various phases of clinical development across a variety of oncology indications. These combination therapies may result in future competitive pressure on Rubraca.

Outside of the PARP class, Avastin®/bevacizumab is approved in the US in ovarian cancer for the following indications:

- epithelial ovarian, fallopian tube, or primary peritoneal cancer in combination with carboplatin and paclitaxel, followed by Avastin as a single agent, for Stage III or IV disease following initial surgical resection;
- epithelial ovarian, fallopian tube, or primary peritoneal cancer in combination with paclitaxel, pegylated liposomal doxorubicin, or topotecan for platinum-resistant recurrent disease who received no more than 2 prior chemotherapy regimens; and
- epithelial ovarian, fallopian tube, or primary peritoneal cancer in combination with carboplatin and paclitaxel or carboplatin and gemcitabine, followed by Avastin as a single agent, for platinum-sensitive recurrent disease.

Additionally, Avastin®/bevacizumab is approved in the EU in ovarian cancer for the following indications:

- in combination with carboplatin and paclitaxel for the front-line treatment of adult patients with advanced (International Federation of Gynecology and Obstetrics (FIGO) stages III B, III C and IV) epithelial ovarian, fallopian tube, or primary peritoneal cancer;
- in combination with carboplatin and gemcitabine or in combination with carboplatin and paclitaxel, for treatment of adult patients with first recurrence of platinum-sensitive epithelial ovarian, fallopian tube or primary peritoneal cancer who have not received prior therapy with bevacizumab or other VEGF inhibitors or VEGF receptor–targeted agents; and
- in combination with paclitaxel, topotecan, or pegylated liposomal doxorubicin is indicated for the treatment of adult patients with platinum-resistant recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who received no more than two prior chemotherapy regimens and who have not received prior therapy with bevacizumab or other VEGF inhibitors or VEGF receptor–targeted agents.

Other out-of-class agents approved for use in advanced ovarian cancer include chemotherapeutic agents (e.g. platinum-based doublets, platinum monotherapy, non-platinum chemotherapy, etc.), Doxil® (Janssen Biotech, Inc.), and Hycamtin® (Novartis Pharmaceuticals Corporation). There are additional out-of-class agents in clinical development that may pose a future competitive threat to Rubraca.

***Lucitanib Competition***

Competitive threats to lucitanib include other inhibitors of VEGFR, PDGFR and FGFR, but most significantly Eisai Inc.'s Lenvima®/lenvatinib. Lenvima is approved for the following indications in the United States:

- for the treatment of patients with locally recurrent or metastatic, progressive, radioactive iodine-refractory differentiated thyroid cancer;
- in combination with everolimus, for the treatment of patients with advanced renal cell carcinoma following one prior anti-angiogenic therapy;
- for the first-line treatment of patients with unresectable hepatocellular carcinoma; and
- in combination with Merck & Co., Inc.'s PD-1 inhibitor Keytruda (pembrolizumab), for the treatment of patients with advanced endometrial carcinoma that is not microsatellite instability-high or mismatch repair deficient, who have disease progression following prior systemic therapy and are not candidates for curative surgery or radiation.

In addition, Eisai and Merck have established a strategic collaboration for the worldwide co-development and co-commercialization of Lenvima, and have a broad clinical program underway to evaluate Lenvima, alone and in combination with Keytruda, in a wide variety of tumor types.

***FAP-2286 Competition***

Competitive threats to our product candidate FAP-2286 include those that are currently approved and widely available or are established as standards of care for the treatment of indications for which FAP-2286 may be developed, if the preclinical candidate advances into clinical development. At this preclinical stage, our development strategy for

FAP-2286 is under evaluation, and specific competitive threats will be identified and taken into consideration as the program evolves.

More generally, there is an increasing commitment of resources in the pharmaceutical industry to emerging areas such as antibody drug conjugate therapies and radio-labeled therapeutics and screening agents, which may in the future compete in the indications for which we choose to develop FAP-2286. For example, in June 2019, Sofie Biosciences licensed rights including small molecule inhibitors of FAP for imaging and therapeutic use from University Medical Centre Heidelberg. In addition, other potential FAP-directed radionuclide therapeutics are in preclinical development by other parties.

Radionuclide therapeutics with targets other than FAP may compete with FAP-2286, should we develop FAP-2286 in the same tumor types. For example, in September 2017, Endocyte, Inc. licensed rights to develop and commercialize agents targeting prostate-specific membrane antigen, including the drug candidate 177Lu-PSMA-617, a radioligand therapeutic, from ABX GmbH. Endocyte was acquired by Novartis in 2018, and 177Lu-PSMA-617 is currently in a Phase 3 trial for the treatment of metastatic castration-resistant prostate cancer. In addition, other targeted radionuclide therapeutics are in earlier stage clinical development, including but not limited to 3BP-227 (Ipsen) which targets neurotensin receptor type 1, BAY2287411 (Bayer) which targets mesothelin, BAY2701439 (Bayer) which targets HER-2, and BAY 2315497 (Bayer) which targets PSMA.

Furthermore, universities and private and public research institutes are active in cancer research, the results of which may result in direct competition with FAP-2286 or our other product candidates. For example, the German Center of Cancer Research and University Medical Center Heidelberg, the owners of the patent rights to PSMA 617 (which were licensed to ABX and, in turn, to Novartis), may continue to engage in research relating to radioligand therapeutics.

**License Agreements**

***Pfizer Inc.***

In June 2011, we entered into a license agreement with Pfizer, Inc. (“Pfizer”) to obtain the exclusive global rights to develop and commercialize Rubraca. The exclusive rights are exclusive even as to Pfizer and include the right to grant sublicenses. Pursuant to the terms of the license agreement, we made a $7.0 million upfront payment to Pfizer and are required to make additional payments to Pfizer for the achievement of certain development and regulatory and sales milestones and royalties on sales as required by the license agreement. Prior to the FDA approval of Rubraca, we made milestone payments of $1.4 million, which were recognized as acquired in-process research and development expense.

On August 30, 2016, we entered into a first amendment to the worldwide license agreement with Pfizer, which amends the June 2011 existing worldwide license agreement to permit us to defer payment of the milestone payments payable upon (i) FDA approval of an NDA for 1st Indication in US and (ii) EMA approval of an MAA for 1st Indication in the EU, to a date that is 18 months after the date of achievement of such milestones.

On December 19, 2016, Rubraca received its initial FDA approval. This approval resulted in a $0.75 million milestone payment to Pfizer as required by the license agreement, which was paid in the first quarter of 2017. This FDA approval also resulted in an obligation to pay a $20.0 million milestone payment, for which we exercised the option to defer payment by agreeing to pay $23.0 million within 18 months after the date of the FDA approval. We paid the $23.0 million milestone payment in June 2018.

On April 6, 2018, Rubraca received a second FDA approval. This approval resulted in an obligation to pay a $15.0 million milestone payment, which we paid in April 2018.

In May 2018, Rubraca received its initial European Commission marketing authorization. This approval resulted in an obligation to pay a $20.0 million milestone payment, which we paid in June 2018.

In January 2019, Rubraca received a second European Commission approval. This approval resulted in an obligation to pay a $15.0 million milestone payment, which we paid in February 2019.

In June 2019, we paid a $0.75 million milestone payment due to the launch of Rubraca as maintenance therapy in Germany in March 2019.

These milestone payments were recognized as intangible assets and are amortized over the estimated remaining useful life of Rubraca.

We are obligated under the license agreement to use commercially reasonable efforts to develop and commercialize Rubraca and we are responsible for all ongoing development and commercialization costs for Rubraca. We are required to make regulatory milestone payments to Pfizer of up to an additional $16.0 million in aggregate if specified clinical study objectives and regulatory filings, acceptances and approvals are achieved. In addition, we are obligated to make sales milestone payments to Pfizer if specified annual sales targets for Rubraca are met, which relate to annual sales targets of $250.0 million and above, which, in the aggregate, could amount to total milestone payments of $170.0 million, and tiered royalty payments at a mid-teen percentage rate on net sales, with standard provisions for royalty offsets to the extent we need to obtain any rights from third parties to commercialize Rubraca.

The license agreement with Pfizer will remain in effect until the expiration of all of our royalty and sublicense revenue obligations to Pfizer, determined on a product-by-product and country-by-country basis, unless we elect to terminate the license agreement earlier. If we fail to meet our obligations under the agreement and are unable to cure such failure within specified time periods, Pfizer can terminate the agreement, resulting in a loss of our rights to Rubraca and an obligation to assign or license to Pfizer any intellectual property rights or other rights we may have in Rubraca, including our regulatory filings, regulatory approvals, patents and trademarks for Rubraca.

***AstraZeneca UK Limited***

In April 2012, we entered into a license agreement with AstraZeneca UK Limited ("AstraZeneca") to acquire exclusive rights associated with Rubraca under a family of patents and patent applications that claim methods of treating patients with PARP inhibitors in certain indications. The license enables the development and commercialization of Rubraca for the uses claimed by these patents. AstraZeneca receives royalties on net sales of Rubraca.

***Advenchen Laboratories LLC***

In connection with our acquisition of EOS in November 2013, we gained rights to develop and commercialize lucitanib, an oral, selective tyrosine kinase inhibitor. As further described below, in October 2008, EOS entered into an exclusive license agreement with Advenchen Laboratories LLC ("Advenchen") to develop and commercialize lucitanib on a global basis, excluding China.

We are obligated to pay Advenchen tiered royalties at percentage rates in the mid-single digits on net sales of lucitanib, based on the volume of annual net sales achieved. In addition, after giving effect to the first and second amendments to the license agreement, we are required to pay to Advenchen 25% of any consideration, excluding royalties, we receive from sublicensees, in lieu of the milestone obligations set forth in the agreement. We are obligated under the agreement to use commercially reasonable efforts to develop and commercialize at least one product candidate containing lucitanib, and we are also responsible for all remaining development and commercialization costs for lucitanib.

The license agreement with Advenchen will remain in effect until the expiration of all our royalty obligations to Advenchen, determined on a product-by-product and country-by-country basis, unless we elect to terminate the agreement earlier. If we fail to meet our obligations under the agreement and are unable to cure such failure within specified time periods, Advenchen can terminate the agreement, resulting in a loss of our rights to lucitanib.

***3B Pharmaceuticals GmbH ("3BP")***

In September 2019, we entered into a global license and collaboration agreement with 3BP to develop and commercialize a PTRT and imaging agent targeting FAP. The lead candidate, designated internally as FAP-2286, is being developed pursuant to a global development plan agreed to by the parties. We are responsible for the costs of all preclinical and clinical development activities described in the plan, including the costs for a limited number of 3BP full-time equivalents and external costs incurred during the preclinical development phase of the collaboration. Upon the signing of the license and collaboration agreement in September 2019, we made a $9.4 million upfront payment to 3BP, which we recognized as acquired in-process research and development expense.

Pursuant to the terms of the FAP agreement, we are required to make additional payments to 3BP for annual technology access fees and upon the achievement of certain development and regulatory milestone events (or on certain dates, whichever occur earlier). We are also obligated to pay 3BP single- to low-double-digit royalties on net sales of the FAP-targeted therapeutic product and imaging agent, based on the volume of annual net sales achieved. In addition, 3BP is entitled to receive 34% of any consideration, excluding royalties on the therapeutic product, pursuant to any sublicenses we may grant.

We are obligated under the license and collaboration agreement to use diligent efforts to develop FAP-2286 and commercialize a FAP-targeted therapeutic product and imaging agent, and we are responsible for all commercialization costs in our territory. The agreement with 3BP will remain in effect until the expiration of our royalty obligations to 3BP, determined on a product-by-product and country-by-country basis, unless we elect to terminate the agreement earlier. If we fail to meet our obligations under the agreement and are unable to cure such failure within specified time periods, 3BP can terminate the agreement, resulting in a loss of our rights. 3BP also has the right to terminate the agreement under certain circumstances in connection with our change of control in which the acquiring party retains a product competitive with the FAP-targeted therapeutic product or, in the event marketing authorization has not yet been obtained, does not agree to the then-current global development plan.

In February 2020, we finalized the terms of a drug discovery collaboration agreement with 3BP to identify up to three additional, undisclosed targets for peptide-targeted radionuclide therapy, to which we will obtain global rights for any resulting product candidates. We are responsible for the costs of all preclinical and clinical development activities conducted under the discovery program, including the costs for a limited number of 3BP full-time equivalents and external costs incurred during the discovery and preclinical development phase for each collaboration target. The agreement was effective December 31, 2019, for which we incurred a $2.1 million technology access fee, which we accrued and recognized as a research and development expense.

Pursuant to the terms of the agreement, we are required to make additional payments to 3BP for annual technology access fees and upon the achievement of certain development and regulatory milestone events (or on certain dates, whichever occur earlier). We are also obligated to pay 3BP a 6% royalty on net sales of License Products (as defined in the agreement), based on the volume of quarterly net sales achieved.

We are obligated under the discovery collaboration agreement to use diligent efforts to develop and commercialize the product candidates, if any, that result from the discovery program, and we are responsible for all clinical development and commercialization costs. The agreement with 3BP will remain in effect until the expiration of our royalty obligations to 3BP, determined on a product-by-product and country-by-country basis, unless we elect to terminate the agreement earlier. If we fail to meet our obligations under the agreement and are unable to cure such failure within specified time periods, 3BP can terminate the agreement, resulting in a loss of our rights.

**Government Regulation**

Government authorities in the United States (including federal, state and local authorities) and in other countries, extensively regulate, among other things, the manufacturing, research and clinical development, marketing, labeling and packaging, storage, distribution, post-approval monitoring and reporting, advertising and promotion, pricing and export and import of pharmaceutical products. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Moreover, failure to comply with applicable regulatory requirements may result in, among other things, warning letters, clinical holds, civil or criminal penalties, recall or seizure of products, injunction, disbarment, partial or total suspension of production or withdrawal of the product from the market.

***U.S. Government Regulation***

In the United States, the FDA regulates drugs under the Federal Food, Drug and Cosmetic Act ("FDCA") and its implementing regulations. Drugs are also subject to other federal, state and local statutes and regulations. The process required by the FDA before product candidates may be marketed in the United States generally involves the following:

- completion of extensive non-clinical laboratory tests and non-clinical animal studies, all performed in accordance with the FDA's Good Laboratory Practice regulations;

- submission to the FDA of an IND which must become effective before human clinical trials may begin and must be updated at least annually;
- performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the product candidate for each proposed indication;
- submission to the FDA of a marketing authorization application in the form of an NDA for the initial commercial sale of a product, or of a sNDA, for approval of a new indication if the product is already approved for another indication;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facilities at which the active pharmaceutical ingredient ("API") and finished drug product are produced and tested to assess compliance with Current Good Manufacturing Practices ("cGMP") and/or sites involved in clinical studies to assess compliance with Good Clinical Practices ("GCP");
- if FDA convenes an advisory committee, satisfactory completion of the advisory committee review; and
- FDA review and approval of the marketing authorization application and product prescribing information prior to any commercial marketing or sale of the drug for the intended use.

An IND is a request for authorization from the FDA to administer a product candidate to humans. The central focus of an IND submission is on the general investigational plan and the protocol(s) for human studies. The IND also includes results of animal studies or other human studies, as appropriate, as well as manufacturing information, analytical data and any available clinical data or literature to support the use of the product candidate. An IND must become effective before human clinical trials may begin. An IND will automatically become effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to the proposed clinical trials, including concerns that human research subjects will be exposed to unreasonable health risks. In such a case, the IND may be placed on clinical hold requiring delay of a proposed clinical investigation, and the IND sponsor and the FDA must resolve any outstanding concerns or questions before clinical trials can begin. Accordingly, submission of an IND may or may not result in the FDA allowing clinical trials to commence.

Clinical trials involve the administration of the drug candidate to human subjects under the supervision of qualified investigators in accordance with GCP, which include the requirement that all research subjects provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the efficacy criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. Additionally, approval must also be obtained from an Institutional Review Board ("IRB") for each medical center proposing to conduct the clinical trial before the trials may be initiated, and the IRB must monitor the study until completed. Clinical trials are subject to central registration and results reporting requirements, such as on www.clinicaltrials.gov.

The clinical investigation of a drug is generally divided into three phases. Although the phases are usually conducted sequentially, they may overlap or be combined. The three phases of an investigation are as follows:

- Phase 1. Phase 1 includes the initial introduction of the product candidate into humans. Phase 1 clinical trials are typically closely monitored and may be conducted in patients with the target disease or condition or in healthy volunteers. These studies are designed to evaluate the safety, dosage tolerance, metabolism and pharmacologic actions of product candidate in humans, the side effects associated with increasing doses, and if possible, to gain early evidence on effectiveness. During Phase 1 clinical trials, sufficient information about the product candidate's pharmacokinetics and pharmacological effects may be obtained to permit the design of well-controlled and scientifically valid Phase 2 clinical trials. The total number of participants included in Phase 1 clinical trials varies but is generally in the range of 20 to 80.
- Phase 2. Phase 2 includes controlled clinical trials conducted to preliminarily or further evaluate the effectiveness of the product candidate for a particular indication(s) in patients with the disease or condition under study, to determine dosage tolerance and optimal dosage, and to identify possible adverse side effects and safety risks associated with the drug. Phase 2 clinical trials are typically well-controlled, closely monitored, and conducted in a limited patient population, usually involving no more than several hundred participants.
- Phase 3. Phase 3 clinical trials are generally controlled clinical trials conducted in an expanded patient population generally at geographically dispersed clinical trial sites. They are performed after preliminary

evidence suggesting effectiveness of the drug has been obtained and are intended to further evaluate dosage, clinical effectiveness and safety, to establish the overall benefit-risk relationship of the investigational drug product and to provide an adequate basis for product approval. Phase 3 clinical trials usually involve several hundred to several thousand participants.

A pivotal study is a clinical study which adequately meets regulatory agency requirements for the evaluation of a drug candidate's efficacy and safety such that it can be used to justify the approval of the product. Generally, pivotal studies are also Phase 3 studies but may be Phase 2 studies if the trial design provides a well-controlled and reliable assessment of clinical benefit, particularly in situations where there is an unmet medical need.

The FDA, an IRB or the clinical trial sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as an Independent Data Monitoring Committee ("IDMC"). The IDMC receives special access to un-blinded data during the clinical trial and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. We may also suspend or terminate a clinical trial based on evolving business objectives and/or competitive climate.

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, detailed product development information is submitted to the FDA in the form of an NDA or sNDA requesting approval to market the product for one or more indications.

The application includes all relevant data available from pertinent non-clinical and clinical trials, including negative or ambiguous results, as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls and proposed labeling, among other things. Data can come from company-sponsored clinical trials intended to test the safety and effectiveness of a use of a product, or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and effectiveness of the product candidate to the satisfaction of the FDA.

Once the marketing application submission has been accepted for filing, the FDA's goal is to review applications within 10 months of acceptance for filing or, if the sponsor has been granted priority review designation, on the basis of an improvement in the treatments of a serious condition, six months from acceptance for filing. The review process is often significantly extended by FDA requests for additional information or clarification. The FDA may refer the application to an advisory committee for review, evaluation and recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it typically follows such recommendations.

After the FDA evaluates the NDA or sNDA and conducts inspections of clinical research facilities and/or manufacturing facilities where the drug product and/or its API will be produced, it may issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete, and the application is not ready for approval. A Complete Response Letter may require additional clinical data and/or an additional pivotal Phase 3 clinical trial(s), and/or other significant, expensive and time-consuming requirements related to clinical trials, non-clinical studies or manufacturing. Even if such additional information is submitted, the FDA may ultimately decide that the application does not satisfy the criteria for approval. The FDA could also approve the NDA with a Risk Evaluation and Mitigation Strategies plan to mitigate risks, which could include medication guides, physician communication plans or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling, development of adequate controls and specifications or a commitment to conduct one or more post-market studies or clinical trials. Such post-market testing may include Phase IV clinical trials and surveillance to further assess and monitor the product's safety and effectiveness after commercialization. Regulatory approval of oncology products often requires that patients in clinical trials be followed for long periods to determine the overall survival benefit of the drug.

Products manufactured or distributed pursuant to FDA approvals are subject to continuing regulation by the FDA, including recordkeeping requirements and reporting of adverse experiences with the drug. Adverse event experience with the product must be reported to the FDA in a timely fashion and pharmacovigilance programs to proactively look

for these adverse events are mandated by the FDA. Newly discovered or developed safety or effectiveness data may require changes to a product's approved labeling, including the addition of new warnings and contraindications and also may require the implementation of other risk management measures.

Drug manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for quality and compliance, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Following such inspections, the FDA may issue notices on Form FDA 483 and Warning Letters that could cause us to modify certain activities. A Form FDA 483 notice, if issued at the conclusion of an FDA inspection, can list conditions the FDA investigators believe may have violated cGMP or other FDA regulations or guidance. Failure to adequately and promptly correct the observations(s) can result in further regulatory enforcement action. In addition to Form FDA 483 notices and Warning Letters, failure to comply with the statutory and regulatory requirements can subject a manufacturer to possible legal or regulatory action, such as suspension of manufacturing, seizure of product, injunctive action or possible civil penalties. In addition, changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

***Government Regulation Outside of the United States***

In addition to regulations in the United States, we are subject to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of our products. The approval process and requirements governing the conduct of clinical trials, product licensing, pricing, and reimbursement vary greatly from country to country, and the time may be longer or shorter than that required for FDA approval.

Regardless of whether we hold FDA approval for a product, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries. Certain countries outside of the United States have a similar process that requires the submission of a clinical trial application much like the IND prior to the commencement of human clinical trials. In Europe, for example, a clinical trial application, ("CTA") must be submitted to each country's national health authority and an independent ethics committee, much like the FDA and IRB, respectively. Once the CTA is approved in accordance with a country's requirements, clinical trial development may proceed.

Medicines can be authorized in the EU by using either the centralized authorization procedure or national authorization procedures. Under the centralized procedure, marketing authorization applications are submitted to the EMA whose CHMP reviews the application and issues an opinion on it. The opinion is considered by the European Commission ("EC") which is responsible for deciding applications. If the application is approved, the EC grants a single marketing authorization that is valid for all EU member states as well as Iceland, Liechtenstein and Norway. The centralized procedure is compulsory for human medicines that contain a new active substance indicated for the treatment of certain diseases, including cancer.

The national authorization procedures, the decentralized and mutual recognition procedures, are available for products for which the centralized procedure is not compulsory. Using the decentralized procedure, an applicant may apply for simultaneous authorization in more than one EU country of medicinal products that have not yet been authorized in any EU country and that do not fall within the mandatory scope of the centralized procedure. Under the mutual recognition procedure, a medicine is first authorized in one EU Member State, in accordance with the national procedures of that country. Following this, further marketing authorizations can be sought from other EU countries in a procedure whereby the countries concerned agree to recognize the validity of the original, national marketing authorization

***Available Special Regulatory Procedures***

*Formal Meetings*

We are encouraged to engage and seek guidance from health authorities relating to the development and review of investigational drugs, as well as marketing applications. In the United States, there are different types of official meetings that may occur between us and the FDA. Each meeting type is subject to different procedures. Conclusions and agreements from each of these meetings are captured in the official final meeting minutes issued by the FDA.

The EMA also provides the opportunity for dialogue with us. This is usually done in the form of Scientific Advice, which is given by the Scientific Advice Working Party of CHMP. A fee is incurred with each Scientific Advice meeting.

Advice from either the FDA or EMA is typically provided based on questions concerning, for example, quality (chemistry, manufacturing and controls testing), nonclinical testing and clinical studies and pharmacovigilance plans and risk-management programs. Such advice is not legally binding on the sponsor. To obtain binding commitments from the FDA in the United States, Special Protocol Assessment ("SPA") procedures are available. A SPA is an evaluation by the FDA of a protocol with the goal of reaching an agreement with the sponsor that the protocol design, clinical endpoints and statistical analyses are acceptable to support regulatory approval of the product candidate with respect to effectiveness in the indication studied. The FDA's agreement to a SPA is binding upon the FDA except in limited circumstances, such as if the FDA identifies a substantial scientific issue essential to determining the safety or effectiveness of the product after clinical studies begin, or if the study sponsor fails to follow the protocol that was agreed upon with the FDA. There is no guarantee that a study will ultimately be adequate to support an approval even if the study is subject to a SPA.

*Orphan Drug Designation*

The FDA may grant orphan drug designation to drugs intended to treat a rare disease or condition that affects fewer than 200,000 individuals in the United States, or if it affects more than 200,000 individuals in the United States and there is no reasonable expectation that the cost of developing and making the drug for this type of disease or condition will be recovered from sales in the United States. In the EU, the EMA's Committee for Orphan Medicinal Products grants orphan drug designation to promote the development of products that are intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions affecting not more than five in 10,000 persons in the EU Community. Additionally, designation is granted for products intended for the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition and when, without incentives, it is unlikely that sales of the drug in the EU would be sufficient to justify the necessary investment in developing the drug or biological product.

In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. In addition, if a product receives the first FDA approval for the indication for which it has orphan designation, the product is entitled to orphan drug exclusivity, which means the FDA may not approve any other application to market the same drug for the same indication for a period of seven years, except in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity.

In the EU, orphan drug designation also entitles a party to financial incentives such as reduction of fees or fee waivers and 10 years of market exclusivity is granted following drug or biological product approval. This period may be reduced to six years if the orphan drug designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity.

Orphan drug designation must be requested before submitting an application for marketing approval. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

*Pediatric Development*

In the United States, the FDCA provides for an additional six months of marketing exclusivity for a drug if reports are filed of investigations studying the use of the drug product in a pediatric population in response to a written request from the FDA. Separate from this potential exclusivity benefit, NDAs must contain data (or a proposal for post-marketing

activity) to assess the safety and effectiveness of an investigational drug product for the claimed indications in all relevant pediatric populations in order to support dosing and administration for each pediatric subpopulation for which the drug is safe and effective. The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults or full or partial waivers if certain criteria are met. Discussions about pediatric development plans can be discussed with the FDA at any time, but usually occur any time between the end-of-Phase II meeting and submission of the NDA.

For the EMA, a Pediatric Investigation Plan, and/or a request for waiver or deferral, has to be agreed prior to submitting an initial marketing authorization application and prior to submitting a variation to an existing Marketing Authorization to add an additional indication.

*Breakthrough Therapy Designation in the United States*

The U.S. Congress created the Breakthrough Therapy designation program as a result of the passage of the Food and Drug Administration Safety and Innovation Act of 2012. FDA may grant Breakthrough Therapy status to a drug intended for the treatment of a serious condition when preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. The Breakthrough Therapy designation, which may be requested by a sponsor when filing or amending an IND, is intended to facilitate and expedite the development and FDA review of a product candidate. Specifically, the Breakthrough Therapy designation may entitle the sponsor to more frequent meetings with the FDA during drug development, intensive guidance on clinical trial design and expedited FDA review by a cross-disciplinary team comprised of senior managers. The designation does not guarantee a faster development or review time as compared to other drugs, however, nor does it assure that the drug will obtain ultimate marketing approval by the FDA. Once granted, the FDA may withdraw this designation at any time.

*Expedited Review and Approval in the United States*

The FDA has various programs, including Fast Track, priority review and accelerated approval, which are intended to expedite or simplify the process for reviewing drugs and biologics, and/or provide for the approval of a drug or biologic on the basis of a surrogate endpoint. Even if a drug qualifies for one or more of these programs, the FDA may later decide that the drug no longer meets the conditions for qualification or that the time period for FDA review or approval will be shortened. Generally, drugs that are eligible for these programs are those for serious or life-threatening conditions, those with the potential to address unmet medical needs and those that offer meaningful benefits over existing treatments. For example, based on results of the Phase 3 clinical trial(s) submitted in an NDA, upon the request of an applicant, the FDA may grant the NDA a priority review designation, which sets the target date for FDA action on the application at six months from the 60-day filing date, if the drug is a new molecular entity, rather than to the standard FDA review period of 10 months. Priority review is granted where preliminary estimates indicate that a product, if approved, has the potential to provide a safe and effective therapy where no satisfactory alternative therapy exists, or a significant improvement compared to marketed products is possible. Priority review designation does not change the scientific/medical standard for approval or the quality of evidence necessary to support approval.

Fast Track is a designation which is more similar to the Breakthrough Therapy designation, but is granted based on preliminary data including non-clinical or mechanistic data, and allows more frequent communication with FDA to expedite drug development

Accelerated approval provides for an earlier approval for a new drug that is intended to treat a serious or life-threatening disease or condition upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit and is better than available therapy. A surrogate endpoint is a laboratory measurement or physical sign used as an indirect or substitute measurement representing a clinically meaningful outcome. The FDA will also consider the severity, rarity or prevalence of the condition. As a condition of approval for drugs granted accelerated approval, one or more post-marketing confirmatory studies are required to confirm as predicted by the surrogate marker trial an effect on clinical benefit, which is defined as having a positive effect on how a patient feels, functions or survives.

*Accelerated Review in the European Union*

Under the Centralized Procedure in the EU, the maximum timeframe for the evaluation of a marketing authorization application is 210 days (excluding clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the CHMP). Accelerated evaluation might be granted by the CHMP in exceptional cases, when a medicinal product is expected to be of a major public health interest, defined by three cumulative criteria: the seriousness of the disease (e.g. heavy disabling or life-threatening diseases) to be treated; the absence or insufficiency of an appropriate alternative therapeutic approach; and anticipation of high therapeutic benefit. In this circumstance, EMA ensures that the opinion of the CHMP is given within 150 days of submission of the MAA, excluding clock stops.

***Pharmaceutical Coverage, Pricing and Reimbursement***

Significant uncertainty exists as to the coverage and reimbursement status of any drug products for which we obtain regulatory approval. In the United States and markets in other countries, sales of any products for which we receive regulatory approval for commercial sale depend in part on the availability of reimbursement from third-party payors. Third-party payors include government health administrative authorities, managed care providers, private health insurers and other organizations. The process for determining whether a payor will provide coverage for a drug product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the drug product. Third-party payors may limit coverage to specific drug products on an approved list, or formulary, which might not include all of the FDA-approved drugs for a particular indication. Third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost effectiveness of our products, in addition to the costs required to obtain FDA approvals. The development of a product dossier and a Budget Impact Model may be helpful in assisting the payors in evaluating cost effectiveness. Our approved products may not be considered medically necessary or cost-effective. A payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be established. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development. Third-party payors may also impose price protection in their contracts with manufacturers to limit the manufacturer's ability to increase price in exchange of providing equal access to the drug product vs. other competing drugs.

There have been a number of federal and state proposals in recent years regarding the pricing of pharmaceutical products, government control and other changes to the healthcare system of the United States. The U.S. government enacted legislation providing a partial prescription drug benefit for Medicare beneficiaries. Government payment for some of the costs of prescription drugs may increase demand for any products for which we receive marketing approval; however, to obtain payments under this program, we are required to sell products to Medicare recipients through prescription drug plans operating pursuant to this legislation. These plans will likely negotiate discounted prices for our products. Additionally, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the "Affordable Care Act") was enacted in 2010 with a goal of reducing the cost of healthcare and substantially changing the way healthcare is financed by both government and private insurers. Among other cost containment measures, the Affordable Care Act established:

- An annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents;
- A Medicare Part D coverage gap discount program, in which pharmaceutical manufacturers who wish to have their drugs covered under Part D must offer discounts to eligible beneficiaries during their coverage gap period (the "donut hole"); and
- A formula that increases the rebates a manufacturer must pay under the Medicaid Drug Rebate Program.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the Affordable Care Act. We expect that the current presidential administration and U.S. Congress will likely continue to seek to modify, repeal, or otherwise invalidate all, or certain provisions of, the Affordable Care Act. Most recently, the Tax Cuts and Jobs Act was enacted, which, among other things, removes penalties for not complying with Affordable Care Act's individual mandate to carry health insurance. There is still uncertainty with respect to the impact President Trump's administration and the U.S. Congress may have, if any, and any changes will likely take time to unfold, and could have

an impact on coverage and reimbursement for healthcare items and services covered by plans that were authorized by the Affordable Care Act.

Recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed bills designed to, among other things, reform government program reimbursement methodologies. Individual states in the United States have also become increasingly active in implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. We expect that federal, state and local governments in the United States will continue to consider legislation to limit the growth of healthcare costs, including the cost of prescription drugs. Future legislation could limit payments for pharmaceuticals such as our products.

Moreover, payment methodologies, including payment for companion diagnostics, have been subject to changes due to healthcare legislation and regulatory initiatives. For example, the Centers for Medicare and Medicaid Services("CMS") began bundling the Medicare payments for certain laboratory tests ordered while a patient received services in a hospital outpatient setting. Additionally, on April 1, 2014, the Protecting Access to Medicare Act of 2014, or PAMA, was signed into law, which, among other things, significantly alters the current payment methodology under the Clinical Laboratory Fee Schedule. Beginning on January 1, 2018, the Medicare payment rate for each clinical diagnostic lab test, with some exceptions, is equal to the weighted median private payer payment for the test, as calculated using data collected by applicable laboratories during the data collection period and reported to CMS during a specified data reporting period. Also under PAMA, CMS is required to adopt temporary billing codes to identify new clinical diagnostic laboratory tests and advanced diagnostic laboratory tests that do not already have unique diagnostic codes, and that have been cleared or approved by the FDA.

Different pricing and reimbursement schemes exist in other countries and vary widely from country to country. In the European Community, governments influence the price of pharmaceutical products through their pricing and reimbursement rules and control of national health care systems that fund a large part of the cost of those products to consumers. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost-effectiveness of a particular product candidate to currently available therapies. Other member states allow companies to fix their own prices for medicines but monitor and control company profits. The downward pressure on health care costs in general, particularly prescription drugs, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert a commercial pressure on pricing within a country. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, products launched in the EU do not follow price structures of the United States and generally prices tend to be significantly lower.

The marketability of any products for which we receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. In addition, emphasis on reducing the rate of healthcare spending in the United States has increased, and we expect will continue to increase the pressure on pharmaceutical pricing. There has been particular and increasing legislative interest in the United States with respect to drug pricing practices, particularly with respect to drugs that have been subject to relatively large price increases over relatively short time periods. Certain independent charitable foundations operate programs that provide grants to defray medical expenses (including cost-sharing obligations for drug treatments and health insurance premiums) for patients who meet certain financial need criteria and suffer from specific chronic illnesses or rare disorders. There has been recent enforcement interest regarding donations by pharmaceutical manufacturers to such foundations on the bases that such donations were used in part to guide patients to those donors' products or that the donors obtained data on how the donations were used, including how often donations correlate to the frequency of referrals to donors' products. There have been several U.S. Congressional inquiries and proposed bills designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our products.

***Advertising and Promotion***

The FDA and other U.S. federal regulatory agencies closely regulate the marketing and promotion of drugs through, among other things, the FDCA and the FDA's implementing regulations and standards. The FDA's review of marketing and promotional activities encompasses, but is not limited to, direct-to-consumer advertising, healthcare provider-directed advertising and promotion, sales representative communications to healthcare professionals, communications regarding unapproved or "off-label" uses, industry sponsored scientific and educational activities and promotional activities involving the internet. A product cannot be commercially promoted before it is approved. After approval, product promotion can include only those claims relating to safety and effectiveness that are consistent with the labeling approved by the FDA. FDA regulations also impose stringent restrictions on manufacturers' communications regarding off-label uses. Failure to comply with applicable FDA requirements and restrictions regarding unapproved uses of a drug or for other violations of its advertising and labeling laws and regulations, may result in adverse publicity and enforcement action by the FDA, the Department of Justice or the Office of the Inspector General of the Department of Health and Human Services, as well as state authorities. A range of penalties are possible that could have significant commercial consequences, including product seizures, injunctions, administrative remedies, civil and/or criminal fines, agreements that materially restrict the manner in which a company promotes or distributes its products, or regulatory enforcement letters which may require corrective advertising or other corrective communications to healthcare professionals or consumers.

***Other Healthcare Laws and Compliance Requirements***

We are subject to various laws targeting fraud and abuse in the healthcare industry, including federal and state anti-kickback laws and false-claims laws. Violations of these laws can lead to civil and criminal penalties, including fines, imprisonment and administrative remedies such as exclusion from participation in federal healthcare programs.

The federal Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce either the referral of an individual, or the furnishing, recommending, or arranging for a good or service, for which payment may be made under a federal healthcare program, such as Medicare and Medicaid. The reach of the Anti-Kickback Statute was broadened by the Affordable Care Act, which, among other things, amended the intent requirement of the federal Anti-Kickback Statute and criminal healthcare fraud statutes contained within 42 U.S.C. § 1320a-7b. Pursuant to the statutory amendment, a person or entity no longer needs to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation. In addition, the government may assert that a claim submitted in violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act (discussed below) or the civil monetary penalties statute. Many states have adopted laws similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for healthcare items or services reimbursed by any source, not only the Medicare and Medicaid programs.

The federal False Claims Act imposes liability on any person who, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment by a federal program, including federal healthcare programs. The "qui tam" provisions of the False Claims Act allow a private individual to bring civil actions on behalf of the federal government alleging that the defendant has submitted a false claim to the federal government, and to share in any monetary recovery. In addition, various states have enacted false claims laws analogous to the False Claims Act. Many of these state laws apply where a claim is submitted to any third-party payor and not merely a federal healthcare program. When an entity is determined to have violated the federal False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil fines and penalties.

In addition, a person who offers or transfers to a Medicare or Medicaid beneficiary any remuneration, including waivers of co-payments and deductible amounts (or any part thereof), that the person knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner or supplier of Medicare or Medicaid-payable items or services, may be liable for civil monetary penalties of up to $20,000 for each wrongful act. Moreover, in certain cases, providers who routinely waive copayments and deductibles for Medicare and Medicaid beneficiaries can also be held liable under the federal Anti-kickback Statute and False Claims Act, which can impose additional penalties. One of the statutory exceptions to this prohibition is non-routine, unadvertised waivers of copayments or deductible amounts based on individualized determinations of financial need or exhaustion of reasonable collection efforts. The Office of Inspector General of the Department of Health and Human Services emphasizes, however, that this exception should

only be used occasionally to address special financial needs of a particular patient. Although this prohibition applies only to federal healthcare program beneficiaries, the routine waivers of copayments and deductibles offered to patients covered by commercial payers may implicate applicable state laws related to, among other things, unlawful schemes to defraud, excessive fees for services, tortious interference with patient contracts and statutory or common law fraud. To the extent our patient assistance programs are found to be inconsistent with applicable laws, we may be required to restructure or discontinue such programs or be subject to significant penalties.

In addition to the laws described above, the Affordable Care Act also imposed new reporting requirements on drug manufacturers for payments made to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Failure to submit required information to CMS may result in civil monetary penalties of up to an aggregate of $169,170 per year (or up to an aggregate of $1.128 million per year for "knowing failures"), for all payments, transfers of value, or ownership or investment interests that are not timely, accurately and completely reported in an annual submission. Applicable drug manufacturers are required to collect data for each calendar year and submit reports to CMS by March 31st of each subsequent calendar year. In addition, there is also an increasing number of state laws that require manufacturers to make reports to states on pricing and marketing information. These laws impose administrative and compliance burdens that may affect our sales, marketing, and other promotional activities.

For marketed products which are covered in the United States by the Medicaid program, we have various obligations, including government price calculation and reporting and rebate requirements which generally require products be offered at substantial rebates/discounts to Medicaid and certain purchasers (including "covered entities" purchasing under the 340B Drug Discount Program). We are also required to discount such products to authorized users of the Federal Supply Schedule of the General Services Administration, under which additional laws and requirements apply. These programs require submission of pricing data and calculation of discounts and rebates pursuant to complex statutory formulas, as well as the execution of government procurement contracts governed by the Federal Acquisition Regulations. The guidance governing such calculations is not always clear and may require significant investment in personnel, systems and resources in order to comply. Failure to properly calculate our prices, or offer required discounts or rebates could subject us to substantial penalties.

One component of the rebate and discount calculations under the Medicaid and 340B programs is the "additional rebate", a complex calculation which is based, in part, on the rate at which a branded drug's price increases over time as compared to the rate of inflation (based on the CPI-U published by the United States Department of Labor). This calculation is based on the baseline pricing data for the first full quarter of sales associated with a branded drug's NDA, and baseline data cannot generally be reset, even on transfer of the NDA to another manufacturer. This "additional rebate" calculation can, in some cases where price increases have been relatively high versus the first quarter of sales of the NDA, result in Medicaid rebates up to 100% of a drug's "average manufacturer price" and 340B prices of one penny. Separately, subject to the control of Directive 89/105/EEC, pricing and reimbursement in the EU/EEA ("European Economic Area") is governed by national rules and policies and may vary from Member State to Member State.

Also, the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") created several new federal crimes, including health care fraud and false statements relating to health care matters. Most healthcare providers who are expected to prescribe our products and from whom we obtain patient health information are subject to privacy and security requirements under HIPAA. Although we are not directly subject to HIPAA, we could be subject to criminal penalties if we knowingly obtain individually identifiable health information from a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

The privacy and protection of consumer information remains a developing area and we continue to monitor legislative and regulatory developments both in the United States as well as Europe. For example, the California Consumer Privacy Act ("CCPA") became effective on January 1, 2020 and, as enacted, requires us to make new disclosures to consumers about our data collection, use, and sharing practices. It also provides a new cause of action for data breaches. While the CCPA is subject to further rulemaking proceedings by the California Attorney General, the CCPA could create liability for us or increase our cost of doing business. Other countries also have, or are developing, laws governing the collection, use and transmission of personal information. For example, the EU Data Privacy Directive (95/46/EC), which was replaced on May 25, 2018 by the more restrictive General Data Protection Regulation (Regulation (EU) 2016/679) and the Swiss Federal Data Protection Act and Data Protection Ordinance, regulate the processing of personal data within the EU and between countries in the EU and countries outside of the EU, including

the U.S. Failure to provide adequate privacy protections and maintain compliance with the EU-U.S. and Swiss-U.S Privacy Shield Frameworks, could jeopardize business transactions across borders and result in significant penalties. Similar to the impact of the CCPA, these laws could create liability for us or increase our cost of doing business.

***Regulation of Diagnostic Tests***

In the United States, the FDCA and its implementing regulations, and other federal and state statutes and regulations govern, among other things, medical device design and development, non-clinical and clinical testing, premarket clearance or approval, registration and listing, manufacturing, labeling, storage, advertising and promotion, sales and distribution, export and import, and post-market surveillance. Diagnostic tests are classified as medical devices under the FDCA. Unless an exemption applies, diagnostic tests require marketing clearance or approval from the FDA prior to commercial distribution. The two primary types of FDA marketing authorization applicable to a medical device are premarket notification, also called 510(k) clearance, and premarket approval, or PMA approval. Because the diagnostic tests being developed by our third-party collaborators are of substantial importance in preventing impairment of human health, they are subject to the PMA approval process.

PMA applications must be supported by valid scientific evidence, which typically requires extensive data, including technical, non-clinical, clinical and manufacturing data, to demonstrate to the FDA's satisfaction the safety and effectiveness of the device. For diagnostic tests, a PMA application typically includes data regarding analytical and clinical validation studies. As part of its review of the PMA, the FDA will conduct a pre-approval inspection of the manufacturing facility or facilities to ensure compliance with the Quality System Regulation, or QSR, which requires manufacturers to follow design, testing, control, documentation and other quality assurance procedures. FDA review of an initial PMA application is required by statute to take between six to ten months, although the process typically takes longer, and may require several years to complete. If the FDA evaluations of both the PMA application and the manufacturing facilities are favorable, the FDA will either issue an approval letter or an approvable letter, which usually contains a number of conditions that must be met in order to secure the final approval of the PMA. If the FDA's evaluation of the PMA or manufacturing facilities is not favorable, the FDA will deny approval of the PMA or issue a not approvable letter. A not approvable letter will outline the deficiencies in the application and, where practical, will identify what is necessary to make the PMA approvable. The FDA may also determine that additional clinical trials are necessary, in which case the PMA approval may be delayed for several months or years while the trials are conducted and then the data submitted in an amendment to the PMA. Once granted, PMA approval may be withdrawn by the FDA if compliance with post approval requirements, conditions of approval or other regulatory standards is not maintained, or problems are identified following initial marketing.

We and our third-party collaborators who are developing companion diagnostics work cooperatively to generate the data required for submission with a PMA application, and remain in close contact with the Center for Devices and Radiological Health ("CDRH") at the FDA to ensure that any changes in requirements are incorporated into the development plans. Meetings with the FDA with regard to our drug product candidates, as well as companion diagnostic product candidates, typically include representatives from the Center for Drug Evaluation and Research and CDRH when appropriate to ensure that the NDA and PMA submissions are coordinated to enable FDA to conduct a parallel review of both submissions. The FDA has issued guidance documents addressing the development and approval process for "In Vitro Companion Diagnostic Devices." According to these guidance documents, for novel therapeutic products such as our product candidates, the PMA for a companion diagnostic device should generally be developed and approved or cleared contemporaneously with the therapeutic.

In the EEA, in vitro medical devices are required to conform to the essential requirements of the E.U. Directive on in vitro diagnostic medical devices (Directive No 98/79/EC, as amended). To demonstrate compliance with the essential requirements, the manufacturer must undergo a conformity assessment procedure. The conformity assessment varies according to the type of medical device and its classification. For low-risk devices, the conformity assessment can be carried out internally, but for higher risk devices it requires the intervention of an accredited EEA Notified Body. If successful, the conformity assessment concludes with the drawing up by the manufacturer of an EC Declaration of Conformity entitling the manufacturer to affix the CE mark to its products and to sell them throughout the EEA. The data generated for the U.S. registration will be sufficient to satisfy the regulatory requirements for the EU and other countries.

**Patents and Proprietary Rights**

The proprietary nature of, and protection for, our product candidates, processes and know-how are important to our business. Our success depends in part on our ability to protect the proprietary nature of our product candidates, technology, and know-how, to operate without infringing on the proprietary rights of others, and to prevent others from infringing our proprietary rights. We seek patent protection in the United States and internationally for our product candidates and other technology. Our policy is to patent or in-license the technology, inventions and improvements that we consider important to the development of our business. We also rely on trade secrets, know-how and continuing innovation to develop and maintain our competitive position. We cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future, nor can we be sure that any of our existing patents or any patents granted to us in the future will be commercially useful in protecting our technology.

In June 2011, we obtained an exclusive, worldwide license from Pfizer to develop and commercialize rucaparib. In April 2012, we obtained an exclusive license from AstraZeneca under a family of patents and patent applications which permits the development and commercialization of rucaparib for certain methods of treating patients with PARP inhibitors. We applied for patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act") for U.S. Patent 6,495,541 directed to the rucaparib composition of matter and requested patent term extension to the fourth quarter of 2023. We obtained a one-year interim patent term extension while our patent term extension application remains under review. Additionally, other patents and patent applications are directed to methods of making, methods of using, dosing regimens, various salt and polymorphic forms and formulations and have expiration dates through potentially 2035, including the rucaparib camsylate salt/polymorph patent family licensed from Pfizer, which expires in 2031 and a patent family directed to high dosage strength rucaparib tablets that expires in 2035. As of 2020, the rucaparib camsylate salt/polymorph patent is issued in 49 countries to date (including US and Europe), with applications pending in 9 countries, and the high dosage strength rucaparib tablets patent is issued in the U.S., pending in Europe and pending or issued in 15 other countries. Two oppositions were filed in the granted European counterpart of the rucaparib camsylate salt/polymorph patent on June 20, 2017. European oppositions are commonly filed against patents related to pharmaceutical products. The European Patent Office's Opposition Division held an oral hearing on December 4, 2018, during which it upheld claims, narrowed from the originally granted patent, to certain crystalline forms of rucaparib camsylate, including, but not limited to, rucaparib S-camsylate Form A, the crystalline form in Rubraca. Clovis and one opponent, Hexal, appealed the written decision of the European Opposition Division and filed reply appeal briefs in early November 2019. All claims in the originally granted patent will remain in force until the Technical Board of Appeal issues its decision. The rucaparib camsylate salt/polymorph patent expires in 2031. We have filed for patent term extension under a supplementary protection certificate for Rubraca in the European counterpart of the rucaparib camsylate salt/polymorph patent and believe that extension could be available to 2033. Patents in our high dosage strength rucaparib tablets patent family issued in the United States, with claims that cover the commercial Rubraca product, including all commercial dosage strengths expire in 2035. Additionally, in Europe, regulatory exclusivity is available for ten years, plus one year for a new indication, therefore, we have regulatory exclusivity for Rubraca in Europe until 2028, and if an additional indication is approved, until 2029.

We obtained rights to lucitanib by acquiring EOS in November 2013, along with its license agreement with Advenchen. We have rights to develop and commercialize lucitanib on a global basis, excluding China. Composition of matter and method of use patent protection for lucitanib and a group of structurally-related compounds is issued in the U.S., Europe and Japan and is issued or pending in other jurisdictions. In the U.S., the composition of matter patent will expire in 2030, and in other jurisdictions, it expires in 2028. We believe that patent term extension could be available to extend our composition of matter patent up to five years beyond the scheduled expiration under the Hatch-Waxman Act in the U.S., and similar provisions in other jurisdictions. Additionally, patents directed to methods of manufacturing lucitanib are issued in the United States, Europe, Japan, and China.

In September 2019, we acquired rights from 3BP, to develop and commercialize a peptide-targeted radionuclide therapy ("PTRT") and imaging agent targeting fibroblast activation protein alpha ("FAP"), including FAP-2286. We hold global development rights, and U.S. and global commercialization rights, excluding Europe (inclusive of Russia, Turkey and Israel), where 3BP retains rights. Patent applications are pending that claim FAP-2286 generically and specifically (including with respect to composition of matter) that, if issued, would have expiration dates in 2040.

In addition, we intend to seek patent protection whenever available for any products or product candidates and related technology we acquire in the future.

The patent positions of pharmaceutical firms like us are generally uncertain and involve complex legal, scientific and factual questions. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued. Consequently, we do not know whether any of the product candidates we acquire, or license will gain patent protection or, if any patents are issued, whether they will provide significant proprietary protection or will be challenged, circumvented or invalidated. Because patent applications in the United States and certain other jurisdictions are maintained in secrecy for 18 months, and since publication of discoveries in the scientific or patent literature often lags behind actual discoveries, until that time we cannot be certain that we were the first to file any patent application related to our product candidates. Moreover, we may have to participate in interference proceedings declared by the United States Patent and Trademark Office ("U.S. PTO") to determine priority of invention or in opposition or other third-party proceedings in the U.S. or a foreign patent office, either of which could result in substantial cost to us, even if the eventual outcome is favorable to us. There can be no assurance that the patents, if issued, would be held valid by a court of competent jurisdiction. An adverse outcome in a third-party patent dispute could subject us to significant liabilities to third parties, require disputed rights to be licensed from third parties or require us to cease using specific compounds or technology.

The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries in which we file, the patent term is 20 years from the earliest date of filing a non-provisional patent application. In the United States, a patent's term may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the U.S. PTO in granting a patent or may be shortened if a patent is terminally disclaimed over another patent.

The patent term of a patent that covers an FDA-approved drug may also be eligible for patent term extension, which permits patent term restoration as compensation for the patent term lost during the FDA regulatory review process. The Hatch-Waxman Act permits a patent term extension of up to five years beyond the expiration of the patent. The length of the patent term extension is related to the length of time the drug is under regulatory review. Patent extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only one patent applicable to an approved drug may be extended. Similar provisions are available in Europe and other non-U.S. jurisdictions to extend the term of a patent that covers an approved drug. In the future, if and when our pharmaceutical products receive FDA approval, we expect to apply for patent term extensions on patents covering those products.

To protect our rights to any of our issued patents and proprietary information, we may need to litigate against infringing third parties, or avail ourselves of the courts or participate in hearings to determine the scope and validity of those patents or other proprietary rights. These types of proceedings are often costly and could be very time-consuming to us, and we cannot assure you that the deciding authorities will rule in our favor. An unfavorable decision could allow third parties to use our technology without being required to pay us licensing fees or may compel us to license needed technologies to a third-party. Such a decision could even result in the invalidation or a limitation in the scope of our patents or forfeiture of the rights associated with our patents or pending patent applications. To the extent prudent, we intend to bring litigation against third parties that we believe are infringing one or more of our patents.

In addition, we have sought and intend to continue seeking orphan drug status whenever it is available. If a product which has an orphan drug designation subsequently receives the first regulatory approval for the indication for which it has such designation, the product is entitled to orphan exclusivity, meaning that the applicable regulatory authority may not approve any other applications to market the same drug for the same indication, except in certain very limited circumstances, for a period of seven years in the United States and ten years in the EU. Orphan drug designation does not prevent competitors from developing or marketing different drugs for an indication.

We also rely on trade secret protection for our confidential and proprietary information. No assurance can be given that others will not independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose such technology, or that we can meaningfully protect our trade secrets. However, we believe that the substantial costs and resources required to develop technological innovations will help us to protect the competitive advantage of our products.

It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information developed or made known to the individual during the

course of the individual's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. In the case of employees, the agreements provide that all inventions conceived by the individual shall be our exclusive property. There can be no assurance, however, that these agreements will provide meaningful protection or adequate remedies for our trade secrets in the event of unauthorized use or disclosure of such information.

**Manufacturing**

We currently contract with third parties for the manufacture of our product candidates for commercial use, or non-clinical studies and clinical trials and intend to do so in the future. We currently have long-term agreements with third-party contract manufacturing organizations ("CMOs") for the production of the active ingredient and final product for Rubraca. We do not own or operate manufacturing facilities for the production of commercial and clinical quantities of our product candidates. We currently have no plans to build our own clinical or commercial scale manufacturing capabilities. To meet our projected needs for commercial manufacturing, we are working with our current third-party suppliers to ensure sufficient capacity to meet our manufacturing requirements. Although we rely on contract manufacturers, we have personnel with extensive manufacturing experience to oversee the relationships with our contract manufacturers.

We have developed the process for manufacturing Rubraca's active pharmaceutical ingredient ("API") to a degree sufficient to meet clinical demands and, as production capacity is increased as described below under "Lonza Agreement," projected commercial requirements. Manufacturing of Rubraca API is being performed by Lonza Ltd ("Lonza"). Manufacturing operations for an advanced intermediate, which is the inventory prior to conversion to API, has been expanded to a second Lonza site during 2019. The Rubraca drug product formulation and manufacturing process to produce that formulation have been developed to a degree sufficient to meet clinical demands and projected commercial requirements. A single third-party CMO capable of both formulation development and drug product manufacturing is currently producing the Rubraca drug product.

To date, our third-party manufacturers have met our manufacturing requirements and we expect them to meet anticipated full-scale commercial demands.

***Lonza Agreement - Rubraca***

On October 3, 2016, we entered into an agreement with Lonza for the long-term manufacture and supply of the API for rucaparib. Under this agreement, Lonza is a non-exclusive manufacturer of the Rubraca API during the 10-year term of the agreement. Lonza constructed, in an existing Lonza facility, a production train that is exclusively dedicated to the manufacture of the Rubraca API. The dedicated production train provides manufacturing capacity to meet our currently anticipated needs for commercial supply of Rubraca API. We are obligated to make scheduled capital program fee payments toward capital equipment and other costs associated with the construction of the dedicated production train. Further, once the production train became operational in October 2018, we are obligated to pay a fixed facility fee each quarter for the duration of the Agreement, which expires on December 31, 2025, unless extended by mutual consent of the parties.

Either party may terminate the agreement due to a material breach of the agreement by the other party, subject to prior written notice and a cure period. We may terminate the agreement, subject to 90 days' prior written notice, in the event Rubraca is withdrawn from the market for certain reasons. In the event of such a termination by us, or termination by Lonza due to material breach by us, we are obligated to compensate Lonza for any services rendered, or for which costs have been incurred by Lonza in anticipation of services to be provided to us, and to pay to Lonza the remaining amount of any capital program fees and quarterly fixed facility fees for the remainder of the term of the agreement. In the event we terminate the agreement due to material breach by Lonza, Lonza is obligated to repay all or a portion of the capital program fees previously paid by us.

***Lucitanib***

The API for lucitanib is currently being produced by Lonza. To date, the current production process has been sufficient to satisfy immediate clinical demands. We may undertake additional development work to further optimize the active pharmaceutical ingredient manufacturing process. The finished drug product for lucitanib is currently being manufactured at a CMO. The current product and process are sufficiently developed to meet immediate clinical

demands. Additional scale-up work and/or additional production capacity will be necessary to support larger clinical development or commercialization requirements.

**Commercial Operations**

Our commercial organizations in the U.S. and Europe are in place and supporting the commercial sale of Rubraca. We believe the oncology market for Rubraca is addressable with a targeted sales and marketing organization, with capabilities that include the management of key accounts such as managed care organizations, group-purchasing organizations, oncology group networks and government accounts. We sell Rubraca through a limited distribution network consisting of select number of specialty pharmacies and distributors. Healthcare providers prescribe Rubraca to patients and the specialty pharmacies and distributors dispense Rubraca directly to patients. We intend to continue promoting Rubraca ourselves for its current indications and any additional indications we may obtain in the future. We retain the rights to Rubraca in the rest of the world.

**Customers**

We are currently approved to sell Rubraca in the U.S. and the EU markets. We distribute our product principally through a limited number of specialty distributor and specialty pharmacy providers, collectively, our customers. Our customers subsequently sell our products to patients and health care providers. We do not believe the loss of one of these customers would significantly impact the ability to distribute our product as we expect that sales volume would be absorbed evenly by the remaining customers. Separately, we have arrangements with certain payors and other third parties that provide for government-mandated and privately-negotiated rebates, chargebacks and discounts.

**Employees**

As of February 14, 2020, we employed 484 full-time employees. None of our employees is represented by labor unions, and a very small number of international employees are covered by collective bargaining agreements. We consider our relationship with our employees to be good.

**About Clovis**

We were incorporated under the laws of the State of Delaware in April 2009 and completed our initial public offering of our common stock in November 2011. Our common stock is listed on the NASDAQ Global Select Market under the symbol "CLVS." Our principal executive offices are located at 5500 Flatiron Parkway, Suite 100, Boulder, Colorado 80301, and our telephone number is (303) 625-5000. We maintain additional offices in San Francisco, California, Oakland, California, Cambridge, UK, London, UK, Milan, Italy and in several other locations in Europe. Our website address is *www.clovisoncology.com*. Our website and the information contained on, or that can be accessed through, the website will not be deemed to be incorporated by reference in, and are not considered part of, this report.

**Available Information**

As a public company, we file reports and proxy statements with the Securities and Exchange Commission ("SEC"). These filings include our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and proxy statements on Schedule 14A, as well as any amendments to those reports and proxy statements, and are available free of charge through our website as soon as reasonably practicable after we file them with, or furnish them to, the SEC. Once at *www.clovisoncology.com*, go to Investors & News/SEC Filings to locate copies of such reports. The SEC also maintains a website at www.sec.gov that contains reports, proxy statements and other information regarding us and other issuers that file electronically with the SEC.

## ITEM 1A. RISK FACTORS

*Our business faces significant risks and uncertainties. Certain factors may have a material adverse effect on our business prospects, financial condition and results of operations, and you should carefully consider them. Accordingly, in evaluating our business, we encourage you to consider the following discussion of risk factors, in its entirety, in addition to other information contained in or incorporated by reference into this Annual Report on Form 10-K and our other public filings with the SEC. Other events that we do not currently anticipate or that we currently deem immaterial may also affect our business, prospects, financial condition and results of operations.*

**Risks Related to Our Financial Position and Capital Requirements**

***We have incurred significant losses since our inception and anticipate that we will continue to incur losses for the foreseeable future, which makes it difficult to assess our future viability.***

We are a biopharmaceutical company with a limited operating history. Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. We have focused primarily on in-licensing and developing our products. We are not profitable and have incurred losses in each year since our inception in April 2009. We have only a limited operating history upon which you can evaluate our business and prospects. There are many risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the biopharmaceutical area. Two of our earlier product candidates, CO-101 and CO-1686, encountered development and/or regulatory setbacks after initial promising data, leading us to discontinue enrollment in then-ongoing clinical trials. We have received regulatory approval to market Rubraca in the U.S. and in EU, but do not know whether Rubraca will be approved in other jurisdictions or in additional tumor types and indications, or whether it will achieve market acceptance and be commercially successful in the long run. We have only recently started to generate revenues from product sales, but these revenues have not been sufficient and won't be sufficient in the near term, to support our operations. We continue to incur significant research and development and other expenses related to our ongoing operations. For the years ended December 31, 2019, 2018 and 2017, we had net losses of $400.4 million, $368.0 million and $346.4 million, respectively. As of December 31, 2019, we had an accumulated deficit of $2,243.5 million. We expect to continue to incur losses for the foreseeable future. As such, we are subject to all of the risks incident to the development of new biopharmaceutical products and related companion diagnostics, and we may encounter unforeseen expenses, difficulties, complications, regulatory scrutiny, delays and other unknown factors that may adversely affect our business. If any of our product candidates fail in clinical trials or do not gain regulatory approval, or if Rubraca or any of our product candidates, if approved, fail to achieve market acceptance, we may never become profitable. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders' equity and working capital.

***We will require substantial additional funding which may not be available to us on acceptable terms, or at all. If we fail to obtain additional financing, we may be unable to complete the development and commercialization of our products or continue our development programs.***

Our operations have consumed substantial amounts of cash since inception. We expect to continue to spend substantial amounts to advance the clinical development of our products and launch and commercialize our products.

Based on current estimates, we believe that our existing cash, cash equivalents and available-for-sale securities will allow us to fund our operating plan through at least the next 12 months. We do not have any material committed external source of funds or other support for our development efforts, other than the ATHENA clinical trial financing agreement with TPG to support the funding of the ATHENA trial.

Until we can generate a sufficient amount of product revenue to finance our cash requirements, which we may never do in sufficient amounts, we expect to finance future cash needs through a combination of public or private equity or debt offerings, and collaborations, strategic alliances and other similar licensing arrangements. We cannot be certain that additional funding will be available on acceptable terms, or at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our products, or our plans for acquisition or in-license of new product candidates. We may also seek collaborators for one or more of our current or future product candidates on terms that are less favorable than might otherwise be available. Any of these events could significantly harm our business, financial condition and prospects.

***Servicing our long-term debt requires a significant amount of cash, and we may not have sufficient cash flow from our business to pay our substantial debt.***

In September 2014, we completed a private placement of $287.5 million aggregate principal amount of 2.5% convertible senior notes due 2021 (the "2021 Notes"), resulting in net proceeds to the Company of $278.3 million after deducting offering expenses. In April 2018, we completed an underwritten public offering of $300.0 million aggregate

principal amount of 1.25% convertible senior notes due 2025 (the "2025 Notes"), resulting in net proceeds to the Company of $290.9 million after deducting offering expenses. In August 2019, we completed a private placement of $263.0 million aggregate principal amount of 4.50% convertible senior notes due 2024 (the "2024 Notes", and together with the 2021 Notes and 2025 Notes, the "Notes"). The 2021 Notes are governed by the terms of the indenture between the Company, as issuer, and The Bank of New York Mellon Trust Company, N.A., as trustee. Interest is payable on the 2021 Notes semi-annually, and the 2021 Notes mature on September 15, 2021, unless redeemed, repurchased or converted prior to that date. In addition, if, as defined by the terms of the indenture, a fundamental change occurs, holders of the 2021 Notes may require us to repurchase for cash all or any portion of their 2021 Notes at a purchase price equal to 100% of the principal amount of the 2021 Notes to be repurchased plus accrued and unpaid interest, to, but excluding, the fundamental change repurchase date. The 2025 Notes are governed by the terms of the indenture between the Company, as issuer, and The Bank of New York Mellon Trust Company, N.A., as trustee. Interest is payable on the 2025 Notes semi-annually, and the 2025 Notes mature on May 1, 2025, unless redeemed, repurchased or converted prior to that date. In addition, if, as defined by the terms of the indenture, a fundamental change occurs, holders of the 2025 Notes may require us to repurchase for cash all or any portion of their 2025 Notes at a purchase price equal to 100% of the principal amount of the Notes to be repurchased plus accrued and unpaid interest, to, but excluding, the fundamental change repurchase date. The 2024 Notes are governed by the terms of the indenture between the Company, as issuer, and The Bank of New York Mellon Trust company, N.A., as trustee. Interest is payable on the 2024 Notes semi-annually, and the 2024 Notes mature on August 1, 2024, unless repurchased or converted prior to that date. In addition, if as defined by the terms in the indenture, a fundamental change occurs, holders of the 2024 Notes may requires us to repurchase for cash all or any portion of their 2024 Notes at a purchase price equal to 100% of the principal amount of the 2024 Notes to be repurchased plus accrued and unpaid interest, to, but excluding, the fundamental change repurchase date.

Our ability to make scheduled payments of interest and principal on the Notes, or to pay the repurchase price for the Notes on a fundamental change, depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control. We may not have sufficient cash in the future to service our debt. If we are unable to generate such cash flow or secure additional sources of funding, we may be required to adopt one or more alternatives, such as restructuring debt or obtaining additional equity capital on terms that may be onerous or highly dilutive. For example, we were able to refinance a portion of the 2021 Notes from the proceeds of the issuance of the 2024 Notes, but the terms of the 2024 Notes are not as favorable from a financial perspective as the 2021 Notes and our stock price declined significantly upon the issuance of the 2024 Notes in part as a result of the assumed significant dilutive impact any future conversion of these Notes would have on our common stock. Our ability to refinance our indebtedness will depend on the capital markets and our financial condition at such time. In the near term, we will need to refinance the remaining $97 million principal amount of the 2021 Notes prior to their maturity in September 2021 as we will not be able to generate sufficient cash from our operations to pay off the 2021 Notes at maturity. We may not be able to engage in any of these activities or engage in these activities on desirable terms. If we fail to meet our obligations under the Notes, we will be in default, which may also cause a default under, and an acceleration of, our other debt obligations.

***We may not be able to raise the funds necessary to repurchase the Notes upon a fundamental change, and our future debt may contain limitations on our ability to repurchase the Notes.***

If we undergo a fundamental change, as defined in the indenture, prior to the maturity date of the Notes, holders may require us to repurchase for cash all or any portion of the Notes at a fundamental change repurchase price equal to 100% of the principal amount of the Notes to be repurchased plus accrued and unpaid interest to, but excluding, the fundamental change repurchase date. We may not have or be able to borrow the funds required to repurchase the Notes on the fundamental change repurchase date. In addition, our ability to repurchase the Notes may otherwise be limited by law, regulatory authority or agreements governing our future indebtedness. Our failure to repurchase the Notes at a time when the repurchase is required by the indenture would constitute a default under the indenture. A default under the indenture or the fundamental change itself could also lead to a default under agreements governing our future indebtedness. If the repayment of the related indebtedness were to be accelerated after any applicable notice or grace periods, we may not have sufficient funds to repay the indebtedness and repurchase the Notes when required.

***We may incur substantially more debt or take other actions which would intensify the risks discussed above; and we may not generate cash flow from operations in the future sufficient to satisfy our obligations under the Notes and any future indebtedness we may incur.***

We may incur substantial additional debt in the future, subject to the restrictions contained in any debt instruments that we enter into in the future, some of which may be secured debt. We are not restricted under the terms of the indenture governing the Notes from incurring additional debt, securing existing or future debt, recapitalizing our debt or taking a number of other actions that are not limited by the terms of the indenture governing the Notes that could have the effect of diminishing our ability to make payments on the Notes when due. Our ability to refinance the Notes or future indebtedness will depend on the capital markets and our financial condition at such time. In addition, agreements that govern any future indebtedness that we may incur may contain financial and other restrictive covenants that will limit our ability to engage in activities that may be in our long-term best interests. Our failure to comply with those covenants could result in an event of default that, if not cured or waived, could result in the acceleration of some or all of our debt.

***Provisions in the indenture could delay or prevent an otherwise beneficial takeover of us.***

Certain provisions in the Notes and the indentures governing the Notes could make a third-party attempt to acquire us more difficult or expensive. For example, if a takeover constitutes a fundamental change, then holders will have the right to require us to repurchase their notes for cash. In addition, if a takeover constitutes a make-whole fundamental change, then we may be required to temporarily increase the conversion rate. In either case, and in other cases, our obligations under the Notes and the indentures governing the Notes could increase the cost of acquiring us or otherwise discourage a third party from acquiring us or removing incumbent management, including in a transaction that holders or holders of our common stock may view as favorable.

***We and certain of our officers and directors have been named as defendants in several lawsuits that could result in substantial costs and divert management's attention.***

We and certain of our officers have been named as defendants in a number of lawsuits that generally allege that we and certain of our officers violated federal securities laws by making allegedly false and misleading statements regarding the progress toward FDA approval and the potential for market success of rociletinib. Some of these lawsuits have been settled while others remain outstanding and others may still be brought. See "Part I, Item 3-Legal Proceedings" in this report.

We intend to engage in a vigorous defense of these lawsuits; however, we are unable to predict the outcome of these matters at this time. If we are not successful in our defense of these litigation matters, we could be forced to make significant payments to, or enter into other settlements with, our security holders and their lawyers (and in certain circumstances reimburse costs and expenses incurred by the underwriters), and such payments or settlement arrangements could have a material adverse effect on our business, operating results and financial condition. For example, we could suffer a significant adverse impact on our reputation and divert management's attention and resources from other priorities, any of which could have a material adverse effect on our business. In addition, any of these matters could require payments that are not covered by, or exceed the limits of, our available directors' and officers' liability insurance, which could have a material adverse effect on our operating results or financial condition. We will not receive any further contributions from our insurance carriers for any amounts (including damages, settlement costs or legal fees) relating to the Company's regulatory update announcement in November 2015 that the FDA requested additional clinical data on the efficacy and safety of rociletinib.

Additional lawsuits with similar claims may be filed by other parties against us and our officers and directors. Even if such claims are not successful, these lawsuits or other future similar actions, or other regulatory inquiries or investigations, may result in substantial costs and have a significant adverse impact on our reputation and divert management's attention and resources, which could have a material adverse effect on our business, operating results or financial condition.

**Risks Related to Our Business and Industry**

***We are highly dependent on the commercial success of Rubraca; Rubraca may not achieve market acceptance and may not be commercially successful and we may not attain profitability and positive cash flow from operations.***

Rubraca is commercially available in the U.S. and the EU. The degree of market acceptance and the commercial success of Rubraca will depend on a number of factors, including:

- the effectiveness of our sales and marketing strategy and operations;
- maintaining compliance with all regulatory requirements applicable to Rubraca and our commercial activities, including the post-marketing requirements and post-marketing commitments required by the FDA and the EMA, to verify Rubraca's clinical benefit or safety by completing certain confirmatory trials, pharmacology studies and additional diagnostic development;
- the acceptance of Rubraca by patients and the medical community and the availability, perceived advantages and relative cost, safety and efficacy of alternative and competing products and therapies;
- the continued acceptable safety profile of Rubraca and the occurrence of any unexpected side effects, adverse reactions or misuse, or any unfavorable publicity in these areas;
- the ability of our third-party manufacturers to manufacture commercial supplies of Rubraca, to remain in good standing with regulatory agencies, and to develop, validate and maintain commercially viable manufacturing processes that are, to the extent required, compliant with cGMP regulations;
- the availability of coverage and adequate reimbursement from managed care plans, private health insurers and other third-party payors and the willingness and ability of patients to pay for Rubraca;
- the development or commercialization of competing products or therapies;
- marketing and distribution support for Rubraca, including the degree to which the approved labeling supports promotional initiatives for commercial success;
- the actual market size for Rubraca, which may be different than expected;
- our ability to enforce our intellectual property rights in and to Rubraca;
- our ability to avoid third party patent interference or patent infringement claims; and
- our ability to obtain regulatory approvals, including for pricing and reimbursement, to commercialize Rubraca in markets outside of the U.S.

As many of these factors are beyond our control, we cannot assure you that we will ever be able to generate meaningful revenue through the sale of Rubraca. In addition, we may experience significant fluctuations in sales of Rubraca from period to period. Our sNDA for Rubraca for a prostate cancer indication is currently under review and we are evaluating Rubraca in other indications. However, we have only one other product candidate, lucitanib, in clinical development. Any inability on our part to successfully commercialize Rubraca in the United States, Europe and any other territories where it may be approved, or any significant delay in such approvals, could have a material adverse impact on our ability to execute upon our business strategy and, ultimately, to generate sufficient revenues from Rubraca to reach or maintain profitability or sustain our anticipated levels of operations.

***Rubraca may cause undesirable side effects or have other properties that could limit its commercial potential.***

If we or others identify previously unknown side effects or if known side effects are more frequent or severe than in the past, then:

- sales of Rubraca may decline;
- regulatory approvals for Rubraca may be restricted or withdrawn;
- we may decide to, or be required to, send product warning letters or field alerts to physicians, pharmacists and hospitals;

- additional nonclinical or clinical studies, changes in labeling or changes to manufacturing processes, specifications and/or facilities may be required;
- government investigations or lawsuits, including class action suits, may be brought against us; and
- our reputation may suffer.

Any of the above occurrences would harm or prevent sales of Rubraca, increase our expenses and impair our ability to successfully commercialize Rubraca. As Rubraca is commercially available, it may be used in a wider population and in a less rigorously controlled environment than in clinical studies. As a result, regulatory authorities, healthcare practitioners, third-party payors or patients may perceive or conclude that the use of Rubraca is associated with previously unknown serious adverse effects, undermining our commercialization efforts.

***If our sales, marketing and distribution capabilities for Rubraca or our product candidates for which we obtain marketing approval are inadequate, we may be unable to generate revenue from sales of our products.***

Prior to the launch of Rubraca, we had not commercialized any drug products as a company. To achieve commercial success for Rubraca and any product candidate that may be approved by the FDA or comparable foreign regulatory authorities, we must continue to expand our sales, marketing, managerial and other nontechnical capabilities or make arrangements with third parties to perform these services. We are competing with companies that currently have extensive, well-funded, and more experienced sales and marketing operations. We may be unable to compete successfully against these more established companies.

We have built a field organization and other capabilities for the sales, marketing and distribution of Rubraca in the United States and in Europe, and there are significant risks involved with building and managing a sales organization. Factors that may inhibit our efforts to effectively commercialize Rubraca on our own include:

- our inability to recruit, train, retain and incentivize adequate numbers of qualified and effective sales and marketing personnel;
- the inability of sales personnel to generate sufficient sales leads and to obtain access to physicians or persuade adequate numbers of physicians to use or prescribe Rubraca; and
- our inability to effectively manage a geographically dispersed sales and marketing team.

If we are unable to maintain effective sales, marketing and distribution capabilities for Rubraca or if we are unable to fully establish and maintain sales, marketing and distribution capabilities for Rubraca outside of the United States or for any other product candidate for which we obtain marketing approval, whether independently or with third parties, we may not be able to generate product revenue or may not become profitable. If the cost of establishing and maintaining a sales and marketing organization exceeds the cost-effectiveness of doing so, we may not become profitable.

With respect to our product candidates, we may elect to collaborate with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems in certain territories. To the extent that we enter into licensing or co-promotion arrangements for any of our product candidates, our product revenue may be lower than if we directly marketed or sold our approved products. In addition, any revenue we receive as a result of such arrangements would depend in whole or in part upon the efforts of such third parties, which may not be successful and are generally not within our control. If we are unable to enter into such arrangements on acceptable terms or at all, we may not be able to successfully commercialize our product candidates that receive regulatory approval. If we are not successful in commercializing our product candidates, either on our own or through collaborations with one or more third parties, our future product revenue will suffer and we may incur significant additional losses.

***We cannot give any assurance that the Rubraca development program in other lines of therapies and indications will be successful or that our other product candidates will receive regulatory approval.***

To date, we have invested a significant portion of our efforts and financial resources in the acquisition and development of our product candidates. Our business depends entirely on the successful development and commercialization of our product candidates.

Each of our product candidates requires clinical development, management of clinical, non-clinical and manufacturing activities, regulatory approval in multiple jurisdictions, obtaining manufacturing supply, building of a commercial organization and significant marketing efforts in order to generate any revenues from product sales. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the FDA or comparable foreign regulatory authorities. To date, we have received regulatory approval from the FDA and EMA to market Rubraca in the United States and the EU, respectively. We may not receive regulatory approvals for Rubraca for broader indications and lines of therapy or other tumor types and we may never receive regulatory approval for other product candidates. In addition, certain of our product development plans may contemplate the development of companion diagnostics by third-party collaborators. Companion diagnostics are subject to regulation as medical devices and must themselves be approved for marketing by the FDA or certain other foreign regulatory agencies before our product candidates may be commercialized.

We cannot be certain that Rubraca will be successfully developed to expand its current label to include other indications or that any of our product candidates will be successful in clinical trials or receive regulatory approval. Further, our product candidates may not receive regulatory approval even if they are successful in clinical trials. Two of our product candidates, CO-101 and rociletinib, encountered development and regulatory setbacks after initial promising data, leading us to discontinue enrollment in ongoing clinical trials. Even if we successfully obtain regulatory approvals to market one or more of our other product candidates, our revenues will be dependent, in part, upon our diagnostic collaborators' ability to obtain regulatory approval of the companion diagnostics, where required, to be used with our product candidates, as well as the size of the markets in the territories for which we gain regulatory approval and have commercial rights. If the markets that we are targeting are not as significant as we estimate, we may not generate significant revenues from sales of such products, if approved.

We plan to seek regulatory approval to commercialize our product candidates, and for other indications for Rubraca, in the United States, the EU and in additional foreign countries. While the scope of regulatory approval is similar in other countries, obtaining separate regulatory approval in many other countries requires compliance with numerous and varying regulatory requirements of such countries regarding safety and efficacy and governing, among other things, clinical trials and commercial sales, pricing and distribution of our product candidates, and we cannot predict success in these jurisdictions.

***Clinical drug development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results.***

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of non-clinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through non-clinical studies and initial clinical trials. It is not uncommon for companies in the biopharmaceutical industry to suffer significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Indeed, based on the negative results of a pivotal study, we ceased further development of our previous product candidate CO-101, and we decided to discontinue ongoing development of rociletinib as a result of the issuance of a Complete Response Letter by the FDA. Additionally, our future clinical trial results may not be successful.

Although we have clinical trials ongoing, we may experience delays in our ongoing clinical trials, and we do not know whether planned clinical trials will begin on time, need to be redesigned, enroll patients on time or be completed on schedule, if at all. Clinical trials can be delayed for a variety of reasons, including delays related to:

- obtaining regulatory approval to commence a trial;
- reaching agreement on acceptable terms with prospective contract research organizations ("CROs") and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtaining institutional review board ("IRB") approval at each site;
- recruiting suitable patients to participate in a trial;
- developing and validating companion diagnostics on a timely basis;
- having patients complete a trial or return for post-treatment follow-up;

- clinical sites deviating from trial protocol or dropping out of a trial;
- adding new clinical trial sites; or
- manufacturing sufficient quantities of product candidate for use in clinical trials.

Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors including the size and nature of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the design of the clinical trial, competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating. Furthermore, we rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials, and while we have agreements governing their committed activities, we have limited influence over their actual performance.

We could encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by the Data Safety Monitoring Board for such trial or by the FDA or other regulatory authorities. Such authorities may impose a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. If we experience delays in the completion of, or termination of, any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may harm our business, financial condition and prospects significantly. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

***The regulatory approval processes of the FDA, EMA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for Rubraca in other indications and lines of therapy or for our other product candidates, our business will be substantially harmed.***

The time required to obtain approval by the FDA, EMA and comparable foreign authorities is unpredictable, but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. We have obtained regulatory approval for Rubraca in the United States and the EU, and it is possible that Rubraca may not obtain regulatory approval for broader indications and lines of therapy or other tumor types or that any of our other existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval. Indeed, with the issuance of a Complete Response Letter by the FDA with respect to the rociletinib NDA, we decided to discontinue ongoing development of rociletinib.

Our product candidates could fail to receive regulatory approval or approval may be delayed for many reasons, including the following:

- the FDA, EMA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA, EMA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA, EMA or comparable foreign regulatory authorities for approval;
- the FDA, EMA or comparable foreign regulatory authorities may disagree with our interpretation of data from non-clinical studies or clinical trials;

- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of an NDA, MAA or other submission or to obtain regulatory approval in the United States, the EU or elsewhere;
- the FDA, EMA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies;
- the FDA, EMA or comparable foreign regulatory authorities may fail to approve the companion diagnostics we contemplate developing with partners; and
- the approval policies or regulations of the FDA, EMA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

This lengthy approval process, as well as the unpredictability of future clinical trial results, may result in our failing to obtain regulatory approval to market our product candidates, which would significantly harm our business, results of operations and prospects.

***Even if we receive regulatory approval for our product candidates, we will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense. Additionally, our product candidates, if and when approved, could be subject to labeling and other restrictions and market withdrawal, and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products.***

Any regulatory approvals that we receive for our product candidates may also be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing and clinical trials and surveillance to monitor the safety and efficacy of the product candidate. In addition, if the FDA, EMA or comparable foreign regulatory authority approves any of our product candidates, the manufacturing processes, pricing, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with current good manufacturing practices and good clinical practices for any clinical trials that we conduct post-approval. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market or voluntary or mandatory product recalls;
- fines, warning letters or holds on clinical trials;
- refusal by the FDA, EMA and comparable foreign authorities to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; and
- injunctions or the imposition of civil or criminal penalties.

All of the foregoing limitations, obligations, and requirements also apply to Rubraca, for which we have received regulatory approval in the United States and the EU for certain indications.

We may seek approval from U.S. and foreign regulatory authorities for one or more product candidates on a conditional basis with full approval conditioned upon fulfilling the requirements of regulators. For example, we received accelerated approval from the FDA for the initial indication for Rubraca and conditional marketing authorization from the EMA for the initial indication for Rubraca. Each of these approval pathways has certain conditions to approval, some of which may be post-approval, such as the conduct of a post-approval, or confirmatory, trial using due diligence. If we are unable to fulfill the requirements of regulators that are conditions of a product's accelerated or conditional approval, if the confirmatory trial shows unfavorable results or increased or additional undesirable side effects, or if regulators re-evaluate the data or risk-benefit profile of our product candidate, the availability of accelerated or conditional approval may be withdrawn or our conditional approval may not result in full approval or may be revoked or not renewed. Alternatively, we may be required to change a product candidate's labeled indications or even withdraw the product, if approved, from the market.

The FDA's, EMA's and comparable foreign authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States, the EU or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, and we may not achieve or sustain profitability, which would adversely affect our business. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

***Rubraca and our other product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label or result in significant negative consequences following marketing approval, if any.***

Adverse events ("AEs") attributable to our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA, EMA or other comparable foreign authorities. Clinical studies conducted to date have generated AEs related to our product candidates, some of which have been serious. Patients treated with Rubraca have commonly experienced nausea, vomiting, constipation, dysgeusia, anemia/decreased hemoglobin, decreased appetite, diarrhea, abdominal pain, thrombocytopenia and fatigue/asthenia. In studies of lucitanib, hypertension, proteinuria and subclinical hypothyroidism requiring supplementation are the most common AEs observed. As is the case with all oncology drugs, it is possible that there may be other potentially harmful characteristics associated with their use in future trials, including larger and lengthier Phase III clinical trials. As we evaluate the use of our product candidates in combination with other active agents, we may encounter safety issues as a result of the combined safety profiles of each agent, which could pose a substantial challenge to that development strategy.

Results of our trials could reveal a high and unacceptable severity and prevalence of these or other side effects. In such an event, our trials could be suspended or terminated and the FDA, EMA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. The drug-related AEs could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

Additionally, if we or others later identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approvals of such product;
- regulatory authorities may require additional warnings on the label;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could significantly harm our business, results of operations and prospects.

***Failure to successfully validate, develop and obtain regulatory approval for companion diagnostics could harm our drug development strategy.***

Where appropriate in the context of our clinical development strategy, we seek to identify patient subsets within a disease category who may derive selective and meaningful benefit from the product candidates we are developing. In collaboration with partners, we may develop companion diagnostics to help us to more accurately identify patients within a particular subset, both during our clinical trials and in connection with the commercialization of our product candidates. Companion diagnostics are subject to regulation by the FDA, EMA and comparable foreign regulatory authorities as medical devices and require separate regulatory approval prior to commercialization. We do not develop

companion diagnostics internally and thus we are dependent on the sustained cooperation and effort of our third-party collaborators in developing and obtaining approval for these companion diagnostics. We and our collaborators may encounter difficulties in developing and obtaining approval for the companion diagnostics, including issues relating to selectivity/specificity, analytical validation, reproducibility, or clinical validation. Any delay or failure by our collaborators to develop or obtain regulatory approval of the companion diagnostics could delay or prevent approval of our product candidates. In addition, our collaborators may encounter production difficulties that could constrain the supply of the companion diagnostics, and both they and we may have difficulties gaining acceptance of the use of the companion diagnostics in the clinical community. If such companion diagnostics fail to gain market acceptance, it would have an adverse effect on our ability to derive revenues from sales of our products. In addition, the diagnostic company with whom we contract may decide to discontinue selling or manufacturing the companion diagnostic that we anticipate using in connection with development and commercialization of our product candidates or our relationship with such diagnostic company may otherwise terminate. We may not be able to enter into arrangements with another diagnostic company to obtain access to an alternative diagnostic test for use in connection with the development and commercialization of our product candidates or do so on commercially reasonable terms, which could adversely affect and/or delay the development or commercialization of our product candidates.

***We rely on third parties to conduct our non-clinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.***

We have relied upon and plan to continue to rely upon third-party CROs to monitor and manage data for our ongoing non-clinical and clinical programs. We rely on these parties for execution of our non-clinical and clinical studies, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on the CROs does not relieve us of our regulatory responsibilities. We and our CROs are required to comply with GCP, which are regulations and guidelines enforced by the FDA, the EMA and comparable foreign regulatory authorities for all of our products in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, the EMA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations. In addition, our clinical trials must be conducted with product produced under cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

Our CROs have the right to terminate their agreements with us in the event of an uncured material breach. In addition, some of our CROs have an ability to terminate their respective agreements with us if it can be reasonably demonstrated that the safety of the subjects participating in our clinical trials warrants such termination, if we make a general assignment for the benefit of our creditors or if we are liquidated.

If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. In addition, our CROs are not our employees, and except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our on-going clinical and non-clinical programs. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed.

Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially influence our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse effect on our business, financial condition and prospects.

***We rely completely on third parties to manufacture our clinical drug supplies and our commercial supplies of Rubraca, and our development and commercialization of any of our product candidates could be stopped, delayed or made less profitable if those third parties fail to maintain approval of the FDA, EMA or comparable foreign regulatory authorities, fail to provide us with sufficient quantities of drug product or fail to do so at acceptable quality levels or prices.***

We do not currently have nor do we plan to acquire the infrastructure or capability internally to manufacture our clinical drug supplies for use in the conduct of our clinical trials, and we lack the resources and the capability to manufacture any of our product candidates on a clinical or commercial scale. We do not control the manufacturing operations of, and are completely dependent on our contract manufacturing partners for compliance with the cGMP regulatory requirements for manufacture of both active drug substances and finished drug products. If our contract manufacturers cannot successfully manufacture material that conforms to the strict regulatory requirements of the FDA, EMA or comparable foreign regulatory authorities, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. In addition, we have limited control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly affect our ability to develop, obtain regulatory approval for or market our product candidates, if approved.

We rely on our manufacturers to purchase from third-party suppliers the materials necessary to produce our products. There are a limited number of suppliers of raw materials that we use to manufacture our drugs, including Chinese suppliers, and there may be a need to assess alternate suppliers to prevent a possible disruption of the manufacture of the materials necessary to produce our products for clinical trials and for commercial sale. We do not have direct control over the process or timing of the acquisition of these raw materials by our manufacturers. Moreover, we currently do not have any direct agreements for the commercial production of these raw materials. Any significant delay in the supply of a product or product candidate, or the raw material components thereof, due to the need to replace a third-party manufacturer, could considerably delay completion of our clinical trials and potential regulatory approval of our product candidates. If our manufacturers or we are unable to purchase these raw materials after regulatory approval has been obtained for our product candidates, the commercial launch of our product candidates would be delayed or there would be a shortage in supply, which would impair our ability to generate revenues from the sale of our product candidates.

We are dependent on our third-party manufacturers to conduct process development and scale-up work necessary to support greater clinical development and commercialization requirements for our product candidates. Carrying out these activities in a timely manner, and on commercially reasonable terms, is critical to the successful development and commercialization of our product candidates. We expect that our third-party manufacturers are capable of providing sufficient quantities of our product candidates to meet anticipated clinical and full-scale commercial demands, however if third parties with whom we currently work are unable to meet our supply requirements, we will need to secure alternate suppliers. While we believe that there are other contract manufacturers having the technical capabilities to manufacture our product candidates, we cannot be certain that identifying and establishing relationships with such sources would not result in significant delay or material additional costs. It may also take a significant period of time to establish an alternative source of supply for our products, product candidates and components and to have any such new source approved by the FDA or any applicable foreign regulatory authorities.

We expect to continue to depend on third-party contract manufacturers for the foreseeable future. While we have long-term agreements with Lonza for the manufacture of API for Rubraca and with the manufacturer of the finished drug product, those are our single sources for the supply of Rubraca API and finished drug product, respectively, and we have not entered into agreements with any alternate suppliers. We currently obtain our supplies of finished drug product through individual purchase orders as described in the current supply agreement.

***We are subject to risks associated with the availability of key raw materials, such as the radioisotopes used in the manufacture of our product candidates.***

The manufacture of our product candidate $^{177}$Lu-FAP-2286 and companion imaging agent $^{68}$Ga-FAP-2286 will require the use of raw materials that are subject, at times, to global supply constraints that have the potential to delay our work on the products incorporating those raw materials. For example, any limitation on our ability to source adequate supply of lutetium-177 for $^{177}$Lu-FAP-2286 could prevent us from gathering sufficient data in clinical trials, or to the extent that we obtain regulatory approval for marketing for this product candidate, a limited supply may prevent us from

meeting commercial demands. Supply constraints for lutetium-177 could also materially increase the manufacturing costs of $^{177}$Lu-FAP-2286, which would increase the cost of our clinical trials and reduce the commercial potential of the product candidate.

In addition, we plan to use gallium-68 in our development of imaging agent $^{68}$Ga-FAP-2286. Increased future demand for gallium-68 may exceed current production capacities. If we are not able to obtain sufficient quantities of gallium-68 for use in $^{68}$Ga-FAP-2286, we may not be able to gather sufficient data on $^{68}$Ga-FAP-2286 to use in clinical trials or to possibly seek the approval of $^{68}$Ga-FAP-2286. In addition, to the extent the approval of our product candidates depends on the screening and monitoring of the patient population with a companion imaging agent such as $^{68}$Ga-FAP-2286 in our clinical trials, we would experience a corresponding delay in approval and commercialization of these product candidates if we are not able to obtain sufficient gallium-68.

***Our commercial success depends upon attaining significant market acceptance of our product candidates, if approved, among physicians, patients, healthcare payors and major operators of cancer clinics.***

Even if we obtain regulatory approval for our other product candidates, the product may not gain market acceptance among physicians, health care payors, patients and the medical community, which are critical to commercial success. Market acceptance of any product candidate for which we receive approval depends on a number of factors, including:

- the efficacy and safety as demonstrated in clinical trials;
- the timing of market introduction of such product candidate as well as competitive products;
- the clinical indications for which the drug is approved and the product label approved by regulatory authorities, including any warnings that may be required on the label;
- the approval, availability, market acceptance and reimbursement for the companion diagnostic;
- acceptance by physicians, major operators of cancer clinics and patients of the drug as a safe and effective treatment;
- the potential and perceived advantages of such product candidate over alternative treatments, especially with respect to patient subsets that we are targeting with such product candidate;
- the safety of such product candidate seen in a broader patient group, including its use outside the approved indications;
- the cost, safety and efficacy of the product in relation to alternative treatments;
- the availability of adequate reimbursement and pricing by third-party payors and government authorities;
- relative convenience and ease of administration;
- the prevalence and severity of adverse side effects; and
- the effectiveness of our sales and marketing efforts.

If our product candidates are approved but fail to achieve an adequate level of acceptance by physicians, healthcare payors and patients, we will not be able to generate significant revenues, and we may not become or remain profitable.

***We face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively.***

The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. In addition, the competition in the oncology market is intense. We have competitors both in the United States and internationally, including major multinational pharmaceutical companies, biotechnology companies and universities and other research institutions (see Part I, Item 1-Business, Competition section).

Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff and experienced marketing and manufacturing organizations. GlaxoSmithKline plc gained rights to Zejula through its acquisition of Tesaro Inc., which was completed in January 2019. Additional mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in

our competitors. As a result, these companies may obtain regulatory approval more rapidly than we are able and may be more effective in selling and marketing their products as well. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors may succeed in developing, acquiring or licensing, on an exclusive basis, drug products that are more effective or less costly than any drug candidate that we are currently developing or that we may develop. If approved, our product candidates will face competition from commercially available drugs, as well as drugs that are in the development pipelines of our competitors and later enter the market.

Established pharmaceutical companies may invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make our product candidates less competitive. In addition, any new product that competes with an approved product must demonstrate compelling advantages in efficacy, convenience, tolerability and safety in order to overcome price competition and to be commercially successful. Accordingly, our competitors may succeed in obtaining patent protection, receiving FDA, European Commission or other regulatory approval or discovering, developing and commercializing medicines before we do, which would have a material adverse effect on our business.

***Reimbursement may be limited or unavailable in certain market segments for our product candidates, which could make it difficult for us to sell our products profitably.***

There is significant uncertainty related to the third-party coverage and reimbursement of newly approved drugs. We have received marketing authorization for Rubraca in the United States and the EU for multiple indications. We intend to seek additional approvals to market Rubraca and other product candidates in the United States, Europe and other selected foreign jurisdictions. Market acceptance and sales of our products in both domestic and international markets will depend significantly on the availability of adequate coverage and reimbursement from third-party payors for any of our products and may be affected by existing and future healthcare reform measures. Government and other third-party payors are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement for new drugs and, as a result, they may not cover or provide adequate payment for our products. These payors may conclude that our products are less safe, less effective or less cost-effective than existing or later introduced products, and third-party payors may not approve our products for coverage and reimbursement or may cease providing coverage and reimbursement for these products.

Obtaining coverage and reimbursement approval for a product from a government or other third-party payor is a time consuming and costly process that could require us to provide to the payor supporting scientific, clinical and cost-effectiveness data for the use of our products. We may not be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement. We cannot be sure that coverage or adequate reimbursement will be available for any of our products. Even if we obtain coverage for our products, third-party payors may not establish adequate reimbursement amounts, which may reduce the demand for, or the price of, our products. If reimbursement of our future products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, we may be unable to achieve or sustain profitability.

In both the United States and certain foreign jurisdictions, there have been and we expect there will continue to be a number of legislative and regulatory changes to the health care system that could affect our ability to sell our products profitably. The U.S. government and other governments have shown significant interest in pursuing healthcare reform. In particular, the Medicare Modernization Act of 2003 revised the payment methodology for many products under the Medicare program in the United States. This has resulted in lower rates of reimbursement. In 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the "Affordable Care Act"), was enacted. The Affordable Care Act substantially changed the way healthcare is financed by both governmental and private insurers. Such government-adopted reform measures may adversely affect the pricing of healthcare products and services in the United States or internationally and the amount of reimbursement available from governmental agencies or other third-party payors.

Moreover, payment methodologies, including payment for companion diagnostics, may be subject to changes in healthcare legislation and regulatory initiatives. For example, the CMS has begun bundling the Medicare payments for certain laboratory tests ordered while a patient received services in a hospital outpatient setting and, in 2018, the CMS began paying for clinical laboratory services based on a weighted average of reported prices that private payors, Medicare Advantage plans, and Medicaid Managed Care plans pay for laboratory services.

There have been, and likely will continue to be, legislative and regulatory proposals at the federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. Recently there has also been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed bills designed to, among other things, reform government program reimbursement methodologies. Individual states in the United States have also become increasingly active in implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare may adversely affect the demand for any drug products for which we may obtain regulatory approval, as well as our ability to set satisfactory prices for our products, to generate revenues, and to achieve and maintain profitability.

In some foreign countries, particularly in Europe, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct additional clinical trials that compare the cost-effectiveness of our product candidates to other available therapies. If reimbursement of our product candidates is unavailable or limited in scope or amount in a particular country, or if pricing is set at unsatisfactory levels, we may be unable to achieve or sustain profitability of our products in such country.

***If we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy. Further, we will need to grow our organization, and we may experience difficulties in managing this growth, which could disrupt our operations.***

Our industry has experienced a high rate of turnover of management personnel in recent years. Our ability to compete in the highly competitive biotechnology and pharmaceuticals industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on our management, scientific and medical personnel, especially Patrick J. Mahaffy, our President and Chief Executive Officer, Lindsey Rolfe, our Executive Vice President of Clinical and Preclinical Development and Pharmacovigilance and Chief Medical Officer and Gillian C. Ivers-Read, our Executive Vice President, Technical Operations and Chief Regulatory Officer, whose services are critical to the successful implementation of our product candidate acquisition, development and regulatory strategies.

Despite our efforts to retain valuable employees, members of our management, scientific, development and commercial teams may terminate their employment with us on short notice. Pursuant to their employment arrangements, each of our executive officers may voluntarily terminate their employment at any time by providing as little as thirty days advance notice. Our employment arrangements with all of our employees provide for at-will employment, which means that any of our employees could leave our employment at any time, with or, other than our executive officers, without notice. The loss of the services of any of our executive officers or other key employees and our inability to find suitable replacements could potentially harm our business, financial condition and prospects. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level and senior managers as well as junior, mid-level and senior scientific and medical personnel.

As of February 14, 2020, we employed 484 full-time employees. As our development plans and strategies develop, we expect to expand our employee base for managerial, operational, financial and other resources. Future growth will impose significant added responsibilities on members of management, including the need to identify, recruit, maintain, motivate and integrate additional employees. Also, our management may need to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations which may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects. If our management is unable to effectively manage our expected growth, our expenses may increase more than expected, our ability to generate revenues could be reduced and we may not be able to implement our business strategy.

We may not be able to attract or retain qualified management and scientific personnel in the future due to the intense competition for a limited number of qualified personnel among biopharmaceutical, biotechnology, pharmaceutical and other businesses. Many of the other pharmaceutical companies that we compete against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high quality candidates than what we have to offer. In order to induce valuable employees to continue their employment with us, we have provided stock options that vest over time. The value to employees of stock options that vest over time is significantly affected by movements in our stock price that are beyond our control, and may at any time be insufficient to counteract more lucrative offers from other companies. If we are unable to continue to attract and retain high quality personnel, the rate and success at which we can develop and commercialize product candidates will be limited.

***Our employees and independent contractors, including principal investigators, CROs, consultants and vendors, may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have a material adverse effect on our business.***

We are exposed to the risk that our employees and independent contractors, including principal investigators, CROs, consultants and vendors, may engage in misconduct or other illegal activity. Misconduct by those parties could include intentional, reckless and/or negligent failures to comply with the laws and regulations of the FDA and other similar regulatory agencies, provide accurate information to such authorities, comply with manufacturing standards we have established, including cGMP requirements, comply with federal and state data privacy, securities, fraud and abuse and other healthcare laws and regulations in the United States and abroad, report financial information or data accurately, or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee or contractor misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a Code of Business Ethics and other compliance policies, but it is not always possible to identify and deter misconduct by employees and contractors, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant effect on our business and results of operations, including the imposition of significant fines or other sanctions.

***Our relationships with healthcare professionals, investigators, consultants, customers (actual and potential) and third-party payors are and will continue to be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, transparency and disclosure (or "sunshine") laws, government price reporting, and health information privacy and security laws. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.***

Our operations may be directly, or indirectly through our customers, subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act. These laws may affect, among other things, our current activities with clinical study investigators and research subjects, as well as proposed and future sales, marketing, disease awareness, and patient assistance programs. In addition, we may be subject to patient privacy regulation by both the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, including any kickback, bribe, or certain rebate, directly or indirectly, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment will be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or special intent to violate the law in order to have committed a violation; in addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act;

- federal false claims laws, including the False Claims Act, which impose criminal and civil penalties, including through civil "qui tam" or "whistleblower" actions, against individuals or entities from knowingly presenting, or causing to be presented, claims for payment or approval from federal programs, such as Medicare and Medicaid, that are false or fraudulent, or knowingly making a false statement to improperly avoid, decrease or conceal an obligation to pay money to the federal government;
- the Health Insurance Portability and Accountability Act of 1996, or HIPAA which imposes criminal and civil liability for, among other things, willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations, which also imposes certain requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses, as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal civil monetary penalties statute, which prohibits, among other things, the offering or giving of remuneration to a Medicare or Medicaid beneficiary that the person knows or should know is likely to influence the beneficiary's election of a particular supplier of items or services reimbursable by a Federal or state governmental program;
- the federal Physician Payment Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the Centers for Medicare and Medicaid Services, or CMS, information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- federal government price reporting laws, which require drug manufacturers to calculate and report complex pricing metrics to government agencies, including CMS, where such reported prices may be used in the calculation of reimbursement and/or discounts on marketed products. Participation in these programs and compliance with the applicable requirements may result in potentially significant discounts on products subject to reimbursement under federal healthcare programs and increased infrastructure costs, and may potentially limit a drug manufacturer's ability to offer certain marketplace discounts; and
- analogous state laws and regulations, such as state anti-kickback, false claims, consumer protection and unfair competition laws which may apply to pharmaceutical business practices, including but not limited to, research, distribution, sales and marketing arrangements as well as submitting claims involving healthcare items or services reimbursed by any third-party payer, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government that otherwise restricts payments that may be made to healthcare providers and other potential referral sources; state laws that require drug manufacturers to file reports with states regarding pricing and marketing information, such as the tracking and reporting of gifts, compensations and other remuneration and items of value provided to healthcare professionals and entities; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

In addition, the research and development of our product candidates outside the United States, and any sales of our products or product candidates once commercialized outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

Efforts to ensure that our business arrangements will comply with applicable healthcare laws may involve substantial costs, including investments in infrastructure and additional resources. Because of the breadth of these laws and the

narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities, including our consulting agreements and other relationships with physicians, could be subject to challenge under one or more of such laws. Governmental and enforcement authorities may conclude that our business practices do not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to, without limitation, civil, criminal, and administrative penalties, damages, monetary fines, disgorgement, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

***Compliance with data privacy laws and regulations is complex and could expose us to a variety of risks.***

We operate in an environment that relies on the collection, processing, analysis and interpretation of large sets of individuals' personal information, and that also, in many situations, requires that data to be transferred across borders of numerous countries in which there are different, and potentially conflicting, data privacy laws in effect. For example, the EU General Data Protection Regulation ("GDPR"), which took effect in May 2018, and the California Consumer Privacy Act, which took effect in January 2020, impose stringent requirements on how we and third parties with whom we contract collect, share, export or otherwise process personal information, and provide for significant penalties for noncompliance. Breaches of our systems or those of our third-party contractors, or other failures to protect the data we collect from misuse or breach by third parties, could expose such personal information to unauthorized persons.

Any event involving the substantial loss of personal information or other privacy violations could give rise to significant liability, reputational harm, damaged relationships with business partners, and potentially substantial monetary penalties under laws enacted or being enacted around the world. Such events could also lead to restrictions on our ability to use personal information and/or transfer personal information across country borders.

***Our business activities may be subject to the Foreign Corrupt Practices Act ("FCPA") and similar anti-bribery and anti-corruption laws.***

We are subject to a number of anti-corruption laws, including the U.S. FCPA and the U.K. Bribery Act. Our failure to comply with anti-corruption laws applicable to us could result in penalties, which could harm our reputation and harm our business, financial condition, results of operations, cash flows or prospects. The FCPA generally prohibits companies and their intermediaries from making improper payments to foreign officials for the purpose of obtaining or keeping business and/or other benefits. The FCPA also requires public companies to maintain accurate books and records and devise a system of sufficient internal accounting controls. We regularly review and update our policies and procedures and internal controls designed to provide reasonable assurance that we, our employees, distributors and other intermediaries comply with the anti-corruption laws to which we are subject. However, there are inherent limitations to the effectiveness of any policies, procedures and internal controls, including the possibility of human error and the circumvention or overriding of the policies, procedures and internal controls. There can be no assurance that such policies or procedures or internal controls will work effectively at all times or protect us against liability under these or other laws for actions taken by our employees, distributors and other intermediaries with respect to our business.

The SEC and the Department of Justice continue to view FCPA enforcement activities as a high priority. There is no certainty that all of our employees, agents, contractors or collaborators, or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers or our employees, requirements to obtain export licenses, cessation of business activities in sanctioned countries, implementation of compliance programs and prohibitions on the conduct of our business. Any such violations could materially damage our reputation, our brand, our international operations, our ability to attract and retain employees, and our business, prospects, operating results, and financial condition.

***If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.***

We face an inherent risk of product liability. For example, we may be sued if any product we develop allegedly causes injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such

product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability and a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates, if approved. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our product candidates or products that we may develop;
- injury to our reputation;
- withdrawal of clinical trial participants;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- increase in insurance premiums;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenues from product sales;
- the inability to commercialize our product candidates; and
- a decline in our stock price.

Our inability to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop. We have a program of product liability insurance covering our ongoing clinical trials; however, the amount of insurance we maintain may not be adequate to cover all liabilities that we may incur. Although we maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We will have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts.

***Our internal computer systems, or those used by our CROs or other contractors or consultants, may fail or suffer security breaches.***

We and our business partners maintain sensitive company data on our computer networks, including our intellectual property and proprietary business information, as well as certain clinical trial information. Cybersecurity attacks are becoming more commonplace and include, but are not limited to, malicious software, attempts to gain unauthorized access to data and other electronic security breaches that could lead to disruptions in systems, misappropriation of information and corruption of data. Despite the implementation of security measures, our internal computer systems and those of our CROs and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we have not experienced any such material system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and business operations. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development of our product candidates could be delayed.

***The United Kingdom's departure from the EU could be costly and difficult to comply with and could harm our business.***

The United Kingdom ("UK") formally left the EU on January 31, 2020. We have based in the UK a significant portion of our non-U.S. clinical, regulatory affairs, and pharmacovigilance operations, as well as our European commercial organization. In anticipation of Brexit, we have taken steps to relocate certain activities from the UK in order to remain in compliance, post-Brexit, with certain laws and regulations in the EU. While the regulatory environment in the UK is currently consistent with that of the EU, Brexit could lead to legal uncertainty and potentially divergent national laws and regulations as the UK determines which EU laws to replace or replicate. As such, we could be required to comply with regulatory requirements in the UK that are in addition to, or inconsistent with, the regulatory requirements of the EU, resulting in the duplication of certain costs and new challenges to operate in Europe. The full effect of Brexit is uncertain, and consequently, we cannot at this time fully predict what the outcome may have on our business, particularly if our European operations or presence become a more significant part of our business.

***Fluctuations in the value of the Euro or UK pound sterling could negatively impact our results of operations and increase our costs.***

We generate revenues from sales of Rubraca in the UK and the EU. We also conduct research and development activities in the UK and other European countries and some of the payments for these activities are denominated in Euros and UK pounds sterling. As a result, we are exposed to foreign exchange risk, and our results of operations may be impacted by fluctuations in the exchange rate between the U.S. dollar and the Euro or UK pound sterling, such as the decline in value of the UK pound sterling following the results of the UK's referendum on withdrawal from the EU. We currently have not entered into any foreign currency hedging contracts to reduce the effect of changes in foreign currency exchange rates, and foreign currency hedging is inherently risky and may result in unanticipated losses.

***Our business involves the use of hazardous materials and we and our third-party manufacturers and suppliers must comply with environmental laws and regulations, which can be expensive and restrict how we do business.***

Our research and development activities and our third-party manufacturers' and suppliers' activities involve the controlled storage, use and disposal of hazardous materials owned by us, including the components of our product candidates and other hazardous compounds, and which is expected to include radioactive material contained in FAP-2286. We and our manufacturers and suppliers are subject to laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials. In some cases, these hazardous materials and various wastes resulting from their use are stored at our and our manufacturers' facilities, pending use and disposal. We cannot completely eliminate the risk of contamination, which could cause an interruption of our research and development efforts and business operations, injury to our employees and others, environmental damage resulting in costly clean-up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. Although we believe that the safety procedures utilized by our third-party manufacturers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources. We do not currently carry biological or hazardous waste insurance coverage.

***Environmental, social and governance matters may impact our business and reputation.***

Increasingly, in addition to the importance of their financial performance, companies are being judged by their performance on a variety of environmental, social and governance ("ESG") matters, which are considered to contribute to the long-term sustainability of companies' performance.

A variety of organizations measure the performance of companies on such ESG topics, and the results of these assessments are widely publicized. In addition, investment in funds that specialize in companies that perform well in such assessments are increasingly popular, and major institutional investors have publicly emphasized the importance of such ESG measures to their investment decisions. Topics taken into account in such assessments include, among others, the company's efforts and impacts on climate change and human rights, ethics and compliance with law, and the role of the company's board of directors in supervising various sustainability issues. In addition to the topics typically considered in such assessments, in our healthcare industry, issues of the public's ability to access our medicines are of particular importance.

In light of investors' increased focus on ESG matters, there can be no certainty that we will manage such issues successfully, or that we will successfully meet society's expectations as to our proper role. Any failure or perceived failure by us in this regard could have a material adverse effect on our reputation and on our business, share price, financial condition, or results of operations, including the sustainability of our business over time.

***Climate change, extreme weather events, earthquakes and other natural disasters could adversely affect our business.***

In recent years, extreme weather events and changing weather patterns such as storms, flooding, droughts, fires and temperature changes have become more common. As a result, we are potentially exposed to varying natural disaster or extreme weather risks such as hurricanes, tornadoes, fires, droughts or floods, or other events that may result from the impact of climate change on the environment, such as sea level rise. For example, in the event of a major earthquake, we could experience business interruptions, destruction of facilities, and loss of life, all of which could have a material adverse effect on our business, financial condition, or results of operations.

The potential impacts of climate change may also include increased operating costs associated with additional regulatory requirements and investments in reducing energy, water use and greenhouse gas emissions.

**Risks Related to Our Intellectual Property**

***If our efforts to protect the proprietary nature of the intellectual property related to our technologies are not adequate, we may not be able to compete effectively in our market.***

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our technologies. Any disclosure to or misappropriation by third parties of our confidential proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in our market.

The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. The patent applications that we own or license may fail to result in issued patents in the United States or in other foreign countries. Even if the patents do successfully issue, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing around our claims. If the breadth or strength of protection provided by the patent applications we hold or pursue with respect to our product candidates is threatened, it could threaten our ability to commercialize our product candidates. Further, if we encounter delays in our clinical trials, the period of time during which we could market our product candidates under patent protection would be reduced. Since patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain that we were the first to file any patent application related to our product candidates. Furthermore, an interference proceeding can be provoked by a third-party or instituted by the United States Patent and Trademark Office ("U.S. PTO") to determine who was the first to invent any of the subject matter covered by the patent claims of our applications.

In addition to the protection afforded by patents, we seek to rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable, processes for which patents are difficult to enforce and any other elements of our drug development processes that involve proprietary know-how, information or technology that is not covered by patents. Although we require all of our employees to assign their inventions to us, and all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology to enter into confidentiality agreements, we cannot be certain that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Further, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent material disclosure of the intellectual property related to our technologies to third parties, we will not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, results of operations and financial condition.

***Third-party claims of intellectual property infringement may prevent or delay our drug discovery and development efforts.***

Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. There is a substantial amount of litigation involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including interference, inter parties review and reexamination proceedings before the U.S. PTO or oppositions and other comparable proceedings in foreign jurisdictions. Numerous United States and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may give rise to claims of infringement of the patent rights of others.

Third parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications, which may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our product candidates, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtain a license under the applicable patents, or until such patents expire or they are finally determined to be held invalid or unenforceable. Similarly, if any third-party patent were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy or patient selection methods, the holders of any such patent may be able to block our ability to develop and commercialize the applicable product candidate unless we obtain a license, limit our uses, or until such patent expires or is finally determined to be held invalid or unenforceable. In either case, such a license may not be available on commercially reasonable terms or at all.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, limit our uses, pay royalties or redesign our infringing product candidates, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize one or more of our product candidates, which could harm our business significantly.

***The patent protection, patent prosecution and patent enforcement for some of our product candidates is dependent on third parties.***

While we normally seek and gain the right to fully prosecute, maintain and enforce the patents relating to our product candidates, there may be times when platform technology patents that relate to our product candidates are controlled by our licensors. This is the case with the method of use patents licensed under the AstraZeneca license. If AstraZeneca or any of our future licensing partners fail to appropriately prosecute, maintain or enforce, as applicable, patent protection for patents covering any of our product candidates, our ability to develop and commercialize those product candidates may be adversely affected and we may not be able to prevent competitors from making, using and selling competing products.

***We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time consuming and unsuccessful.***

Competitors may infringe our patents or the patents of our licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid or is unenforceable, or may

refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated, held unenforceable or interpreted narrowly and could put our patent applications at risk of not issuing.

Interference proceedings provoked by third parties or brought by the U.S. PTO may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our licensors. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees.

We may not be able to prevent, alone or with our licensors, misappropriation of our trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as in the United States. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

***We may not be able to protect our intellectual property rights throughout the world.***

Filing, prosecuting and defending patents on all of our product candidates throughout the world would be prohibitively expensive. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products in jurisdictions where we do not have any issued patents and our patent claims or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business.

***If we breach any of the agreements under which we license commercialization rights to our product candidates from third parties, we could lose license rights that are important to our business.***

We license the use, development and commercialization rights for all of our product candidates, and may enter into similar licenses in the future. Under each of our existing license agreements we are subject to commercialization and development, diligence obligations, milestone payment obligations, royalty payments and other obligations. If we fail to comply with any of these obligations or otherwise breach our license agreements, including by failing to use commercially reasonable efforts to develop or commercialize the product candidate, our licensing partners may have the right to terminate the license in whole or in part. Generally, the loss of any one of our licenses or other licenses in the future could materially harm our business, prospects, financial condition and results of operations.

***Intellectual property rights do not necessarily address all potential threats to our competitive advantage.***

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, or permit us to maintain our competitive advantage. The following examples are illustrative:

- others may be able to make compounds that are similar to our product candidates but that are not covered by the claims of the patents that we own or have exclusively licensed;
- we or our licensors or strategic partners might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed;

- we or our licensors or strategic partners might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we own or have exclusively licensed may not provide us with any competitive advantages, or may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable; and
- the patents of others may have an adverse effect on our business.

Should any of these events occur, they could significantly harm our business, results of operations and prospects.

**Risks Related to Ownership of our Common Stock, Convertible Senior Notes and Long-term Debt**

***There may not be a viable public market for our common stock and as a result it may be difficult for you to sell your shares of our common stock.***

Our common stock had not been publicly traded prior to our initial public offering in November 2011. An active trading market for our common stock on the NASDAQ Global Select Market may not be sustained. As a result of these and other factors, you may be unable to resell your shares at a price that is attractive to you or at all. Further, an inactive market may also impair our ability to raise capital by selling shares of our common stock and may impair our ability to enter into strategic partnerships or acquire companies or products by using our shares of common stock as consideration.

***The price of our stock has been, and may continue to be, volatile, and you could lose all or part of your investment.***

The trading price of our common stock has been, and may continue to be, volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. During the 12-month period ended December 31, 2019, the price of our common stock on the NASDAQ Global Select Market ranged from $2.93 per share to $32.05 per share. In addition to the factors discussed in this "Risk Factors" section and elsewhere in this report, these factors include:

- adverse results of regulatory actions or decisions;
- our failure to successfully commercialize our products;
- actual or anticipated adverse results or delays in our clinical trials;
- unanticipated serious safety concerns related to the use of any of our products;
- changes in laws or regulations applicable to our products, including but not limited to clinical trial requirements for approvals;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our products;
- our decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial;
- inability to obtain adequate product supply for any approved drug product or inability to do so at acceptable prices;
- our dependence on third parties, including CMOS and CROs, as well as our partners that provide us with companion diagnostic products;
- additions or departures of key scientific or management personnel;

- failure to meet or exceed any financial guidance or expectations regarding development milestones that we may provide to the public;
- actual or anticipated variations in quarterly operating results;
- failure to meet or exceed the estimates and projections of the investment community;
- overall performance of the equity markets and other factors that may be unrelated to our operating performance or the operating performance of our competitors, including changes in market valuations of similar companies;
- conditions or trends in the biotechnology and biopharmaceutical industries;
- introduction of new products offered by us or our competitors;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- issuances of debt or equity securities and perceptions of our ability to issue additional debt and equity securities to refinance our debt obligations and to fund our operations;
- significant lawsuits, including patent or stockholder litigation;
- sales of our common stock by us or our stockholders in the future;
- trading volume of our common stock;
- publication of research reports about us or our industry or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- ineffectiveness of our internal controls;
- general political and economic conditions;
- effects of natural or man-made catastrophic events; and
- other events or factors, many of which are beyond our control.

In addition, the stock market in general, and the NASDAQ Global Select Market and biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. The realization of any of the above risks or any of a broad range of other risks, including those described in these “Risk Factors,” could have a dramatic and material adverse effect on the market price of our common stock.

Because our outstanding Notes are convertible into shares of our common stock, volatility or depressed prices of our common stock could have a similar effect on the trading price of our Notes. In addition, the existence of the Notes may encourage short selling in our common stock by market participants because the conversion of the Notes could depress the price of our common stock.

The conversion of some or all of the Notes may dilute the ownership interest of existing stockholders. Holders of the outstanding 2021 Notes are able to convert them at any time prior to the close of business on the business day immediately preceding September 15, 2021. Holders of the outstanding 2025 Notes are able to convert them at any time prior to the close of business on the business day immediately preceding May 1, 2025. Holders of the outstanding 2024 Notes are able to convert them at any time prior to the close of business on the business day immediately preceding August 1, 2024. Upon conversion, holders of the Notes will receive shares of common stock. Any sales in the public market of shares of common stock issued upon conversion of such Notes could adversely affect the trading price of our common stock. We cannot predict the size of future issuances or the effect, if any, that they may have on the market price of our common stock. The issuance and sale of substantial amounts of common stock, or the perception that such issuances and sales may occur, could adversely affect the market price of our common stock and impair our ability to raise capital through the sale of additional equity or convertible debt securities.

Following periods of volatility in a company’s stock price, litigation has often been initiated against companies. Following the decline in our stock price related to the rociletinib regulatory update in November 2015, a number of lawsuits have been filed against us and settled. The remaining litigation related to rociletinib are discussed in Part I, Item

3-Legal Proceedings. These proceedings and other similar litigation, if instituted against us, could result in substantial costs and diversion of management's attention and resources, which could materially and adversely affect our business and financial condition.

***Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall.***

Shares of common stock that are either subject to outstanding options or reserved for future issuance under our equity incentive plans and the Notes will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules and the terms of the Notes. If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

***Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.***

We expect that significant additional capital will be needed in the future to continue our planned operations. To raise capital, we may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights, preferences and privileges senior to those of holders of our common stock.

Pursuant to our equity incentive plan(s), our compensation committee (or its designee) is authorized to grant equity-based incentive awards to our employees, directors and consultants. See Part II, Item 5-Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities for the number of shares of our common stock available for future grant under our 2011 Stock Incentive Plan. Future option and restricted stock unit grants and issuances of common stock under our 2011 Plan may have an adverse effect on the market price of our common stock. In addition, a substantial number of shares of our common stock are reserved for issuance upon conversion of the Notes.

***Some provisions of our charter documents and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders and may prevent attempts by our stockholders to replace or remove our current management.***

Provisions in our amended and restated certificate of incorporation and bylaws, as well as provisions of Delaware law, could make it more difficult for a third-party to acquire us or increase the cost of acquiring us, even if doing so would benefit our stockholders or remove our current management. These provisions include:

- authorizing the issuance of "blank check" preferred stock, the terms of which may be established and shares of which may be issued without stockholder approval;
- limiting the removal of directors by the stockholders;
- creating a staggered board of directors;
- prohibiting stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders;
- eliminating the ability of stockholders to call a special meeting of stockholders;
- permitting our board of directors to accelerate the vesting of outstanding option grants upon certain transactions that result in a change of control; and
- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings.

These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management. Because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the General Corporation Law of the State of Delaware, which may discourage, delay or prevent someone from acquiring us or merging with us whether or not it is desired by or beneficial to our

stockholders. Under Delaware law, a corporation may not, in general, engage in a business combination with any holder of 15% or more of its capital stock unless the holder has held the stock for three years or, among other things, the board of directors has approved the transaction. Any provision of our certificate of incorporation or bylaws or Delaware law that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock, and could also affect the price that some investors are willing to pay for our common stock. Additionally, certain provisions of our outstanding Notes could make it more difficult or more expensive for a third party to acquire us. The repurchase price of the Notes must be paid in cash, and this obligation may have the effect of discouraging, delaying or preventing an acquisition of the Company that would otherwise be beneficial to our security holders.

***If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.***

The trading market for our common stock depends in part on the research and reports that securities or industry analysts publish about us or our business. If one or more of the analysts who cover us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price would likely decline. If one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

***Our operating results are difficult to predict and may fluctuate. If our operating results are below the expectations of securities analysts or investors, the trading price of our stock could decline.***

Our operating results are difficult to predict and may fluctuate significantly from quarter to quarter and year to year. As a result, although we may provide sales guidance for Rubraca from time to time, you should not rely on Rubraca sales results in any period as being indicative of future performance. In addition, such guidance is based on assumptions that may be incorrect or that may change from quarter to quarter, and it may be particularly difficult to correctly forecast sales in indications for which we have recently received marketing approval. Moreover, sales of Rubraca have, on occasion, been below the expectations of securities analysts and investors and have been below prior period sales, and sales of Rubraca in the future may also be below prior period sales, our own guidance and/or the expectations of securities analysts and investors. To the extent that we do not meet any guidance we may give or the expectations of analysts or investors, our stock price may be adversely impacted, perhaps significantly. We believe that our quarterly and annual results of operations may be affected by a variety of factors, including:

- customer ordering patterns for Rubraca, which may vary significantly from period to period;
- the overall level of demand for Rubraca, including the impact of any competitive products and the duration of therapy for patients receiving Rubraca;
- the extent to which coverage and reimbursement for Rubraca is available from government and health administration authorities, private health insurers, managed care programs and other third-party payors;
- our ability to establish or demonstrate to patients and the medical community the safety, efficacy or value of Rubraca and its perceived advantages compared to existing and future therapies in the recurrent ovarian cancer indications and other indications for which Rubraca may receive approval in the future;
- changes in the amount of deductions from gross sales, including government-mandated rebates, chargebacks and discounts that can vary because of changes to the government discount percentage, including increases in the government discount percentage resulting from price increases we have taken or may take in the future, or due to different levels of utilization by entities entitled to government rebates and discounts and changes in patient demographics;
- increases in the scope of eligibility for customers to purchase Rubraca at the discounted government price or to obtain government-mandated rebates on purchases of Rubraca;
- changes in our cost of sales;
- the incidence rate of new patients in Rubraca's approved indications;
- the timing, cost and level of investment in our sales and marketing efforts to support Rubraca sales; and
- the timing, cost and level of investment in our research and development and other activities involving Rubraca, lucitanib and our other product candidates by us or our collaborators.

Further, changes in our operations, such as increased development, manufacturing and clinical trial expenses in connection with our development programs, or our undertaking of additional programs, or business activities, or entry into strategic transactions, including potential future acquisitions of products, technologies or businesses may also cause significant fluctuations in our expenses.

***Our ATHENA clinical trial financing agreement contains a number of covenants and other provisions, which, if violated, could result in the immediate acceleration of our outstanding indebtedness.***

Pursuant to our ATHENA clinical trial financing agreement, we are required to repay amounts we borrow from the lenders, capped at specific quarterly amounts, based upon the revenues generated from the sales of Rubraca and other amounts we receive in connection with any out-licensing arrangement or settlement we may enter into with respect to Rubraca. If the total payments made on or prior to December 30, 2025 are less than the total amount borrowed prior to such time, we also would be required to make an additional lump-sum payment to the lenders equal to the amount of that shortfall on that date. Following that date, quarterly payments continue until the lenders have received payments equal to twice the amount borrowed under the financing agreement.

Pursuant to the financing agreement, we have agreed to certain limitations on our operations, including limitations on dividends, stock repurchases and repayments of certain indebtedness, and to certain covenants, including with respect to the conduct of the ATHENA trial. Our obligations under the financing agreement are secured by first priority security interests in all of our assets related to Rubraca, including intellectual property rights.

If an event of default (including a breach or default under, or termination of, any of our material in-license agreements and defaults under our other material indebtedness) occurs under the financing agreement, the lenders have the right to demand immediate repayment of our obligations, which may be as high as the greater of (x) twice the amount borrowed thereunder and (y) the amount borrowed thereunder plus either $35 million (if the payment is made in 2019) or $50 million (if the payment is made after 2019).

In addition, if we do not pay our obligations under the financing agreement when due, including at maturity or upon the occurrence of a liquidity event, which includes a change of control of us or upon demand following the occurrence of an event of default, the lenders would have the right to foreclose on the assets we have pledged as collateral and sell those assets, with the proceeds of the sale being applied to repay the indebtedness.

There can be no assurance that we will not breach the covenants or other terms of, or that an event of default will not occur under, the financing agreement and, if a breach or event of default occurs, there can be no assurance that we will be able to obtain necessary waivers or amendments from the lenders or refinance the related indebtedness on terms we find acceptable, or at all. A default under the financing agreement may also trigger defaults under the indentures governing our senior convertible notes.

As a result, any failure to pay our obligations when due, any breach or default of our covenants or other obligations under the financing agreement, or any other event that allows any lender to demand immediate repayment of borrowings, could have a material adverse effect on our business, results of operations, financial condition and prospects. Furthermore, the financing agreement may make us less attractive to potential acquirers; and in the event of a change of control of us, the required discharge of the financing agreement out of our available cash or acquisition proceeds would reduce proceeds available to our stockholders.

For these and other reasons, it is difficult for us to accurately forecast future sales of Rubraca, operating expenses or future profits or losses. As a result, our operating results in future periods could be below any guidance we may give or the expectations of securities analysts or investors, which could cause the trading price of our common stock to decline, perhaps substantially.

## ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

## ITEM 2. PROPERTIES

Our principal offices are located at five leased facilities, a 29,256 square foot facility in Boulder, Colorado used primarily for corporate functions, a 24,877 square foot facility in San Francisco, California, a 32,660 square foot facility in Oakland, CA used for clinical development operations and research laboratory space, a 11,805 square foot facility in Cambridge, United Kingdom used for our European regulatory and clinical operations and a 416 square foot facility in Milan, Italy used for clinical operations. These leases expire in January 2023, December 2021, April 2028, July 2029 and March 2020, respectively. We also lease office space in several locations throughout Europe. We believe that our existing facilities are sufficient for our needs for the foreseeable future.

## ITEM 3. LEGAL PROCEEDINGS

*Rociletinib-Related Litigation*

Following Clovis' regulatory announcement in November 2015 of adverse developments in its ongoing clinical trials for rociletinib, Clovis and certain of its current and former executives were named in various securities lawsuits, the largest of which was a putative class action lawsuit in the District of Colorado (the "Medina Action") which was settled on October 26, 2017 (the "Medina Settlement"). The remaining actions are discussed below.

In March 2017, two putative shareholders of the Company, Macalinao and McKenry (the "Derivative Plaintiffs"), filed shareholder derivative complaints against certain directors and officers of the Company in the Court of Chancery of the State of Delaware. On May 4, 2017, the Macalinao and McKenry actions were consolidated for all purposes in a single proceeding under the caption In re Clovis Oncology, Inc. Derivative Litigation, Case No, 2017-0222 (the "Consolidated Derivative Action").

On May 18, 2017, the Derivative Plaintiffs filed a Consolidated Verified Shareholder Derivative Complaint (the "Consolidated Derivative Complaint"). The Consolidated Derivative Complaint generally alleged that the defendants breached their fiduciary duties owed to the Company by allegedly causing or allowing misrepresentations of the Company's business operations and prospects, failing to ensure that the TIGER-X clinical trial was being conducted in accordance with applicable rules, regulations and protocols, and engaging in insider trading. The Consolidated Derivative Complaint sought, among other things, an award of money damages.

On July 31, 2017, the defendants filed a motion to dismiss the Consolidated Derivative Complaint. Plaintiffs filed an opposition to the motion to dismiss on August 31, 2017, and the defendants filed a reply in further support of the motion to dismiss on September 26, 2017.

While the motion to dismiss remained pending, on November 19, 2018, Plaintiffs filed a motion for leave to file a supplemental consolidated complaint, and on November 20, 2018, the Court granted that motion. On November 27, 2018, Plaintiffs filed their supplemental complaint (the "Supplemental Derivative Complaint"), which adds allegations concerning the Company's, Mr. Mahaffy's and Mr. Mast's settlements with the United States Securities and Exchange Commission. Pursuant to a briefing schedule entered by the Court, the defendants filed a supplemental motion to dismiss the Supplemental Derivative Complaint on February 6, 2019; plaintiffs filed an opposition brief on February 22, 2019; and the defendants filed a reply brief on March 5, 2019. The Court held oral arguments on the defendants' motions to dismiss on June 19, 2019. At the oral arguments, the Court ordered the parties to submit supplemental letter briefs on the motion to dismiss.

On October 1, 2019, Vice Chancellor Joseph R. Slights III of the Delaware Chancery Court, issued a Memorandum Opinion granting in part and denying in part defendants' motions to dismiss. The Supplemental Derivative Complaint was dismissed as to Plaintiffs' derivative claims for unjust enrichment and insider trading. The Court allowed Plaintiffs' remaining derivative claim for breach of fiduciary duty to proceed. Defendants filed an answer to the Supplemental Derivative Complaint on December 27, 2019.

On December 17, 2019, the parties participated in a mediation, which did not result in a settlement. On December 22, 2019, the Company's board of directors formed a Special Litigation Committee (the "SLC") to conduct an investigation of the claims asserted in the Supplemental Derivative Complaint. On February 18, 2020, the SLC moved to stay all proceedings in the Consolidated Derivative Action pending completion of its investigation. Plaintiff's opposition to the motion to stay is due on March 3, 2020 and the SLC's reply is due on March 13, 2020.

While the SLC's investigation remains ongoing, the Company does not believe this litigation will have a material impact on its financial position or results of operations.

On March 20, 2017, a purported shareholder of the Company, filed a shareholder derivative complaint (the "Guo Complaint") against certain officers and directors of the Company in the United States District Court for the District of Colorado. The Guo Complaint generally alleged that the defendants breached their fiduciary duties owed to the Company by either recklessly or with gross negligence approving or permitting misrepresentations of the Company's business operations and prospects. The Guo Complaint also alleged claims for waste of corporate assets and unjust enrichment. Finally, the Guo Complaint alleged that certain of the individual defendants violated Section 14(a) of the Securities Exchange Act, by allegedly negligently issuing, causing to be issued, and participating in the issuance of materially misleading statements to stockholders in the Company's Proxy Statement on Schedule DEF 14A in connection with the 2015 Annual Meeting of Stockholders, held on June 11, 2015. The Guo Complaint sought, among other things, an award of money damages.

On June 19, 2017, the parties filed a joint motion to stay the Guo action pending resolution of the motion to dismiss the Consolidated Derivative Complaint. On June 20, 2017, the court granted the motion to stay. Based on the October 1, 2019 ruling in the Consolidated Derivative Action, on October 22, 2019, the court lifted the stay. The parties participated in a scheduling conference on December 9, 2019, following which the court set the dates for pre-trial conference and trial for March 2, 2021 and March 29, 2021, respectively. On December 23, 2019, the plaintiff filed an amended complaint, and on February 7, 2020, the plaintiff filed a second amended complaint. Pursuant to a stipulated scheduling order entered by the court on February 10, 2020, the defendants' motion to dismiss is due on February 28, 2020.

The Company intends to vigorously defend against the allegations in the second amended Guo complaint, but there can be no assurance that the defense will be successful.

*European Patent Opposition*

Two oppositions were filed in the granted European counterpart of the rucaparib camsylate salt/polymorph patent on June 20, 2017. The European Patent Office's Opposition Division held an oral hearing on December 4, 2018, during which it upheld claims, narrowed from the originally granted patent, to certain crystalline forms of rucaparib camsylate, including, but not limited to, rucaparib S-camsylate Form A, the crystalline form in Rubraca. Clovis and one opponent, Hexal, appealed the written decision of the European Opposition Division and filed reply appeal briefs in early November 2019.

## ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

## PART II

## ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

### Market Information and Holders

Our common stock trades on the NASDAQ Global Select market under the symbol "CLVS".

On February 18, 2020, there were 21 holders of record of our common stock. The holders of record number does not include a substantially greater number of holders whose shares are held of record in nominee or street name accounts through banks, brokers and/or other financial institutions.

### Dividends

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain all available funds and any future earnings to support our operations and finance the growth and development of our business. We do not intend to pay cash dividends on our common stock for the foreseeable future. Any future determination related to our

dividend policy will be made at the discretion of our board of directors and will depend upon, among other factors, our results of operations, financial condition, capital requirements, contractual restrictions, business prospects and other factors our board of directors may deem relevant. Pursuant to our ATHENA clinical trial financing agreement, we have agreed to limitations on making certain junior payments, including the payment of dividends.

**Securities Authorized for Issuance Under Equity Compensation Plans**

**Equity Compensation Plan Information**
**As of December 31, 2019**

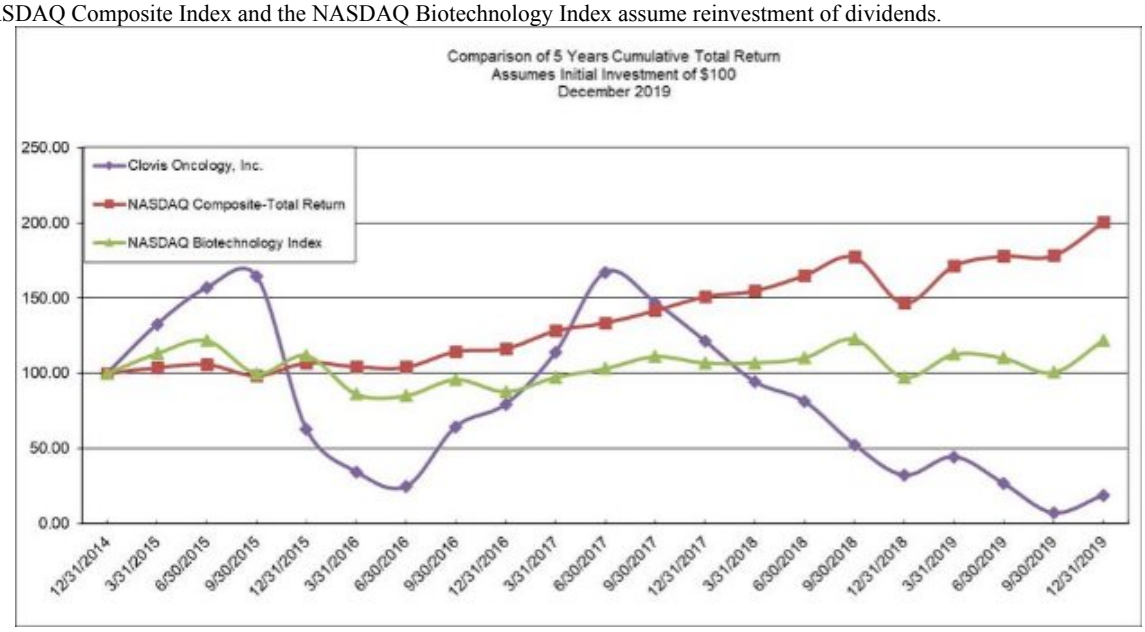
| Plan Category | Number of securities to be issued upon exercise of outstanding options and restricted stock (a) | Weighted-average exercise price of outstanding options (b) | Number of securities remaining available for issuance under equity compensation plans (excluding securities reflected in column (a)) (c) |
|---|---|---|---|
| Equity compensation plans approved by security holders (1) (2) | 8,458,372 | $ 42.24 | 4,213,252 |
| Equity compensation plans not approved by security holders | — | — | — |
| Total | 8,458,372 | $ 42.24 | 4,213,252 |

(1) As of December 31, 2019, 13,816,124 shares were authorized for issuance under our 2011 Stock Incentive Plan ("2011 Plan"), which became effective upon closing of our initial public offering in November 2011, including 191,496 remaining shares available for future issuance under the 2009 Equity Incentive Plan ("2009 Plan"), which were transferred to the 2011 Plan. The number of shares of our common stock reserved for issuance under the 2011 Plan will be increased (i) from time to time by the number of shares of our common stock forfeited upon the expiration, cancellation, forfeiture, cash settlement or other termination of awards under the 2009 Plan and (ii) at the discretion of our board of directors, on the date of each annual meeting of our stockholders, by up to the lesser of (x) a number of additional shares of our common stock representing 4% of our then-outstanding shares of common stock on such date and (y) 2,758,621 shares of our common stock.

(2) As of December 31, 2019, 300,416 shares were reserved for issuance under our 2011 Employee Stock Purchase Plan ("ESPP"), which became effective upon closing of our initial public offering in November 2011. The number of shares of our common stock reserved for issuance under the ESPP will be increased at the discretion of our board of directors, on the date of each annual meeting of our stockholders, by up to the lesser of (x) a number of additional shares of our common stock representing 1% of our then-outstanding shares of common stock on such date and (y) 344,828 shares of our common stock.

**Performance Graph** [1]

The following graph shows a comparison from December 31, 2014 through December 31, 2019 of the cumulative total return on an assumed investment of $100 in cash in our common stock, the NASDAQ Composite Index and the NASDAQ Biotechnology Index. Such returns are based on historical results and are not intended to suggest future performance. Data for the NASDAQ Composite Index and the NASDAQ Biotechnology Index assume reinvestment of dividends.




*(1) This performance graph shall not be deemed "soliciting material" or to be "filed" with the SEC for purposes of Section 18 of the Securities and Exchange Act of 1934, as amended, or otherwise subject to the liabilities under that Section, and shall not be deemed incorporated by reference into any filing of Clovis Oncology, Inc. under the Securities Act of 1933, as amended.*

## ITEM 6. SELECTED FINANCIAL DATA

The following table sets forth certain of our selected historical financial data at the dates and for the periods indicated. The selected historical statement of operations data presented below for the years ended December 31, 2019, 2018 and 2017 and the historical balance sheet data as of December 31, 2019 and 2018 have been derived from our audited financial statements, which are included elsewhere in this Annual Report on Form 10-K. The historical statement of operations data presented below for the years ended December 31, 2016 and 2015 and the historical balance sheet data as of December 31, 2017, 2016 and 2015 have been derived from our audited financial statements that do not appear in this report.

Our historical results are not necessarily indicative of results expected in any future period.

The selected historical financial data presented below should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and the related notes thereto, which are included elsewhere in this Annual Report on Form 10-K. The selected historical financial information in this section is not intended to replace our financial statements and the related notes thereto.

**Statement of Operations Data:**

| | Year Ended December 31, | | | | |
|---|---|---|---|---|---|
| | 2019 | 2018 | 2017 | 2016 | 2015 |
| | (in thousands, except per share amounts) | | | | |
| Revenues: | | | | | |
| Product revenue | $ 143,006 | $ 95,388 | $ 55,511 | $ 78 | $ — |
| Operating expenses: | | | | | |
| Cost of sales - product | 29,926 | 19,444 | 10,251 | 70 | — |
| Cost of sales - intangible asset amortization | 4,760 | 2,630 | 1,486 | — | — |
| Research and development | 283,146 | 231,347 | 142,498 | 251,129 | 269,251 |
| Selling, general and administrative | 182,769 | 175,781 | 138,907 | 40,731 | 30,524 |
| Acquired in-process research and development | 9,440 | — | — | 1,300 | 12,000 |
| Impairment of intangible asset | — | — | — | 104,517 | 89,557 |
| Change in fair value of contingent purchase consideration | — | — | — | (24,936) | (24,611) |
| Other operating expenses | 9,711 | — | — | — | — |
| Total expenses | 519,752 | 429,202 | 293,142 | 372,811 | 376,721 |
| Operating loss | (376,746) | (333,814) | (237,631) | (372,733) | (376,721) |
| Other income (expense): | | | | | |
| Interest expense | (19,405) | (13,183) | (10,428) | (8,491) | (8,372) |
| Foreign currency (loss) gain | (547) | (346) | (82) | (580) | 2,740 |
| Legal settlement loss | (26,750) | (27,975) | (105,477) | — | — |
| Gain on extinguishment of debt | 18,480 | — | — | — | — |
| Other income | 6,342 | 7,917 | 3,643 | 633 | 416 |
| Other income (expense), net | (21,880) | (33,587) | (112,344) | (8,438) | (5,216) |
| Loss before income taxes | (398,626) | (367,401) | (349,975) | (381,171) | (381,937) |
| Income tax (expense) benefit | (1,798) | (608) | 3,578 | 32,034 | 29,076 |
| Net loss | $ (400,424) | $ (368,009) | $ (346,397) | $ (349,137) | $ (352,861) |
| Basic and diluted net loss per common share | $ (7.43) | $ (7.07) | $ (7.36) | $ (9.07) | $ (9.79) |
| Basic and diluted weighted average common shares outstanding | 53,873 | 52,066 | 47,047 | 38,478 | 36,026 |

**Balance Sheet Data:**

| | As of December 31, | | | | |
|---|---|---|---|---|---|
| | 2019 | 2018 | 2017 | 2016 | 2015 |
| | (in thousands) | | | | |
| Cash, cash equivalents and available-for-sale securities | $ 296,659 | $ 520,146 | $ 563,731 | $ 266,183 | $ 528,588 |
| Working capital | 233,384 | 446,550 | 545,423 | 213,813 | 464,125 |
| Total assets | 669,604 | 863,560 | 735,230 | 364,557 | 713,386 |
| Convertible senior notes | 644,751 | 575,470 | 282,406 | 281,126 | 279,885 |
| Common stock and additional paid-in capital | 2,114,123 | 2,034,195 | 1,887,249 | 1,174,989 | 1,130,016 |
| Total stockholders' (deficit) equity | (174,257) | 146,469 | 367,636 | (3,634) | 300,650 |

## ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

*You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and related notes appearing at the end of this Annual Report on Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report on Form 10-K, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. You should read the "Risk Factors" section of this report for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.*

### Overview

We are a biopharmaceutical company focused on acquiring, developing and commercializing innovative anti-cancer agents in the United States, Europe and additional international markets. We target our development programs for the treatment of specific subsets of cancer populations, and simultaneously develop, with partners, for those indications that require them, diagnostic tools intended to direct a compound in development to the population that is most likely to benefit from its use.

Our marketed product Rubraca® (rucaparib), an oral small molecule inhibitor of poly ADP-ribose polymerase ("PARP"), is marketed in the United States for two indications specific to recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer. The initial indication received approval from the FDA in December 2016 and covers the treatment of adult patients with deleterious BRCA (human genes associated with the repair of damaged DNA) mutation (germline and/or somatic)-associated epithelial ovarian, fallopian tube, or primary peritoneal cancer who have been treated with two or more chemotherapies and selected for therapy based on an FDA-approved companion diagnostic for Rubraca. In April 2018, the FDA also approved Rubraca for the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy. The approval in this second, broader and earlier-line indication on a priority review timeline was based on positive data from the phase 3 ARIEL3 clinical trial. Diagnostic testing is not required for patients to be prescribed Rubraca in this maintenance treatment indication.

In May 2018, the European Commission granted a conditional marketing authorization for Rubraca as monotherapy treatment of adult patients with platinum-sensitive, relapsed or progressive, BRCA mutated (germline and/or somatic), high-grade epithelial ovarian, fallopian tube, or primary peritoneal cancer, who have been treated with two or more prior lines of platinum-based chemotherapy, and who are unable to tolerate further platinum-based chemotherapy. This conditional approval requires the completion of certain confirmatory post marketing commitments. In January 2019, the European Commission granted a variation to the marketing authorization to include the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy. With this approval, Rubraca is now authorized in the EU for certain patients in the recurrent ovarian cancer maintenance setting regardless of their BRCA mutation status. Following successful reimbursement negotiations in each country, commercial launches of Rubraca are underway in each of Germany, England, Italy and France and planned in Spain shortly.

Additional 2019 Rubraca key regulatory and clinical developments include the following:

- In November 2019, we submitted the supplemental New Drug Application ("sNDA") for Rubraca as a monotherapy treatment of adult patients with BRCA1/2-mutant recurrent, metastatic castrate-resistant prostate cancer. On January 15, 2020, we announced that the FDA accepted the sNDA and granted priority review status to the application with a Prescription Drug User Fee Act ("PDUFA") date of May 15, 2020. We are actively preparing for the launch of Rubraca in prostate cancer in the U.S., which we will commence upon receipt of FDA approval.
- We initiated the Phase 2 LODESTAR study in December 2019 to evaluate Rubraca in homologous recombination repair genes across tumor types. The study will evaluate rucaparib as monotherapy treatment in patients with recurrent solid tumors associated with a deleterious mutation in homologous recombination repair ("HRR") genes. Based on our interactions with the FDA, this study may be registration-enabling for a targeted gene- and tumor-agnostic label, if data from the trial support an accelerated approval.

Beyond our initial labeled indication, we have a clinical development program underway to further evaluate Rubraca in a variety of solid tumor types, either as monotherapy or in combination with other agents, including several studies as part of our ongoing clinical collaboration with Bristol-Myers Squibb Company to evaluate its immunotherapy OPDIVO® (nivolumab) in combination with Rubraca. We hold worldwide rights for Rubraca.

In addition to Rubraca, we have a second product candidate currently in clinical development. Lucitanib is an investigational, oral, potent inhibitor of the tyrosine kinase activity of vascular endothelial growth factor receptors 1 through 3 ("VEGFR1-3"), platelet-derived growth factor receptors alpha and beta ("PDGFR α/β") and fibroblast growth factor receptors 1 through 3 ("FGFR1-3"). We believe that data for a drug similar to lucitanib that inhibits these same pathways – when combined with a PD-1 inhibitor – represent a scientific rationale for development of lucitanib in combination with a PD-1 inhibitor, and in February 2019, lucitanib was added to our clinical collaboration with BMS. Encouraging data of VEGF and PARP inhibitors in combination also supports the evaluation of lucitanib combined with Rubraca. Thus, currently enrolling Phase 1b/2 combination studies involving lucitanib consist of the Clovis-sponsored LIO-1 study of lucitanib in combination with nivolumab in advanced gynecologic cancers and other solid tumors and an arm of the Clovis-sponsored SEASTAR study evaluating lucitanib in combination with Rubraca in advanced solid tumors. In addition to the LIO-1 study, the BMS-sponsored Phase 1/2 study CheckMate 79X is planned to initiate in early 2020 to evaluate multiple combinations of nivolumab with other therapies, including an arm with lucitanib in patients with second-line non-small cell lung cancer. We hold the global (excluding China) development and commercialization rights for lucitanib.

In September 2019, we entered into a license and collaboration agreement with 3BP to develop a peptide-targeted radionuclide therapy ("PTRT") and imaging agent targeting fibroblast-activating protein alpha ("FAP"). FAP is highly expressed by cancer-associated fibroblasts found in a majority of tumor types, potentially making it a suitable target across a wide array of solid tumors. PTRT is an emerging class of drugs and it involves the injection of a small amount of radioactive material – a radionuclide – that is combined with a cancer-targeting peptide for use as a targeted radiopharmaceutical. The targeting peptide is able to recognize and bind to specific receptors on the cancer cell, such as antigens and cell receptors. When used in a targeted radiopharmaceutical, the peptide is designed to attach to cancer cells, and the intended result is to deliver a high dose of radiation to the tumor while sparing normal tissue because of its rapid systemic clearance. In order for the targeted radiopharmaceutical to be safe and efficacious, it must rapidly attach to cancer cells or in close vicinity to the cancer cells, be retained in or at the tumor site for a sufficient period of time that the radionuclide can have activity on the cancer cells, have minimal attachment to non-cancer cells and then be rapidly cleared from the body.

Following completion of preclinical work to support an IND for the lead candidate under our license and collaboration agreement, designated internally as FAP-2286, we plan to conduct global clinical trials. We anticipate submitting the IND in the second half of 2020 to support an initial Phase 1 study to determine the dose and tolerability of FAP-2286 as a therapeutic agent. We hold U.S. and global rights to FAP-2286, excluding Europe (inclusive of Russia, Turkey and Israel), where 3BP retains rights. We also have agreed with 3BP to collaborate on a discovery program directed to up to three additional, undisclosed targets for peptide-targeted radionuclide therapy, to which we would obtain global rights for any resulting product candidates.

We commenced operations in April 2009. To date, we have devoted substantially all of our resources to identifying and in-licensing product candidates, performing development activities with respect to those product candidates and the general and administrative support of these operations. For the year ended December 31, 2019, we generated $143.0 million product revenue related to sales of Rubraca. We have principally funded our operations using the net proceeds from the sale of convertible preferred stock, the issuance of convertible promissory notes, public offerings of our common stock, convertible senior notes offerings and our financing agreement related to our ATHENA trial.

We have never been profitable and, as of December 31, 2019, we had an accumulated deficit of $2,243.5 million. We incurred net losses of $400.4 million, $368.0 million and $346.4 million for the years ended December 31, 2019, 2018 and 2017, respectively, and had cash, cash equivalents and available-for-sale securities totaling $296.7 million at December 31, 2019.

We expect to incur significant losses for the foreseeable future, as we incur costs related to commercial activities associated with Rubraca. On May 1, 2019, we entered into a financing agreement in aggregate amount up to $175.0 million whereby we expect to borrow amounts required to reimburse our actual expenses incurred during each fiscal quarter, as such expenses are incurred, related to our ATHENA trial. We have agreed to repay the aggregate borrowed

amount plus a return from revenues generated from sales of Rubraca on a quarterly basis, which is anticipated to begin in 2022. See Note 10, *Long-term Debt*, for additional information.

In August 2019, we completed a private placement to qualified institutional buyers of $263.0 million aggregate principal amount of 4.50% convertible senior notes due 2024 (the "2024 Notes") resulting in net proceeds to us of $254.9 million, after deducting underwriting discounts and commissions and offering expenses. We used $171.8 million of the total $254.9 million net proceeds from the offering to repurchase $190.3 million principal amount of the 2021 Notes for approximately $171.8 million in privately negotiated transactions with a limited number of holders. We intend to use the remaining net proceeds from this offering for general corporate purposes, including sales and marketing expenses associated with Rubraca, funding of our development programs, payment of milestones pursuant to our license agreements, general and administrative expenses, acquisition or licensing of additional product candidates or businesses, repurchase or repayment of other debt obligations and working capital.

In January 2020, we completed a registered direct offering of 17,777,679 shares of our common stock at a price of $9.25 per share to a limited number of holders of our 2024 Notes. We used the proceeds of the offering to repurchase from such holders an aggregate of $123.4 million principal amount of 2024 Notes in privately negotiated transactions. In addition, we paid customary fees and expenses in connection with the transactions.

Based on our current estimates, we believe that our cash, cash equivalents and available-for-sale securities will allow us to fund activities through at least the next 12 months. Until we can generate a sufficient amount of revenue from Rubraca, we expect to finance our operations in part through additional public or private equity or debt offerings and may seek additional capital through arrangements with strategic partners or from other sources. Adequate additional financing may not be available to us on acceptable terms, or at all. Our failure to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategy. We will need to generate significant revenues to achieve profitability, and we may never do so.

**Product License Agreements**

For a discussion of our product license agreements, see Note 14, *License Agreements*, in the Notes to Consolidated Financial Statements included in Part II, Item 8, *Financial Statements and Supplementary Data*, of this Annual Report on Form 10-K.

**Financial Operations Overview**

***Revenue***

During 2019, we recorded $143.0 million in revenue related to sales of Rubraca. For further discussion of our revenue recognition policy, see "Critical Accounting Policies and Significant Judgments and Estimates" below. Our ability to generate revenue and become profitable depends upon our ability to successfully commercialize products. Any inability on our part to successfully commercialize Rubraca in the United States, Europe and any foreign territories where it may be approved, or any significant delay in such approvals, could have a material adverse impact on our ability to execute upon our business strategy and, ultimately, to generate sufficient revenues from Rubraca to reach or maintain profitability or sustain our anticipated levels of operations.

We supply commercially labeled Rubraca free of charge to eligible patients who qualify due to financial need through our patient assistance program and the majority of these patients are on Medicare. This product is distributed through a separate vendor who administers the program on our behalf. It is not distributed through our specialty distributor and specialty pharmacy network. This product is neither included in the transaction price nor the variable considerations to arrive at product revenue. Manufacturing costs associated with this free product is included in selling, general and administrative expenses. For the year ended December 31, 2019 and December 31, 2018, the supply of this free drug was approximately 20% and 26%, respectively, of the overall commercial supply or the equivalent of $34.8 million and $33.4 million, respectively, in commercial value.

***Research and Development Expenses***

Research and development expenses consist of costs incurred for the development of our product candidates and companion diagnostics, which include:

- license fees and milestone payments related to the acquisition of in-licensed products, which are reported on our Consolidated Statements of Operations and Comprehensive Loss as acquired in-process research and development;
- employee-related expenses, including salaries, benefits, travel and share-based compensation expense;
- expenses incurred under agreements with CROs and investigative sites that conduct our clinical trials;
- the cost of acquiring, developing and manufacturing clinical trial materials;
- costs associated with non-clinical activities and regulatory operations;
- market research, disease education and other commercial product planning activities, including the hiring of a sales and marketing and medical affairs organization in preparation for commercial launch of Rubraca; and
- activities associated with the development of companion diagnostics for our product candidates.

Research and development costs are expensed as incurred. License fees and milestone payments related to in-licensed products and technology are expensed if it is determined that they have no alternative future use. Costs for certain development activities, such as clinical trials and manufacturing of clinical supply, are recognized based on an evaluation of the progress to completion of specific tasks using data such as patient enrollment, clinical site activations or information provided to us by our vendors. Our research and development expenses increased for 2019 compared to 2018. Beginning with 2020, we expect research and development costs to flatten, and then trend lower in the following years, as the largest of our sponsored clinical trials near completion.

The following table identifies research and development and acquired in-process research and development costs on a program-specific basis for our products under development. Personnel-related costs, depreciation and share-based compensation are not allocated to specific programs, as they are deployed across multiple projects under development and, as such, are separately classified as personnel and other expenses in the table below.

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2019 | 2018 | 2017 |
| | (in thousands) | | |
| **Rucaparib Expenses** | | | |
| Research and development | $ 184,617 | $ 153,083 | $ 72,901 |
| Rucaparib Total | 184,617 | 153,083 | 72,901 |
| **FAP Expenses** | | | |
| Acquired in-process research and development | 9,440 | — | — |
| Research and development | 3,633 | — | — |
| 3BP Total | 13,073 | — | — |
| **Lucitanib Expenses** | | | |
| Research and development | 5,128 | 786 | (1,187) |
| Lucitanib Total | 5,128 | 786 | (1,187) |
| **Rociletinib Expenses** | | | |
| Research and development | 1,101 | 2,391 | 7,712 |
| Rociletinib Total | 1,101 | 2,391 | 7,712 |
| Personnel and other expenses | 88,667 | 75,087 | 63,072 |
| Total | **$ 292,586** | **$ 231,347** | **$ 142,498** |

***Selling, General and Administrative Expenses***

Selling, general and administrative expenses consist principally of salaries and related costs for personnel in executive, commercial, finance, legal, investor relations, human resources and information technology functions. Other general and administrative expenses include facilities expenses, communication expenses, information technology costs, corporate insurance and professional fees for legal, consulting and accounting services. With the FDA approval of Rubraca on December 19, 2016, all sales and marketing expenses associated with Rubraca are included in selling, general and administrative expenses. We anticipate that our selling, general and administrative expenses will continue to increase in the future in support of our commercial activities related to Rubraca in the U.S. and Europe.

***Acquired In-Process Research and Development Expenses***

Acquired in-process research and development expenses consist of upfront payments to acquire a new drug compound, as well as subsequent milestone payments. Acquired in-process research and development payments are immediately expensed provided that the drug has not achieved regulatory approval for marketing and, absent obtaining such approval, has no alternative future use. Once regulatory approval is received, payments to acquire rights, and the related milestone payments, are capitalized and the amortization of such assets recorded to product cost of sales.

***Other Income and Expense***

Other income and expense are primarily comprised of foreign currency gains and losses resulting from transactions with CROs, investigational sites and contract manufacturers where payments are made in currencies other than the U.S. dollar. Other expense also includes interest expense recognized related to our convertible senior notes.

**Critical Accounting Policies and Significant Judgments and Estimates**

Our discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, expenses and revenue and related disclosures. On an ongoing basis, we evaluate our estimates and judgments, including those related to revenue, intangible asset impairment, clinical trial accruals and share-based compensation expense. We base our estimates on historical experience, known trends and events and various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Our significant accounting policies are described in more detail in the notes to our consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K. We believe the following accounting policies to be most critical to the judgments and estimates used in the preparation of our financial statements.

***Revenue Recognition***

We are currently approved to sell Rubraca in the United States and the EU markets. We distribute our product principally through a limited number of specialty distributor and specialty pharmacy providers, collectively, our customers. Our customers subsequently sell our products to patients and health care providers. Separately, we have arrangements with certain payors and other third parties that provide for government-mandated and privately-negotiated rebates, chargebacks and discounts.

Revenue from product sales are recognized when the performance obligation is satisfied, which is when customers obtain control of our product at a point in time, typically upon delivery. Revenues from product sales are recorded at the net sales price (transaction price), which includes estimates of variable consideration for which reserves are established and which result from price concessions that include rebates, chargebacks, discounts, co-pay assistance, estimated product returns and other allowances that are offered within contracts between us and our customers, health care providers, payors and other indirect customers relating to the sales of our product. These reserves are based on the amounts earned or to be claimed on the related sales and are classified as reductions of accounts receivable (if the amount is payable to the customers) or a current liability (if the amount is payable to a party other than a customer). Where appropriate, these estimates take into consideration a range of possible outcomes which are probability-weighted for relevant factors such as our historical experience, current contractual and statutory requirements, specific known market events and trends, industry data and forecasted customer buying and payment patterns. Overall, these reserves reflect our best estimates of the amount of consideration to which we are entitled based on the terms of the contract. The amount of variable consideration which is included in the transaction price may be constrained and is included in the net sales price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. Actual amounts of consideration ultimately received may differ from our estimates. If actual results in the future vary from our estimates, we adjust these estimates, which would affect product revenue and earnings in the period such variances become known.

Effective January 1, 2018, we adopted Accounting Standards Codification ("ASC") Topic 606, "Revenue from Contracts with Customers". Upon adoption, we recognized revenue when our customers, the specialty distributors and specialty pharmacy providers, take control of our product. This resulted in us recognizing revenue approximately two to four weeks earlier than before adopting the new standard. We used the modified retrospective method to adopt the new standard. This means that we did not restate previously issued financial statements, but recorded a one-time adjustment to retained earnings of $2.4 million. This adjustment represents the sales of our product to our customers prior to January 1, 2018, that had not been sold to patients or healthcare providers, offset by related gross-to-net adjustments and other direct costs, including royalties and sales incentive compensation.

During 2017, revenue was recognized for U.S. tax purposes when our product was sold to the specialty distributors and pharmacies, a method that differs from book treatment. This difference in revenue recognition resulted in the establishment of the deferred tax asset for the sales value of our product held by our specialty distributor and pharmacy providers at December 31, 2017. The deferred tax asset was offset by a full valuation allowance and has no impact to our statement of operations. With the adoption of ASC 606 effective January 1, 2018, revenue is recognized when our product is sold to the specialty distributors pharmacies, which will match the tax treatment resulting in no deferred tax asset.

For the year ended December 31, 2019, we recognized $143.0 million of product revenue. For a complete discussion of the accounting for product revenue, see Note 3, *Revenue Recognition*.

***Accrued Research and Development Expenses***

As part of the process of preparing our financial statements, we are required to estimate our accrued expenses. This process involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of the actual cost. The majority of our service providers invoice us monthly in arrears for services performed or when contractual milestones are met. We make estimates of our accrued expenses as of each balance sheet date in our financial statements based on facts and circumstances known to us at that time. We periodically confirm the accuracy of our estimates with the service providers and make adjustments if necessary. Examples of estimated accrued research and development expenses include:

- fees paid to CROs in connection with clinical studies;
- fees paid to investigative sites in connection with clinical studies;
- fees paid to vendors in connection with non-clinical development activities;
- fees paid to vendors associated with the development of companion diagnostics; and
- fees paid to vendors related to product manufacturing, development and distribution of clinical supplies.

We base our expenses related to clinical studies on our estimates of the services received and efforts expended pursuant to contracts with multiple CROs that conduct and manage clinical studies on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the clinical expense. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. In accruing service fees, we estimate the time period over which services will be performed, enrollment of patients, number of sites activated and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual or prepaid accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in us reporting amounts that are too high or too low in any particular period.

***Share-Based Compensation***

Determining the amount of share-based compensation to be recorded requires us to develop estimates of the fair value of stock options as of their grant date. Compensation expense is recognized over the vesting period of the award. Calculating the fair value of share-based awards requires that we make highly subjective assumptions. We use the Black-Scholes option pricing model to value our stock option awards. Use of this valuation methodology requires that we make assumptions as to the expected dividend yield, price volatility of our common stock, the risk-free interest rate for a

period that approximates the expected term of our stock options and the expected term of our stock options. We utilize a dividend yield of zero based on the fact that we have never paid cash dividends and have no current intention to pay cash dividends.

The fair value of stock options for the years ended December 31, 2019, 2018 and 2017 was estimated at the grant date using the following weighted average assumptions for the respective periods:

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2019 | 2018 | 2017 |
| Dividend yield | — | — | — |
| Volatility (a) | 93 % | 88 % | 89 % |
| Risk-free interest rate (b) | 1.67 % | 2.92 % | 2.16 % |
| Expected term (years) (c) | 5.9 | 5.9 | 5.8 |

(a) *Volatility*: The expected volatility was estimated using our historical data.
(b) *Risk-free interest rate*: The rate is based on the yield on the grant date of a zero-coupon U.S. Treasury bond whose maturity period approximates the option's expected term.
(c) *Expected term*: The expected term of the award was estimated using our historical data.

We recognized share-based compensation expense of approximately $54.3 million, $49.1 million and $44.7 million for the years ended December 31, 2019, 2018 and 2017, respectively. As of December 31, 2019, the unrecognized share-based compensation expense related to unvested options, adjusted for expected forfeitures, was $36.9 million, which is expected to be recognized over a weighted-average remaining vesting period of 1.9 years. As of December 31, 2019, the unrecognized share-based compensation expense related to RSUs, adjusted for expected forfeitures, was $45.1 million, which is expected to be recognized over an estimated weighted-average remaining vesting period of 2.1 years. We expect our share-based compensation to continue to grow in future periods due to the potential increases in the value of our common stock and headcount.

We estimate the level of forfeitures expected to occur and record compensation expense only for those awards that we ultimately expect will vest.

***Inventory***

Inventories are stated at the lower of cost or estimated net realizable value, on a first-in, first-out ("FIFO") basis. Inventories include active pharmaceutical ingredient ("API"), contract manufacturing costs and overhead allocations. We began capitalizing incurred inventory related costs upon the regulatory approval of Rubraca. Prior to the regulatory approval of Rubraca, we incurred costs for the manufacture of the drug that could potentially be available to support the commercial launch of Rubraca and all such costs were recognized as research and development expense.

We regularly analyze our inventory levels for excess quantities and obsolescence (expiration), considering factors such as historical and anticipated future sales compared to quantities on hand and the remaining shelf-life of Rubraca. Rubraca finished goods have a shelf-life of four years from the date of manufacture. We expect to sell the finished goods prior to expiration. The API currently has a shelf-life of four years from the date of manufacture but can be retested at an immaterial cost with no expected reduction in potency, thereby extending its shelf-life as needed. We expect to consume substantially all of the API over a period of approximately nine years based on our long-range sales projections of Rubraca.

We write down inventory that has become obsolete, inventory that has a cost basis in excess of its estimated realizable value and/or inventory in excess of expected sales requirements. Expired inventory would be disposed of and the related costs would be written off as cost of product revenue. Inventories that are not expected to be consumed within 12 months following the balance sheet date are classified as long-term inventories. Long-term inventories primarily consist of API.

API is currently produced by a single supplier. As the API has undergone significant manufacturing specific to its intended purpose at the point it is purchased by us, we classify the API as work-in-process inventory. In addition, we currently manufacture Rubraca finished goods with a single third-party manufacturer. The disruption or termination of the supply of API or the disruption or termination of the manufacturing of our commercial products could have a material adverse effect on our business, financial position and results of operations.

Inventory used in clinical trials is expensed as research and development expense when it has been identified for such use.

At December 31, 2019, we had $26.5 million of current inventory and $98.1 million of long-term inventory. In addition, we had $12.4 million cash deposit on inventory, which consists of advanced intermediate, which is the inventory prior to conversion to API.

***Intangible Assets***

Definite-lived intangible assets related to capitalized milestones under license agreements are amortized on a straight-line basis over their remaining useful lives, which are estimated to be the remaining patent life. If our estimate of the product's useful life is shorter than the remaining patent life, then a shorter period is used. Amortization expense is recorded as a component of cost of sales in the Consolidated Statements of Operations and Comprehensive Loss.

Intangible assets are evaluated for impairment at least annually in the fourth quarter or more frequently if impairment indicators exist. Events that could result in an impairment, or trigger an interim impairment assessment, include the decision to discontinue the development of a drug, the receipt of additional clinical or nonclinical data regarding our drug candidate or a potentially competitive drug candidate, changes in the clinical development program for a drug candidate, or new information regarding potential sales for the drug. In connection with any impairment assessment, the fair value of the intangible assets as of the date of assessment is compared to the carrying value of the intangible asset. Impairment losses are recognized if the carrying value of an intangible asset is both not recoverable and exceeds its fair value.

**Results of Operations**

***Comparison of the Year Ended December 31, 2019 to the Year Ended December 31, 2018 (in thousands)***

| | Year ended December 31, | | Change Favorable/(Unfavorable) | |
|---|---|---|---|---|
| | 2019 | 2018 | $ | % |
| Revenues: | | | | |
| Product revenue | $ 143,006 | $ 95,388 | $ 47,618 | 50 % |
| Operating expenses: | | | | |
| Cost of sales - product | 29,926 | 19,444 | (10,482) | (54)% |
| Cost of sales - intangible asset amortization | 4,760 | 2,630 | (2,130) | (81)% |
| Research and development | 283,146 | 231,347 | (51,799) | (22)% |
| Selling, general and administrative | 182,769 | 175,781 | (6,988) | (4)% |
| Acquired in-process research and development | 9,440 | — | (9,440) | (100)% |
| Other operating expenses | 9,711 | — | (9,711) | (100)% |
| Total expenses | 519,752 | 429,202 | (90,550) | (21)% |
| Operating loss | (376,746) | (333,814) | (42,932) | (13)% |
| Other income (expense): | | | | |
| Interest expense | (19,405) | (13,183) | (6,222) | (47)% |
| Foreign currency loss | (547) | (346) | (201) | (58)% |
| Legal settlement loss | (26,750) | (27,975) | 1,225 | 4 % |
| Gain on extinguishment of debt | 18,480 | — | 18,480 | 100 % |
| Other income | 6,342 | 7,917 | (1,575) | (20)% |
| Other income (expense), net | (21,880) | (33,587) | 11,707 | 35 % |
| Loss before income taxes | (398,626) | (367,401) | (31,225) | (8)% |
| Income tax expense | (1,798) | (608) | (1,190) | (196)% |
| Net loss | $ (400,424) | $ (368,009) | $ (32,415) | (9)% |

***Product Revenue.*** Product revenue for the year ended December 31, 2019 increased primarily due to continued growth in sales of Rubraca, which is approved for sale in the United States and EU markets. We completed our launch of Rubraca as maintenance therapy in Germany and the UK in March 2019. Product revenue is recorded net of variable considerations comprised of rebates, chargebacks and other discounts. Product revenue for the year ended December 31,

2019 was $137.2 million in the United States and $5.8 million outside of the United States. Variable considerations represented 15.0% and 10.4% of the transaction price recognized in the year ended December 31, 2019 and 2018, respectively. This increase is primarily due to government and group purchasing organization rebates; in addition, our launch in Germany and the UK in March 2019 contributed to the increase. Amounts are summarized as follows:

| | Year ended December 31, 2019 | | Year ended December 31, 2018 | |
|---|---|---|---|---|
| | $ (in thousands) | % of Gross Sales | $ (in thousands) | % of Gross Sales |
| Transaction price | $ 168,317 | 100.0% | $ 106,479 | 100.0% |
| Sales deductions: | | | | |
| Government rebates and chargebacks | 15,208 | 9.0% | 6,379 | 6.0% |
| Discounts and fees | 10,103 | 6.0% | 4,712 | 4.4% |
| Total sales deductions | 25,311 | 15.0% | 11,091 | 10.4% |
| Product revenue | $ 143,006 | 85.0% | $ 95,388 | 89.6% |

***Cost of Sales - Product.*** Product cost of sales for the year ended December 31, 2019 increased due to the increase in product revenue. Product cost of sales primarily relate to manufacturing, freight and royalties costs associated with Rubraca sales in the period.

***Cost of Sales – Intangible Asset Amortization***. For the year ended December 31, 2019 and 2018, we recognized cost of sales of $4.8 million and $2.6 million, respectively, associated with the amortization of capitalized milestone payments related to the approvals of Rubraca by the FDA and the European Commission.

***Research and Development Expenses.*** Research and development expenses increased during the year ended December 31, 2019 due to higher research and development costs for Rubraca. Clinical trial costs for Rubraca were higher compared to the same period a year ago due to increased enrollment in our TRITON3 study for prostate cancer. We have increased costs related to our new ATLAS study for bladder cancer and our ATHENA combination study with Bristol-Myers Squibb Company's immunotherapy OPDIVO for ovarian cancer. Since our ATLAS study for bladder cancer was discontinued in April 2019, costs for this study decreased during the remainder of 2019. In addition, personnel costs increased during the year ended December 31, 2019 due to higher headcount to support increased Rubraca clinical trial activities.

Clinical trial costs for lucitanib were $4.3 million higher than the year ended December 31, 2018 primarily due to increase enrollment in our Phase 1b/2 studies. In addition, we incurred $3.6 million for FAP-2286 as we have begun to pursue a clinical development program in multiple tumor types.

***Selling, General and Administrative Expenses.*** Selling, general and administrative expenses increased during the year ended December 31, 2019 primarily due to increased commercialization activities for Rubraca and the increase of costs associated with building out the European infrastructure for commercialization which began in March 2019. This includes an increase of $4.3 million in personnel costs and $3.6 million in marketing costs.

***Acquired In-Process Research and Development Expenses.*** Upon the signing of the license and collaboration agreement with 3BP in September 2019, we made a $9.4 million upfront payment to 3BP.

***Other Operating Expenses.*** During the year ended December 31, 2019, we recognized other operating expenses related to the write off of some damaged API and certain costs related to our dedicated production train at Lonza.

***Interest Expense.*** Interest expense increased during the year ended December 31, 2019 due to the issuance of the 2025 Notes in April 2018 and the 2024 Notes in August 2019.

***Legal Settlement Loss.*** During the second quarter of 2019, we recorded a charge of $26.8 million to settle a complaint filed by Antipodean Domestic Partners (the "Antipodean Complaint"). During the first quarter of 2018, we recorded a charge of $8.0 million related to an agreement to resolve a potential litigation claim against us and our officers. We also recorded a charge of $20.0 million related to an agreement reached with the SEC to resolve its investigation.

***Gain on Extinguishment of Debt.*** In August 2019, we repurchased $190.3 million principal amount of the outstanding 2021 Notes and $2.0 million of accrued interest for an aggregate repurchase price of $171.8 million. This repurchase resulted in the write off of $2.0 million in unamortized debt issuance costs and the recognition of $18.5 million gain on extinguishment of debt.

***Other Income.*** Other income decreased during the year ended December 31, 2019 due to interest income earned on our available-for-sale securities.

***Comparison of the Year Ended December 31, 2018 to the Year Ended December 31, 2017 (in thousands)***

| | Year ended December 31, | | Change Favorable/(Unfavorable) | |
|---|---|---|---|---|
| | 2018 | 2017 | $ | % |
| Revenues: | | | | |
| Product revenue | $ 95,388 | $ 55,511 | $ 39,877 | 72 % |
| Operating expenses: | | | | |
| Cost of sales - product | 19,444 | 10,251 | (9,193) | (90)% |
| Cost of sales - intangible asset amortization | 2,630 | 1,486 | (1,144) | (77)% |
| Research and development | 231,347 | 142,498 | (88,849) | (62)% |
| Selling, general and administrative | 175,781 | 138,907 | (36,874) | (27)% |
| Total expenses | 429,202 | 293,142 | (136,060) | (46)% |
| Operating loss | (333,814) | (237,631) | (96,183) | (40)% |
| Other income (expense): | | | | |
| Interest expense | (13,183) | (10,428) | (2,755) | (26)% |
| Foreign currency loss | (346) | (82) | (264) | (322)% |
| Legal settlement loss | (27,975) | (105,477) | 77,502 | 73 % |
| Other income | 7,917 | 3,643 | 4,274 | 117 % |
| Other expense, net | (33,587) | (112,344) | 78,757 | 70 % |
| Loss before income taxes | (367,401) | (349,975) | (17,426) | (5)% |
| Income tax (expense) benefit | (608) | 3,578 | (4,186) | (117)% |
| Net loss | $ (368,009) | $ (346,397) | $ (21,612) | (6)% |

***Product Revenue.*** Product revenue for the year ended December 31, 2018 increased primarily due to continued growth in sales of Rubraca, which was approved for sale in the United States markets and we began shipping on December 19, 2016. Growth in sales is also due to the additional maintenance treatment indication that was approved in the United States in April 2018. Product revenue is recorded net of variable considerations comprised of rebates, chargebacks and other discounts. Variable considerations represented 10.4% and 8.1% of the transaction price recognized in the year ended December 31, 2018 and 2017, respectively. This increase primarily relates to an increase in older patients on Medicare as well as additional patients filling prescriptions at low-income clinics. Amounts are summarized as follows:

| | Year ended December 31, 2018 | | Year ended December 31, 2017 | |
|---|---|---|---|---|
| | $ (in thousands) | % of Gross Sales | $ (in thousands) | % of Gross Sales |
| Transaction price | $ 106,479 | 100.0% | $ 60,384 | 100.0% |
| Sales deductions: | | | | |
| Government rebates and chargebacks | 6,379 | 6.0% | 2,575 | 4.3% |
| Discounts and fees | 4,712 | 4.4% | 2,298 | 3.8% |
| Total sales deductions | 11,091 | 10.4% | 4,873 | 8.1% |
| Product revenue | $ 95,388 | 89.6% | $ 55,511 | 91.9% |

***Cost of Sales - Product.*** Product cost of sales for the year ended December 31, 2018 increased due to the increase in product revenue. Product cost of sales primarily relate to manufacturing, freight and royalties costs associated with Rubraca sales in the period. Manufacturing costs associated with sales in the year ended December 31, 2017 were expensed as incurred based on our policy to expense costs associated with the manufacture of our products prior to regulatory approval, and therefore, a minimal amount is included as product cost of sales. These costs increased in the year ended December 31, 2018, as we depleted these inventories as of the fourth quarter of 2017.

***Cost of Sales – Intangible Asset Amortization***. For the year ended December 31, 2018 and 2017, we recognized cost of sales of $2.6 million and $1.5 million, respectively, associated with the amortization of capitalized milestone payments related to the approvals of Rubraca by the FDA in December 2016 and April 2018 and by the European Commission in May 2018.

***Research and Development Expenses.*** Research and development expenses increased during the year ended December 31, 2018 due to higher research and development costs for rucaparib. Clinical trial costs for rucaparib were higher compared to the same period a year ago due to higher costs from increased enrollment in ARIEL4, our confirmatory ovarian cancer trials, and increased enrollment in our TRITON2 and TRITON3 studies for prostate cancer. We have increased costs related to our new ATLAS study for bladder cancer, our ATHENA combination study with Bristol-Myers Squibb Company's immunotherapy OPDIVO for ovarian cancer and our RUCA-J study for ovarian cancer in Japan. In addition, personnel costs increased during the year ended December 31, 2018 due to higher headcount to support increased rucaparib clinical trial activities.

Clinical trial costs for rociletinib were $5.3 million lower than the year ended December 31, 2017 primarily due to patients discontinuing drug treatment and investigational sites closing for all the TIGER studies in non-small cell lung cancer.

***Selling, General and Administrative Expenses.*** Selling, general and administrative expenses increased during the year ended December 31, 2018 due to increased commercialization activities for Rubraca and the increase of costs associated with building out the European infrastructure in anticipation of commercialization there, which includes an increase of $2.9 million in facilities expense and $2.2 million in personnel costs. In addition, there was an increase of $4.3 million in legal expense and $3.4 million in stock compensation expense.

***Interest Expense.*** Interest expense increased during the year ended December 31, 2018 due to the issuance of the 2025 Notes on April 19, 2018.

***Foreign Currency Loss.*** Foreign currency loss increased during the year ended December 31, 2018 primarily due to the foreign currency rate utilized to translate our Euro-denominated goodwill into U.S. dollars.

***Legal Settlement Loss.*** During the first quarter of 2018, we recorded a charge of $8.0 million related to an agreement to resolve a potential litigation claim against us and our officers. We also recorded a charge of $20.0 million related to an agreement reached with the SEC to resolve its investigation. During 2017, we recorded a $105.5 million legal settlement loss, net of insurance receivable, related to a stipulation agreement of settlement whereby we issued the plaintiff and participating class members a total consideration comprised of $25.0 million in cash and the issuance of 1.5 million shares. The cash portion of the consideration was funded by our insurance carriers.

***Other Income.*** Other income increased during the year ended December 31, 2018 due to interest income earned on our available-for-sale securities.

**Liquidity and Capital Resources**

To date, we have funded our operations through a financing agreement related to our ATHENA trial, the public offering of our common stock and the private placement of convertible debt securities and preferred stock.

The following table sets forth the primary sources and uses of cash for each of the periods set forth below:

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2019 | 2018 | 2017 |
| | | (in thousands) | |
| Net cash used in operating activities | $ (323,615) | $ (365,997) | $ (260,904) |
| Net cash provided by (used in) investing activities | 143,398 | (264,242) | (54,102) |
| Net cash provided by financing activities | 119,888 | 388,464 | 562,075 |
| Effect of exchange rate changes on cash and cash equivalents | 286 | (547) | 943 |
| Net decrease in cash and cash equivalents | $ (60,043) | $ (242,322) | $ 248,012 |

***Operating Activities***

Net cash used in operating activities resulted primarily from our net losses adjusted for non-cash items and changes in components of working capital. Net cash used in operating activities was lower during the year ended December 31, 2019 compared to prior year primarily due to higher amounts paid for inventory during the year ended December 31, 2018, partially offset by a higher net loss as adjusted for non-cash items primarily due to legal settlement loss and gain on extinguishment of debt.

Net cash used in operating activities was higher during the year ended December 31, 2018 compared to the prior year due to a higher net loss as adjusted for non-cash items and increases in the operating assets needed to support the commercialization of Rubraca, most notably related to inventory.

***Investing Activities***

Net cash provided by investing activities for the year ended December 31, 2019 included sales of available-for-sale securities of $622.0 million partially offset by purchases of available-for-sale securities of $459.8 million and milestone payments of $15.8 million.

Net cash used in investing activities for the year ended December 31, 2018 included milestone payments of $55.0 million and purchases of available-for-sale securities of $500.0 million partially offset by cash from sales of available-for-sale securities of $300.0 million.

***Financing Activities***

Net cash provided by financing activities for the year ended December 31, 2019 included proceeds of $254.9 million from the issuance of our 2024 Notes, $32.9 million proceeds from borrowings under our financing agreement and $3.3 million received from employee stock option exercises and issuance of stock under the employee stock purchase plan, partially offset by the $170.0 million extinguishment of a portion of our 2021 Notes.

Net cash provided by financing activities for the year ended December 31, 2018 included $4.0 million received from employee stock option exercises and stock purchases under the employee stock purchase plan. We completed the sale of $93.9 million of common stock, net of issuance costs, during the year ended December 31, 2018. In addition, we issued $290.9 million of convertible senior notes, net of issuance costs, during the year ended December 31, 2018.

***Operating Capital Requirements***

In the United States, Rubraca is approved by the FDA for two indications for patients with recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer. In the EU, Rubraca is approved by the EMA for two indications for patients with recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer. We expect to incur significant losses for the foreseeable future, as we commercialize Rubraca and expand our selling, general and administrative functions to support the growth in our commercial organization.

As of December 31, 2019, we had cash, cash equivalents and available-for-sale securities totaling $296.7 million and total current liabilities of $133.1 million.

Because of the numerous risks and uncertainties associated with research, development and commercialization of pharmaceutical products, we are unable to estimate the exact amounts of our working capital requirements. Our future funding requirements will depend on many factors, including but not limited to:

- the number and characteristics of the product candidates, companion diagnostics and indications we pursue;
- the achievement of various development, regulatory and commercial milestones resulting in required payments to partners pursuant to the terms of our license agreements;
- the scope, progress, results and costs of researching and developing our product candidates and related companion diagnostics and conducting clinical and non-clinical trials;
- the timing of, and the costs involved in, obtaining regulatory approvals for our product candidates and companion diagnostics;
- the cost of commercialization activities, including marketing and distribution costs;

- the cost of manufacturing any of our product candidates we successfully commercialize;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, including litigation costs and outcome of such litigation; and
- the timing, receipt and amount of sales, if any, of our products.

***Contractual Obligations and Commitments***

The following table summarizes our contractual obligations at December 31, 2019 (in thousands):

| | Less than 1 Year | 1 to 3 Years | 3 to 5 Years | More Than 5 Years | Total |
|---|---|---|---|---|---|
| Convertible senior notes | $ — | $ 97,188 | $ 263,000 | $ 300,000 | $ 660,188 |
| Interest on convertible senior notes | 18,015 | 32,891 | 26,272 | 1,260 | 78,438 |
| Operating lease commitments | 5,735 | 9,112 | 5,932 | 10,865 | 31,644 |
| Finance lease commitments | 2,287 | 4,574 | 4,574 | 2,287 | 13,722 |
| Purchase and other commitments (a) | 30,841 | 24,784 | 24,784 | 12,392 | 92,801 |
| Total | $ 56,878 | $ 168,549 | $ 324,562 | $ 326,804 | $ 876,793 |

(a) On October 3, 2016, we entered into a Manufacturing and Services Agreement (the "Agreement") with a non-exclusive third-party supplier for the production of the active ingredient for Rubraca. Under the terms of the Agreement, we will provide the third-party supplier a rolling forecast for the supply of the active ingredient in Rubraca that will be updated by us on a quarterly basis. We are obligated to order material sufficient to satisfy an initial quantity specified in any forecast. In addition, the third-party supplier constructed, in its existing facility, a production train that is exclusively dedicated to the manufacture of the Rubraca active ingredient. We are obligated to make scheduled capital program fee payments toward capital equipment and other costs associated with the construction of the dedicated production train. Once the facility became operational in October 2018, we are obligated to pay a fixed facility fee each quarter for the duration of the Agreement, which expires on December 31, 2025, unless extended by mutual consent of the parties.

*Royalty and License Fee Commitments*

***Rubraca.*** We have certain obligations under licensing agreements with third parties contingent upon achieving various development, regulatory and commercial milestones. On August 30, 2016, we entered into a first amendment to the worldwide license agreement with Pfizer, which amends the June 2011 existing worldwide license agreement to permit us to defer payment of the milestone payments payable upon (i) FDA approval of an NDA for 1st Indication in US and (ii) European Commission approval of an MAA for 1st Indication in the EU, to a date that is 18 months after the date of achievement of such milestones.

On December 19, 2016, Rubraca received its initial FDA approval. This approval resulted in a $0.75 million milestone payment to Pfizer as required by the license agreement, which was paid in the first quarter of 2017. This FDA approval also resulted in an obligation to pay a $20.0 million milestone payment, for which we exercised the option to defer payment by agreeing to pay $23.0 million within 18 months after the date of the FDA approval. We paid the $23.0 million milestone payment in June 2018.

On April 6, 2018, Rubraca received a second FDA approval. This approval resulted in an obligation to pay a $15.0 million milestone payment, which we paid in April 2018.

In May 2018, Rubraca received its initial European Commission marketing authorization. This approval resulted in an obligation to pay a $20.0 million milestone payment, which we paid in June 2018.

In January 2019, Rubraca received a second European Commission approval. This approval resulted in an obligation to pay a $15.0 million milestone payment, which we paid in February 2019.

In June 2019, we paid a $0.75 million milestone payment due to the launch of Rubraca as maintenance therapy in Germany in March 2019.

These milestone payments were recognized as intangible assets and are amortized over the estimated remaining useful life of Rubraca.

We are obligated under the license agreement to use commercially reasonable efforts to develop and commercialize Rubraca and we are responsible for all ongoing development and commercialization costs for Rubraca. We are required to make regulatory milestone payments to Pfizer of up to an additional $16.0 million in aggregate if specified clinical study objectives and regulatory filings, acceptances and approvals are achieved. In addition, we are obligated to make sales milestone payments to Pfizer if specified annual sales targets for Rubraca are met, which relate to annual sales targets of $250.0 million and above, which, in the aggregate, could amount to total milestone payments of $170.0 million, and tiered royalty payments at a mid-teen percentage rate on net sales, with standard provisions for royalty offsets to the extent we need to obtain any rights from third parties to commercialize Rubraca.

***FAP Program.*** In September 2019, we entered into a global license and collaboration agreement with 3BP to develop and commercialize a PTRT and imaging agent targeting FAP. The lead candidate, designated internally as FAP-2286, is being developed pursuant to a global development plan agreed to by the parties. We are responsible for the costs of all preclinical and clinical development activities described in the plan, including the costs for a limited number of 3BP full-time equivalents and external costs incurred during the preclinical development phase of the collaboration. Upon the signing of the license and collaboration agreement in September 2019, we made a $9.4 million upfront payment to 3BP, which we recognized as acquired in-process research and development expense.

Pursuant to the terms of the FAP agreement, we are required to make additional payments to 3BP for annual technology access fees and upon the achievement of certain development and regulatory milestone events (or on certain dates, whichever occur earlier). We are also obligated to pay 3BP single- to low-double-digit royalties on net sales of the FAP-targeted therapeutic product and imaging agent, based on the volume of annual net sales achieved. In addition, 3BP is entitled to receive 34% of any consideration, excluding royalties on the therapeutic product, pursuant to any sublicenses we may grant.

We are obligated under the license and collaboration agreement to use diligent efforts to develop FAP-2286 and commercialize a FAP-targeted therapeutic product and imaging agent, and we are responsible for all commercialization costs in our territory. The agreement with 3BP will remain in effect until the expiration of our royalty obligations to 3BP, determined on a product-by-product and country-by-country basis, unless we elect to terminate the agreement earlier. If we fail to meet our obligations under the agreement and are unable to cure such failure within specified time periods, 3BP can terminate the agreement, resulting in a loss of our rights. 3BP also has the right to terminate the agreement under certain circumstances in connection with our change of control in which the acquiring party retains a product competitive with the FAP-targeted therapeutic product or, in the event marketing authorization has not yet been obtained, does not agree to the then-current global development plan.

In February 2020, we finalized the terms of a drug discovery collaboration agreement with 3BP to identify up to three additional, undisclosed targets for peptide-targeted radionuclide therapy, to which we will obtain global rights for any resulting product candidates. We are responsible for the costs of all preclinical and clinical development activities conducted under the discovery program, including the costs for a limited number of 3BP full-time equivalents and external costs incurred during the discovery and preclinical development phase for each collaboration target. The agreement was effective December 31, 2019, for which we incurred a $2.1 million technology access fee, which we accrued and recognized as a research and development expense.

Pursuant to the terms of the agreement, we are required to make additional payments to 3BP for annual technology access fees and upon the achievement of certain development and regulatory milestone events (or on certain dates, whichever occur earlier). We are also obligated to pay 3BP a 6% royalty on net sales of License Products (as defined in the agreement), based on the volume of quarterly net sales achieved.

We are obligated under the discovery collaboration agreement to use diligent efforts to develop and commercialize the product candidates, if any, that result from the discovery program, and we are responsible for all clinical development and commercialization costs. The agreement with 3BP will remain in effect until the expiration of our royalty obligations to 3BP, determined on a product-by-product and country-by-country basis, unless we elect to terminate the agreement earlier. If we fail to meet our obligations under the agreement and are unable to cure such failure within specified time periods, 3BP can terminate the agreement, resulting in a loss of our rights.

Pursuant to terms of each of our product license agreements, we will pay royalties to our licensors on sales, if any, of the respective products.

**Off-Balance Sheet Arrangements**

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined under the rules promulgated by the U.S. Securities and Exchange Commission.

**Tax Loss Carryforwards**

As of December 31, 2019, we have net operating loss ("NOL") carryforwards of approximately $1.5 billion to offset future federal income taxes. We also have research and development and orphan drug tax credit carryforwards of $249.7 million to offset future federal income taxes. The federal net operating loss carryforwards and research and development and orphan drug tax credit carryforwards expire at various times through 2039.

We believe that a change in ownership as defined under Section 382 of the U.S. Internal Revenue Code occurred as a result of our public offering of common stock completed in April 2012. Future utilization of the federal net operating losses and tax credit carryforwards accumulated from inception to the change in ownership date will be subject to annual limitations to offset future taxable income. It is possible that a change in ownership will occur in the future, which will limit the NOL amounts generated since the last estimated change in ownership. At December 31, 2019, we recorded a 100% valuation allowance against our net deferred tax assets in the U.S. of approximately $751 million, as we believe it is more likely than not that the tax benefits will not be fully realized. In the future, if we determine that a portion or all of the tax benefits associated with our tax carryforwards will be realized, net income would increase in the period of determination.

**Recently Adopted and Issued Accounting Standards**

For a discussion of recently adopted and issued accounting standards, see Note 2, *Summary of Significant Accounting Policies*, in the Notes to Consolidated Financial Statements included in Part II, Item 8, *Financial Statements and Supplementary Data*, of this Annual Report on Form 10-K.

## ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to market risk related to changes in interest rates. As of December 31, 2019, we had cash, cash equivalents and available-for-sale securities of $296.7 million, consisting of bank demand deposits, money market funds and U.S. treasury securities. The primary objectives of our investment policy are to preserve principal and maintain proper liquidity to meet operating needs. Our investment policy specifies credit quality standards for our investments and limits the amount of credit exposure to any single issue, issuer or type of investment. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our investments are in short-term securities. Our available-for-sale securities are subject to interest rate risk and will decline in value if market interest rates increase. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, an immediate 100 basis point change in interest rates would not have a material effect on the fair value of our portfolio.

We contract with contract research organizations, investigational sites and contract manufacturers globally where payments are made in currencies other than the U.S. dollar. In addition, on October 3, 2016, we entered into a Manufacturing and Services Agreement with a Swiss company for the production and supply of the active ingredient for Rubraca. Under the terms of this agreement, payments for the supply of the active ingredient in Rubraca as well as scheduled capital program fee payment toward capital equipment and other costs associated with the construction of a dedicated production train will be made in Swiss francs. Once the production facility became operational in October 2018, we are obligated to pay a fixed facility fee each quarter for the duration of the agreement, which expires on December 31, 2025.

As of December 31, 2019, $92.8 million of purchase commitments exist under the Swiss Manufacturing and Services Agreement and we are required to remit amounts due in Swiss francs. Due to other variables that may exist, it is difficult to quantify the impact of a particular change in exchange rates. However, we estimate that if the value of the US dollar was to strengthen by 10% compared to the value of Swiss franc as of December 31, 2019, it would decrease the total US

dollar purchase commitment under the Swiss Manufacturing and Services Agreement by approximately $13.7 million. Similarly, a 10% weakening of the US dollar compared to the Swiss franc would increase the total US dollar purchase commitment by approximately $3.9 million.

While we periodically hold foreign currencies, primarily Euro, Pound Sterling and Swiss Franc, we do not use other financial instruments to hedge our foreign exchange risk. Transactions denominated in currencies other than the functional currency are recorded based on exchange rates at the time such transactions arise. As of December 31, 2019, and 2018, approximately 4% and 6%, respectively, of our total liabilities were denominated in currencies other than the functional currency.

## ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The financial statements required by this Item are included in Item 15 of this report and are presented beginning on page F-1.

## ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

## ITEM 9A. CONTROLS AND PROCEDURES

### Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures

Our disclosure controls and procedures are designed to ensure that information required to be disclosed in the reports we file or submit under the Securities Exchange Act of 1934, as amended ("Exchange Act") is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms, and that such information is accumulated and communicated to our management, including the Chief Executive Officer and the Principal Financial and Accounting Officer, to allow timely decisions regarding required disclosures. Any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objective.

As of December 31, 2019, our management, with the participation of our Chief Executive Officer and Chief Finance Officer, performed an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act. Based on this evaluation, our Chief Executive Officer and Chief Finance Officer concluded that, as of December 31, 2019, the design and operation of our disclosure controls and procedures were effective at the reasonable assurance level.

### Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining effective internal control over financial reporting and for the assessment of the effectiveness of internal control over financial reporting. Internal control over financial reporting is a process designed by, or under the supervision of, a company's principal executive officer and principal financial officer and affected by our board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. Our internal control over financial reporting includes those policies and procedures that:

- pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of our assets;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of the consolidated financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the consolidated financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions or the degree of compliance with the policies or procedures may deteriorate.

As of December 31, 2019, our management, with the participation of our Chief Executive Officer and Chief Finance Officer, assessed the effectiveness of our internal control over financial reporting as defined in Rules 13a-15(f) or 15d-15(f) of the Exchange Act. In making its assessment, management used the criteria established in *Internal Control—Integrated Framework* (2013 framework) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on its assessment, our management determined that, as of December 31, 2019, we maintained effective internal control over financial reporting based on those criteria.

In addition, the effectiveness of our internal control over financial reporting as of December 31, 2019 has been audited by Ernst & Young, LLP, an independent registered public accounting firm.

**Changes in Internal Control Over Financial Reporting**

There were no changes in our internal controls over financial reporting during the quarter ended December 31, 2019 that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

**Report of Independent Registered Public Accounting Firm**

To the Stockholders and the Board of Directors of Clovis Oncology, Inc.

**Opinion on Internal Control Over Financial Reporting**
We have audited Clovis Oncology, Inc.'s internal control over financial reporting as of December 31, 2019, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). In our opinion, Clovis Oncology, Inc. (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2019, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company, as of December 31, 2019 and 2018, and the related consolidated statements of operations and comprehensive loss, stockholders' equity (deficit), and cash flows for each of the three years in the period ended December 31, 2019, and the related notes and our report dated February 26, 2020 expressed and unqualified opinion thereon.

**Basis for Opinion**
The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

**Definition and Limitations of Internal Control Over Financial Reporting**
A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ Ernst & Young LLP

Denver, Colorado
February 26, 2020

## ITEM 9B. OTHER INFORMATION

None.

## PART III

Certain information required by Part III is omitted from this Annual Report on Form 10-K and is incorporated herein by reference from our definitive proxy statement relating to our 2019 annual meeting of stockholders, pursuant to Regulation 14A of the Securities Exchange Act of 1934, as amended, also referred to in this Form 10-K as our 2020 Proxy Statement, which we expect to file with the SEC no later than April 29, 2020.

## ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Information regarding our directors, including the audit committee and audit committee financial experts, and executive officers and compliance with Section 16(a) of the Exchange Act will be included in our 2020 Proxy Statement and is incorporated herein by reference.

We have adopted a Code of Business Ethics for all of our directors, officers and employees as required by NASDAQ governance rules and as defined by applicable SEC rules. Stockholders may locate a copy of our Code of Business Ethics on our website at *www.clovisoncology.com* or request a copy without charge from:

Clovis Oncology, Inc.
Attention: Investor Relations
5500 Flatiron Parkway, Suite 100
Boulder, CO 80301

We will post to our website any amendments to the Code of Business Ethics and any waivers that are required to be disclosed by the rules of either the SEC or NASDAQ.

## ITEM 11. EXECUTIVE COMPENSATION

The information required by this item regarding executive compensation will be included in our 2020 Proxy Statement and is incorporated herein by reference.

## ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this item regarding security ownership of certain beneficial owners and management will be included in the 2020 Proxy Statement and is incorporated herein by reference.

## ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by this item regarding certain relationships and related transactions and director independence will be included in the 2020 Proxy Statement and is incorporated herein by reference.

## ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required by this item regarding principal accounting fees and services will be included in the 2020 Proxy Statement and is incorporated herein by reference.

## PART IV

### ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

**(a) The following documents are being filed as part of this report:**

(1) Financial Statements.

Reference is made to the Index to Financial Statements of Clovis Oncology, Inc. appearing on page F-1 of this report.

(2) Financial Statement Schedules.

All financial statement schedules have been omitted because they are not applicable or not required or because the information is included elsewhere in the Financial Statements or the Notes thereto.

(3) Exhibits.

Reference is made to the Index to Exhibits filed as a part of this Annual Report on Form 10-K.

## INDEX TO EXHIBITS

| Exhibit Number | Exhibit Description |
|---|---|
| 3.1(5) | Amended and Restated Certificate of Incorporation of Clovis Oncology, Inc. |
| 3.2(19) | Certificate of Amendment to Amended and Restated Certificate of Incorporation of Clovis Oncology, Inc. |
| 3.3(5) | Amended and Restated Bylaws of Clovis Oncology, Inc. |
| 4.1(3) | Form of Common Stock Certificate of Clovis Oncology, Inc. |
| 4.2(7) | Indenture, dated as of September 9, 2014, by and between the Company and The Bank of New York Mellon Trust Company, N.A. |
| 4.3(14) | Indenture dated as of April 19, 2018, by and between Clovis Oncology, Inc. and The Bank of New York Mellon Trust Company, N.A., as Trustee. |
| 4.4(14) | First Supplemental Indenture dated as of April 19, 2018, by and between Clovis Oncology, Inc. and The Bank of New York Mellon Trust Company, N.A. |
| 4.5(20) | Indenture dated as of August 13, 2019, by and between Clovis Oncology, Inc. and The Bank of New York Mellon Trust Company, N.A., as Trustee |
| 4.6 | Description of the Registrant's Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934 |
| 10.1*(4) | License Agreement, dated as of June 2, 2011, by and between Clovis Oncology, Inc. and Pfizer Inc. |
| 10.2+(1) | Clovis Oncology, Inc. 2009 Equity Incentive Plan. |
| 10.3+(4) | Clovis Oncology, Inc. 2011 Stock Incentive Plan. |
| 10.4+(1) | Form of Clovis Oncology, Inc. 2009 Equity Incentive Plan Stock Option Agreement. |
| 10.5+(4) | Form of Clovis Oncology, Inc. 2011 Stock Incentive Plan Stock Option Agreement. |
| 10.6+(3) | Employment Agreement, dated as of August 24, 2011, by and between Clovis Oncology, Inc. and Patrick J. Mahaffy. |
| 10.7+(3) | Employment Agreement, dated as of August 24, 2011, by and between Clovis Oncology, Inc. and Gillian C. Ivers-Read. |
| 10.8+(1) | Indemnification Agreement, dated as of May 15, 2009, between Clovis Oncology, Inc. and Paul Klingenstein. |
| 10.9+(1) | Indemnification Agreement, dated as of May 15, 2009, between Clovis Oncology, Inc. and James C. Blair. |
| 10.10+(1) | Indemnification Agreement, dated as of May 15, 2009, between Clovis Oncology, Inc. and Edward J. McKinley. |
| 10.11+(1) | Indemnification Agreement, dated as of May 15, 2009, between Clovis Oncology, Inc. and Thorlef Spickschen. |
| 10.12+(1) | Indemnification Agreement, dated as of May 15, 2009, between Clovis Oncology, Inc. and M. James Barrett. |

| Exhibit Number | Exhibit Description |
|---|---|
| 10.13+(1) | Indemnification Agreement, dated as of May 15, 2009, between Clovis Oncology, Inc. and Brian G. Atwood. |
| 10.14+(1) | Indemnification Agreement, dated as of May 12, 2009, between Clovis Oncology, Inc. and Patrick J. Mahaffy. |
| 10.15+(1) | Indemnification Agreement, dated as of May 12, 2009, between Clovis Oncology, Inc. and Erle T. Mast. |
| 10.16+(1) | Indemnification Agreement, dated as of May 12, 2009, between Clovis Oncology, Inc. and Gillian C. Ivers-Read. |
| 10.17+(15) | Clovis Oncology, Inc. 2011 Employee Stock Purchase Plan, as amended. |
| 10.18+(4) | Clovis Oncology, Inc. 2011 Cash Bonus Plan. |
| 10.19+(2) | Indemnification Agreement, dated as of June 13, 2013, between Clovis Oncology, Inc. and Ginger L. Graham. |
| 10.20+(2) | Indemnification Agreement, dated as of June 13, 2013, between Clovis Oncology, Inc. and Keith Flaherty. |
| 10.21(6) | Stock Purchase Agreement, dated as of November 19, 2013, by and among the Company, EOS, the Sellers listed on Exhibit A thereto and Sofinnova Capital V FCPR, acting in its capacity as the Sellers' Representative. |
| 10.22*(6) | Development and Commercialization Agreement, dated as of October 24, 2008, by and between Advenchen Laboratories LLC and Ethical Oncology Science S.P.A., as amended by the First Amendment, dated as of April 13, 2010 and the Second Amendment, dated as of July 30, 2012. |
| 10.23+(10) | Indemnification Agreement, effective as of August 3, 2015, between Clovis Oncology, Inc. and Lindsey Rolfe. |
| 10.24+(17) | Amended and Restated Employment Agreement, dated as of February 27, 2019, by and between Clovis Oncology UK Limited, Clovis Oncology, Inc. and Dr. Lindsey Rolfe. |
| 10.25+(8) | Indemnification Agreement, dated as of February 17, 2016, between Clovis Oncology, Inc. and Daniel W. Muehl. |
| 10.26+(13) | Employment Agreement, dated as of July 6, 2017, by and between Clovis Oncology, Inc. and Daniel Muehl. |
| 10.27*(9) | First Amendment to License Agreement, between Clovis Oncology, Inc. and Pfizer Inc., dated as of August 30, 2016. |
| 10.28+(11) | Form of Clovis Oncology, Inc. 2011 Stock Incentive Plan RSU Agreement. |
| 10.29*(11) | Manufacturing Services Agreement, by and between Clovis Oncology, Inc. and Lonza Ltd, dated as of October 3, 2016. |
| 10.30*(12) | Strata Trial Collaboration Agreement, by and between Clovis Oncology, Inc. and Strata Oncology, Inc., dated as of January 30, 2017. |
| 10.31+(16) | Indemnification Agreement, dated as of October 11, 2018, between Clovis Oncology, Inc. and Robert W. Azelby. |
| 10.32+(16) | Indemnification Agreement, dated as of October 11, 2018, between Clovis Oncology, Inc. and Richard A. Fair. |

| Exhibit Number | Exhibit Description |
|---|---|
| 10.33+(17) | Employment Agreement, dated as of July 6, 2017, by and between Clovis Oncology, Inc. and Paul Gross. |
| 10.34+(17) | Indemnification Agreement, dated as of September 9, 2016, between Clovis Oncology, Inc. and Paul E. Gross. |
| 10.35 (18) | Financing Agreement, dated as of May 1, 2019 among Clovis Oncology, Inc., certain of its subsidiaries named therein, as Guarantors, the Lenders from time to time party thereto, and the Administrative Agent party thereto. |
| 10.36(18) | Pledge and Security Agreement, dated as of May 1, 2019 among each of the Grantors party thereto and the Administrative Agent party thereto. |
| 21.1(15) | List of Subsidiaries of Clovis Oncology, Inc. |
| 23.1 | Consent of Independent Registered Public Accounting Firm. |
| 31.1 | Certification of principal executive officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as amended. |
| 31.2 | Certification of principal financial officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as amended. |
| 32.1 | Certification of principal executive officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. |
| 32.2 | Certification of principal financial officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. |
| 101 | The following materials from Clovis Oncology, Inc.'s Annual Report on Form 10-K for the year ended December 31, 2019 formatted in Inline Extensible Business Reporting Language ("iXBRL"): (i) the Consolidated Statements of Operations and Comprehensive Loss, (ii) the Consolidated Balance Sheets, (iii) the Consolidated Statements of Stockholders' Equity (Deficit), (iv) the Consolidated Statement of Cash Flows and (v) Notes to Consolidated Financial Statements |
| 104 | The cover page from Clovis Oncology, Inc.'s Annual Report on Form 10-K for the year ended December 31, 2019 is formatted in iXBRL. |

(1) Filed as an exhibit with the Registrant's Registration Statement on Form S-1 (File No. 333-175080) on June 23, 2011.
(2) Filed as an exhibit with the Registrant's Current Report on Form 8-K (File No. 001-35347) on June 14, 2013.
(3) Filed as an exhibit with Amendment No. 2 to the Registrant's Registration Statement on Form S-1 (File No. 333-175080) on August 31, 2011.
(4) Filed as an exhibit with Amendment No. 3 to the Registrant's Registration Statement on Form S-1 (File No. 333-175080) on October 31, 2011.
(5) Filed as an exhibit with the Registrant's Annual Report on Form 10-K on March 15, 2012.
(6) Filed as an exhibit with the Registrant's Current Report on Form 8-K (File No. 001-35347) on November 19, 2013.
(7) Filed as an exhibit with the Registrant's Current Report on Form 8-K (File No. 001-35347) on September 9, 2014.
(8) Filed as an exhibit with the Registrant's Current Report on Form 8-K (File No. 001-35347) on April 1, 2016.
(9) Filed as an exhibit with the Registrant's Quarterly Report on Form 10-Q on November 4, 2016.
(10) Filed as an exhibit with the Registrant's Annual Report on Form 10-K on February 29, 2016.
(11) Filed as an exhibit with the Registrant's Annual Report on Form 10-K on February 23, 2017.
(12) Filed as an exhibit with the Registrant's Quarterly Report on Form 10-Q on May 4, 2017.
(13) Filed as an exhibit with the Registrant's Current Report on Form 8-K (File No. 001-35347) on July 7, 2017.
(14) Filed as an exhibit with the Registrant's Current Report on Form 8-K (File No. 001-35347) on April 19, 2018.

(15) Filed as an exhibit with the Registrant's Quarterly Report on Form 10-Q on August 2, 2018.
(16) Filed as an exhibit with the Registrant's Current Report on Form 8-K (File No. 001-35347) on October 12, 2018.
(17) Filed as an exhibit with the Registrant's Annual Report on Form 10-K on February 28, 2019.
(18) Filed as an exhibit with the Registrant's Current Report on Form 8-K (File No. 001-35347) on May 2, 2019.
(19) Filed as an exhibit with the Registrant's Current Report on Form 8-K (File No. 001-35347) on June 6, 2019.
(20) Filed as an exhibit with the Registrant's Current Report on Form 8-K (File No. 001-35347) on August 13, 2019.
+ Indicates management contract or compensatory plan.
* Confidential treatment has been sought or granted with respect to portions of this exhibit, which portions have been omitted and filed separately with the Securities and Exchange Commission.

## INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

**Index to Consolidated Financial Statements**

## Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Clovis Oncology, Inc.

**Opinion on the Financial Statements**
We have audited the accompanying consolidated balance sheets of Clovis Oncology, Inc. (the Company) as of December 31, 2019 and 2018, the related consolidated statements of operations and comprehensive loss, stockholders' equity (deficit), and cash flows for each of the three years in the period ended December 31, 2019, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2019 and 2018, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2019, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2019, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) and our report dated February 26, 2020 expressed an unqualified opinion thereon.

**Adoption of ASU No. 2016-02 and ASU No. 2014-09**
As discussed in Note 2 to the consolidated financial statements, the Company changed its method of accounting for leases in the December 31, 2019 consolidated financial statements due to the adoption of ASU No. 2016-02, *Leases*, and the Company changed its method of accounting for revenue recognition in the December 31, 2018 consolidated financial statements due to the adoption of ASU No. 2014-09, *Revenue from Contracts with Customers*.

**Basis for Opinion**
These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

**Critical Audit Matters**
The critical audit matters communicated below are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of a critical audit matter does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

| | *Research and development accrual* |
|---|---|
| Description of the Matter | At December 31, 2019, the Company accrued $53.2 million of research and development costs. The completeness and valuation of certain clinical study fees incurred in the Company's accrued research and development costs are subject to risk of estimation uncertainty related to services received and efforts expended. As discussed in Note 2 of the Company's consolidated financial statements, costs for certain development activities, such as clinical trials, are recognized based on an evaluation of the progress to completion of specific tasks using data such as patient enrollment, clinical site activations or information provided to the Company by its vendors on their |

actual costs incurred. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred.

Auditing management's accrual of research and development costs was complex and judgmental due to the significant estimation required by management in determining the time period over which services will be performed, enrollment of patients, number of sites activated and the level of effort to be expended in each period. The Company has contracts with multiple contract research organizations ("CROs") that conduct and manage clinical studies on its behalf. The financial terms of these agreements are subject to negotiation and amendment, vary from contract to contract and may result in uneven payment flows.

How We Addressed the Matter in Our Audit

We obtained an understanding, evaluated the design and tested the operating effectiveness of controls over the Company's accounting for accrued research and development costs. For example, we tested controls over management's review of the research and development accrual calculation, including review of the confirmations from CROs, patient enrollment, sites activated, and the associated contract costs.

To test the estimated accrued research and development, we performed audit procedures that included, among others, assessing methodologies and testing the significant assumptions discussed above, testing the underlying data used by management, and assessing the historical accuracy of management's estimates. We performed inquiries of clinical research managers to understand the status of significant trials, discussed any delays or new developments with the studies to understand the impact of the activity on the accounting for the studies, and confirmed directly with CROs the status of significant cost drivers, such as patient enrollment and site activation.

*TPG Financing Agreement*

Description of the Matter

As discussed in Note 10 of the consolidated financial statements, the Company entered into a financing agreement in 2019 in which they plan to borrow amounts required to reimburse actual costs and expenses incurred in the ATHENA clinical trial during each fiscal quarter. They are obligated to make loan payments on a quarterly basis and timing and amount of repayment is dependent on several defined events. The payments are based on a certain percentage of revenues, with a maximum repayment amount each quarter. Therefore, the amounts borrowed and amounts repaid under the loan are variable. Each period, the Company will determine a new effective interest rate based on the revised estimate of expected remaining cash flows. The new effective interest rate will be used to recognize interest expense prospectively for the remaining periods.

Auditing the financing agreement is complex and required the involvement of professionals with specialized skills and knowledge due to the complex terms of the agreement. Additionally, the estimation of future expected cash flows is subjective, and is affected by expected future market or economic conditions. The assessment of these terms and future cash flows has a significant effect on the accounting for the agreement.

How We Addressed the Matter in Our Audit

We obtained an understanding, evaluated the design and tested the operating effectiveness of controls over the Company's accounting for the financing agreement, including management's review of the accounting for the terms of the agreement and the assumptions used in the calculation of the interest rate, including the revenue growth rates and projected clinical expenses incurred.

To test the financing agreement, we performed audit procedures that included, among others, assessing the initial and subsequent accounting for the transaction with the involvement of professionals with specialized skills and knowledge and testing the assumptions underlying the expected cash flows used to calculate the interest rate, including the revenue growth rates and projected clinical expenses incurred. We evaluated the projected cash flows and tested each of the underlying significant

assumptions discussed above. We compared the assumptions used by management to current industry and economic trends and evaluated whether changes to the Company's customer base or product approvals and other factors would affect the assumptions. We also evaluated management's estimation of the probability of whether certain conditions or events, which drive certain accounting conclusions, were probable at December 31, 2019. We assessed the historical accuracy of management's estimates and performed sensitivity analyses of the significant assumptions to evaluate the changes in the calculated interest expense that would result from changes in those assumptions.

We have served as the Company's auditor since 2009.

/s/ Ernst & Young LLP

Denver, Colorado
February 26, 2020

**CLOVIS ONCOLOGY, INC.**

**Consolidated Statements of Operations and Comprehensive Loss**

| | Year ended December 31, | | |
|---|---|---|---|
| | 2019 | 2018 | 2017 |
| | (in thousands, except per share amounts) | | |
| Revenues: | | | |
| Product revenue | $ 143,006 | $ 95,388 | $ 55,511 |
| Operating expenses: | | | |
| Cost of sales - product | 29,926 | 19,444 | 10,251 |
| Cost of sales - intangible asset amortization | 4,760 | 2,630 | 1,486 |
| Research and development | 283,146 | 231,347 | 142,498 |
| Selling, general and administrative | 182,769 | 175,781 | 138,907 |
| Acquired in-process research and development | 9,440 | — | — |
| Other operating expenses | 9,711 | — | — |
| Total expenses | 519,752 | 429,202 | 293,142 |
| Operating loss | (376,746) | (333,814) | (237,631) |
| Other income (expense): | | | |
| Interest expense | (19,405) | (13,183) | (10,428) |
| Foreign currency loss | (547) | (346) | (82) |
| Legal settlement loss | (26,750) | (27,975) | (105,477) |
| Gain on extinguishment of debt | 18,480 | — | — |
| Other income | 6,342 | 7,917 | 3,643 |
| Other income (expense), net | (21,880) | (33,587) | (112,344) |
| Loss before income taxes | (398,626) | (367,401) | (349,975) |
| Income tax (expense) benefit | (1,798) | (608) | 3,578 |
| Net loss | (400,424) | (368,009) | (346,397) |
| Other comprehensive income (loss): | | | |
| Foreign currency translation adjustments, net of tax | (272) | (2,543) | 5,517 |
| Net unrealized gain (loss) on available-for-sale securities, net of tax | 41 | 82 | (110) |
| Other comprehensive (loss) income: | (231) | (2,461) | 5,407 |
| Comprehensive loss | $ (400,655) | $ (370,470) | $ (340,990) |
| | | | |
| Loss per basic and diluted common share: | | | |
| Basic and diluted net loss per common share | $ (7.43) | $ (7.07) | $ (7.36) |
| Basic and diluted weighted average common shares outstanding | 53,873 | 52,066 | 47,047 |

See accompanying Notes to Consolidated Financial Statements.

**CLOVIS ONCOLOGY, INC.**

**Consolidated Balance Sheets**

| | December 31, 2019 | December 31, 2018 |
|---|---|---|
| **ASSETS** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 161,833 | $ 221,876 |
| Accounts receivable, net | 20,562 | 12,889 |
| Inventories, net | 26,519 | 27,072 |
| Available-for-sale securities | 134,826 | 298,270 |
| Prepaid research and development expenses | 3,881 | 3,579 |
| Other current assets | 18,847 | 8,613 |
| Total current assets | 366,468 | 572,299 |
| Inventories | 98,053 | 113,908 |
| Deposit on inventory | 12,350 | 12,350 |
| Property and equipment, net | 15,287 | 26,524 |
| Right-of-use assets, net | 28,141 | — |
| Intangible assets, net | 62,920 | 51,930 |
| Goodwill | 63,074 | 63,074 |
| Other assets | 23,311 | 23,475 |
| Total assets | $ 669,604 | $ 863,560 |
| **LIABILITIES AND STOCKHOLDERS' EQUITY** | | |
| Current liabilities: | | |
| Accounts payable | $ 32,237 | $ 28,517 |
| Accrued research and development expenses | 53,214 | 29,676 |
| Lease liabilities | 5,405 | — |
| Other accrued expenses | 42,228 | 67,556 |
| Total current liabilities | 133,084 | 125,749 |
| Long-term lease liabilities - less current portion | 29,479 | — |
| Convertible senior notes | 644,751 | 575,470 |
| Borrowings under financing agreement | 34,991 | — |
| Other long-term liabilities | 1,556 | 15,872 |
| Total liabilities | 843,861 | 717,091 |
| Commitments and contingencies (Note 13) | | |
| Stockholders' equity: | | |
| Preferred stock, par value $0.001 per share; 10,000,000 shares authorized, no shares issued and outstanding at December 31, 2019 and December 31, 2018 | — | — |
| Common stock, $0.001 par value per share, 200,000,000 and 100,000,000 shares authorized at December 31, 2019 and December 31, 2018, respectively; 54,956,341 and 52,797,516 shares issued and outstanding at December 31, 2019 and December 31, 2018, respectively | 55 | 53 |
| Additional paid-in capital | 2,114,068 | 2,034,142 |
| Accumulated other comprehensive loss | (44,865) | (44,634) |
| Accumulated deficit | (2,243,515) | (1,843,092) |
| Total stockholders' (deficit) equity | (174,257) | 146,469 |
| Total liabilities and stockholders' equity (deficit) | $ 669,604 | $ 863,560 |

See accompanying Notes to Consolidated Financial Statements.

**CLOVIS ONCOLOGY, INC.**

**Consolidated Statements of Stockholders' Equity (Deficit)**

| | Common Stock | | Additional Paid-In | Accumulated Other Comprehensive | Accumulated | |
|---|---|---|---|---|---|---|
| | Shares | Amount | Capital | Income (Loss) | Deficit | Total |
| | (in thousands, except for share amounts) | | | | | |
| Balance at January 1,2017 | 38,724,090 | $ 39 | $ 1,174,948 | $ (47,580) | $ (1,131,042) | $ (3,635) |
| Issuance of common stock, net of issuance costs | 9,670,454 | 10 | 545,828 | — | — | 545,838 |
| Issuance of common stock under employee stock purchase plan | 51,681 | — | 2,313 | — | — | 2,313 |
| Exercise of stock options | 465,658 | 1 | 13,924 | — | — | 13,925 |
| Issuance of common stock from vesting of restricted stock units | 180,912 | — | — | — | — | — |
| Share-based compensation expense | — | — | 44,707 | — | — | 44,707 |
| Legal settlement | 1,472,324 | 1 | 105,476 | — | — | 105,477 |
| Net unrealized loss on available-for-sale securities | — | — | — | (110) | — | (110) |
| Foreign currency translation adjustments | — | — | — | 5,517 | — | 5,517 |
| Net loss | — | — | — | — | (346,397) | (346,397) |
| Balance at December 31, 2017 | 50,565,119 | 51 | 1,887,196 | (42,173) | (1,477,439) | 367,635 |
| Issuance of common stock, net of issuance costs | 1,837,898 | 2 | 93,888 | — | — | 93,890 |
| Issuance of common stock under employee stock purchase plan | 82,820 | — | 2,097 | — | — | 2,097 |
| Exercise of stock options | 72,886 | — | 1,870 | — | — | 1,870 |
| Issuance of common stock from vesting of restricted stock units | 238,793 | — | — | — | — | — |
| Share-based compensation expense | — | — | 49,090 | — | — | 49,090 |
| Net unrealized gain on available-for-sale securities | — | — | — | 82 | — | 82 |
| Foreign currency translation adjustments | — | — | — | (2,543) | — | (2,543) |
| Adoption of new revenue recognition standard | — | — | — | — | 2,357 | 2,357 |
| Net loss | — | — | — | — | (368,009) | (368,009) |
| Balance at December 31, 2018 | 52,797,516 | 53 | 2,034,141 | (44,634) | (1,843,091) | 146,469 |
| Issuance of common stock under employee stock purchase plan | 175,634 | — | 1,905 | — | — | 1,905 |
| Exercise of stock options | 188,829 | — | 1,361 | — | — | 1,361 |
| Issuance of common stock from vesting of restricted stock units | 312,304 | — | — | — | — | — |
| Share-based compensation expense | — | — | 54,304 | — | — | 54,304 |
| Legal settlement | 1,482,058 | 2 | 22,745 | — | — | 22,747 |
| Net unrealized gain on available-for-sale securities | — | — | — | 41 | — | 41 |
| Foreign currency translation adjustments | — | — | — | (272) | — | (272) |
| Other financing costs | — | — | (388) | — | — | (388) |
| Net loss | — | — | — | — | (400,424) | (400,424) |
| Balance at December 31, 2019 | 54,956,341 | $ 55 | $ 2,114,068 | $ (44,865) | $ (2,243,515) | $ (174,257) |

See accompanying Notes to Consolidated Financial Statements.

**CLOVIS ONCOLOGY, INC.**

**Consolidated Statements of Cash Flows**

| | Year ended December 31, | | |
|---|---|---|---|
| | 2019 | 2018 | 2017 |
| | (in thousands) | | |
| **Operating activities** | | | |
| Net loss | $ (400,424) | $ (368,009) | $ (346,397) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | | |
| Share-based compensation expense | 54,304 | 49,090 | 44,707 |
| Depreciation and amortization | 7,768 | 4,601 | 2,504 |
| Amortization of premiums and discounts on available-for-sale securities | (1,521) | 1,345 | 354 |
| Amortization of debt issuance costs | 2,858 | 2,178 | 1,279 |
| Legal settlement loss | 22,747 | — | 105,477 |
| Gain on extinguishment of debt | (18,480) | — | — |
| Loss on sale of property and equipment | 804 | — | — |
| Deferred income taxes | — | — | (3,218) |
| Changes in operating assets and liabilities: | | | |
| Accounts receivable | (7,518) | (3,371) | (6,061) |
| Inventory | (26,160) | (49,936) | (27,508) |
| Prepaid and accrued research and development expenses | 23,233 | 9,145 | (17,297) |
| Deposit on inventory | — | (12,350) | (20,461) |
| Other operating assets and liabilities | (6,837) | (8,750) | (6,476) |
| Accounts payable | 12,289 | 5,770 | 5,637 |
| Other accrued expenses | 13,322 | 4,290 | 6,556 |
| Net cash used in operating activities | (323,615) | (365,997) | (260,904) |
| **Investing activities** | | | |
| Purchases of property and equipment | (3,290) | (9,242) | (487) |
| Proceeds from sale of property and equipment | 275 | — | — |
| Deposits for sale of property and equipment | — | — | (2,515) |
| Purchases of available-for-sale securities | (459,835) | (500,000) | (263,500) |
| Sales of available-for-sale securities | 621,998 | 300,000 | 213,500 |
| Acquired in-process research and development - milestone payment | (15,750) | (55,000) | (1,100) |
| Net cash provided by (used in) investing activities | 143,398 | (264,242) | (54,102) |
| **Financing activities** | | | |
| Proceeds from the sale of common stock, net of issuance costs | — | 93,890 | 545,838 |
| Proceeds from the issuance of convertible senior notes, net of issuance costs | 254,879 | 290,887 | — |
| Proceeds from borrowings under financing agreement, net of issuance costs | 32,871 | — | — |
| Proceeds from the exercise of stock options and employee stock purchases | 3,266 | 3,967 | 16,237 |
| Payments on capital leases | (1,115) | (245) | — |
| Extinguishment of convertible senior notes | (169,853) | — | — |
| Payments on other long-term liabilities | (160) | (35) | — |
| Net cash provided by financing activities | 119,888 | 388,464 | 562,075 |
| Effect of exchange rate changes on cash and cash equivalents | 286 | (547) | 943 |
| (Decrease) increase in cash and cash equivalents | (60,043) | (242,322) | 248,012 |
| Cash and cash equivalents at beginning of period | 221,876 | 464,198 | 216,186 |
| Cash and cash equivalents at end of period | $ 161,833 | $ 221,876 | $ 464,198 |
| Supplemental disclosure of cash flow information: | | | |
| Cash paid for interest | $ 10,515 | $ 9,188 | $ 7,188 |
| Non-cash investing and financing activities: | | | |
| Vesting of restricted stock units | $ 5,442 | $ 10,808 | $ 12,170 |

See accompanying Notes to Consolidated Financial Statements.

**CLOVIS ONCOLOGY, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**1. Nature of Business**

We are a biopharmaceutical company focused on acquiring, developing and commercializing innovative anti-cancer agents in the United States, Europe and additional international markets. We target our development programs for the treatment of specific subsets of cancer populations, and simultaneously develop, with partners, for those indications that require them, diagnostic tools intended to direct a compound in development to the population that is most likely to benefit from its use.

Our marketed product Rubraca® (rucaparib), an oral small molecule inhibitor of poly ADP-ribose polymerase ("PARP"), is marketed in the United States for two indications specific to recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer. The initial indication received approval from the FDA in December 2016 and covers the treatment of adult patients with deleterious BRCA (human genes associated with the repair of damaged DNA) mutation (germline and/or somatic)-associated epithelial ovarian, fallopian tube, or primary peritoneal cancer who have been treated with two or more chemotherapies and selected for therapy based on an FDA-approved companion diagnostic for Rubraca. In April 2018, the FDA also approved Rubraca for the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy. The approval in this second, broader and earlier-line indication on a priority review timeline was based on positive data from the phase 3 ARIEL3 clinical trial. Diagnostic testing is not required for patients to be prescribed Rubraca in this maintenance treatment indication. We hold worldwide rights to Rubraca.

In May 2018, the European Commission granted a conditional marketing authorization for Rubraca as monotherapy treatment of adult patients with platinum-sensitive, relapsed or progressive, BRCA mutated (germline and/or somatic), high-grade epithelial ovarian, fallopian tube, or primary peritoneal cancer, who have been treated with two or more prior lines of platinum-based chemotherapy, and who are unable to tolerate further platinum-based chemotherapy. This conditional approval requires the completion of certain confirmatory post marketing commitments. In January 2019, the European Commission granted a variation to the marketing authorization to include the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy. With this approval, Rubraca is now authorized in the EU for certain patients in the recurrent ovarian cancer maintenance setting regardless of their BRCA mutation status. Following successful reimbursement negotiations in each country, commercial launches of Rubraca are underway in each of Germany, England, Italy and France and planned in Spain shortly.

In addition to Rubraca, we have a second product candidate currently in clinical development. Lucitanib is an investigational, oral, potent inhibitor of the tyrosine kinase activity of vascular endothelial growth factor receptors 1 through 3 ("VEGFR1-3"), platelet-derived growth factor receptors alpha and beta ("PDGFR α/β") and fibroblast growth factor receptors 1 through 3 ("FGFR1-3"). We believe that data for a drug similar to lucitanib that inhibits these same pathways – when combined with a PD-1 inhibitor – represent a scientific rationale for development of lucitanib in combination with a PD-1 inhibitor, and in February 2019, lucitanib was added to our clinical collaboration with BMS. Encouraging data of VEGF and PARP inhibitors in combination also supports the evaluation of lucitanib combined with Rubraca. Thus, currently enrolling Phase 1b/2 combination studies involving lucitanib consist of the Clovis-sponsored LIO-1 study of lucitanib in combination with nivolumab in advanced gynecologic cancers and other solid tumors and an arm of the Clovis-sponsored SEASTAR study evaluating lucitanib in combination with Rubraca in advanced solid tumors. In addition to the LIO-1 study, the BMS-sponsored Phase 1/2 study CheckMate 79X is planned to initiate in early 2020 to evaluate multiple combinations of nivolumab with other therapies, including an arm with lucitanib in patients with second-line non-small cell lung cancer. We hold the global (excluding China) development and commercialization rights for lucitanib.

In September 2019, we entered into a license and collaboration agreement with 3BP to develop a peptide-targeted radionuclide therapy ("PTRT") and imaging agent targeting fibroblast-activating protein alpha ("FAP"). FAP is highly expressed by cancer-associated fibroblasts found in a majority of tumor types, potentially making it a suitable target across a wide array of solid tumors. PTRT is an emerging class of drugs and it involves the injection of a small amount of radioactive material – a radionuclide – that is combined with a cancer-targeting peptide for use as a targeted radiopharmaceutical. The targeting peptide is able to recognize and bind to specific receptors on the cancer cell, such as

antigens and cell receptors. When used in a targeted radiopharmaceutical, the peptide is designed to attach to cancer cells, and the intended result is to deliver a high dose of radiation to the tumor while sparing normal tissue because of its rapid systemic clearance. In order for the targeted radiopharmaceutical to be safe and efficacious, it must rapidly attach to cancer cells or in close vicinity to the cancer cells, be retained in or at the tumor site for a sufficient period of time that the radionuclide can have activity on the cancer cells, have minimal attachment to non-cancer cells and then be rapidly cleared from the body.

Following completion of preclinical work to support an IND for the lead candidate under our license and collaboration agreement, designated internally as FAP-2286, we plan to conduct global clinical trials. We anticipate submitting the IND in the second half of 2020 to support an initial Phase 1 study to determine the dose and tolerability of FAP-2286 as a therapeutic agent. We hold U.S. and global rights to FAP-2286, excluding Europe (inclusive of Russia, Turkey and Israel), where 3BP retains rights. We also have agreed with 3BP to collaborate on a discovery program directed to up to three additional, undisclosed targets for peptide-targeted radionuclide therapy, to which we would obtain global rights for any resulting product candidates.

**Liquidity**

We have incurred significant net losses since inception and have relied on our ability to fund our operations through debt and equity financings. We expect operating losses and negative cash flows to continue for the foreseeable future. As we continue to incur losses, transition to profitability is dependent upon achieving a level of revenue from Rubraca adequate to support our cost structure. We may never achieve profitability, and unless and until we do, we will continue to need to raise additional cash.

On May 1, 2019, we entered into a financing agreement in aggregate amount up to $175.0 million whereby we expect to borrow amounts required to reimburse our actual expenses incurred during each fiscal quarter, as such expenses are incurred, related to our ATHENA trial. We have agreed to repay the aggregate borrowed amount plus a return from revenues generated from sales of Rubraca on a quarterly basis, which is anticipated to begin in 2022. See Note 10, *Long-term Debt*, for additional information.

In August 2019, we completed a private placement to qualified institutional buyers of $263.0 million aggregate principal amount of 2024 Notes resulting in net proceeds to us of $254.9 million, after deducting underwriting discounts and commissions and offering expenses. We used $171.8 million of the total $254.9 million net proceeds from the offering to repurchase $190.3 million principal amount of the 2021 Notes in privately negotiated transactions with a limited number of holders. We intend to use the remaining net proceeds from this offering for general corporate purposes, including sales and marketing expenses associated with Rubraca, funding of our development programs, payment of milestones pursuant to our license agreements, general and administrative expenses, acquisition or licensing of additional product candidates or businesses, repurchase or repayment of other debt obligations and working capital.

In January 2020, we completed a registered direct offering of 17,777,679 shares of our common stock at a price of $9.25 per share to a limited number of holders of our 2024 Notes. We used the proceeds of the offering to repurchase from such holders an aggregate of $123.4 million principal amount of 2024 Notes in privately negotiated transactions. In addition, we paid customary fees and expenses in connection with the transactions.

Based on current estimates, we believe that our existing cash, cash equivalents and available-for-sale securities will allow us to fund our operating plan through at least the next 12 months.

**2. Summary of Significant Accounting Policies**

**Basis of Presentation**

The accompanying financial statements have been prepared in accordance with U.S. generally accepted accounting principles ("U.S. GAAP"). The consolidated financial statements include our accounts and our wholly-owned subsidiaries. All significant intercompany balances and transactions have been eliminated in consolidation.

**Use of Estimates**

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, expenses and revenue and related disclosures. On an ongoing basis, we evaluate our estimates, including estimates related to revenue deductions, intangible asset impairment, clinical trial accruals and share-based compensation expense. We base our estimates on historical experience and other market-specific or other relevant assumptions that we believe to be reasonable under the circumstances. Actual results may differ from those estimates or assumptions.

**Revenue Recognition**

We are currently approved to sell Rubraca in the United States and the EU markets. We distribute our product principally through a limited number of specialty distributor and specialty pharmacy providers, collectively, our customers. Our customers subsequently sell our products to patients and health care providers. Separately, we have arrangements with certain payors and other third-parties that provide for government-mandated and privately-negotiated rebates, chargebacks and discounts. See Note 3, *Revenue Recognition*.

**Cost of Sales – Product**

Product cost of sales consists primarily of materials, third-party manufacturing costs as well as freight and royalties owed to our licensing partners for Rubraca sales.

**Cost of Sales – Intangible Asset Amortization**

Cost of sales for intangible asset amortization consists of the amortization of capitalized milestone payments made to our licensing partners upon FDA approval of Rubraca. Milestone payments are amortized on a straight-line basis over the estimated remaining patent life of Rubraca.

**Fair Value of Financial Instruments**

Cash, cash equivalents, available-for-sale securities and contingent purchase consideration are carried at fair value. Financial instruments, including other current assets and accounts payable, are carried at cost, which approximates fair value given their short-term nature (see Note 5, *Fair Value Measurements*).

**Cash, Cash Equivalents and Available-for-Sale Securities**

We consider all highly liquid investments with original maturities at the date of purchase of three months or less to be cash equivalents. Cash and cash equivalents include bank demand deposits and money market funds that invest primarily in certificate of deposits, commercial paper and U.S. government and U.S. government agency obligations.

Marketable securities are considered to be available-for-sale securities and consist of U.S. treasury securities. Available-for-sale securities are reported at fair value on the Consolidated Balance Sheets and unrealized gains and losses are included in accumulated other comprehensive income/loss on the Consolidated Balance Sheets. Realized gains and losses, amortization of premiums and discounts and interest and dividends earned are included in other income (expense) on the Consolidated Statements of Operations and Comprehensive Loss. The cost of investments for purposes of computing realized and unrealized gains and losses is based on the specific identification method. Investments with maturities beyond one year are classified as short-term based on our intent to fund current operations with these securities or to make them available for current operations.

A decline in the market value of a security below its cost that is deemed to be other than temporary is charged to earnings and results in the establishment of a new cost basis for the security. Factors evaluated to determine if an investment is other-than-temporarily impaired include significant deterioration in earnings performance, credit rating, asset quality or business prospects of the issuer; adverse changes in the general market conditions in which the issuer operates; and our intent and ability to hold the security until an anticipated recovery in value occurs.

**Accounts Receivable**

As of December 31, 2019 and 2018, we had no allowance for doubtful accounts. We provide an allowance for doubtful accounts based on experience and specifically identified risks. Accounts receivable are carried at fair value and charged off against the allowance for doubtful accounts when we determine that recovery is unlikely and we cease collection efforts.

**Inventory**

Inventories are stated at the lower of cost or estimated net realizable value, on a first-in, first-out ("FIFO") basis. Inventories include active pharmaceutical ingredient ("API"), contract manufacturing costs and overhead allocations. We began capitalizing incurred inventory related costs upon the regulatory approval of Rubraca. Prior to the regulatory approval of Rubraca, we incurred costs for the manufacture of the drug that could potentially be available to support the commercial launch of Rubraca and all such costs were recognized as research and development expense.

We regularly analyze our inventory levels for excess quantities and obsolescence (expiration), considering factors such as historical and anticipated future sales compared to quantities on hand and the remaining shelf-life of Rubraca. Rubraca finished goods have a shelf-life of four years from the date of manufacture. We expect to sell the finished goods prior to expiration. The API currently has a shelf-life of four years from the date of manufacture but can be retested at an immaterial cost with no expected reduction in potency, thereby extending its shelf-life as needed. We expect to consume substantially all of the API over a period of approximately nine years based on our long-range sales projections of Rubraca.

We write down inventory that has become obsolete, inventory that has a cost basis in excess of its estimated realizable value and/or inventory in excess of expected sales requirements. Expired inventory would be disposed of and the related costs would be written off as cost of product revenue. Inventories that are not expected to be consumed within 12 months following the balance sheet date are classified as long-term inventories. Long-term inventories primarily consist of API.

API is currently produced by Lonza. As the API has undergone significant manufacturing specific to its intended purpose at the point it is purchased by us, we classify the API as work-in-process inventory. In addition, we currently manufacture Rubraca finished goods with a single third-party manufacturer. The disruption or termination of the supply of API or the disruption or termination of the manufacturing of our commercial products could have a material adverse effect on our business, financial position and results of operations. API that is written off due to damage and certain costs related to our dedicated production train at Lonza are included in Other Operating Expenses in the Consolidated Statements of Operations and Comprehensive Loss.

Inventory used in clinical trials is expensed as research and development expense when it has been identified for such use.

**Property and Equipment**

Property and equipment are stated at cost, less accumulated depreciation. Property and equipment are depreciated using the straight-line method over the estimated useful lives of the assets. Equipment purchased for use in manufacturing and clinical trials is evaluated to determine whether the equipment is solely beneficial for a drug candidate in the development stage or whether it has an alternative use. Equipment with an alternative use is capitalized. Leased assets meeting certain finance lease criteria are capitalized and the present value of the related lease payments is recorded as a liability. Assets under finance lease arrangements are depreciated using the straight-line method over the estimated useful lives. Leasehold improvements are amortized over the economic life of the asset or the lease term,

whichever is shorter. Maintenance and repairs are expensed as incurred. The estimated useful lives of our capitalized assets are as follows:

| | Estimated Useful Life |
|---|---|
| Computer hardware and software | 3 to 5 years |
| Leasehold improvements | 6 years |
| Laboratory, manufacturing and office equipment | 5 to 7 years |
| Furniture and fixtures | 10 years |

**Long-Lived Assets**

We review long-lived assets for impairment when events or changes in circumstances indicate that the carrying value of the assets may not be recoverable. Recoverability is measured by comparison of the assets' book value to future net undiscounted cash flows that the assets are expected to generate. If the carrying value of the assets exceed their future net undiscounted cash flows, an impairment charge is recognized for the amount by which the carrying value of the assets exceeds the fair value of the assets.

**Intangible Assets, Net**

Definite-lived intangible assets related to capitalized milestones under license agreements are amortized on a straight-line basis over their remaining useful lives, which are estimated to be the remaining patent life. If our estimate of the product's useful life is shorter than the remaining patent life, then a shorter period is used. Amortization expense is recorded as a component of cost of sales on the Consolidated Statements of Operations and Comprehensive Loss.

Intangible assets are evaluated for impairment at least annually in the fourth quarter or more frequently if impairment indicators exist. Events that could result in an impairment, or trigger an interim impairment assessment, include the decision to discontinue the development of a drug, the receipt of additional clinical or nonclinical data regarding our drug candidate or a potentially competitive drug candidate, changes in the clinical development program for a drug candidate, or new information regarding potential sales for the drug. In connection with any impairment assessment, the fair value of the intangible assets as of the date of assessment is compared to the carrying value of the intangible asset. Impairment losses are recognized if the carrying value of an intangible asset is both not recoverable and exceeds its fair value.

**Goodwill**

Goodwill represents the excess of the purchase price over the fair value of net assets acquired in a business combination accounted for under the acquisition method of accounting and is not amortized, but is subject to impairment testing at least annually in the fourth quarter or when a triggering event is identified that could indicate a potential impairment. We are organized as a single reporting unit and perform impairment testing by comparing the carrying value of the reporting unit to the fair value of the Company. Goodwill was recorded as a result of the EOS acquisition in November 2013.

**Other Current Assets**

Other current assets are comprised of the following (in thousands):

| | December 31, 2019 | December 31, 2018 |
|---|---|---|
| Prepaid insurance | $ 505 | $ 243 |
| Prepaid advertising | — | 1,802 |
| Prepaid IT | 698 | 666 |
| Prepaid expenses - other | 3,371 | 2,672 |
| Value-added tax ("VAT") receivable | 11,920 | — |
| Receivable - other | 2,176 | 2,274 |
| Other | 177 | 956 |
| Total | $ 18,847 | $ 8,613 |

**Other Accrued Expenses**

Other accrued expenses are comprised of the following (in thousands):

| | December 31, 2019 | December 31, 2018 |
|---|---|---|
| Accrued personnel costs | $ 16,915 | $ 15,265 |
| Accrued interest payable | 5,903 | 2,721 |
| Income tax payable | 3,505 | 847 |
| Accrued corporate legal fees and professional services | 310 | 677 |
| Accrued royalties | 6,038 | 4,854 |
| Accrued variable considerations | 5,748 | 2,183 |
| Current portion of capital lease obligations | — | 1,031 |
| Purchase of API received not yet invoiced | — | 35,472 |
| Accrued expenses - other | 3,809 | 4,506 |
| Total | $ 42,228 | $ 67,556 |

**Research and Development Expense**

Research and development costs are charged to expense as incurred and include, but are not limited to, salary and benefits, share-based compensation, clinical trial activities, drug development and manufacturing, companion diagnostic development and third-party service fees, including contract research organizations and investigative sites.

Costs for certain development activities, such as clinical trials, are recognized based on an evaluation of the progress to completion of specific tasks using data such as patient enrollment, clinical site activations or information provided to us by our vendors on their actual costs incurred. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred and are reflected on the Consolidated Balance Sheets as prepaid or accrued research and development expenses.

**Acquired In-Process Research and Development Expense**

We have acquired and expect to continue to acquire the rights to develop and commercialize new drug candidates. The upfront payments to acquire a new drug compound, as well as subsequent milestone payments, are immediately expensed as acquired in-process research and development provided that the drug has not achieved regulatory approval for marketing and, absent obtaining such approval, has no alternative future use. Once regulatory approval is received, payments to acquire rights, and the related milestone payments, are capitalized and the amortization of such assets recorded to product cost of sales.

**Share-Based Compensation Expense**

Share-based compensation is recognized as expense for all share-based awards made to employees and directors and is based on estimated fair values. We determine equity-based compensation at the grant date using the Black-Scholes option pricing model. The value of the award that is ultimately expected to vest is recognized as expense on a straight-line basis over the requisite service period. Any changes to the estimated forfeiture rates are accounted for prospectively.

**Advertising Expense**

In connection with the FDA approval and commercial launch of Rubraca in 2016, we began to incur advertising costs. Advertising costs are expense when services are performed or goods are delivered. We incurred $21.2 million, $15.9 million and $11.7 million in expense for the years ended December 31, 2019, 2018 and 2017, respectively.

**Legal Settlement Loss**

Following our regulatory announcement in November 2015 of adverse developments in our ongoing clinical trials for rociletinib, we and certain of our current and former executives were named in various securities lawsuits. As a result of these lawsuits, during 2019, we recorded a charge of $26.8 million to settle the Antipodean Complaint. During 2018, we recorded a charge of $8.0 million related to an agreement to resolve a potential litigation claim against us and our

officers and we also recorded a charge of $20.0 million related to an agreement reached with the SEC to resolve its investigation. During 2017, we recorded a $105.5 million legal settlement loss, net of insurance receivable, related to a stipulation agreement of settlement whereby we issued the plaintiff and participating class members a total consideration comprised of $25.0 million in cash and the issuance of 1.5 million shares. The cash portion of the consideration was funded by our insurance carriers. For the remaining actions related to rociletinib, see Note 13, *Commitments and Contingencies*, for additional information.

**Concentration of Credit Risk**

Financial instruments that potentially subject us to concentrations of credit risk are primarily cash, cash equivalents and available-for-sale securities. We maintain our cash and cash equivalent balances in the form of money market accounts with financial institutions that we believe are creditworthy. Available-for-sale securities are invested in accordance with our investment policy. The investment policy includes guidelines on the quality of the institutions and financial instruments and defines allowable investments that we believe minimizes the exposure to concentration of credit risk. We have no financial instruments with off-balance sheet risk of accounting loss.

**Foreign Currency**

The assets and liabilities of our foreign operations are translated into U.S. dollars at current exchange rates and the results of operations are translated at the average exchange rates for the reported periods. The resulting translation adjustments are included in accumulated other comprehensive loss on the Consolidated Balance Sheets. Transactions denominated in currencies other than the functional currency are recorded based on exchange rates at the time such transactions arise. Transaction gains and losses are recorded to foreign currency gains (losses) on the Consolidated Statements of Operations and Comprehensive Loss. As of December 31, 2019 and 2018, approximately 4% and 6%, respectively, of our total liabilities were denominated in currencies other than the functional currency.

**Income Taxes**

We account for income taxes under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases using enacted tax rates in effect for the year in which the differences are expected to affect taxable income. Tax benefits are recognized when it is more likely than not that a tax position will be sustained during an audit. Deferred tax assets are reduced by a valuation allowance if current evidence indicates that it is considered more likely than not that these benefits will not be realized.

**Recently Adopted Accounting Standards**

We adopted ASU 2016-02, “Leases (Topic 842)”, as of January 1, 2019 using the modified retrospective method which leaves the comparative period reporting unchanged. Comparative reporting periods are presented in accordance with Topic 840, while periods subsequent to the effective date are presented in accordance with Topic 842. We have elected to adopt the package practical expedient which allows us: 1) to not reassess whether any expired or existing contracts are or contain leases, 2) to not reassess the lease classification for any expired or existing leases and 3) to not reassess initial direct costs for any existing leases. We also elected not to recognize on the balance sheet leases with terms of 12 months or less. For these short-term leases, we will recognize the lease payments in profit or loss on a straight-line basis over the lease term and the variable lease payments in the period in which the obligation for those payments is incurred.

Adoption of the new lease standard resulted in the recording of net right-of-use assets and lease liabilities of $24.9 million and $31.4 million, respectively, as of January 1, 2019.

In February 2018, the Financial Accounting Standards Board (“FASB”) issued ASU 2018-02, “Income Statement – Reporting Comprehensive Income (Topic 220): Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income”, which allow a reclassification from accumulated other comprehensive income (loss) (“AOCI”) to retained earnings for stranded tax effects resulting from the change in the U.S. federal corporate income tax rate on the gross deferred tax amounts at the date of enactment of the Tax Cuts and Jobs Act of 2017 (the “2017 Tax Act”). The guidance is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. We adopted the new standard on January 1, 2019 and elected not to reclassify the income tax effects of the Tax

Act from AOCI to retained earnings. We continue to release disproportionate income tax effects from AOCI based on the aggregate portfolio approach. The adoption of this standard did not have an impact on our consolidated financial statements.

In June 2018, the FASB issued ASU 2018-07, "Compensation – Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting", simplifies the accounting for share-based payment granted to nonemployees for goods and services. Under the standard, most of the guidance on such payments to nonemployees would be aligned with the requirements for share-based payments granted to employees. The guidance is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. We adopted ASU 2018-07 as of January 1, 2019. There was no material impact on our consolidated financial statements and related disclosures.

In December 2019, the FASB issued ASU No. 2019-12, Income Taxes (Topic 740), "Simplifying the Accounting for Income Taxes", which removes certain exceptions to the general principles of ASC 740 and improves consistent application of and simplifies GAAP for other areas of Topic 740 by clarifying and amending existing guidance. The Company early adopted ASU 2019-12 effective the quarter ended December 31, 2019. There was no material impact on our consolidated financial statements and related disclosures.

Effective January 1, 2018, we adopted ASC Topic 606, "Revenue from Contracts with Customers". Upon adoption, we recognized revenue when our customers, the specialty distributors and specialty pharmacy providers, take control of our product. This resulted in us recognizing revenue approximately two to four weeks earlier than before adopting the new standard. We used the modified retrospective method to adopt the new standard. This means that we did not restate previously issued financial statements, but recorded a one-time adjustment to retained earnings of $2.4 million. This adjustment represents the sales of our product to our customers prior to January 1, 2018, that had not been sold to patients or healthcare providers, offset by related gross-to-net adjustments and other direct costs, including royalties and sales incentive compensation.

**Recently Issued Accounting Standards**

From time to time, the FASB or other standards setting bodies issue new accounting pronouncements. Updates to the FASB Accounting Standards Codification ("ASC") are communicated through issuance of an ASU.

In June 2016, the FASB issued ASU 2016-13, "Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments". The guidance is effective for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years. Early adoption is permitted. We will adopt ASU 2016-13 as of January 1, 2020 and we expect to recognize an allowance for credit losses related to our available-for-sale securities and accounts receivable. Upon the adoption of ASU 2016-13 on January 1, 2020, we are required to determine whether a decline in the fair value below the amortized cost basis (i.e., impairment) of an available-for-sale debt is security is due to credit-related factors or noncredit-related factors. Any impairment that is not credit related is recognized in accumulated other comprehensive loss, net of applicable taxes. When evaluating an impairment, entities may not use the length of time a security has been in an unrealized loss position as a factor, either by itself or in combination with other factors, to conclude that a credit loss does not exist. We applied this impairment model for available-for-sale debt securities as of January 1, 2020 and no impairment was recognized upon adoption. In addition, we expect to recognize a minimal allowance for credit losses related to our accounts receivable.

In August 2018, the FASB issued ASU 2018-13, "Fair Value Measurement (Topic 820): Disclosure Framework – Changes to the Disclosure Requirements for Fair Value Measurement". The guidance is effective for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years. We will adopt ASU 2018-02 as of January 1, 2020. We don't anticipate a material impact on our consolidated financial statements and related disclosures.

**3. Revenue Recognition**

We are currently approved to sell Rubraca in the United States and the EU markets. We distribute our product principally through a limited number of specialty distributor and specialty pharmacy providers, collectively, our customers. Our customers subsequently sell our products to patients and health care providers. We do not believe the loss of one of these customers would significantly impact the ability to distribute our product as we expect that sales volume would be absorbed evenly by the remaining customers. Separately, we have arrangements with certain payors and other third parties that provide for government-mandated and privately-negotiated rebates, chargebacks and discounts.

*Product Revenue*

Revenue from product sales are recognized when the performance obligation is satisfied, which is when customers obtain control of our product at a point in time, typically upon delivery. We expense incremental costs of obtaining a contract as and when incurred if the expected amortization period of the asset that we would have recognized is one year or less.

*Reserves for Variable Consideration*

Revenues from product sales are recorded at the net sales price (transaction price), which includes estimates of variable consideration for which reserves are established and which result from price concessions that include rebates, chargebacks, discounts, co-pay assistance, estimated product returns and other allowances that are offered within contracts between us and our customers, health care providers, payors and other indirect customers relating to the sales of our product. These reserves are based on the amounts earned or to be claimed on the related sales and are classified as reductions of accounts receivable (if the amount is payable to the customers) or a current liability (if the amount is payable to a party other than a customer). Where appropriate, these estimates take into consideration a range of possible outcomes which are probability-weighted for relevant factors such as our historical experience, current contractual and statutory requirements, specific known market events and trends, industry data and forecasted customer buying and payment patterns. Overall, these reserves reflect our best estimates of the amount of consideration to which we are entitled based on the terms of the contract. The amount of variable consideration which is included in the transaction price may be constrained and is included in the net sales price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. Actual amounts of consideration ultimately received may differ from our estimates. If actual results in the future vary from our estimates, we adjust these estimates, which would affect product revenue and earnings in the period such variances become known.

*Rebates*. Rebates include mandated discounts under the Medicaid Drug Rebate Program and the Medicare coverage gap program. Rebates are amounts owed after the final dispensing of products to a benefit plan participant and are based upon contractual agreements or legal requirements with the public-sector benefit providers. These reserves are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability which is included in accrued expenses on the Consolidated Balance Sheets. We estimate our Medicaid and Medicare rebates based upon a range of possible outcomes that are probability-weighted for the estimated payor mix. The accrual is based on the expected utilization from historical data we have accumulated since the Rubraca product launch. Rebates are generally invoiced and paid quarterly in arrears so that the accrual balance consists of an estimate of the amount expected to be incurred for the current quarter's activity, plus an accrual balance for known or estimated prior quarters' unpaid rebates.

*Chargebacks*. Chargebacks are discounts that occur when contracted customers, which currently consist primarily of group purchasing organizations, Public Health Service organizations and federal government entities purchasing via the Federal Supply Schedule, purchase directly from our specialty distributors at a discounted price. The specialty distributor, in turn, charges back the difference between the price initially paid by the specialty distributor and the discounted price paid to the specialty distributor by the healthcare provider. These reserves are established in the same period that the related revenue is recognized, resulting in a reduction of product revenue and accounts receivable. The accrual for specialty distributor chargebacks is estimated based on known chargeback rates and known sales to specialty distributors adjusted for the estimated utilization by healthcare providers.

*Discounts and Fees*. Our payment terms are generally 30 days. Specialty distributors and specialty pharmacies are offered various forms of consideration, including service fees and prompt pay discounts for payment within a specified

period. We expect these customers will earn prompt pay discounts and therefore, we deduct the full amount of these discounts and service fees from product sales when revenue is recognized.

*Co-pay assistance*. Patients who have commercial insurance and meet certain eligibility requirements may receive co-pay assistance. The intent of this program is to reduce the patient's out of pocket costs. Liabilities for co-pay assistance are based on actual program participation provided by third-party administrators at month end.

*Returns*. Consistent with industry practice, we generally offer customers a right of return limited only to product that will expire in six months or product that is six months beyond the expiration date. To date, we have had minimal product returns and we currently do not have an accrual for product returns. We will continue to assess our estimate for product returns as we gain additional historical experience.

For the year ended December 31, 2019 and 2018, we recognized $143.0 million and $95.4 million, respectively, of product revenue. Based on our policy to expense costs associated with the manufacture of our products prior to regulatory approval, certain of the costs of Rubraca units recognized as revenue during the year ended December 31, 2017 were expensed prior to the December 19, 2016 FDA approval, and a minimal amount was included in cost of sales during the year ended December 31, 2017. The majority of product sales were of pre-commercialization inventory in 2017. Cost of sales increased in 2018 in relation to product revenue as we depleted these inventories.

Product revenue from each of our customers who individually accounted for 10% or more of total revenues consisted of the following:

| | December 31, 2019 | December 31, 2018 |
|---|---|---|
| Customer A | 25% | 31% |
| Customer B | 20% | 24% |
| Customer C | 15% | 13% |
| Customer D | 12% | 12% |
| Customer E | 10% | 7% |

**4. Property and Equipment**

Property and equipment consisted of the following (in thousands):

| | December 31, | |
|---|---|---|
| | 2019 | 2018 |
| Laboratory, manufacturing and office equipment | $ 1,290 | $ 2,913 |
| Leasehold improvements | 16,946 | 15,204 |
| Leased equipment at Lonza | — | 9,971 |
| Furniture and fixtures | 2,805 | 2,424 |
| Computer hardware and software | 1,699 | 1,329 |
| Total property and equipment | 22,740 | 31,841 |
| Less: accumulated depreciation | (7,453) | (5,317) |
| Total property and equipment, net | $15,287 | $26,524 |

Upon the adoption of ASU 2016-02, "Leases (Topic 842)" on January 1, 2019, we recognized the leased equipment at Lonza as a finance lease, which resulted in recording a right-of-use asset on the balance sheet. The leased equipment at Lonza is included in right-of-use assets, net on the Consolidated Balance Sheets.

Depreciation expense related to property and equipment was approximately $3.0 million, $2.0 million and $1.0 million for the years ended December 31, 2019, 2018 and 2017, respectively.

**5. Fair Value Measurements**

Fair value is defined as the exchange price that would be received to sell an asset or paid to transfer a liability (at exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. The three levels of inputs that may be used to measure fair value include:

Level 1: Quoted prices in active markets for identical assets or liabilities. Our Level 1 assets consist of money market investments. We do not have Level 1 liabilities.

Level 2: Observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities in active markets or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities. Our Level 2 assets consist of U.S. treasury securities. We do not have Level 2 liabilities.

Level 3: Unobservable inputs that are supported by little or no market activity. We do not have Level 3 assets or liabilities.

The following table identifies our assets that were measured at fair value on a recurring basis (in thousands):

| | Balance | Level 1 | Level 2 | Level 3 |
|---|---|---|---|---|
| **December 31, 2019** | | | | |
| Assets: | | | | |
| Money market | $ 61,882 | $ 61,882 | $ — | $ — |
| U.S. treasury securities | 189,736 | 54,910 | 134,826 | — |
| Total assets at fair value | $251,618 | $116,792 | $134,826 | $ — |
| **December 31, 2018** | | | | |
| Assets: | | | | |
| Money market | $ 81,968 | $ 81,968 | $ — | $ — |
| U.S. treasury securities | 308,251 | 9,981 | 298,270 | — |
| Total assets at fair value | $390,219 | $ 91,949 | $298,270 | $ — |

There were no liabilities that were measured at fair value on a recurring basis as of December 31, 2019.

Financial instruments not recorded at fair value include our convertible senior notes. At December 31, 2019, the carrying amount of the 2021 Notes was $96.4 million, which represents the aggregate principal amount net of remaining debt issuance costs, and the fair value was $85.8 million. At December 31, 2019, the carrying amount of the 2024 Notes was $255.4 million, which represents the aggregate principal amount net of remaining debt issuance costs, and the fair value was $366.1 million. At December 31, 2019, the carrying amount of the 2025 Notes was $293.0 million, which represents the aggregate principal amount net of remaining debt issuance costs, and the fair value was $190.0 million. The fair value was determined using Level 2 inputs based on the indicative pricing published by certain investment banks or trading levels of the convertible senior notes, which are not listed on any securities exchange or quoted on an inter-dealer automated quotation system. See Note 10, *Long-term Debt* for discussion of the convertible senior notes. The carrying amounts of accounts payable and accrued expenses approximate their fair value due to their short-term maturities.

**6. Available-for-Sale Securities**

As of December 31, 2019, available-for-sale securities consisted of the following (in thousands):

| | Amortized Cost | Gross Unrealized Gains | Gross Unrealized Losses | Aggregate Fair Value |
|---|---|---|---|---|
| U.S. treasury securities | $ 134,826 | $ — | $ — | $ 134,826 |

As of December 31, 2018, available-for-sale securities consisted of the following (in thousands):

| | | Gross | Gross | Aggregate |
|---|---|---|---|---|

| | Amortized Cost | Unrealized Gains | Unrealized Losses | Fair Value |
|---|---|---|---|---|
| U.S. treasury securities | $ 298,305 | $ — | $ (35) | $ 298,270 |

As of December 31, 2019, the fair value and gross unrealized losses of available-for-sale securities that have been in a continuous unrealized loss position for less than 12 months were as follows (in thousands):

| | Aggregate Fair Value | Gross Unrealized Losses |
|---|---|---|
| U.S. treasury securities | $ 60,033 | $ (9) |

As of December 31, 2019, there were no available-for-sale securities that have been in a continuous unrealized loss position for more than 12 months.

As of December 31, 2019, the amortized cost and fair value of available-for-sale securities by contractual maturity were (in thousands):

| | Amortized Cost | Fair Value |
|---|---|---|
| Due in one year or less | $ 134,826 | $ 134,826 |
| Due in one year to two years | — | — |
| Total | $ 134,826 | $ 134,826 |

**7. Inventories**

The following table presents inventories as of December 31, 2019 and December 31, 2018 (in thousands):

| | December 31, 2019 | December 31, 2018 |
|---|---|---|
| Work-in-process | $ 104,139 | $ 126,620 |
| Finished goods, net | 20,433 | 14,360 |
| Total inventories | $ 124,572 | $ 140,980 |

Some of the costs related to our finished goods on-hand as of December 31, 2018 were expensed as incurred prior to the commercialization of Rubraca on December 19, 2016.

At December 31, 2019, we had $26.5 million of current inventory and $98.1 million of long-term inventory. In addition, we had $12.4 million long-term deposit on inventory, which consists of advanced intermediate, which is the inventory prior to conversion to API.

**8. Intangible Assets**

At December 31, 2019 and 2018, intangible assets related to capitalized milestones under license agreements consisted of the following (in thousands):

| | December 31, 2019 | December 31, 2018 |
|---|---|---|
| Intangible asset - milestones | $ 71,850 | $ 56,100 |
| Accumulated amortization | (8,930) | (4,170) |
| Total intangible asset, net | $ 62,920 | $ 51,930 |

The increase in our intangible asset – milestones since December 31, 2018 is due to a $15.0 million milestone payment to Pfizer related to the January 2019 European Commission approval and a $0.75 million milestone payment in June 2019 due to the launch of Rubraca as maintenance therapy in Germany in March 2019. See Note 14, *License Agreements* for further discussion of these approvals.

The estimated useful lives of these intangible assets are based on the estimated remaining patent life of Rubraca and

extend through 2031 in Europe and 2035 in the U.S.

We recorded an amortization expense of $4.8 million and $2.6 million related to capitalized milestone payments during the year ended December 31, 2019 and December 31, 2018, respectively. Amortization expense is included in cost of sales – intangible asset amortization on the Consolidated Statements of Operations and Comprehensive Loss.

Estimated future amortization expense for intangible assets as of December 31, 2019 is as follows (in thousands):

| | |
|---|---|
| 2020 | $ 4,847 |
| 2021 | 4,847 |
| 2022 | 4,847 |
| 2023 | 4,847 |
| 2024 | 4,847 |
| Thereafter | 38,685 |
| | $ 62,920 |

**9. Lease**

At the inception of an arrangement, we determine whether the arrangement is or contains a lease based on the unique facts and circumstances. Most leases with a term greater than one year are recognized on the balance sheet as right-of-use assets, lease liabilities and, if applicable, long-term lease liabilities. We elected not to recognize on the balance sheet leases with terms of one year or less. Lease liabilities and their corresponding right-of-use assets are recorded based on the present value of lease payments over the expected lease term. The interest rate implicit in lease contracts is typically not readily determinable. As such, we utilize the appropriate incremental borrowing rate, which is the rate incurred to borrow on a collateralized basis over a similar term at an amount equal to the lease payments in a similar economic environment. Certain adjustments to the right-of-use asset may be required for items such as initial direct costs paid or incentives received.

The components of a lease should be split into three categories: lease components (e.g. land, building, etc.), non-lease components (e.g. common area maintenance, maintenance, consumables, etc.) and non-components (e.g. property taxes, insurance, etc.). Then the fixed and in-substance fixed contract consideration (including any related to non-components) must be allocated based on fair values assigned to the lease components and non-lease components.

Our facilities operating leases have lease components, non-lease components and non-components, which we have separated because the non-lease components and non-components have variable lease payments and are excluded from the measurement of the lease liabilities. The lease component results in a right-of-use asset being recorded on the balance sheet and amortized as lease expense on a straight-line basis to the statements of operations.

We lease all of our office facilities in the U.S. and Europe. Leases with an initial term of 12 months or less are not recorded on the balance sheet; we recognize lease expense for these leases on a straight-line basis over the lease term. Most leases include one or more options to renew. The exercise of lease renewal options is at our sole discretion. Our lease agreements do not contain any material residual value guarantees or material restrictive covenants.

We have a finance lease for certain equipment at the dedicated production train at Lonza, our non-exclusive manufacturer of the Rubraca API.

The components of lease expense and related cash flows were as follows (in thousands):

| | Year ended December 31, 2019 |
|---|---|
| **Lease cost** | |
| Finance lease cost: | |
| Amortization of right-of-use assets | $ 1,898 |
| Interest on lease liabilities | 759 |
| Operating lease cost | 4,003 |
| Short-term lease cost | 301 |

| | | |
|---|---|---|
| Variable lease cost | | 2,261 |
| **Total lease cost** | $ | 9,222 |
| | | |
| Operating cash flows from finance leases | $ | 759 |
| Operating cash flows from operating leases | $ | 4,003 |
| Financing cash flows from finance leases | $ | 1,115 |

The weighted-average remaining lease term and weighted-average discount rate were as follows:

| | December 31, 2019 |
|---|---|
| Weighted-average remaining lease term (years) | |
| Operating leases | 6.9 |
| Finance leases | 6.0 |
| Weighted-average discount rate | |
| Operating leases | 8% |
| Finance leases | 8% |

Future minimum commitments due under these lease agreements as of December 31, 2019 are as follows (in thousands):

| | Operating Leases | Finance Leases | Total |
|---|---|---|---|
| 2020 | 5,735 | 2,287 | 8,022 |
| 2021 | 5,684 | 2,287 | 7,971 |
| 2022 | 3,428 | 2,287 | 5,715 |
| 2023 | 2,989 | 2,287 | 5,276 |
| 2024 | 2,943 | 2,287 | 5,230 |
| Thereafter | 10,865 | 2,287 | 13,152 |
| Present value adjustment | (7,630) | (2,852) | (10,482) |
| Present value of lease payments | $ 24,014 | $ 10,870 | $ 34,884 |

**10. Long-term Debt**

***2021 Notes***

In September 2014, we completed a private placement of $287.5 million aggregate principal amount of 2.5% convertible senior notes due 2021 (the "2021 Notes") resulting in net proceeds of $278.3 million after deducting offering expenses. In accordance with the accounting guidance, the conversion feature did not meet the criteria for bifurcation, and the entire principal amount was recorded as a long-term liability on the Consolidated Balance Sheets.

The 2021 Notes are governed by the terms of the indenture between the Company, as issuer, and The Bank of New York Mellon Trust Company, N.A., as trustee. The 2021 Notes are senior unsecured obligations and bear interest at a rate of 2.5% per year, payable semi-annually in arrears on March 15 and September 15 of each year. The 2021 Notes will mature on September 15, 2021, unless earlier converted, redeemed or repurchased.

Holders may convert all or any portion of the 2021 Notes at any time prior to the close of business on the business day immediately preceding the maturity date. Upon conversion, the holders will receive shares of our common stock at an initial conversion rate of 16.1616 shares per $1,000 in principal amount of 2021 Notes, equivalent to a conversion price of approximately $61.88 per share. The conversion rate is subject to adjustment upon the occurrence of certain events described in the indenture. In addition, following certain corporate events that occur prior to the maturity date or upon our issuance of a notice of redemption, we will increase the conversion rate for holders who elect to convert the 2021 Notes in connection with such a corporate event or during the related redemption period in certain circumstances.

On or after September 15, 2018, we may redeem the 2021 Notes, at our option, in whole or in part, if the last reported sale price of our common stock has been at least 150% of the conversion price then in effect for at least 20 trading days

(whether or not consecutive) during any 30 consecutive trading day period ending not more than two trading days preceding the date on which we provide written notice of redemption at a redemption price equal to 100% of the principal amount of the 2021 Notes to be redeemed plus accrued and unpaid interest to, but excluding, the redemption date. No sinking fund is provided for the 2021 Notes.

If we undergo a fundamental change, as defined in the indenture, prior to the maturity date of the 2021 Notes, holders may require us to repurchase for cash all or any portion of the 2021 Notes at a fundamental change repurchase price equal to 100% of the principal amount of the 2021 Notes to be repurchased plus accrued and unpaid interest, to, but excluding, the fundamental change repurchase date.

The 2021 Notes rank senior in right of payment to any of our indebtedness that is expressly subordinated in right of payment to the 2021 Notes; equal in right of payment to all of our liabilities that are not so subordinated; effectively junior in right of payment to any secured indebtedness to the extent of the value of the assets securing such indebtedness; and structurally junior to all indebtedness and other liabilities (including trade payables) of our subsidiaries.

Concurrently with the 2024 Notes offering, in separate transactions, we entered into privately negotiated transactions with a limited number of holders to repurchase, for settlement in August 2019, $190.3 million aggregate principal amount of our outstanding 2021 Notes for an aggregate repurchase price of $171.8 million, including accrued interest. This repurchase resulted in the recognition of $18.5 million gain on extinguishment of debt.

In connection with the issuance of the 2021 Notes, we incurred $9.2 million of debt issuance costs, of which $2.0 million of unamortized debt issuance costs were derecognized in connection with the repurchase of the 2021 Notes. The remaining debt issuance costs are presented as a deduction from the convertible senior notes on the Consolidated Balance Sheets and are amortized as interest expense over the expected life of the 2021 Notes using the effective interest method. We determined the expected life of the debt was equal to the seven-year term of the 2021 Notes.

***2025 Notes***

In April 2018, we completed an underwritten public offering of $300.0 million aggregate principal amount of 1.25% convertible senior notes due 2025 (the "2025 Notes") resulting in net proceeds of $290.9 million, after deducting underwriting discounts and commissions and offering expenses. In accordance with the accounting guidance, the conversion feature did not meet the criteria for bifurcation, and the entire principal amount was recorded as a long-term liability on the Consolidated Balance Sheets.

The 2025 Notes are governed by the terms of the indenture between the Company, as issuer, and The Bank of New York Mellon Trust Company, N.A., as trustee, as supplemented by the terms of that certain first supplemental indenture thereto. The 2025 Notes are senior unsecured obligations and bear interest at a rate of 1.25% per year, payable semi-annually in arrears on May 1 and November 1 of each year. The 2025 Notes will mature on May 1, 2025, unless earlier converted, redeemed or repurchased.

Holders may convert all or any portion of the 2025 Notes at any time prior to the close of business on the business day immediately preceding the maturity date. Upon conversion, the holders will receive shares of our common stock at an initial conversion rate of 13.1278 shares per $1,000 in principal amount of 2025 Notes, equivalent to a conversion price of approximately $76.17 per share. The conversion rate is subject to adjustment upon the occurrence of certain events described in the indenture. In addition, following certain corporate events that occur prior to the maturity date or upon our issuance of a notice of redemption, we will increase the conversion rate for holders who elect to convert the 2025 Notes in connection with such a corporate event or during the related redemption period in certain circumstances.

On or after May 2, 2022, we may redeem the 2025 Notes, at our option, in whole or in part, if the last reported sale price of our common stock has been at least 150% of the conversion price then in effect for at least 20 trading days (whether or not consecutive) during any 30 consecutive trading day period ending not more than two trading days preceding the date on which we provide written notice of redemption at a redemption price equal to 100% of the principal amount of the 2025 Notes to be redeemed plus accrued and unpaid interest to, but excluding, the redemption date. No sinking fund is provided for the 2025 Notes.

If we undergo a fundamental change, as defined in the indenture, prior to the maturity date of the 2025 Notes, holders may require us to repurchase for cash all or any portion of the 2025 Notes at a fundamental change repurchase price

equal to 100% of the principal amount of the 2025 Notes to be repurchased plus accrued and unpaid interest to, but excluding, the fundamental change repurchase date.

The 2025 Notes rank senior in right of payment to any of our indebtedness that is expressly subordinated in right of payment to the 2025 Notes; equal in right of payment to all of our liabilities that are not so subordinated, including the 2021 Notes; effectively junior in right of payment to any secured indebtedness to the extent of the value of the assets securing such indebtedness; and structurally junior to all indebtedness and other liabilities (including trade payables) of our subsidiaries.

In connection with the issuance of the 2025 Notes, we incurred $9.1 million of debt issuance costs. The debt issuance costs are presented as a deduction from the convertible senior notes on the Consolidated Balance Sheets and are amortized as interest expense over the expected life of the 2025 Notes using the effective interest method. We determined the expected life of the debt was equal to the seven-year term of the 2025 Notes.

***2024 Notes***

In August 2019, we completed a private placement to qualified institutional buyers of $263.0 million aggregate principal amount of 4.50% convertible senior notes due 2024 (the "2024 Notes") resulting in net proceeds of $254.9 million, after deducting underwriting discounts and commissions and offering expenses. In accordance with the accounting guidance, the conversion feature did not meet the criteria for bifurcation, and the entire principal amount was recorded as a long-term liability on the Consolidated Balance Sheets.

The 2024 Notes are governed by the terms of the indenture between the Company, as issuer, and The Bank of New York Mellon Trust Company, N.A., as trustee. The 2024 Notes are senior unsecured obligations and bear interest at a rate of 4.50% per year, payable semi-annually in arrears on February 1 and August 1 of each year. The 2024 Notes will mature on August 1, 2024, unless earlier repurchased or converted.

Holders may convert all or any portion of the 2024 Notes at any time prior to the close of business on the business day immediately preceding the maturity date. Upon conversion, the holders will receive shares of our common stock at an initial conversion rate of 137.2213 shares per $1,000 in principal amount of 2024 Notes, equivalent to a conversion price of approximately $7.29 per share. The conversion rate is subject to adjustment upon the occurrence of certain events described in the indenture. In addition, following certain corporate events that occur prior to the maturity date or upon our issuance of a notice of redemption, we will increase the conversion rate for holders who elect to convert the 2024 Notes in connection with such a corporate event or during the related redemption period in certain circumstances.

We will not have the right to redeem the 2024 Notes prior to their maturity. If we undergo a fundamental change, as defined in the indenture, prior to the maturity date of the 2024 Notes, holders may require us to repurchase for cash all or any portion of the 2024 Notes at a fundamental change repurchase price equal to 100% of the principal amount of the 2024 Notes to be repurchased plus accrued and unpaid interest to, but excluding, the fundamental change repurchase date. No sinking fund is provided for the 2024 Notes.

The 2024 Notes rank senior in right of payment to any of our indebtedness that is expressly subordinated in right of payment to the 2024 Notes; equal in right of payment to all of our liabilities that are not so subordinated, including the 2021 Notes and 2025 Notes; effectively junior in right of payment to any secured indebtedness to the extent of the value of the assets securing such indebtedness, including our borrowing under the TPG financing agreement; and structurally junior to all indebtedness and other liabilities (including trade payables) of our subsidiaries.

In connection with the issuance of the 2024 Notes, we incurred $8.0 million of debt issuance costs. The debt issuance costs are presented as a deduction from the convertible senior notes on the Consolidated Balance Sheets and are amortized as interest expense over the expected life of the 2024 Notes using the effective interest method. We determined the expected life of the debt was equal to the five-year term of the 2024 Notes.

As of December 31, 2019 and 2018, the balance of unamortized debt issuance costs related to the 2021 Notes, 2025 Notes and 2024 Notes was $15.4 million and $12.0 million, respectively.

In January 2020, we completed a registered direct offering of an aggregate 17,777,679 shares of our common stock at a price of $9.25 per share to a limited number of holders of our 2024 Notes. We used the proceeds of the share offering

to repurchase from such holders an aggregate of $123.4 million principal amount of 2024 Notes in privately negotiated transactions. In addition, we paid customary fees and expenses in connection with the transactions. Following these transactions, an aggregate $139.6 million principal amount of 2024 Notes remains outstanding and $3.5 million of unamortized debt issuance costs were derecognized.

The following is a summary of our convertible senior notes at December 31, 2019:

| | Interest Rate | Principal Amount (in thousands) | Due Date |
|---|---|---|---|
| 2021 Notes | 2.50% | $ 97,188 | September 15, 2021 |
| 2025 Notes | 1.25% | 300,000 | May 1, 2025 |
| 2024 Notes | 4.50% | 263,000 | August 1, 2024 |
| Total | | $ 660,188 | |

***TPG Financing Agreement***

On May 1, 2019, we entered into a financing agreement (the "Financing Agreement") with certain affiliates of TPG Sixth Street Partners, LLC ("TPG") in which we plan to borrow from TPG amounts required to reimburse our actual costs and expenses incurred during each fiscal quarter (limited to agreed budgeted amounts), as such expenses are incurred, related to the ATHENA clinical trial, in an aggregate amount of up to $175 million (the amount actually borrowed, the "Borrowed Amount"). ATHENA is our largest clinical trial, with a planned target enrollment of 1,000 patients across more than 270 sites in at least 25 countries. The Clovis-sponsored phase 3 ATHENA study in advanced ovarian cancer is the first-line maintenance treatment setting evaluating Rubraca plus nivolumab (PD-1 inhibitor), Rubraca, nivolumab and a placebo in newly-diagnosed patients who have completed platinum-based chemotherapy. This study initiated in the second quarter of 2018 and is currently enrolling patients.

We expect to incur borrowings under the Financing Agreement on a quarterly basis, beginning with such expenses incurred during the quarter ended March 31, 2019 and ending generally on the earliest to occur of (i) the termination of the ATHENA Trial, (ii) the date of completion of all activities under the ATHENA Trial Clinical Study Protocol, (iii) the date on which we pay the Discharge Amount (as defined in the Financing Agreement), (iv) the date of the occurrence of a change of control of us (or a sale of all or substantially all of our assets related to Rubraca) or our receipt of notice of certain breaches by us of our obligations under material in-license agreements related to Rubraca and (v) September 30, 2022.

We are obligated to repay on a quarterly basis, beginning on the earliest to occur of (i) the termination of the ATHENA Trial, (ii) the approval by the FDA of an update to the label portion of the Rubraca new drug application ("NDA") to include in such label the treatment of an indication resulting from the ATHENA Trial, (iii) the date on which we determine that the results of the ATHENA Trial are insufficient to achieve such an expansion of the Rubraca label to cover an indication based on the ATHENA Trial and (iv) September 30, 2022 (the "Repayment Start Date").

- 9.75% (which rate may be increased incrementally up to approximately 10.25% in the event the Borrowed Amount exceeds $166.5 million) of the direct Rubraca net sales recorded by us and our subsidiaries worldwide and our future out-licensees in the United States, if any, during such quarter;

- 19.5% of any royalty payments received by us and our subsidiaries during such quarter based on the sales of Rubraca by our future out-licensees outside the United States, if any; and

- 19.5% of any other amounts received by us and our subsidiaries in connection with any other commercialization arrangement for Rubraca, including any upfront and milestone payments and proceeds of infringement claims (which payments are not subject to the caps described below).

Quarterly payments are capped at $8.5 million, unless the label portion of the Rubraca NDA is expanded by the FDA to include such label the treatment of an indication resulting from the ATHENA Trial, in which case the quarterly payment is capped at $13.5 million. In the event the aggregate Borrowed Amount exceeds $166.5 million, such quarterly limits will be incrementally increased to a maximum of approximately $8.94 million and $14.19 million, respectively. The maximum amount required to be repaid under the agreement is two times the aggregate Borrowed Amount, which may be $350 million in the event we borrow the full $175 million under the Financing Agreement.

In the event we have not made payments on or before December 30, 2025 equal to at least the Borrowed Amount, we are required to make a lump sum payment in an amount equal to such Borrowed Amount less the aggregate of all prior quarterly payments described above. All other payments are contingent on the performance of Rubraca. There is no final maturity date on the Financing Agreement.

Our obligations under the Financing Agreement will be secured under a Pledge and Security agreement by a first priority security interest in all of our assets related to Rubraca, including intellectual property rights and a pledge of the equity of our wholly owned subsidiaries, Clovis Oncology UK Limited and Clovis Oncology Ireland Limited. In addition, the obligations will initially be guaranteed by Clovis Oncology UK Limited and Clovis Oncology Ireland Limited, secured by a first priority security interest in all the assets of those subsidiaries.

Pursuant to the Financing Agreement, we have agreed to certain limitations on our operations, including limitations on making certain restricted junior payments, including payment of dividends, limitation on liens and certain limitations on the ability of our non-guarantor subsidiaries to own certain assets related to Rubraca and to incur indebtedness.

We may terminate the Financing Agreement at any time by paying the lenders an amount (the "Discharge Amount") equal to the sum of (a) (A) the greater of (x) the Borrowed Amount plus (i) if such date is during calendar year 2019, $35 million or (ii) if such date is during calendar year 2020 or thereafter, $50 million and (y) (i) if such date is prior to the Repayment Start Date, 1.75 times the Borrowed Amount or (ii) if such date is after the Repayment Start Date, 2.00 times the Borrowed Amount minus (B) the aggregate amount of all quarterly payments previously paid to the lenders plus (b) all other obligations which have accrued but which have not been paid under the loan documents, including expense reimbursement.

In the event of (i) a change of control of us, we must pay the Discharge Amount to the lenders and (ii) an event of default under the Financing Agreement (which includes, among other events, breaches or defaults under or terminations of our material in-license agreements related to Rubraca and defaults under our other material indebtedness), the lenders have the right to declare the Discharge Amount to be immediately due and payable.

For the year ended December 31, 2019, we recorded $35.0 million as a long-term liability on the Consolidated Balance Sheets and future quarterly draws will be recorded as a long-term liability on the Consolidated Balance Sheets. In connection with the transaction, we incurred $1.8 million of debt issuance costs. The debt issuance costs are presented as a deduction from the TPG financing liability on the Consolidated Balance Sheets and are amortized as interest expense over the expected life of the Financing Agreement using the straight-line method. As of December 31, 2019, the balance of unamortized debt issuance costs was $1.6 million.

For the year ended December 31, 2019, we used an effective interest rate of 14.5%. For subsequent periods, we will use the prospective method whereby a new effective interest rate is determined based on the revised estimate of remaining cash flows. The new rate is the discount rate that equates the present value of the revised estimate of remaining cash flows with the carrying amount of the debt, and it will be used to recognize interest expense for the remaining periods. Under this method, the effective interest rate is not constant, and any change in expected cash flows is recognized prospectively as an adjustment to the effective yield.

The following table sets forth total interest expense recognized during the years ended December 31, 2019, 2018 and 2017 (in thousands):

| | Year ended December 31, | | |
|---|---|---|---|
| | 2019 | 2018 | 2017 |
| Interest on convertible notes | $13,680 | $ 9,812 | $ 7,188 |
| Amortization of debt issuance costs | 2,858 | 2,178 | 1,279 |
| Interest on finance lease | 759 | — | — |
| Interest on borrowings under financing agreement | 1,997 | — | — |
| Accretion of interest on milestone liability | — | 977 | 1,961 |
| Interest on capital lease liability | — | 216 | — |
| Other interest | 111 | — | — |
| Total interest expense | $19,405 | $13,183 | $10,428 |

**11. Stockholders' Equity**

**Common Stock**

In January 2017, we sold 5,750,000 shares of our common stock in a public offering at $41.00 per share. The net proceeds from the offering were $221.2 million, after deducting underwriting discounts and commissions and offering expenses.

In June 2017, we sold 3,920,454 shares of our common stock in a public offering at $88.00 per share. The net proceeds from the offering were $324.6 million, after deducting underwriting discounts and commissions and offering expenses.

In April 2018, we sold 1,837,898 shares of our common stock in a public offering at $54.41 per share. The net proceeds from the offering were $93.9 million, after deducting underwriting discounts and commissions and offering expenses.

The holders of common stock are entitled to one vote per share on all matters to be voted upon by our stockholders. Subject to the preferences that may be applicable to any outstanding shares of preferred stock, the holders of common stock are entitled to receive ratably such dividends, if any, as may be declared by our Board of Directors.

**Accumulated Other Comprehensive Loss**

Accumulated other comprehensive loss consists of changes in foreign currency translation adjustments, which includes changes in a subsidiary's functional currency, and unrealized gains and losses on available-for-sale securities.

The changes in accumulated balances related to each component of other comprehensive income (loss) are summarized as follows (in thousands):

| | Foreign Currency Translation Adjustments | Unrealized (Losses) Gains | Total Accumulated Other Comprehensive Loss |
|---|---|---|---|
| Balance at December 31, 2017 | $ (41,917) | $ (256) | $ (42,173) |
| Other comprehensive income (loss) | (2,543) | 82 | (2,461) |
| Total before tax | (44,460) | (174) | (44,634) |
| Tax effect | — | — | — |
| Balance at December 31, 2018 | (44,460) | (174) | (44,634) |
| Other comprehensive income (loss) | (272) | 41 | (231) |
| Total before tax | (44,732) | (133) | (44,865) |
| Tax effect | — | — | — |
| Balance at December 31, 2019 | $ (44,732) | $ (133) | $ (44,865) |

The period change in each of the periods was primarily due to the foreign currency translation of the goodwill and deferred income taxes associated with the acquisition of EOS in November 2013. There were no reclassifications out of accumulated other comprehensive loss in the years ended December 31, 2019, 2018 and 2017.

Effective October 1, 2018, substantially all assets and activities related to EOS were transferred from our Italian subsidiary to the U.S. This had the impact of changing the functional currency of goodwill from the Euro to USD. Therefore, the balance of goodwill will no longer change due to foreign currency gains and losses.

**12. Share-Based Compensation**

**Stock Options**

In August 2011, our Board of Directors approved the 2011 Stock Incentive Plan (the "2011 Plan"), which became effective upon the closing of our initial public offering in November 2011. The 2011 Plan provides for the granting of incentive and nonqualified stock options, stock appreciation rights, restricted stock, restricted stock units, performance awards and other share-based awards to our employees, directors and consultants. Common shares authorized for issuance under the 2011 Plan were 13,816,124 at December 31, 2019, which represents the initial reserve of 1,250,000 shares of common stock plus 191,496 shares of common stock remaining for future grant from the 2009 Equity Incentive Plan (the "2009 Plan"), which was terminated upon the closing of our initial public offering in November 2011, and 12,374,628 new shares authorized by the Board of Directors at the annual meetings of stockholders. Future forfeitures and cancellations of options previously granted under the 2009 Plan were transferred to and also available for grant under the 2011 Plan. Stock options granted vest ratably over either a one-year period or three-year period for Board of Director grants. Employee stock options generally vest over a four-year period with 25% of the options cliff-vesting after year one and the remaining options vesting ratably over each subsequent month. All stock options expire 10 years from the date of grant.

Share-based compensation expense for the years ended December 31, 2019, 2018 and 2017, respectively, was recognized in the accompanying Consolidated Statements of Operations and Comprehensive Loss as follows (in thousands):

| | Year ended December 31, | | |
|---|---|---|---|
| | 2019 | 2018 | 2017 |
| Research and development | $25,838 | $20,489 | $ 20,335 |
| Selling, general and administrative | 28,466 | 28,601 | 24,372 |
| Total share-based compensation expense | $54,304 | $49,090 | $ 44,707 |

We did not recognize a tax benefit related to share-based compensation expense during the years ended December 31, 2019, 2018 and 2017 as we maintain net operating loss carryforwards and have established a valuation allowance against the entire net deferred tax asset as of December 31, 2019.

The following table summarizes the activity relating to our options to purchase common stock:

| | Number of Options | Weighted Average Exercise Price | Weighted Average Remaining Contractual Term (Years) | Aggregate Intrinsic Value (Thousands) |
|---|---|---|---|---|
| Outstanding at December 31, 2018 | 6,311,513 | $ 46.05 | | |
| Granted | 1,079,112 | 18.52 | | |
| Exercised | (188,829) | 7.21 | | |
| Forfeited | (914,771) | 47.82 | | |
| Outstanding at December 31, 2019 | 6,287,025 | $ 42.24 | 6.0 | $ 1,951 |
| Vested and expected to vest at December 31, 2019 | 6,103,407 | $ 42.62 | 5.9 | $ 1,816 |
| Vested and exercisable at December 31, 2019 | 4,677,456 | $ 45.84 | 5.1 | $ 895 |

The aggregate intrinsic value in the table above represents the pretax intrinsic value, based on our closing stock price of $10.43 as of December 31, 2019, which would have been received by the option holders had all option holders with in-the-money options exercised their options as of that date.

The following table summarizes information about our stock options as of and for the years ended December 31, 2019, 2018 and 2017 (in thousands, except weighted-average grant date fair value per share):

| | Year ended December 31, | | |
|---|---|---|---|
| | 2019 | 2018 | 2017 |
| Weighted-average grant date fair value per share | $ 13.53 | $ 32.09 | $ 48.79 |
| Intrinsic value of options exercised | $ 1,525 | $ 1,714 | $ 18,987 |
| Cash received from stock option exercises | $ 1,361 | $ 1,869 | $ 13,924 |

As of December 31, 2019, the unrecognized share-based compensation expense related to unvested options, adjusted for expected forfeitures, was $36.9 million and the estimated weighted-average remaining vesting period was 1.9 years.

The fair value of each share-based award is estimated on the grant date using the Black-Scholes option pricing model based upon the weighted-average assumptions provided in the following table:

| | Year ended December 31, | | |
|---|---|---|---|
| | 2019 | 2018 | 2017 |
| Dividend yield | — | — | — |
| Volatility (a) | 93 % | 88 % | 89 % |
| Risk-free interest rate (b) | 1.67 % | 2.92 % | 2.16 % |
| Expected term (years) (c) | 5.9 | 5.9 | 5.8 |

(a) *Volatility*: The expected volatility was estimated using our historical data.
(b) *Risk-free interest rate:* The rate is based on the yield on the grant date of a zero-coupon U.S. Treasury bond whose maturity period approximates the option's expected term.
(c) *Expected term:* The expected term of the award was estimated using our historical data.

The total fair value of stock options vested during the years ended December 31, 2019, 2018 and 2017 was $32.8 million, $43.3 million and $36.0 million, respectively.

**Restricted Stock**

During 2016, we issued restricted stock units ("RSUs") to certain employees under the 2011 Stock Incentive Plan. The RSUs vest either (i) over two years, with 50% vesting one year from the date of grant and the remaining 50% vesting two years from the date of grant or (ii) over four years, with 25% vesting one year from the date of grant and the remaining 75% vesting ratably each subsequent quarter over the following three years, as defined in the grant agreement. Vested RSUs are payable in shares of our common stock at the end of the vesting period. RSUs are measured based on the fair value of the underlying stock on the grant date. The minimum statutory tax on the value of common stock shares issued to employees upon vesting are paid by us through the sale of registered shares of our common stock.

The following table summarizes the activity related to our unvested RSUs:

| | Number of Units | Weighted Average Grant Date Fair Value |
|---|---|---|
| Unvested at December 31, 2018 | 795,684 | $ 47.73 |
| Granted | 2,120,276 | 24.67 |
| Vested | (312,304) | 47.29 |
| Forfeited | (432,309) | 32.19 |
| Outstanding at December 31, 2019 | 2,171,347 | $ 28.37 |
| Unvested at December 31, 2019 | 1,930,581 | $ 28.42 |

As of December 31, 2019, the unrecognized share-based compensation expense related to RSUs, adjusted for expected forfeitures, was $45.1 million and the estimated weighted-average remaining vesting period was 2.1 years

**Common Stock Reserved for Issuance**

As of December 31, 2019, we reserved shares of common stock for future issuance as follows:

| | Common Stock Outstanding | Available for Grant or Future Issuance | Total Shares of Common Stock Reserved |
|---|---|---|---|
| 2009 Equity Incentive Plan | 188,673 | — | 188,673 |
| 2011 Stock Incentive Plan | 8,269,699 | 3,912,836 | 12,182,535 |
| 2011 Employee Stock Purchase Plan | — | 300,416 | 300,416 |
| Total | 8,458,372 | 4,213,252 | 12,671,624 |

**Employee Stock Purchase Plan**

In August 2011, our Board of Directors approved the Clovis Oncology, Inc. 2011 Employee Stock Purchase Plan (the "Purchase Plan"). Each year, on the date of our annual meeting of stockholders and at the discretion of our board of directors, the amount of shares reserved for issuance under the Purchase Plan may be increased by up to the lesser of (1) a number of additional shares of our common stock representing 1% of our then-outstanding shares of common stock, (2) 344,828 shares of our common stock and (3) a lesser number of shares as approved by the Board. The Purchase Plan provides for consecutive six-month offering periods, during which participating employees may elect to have up to 10% of their compensation withheld and applied to the purchase of common stock at the end of each offering period. The purchase price of the common stock is 85% of the lower of the fair value of a share of common stock on the first trading date of each offering period or the fair value of a share of common stock on the last trading day of the offering period. The Purchase Plan will terminate on August 24, 2021, the tenth anniversary of the date of initial adoption of the Purchase Plan. We sold 175,634 and 82,820 shares to employees in 2019 and 2018, respectively. There were 300,416 shares available for sale under the Purchase Plan as of December 31, 2019. The weighted-average estimated grant date fair value of purchase awards under the Purchase Plan during the years ended December 31, 2019 and 2018 was $6.60 and $15.93 per share, respectively. The total share-based compensation expense recorded as a result of the Purchase Plan was approximately $1.0 million, $0.9 million and $1.0 million during the years ended December 31, 2019, 2018 and 2017, respectively.

The fair value of purchase awards granted to our employees during the years ended December 31, 2019, 2018 and 2017 was estimated using the Black-Scholes option pricing model based upon the weighted-average assumptions provided in the following table:

| | Year ended December 31, | | |
|---|---|---|---|
| | 2019 | 2018 | 2017 |
| Dividend yield | — | — | — |
| Volatility (a) | 79 % | 51 % | 79 % |
| Risk-free interest rate (b) | 2.20 % | 1.90 % | 0.90 % |
| Expected term (years) (c) | 0.5 | 0.5 | 0.5 |

(a) *Volatility*: The expected volatility was estimated using our historical data.
(b) *Risk-free interest rate:* The rate is based on the U.S. Treasury yield in effect at the time of grant with terms similar to the contractual term of the purchase right.
(c) *Expected term:* The expected life of the award represents the six-month offering period for the Purchase Plan.

**13. Commitments and Contingencies**

*Manufacture and Services Agreement Commitments*

On October 3, 2016, we entered into a Manufacturing and Services Agreement (the "Agreement") with a non-exclusive third-party supplier for the production of the active ingredient for Rubraca. Under the terms of the Agreement, we will provide the third-party supplier a rolling forecast for the supply of the active ingredient in Rubraca that will be updated by us on a quarterly basis. We are obligated to order material sufficient to satisfy an initial quantity specified in a forecast. In addition, the third-party supplier will construct, in its existing facility, a production train that will be exclusively dedicated to the manufacture of the Rubraca active ingredient. We are obligated to make scheduled capital program fee payments toward capital equipment and other costs associated with the construction of the dedicated production train. Further, once the facility is operational, we are obligated to pay a fixed facility fee each quarter for the duration of the Agreement, which expires on December 31, 2025, unless extended by mutual consent of the parties. As of December 31, 2019, $92.8 million of purchase commitments exist under the Agreement.

At the time we entered into the Agreement, we evaluated the Agreement as a whole and bifurcated into lease and non-lease components, which consisted of an operating lease of warehouse space, capital lease of equipment, purchase of leasehold improvements and manufacturing costs based upon the relative fair values of each of the deliverables. During October 2018, the production train was placed into service and we recorded the various components of the Agreement.

*Legal Proceedings*

We and certain of our officers were named as defendants in several lawsuits, as described below. We cannot reasonably predict the outcome of these legal proceedings, nor can we estimate the amount of loss or range of loss, if any, that may result. An adverse outcome in these proceedings could have a material adverse effect on our results of operations, cash flows or financial condition.

**Rociletinib-Related Litigation**

Following Clovis' regulatory announcement in November 2015 of adverse developments in its ongoing clinical trials for rociletinib, Clovis and certain of its current and former executives were named in various securities lawsuits, the largest of which was a putative class action lawsuit in the District of Colorado (the "Medina Action") which was settled on October 26, 2017 (the "Medina Settlement"). The remaining actions are discussed below.

In March 2017, two putative shareholders of the Company, Macalinao and McKenry (the "Derivative Plaintiffs"), filed shareholder derivative complaints against certain directors and officers of the Company in the Court of Chancery of the State of Delaware. On May 4, 2017, the Macalinao and McKenry actions were consolidated for all purposes in a single proceeding under the caption In re Clovis Oncology, Inc. Derivative Litigation, Case No, 2017-0222 (the "Consolidated Derivative Action").

On May 18, 2017, the Derivative Plaintiffs filed a Consolidated Verified Shareholder Derivative Complaint (the "Consolidated Derivative Complaint"). The Consolidated Derivative Complaint generally alleged that the defendants

breached their fiduciary duties owed to the Company by allegedly causing or allowing misrepresentations of the Company's business operations and prospects, failing to ensure that the TIGER-X clinical trial was being conducted in accordance with applicable rules, regulations and protocols, and engaging in insider trading. The Consolidated Derivative Complaint sought, among other things, an award of money damages.

On July 31, 2017, the defendants filed a motion to dismiss the Consolidated Derivative Complaint. Plaintiffs filed an opposition to the motion to dismiss on August 31, 2017, and the defendants filed a reply in further support of the motion to dismiss on September 26, 2017.

While the motion to dismiss remained pending, on November 19, 2018, Plaintiffs filed a motion for leave to file a supplemental consolidated complaint, and on November 20, 2018, the Court granted that motion. On November 27, 2018, Plaintiffs filed their supplemental complaint (the "Supplemental Derivative Complaint"), which adds allegations concerning the Company's, Mr. Mahaffy's and Mr. Mast's settlements with the United States Securities and Exchange Commission. Pursuant to a briefing schedule entered by the Court, the defendants filed a supplemental motion to dismiss the Supplemental Derivative Complaint on February 6, 2019; plaintiffs filed an opposition brief on February 22, 2019; and the defendants filed a reply brief on March 5, 2019. The Court held oral arguments on the defendants' motions to dismiss on June 19, 2019. At the oral arguments, the Court ordered the parties to submit supplemental letter briefs on the motion to dismiss.

On October 1, 2019, Vice Chancellor Joseph R. Slights III of the Delaware Chancery Court, issued a Memorandum Opinion granting in part and denying in part defendants' motions to dismiss. The Supplemental Derivative Complaint was dismissed as to Plaintiffs' derivative claims for unjust enrichment and insider trading. The Court allowed Plaintiffs' remaining derivative claim for breach of fiduciary duty to proceed. Defendants filed an answer to the Supplemental Derivative Complaint on December 27, 2019.

On December 17, 2019, the parties participated in a mediation, which did not result in a settlement. On December 22, 2019, the Company's board of directors formed a Special Litigation Committee (the "SLC") to conduct an investigation of the claims asserted in the Supplemental Derivative Complaint. On February 18, 2020, the SLC moved to stay all proceedings in the Consolidated Derivative Action pending completion of its investigation. Plaintiff's opposition to the motion to stay is due on March 3, 2020 and the SLC's reply is due on March 13, 2020.

While the SLC's investigation remains ongoing, the Company does not believe this litigation will have a material impact on its financial position or results of operations.

On March 20, 2017, a purported shareholder of the Company, filed a shareholder derivative complaint (the "Guo Complaint") against certain officers and directors of the Company in the United States District Court for the District of Colorado. The Guo Complaint generally alleged that the defendants breached their fiduciary duties owed to the Company by either recklessly or with gross negligence approving or permitting misrepresentations of the Company's business operations and prospects. The Guo Complaint also alleged claims for waste of corporate assets and unjust enrichment. Finally, the Guo Complaint alleged that certain of the individual defendants violated Section 14(a) of the Securities Exchange Act, by allegedly negligently issuing, causing to be issued, and participating in the issuance of materially misleading statements to stockholders in the Company's Proxy Statement on Schedule DEF 14A in connection with the 2015 Annual Meeting of Stockholders, held on June 11, 2015. The Guo Complaint sought, among other things, an award of money damages.

On June 19, 2017, the parties filed a joint motion to stay the Guo action pending resolution of the motion to dismiss the Consolidated Derivative Complaint. On June 20, 2017, the court granted the motion to stay. Based on the October 1, 2019 ruling in the Consolidated Derivative Action, on October 22, 2019, the court lifted the stay. The parties participated in a scheduling conference on December 9, 2019, following which the court set the dates for pre-trial conference and trial for March 2, 2021 and March 29, 2021, respectively. On December 23, 2019, the plaintiff filed an amended complaint, and on February 7, 2020, the plaintiff filed a second amended complaint. Pursuant to a stipulated scheduling order entered by the court on February 10, 2020, the defendants' motion to dismiss is due on February 28, 2020.

The Company intends to vigorously defend against the allegations in the second amended Guo complaint, but there can be no assurance that the defense will be successful.

**European Patent Opposition**

Two oppositions were filed in the granted European counterpart of the rucaparib camsylate salt/polymorph patent on June 20, 2017. The European Patent Office's Opposition Division held an oral hearing on December 4, 2018, during which it upheld claims, narrowed from the originally granted patent, to certain crystalline forms of rucaparib camsylate, including, but not limited to, rucaparib S-camsylate Form A, the crystalline form in Rubraca. Clovis and one opponent, Hexal, appealed the written decision of the European Opposition Division and filed reply appeal briefs in early November 2019.

**14. License Agreements**

**Rubraca**

In June 2011, we entered into a license agreement with Pfizer to obtain the exclusive global rights to develop and commercialize Rubraca. The exclusive rights are exclusive even as to Pfizer and include the right to grant sublicenses. Pursuant to the terms of the license agreement, we made a $7.0 million upfront payment to Pfizer and are required to make additional payments to Pfizer for the achievement of certain development and regulatory and sales milestones and royalties on sales as required by the license agreement. Prior to the FDA approval of Rubraca, we made milestone payments of $1.4 million, which were recognized as acquired in-process research and development expense.

On August 30, 2016, we entered into a first amendment to the worldwide license agreement with Pfizer, which amends the June 2011 existing worldwide license agreement to permit us to defer payment of the milestone payments payable upon (i) FDA approval of an NDA for 1st Indication in US and (ii) EMA approval of an MAA for 1st Indication in the EU, to a date that is 18 months after the date of achievement of such milestones.

On December 19, 2016, Rubraca received its initial FDA approval. This approval resulted in a $0.75 million milestone payment to Pfizer as required by the license agreement, which was paid in the first quarter of 2017. This FDA approval also resulted in an obligation to pay a $20.0 million milestone payment, for which we exercised the option to defer payment by agreeing to pay $23.0 million within 18 months after the date of the FDA approval. We paid the $23.0 million milestone payment in June 2018.

On April 6, 2018, Rubraca received a second FDA approval. This approval resulted in an obligation to pay a $15.0 million milestone payment, which we paid in April 2018.

In May 2018, Rubraca received its initial European Commission marketing authorization. This approval resulted in an obligation to pay a $20.0 million milestone payment, which we paid in June 2018.

In January 2019, Rubraca received a second European Commission approval. This approval resulted in an obligation to pay a $15.0 million milestone payment, which we paid in February 2019.

In June 2019, we paid a $0.75 million milestone payment due to the launch of Rubraca as maintenance therapy in Germany in March 2019.

These milestone payments were recognized as intangible assets and are amortized over the estimated remaining useful life of Rubraca.

We are obligated under the license agreement to use commercially reasonable efforts to develop and commercialize Rubraca and we are responsible for all ongoing development and commercialization costs for Rubraca. We are required to make regulatory milestone payments to Pfizer of up to an additional $16.0 million in aggregate if specified clinical study objectives and regulatory filings, acceptances and approvals are achieved. In addition, we are obligated to make sales milestone payments to Pfizer if specified annual sales targets for Rubraca are met, which relate to annual sales targets of $250.0 million and above, which, in the aggregate, could amount to total milestone payments of $170.0 million, and tiered royalty payments at a mid-teen percentage rate on net sales, with standard provisions for royalty offsets to the extent we need to obtain any rights from third parties to commercialize Rubraca.

The license agreement with Pfizer will remain in effect until the expiration of all of our royalty and sublicense revenue obligations to Pfizer, determined on a product-by-product and country-by-country basis, unless we elect to

terminate the license agreement earlier. If we fail to meet our obligations under the agreement and are unable to cure such failure within specified time periods, Pfizer can terminate the agreement, resulting in a loss of our rights to Rubraca and an obligation to assign or license to Pfizer any intellectual property rights or other rights we may have in Rubraca, including our regulatory filings, regulatory approvals, patents and trademarks for Rubraca.

In April 2012, we entered into a license agreement with AstraZeneca to acquire exclusive rights associated with Rubraca under a family of patents and patent applications that claim methods of treating patients with PARP inhibitors in certain indications. The license enables the development and commercialization of Rubraca for the uses claimed by these patents. AstraZeneca also receives royalties on net sales of Rubraca.

**Lucitanib**

In October 2008, Ethical Oncology Science, S.p.A. ("EOS") (now known as Clovis Oncology Italy S.r.l.) entered into an exclusive license agreement with Advenchen Laboratories LLC ("Advenchen") to develop and commercialize lucitanib on a global basis, excluding China. We are obligated to pay Advenchen tiered royalties at percentage rates in the mid-single digits on net sales of lucitanib, based on the volume of annual net sales achieved. In addition, after giving effect to the first and second amendments to the license agreement, we are required to pay to Advenchen 25% of any consideration, excluding royalties, we receive from sublicensees, in lieu of the milestone obligations set forth in the agreement. We are obligated under the agreement to use commercially reasonable efforts to develop and commercialize at least one product containing lucitanib, and we are also responsible for all remaining development and commercialization costs for lucitanib.

The license agreement with Advenchen will remain in effect until the expiration of all of our royalty obligations to Advenchen, determined on a product-by-product and country-by-country basis, unless we elect to terminate the agreement earlier. If we fail to meet our obligations under the agreement and are unable to cure such failure within specified time periods, Advenchen can terminate the agreement, resulting in a loss of our rights to lucitanib.

In September 2012, EOS entered into a collaboration and license agreement with Les Laboratoires Servier and Institut de Recherches Internationales Servier (collectively, "Servier"), whereby EOS sublicensed to Servier exclusive rights to develop and commercialize lucitanib in all countries outside of the U.S., Japan and China. Following our acquisition of EOS, we and Servier were developing lucitanib pursuant to a development plan agreed to between the parties. During 2017, we completed the committed on-going development activities related to lucitanib and received full reimbursement of our development costs from Servier. Reimbursements are recorded as a reduction to research and development expense on the Consolidated Statements of Operations. In the second quarter of 2018, we received notice from Servier of its election to terminate the license agreement and return its rights to lucitanib to us. Such termination became effective in the fourth quarter of 2018.

**FAP Program**

In September 2019, we entered into a global license and collaboration agreement with 3BP to develop and commercialize a PTRT and imaging agent targeting FAP. The lead candidate, designated internally as FAP-2286, is being developed pursuant to a global development plan agreed to by the parties. We are responsible for the costs of all preclinical and clinical development activities described in the plan, including the costs for a limited number of 3BP full-time equivalents and external costs incurred during the preclinical development phase of the collaboration. Upon the signing of the license and collaboration agreement in September 2019, we made a $9.4 million upfront payment to 3BP, which we recognized as acquired in-process research and development expense.

Pursuant to the terms of the FAP agreement, we are required to make additional payments to 3BP for annual technology access fees and upon the achievement of certain development and regulatory milestone events (or on certain dates, whichever occur earlier). We are also obligated to pay 3BP single- to low-double-digit royalties on net sales of the FAP-targeted therapeutic product and imaging agent, based on the volume of annual net sales achieved. In addition, 3BP is entitled to receive 34% of any consideration, excluding royalties on the therapeutic product, pursuant to any sublicenses we may grant.

We are obligated under the license and collaboration agreement to use diligent efforts to develop FAP-2286 and commercialize a FAP-targeted therapeutic product and imaging agent, and we are responsible for all commercialization costs in our territory. The agreement with 3BP will remain in effect until the expiration of our royalty obligations to

3BP, determined on a product-by-product and country-by-country basis, unless we elect to terminate the agreement earlier. If we fail to meet our obligations under the agreement and are unable to cure such failure within specified time periods, 3BP can terminate the agreement, resulting in a loss of our rights. 3BP also has the right to terminate the agreement under certain circumstances in connection with our change of control in which the acquiring party retains a product competitive with the FAP-targeted therapeutic product or, in the event marketing authorization has not yet been obtained, does not agree to the then-current global development plan.

In February 2020, we finalized the terms of a drug discovery collaboration agreement with 3BP to identify up to three additional, undisclosed targets for peptide-targeted radionuclide therapy, to which we will obtain global rights for any resulting product candidates. We are responsible for the costs of all preclinical and clinical development activities conducted under the discovery program, including the costs for a limited number of 3BP full-time equivalents and external costs incurred during the discovery and preclinical development phase for each collaboration target. The agreement was effective December 31, 2019, for which we incurred a $2.1 million technology access fee, which we accrued and recognized as a research and development expense.

Pursuant to the terms of the agreement, we are required to make additional payments to 3BP for annual technology access fees and upon the achievement of certain development and regulatory milestone events (or on certain dates, whichever occur earlier). We are also obligated to pay 3BP a 6% royalty on net sales of License Products (as defined in the agreement), based on the volume of quarterly net sales achieved.

We are obligated under the discovery collaboration agreement to use diligent efforts to develop and commercialize the product candidates, if any, that result from the discovery program, and we are responsible for all clinical development and commercialization costs. The agreement with 3BP will remain in effect until the expiration of our royalty obligations to 3BP, determined on a product-by-product and country-by-country basis, unless we elect to terminate the agreement earlier. If we fail to meet our obligations under the agreement and are unable to cure such failure within specified time periods, 3BP can terminate the agreement, resulting in a loss of our rights.

**Rociletinib**

In May 2010, we entered into an exclusive worldwide license agreement with Celgene to discover, develop and commercialize a covalent inhibitor of mutant forms of the epidermal growth factor receptor (“EGFR”) gene product. Rociletinib, an oral mutant-selective inhibitor of EGFR, was identified as the lead inhibitor candidate under the license agreement. Following the termination of enrollment in all sponsored clinical studies of rociletinib, we provided notice of termination to Celgene of our license rights to rociletinib, an oral mutant-selective inhibitor of epidermal growth factor receptor (“EGFR”), and that termination became effective in the second quarter of 2019.

Finally, pursuant to terms of each of our product license agreements, we will pay royalties to our licensors on sales, if any, of the respective products.

**15. Net Loss Per Common Share**

Basic net loss per share is calculated by dividing net loss by the weighted-average number of common shares outstanding during the period. Diluted net loss per share is computed by dividing net loss by the weighted-average number of common share equivalents outstanding using the treasury-stock method for the stock options and RSUs and the if-converted method for the convertible senior notes. As a result of our net losses for the periods presented, all potentially dilutive common share equivalents were considered anti-dilutive and were excluded from the computation of diluted net loss per share.

The shares outstanding at the end of the respective periods presented in the table below were excluded from the calculation of diluted net loss per share due to their anti-dilutive effect (in thousands):

| | Year ended December 31, | | |
|---|---|---|---|
| | 2019 | 2018 | 2017 |
| Common shares under option plans | 2,480 | 1,319 | 4,260 |
| Convertible senior notes | 41,598 | 8,584 | 4,646 |
| Total potential dilutive shares | 44,078 | 9,903 | 8,906 |

**16. Income Taxes**

We are subject to U.S. federal, state and foreign income tax. The geographical components of loss before income taxes consisted of the following (in thousands):

| | Year ended December 31, | | |
|---|---|---|---|
| | 2019 | 2018 | 2017 |
| Domestic | $(399,497) | $(368,402) | $(351,338) |
| Foreign | 871 | 1,001 | 1,363 |
| Total loss before income taxes | $(398,626) | $(367,401) | $(349,975) |

The income tax provision consists of the following current and deferred tax expense (benefit) amounts (in thousands):

| | Year ended December 31, | | |
|---|---|---|---|
| | 2019 | 2018 | 2017 |
| Current tax: | | | |
| U.S. Federal & State | $ 3 | $ 15 | $ — |
| Foreign | 1,795 | 593 | (360) |
| Total current expense (benefit) | 1,798 | 608 | (360) |
| Deferred tax: | | | |
| U.S. Federal & State | — | — | (3,218) |
| Foreign | — | — | — |
| Total deferred (benefit) | — | — | (3,218) |
| Total income tax expense (benefit) | $1,798 | $ 608 | $(3,578) |

A reconciliation of the U.S. federal statutory income tax rate to our effective tax rate is provided below:

| | Year ended December 31, | | |
|---|---|---|---|
| | 2019 | 2018 | 2017 |
| Federal income tax benefit at statutory rate | (21.0)% | (21.0)% | (34.0)% |
| State income tax benefit, net of federal benefit | (2.9) | (3.1) | (3.2) |
| Tax credits | (1.1) | (1.3) | (1.2) |
| Change in uncertain tax positions | (4.3) | 0.1 | 0.2 |
| SEC settlement costs | — | 1.1 | — |
| Share based compensation | 2.3 | 0.8 | 0.7 |
| Tax impact of Tax Cuts and Jobs Act of 2017 | — | — | 46.4 |
| Change in valuation allowance | 26.5 | 23.2 | (8.1) |
| Other | 1.0 | 0.4 | (1.8) |
| Effective income tax rate | 0.5 % | 0.2 % | (1.0)% |

The significant components of our deferred tax assets and liabilities are as follows (in thousands):

| | December 31, | |
|---|---|---|
| | 2019 | 2018 |
| Deferred tax assets: | | |
| Net operating loss carryforward | $ 396,100 | $ 351,730 |
| Tax credit carryforwards | 243,901 | 224,738 |
| Interest expense limitation carryforward | 4,449 | 1,192 |
| Intangible assets | 61,459 | 25,992 |
| Share-based compensation expense | 34,006 | 30,044 |
| Foreign currency translation | — | 3,767 |
| Product acquisition costs | 6,288 | 4,518 |
| Lease liabilities | 5,317 | — |
| Accrued liabilities and other | 5,817 | 7,656 |
| Total deferred tax assets | 757,337 | 649,637 |
| Valuation allowance | (750,508) | (647,891) |
| Deferred tax assets, net of valuation allowance | 6,829 | 1,746 |
| Deferred tax liabilities: | | |
| Right-of-use assets | (6,337) | — |
| Prepaid expenses and fixed assets | (492) | (1,746) |
| Total deferred tax liabilities | (6,829) | (1,746) |
| Net deferred tax liability | $ — | $ — |

The Tax Cuts and Jobst Act (the "Act"), enacted in the U.S. on December 22, 2017, subjects a U.S. shareholder to tax on the Global Intangible Low-Taxed Income ("GILTI") earned by certain foreign subsidiaries. The FASB Staff Q&A, Topic 740, No. 5, "Accounting for Global Intangible Low-Taxed Income", states that an entity can make an accounting policy election to either recognize deferred taxes for temporary basis differences expected to reverse as GILTI in future years or to provide for the tax expense related to GILTI in the year the tax is incurred as a period expense only. We have elected to account for GILTI in the year the tax is incurred.

The realization of deferred tax assets is dependent upon a number of factors including future earnings, the timing and amount of which is uncertain. A valuation allowance was established for the net deferred tax asset balance due to management's belief that the realization of these assets is not likely to occur in the foreseeable future. We recorded a net increase to the valuation allowance of $102.6 million and $83.8 million for the years ended December 31, 2019 and 2018, respectively, primarily due to the growth in net operating losses and tax credits during the year.

In addition, the Company recognizes tax benefits if it is more likely than not to be sustained under audit by the relevant taxing authority based on technical merits. An uncertain tax position will not be recognized if it has less than a 50% likelihood of being sustained during audit. If the threshold is met, the tax benefit is measured and recognized at the largest amount above the greater than 50% likelihood threshold at time of settlement. The balance of unrecognized tax benefits at December 31, 2019 of $7.5 million, if recognized, would not impact the Company's effective tax rate as long as they remain subject to a full valuation allowance. The following table summarizes the gross amounts of unrecognized tax benefits (in thousands):

| | Year ended December 31, | |
|---|---|---|
| | 2019 | 2018 |
| Balance at beginning of year | $ 24,775 | $ 24,512 |
| Reductions related to prior periods tax positions | (35) | (166) |
| Additions related to current period tax positions | 398 | 429 |
| Settlements with tax authorities | (17,613) | — |
| Expiration of statute of limitations | — | — |
| Balance at end of year | $ 7,525 | $ 24,775 |

As of December 31, 2019, we had approximately $1.5 billion, $1.6 billion and $1.7 million of U.S., federal, state and foreign net operating loss carryforwards, respectively. The U.S. federal net operating losses, generated prior to the enactment of the Act, will expire from 2029 to 2037 if not utilized and the U.S state net operating losses will expire from

2024 to 2039 if not utilized. We have research and development and orphan drug tax credit carryforwards of $249.7 million that will expire from 2030 through 2039 if not utilized.

We believe that a change in ownership as defined under Section 382 of the U.S. Internal Revenue Code occurred as a result of our public offering of common stock completed in April 2012. Future utilization of the federal net operating losses ("NOL") and tax credit carryforwards accumulated from inception to the change in ownership date will be subject to annual limitations to offset future taxable income. It is possible that a change in ownership will occur in the future, which will limit the NOL amounts generated since the last estimated change of ownership. As of December 31, 2019, our audit by the Internal Revenue Service was finalized for the year ended December 31, 2015. The amount of orphan drug tax credit for years 2009 and 2010 was adjusted, but no additional taxes are due as a result of our net operating losses; this also resulted in a release of the uncertain tax position of $17.6 million. Our federal and state income taxes for the period from January 1, 2009 to December 31, 2014, other than the orphan drug tax credit, and January 1, 2016 through December 31, 2019 remain open to an audit. Our foreign subsidiaries are also subject to tax audits by tax authorities in the jurisdictions where they operate for the periods from December 31, 2015 to December 31, 2019.

We may be assessed interest and penalties related to the settlement of tax positions and such amounts will be recognized within income tax expense when assessed. To date, no interest and penalties have been recognized.

**17. Employee Benefit Plans**

We maintain a retirement plan, which is qualified under section 401(k) of the Internal Revenue Code for our U.S. employees. The plan allows eligible employees to defer, at the employee's discretion, pretax compensation up to the IRS annual limits. We matched contributions up to 4% of the eligible employee's compensation or the maximum amount permitted by law. Total expense for contributions made to U.S. employees was approximately $2.2 million, $2.0 million and $1.9 million for the years ended December 31, 2019, 2018 and 2017, respectively. Our international employees participate in retirement plans or postretirement life insurance plans governed by the local laws in effect for the country in which they reside. We made contributions to the retirement plans or postretirement life insurance plans of international employees of approximately $1.1 million, $0.9 million and $0.3 million for the years ended December 31, 2019, 2018 and 2017, respectively.

**18. Quarterly Information (Unaudited)**

The results of operations on a quarterly basis for the years ended December 31, 2019 and 2018 were as follows (in thousands):

| | March 31, 2019 | June 30, 2019 | September 30, 2019 | December 31, 2019 | March 31, 2018 | June 30, 2018 | September 30, 2018 | December 31, 2018 |
|---|---|---|---|---|---|---|---|---|
| Revenues: | | | | | | | | |
| Product revenue | $ 33,118 | $ 32,978 | $ 37,603 | $ 39,307 | $ 18,523 | $ 23,757 | $ 22,757 | $ 30,351 |
| Operating expenses: | | | | | | | | |
| Cost of sales - product | 7,405 | 6,445 | 8,134 | 7,942 | 4,006 | 4,490 | 4,766 | 6,182 |
| Cost of sales - intangible asset amortization | 1,120 | 1,217 | 1,212 | 1,211 | 372 | 709 | 771 | 778 |
| Research and development | 62,031 | 70,746 | 77,896 | 72,473 | 43,543 | 52,707 | 63,887 | 71,210 |
| Selling, general and administrative | 47,761 | 48,029 | 41,811 | 45,168 | 39,274 | 44,864 | 42,495 | 49,148 |
| Acquired in-process research and development | — | — | 9,440 | — | — | — | — | — |
| Other operating expenses | — | — | 5,539 | 4,172 | — | — | — | — |
| Total expenses | 118,317 | 126,437 | 144,032 | 130,966 | 87,195 | 102,770 | 111,919 | 127,318 |
| Operating loss | (85,199) | (93,459) | (106,429) | (91,659) | (68,672) | (79,013) | (89,162) | (96,967) |
| Other income (expense): | | | | | | | | |
| Interest expense | (3,590) | (3,817) | (5,278) | (6,720) | (2,635) | (3,581) | (3,376) | (3,591) |
| Foreign currency (loss) gain | (192) | (226) | (229) | 100 | (81) | (104) | 151 | (312) |
| Legal settlement loss | — | (25,000) | (1,750) | — | (7,975) | (20,000) | — | — |
| Gain on extinguishment of debt | — | — | 18,480 | — | — | — | — | — |
| Other income | 2,400 | 1,899 | 781 | 1,262 | 1,409 | 1,475 | 2,536 | 2,497 |
| Other income (expense), net | (1,382) | (27,144) | 12,004 | (5,358) | (9,282) | (22,210) | (689) | (1,406) |
| Loss before income taxes | (86,581) | (120,603) | (94,425) | (97,017) | (77,954) | (101,223) | (89,851) | (98,373) |
| Income tax benefit (expense) | 160 | 176 | 350 | (2,484) | 260 | 33 | (13) | (888) |
| Net loss | $ (86,421) | $ (120,427) | $ (94,075) | $ (99,501) | $ (77,694) | $ (101,190) | $ (89,864) | $ (99,261) |
| Basic and diluted net loss per common share | $ (1.63) | $ (2.27) | $ (1.72) | $ (1.81) | $ (1.54) | $ (1.94) | $ (1.71) | $ (1.88) |
| Basic and diluted weighted average common shares outstanding | 52,891 | 53,028 | 54,707 | 54,834 | 50,602 | 52,223 | 52,669 | 52,724 |

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**SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

**CLOVIS ONCOLOGY, INC.**

By: /S/ PATRICK J. MAHAFFY
Patrick J. Mahaffy
*President and Chief Executive Officer; Director*

Date: February 26, 2020

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this report has been signed by the following persons on behalf of the registrant and in the capacities and on the dates indicated:

| Name | Title | Date |
|---|---|---|
| /S/ PATRICK J. MAHAFFY<br>**Patrick J. Mahaffy** | President and Chief Executive Officer; Director<br>*(Principal Executive Officer)* | February 26, 2020 |
| /S/ DANIEL W. MUEHL<br>**Daniel W. Muehl** | Executive Vice President and Chief Finance Officer<br>*(Principal Financial Officer and Principal Accounting Officer)* | February 26, 2020 |
| /S/ BRIAN G. ATWOOD<br>**Brian G. Atwood** | Director | February 26, 2020 |
| /S/ ROBERT W. AZELBY<br>**Robert W. Azelby** | Director | February 26, 2020 |
| /S/ JAMES C. BLAIR<br>**James C. Blair** | Director | February 26, 2020 |
| /S/ RICHARD A. FAIR<br>**Richard A. Fair** | Director | February 26, 2020 |
| /S/ KEITH FLAHERTY<br>**Keith Flaherty** | Director | February 26, 2020 |
| /S/ GINGER L. GRAHAM<br>**Ginger L. Graham** | Director | February 26, 2020 |
| /S/ PAUL KLINGENSTEIN<br>**Paul Klingenstein** | Director | February 26, 2020 |
| /S/ EDWARD J. MCKINLEY<br>**Edward J. McKinley** | Director | February 26, 2020 |
| /S/ THORLEF SPICKSCHEN<br>**Thorlef Spickschen** | Director | February 26, 2020 |

# DESCRIPTION OF THE REGISTRANT'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

As of December 31, 2019, Clovis Oncology, Inc. had one class of securities registered under Section 12 of the Securities Exchange Act of 1934, as amended: common stock, $0.001 par value per share.

The following summary describes our common stock and preferred stock and the material provisions of our amended and restated certificate of incorporation and our amended and restated bylaws and certain provisions of the Delaware General Corporation Law. Because the following is only a summary, it does not contain all of the information that may be important to you. For a complete description, you should refer to our amended and restated certificate of incorporation and amended and restated bylaws, copies of which are on file with the SEC and included as exhibits to our Annual Report on Form 10-K for the year ended December 31, 2019. Unless the context requires otherwise, references in this exhibit to "Clovis," the "Company," "we," "us," and "our" refer to Clovis Oncology, Inc. together with its consolidated subsidiaries.

## Common Stock

The holders of our common stock are entitled to one vote for each share held of record on all matters submitted to a vote of stockholders and are not entitled to cumulative votes with respect to the election of directors. The holders of common stock are entitled to receive dividends ratably, if, as and when dividends are declared from time to time by our board of directors out of legally available funds, after payment of dividends required to be paid on outstanding preferred stock, if any. Any decision to declare and pay dividends in the future will be made at the discretion of our board of directors and will depend on, among other things, our results of operations, cash requirements, financial condition, contractual restrictions and other factors that our board of directors may deem relevant. Upon our liquidation, dissolution or winding up, the holders of common stock are entitled to share ratably in all assets that are legally available for distribution after payment of all debts and other liabilities, subject to the prior rights of any holders of preferred stock then outstanding. The holders of common stock have no other preemptive, subscription, redemption, sinking fund or conversion rights. All outstanding shares of our common stock are fully paid and nonassessable. The shares of common stock to be issued upon closing of an offering will also be fully paid and nonassessable. The rights, preferences and privileges of holders of common stock are subject to, and may be negatively impacted by, the rights of the holders of shares of any series of preferred stock which we may designate and issue in the future.

Our amended and restated certificate of incorporation authorizes us to issue up to 200 million shares of common stock, par value $0.001 per share. As of December 31, 2019, 54,956,341 shares of our common stock were outstanding.

As of December 31, 2019, options to purchase 6,287,025 shares of our common stock at a weighted average exercise price of $42.24 per share were outstanding.

As of December 31, 2019, 2,171,347 shares of our common stock were issuable upon the vesting of restricted stock units outstanding.

As of December 31, 2019, 1,570,713 shares were issuable upon conversion of our 2.50% Convertible Senior Notes due 2021, 3,938,340 shares were issuable upon the conversion of our 1.25% Convertible Senior Notes due 2025 and 19,054,275 shares were issuable upon the conversion of our 4.50% Convertible Senior Notes due 2024 after giving effect to the repurchases that were announced on January 8, 2020 and certain other conversions of such notes during the period from January 1, 2020 to February 21, 2020.

## Transfer Agent and Registrar

Our transfer agent and registrar for our common stock is Continental Stock Transfer & Trust Company.

**Listing**

Our common stock is listed on The Nasdaq Global Select Market under the symbol "CLVS."

**Preferred Stock**

Under our amended and restated certificate of incorporation, our board of directors has the authority, without action by our stockholders, to designate and issue up to 10 million shares of preferred stock, par value $0.001 per share, in one or more series and to designate the rights, preferences and privileges of each series, any or all of which may be greater than the rights of our common stock. It is not possible to state the actual effect of the issuance of any shares of preferred stock upon the rights of holders of our common stock until our board of directors determines the specific rights of the holders of preferred stock. However, the effects might include, among other things, restricting dividends on the common stock, diluting the voting power of the common stock, impairing the liquidation rights of the common stock and delaying or preventing a change in control of our common stock without further action by our stockholders and may adversely affect the market price of our common stock. As of December 31, 2019, no shares of our preferred stock were outstanding.

**Registration Rights**

No holders of our securities are entitled to rights with respect to the registration of their securities under the Securities Act.

**Anti-Takeover Provisions of Delaware Law**

We are subject to Section 203 of the Delaware General Corporation Law. In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a business combination with an interested stockholder for a period of three years following the date the person became an interested stockholder, unless the business combination or the transaction in which the person became an interested stockholder is approved in a prescribed manner. Generally, a business combination includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the interested stockholder. Generally, an interested stockholder is a person who, together with affiliates and associates, owns or, in the case of affiliates or associates of the corporation, within three years prior to the determination of interested stockholder status, owned 15% or more of a corporation's voting stock. The existence of this provision could have anti-takeover effects with respect to transactions not approved in advance by our board of directors, such as discouraging takeover attempts that might result in a premium over the market price of our common stock. The foregoing provisions of the Delaware General Corporation Law may have the effect of deterring or discouraging hostile takeovers or delaying changes in control of our company.

**Charter and Bylaws Anti-Takeover Provisions**

***Classified Board of Directors***

Our amended and restated certificate of incorporation provides that our board of directors is divided into three classes of directors, with the number of directors in each class to be as nearly equal as possible. Our classified board of directors stagger terms of the three classes and has been implemented through one, two and three-year terms for the initial three classes, followed in each case by full three-year terms. With a classified board of directors, only one-third of the members of our board of directors is elected each year. This classification of directors has the effect of making it more difficult for stockholders to change the composition of our board of directors.

***Size of Board of Directors and Removal of Directors***

Our amended and restated certificate of incorporation and amended and restated bylaws provide that:

- the number of directors will be fixed from time to time exclusively pursuant to a resolution adopted by our board of directors, but must consist of not less than three directors, which will prevent stockholders from circumventing the provisions of our classified board of directors;
- directors may be removed only for cause; and

- vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum, or by the sole remaining director, at any meeting of the board of directors.

***Authorized Preferred Stock***

Our amended and restated certificate of incorporation provides for the issuance by our board of directors, without stockholder approval, of shares of preferred stock, with voting power, designations, preferences and other special rights as may be determined in the discretion of our board of directors. The issuance of preferred stock could decrease the amount of earnings and assets available for distribution to the holders of common stock or could adversely affect the rights and powers, including voting rights, of holders of common stock. In certain circumstances, such issuance could have the effect of decreasing the market price of the common stock. Preferred stockholders could also make it more difficult for a third party to acquire our company.

***No Stockholder Action by Written Consent***

Our amended and restated certificate of incorporation and amended and restated bylaws require that any action required or permitted to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and may not be effected by a consent in writing.

***Calling of Special Meetings of Stockholders***

Our amended and restated bylaws provide that special stockholder meetings for any purpose may only be called by a majority of our board of directors, our chairman or our chief executive officer.

***Advance Notice Requirements for Stockholder Proposals and Director Nominations***

Our amended and restated bylaws establish an advance notice procedure for stockholder proposals to be brought before an annual meeting of stockholders, including proposed nominations of candidates for election to the board of directors. Stockholders at an annual meeting may only consider proposals or nominations specified in the notice of meeting or brought before the meeting by or at the direction of the board of directors, or by a stockholder of record on the record date for the meeting, who is entitled to vote at the meeting and who has delivered timely written notice in proper form to our secretary of the stockholder's intention to bring such business before the meeting. These provisions could have the effect of delaying until the next stockholder meeting stockholder actions that are favored by the holders of a majority of our outstanding voting stock. These provisions also could discourage a third party from making a tender offer for our common stock, because even if it acquired a majority of our outstanding voting stock, it would be able to take action as a stockholder, such as electing new directors or approving a merger, only at a duly called stockholders meeting and not by written consent.

***Exclusive Forum Charter Provision***

Our amended and restated certificate of incorporation provides that unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware shall be the sole and exclusive forum for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers, employees or agents to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the General Corporation Law of the State of Delaware or our certificate of incorporation or bylaws, or (iv) any action asserting a claim governed by the internal affairs doctrine, in each such case subject to said Court of Chancery having personal jurisdiction over the indispensable parties named as defendants therein. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and consented to this provision of our amended and restated certificate of incorporation.

The exclusive forum provision does not apply to suits brought to enforce any duty or liability created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. We note, however, that federal courts have concurrent jurisdiction over all suits brought to enforce any duty or liability created by the Securities Act. We note that there is uncertainty as to whether a court would enforce this provision and that investors

cannot waive compliance with the federal securities laws and the rules and regulations thereunder. Although we believe this provision benefits us by providing increased consistency in the application of Delaware law in the types of lawsuits to which it applies, this provision may have the effect of discouraging lawsuits against our directors and officers.

**Indemnification of Directors and Officers**

Our amended and restated certificate of incorporation and amended and restated bylaws provide that we will, to the fullest extent permitted by Delaware corporate law, subject to certain limitations, indemnify any person made or threatened to be made a party to a proceeding by reason of that person's former or present official capacity with us against judgments, penalties, fines, settlements and reasonable expenses. Any such person is also entitled, subject to certain limitations, to payment or reimbursement of reasonable expenses (including attorneys' fees and disbursements and court costs) in advance of the final disposition of the proceeding.

The provision regarding indemnification of our directors and officers in our amended and restated certificate of incorporation will generally not limit liability under state or federal securities laws.

We maintain a directors' and officers' insurance policy pursuant to which our directors and officers are insured against liability for actions taken in their capacities as directors and officers. We believe that these indemnification provisions and insurance are useful to attract and retain qualified directors and officers.

In addition, we have entered into indemnification agreements with each of our directors and named executive officers, which also provide, subject to certain exceptions, for indemnification for related expenses, including, among others, reasonable attorney's fees, judgments, fines and settlements incurred in any action or proceeding. Your investment may be adversely affected to the extent that, in a class action or direct suit, we pay the costs of settlement and damage awards against directors and officers pursuant to these indemnification provisions.

Insofar as the foregoing provisions permit indemnification of directors, officers or persons controlling us for liability arising under the Securities Act, we have been informed that in the opinion of the SEC, this indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

**Exhibit 23.1**

**Consent of Independent Registered Public Accounting Firm**

We consent to the incorporation by reference in the following Registration Statements:

(1) Registration Statements (Form S-3 No. 333-235536) of Clovis Oncology, Inc., and

(2) Registration Statements (Form S-8 Nos. 333-234600, 333-219046, 333-211948, 333-178283, 333-182278, 333-190565, 333-198022, 333-206193, and 333-226523) pertaining to the 2009 Equity Incentive Plan, 2011 Stock Incentive Plan and 2011 Employee Stock Purchase Plan of Clovis Oncology, Inc.;

of our reports dated February 26, 2020, with respect to the consolidated financial statements of Clovis Oncology, Inc., and the effectiveness of internal control over financial reporting of Clovis Oncology, Inc., included in this Annual Report (Form 10-K) of Clovis Oncology, Inc. for the year ended December 31, 2019.

/s/ Ernst & Young LLP

Denver, Colorado
February 26, 2020

**Exhibit 31.1**

I, Patrick J. Mahaffy, certify that:

1. I have reviewed this annual report on Form 10-K of Clovis Oncology, Inc. for the year ended December 31, 2019;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 26, 2020

/s/ PATRICK J. MAHAFFY
Patrick J. Mahaffy
President and Chief Executive Officer

**Exhibit 31.2**

I, Daniel W. Muehl, certify that:

1. I have reviewed this annual report on Form 10-K of Clovis Oncology, Inc. for the year ended December 31, 2019;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 26, 2020

/s/ DANIEL W. MUEHL
Daniel W. Muehl
Executive Vice President and Chief Finance Officer

**Exhibit 32.1**

**CERTIFICATIONS PURSUANT TO**
**SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**
**(18 U.S.C. SECTION 1350)**

In connection with the Annual Report of Clovis Oncology, Inc., a Delaware corporation (the "Company"), on Form 10-K for the year ended December 31, 2019, as filed with the Securities and Exchange Commission (the "Report"), Patrick J. Mahaffy, as President and Chief Executive Officer of the Company, does hereby certify, pursuant to §906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. §1350), that to his knowledge:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: February 26, 2020

/s/ PATRICK J. MAHAFFY
Patrick J. Mahaffy
President and Chief Executive Officer

**Exhibit 32.2**

**CERTIFICATIONS PURSUANT TO**
**SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**
**(18 U.S.C. SECTION 1350)**

In connection with the Annual Report of Clovis Oncology, Inc., a Delaware corporation (the "Company"), on Form 10-K for the year ended December 31, 2019, as filed with the Securities and Exchange Commission (the "Report"), Daniel W. Muehl, as Executive Vice President and Chief Finance Officer of the Company, does hereby certify, pursuant to §906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. §1350), that to his knowledge:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: February 26, 2020

/s/ DANIEL W. MUEHL
Daniel W. Muehl
Executive Vice President and Chief Finance Officer