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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, 2020.**

☐ **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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

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, 2020, the last business day of the registrant's most recently completed second quarter, was $578,173,019 based on the closing price of the registrant's common stock on the NASDAQ Global Select Market on that date of $6.75 per share.

The number of outstanding shares of the registrant's common stock, par value $0.001 per share, as of February 12, 2021 was 104,529,652.

**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 2021 Annual Meeting of Stockholders, which is to be filed within 120 days after the end of the registrant's fiscal year ended December 31, 2020, 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 and performance 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 clinical benefit and safety 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 and also an indication specific to metastatic castration-resistant prostate cancer ("mCRPC"). 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 2020, the FDA approved Rubraca for the treatment of adult patients with mCRPC associated with a deleterious BRCA mutation (germline and/or somatic) who have been treated previously with androgen receptor-directed therapy and a taxane-based chemotherapy. The FDA approved this third indication under accelerated approval based on objective response rate and duration of response data from the TRITON2 clinical trial. We launched Rubraca for this indication in the U.S. following receipt of the approval. As an accelerated approval, continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials. The TRITON3 clinical trial is expected to serve as the confirmatory study for Rubraca's approval in mCRPC. In August 2020, the FDA approved the use of Foundation Medicine's blood-based diagnostic test, FoundationOne Liquid CDx, as a companion diagnostic for the detection of deleterious BRCA mutation (germline and/or somatic) to select mCRPC patients for treatment with Rubraca.

In Europe, the European Commission granted a conditional marketing authorization in May 2018 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. 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 authorized in Europe for certain patients in the recurrent ovarian cancer maintenance setting regardless of their *BRCA* mutation status. Following successful reimbursement negotiations, Rubraca has been launched in each of Germany, United Kingdom, Italy, France, Spain and the Netherlands, and reimbursement is pending in Switzerland.

In December 2020, Rubraca met the primary study endpoint of significantly improving progression-free survival ("PFS") versus chemotherapy in the ARIEL4 confirmatory study. An interim analysis of overall survival, a secondary endpoint in the study in which 51% of events had occurred in the intent-to-treat population, showed a trend toward an overall survival advantage in the chemotherapy arm, but was confounded by the high rate (64%) of per-protocol crossover to Rubraca following progression on chemotherapy. Additional ARIEL4 study results are expected to be submitted for presentation at a medical congress meeting in 2021. ARIEL4 is a Phase 3 multicenter, randomized study of Rubraca versus chemotherapy, which enrolled relapsed ovarian cancer patients with *BRCA* mutations (inclusive of germline and/or somatic) who had received two or more prior lines of chemotherapy. Completion of ARIEL4 is a post-marketing commitment in the U.S. and Europe.

Beyond our labeled indications, 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 ("Bristol Myers Squibb") to evaluate its immunotherapy Opdivo® (nivolumab) in combination with Rubraca. We anticipate initial data of Rubraca monotherapy versus placebo from our ATHENA study in the second half of 2021, with the results of Rubraca versus Opdivo in all study populations a year or more later. However, the timing of the ATHENA data readouts is dependent on the timing of data maturity driven by PFS events.

We initiated the Phase 2 LODESTAR study in December 2019 to evaluate Rubraca as monotherapy treatment in patients with recurrent solid tumors associated with a deleterious mutation in homologous recombination repair genes. Based on our interactions with the FDA, we believe that this study may be registration-enabling for a targeted gene- and tumor-agnostic label, if data from the trial support the potential for an accelerated approval. Assuming enrollment in this study continues as planned, and subject to the data, we may potentially file a supplemental New Drug Application ("sNDA") with the FDA for this indication in the second half of 2021 or the first half of 2022.

We hold worldwide rights to Rubraca.

Pursuant to our license and collaboration agreement with 3B Pharmaceuticals GmbH ("3BP"), entered into in September 2019, we have initiated development of a peptide-targeted radionuclide therapy ("PTRT") and imaging agent

targeting fibroblast-activating protein ("FAP"). We have completed sufficient 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. Accordingly, we submitted two INDs for FAP-2286 for use as imaging and treatment agents in December 2020 to support an initial 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. The INDs are expected to become effective following receipt and submission, and acceptance by the FDA, of satisfactory chemistry, manufacturing and controls ("CMC") data for the imaging agent from clinical sites. The FAP-targeting imaging agent will be utilized to identify tumors that contain FAP for treatment in the Phase 1 LuMIERE clinical study, which we anticipate initiating in the first half of 2021.

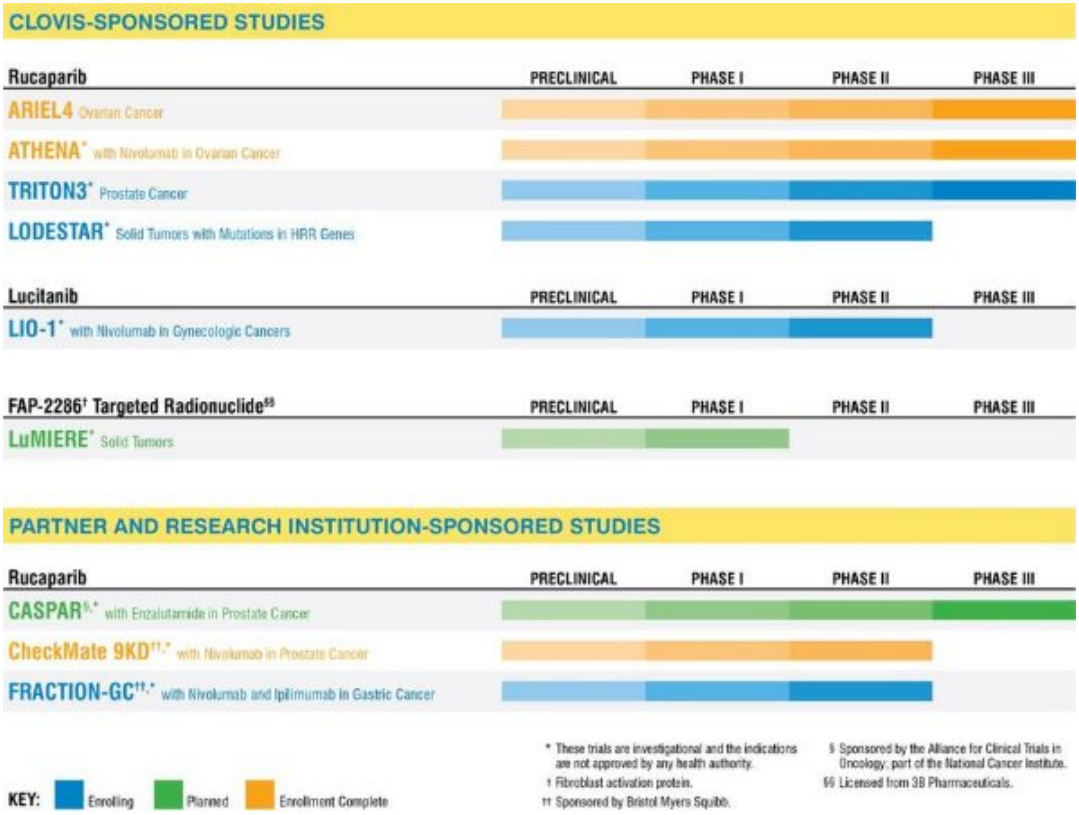
In addition to our planned studies, the University of California San Francisco is sponsoring a separate, investigator-initiated, imaging-only study with gallium-68 labeled FAP-2286 (NCT04621435) to evaluate FAP expression in multiple tumor types; their study is currently recruiting. We hold U.S. and global rights to FAP-2286, excluding Europe (defined to include Russia, Turkey and Israel), where 3BP retains rights. We are also collaborating with 3BP on a discovery program directed to up to three additional, undisclosed targets for targeted radionuclide therapy, to which we would obtain global rights for any resulting product candidates.

Lucitanib, our second product candidate currently in clinical development, is an investigational, oral, potent angiogenesis inhibitor which inhibits 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"). Lucitanib inhibits the same three pathways as Lenvima® (lenvatinib), which has received an FDA approval for use in endometrial cancer in combination with Keytruda® (pembrolizumab), a PD-1 inhibitor. This, together with preclinical data for lucitanib in combination with a PD-1 inhibitor that demonstrated enhanced anti-tumor activity compared to that of single agents, 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 Bristol Myers Squibb. The Clovis-sponsored LIO-1 study of lucitanib in combination with nivolumab in advanced solid tumors and gynecologic cancers is currently enrolling patients in the Phase 2 part of the study. We expect to present interim data from this study at medical meetings in 2021, which are expected to include interim results from the ovarian and endometrial cancer expansion cohorts. We hold the global (excluding China) development and commercialization rights for lucitanib.

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 submitted two INDs in December 2020. The following table summarizes the principal ongoing or planned Clovis- or collaborator-sponsored studies:




In certain of these trials, we or our collaborators 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 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 Europe for patients with recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer. Rubraca also received regulatory approval in the United States as a monotherapy treatment of adult patients with *BRCA1/2*-mutant recurrent, metastatic castrate-resistant prostate 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% 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 United States, Rubraca is approved for the treatment of adult patients with mCRPC associated with a deleterious BRCA mutation (germline and/or somatic) who have been treated previously with androgen receptor-directed therapy and a taxane-based chemotherapy. The FDA approved this indication in May 2020 under accelerated approval based on objective response rate and duration of response data from the TRITON2 clinical trial. We launched Rubraca for this indication in the U.S. following receipt of the approval. As an accelerated approval, continued approval

for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials. The TRITON3 clinical trial is expected to serve as the confirmatory study for Rubraca's approval in mCRPC. In August 2020, the FDA approved the use of Foundation Medicine's blood-based diagnostic test, FoundationOne Liquid CDx, as a companion diagnostic for the detection of deleterious BRCA mutation (germline and/or somatic) to select mCRPC patients for treatment with Rubraca.

In Europe, Rubraca is authorized 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 regardless of their *BRCA* mutation status. Following successful reimbursement negotiations, Rubraca has been launched in each of Germany, United Kingdom, Italy, France, Spain and the Netherlands, and reimbursement is pending in Switzerland.

*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 thus 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 21,000 women will be diagnosed with ovarian cancer in the United States and there will be an estimated nearly 14,000 deaths from ovarian cancer in 2021, and according to GLOBOCAN in 2020, an estimated 66,000 women in Europe are diagnosed each year with ovarian cancer, and ovarian cancer is among those cancers with the highest rate of deaths. According to the American Cancer Society, more than 75% of women are diagnosed with ovarian cancer at an advanced stage, and patients who are diagnosed with

advanced ovarian cancer have a 70-95% chance of recurrence according to the Ovarian Cancer Research Alliance. According to a Clinical Cancer Research 2010 publication, up to 60% of patients with ovarian cancer may be HR-deficient.

Rubraca's approvals in the U.S. and Europe 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 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). An exploratory analysis in the HRD/BRCA wild-type population demonstrated a median PFS of 9.7 months (95% CI: 7.9–13.1) in the Rubraca group (n=106) versus 5.4 months (95% CI: 4.1–5.7) in the placebo group (n=52) (HR: 0.44 [95% CI: 0.29–0.66]); 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). An exploratory analysis in the HRD/BRCA wild-type population demonstrated a median PFS of 11.1 months (95% CI: 8.2-NR) in the Rubraca group (n=106) versus 5.6 months (95% CI: 2.9–8.2) in the placebo group (n=52) (HR: 0.55 [95% CI: 0.35–0.89]; p=0.0135).

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 Europe 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, which enrolled relapsed ovarian cancer patients with *BRCA* mutations (inclusive of germline and/or somatic) who had received two or more prior lines of chemotherapy. The primary endpoint of the study is investigator-assessed progression-free survival ("InvPFS"), with a step-down analysis from the efficacy population (if significant) to the intent to treat ("ITT") population. The efficacy population comprised the group of patients with a deleterious tumor BRCA mutation and excluded those with a BRCA reversion mutation as determined by a blood test. Development of reversion mutations that restore BRCA protein function are associated with resistance to platinum-based chemotherapies and PARP inhibitors in BRCA-mutant cancers, and these occur more frequently in platinum-resistant vs platinum-sensitive patients (13% and 2% respectively in the ARIEL2 study). In December 2020, Rubraca met the primary study endpoint of significantly improving InvPFS versus chemotherapy. Patients with a BRCA reversion mutation represented 7% of patients enrolled in the study and as anticipated, InvPFS results for those patients showed limited benefit from Rubraca therapy. An interim analysis of overall survival, a secondary endpoint in the study in which 51% of events had occurred in the intent-to-treat population, showed a trend toward an overall survival advantage in the chemotherapy arm, but was confounded by the high rate (64%) of per-protocol crossover to Rubraca following progression on chemotherapy. An analysis of the ITT population of patients showed a trend toward an OS advantage for those patients who received Rubraca at any point in the trial versus those who did not. Additional ARIEL4 study results are expected to be submitted for presentation at a medical congress meeting in 2021. Completion of ARIEL4 is a post-marketing commitment in the U.S. and Europe.

*Prostate cancer*

The American Cancer Society estimates that approximately 248,000 men in the United States will be diagnosed with prostate cancer in 2021, and the GLOBOCAN Cancer Fact Sheets estimated that approximately 473,000 men in Europe were diagnosed with prostate cancer in 2020. 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% 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 studies. Enrollment is complete for TRITON2; TRITON3 continues to enroll patients.

The TRITON2 study (NCT02952534) is a multicenter 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 were allocated into three cohorts based on the type of gene mutation and disease status, as 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 and duration of response ("DOR") per modified RECIST v.1.1/PCWG3 criteria assessed by BICR 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.

Efficacy and safety data from TRITON2 formed the basis of a sNDA that was submitted to FDA in late 2019. Evaluable patient populations in the sNDA dataset included the following: 62 RECIST-evaluable patients with a BRCA (germline and/or somatic) mutation and measurable disease (BICR); 115 patients with a BRCA (germline and/or somatic) mutation and measurable or non-measurable disease; and 209 patients with HRD-positive mCRPC. The RECIST-evaluable patient population demonstrated a 44% ORR (N=62; 95% CI 31, 57) by BICR. Objective response rates were similar for patients with a germline BRCA versus somatic BRCA mutation. Median DOR was not evaluable at data cut-off. Additionally, a 55% confirmed PSA response rate (95% CI 45, 64) was observed in an analysis of 115 patients with a deleterious BRCA mutation (germline and/or somatic) and measurable or non-measurable disease.

TRITON2 evaluated the safety of Rubraca 600 mg twice daily as monotherapy treatment in the 209 patients with HRD-positive mCRPC enrolled in the study, including the 115 with BRCA-mutated mCRPC. The most common adverse reactions (greater than or equal to 20% of patients; CTCAE Grade 1-4) occurring in the BRCA mutant population (n=115) were asthenia/fatigue, nausea, anemia, ALT/AST increased, decreased appetite, constipation, rash, thrombocytopenia, vomiting, and diarrhea. The most common laboratory abnormalities (greater than or equal to 35% of patients; CTCAE Grade 1-4) were increase in ALT, decrease in leukocytes, decrease in phosphate, decrease in absolute neutrophil count, decrease in hemoglobin, increase in alkaline phosphatase, increase in creatinine, increase in triglycerides, decrease in lymphocytes, decrease in platelets, and decrease in sodium.

In May 2020, the FDA approved Rubraca for the treatment of adult patients with mCRPC associated with a deleterious BRCA mutation (germline and/or somatic) who have been treated previously with androgen receptor-directed therapy and a taxane-based chemotherapy. The FDA approved this indication under accelerated approval based on objective response rate and duration of response data from the TRITON2 clinical trial. We launched Rubraca for this indication in the U.S. following receipt of the approval. As an accelerated approval, continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials. The TRITON3 clinical trial is expected to serve as the confirmatory study for Rubraca's approval in mCRPC. In August 2020, the FDA approved the use of Foundation Medicine's blood-based diagnostic test, FoundationOne Liquid CDx, as a companion diagnostic for the detection of deleterious BRCA mutation (germline and/or somatic) to select mCRPC patients for treatment with Rubraca.

The TRITON3 study (NCT02975934) is 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.

The Alliance for Clinical Trials in Oncology is sponsoring the Phase 3 CASPAR study (NCT04455750) comparing the combination of enzalutamide and Rubraca to enzalutamide alone in mCRPC. The study is expected to enroll approximately 1,000 patients in the United States at National Clinical Trials Network ("NCTN") sites nationally and is currently the only study evaluating the combination of a PARP inhibitor and a novel anti-androgen with an overall survival endpoint. The Alliance is part of the NCTN sponsored by the National Cancer Institute. CASPAR is expected to begin enrolling patients in the near-term.

*LODESTAR tumor-agnostic study*

The LODESTAR clinical study (NCT04171700) is a Phase 2 study evaluating Rubraca as monotherapy treatment in patients with recurrent solid tumors associated with a deleterious homologous recombination repair ("HRR") gene mutation across a variety of tumor types. These gene mutations include *BRCA1*, *BRCA2*, PALB2, RAD51C, RAD51D in the primary cohort, 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 and is currently enrolling.

*Opdivo combination trials*

Our ongoing collaboration with Bristol Myers Squibb involves the evaluation of the combination of Rubraca with Bristol Myers Squibb'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 Bristol Myers Squibb, 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 approximately 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 and completed enrollment in the second quarter of 2020, evaluates 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. However, the timing of the ATHENA readouts is dependent on the timing of data maturity driven by PFS events. 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.

Bristol Myers Squibb 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 has completed enrollment of patients with biomarker negative or positive disease, for whom tumor tissue samples were used to determine biomarker status. Bristol Myers Squibb initiated the study in the fourth quarter of 2017.

Bristol Myers Squibb 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.

*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*

Three FDA-approved companion diagnostic tests are commercially available to select 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.

In August 2020, Foundation received approval for FoundationOne Liquid CDx, a qualitative next generation sequencing-based in vitro diagnostic test that analyzes mutations in 311 genes (including BRCA1/2) utilizing circulating cell-free DNA isolated from plasma derived from peripheral whole blood. FoundationOne Liquid CDx is approved as a companion diagnostic to select mCRPC and 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.

***FAP-2286 and Radionuclide Therapy Development 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 are also collaborating with 3BP on a discovery program directed to up to three additional, undisclosed targets for targeted radionuclide therapy, to which we would obtain global rights for any resulting product candidates.

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.

*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% 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 administration via intravenous injection of a small amount of radioactive material – a radionuclide – that is combined with a peptide for use as a targeted pharmaceutical. The peptide is able to recognize and bind to specific targets on the cancer cells or in their microenvironment, 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. Radionuclides with different emission properties, primarily beta particles or more potent alpha particles, are used to deliver cytotoxic radiation to the tumor-associated targets. 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. In most cases, the radionuclides may be visualized by using nuclear medicine imaging techniques to evaluate the specificity of the agent, supporting a precision medicine approach to delivery of the therapeutic form of the agent.

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(L)-1 agents. While our initial development focus will be on monotherapy with FAP-2286, we intend to explore these types of combinations pre-clinically and clinically as well.

The FAP-2286 product candidate consists of a peptide that selectively binds to FAP and a linker and site to which radioactive medical isotopes can be attached for use as an imaging agent or therapeutic agent. Our initial development plans include the use of gallium-68 ($^{68}$Ga) as an imaging agent and lutetium-177 ($^{177}$Lu) as a therapeutic agent.

The anti-tumor efficacy of $^{177}$Lu-FAP-2286 has been evaluated preclinically in FAP-expressing tumor models. Data presented at the 2020 ESMO Virtual Congress demonstrated that a single, IV dose of $^{177}$Lu-FAP-2286 resulted in statistically significant tumor growth inhibition in two different mouse xenograft models: (1) HEK293 cells stably transfected with human FAP (HEK-FAP); and (2) Sarc4809 sarcoma patient-derived xenograft model with endogenous FAP expression.

*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 eleven patients at the International Centers for Precision Oncology 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.

*Our FAP-2286 Clinical Development Plan*

In December 2020, we submitted two INDs for FAP-2286 for use as imaging and treatment agents, respectively, to support an initial Phase 1 study, designated the LuMIERE study, to determine the dose and tolerability of $^{177}$Lu-FAP-2286 as a therapeutic agent. Expansion cohorts are planned in multiple tumor types as part of a global development program. The INDs are expected to become effective following receipt and submission of satisfactory CMC data for the gallium-68 labeled imaging agent from clinical sites. The FAP-targeting imaging agent will be utilized to identify tumors that contain FAP for treatment in the Phase 1 clinical study, which we anticipate initiating in the first half of 2021. Studies of FAP-2286 linked to an alpha-emitter are also under consideration.

In addition to our planned study, the University of California San Francisco is sponsoring a separate, investigator-initiated imaging-only study with gallium-68 labelled FAP-2286 to evaluate FAP expression in multiple tumor types (NCT04621435); this study is enrolling patients. Data from the study is expected to inform indication selection for the LuMIERE Phase 2 expansion cohorts.

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

Lucitanib is an investigational, oral, potent angiogenesis inhibitor which inhibits 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").

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 (Fukumura 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. Multiple Phase 1-3 studies are examining the combination of angiogenesis and PD-(L)1 inhibitors in different indications.

Lucitanib inhibits the same three pathways as Lenvima (lenvatinib), which has shown encouraging results when combined with the PD-1 inhibitor Keytruda (pembrolizumab), and this combination has been approved by the FDA on an accelerated basis for the treatment of certain forms of endometrial cancer. This, together with preclinical data for lucitanib in combination with a PD(L)-1 inhibitor as described above, represent a scientific rationale for development of lucitanib in combination with a PD(L)-1 inhibitor, and in February 2019, lucitanib was added to our clinical collaboration with Bristol Myers Squibb evaluating combinations with Opdivo.

LIO-1 is an open-label, Phase 1b/2 study (NCT04042116) of lucitanib in combination with Opdivo in advanced gynecologic cancers and other solid tumors to determine the recommended dose of lucitanib in combination with Opdivo in patients with an advanced solid tumor (Phase 1b); followed by evaluation of the safety and efficacy of lucitanib and Opdivo in patients with an advanced gynecological solid tumor (Phase 2), including ovarian, endometrial and cervical cancers. The primary efficacy endpoint of the LIO-1 study is ORR as assessed by the investigator according to RECIST v1.1.

Initial data presented at the 2020 ESMO Virtual Congress from the Phase 1b part of the study in patients with an advanced solid tumor (n=17) identified the recommended starting Phase 2 dose of oral lucitanib to be used in combination with Opdivo and showed promising signs of antitumor activity. The recommended oral starting dose of lucitanib was established as 6 mg once daily, to be given in combination with Opdivo at a fixed dose of 480 mg intravenously (IV) once every 28 days. Across three dose levels studied (6 mg, 8 mg and 10 mg) of lucitanib in combination with Opdivo at (480 mg once every 28 days), only one dose-limiting toxicity of Grade 3 proteinuria was observed among 17 patients, and there were no apparent differences in TEAE frequencies between dose levels. In this small patient population, TEAEs were consistent with those expected for lucitanib and Opdivo. The Phase 2 part of the study is currently enrolling. We expect to present interim data from LIO-1 at medical meetings in 2021, which are expected to include interim results from the ovarian and endometrial cancer expansion cohorts.

Preclinical and clinical data also support the potential activity of combining angiogenesis and PARP inhibition. According to Cancer Research and Molecular and Cellular Biology, 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.

**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;
- in combination with bevacizumab for the maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in a complete or partial response to first-line platinum-based chemotherapy and whose cancer is associated with HRD-positive status defined by either:
    - a deleterious or suspected deleterious *BRCA* mutation, and/or
    - genomic instability;
- 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;
- for the treatment of adult 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;
- 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; and
- for the treatment of adult patients with deleterious or suspected deleterious germline or somatic homologous recombination repair ("HRR") gene-mutated mCRPC who have progressed following prior treatment with enzalutamide or abiraterone.

Lynparza is approved in Europe 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;
- in combination with bevacizumab for the maintenance treatment of adult patients with advanced (FIGO stages III and IV) 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 in combination with bevacizumab and whose cancer is associated with homologous recombination deficiency HRD-positive status defined by either a *BRCA1/2* mutation and/or genomic instability;

- 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;
- for the maintenance treatment of adult patients with germline *BRCA1/2*-mutations who have metastatic adenocarcinoma of the pancreas and have not progressed after a minimum of 16 weeks of platinum treatment within a first-line chemotherapy regimen; and
- for the treatment of adult patients with metastatic castration-resistant prostate cancer and *BRCA1/2*-mutations (germline and/or somatic) who have progressed following prior therapy that included a new hormonal agent.

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.

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 advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to first-line platinum-based chemotherapy;
- 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; and
- 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 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.

Zejula is approved in Europe:

- 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; and
- as monotherapy for the maintenance treatment of adult patients with advanced epithelial (FIGO Stages III and IV) high-grade ovarian, fallopian tube or primary peritoneal cancer who are in response (complete or partial) following completion of first-line platinum-based chemotherapy.

Additional clinical investigations of Zejula in ovarian, breast prostate 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% of patients with a *BRCA1/2* mutation demonstrated a RECIST response. In October 2019, niraparib was granted Breakthrough Therapy Designation based on data from the Phase 2 GALAHAD study.

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 treatment indications that may be relevant for FAP-2286.

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 use from University Medical Centre Heidelberg. More recently, Point Biopharma has entered into an exclusive licensing agreement with Avacta to use their technology in the development of a range of FAP-activated radiopharmaceuticals.

In addition, other potential FAP-directed radionuclide therapeutics, small molecules, biologics, immunotherapies, and other treatment modalities that target FAP are at various stages of development. For example, AMG506 (also known as MP0310) is a multi-specific FAP x 4-1BB-targeting DARPin® biologic that is being developed by Amgen in collaboration with Molecular Partners, AG. AMG506 is being investigated in at least one clinical trial (NCT04049903 ) in patients with advanced solid tumors.

Roche also has several compounds that are being investigated. RO6874281 is a targeted immunocytokine that combines an engineered interleukin-2 variant (IL2v) with an antibody against FAP. RO6874813 (RG7386), a bispecific antibody that binds to FAP and death receptor 5 (DR5), is being studied in patients with advanced or metastatic solid tumors (NCT02558140).

PSIOxus Therapeutics is developing an oncolytic adenoviral vector (NG-641) designed to deliver genes to tumor cells that produce proteins targeting tumor-associated stromal fibroblasts. The NG-641 virus encodes genes for FAP-targeting bispecific T-cell activator (FAP-TAc), the chemokines CXCL9 and CXCL10, and interferon alpha. NG-641 is being investigated in patients with advanced solid tumors (NCT04053283).

Bioxcel Therapeutics is developing talabostat (BXCL701), a molecule that is designed to inhibit dipeptidyl peptidase (DPP) 8/9 and block immune evasion by targeting FAP. BXCL is being investigated in combination with pembrolizumab in patients with aggressive prostate cancer (NCT03910660) and pancreatic cancer (NCT04123574).

In addition, radionuclide therapeutics with targets other than FAP may compete with FAP-2286 if they target the same tumor type. 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 (NCT03511664) 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. 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), are continuing 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.

In April 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.

In May 2020, Rubraca received a third FDA approval for Rubraca as a monotherapy treatment of adult patients with BRCA1/2-mutant recurrent, metastatic castrate-resistant prostate cancer. This approval resulted in an obligation to pay an $8.0 million milestone payment, which we paid in June 2020.

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 $8.0 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 also receives royalties on net sales of Rubraca.

***Advenchen Laboratories LLC***

On November 19, 2013, we acquired all of the issued and outstanding capital stock of EOS pursuant to the terms set forth in that certain Stock Purchase Agreement, dated as of November 19, 2013 (the "Stock Purchase Agreement"), by and among the Company, EOS, its shareholders (the "Sellers") and Sofinnova Capital V FCPR, acting in its capacity as the Sellers' representative. Following the acquisition, EOS became a wholly-owned subsidiary of the Company. Under the terms of the Stock Purchase Agreement, in addition to the initial purchase price paid at the time of the closing of the acquisition and other license fees due to Advenchen described below, we will also be obligated to pay to the Sellers a milestone payment of $65.0 million upon obtaining the first NDA approval from the FDA with respect to 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 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 discovery collaboration 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 discovery collaboration 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 such as Rubraca and our other product candidates. Our product candidates must be approved by the FDA through the NDA process before they may be legally placed on the market in the United States. In the European Union, a product requires approval from the European Commission ("EC") following a favorable assessment from the European Medicines Agency ("EMA") through the marketing authorization application ("MAA") process for a product falling within the scope of the centralized procedure or a national MAA process (albeit through

mutual recognition or decentralized procedure). Our product candidates will be subject to similar requirements in other countries prior to marketing in those countries. 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 (evaluations of product chemistry, toxicity and formulation) 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 for further research of the drug candidate's safety and/or efficacy. The central focus of an IND submission is on the general investigational plan for the drug candidate 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 and 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 product candidate 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.

Human clinical trials are inherently uncertain, and Phase 1, Phase 2 and Phase 3 testing may not be successfully completed. 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 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.

As result of the United Kingdom ("UK") leaving the EU, the UK is no longer part of the harmonized EU medicines network. The UK government introduced legislation to allow the continued registration, sale and access to medicinal products including regulation to allow implementation of the Northern Ireland Protocol. A comprehensive national regime for the authorization of medicinal products for human use; for the manufacture, import, distribution, sale and supply of those products; for their labelling and advertising; and for pharmacovigilance have been introduced. In Northern Ireland the, EU regulations will continue to apply in accordance with the Northern Ireland Protocol.

***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 Europe, 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 Rubraca and any other drug products for which we obtain regulatory approval. In the United States and markets in other countries, sales of approved pharmaceutical products depend in part on the availability of reimbursement from third-party payors. Third-party payors include government health administrative authorities, managed care providers, public and 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 or European Commission/specific country-approved drugs for a particular indication (or all indications for an approved drug). Third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services and imposing controls to manage costs. 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 approvals. The development of a product dossier and a Budget Impact Model may be helpful in assisting the payors in evaluating cost effectiveness. In any event, 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 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 legal and Congressional challenges to repeal and replace certain aspects of the Affordable Care Act . Most recently, the Tax Cuts and Jobs Act was enacted, which, among other things, removed penalties for not complying with Affordable Care Act's individual mandate to carry health insurance. The Trump administration pursued several initiatives designed to delay the implementation of certain provisions of the Affordable Care Act or otherwise circumvent some of the requirements for health insurance mandated by the Affordable Care Act. There is uncertainty with respect to the impact President Biden'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 Europe, governments influence the price of pharmaceutical products through their pricing and reimbursement rules and control of national health care systems that fund the cost of those products to consumers. These jurisdictions operate a system under which products may only be marketed once a reimbursement price has been agreed for a defined population that, depending on country-specific negotiations, could be equal to European Commission-granted indication or a restricted population. To obtain reimbursement and pricing approval in Europe, some of these European countries may require additional economic evidence. In European countries, repeating price/reimbursement negotiations take place depending on local healthcare situations and can lead to lower reimbursed prices over time.

The downward pressure on health care costs in general, particularly prescription drugs, has become very intense. As a result, increasing high barriers are being erected to the entry of new products. In addition, in some countries, especially in Europe, cross-border imports from low-priced markets exert a commercial pressure on pricing within a country. In

particular, for each new indication, new negotiations are required to obtain reimbursement in European countries; also, pricing negotiations in European countries are often linked to baskets of comparator countries; due to Brexit, it is currently unclear whether changes in country baskets will take place anytime soon. 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 Europe 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 be impacted by government and third-party coverage and reimbursement decisions. 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 in the U.S. and Europe. 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 civil 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, drug manufacturers must report to CMS 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 $176,495 per year (or up to an aggregate of $1.176 million per year for "knowing failures"), adjusted for inflation, 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") outlines several 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 cause of action for data breaches. Beyond California, many other states are developing their own data privacy protections, which, along with 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 General Data Protection Regulation (Regulation (EU) 2016/679), the U.K.'s Data Protection Act 2018 and the Swiss Federal Data Protection Act and Data Protection Ordinance, regulate the processing of personal data within the U.K., the EU and between countries in the EU, U.K. and countries outside of the EU and U.K., including the U.S. Failure to provide adequate privacy protections and maintain compliance with the EU, U.K. and Swiss Privacy Laws, could jeopardize business transactions across borders and result in significant penalties. Similar to the impact of the CCPA or other U.S. state frameworks, these European 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, depending on their classification by FDA.

In the United States, devices are classified into one of three classes (Class I, II, or III) based on the controls deemed necessary by the FDA to reasonably ensure their safety and effectiveness. Class I and II devices are subject to general controls including, but not limited to, performance standards, premarket notification, also called 510(k) clearance, and post market surveillance. Class III devices are those that either support or sustains human life, are of substantial importance in preventing impairment of human health, or present a potential, unreasonable risk of illness or injury. Class III devices are subject to more rigorous review and approval requirements than Class I or II, known as a 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 considered Class III devices, 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, technology 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 were granted patent term extension to November 22, 2023 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. Additionally, other patents and patent applications are directed to methods of making, methods of using, dosing regimens, various salt and polymorphic forms, and formulations with expiration dates through potentially 2035. These patents and patent applications include 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, which expires in 2035. To date, the rucaparib camsylate salt/polymorph patents issued in 51 jurisdictions (including the United States and Europe), with applications pending in 7 jurisdictions. Patents directed to the high dosage strength rucaparib tablets, including all

commercial dosage strengths, issued in the United States and 5 other jurisdictions, and applications are pending in 13 jurisdictions, including before the European Patent Office. United States patents with claims that cover Rubraca and its uses are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book.

Because Rubraca does not contain a previously approved active ingredient, the Hatch-Waxman Act provides a five-year period of new chemical entity ("NCE") exclusivity following its December 19, 2016 approval during which time generic competitors cannot file an Abbreviated New Drug Application ("ANDA") for a generic version of Rubraca, unless the submission contains a Paragraph IV Certification that one or more patents listed in the Orange Book for Rubraca are invalid, unenforceable or will not be infringed by a proposed ANDA product, in which case the submission may be made four years following the original drug approval. That is, under the provisions of the Hatch-Waxman Act, December 19, 2020 was the earliest date that a generic competitor could submit an ANDA to the FDA requesting permission to market a generic version of Rubraca. To date, we do not have an indication that an ANDA has been filed. However, a generic company may have submitted an ANDA, for which we would receive a Paragraph IV Notice Letter in the future. If a Paragraph IV Certification is made, the generic company is required to provide a Paragraph IV Notice Letter advising Clovis of the certification. If that occurs, Clovis will have the opportunity to bring a patent infringement action against the generic company. If such a suit is filed within the 45-day period following receipt of the Paragraph IV Notice Letter, the Hatch-Waxman Act provides for a 30-month stay on FDA's ability to grant final approval of the proposed generic product. The 30-month stay generally runs from the date the Paragraph IV Notice Letter is received. However, when a Paragraph IV certification is received during the five-year period of NCE exclusivity following the date of first NDA approval, the thirty-month stay extends from five years after the date that product was first approved. The 30-month stay may be shortened or lengthened, including due to a settlement of a lawsuit, a court order (including a decision by the district court on the merits of the case), or patent expiration.

Two European patents in the rucaparib camsylate salt/polymorph patent family (European Patent 2534153 and its divisional European Patent 3150610) were opposed. In particular, opposition notices against European Patent 2534153 were filed by two parties on June 20, 2017. During an oral hearing that took place on December 4, 2018, the European Patent Office's Opposition Division maintained European Patent 2534153 in amended and narrowed form with claims 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 AG, appealed the written decision of the European Opposition Division and filed reply appeal briefs in November 2019. An opposition against European Patent 3150610 was filed by Generics (UK) Limited on April 30, 2020 on grounds similar to those raised in the opposition notices against European Patent 2534153, which grounds are common in such proceedings. Moreover, these grounds of opposition, as well as documents based on which lack of patentability has been alleged, were considered by the European Patent Office during the examination stage, and the claims were deemed to comply with the applicable law when granting the patent. Clovis responded to the opposition notice in European Patent 3150610 on January 8, 2021, amending the claims to be directed to the use of rucaparib maleate in a method of inhibiting PARP activity or treating cancer. A preliminary opinion and summons to oral proceedings were issued on January 26, 2021. The oral hearing is scheduled for November 18, 2021. The preliminary opinion provides a non-binding indication of the Opposition Division's initial view based on the documents that have thus far been submitted, which agrees with our positions on a number of grounds of opposition and agrees with an objection made by the opponent, but only with respect to some of the claims. We have the opportunity to submit further arguments and pursue alternative claims in the form of auxiliary requests. While the ultimate results of patent challenges can be difficult to predict, it is our view that a number of factors support patentability, and we believe a successful challenge of all claims would be difficult.

We have filed for patent term extension under a supplementary protection certificate for Rubraca based on European Patent 2534153 and believe that extension could be available to 2033. 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 United States, Europe, and Japan and is issued or pending in other jurisdictions. In the United States, 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 United States, 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 or jurisdictions 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 Europe. 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 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, was 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 a CMO. 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.

In October 2020, we adopted a new U.S. commercial strategy to address a challenging sales environment resulting from a trend toward reduced in-person access for oncology commercial teams to oncology practices in general, which has been further accelerated by COVID-19, which has severely limited oncology patient visits and cancer diagnoses. Physicians increasingly prefer digital communications and virtual peer-to-peer interactions which they can access when they choose. The new hybrid strategy elevates digital programming, virtual communication and peer-to-peer interactions while reducing in-person promotion, and the remaining in-person activities will be much more targeted. This hybrid strategy does not require as large a U.S. commercial organization, and in early November the size of the organization was reduced by approximately 45 employees, resulting in a U.S. commercial team of approximately 85 employees.

**Customers**

We are currently approved to sell Rubraca in the U.S. and Europe 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 12, 2021, we had 429 employees, of which 291 were employed in the U.S. and 138 were employed outside of the U.S. None of our U.S. employees are represented by labor unions, and a very small number of international employees are covered by collective bargaining agreements.

Our success depends upon our ability to retain and attract highly qualified management and technical personnel. Talent management is critical to our ability to execute on our long-term growth strategy. We appreciate the importance of retention, growth and development of our employees. We continue to be committed to an inclusive culture which values equality, opportunity and respect. In support of our inclusive culture, we believe we offer competitive compensation and benefits, including an annual pay gap assessment; provide respectful workplace training to strengthen employee understanding; and strive to recruit a diverse talent pool across all levels of the organization.

Employee safety and wellbeing is of paramount importance to us in any year and was of particular focus in our fiscal year 2020 in light of COVID-19. In response to the pandemic, we provided productivity and collaboration tools and resources for employees working remotely, including training and toolkits to help leaders effectively lead and manage remote teams. In addition, we enhanced and promoted programs to support our employees' physical and mental wellbeing.

**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.*

**Risk Factor Summary**

Our business operations are subject to numerous risks and uncertainties, including those outside of our control, that could cause our business, financial condition or operating results to be harmed, including risks regarding the following:

- the impact of the COVID-19 pandemic on our revenues and our ability to continue to operate our business;
- we will require substantial additional funding which may not be available to us on acceptable terms, or at all, and failure to obtain additional funding may impact our ability to continue our development programs and successfully commercialize Rubraca;
- 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, a portion of which is due this year;
- we have incurred significant losses since our inception and anticipate that we will continue to incur losses for the foreseeable future;
- we may not be able to raise the funds necessary to repay our debt upon a fundamental change, and provisions in our debt could delay or prevent an otherwise beneficial takeover of us;
- we are highly dependent on revenues from the sale of Rubraca, and the rate and degree of market acceptance and commercial viability, including the safety, efficacy and potency of Rubraca and our other product candidates may limit the commercial success of Rubraca;

- if our sales, marketing and distribution capabilities for Rubraca or other product candidates for which we obtain marketing approval are inadequate, we may be unable to generate sufficient revenue from sales of our products;
- 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;
- our expectations regarding the FDA and other regulatory authorities' interpretation of our data and information on our product candidates and the impact on our business of the FDA's and other regulatory authorities' interpretation of our submissions, filing decisions by the FDA and other regulatory authorities, potential advisory committee meeting dates and advisory committee recommendations, and FDA and other regulatory authorities product approval decisions and related timelines;
- the success of competing drugs that are or become available;
- the success and timing of our non-clinical studies and clinical trials;
- our ability to verify the clinical benefit of Rubraca through our confirmatory trials and to satisfy other post-marketing requirements and post-marketing commitments, our ability to obtain and maintain regulatory approval of Rubraca and our other product candidates, and the labeling under Rubraca and any other approval we may obtain;
- our ability to engage and retain third-party manufacturers with sufficient capability and capacity to support the commercialization of Rubraca and our other product candidates, and the performance of such third-party manufacturers;
- our ability to obtain and maintain intellectual property protection for our product candidates, including our ability to defend our intellectual property against challenges;
- our ability to maintain our collaborations with our licensing partners to develop our product candidates;
- the size and growth of potential markets for our product candidates and our ability to serve those markets;
- the loss of key scientific or management personnel;
- regulatory developments in the United States and foreign countries;
- our operating results are difficult to predict and may fluctuate, and if our operating results are below the expectations of investors or analysts, the trading price of our stock could decline;
- the price of our stock has been, and may continue to be volatile, which will impact the value of your investment and our ability to raise additional capital on favorable terms, or at all;
- future sales and issuances of our common stock or rights to purchase our common stock, including through our equity incentive plans, could result in dilution of your investment and cause our stock price to fall.

**Risks Related to the COVID-19 Pandemic**

***The outbreak of COVID-19 could materially adversely affect our business.***

On January 30, 2020, the World Health Organization (the "WHO") declared that the recent novel coronavirus disease (COVID-19) outbreak was a public health emergency of international concern, and on March 11, 2020 the WHO declared the COVID-19 outbreak a pandemic. This has resulted in increased travel restrictions, quarantines, "work-at-home" and "shelter-in-place" orders and extended shutdown of certain non-essential businesses in the United States, and European and Asia-Pacific countries, including countries in which we commercialize Rubraca and countries in which we have planned or active clinical trials. With a renewed rise in the number of cases of the coronavirus in certain parts of the United States and Europe and the ongoing uncertainty regarding future trends in cases, these restrictions, quarantines, shutdowns and other disruption to businesses globally continue to evolve and, in many areas, increase. The effects of the coronavirus are difficult to assess or predict.

Our ability to generate product revenue for the year and quarter ended December 31, 2020 was negatively affected by the COVID-19 pandemic due to fewer diagnoses and fewer patients going to in-person office visits as oncology practices and patients continue to adapt to the impact of the virus. We anticipate that the outbreak will likely have a significant impact on our business in future quarters, and cannot currently predict the extent or duration of that impact.

The outbreak of COVID-19 has had a major impact on the financial markets, the global economy or the economies of particular countries or regions. Specifically, the COVID-19 outbreak could result in reduced operations of third-party manufacturers upon whom we rely, disrupt our supply chain, or otherwise limit our ability to obtain sufficient materials to manufacture Rubraca and our product candidates. While we believe that we have sufficient supply of Rubraca and our product candidates to continue our commercial and clinical operations as planned, Rubraca and our product candidates, or materials contained therein, come from facilities located in areas impacted by COVID-19 or that may be impacted, as the COVID-19 outbreak or its disruption worsens. If any third party in our supply or distribution chain for materials or finished product are adversely impacted by restrictions resulting from the COVID-19 outbreak, including staffing shortages, production slowdowns and disruptions in delivery systems, our supply chain may be disrupted, limiting our ability to manufacture and distribute Rubraca for commercial sales and our product candidates for our clinical trials and research and development operations. There is no guarantee that the recent COVID-19, or any potential future, outbreak would not impact our future supply chain, which could have a material adverse impact on our clinical trial plans and business operations.

Our sales force has had physical access to hospitals, clinics, doctors and pharmacies curtailed and/or has been limited, which may have a material adverse effect on our future sales. While digital tools are available to our field employees to facilitate remote meetings with healthcare providers, we cannot ensure that these methods will be effective. Additionally, patients who might be currently using Rubraca, or might otherwise be eligible to use our products, may be unable to meet with their healthcare providers in-person, which may reduce the number of prescription refills or new patient starts, affecting our revenues from Rubraca both in our currently approved ovarian cancer indications, as well as impacting our current launch in *BRCA*-mutant metastatic castration-resistant prostate cancer, which was approved during the second quarter of 2020.

Furthermore, our clinical trials may be affected by the COVID-19 outbreak. Although we did not see material disruption to our clinical trials as a result of the COVID-19 pandemic for the year ended December 31, 2020, we could see material disruption during 2021. During the second quarter of 2020, we observed a slight decrease in the rate of enrollment in ATHENA, our largest clinical trial, however we completed target enrollment in ATHENA in that quarter. As the outbreak persists in countries in which we conduct or plan to conduct our clinical trials, activities such as site initiation, patient enrollment, trial data collection, and site monitoring visits may be delayed or stalled due to travel and access restrictions, diversion of healthcare resources toward the COVID-19 outbreak, which we have already seen in certain of our trial sites, patient or staff unwillingness to visit hospitals and clinics and participate in our trials, or quarantines and other restrictions that may impede patient or staff movement and study drug availability at trial sites, interrupt healthcare services or otherwise prevent patient compliance with clinical trial protocols. Additionally, we may slow or delay enrollment in certain trials to manage expenses.

In addition, COVID-19 could affect our employees, our agents and their employees or the employees of companies with which we do business, thereby disrupting our business operations. We have implemented work-at-home policies and may experience limitations in employee resources. Our increased reliance on personnel working from home may negatively impact productivity, or disrupt, delay, or otherwise adversely impact our business. The effects of working from home and other burdens imposed by COVID-19 on individuals may impact our employee retention. In addition, our reliance on personnel working from home could increase our cyber security risk, create data accessibility concerns, and make us more susceptible to communication disruptions, any of which could adversely impact our business operations or delay necessary interactions with local and federal regulators, manufacturing sites, research or clinical trial sites and other important agencies and contractors.

On March 18, 2020, the Families First Coronavirus Response Act ("FFCR Act"), and on March 27, 2020, the Coronavirus Aid, Relief and Economic Security ("CARES") Act were each enacted in response to the COVID-19 pandemic. The FFCR Act and the CARES Act contain numerous income tax provisions, such as relaxing limitations on the deductibility of interest and the use of net operating losses arising in taxable years beginning after December 31, 2017. We evaluated the impact of this legislation and the income tax provisions did not result in a material cash benefit to us. Future regulatory guidance under the FFCR Act and the CARES Act (as well as under the Tax Cuts and Jobs Act) remains forthcoming, and such guidance could ultimately increase or lessen their impact on our business and financial condition. It is also highly possible that Congress will enact additional legislation in connection with the COVID-19 pandemic, some of which could impact us.

The trading prices for our common stock and of other biopharmaceutical companies have been highly volatile as a result of the coronavirus pandemic. As a result, we may face difficulties raising capital or which may be on unfavorable terms. In addition, a recession, depression or other sustained adverse market event resulting from the spread of the coronavirus could materially and adversely affect our business and the value of our common stock. A number of governments in places where we have operations have adopted stimulus programs to assist businesses effected by COVID-19, including by facilitating lending arrangements. We may access these loan programs for additional working capital although there can be no guarantee that we will obtain any such loans and we do not currently know the terms of such loan programs.

The effectiveness of external parties, including governmental and non-governmental organizations, in combating the spread and severity of COVID-19 could have a material impact on the losses we experience. These events could cause a material adverse effect on our results of operations in any period and, depending on their severity, could also materially and adversely affect our financial condition.

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

***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 certain affiliates of Sixth Street Partners, LLC ("Sixth Street") 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.***

As of December 31, 2020, we had $64.4 million outstanding aggregate principal amount of 2.5% convertible senior notes due 2021 (the "2021 Notes"), $300.0 million outstanding aggregate principal amount of 1.25% convertible senior notes due 2025 (the "2025 Notes"), $85.8 million outstanding aggregate principal amount of 4.50% convertible senior notes due 2024 (the "2024 Notes (2019 Issuance)"), and $57.5 million outstanding aggregate principal amount of a new series of 4.50% Convertible Senior Notes due 2024 (the "2024 Notes (2020 Issuance)" and together with the 2021 Notes, 2024 Notes and 2025 Notes, the "Notes"). In addition, as of December 31, 2020, we had $99.8 million outstanding aggregate principal amount pursuant to our ATHENA clinical trial financing agreement. The $64.4 million in outstanding aggregate principal amount of the 2021 Notes is due on September 15, 2021, and we are obligated to begin repaying the ATHENA clinical trial financing 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").

Our ability to make scheduled payments of interest and principal on the Notes, to pay the repurchase price for the Notes on a fundamental change or to begin repaying the ATHENA clinical trial financing when due, 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. 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 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 Europe, 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, 2020, 2019 and 2018, we had net losses of $369.2 million, $400.4 million and $368.0 million, respectively. As of December 31, 2020, we had an accumulated deficit of $2,612.7 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 may not be able to raise the funds necessary to repurchase the Notes upon a fundamental change, or the ATHENA clinical trial financing agreement upon a change of control, and our future and current 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. In addition, in the event of a change of control of us, we must pay to the lenders under the ATHENA clinical trial financing agreement, 1.75 times the amount we have borrowed thereunder if the change of control occurs prior to the Repayment Start Date, or 2 times the amount we have borrowed thereunder if the change of control occurs after the Repayment Start Date (minus the amount of all quarterly payments previously paid to the lenders) (the "Discharge Amount"). 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, including limitations on repurchase of certain debt set forth in the ATHENA clinical trial financing agreement. 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

other current indebtedness, such as the ATHENA clinical trial financing agreement, or our future indebtedness. For example, an event of default under the ATHENA clinical trial 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. 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, the ATHENA clinical trial financing agreement 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, such as the ATHENA clinical trial financing agreement. 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 or the ATHENA clinical trial financing agreement 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 and the ATHENA clinical trial financing agreement could delay or prevent an otherwise beneficial takeover of us.***

Certain provisions in the Notes and the indentures governing the Notes, and in the ATHENA clinical trial financing agreement, 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, the indentures governing the Notes and the ATHENA clinical trial financing agreement 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.

**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 Europe. 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. and Europe.

As many of these factors are beyond our control, we cannot assure you that we will be able to continue to grow meaningful revenue through the sale of Rubraca. In addition, we may experience significant fluctuations in sales of Rubraca from period to period. We have two other product candidates, lucitanib, in clinical development and FAP-2286 in pre-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.

***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 Europe, 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, Europe 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 revenue 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 Europe, 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:

- sales of such product may decline;
- regulatory authorities may withdraw or restrict 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;
- additional nonclinical or clinical studies, changes in labeling or changes to manufacturing processes, specifications and/or facilities may be required
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of the above occurrences would harm or prevent sales of such product, prevent us from achieving or maintain market acceptance of a product candidate, 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.

***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, Dr. Lindsey Rolfe, our Executive Vice President of Clinical Development and Pharmacovigilance and Chief Medical Officer, Gillian C. Ivers-Read, our Executive Vice President, Technical Operations and Chief Regulatory Officer and Dr. Thomas Harding, our Chief Scientific Officer, Translational Medicine 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 12, 2021, we employed 429 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. In addition, in response to the COVID-19 pandemic, a majority of our workforce is currently working remotely. This could increase our cybersecurity risk, create data accessibility concerns and make us more susceptible to communication disruptions. 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, or inability to access, even temporarily, 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. Likewise, we rely on third parties for the manufacture of our products and product candidates, including clinical trial supply, and similar events relating to their computer systems could also have a material adverse effect on our business and development programs. 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.

Our business is subject to complex and evolving U.S. and foreign laws and regulations, information security policies and contractual obligations relating to privacy and data protection, including the use, processing, and cross-border transfer of personal information. These laws and regulations are subject to change and uncertain interpretation, and could result in claims, changes to our business practices, or monetary penalties, and otherwise may harm our business. We receive, generate and store significant and increasing volumes of sensitive information and business-critical information, including employee and personal data, research and development information, commercial information, and business and financial information. Cyber-attacks, breaches, interruptions or other data security incidents could result in legal claims or proceedings, liability under federal or state laws that protect the privacy of personal information, regulatory penalties, significant remediation costs, disrupt key business operations and divert attention of management and key information technology resources. In the United States and Europe, notice of breaches of personal information must be made to affected individuals, and for extensive breaches, notice may need to be made to the media or U.S. state attorneys general or other governmental authorities. Such a notice could harm our reputation and ability to compete.

***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.

***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.

Because Rubraca does not contain a previously approved active ingredient, the Hatch-Waxman Act provides a five-year period of new chemical entity ("NCE") exclusivity following its December 19, 2016 approval during which time generic competitors cannot file an Abbreviated New Drug Application (ANDA) for a generic version of Rubraca, unless the submission contains a Paragraph IV Certification that one or more patents listed in the Orange Book for Rubraca are invalid, unenforceable or will not be infringed by a proposed ANDA product, in which case the submission may be made four years following the original drug approval. That is, under the provisions of the Hatch-Waxman Act, December 19, 2020 was the earliest date that a generic competitor could submit an ANDA to the FDA requesting permission to market

a generic version of Rubraca. To date, we do not have an indication that an ANDA has been filed. However, a generic company may have submitted an ANDA, for which we would receive a Paragraph IV Notice Letter in the future. If a Paragraph IV Certification is made, the generic company is required to provide a Paragraph IV Notice Letter advising Clovis of the certification. If that occurs, Clovis will have the opportunity to bring a patent infringement action against the generic company. If such a suit is filed within the 45-day period following receipt of the Paragraph IV Notice Letter, the Hatch-Waxman Act provides for a 30-month stay on FDA's ability to grant final approval of the proposed generic product. The 30-month stay generally runs from the date the Paragraph IV Notice Letter is received. However, when a Paragraph IV certification is received during the five-year period of NCE exclusivity following the date of first NDA approval, the thirty-month stay extends from five years after the date that product was first approved. The 30-month stay may be shortened or lengthened, including due to a settlement of a lawsuit, a court order (including a decision by the district court on the merits of the case), or patent expiration. The party filing the ANDA may also counterclaim in the litigation that one or more of our patents are invalid, unenforceable, and/or not infringed. If all of the Orange-Book listed patents were found invalid, enforceable, and/or not infringed, a competing generic product could be marketed prior to expiration of those patents, which would harm our business.

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.

***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 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**

***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.

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.

***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, 2020, the price of our common stock on the NASDAQ Global Select Market ranged from $3.62 per share to $11.63 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.

***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 $35.0 million (if the payment is made in 2019) or $50.0 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.

***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.

Shares of common stock that are reserved for future issuance under the Notes will become eligible for sale in the public market to the extent permitted by 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.

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.

***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.

## 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, CA used for clinical development operations, 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 393 square foot facility in Milan, Italy used for commercial activities. These leases expire in January 2023, December 2026, April 2028, July 2029 and November 2022, 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

See Note 13, *Commitments and Contingencies*.

## 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 12, 2021, there were 23 holders of record of our common stock. The holders of record number do 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, 2020**

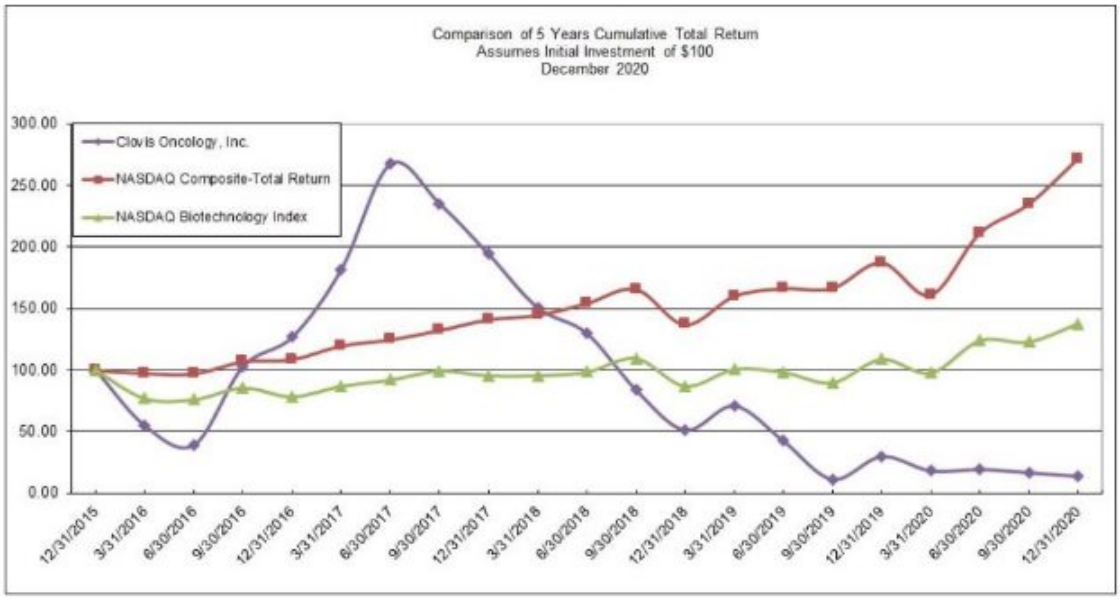
| Plan Category | Number of securities to be issued upon exercise of outstanding options and restricted stock (a) | Weighted-average exercise price of outstanding options (b) | Number of securities remaining available for issuance under equity compensation plans (excluding securities reflected in column (a)) (c) |
|---|---|---|---|
| Equity compensation plans approved by security holders (1) (2) | 9,464,216 | $ 37.79 | 6,310,938 |
| Equity compensation plans not approved by security holders | — | — | — |
| Total | 9,464,216 | $ 37.79 | 6,310,938 |

(1) As of December 31, 2020, 6,470,00 shares were authorized for issuance under our 2020 Stock Incentive Plan ("2020 Plan"), which became effective on April 22, 2020, which is the date the 2020 Plan was approved by our board of directors.

(2) As of December 31, 2020, 361,656 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, 2015 through December 31, 2020 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

Not required.

## 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 and also an indication specific to metastatic castration-resistant prostate cancer ("mCRPC"). 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 2020, the FDA approved Rubraca for the treatment of adult patients with mCRPC associated with a deleterious *BRCA* mutation (germline and/or somatic) who have been treated previously with androgen receptor-directed therapy and a taxane-based chemotherapy. The FDA approved this third indication under accelerated approval based on objective response rate and duration of response data from the TRITON2 clinical trial. We launched Rubraca for this indication in the U.S. following receipt of the approval. As an accelerated approval, continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials. The TRITON3 clinical trial is expected to serve as the confirmatory study for Rubraca's approval in mCRPC. In August 2020, the FDA approved the use of Foundation Medicine's blood-based diagnostic test, FoundationOne Liquid CDx, as a companion diagnostic for the detection of deleterious *BRCA* mutation (germline and/or somatic) to select mCRPC patients for treatment with Rubraca.

In Europe, the European Commission granted a conditional marketing authorization in May 2018 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. 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 authorized in Europe for certain patients in the recurrent ovarian cancer maintenance setting regardless of their *BRCA* mutation status. Following successful reimbursement negotiations, Rubraca has been launched in each of Germany, United Kingdom, Italy, France, Spain and the Netherlands, and reimbursement is pending in Switzerland.

In December 2020, Rubraca met the primary study endpoint of significantly improving PFS versus chemotherapy in the ARIEL4 confirmatory study. Additional ARIEL4 study results are expected to be submitted for presentation at a medical congress meeting in 2021. ARIEL4 is a Phase 3 multicenter, randomized study of Rubraca versus chemotherapy, which enrolled relapsed ovarian cancer patients with *BRCA* mutations (inclusive of germline and/or somatic) who had received two or more prior lines of chemotherapy. Completion of ARIEL4 is a post-marketing commitment in the U.S. and Europe.

Beyond our labeled indications, 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 to evaluate its immunotherapy Opdivo (nivolumab) in combination with Rubraca. We anticipate initial data of Rubraca monotherapy versus placebo from our ATHENA study in the second half of 2021, with the results of Rubraca versus Opdivo in all study populations a year or more later. However, the timing of the ATHENA data readouts is dependent on the timing of data maturity driven by PFS events.

We initiated the Phase 2 LODESTAR study in December 2019 to evaluate Rubraca as monotherapy treatment in patients with recurrent solid tumors associated with a deleterious mutation in homologous recombination repair genes. Based on our interactions with the FDA, we believe that this study may be registration-enabling for a targeted gene- and tumor-agnostic label, if data from the trial support the potential for an accelerated approval. Assuming enrollment in this

study continues as planned, and subject to the data, we may potentially file an sNDA with the FDA for this indication in the second half of 2021 or the first half of 2022.

Pursuant to our license and collaboration agreement with 3BP, entered into in September 2019, we have initiated development of a peptide-targeted radionuclide therapy ("PTRT") and imaging agent targeting fibroblast-activating protein ("FAP"). We have completed sufficient preclinical work to support an IND for the lead candidate under our license and collaboration agreement, designated internally as FAP-2286. Accordingly, we submitted two INDs for FAP-2286 for use as imaging and treatment agents in December 2020 to support an initial 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. The INDs are expected to become effective following receipt and submission, and acceptance by the FDA, of satisfactory chemistry, manufacturing and controls ("CMC") data for the imaging agent from clinical sites. The FAP-targeting imaging agent will be utilized to identify tumors that contain FAP for treatment in the Phase 1 LuMIERE clinical study, which we anticipate initiating in the first half of 2021.

In addition to our planned studies, the University of California San Francisco is sponsoring a separate, investigator-initiated, imaging-only study with gallium-68 labeled FAP-2286 (NCT04621435) to evaluate FAP expression in multiple tumor types; their study is currently recruiting. We hold U.S. and global rights to FAP-2286, excluding Europe (defined to include Russia, Turkey and Israel), where 3BP retains rights. We are also collaborating with 3BP on a discovery program directed to up to three additional, undisclosed targets for targeted radionuclide therapy, to which we would obtain global rights for any resulting product candidates.

Lucitanib, our second product candidate currently in clinical development, is an investigational, oral, potent angiogenesis inhibitor which inhibits 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"). Lucitanib inhibits the same three pathways as Lenvima® (lenvatinib), which has received an FDA approval for use in endometrial cancer in combination with Keytruda® (pembrolizumab), a PD-1 inhibitor. This, together with preclinical data for lucitanib in combination with a PD-1 inhibitor that demonstrated enhanced anti-tumor activity compared to that of single agents, 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 Bristol Myers Squibb. The Clovis-sponsored LIO-1 study of lucitanib in combination with nivolumab in advanced solid tumors and gynecologic cancers is currently enrolling patients in the Phase 2 part of the study. We expect to present interim data from this study at medical meetings in 2021, which are expected to include interim results from the ovarian and endometrial cancer expansion cohorts. We hold the global (excluding China) development and commercialization rights for lucitanib.

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, 2020, we generated $164.5 million product revenue related to sales of Rubraca. We have principally funded our operations using the net proceeds from 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, 2020, we had an accumulated deficit of $2,612.7 million. We incurred net losses of $369.2 million, $400.4 million and $368.0 million for the years ended December 31, 2020, 2019 and 2018, respectively, and had cash and cash equivalents totaling $240.2 million at December 31, 2020.

We expect to incur significant losses for the foreseeable future, as we incur costs related to commercial activities associated with Rubraca. Based on current estimates, we believe that our cash, cash equivalents and liquidity available under our financing agreement related to our ATHENA trial will allow us to fund our operating plan 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 2020, we recorded $164.5 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, 2020 and 2019, the supply of this free drug was approximately 17% and 20%, respectively, of the overall commercial supply or the equivalent of $30.4 million and $34.8 million, respectively, in commercial value.

Our ability to generate product revenue for the year ended December 31, 2020 was negatively affected by the COVID-19 pandemic due to fewer diagnoses and fewer patients going to in-person office visits as oncology practices and patients continue to adapt to the impact of the virus. As a result of the COVID-19 pandemic, our U.S. and European sales forces have had physical access to hospitals, clinics, doctors and pharmacies curtailed and/or have been limited. Our European launches in Italy, Spain and France occurred in an environment in which our field-based personnel in those countries have not been allowed to visit hospitals since late February 2020. Similarly, we launched Rubraca for prostate cancer in the U.S beginning in May 2020, but our physical access to hospital, clinics, doctors and pharmacies has been limited.

***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 and disease education; 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 decreased for 2020 compared to 2019. We expect research and development costs to be lower in the full year 2021 compared to 2020.

We did not see material disruption to our clinical trials as a result of the COVID-19 pandemic for the year ended December 31, 2020 as we completed target enrollment of ATHENA, our largest clinical trial, during the second quarter. However, we may see disruption during 2021. For example, new patient recruitment in certain clinical studies may be affected and the conduct of clinical trials may vary by geography as some regions are more adversely affected. Additionally, we may slow or delay enrollment in certain trials to manage expenses.

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, | | |
|---|---|---|---|
| | 2020 | 2019 | 2018 |
| | | (in thousands) | |
| **Rucaparib Expenses** | | | |
| Research and development | $ 159,364 | $ 184,617 | $ 153,083 |
| Rucaparib Total | 159,364 | 184,617 | 153,083 |
| **FAP Expenses** | | | |
| Research and development | 6,928 | 3,633 | |
| Acquired in-process research and development | — | 9,440 | — |
| FAP Total | 6,928 | 13,073 | — |
| **Lucitanib Expenses** | | | |
| Research and development | 6,860 | 5,128 | 786 |
| Lucitanib Total | 6,860 | 5,128 | 786 |
| **Rociletinib Expenses** | | | |
| Research and development | (1,089) | 1,101 | 2,391 |
| Rociletinib Total | (1,089) | 1,101 | 2,391 |
| Personnel and other expenses | 85,644 | 88,667 | 75,087 |
| Total | **$ 257,707** | **$ 292,586** | **$ 231,347** |

***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. As a result of the COVID-19 pandemic, our U.S. and European sales forces have had physical access to hospitals, clinics, doctors and pharmacies curtailed and/or have been limited, which have decreased sales and marketing expenses during 2020 and will extend to 2021. In addition, due to increased travel restrictions, quarantines, “work-at-home” and “shelter-in-place” orders and extended shutdown of certain non-essential business in the United States, and European and Asia-Pacific countries, in-person conferences and meetings requiring travel have and will continue to decrease resulting in a decrease of our selling, general and administrative expenses.

The COVID-19 pandemic has accelerated a preference by oncology practices for more digital programming, including digital, peer-to-peer interactions and reduced in-person promotion. In order to meet these changing preferences, we are adopting a hybrid commercial strategy combining increased digital promotion activities, greater online resources and more peer-to-peer interactions with reduced and more targeted in-person promotion. Accordingly, new tools and performance indicators based on this hybrid approach were rolled out during the fourth quarter, and the U.S. commercial organization was reduced in size by approximately 45 employees during the fourth quarter. Despite increased investment in digital promotion, we anticipate an effect of adopting this hybrid model will result in annual cost-savings of approximately $10.0 million. We are adopting this strategy in order to better reach customers in the way they want to be reached with the goal of returning to growth, especially as the ongoing impact of COVID-19 is reduced.

***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, 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. 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.

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 or a current liability. 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.

For the year ended December 31, 2020, we recognized $164.5 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, 2020, 2019 and 2018 was estimated at the grant date using the following weighted average assumptions for the respective periods:

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2020 | 2019 | 2018 |
| Dividend yield | — | — | — |
| Volatility (a) | 99 % | 93 % | 88 % |
| Risk-free interest rate (b) | 0.49 % | 1.67 % | 2.92 % |
| Expected term (years) (c) | 6.0 | 5.9 | 5.9 |

(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 $50.8 million, $54.3 million and $49.1 million for the years ended December 31, 2020, 2019 and 2018, respectively. As of December 31, 2020, the unrecognized share-based compensation expense related to unvested options, adjusted for expected forfeitures, was $18.1 million, which is expected to be recognized over a weighted-average remaining vesting period of 1.5 years. As of December 31, 2020, the unrecognized share-based compensation expense related to RSUs, adjusted for expected forfeitures, was $33.6 million, which is expected to be recognized over an estimated weighted-average remaining vesting period of 2.2 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 begin capitalizing incurred inventory related costs upon regulatory approval. Prior to regulatory approval, incurred costs for the manufacture of drugs that could potentially be available to support the commercial launch of our products are 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 seven 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.

At December 31, 2020, we had $30.7 million of current inventory and $104.1 million of long-term inventory.

***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, 2020 to the Year Ended December 31, 2019 (in thousands)***

| | Year ended December 31, | | | | | |
|---|---|---|---|---|---|---|
| | 2020 | | | 2019 | | |
| | U.S. | ex-U.S. | Total | U.S. | ex-U.S. | Total |
| Transaction price | $ 178,427 | $ 36,035 | $ 214,462 | $ 160,450 | $ 7,867 | $ 168,317 |
| Sales deductions: | | | | | | |
| Government rebates and chargebacks | (19,620) | (16,312) | (35,932) | (13,437) | (1,771) | (15,208) |
| Discounts and fees | (12,548) | (1,460) | (14,008) | (9,826) | (277) | (10,103) |
| Total sales deductions | (32,168) | (17,772) | (49,940) | (23,263) | (2,048) | (25,311) |
| Product revenue | 146,259 | 18,263 | 164,522 | 137,187 | 5,819 | 143,006 |
| Operating expenses: | | | | | | |
| External cost of sales - product | 29,526 | 6,602 | 36,128 | 28,179 | 1,747 | 29,926 |
| Cost of sales - intangible asset amortization | 2,287 | 2,890 | 5,177 | 1,956 | 2,804 | 4,760 |
| Research and development | 249,444 | 8,263 | 257,707 | 275,518 | 7,628 | 283,146 |
| Selling, general and administrative | 139,455 | 24,439 | 163,894 | 161,132 | 21,637 | 182,769 |
| Acquired in-process research and development | — | — | — | 9,440 | — | 9,440 |
| Other operating expenses | 3,804 | — | 3,804 | 9,711 | — | 9,711 |
| Total expenses | 424,516 | 42,194 | 466,710 | 485,936 | 33,816 | 519,752 |
| Operating loss | (278,257) | (23,931) | (302,188) | (348,749) | (27,997) | (376,746) |
| Other income (expense): | | | | | | |
| Interest expense | | | (30,508) | | | (19,405) |
| Foreign currency loss | | | (72) | | | (547) |
| (Loss) gain on extinguishment of debt | | | (3,277) | | | 18,480 |
| Loss on convertible senior notes conversion | | | (35,075) | | | — |
| Legal settlement loss | | | — | | | (26,750) |
| Other income | | | 1,361 | | | 6,342 |
| Other income (expense), net | | | (67,571) | | | (21,880) |
| Loss before income taxes | | | (369,759) | | | (398,626) |
| Income tax benefit (expense) | | | 547 | | | (1,798) |
| Net loss | | | $ (369,212) | | | $ (400,424) |

***Product Revenue.*** Product revenue for the year ended December 31, 2020 increased compared to the same period in the prior year primarily due to continued growth in sales of Rubraca, which is approved for sale in the United States and Europe markets. Following successful reimbursement negotiations, Rubraca has been launched in countries in Europe throughout 2019 and 2020. In May 2020, the FDA approved Rubraca as a monotherapy treatment of adult patients with *BRCA1/2*-mutant recurrent, metastatic castrate-resistant prostate cancer and we have launched Rubraca for prostate

cancer in the U.S. Product revenue is recorded net of variable considerations comprised of rebates, chargebacks and other discounts. Product revenue for the year ended December 31, 2020 was $146.3 million in the United States and $18.2 million outside of the United States. Variable considerations represented 23.3% and 15.0% of the transaction price recognized in the year ended December 31, 2020 and 2019, respectively. The increase in variable considerations is primarily due to the European National Health Service rebates related to our sales in Europe. Countries in Europe contract larger government rebates and discounts compared to the U.S. contributing to the overall increase in variable considerations. As sales in Europe increase in percentage terms compared to the U.S., variable considerations will also increase. In the United States, PHS chargebacks increased during the year ended December 31, 2020 compared to the prior year. In addition, in the United States, GPO discounts increased during the year ended December 31, 2020 and beginning in January 2020, we began providing payor rebates, which is included in discounts and fees for the year ended December 31, 2020.

***Cost of Sales - Product.*** Product cost of sales for the year ended December 31, 2020 increased primarily 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.

U.S. product cost of sales for the year ended December 31, 2020 increased $1.3 million compared to the same period in the prior year due to the increase in product revenue.

Ex-U.S. product cost of sales for the year ended December 31, 2020 increased $4.9 million compared to the same period in the prior year due to the increase in product revenue.

***Cost of Sales – Intangible Asset Amortization***. For the year ended December 31, 2020 and 2019, we recognized cost of sales of $5.2 million and $4.8 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.*** Except for activities related to medical research and disease education, research and development expenses are attributable to our U.S. segment. Research and development expenses decreased during the year ended December 31, 2020 compared to the same period in the prior year primarily due to lower research and development costs for Rubraca. The decrease related to our TRITON studies for prostate cancer, our ARIEL studies for ovarian cancer, discontinuation of our ATLAS study, diagnostic development costs and personnel costs. These decreases were partially offset by increased costs related to our ATHENA combination study with Bristol Myers Squibb's immunotherapy OPDIVO for ovarian cancer. The ATHENA study was initiated in the second quarter of 2018 and we completed target enrollment during the second quarter of 2020. In addition, research and development costs related to FAP and lucitanib have increased since the prior year.

***Selling, General and Administrative Expenses.*** Selling, general and administrative expenses decreased during the year ended December 31, 2020 compared to the same period in the prior year due to a decrease of $13.1 million in marketing costs and $3.2 million in share-based compensation expense. In addition, there was a decrease of $4.0 million in travel due to the COVID-19 pandemic.

U.S. selling, general and administrative expenses decreased $21.7 million during the year ended December 31, 2020 compared to the same period in the prior year due to decreases in marketing costs, share-based compensation expense and a decrease in travel due to the COVID-19 pandemic.

Ex-U.S. selling, general and administrative expenses increased $2.8 million during the year ended December 31, 2020 compared to the same period in the prior year due to the commercial activities related to the Rubraca launches in European countries during 2020.

***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, which is related to our U.S. segment.

***Other Operating Expenses.*** During the year ended December 31, 2020, 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, which is related to our U.S. segment. We expect these expenses to increase during 2021 related to our fixed facility fee each quarter since we expect to have sufficient inventory and do not plan to produce inventory at Lonza during 2021.

***Interest Expense.*** Interest expense increased during the year ended December 31, 2020 compared to the same period in the prior year due to the May 2019 financing agreement related to our ATHENA trial. In addition, our convertible senior notes transactions during the year resulted in the write off of $4.3 million of unamortized debt issuance costs, which was recorded as interest expense.

***Loss/Gain on Extinguishment of Debt.*** In April 2020, we entered into a privately negotiated exchange agreement with a Holder of our 2021 Notes, pursuant to which we issued to such Holder of the 2021 Notes approximately $36.1 million in additional 2024 Notes (2019 Issuance) of our currently outstanding 2024 Notes (2019 Issuance) in exchange for approximately $32.8 million in aggregate principal of 2021 Notes held by such Holder, which resulted in a $3.3 million loss on extinguishment of debt.

In August 2019, we repurchased $190.3 million aggregate principal amount of our 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.

***Loss on Convertible Senior Notes Conversion.*** 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. We used the proceeds of the share offering to repurchase an aggregate of $123.4 million principal amount of 2024 Notes (2019 Issuance) in privately negotiated transactions. In addition, we paid customary fees and expenses in connection with the transactions. These transactions resulted in a loss of $7.8 million for the year ended December 31, 2020.

In November 2020, we entered into a privately negotiated exchange and purchase agreement with a holder of our 2024 Notes (2019 Issuance). Pursuant to the agreement, in exchange for approximately $64.8 million aggregate principal amount of 2024 Notes (2019 Issuance) held by the holder, we agreed to issue to the holder a number shares of our common stock (the "Exchanged Shares") utilizing an exchange ratio that is based in part on the daily volume-weighted average prices ("VWAPs") per share of our common stock during a seven-day pricing period following execution of the agreement.

The number of Exchanged Shares was calculated utilizing an exchange ratio that is based in part on the average VWAPs of our common stock (subject to a floor) during a seven-day pricing period beginning on November 5, 2020 and ending on, and including, November 13, 2020. In November 2020, we issued 15,112,848 Exchanged Shares pursuant to the debt exchange transaction. As a result, we recognized a $27.3 million loss on the transactions.

***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.

***Other Income.*** Other income decreased during the year ended December 30, 2020 due to interest income earned on our available-for-sale securities. We did not have available-for-sale securities starting with the quarter ended June 30, 2020 through December 31, 2020.

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

| | Year ended December 31, | | | | | |
|---|---|---|---|---|---|---|
| | 2019 | | | 2018 | | |
| | U.S. | ex-U.S. | Total | U.S. | ex-U.S. | Total |
| Transaction price | $ 160,450 | $ 7,867 | $ 168,317 | $ 106,479 | $ — | $ 106,479 |
| Sales deductions: | | | | | | |
| Government rebates and chargebacks | (13,437) | (1,771) | (15,208) | (6,379) | — | |
| Discounts and fees | (9,826) | (277) | (10,103) | (4,712) | — | |
| Total sales deductions | (23,263) | (2,048) | (25,311) | (11,091) | — | (11,091) |
| Product revenue | 137,187 | 5,819 | 143,006 | 95,388 | — | 95,388 |
| Operating expenses: | | | | | | |
| Cost of sales - product | 28,179 | 1,747 | 29,926 | 19,444 | — | 19,444 |
| Cost of sales - intangible asset amortization | 1,956 | 2,804 | 4,760 | 1,954 | 676 | 2,630 |
| Research and development | 275,518 | 7,628 | 283,146 | 226,925 | 4,422 | 231,347 |
| Selling, general and administrative | 161,132 | 21,637 | 182,769 | 161,743 | 14,038 | 175,781 |
| Acquired in-process research and development | 9,440 | — | 9,440 | — | — | — |
| Other operating expenses | 9,711 | — | 9,711 | — | — | — |
| Total expenses | 485,936 | 33,816 | 519,752 | 410,066 | 19,136 | 429,202 |
| Operating loss | (348,749) | (27,997) | (376,746) | (314,678) | (19,136) | (333,814) |
| Other income (expense): | | | | | | |
| Interest expense | | | (19,405) | | | (13,183) |
| Foreign currency loss | | | (547) | | | (346) |
| Gain on extinguishment of debt | | | 18,480 | | | — |
| Legal settlement loss | | | (26,750) | | | (27,975) |
| Other income | | | 6,342 | | | 7,917 |
| Other income (expense), net | | | (21,880) | | | (33,587) |
| Loss before income taxes | | | (398,626) | | | (367,401) |
| Income tax benefit (expense) | | | (1,798) | | | (608) |
| Net loss | | | $ (400,424) | | | $ (368,009) |

***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 Europe 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.

U.S. product revenue for the year ended December 31, 2019 increased $41.8 million compared to the same period in the prior year due to continued growth in sales of Rubraca.

Ex-U.S. product revenue for the year ended December 31, 2019 increased $5.8 million compared to the same period in the prior year due to our launch of Rubraca as maintenance therapy in Germany and the UK in March 2019.

***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.

U.S. product cost of sales for the year ended December 31, 2019 increased $8.7 million compared to the same period in the prior year due to the increase in product revenue.

Ex-U.S. product cost of sales for the year ended December 31, 2019 increased $1.7 million compared to the same period in the prior year due to the increase in product revenue.

***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.*** Except for activities related to medical research and disease education, research and development expenses are attributable to our U.S. segment. 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. These increases were primarily related to our ex-U.S. segment.

***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, which is related to our U.S. segment.

***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, which is related to our U.S. segment.

***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.

**Liquidity and Capital Resources**

To date, we have principally funded our operations using the net proceeds from public offerings of our common stock, convertible senior notes offerings and our financing agreement related to our ATHENA trial.

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

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2020 | 2019 | 2018 |
| | | (in thousands) | |
| Net cash used in operating activities | $ (252,728) | $ (323,615) | $ (365,997) |
| Net cash provided by (used in) investing activities | 126,328 | 143,398 | (264,242) |
| Net cash provided by financing activities | 203,644 | 119,888 | 388,464 |
| Effect of exchange rate changes on cash and cash equivalents | 1,152 | 286 | (547) |
| Net increase (decrease) in cash and cash equivalents | $ 78,396 | $ (60,043) | $ (242,322) |

***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, 2020 compared to the same period in the prior year primarily due to a lower net loss, as adjusted for non-cash items related to our debt transactions. In addition, there was a reduction in payments made for inventory during the period partially offset by payments made for prepaid and accrued research and development expenses.

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.

***Investing Activities***

Net cash provided by investing activities for the year ended December 31, 2020 included sales of available-for-sale securities of $144.6 million, partially offset by purchases of available-for-sale securities of $10.0 million and a milestone payment of $8.0 million.

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.

***Financing Activities***

Net cash provided by financing activities for the year ended December 31, 2020 included proceeds of $246.7 million from the issuance of common stock, proceeds of $56.6 million from the issuance of our 2024 Notes (2020 Issuance), partially offset by a $164.4 million payment of our 2024 Notes. In addition, we had $65.1 million proceeds from borrowings under our financing agreement.

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 (2019 Issuance), $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.

***Operating Capital Requirements***

Rubraca is approved in the United States and Europe for multiple indications. We expect to incur significant losses for the foreseeable future, as we commercialize Rubraca and as we complete research and development activities related to FAP-2286 and lucitanib.

As of December 31, 2020, we had cash and cash equivalents totaling $240.2 million and total current liabilities of $184.9 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, 2020 (in thousands):

| | Less than 1 Year | 1 to 3 Years | 3 to 5 Years | More Than 5 Years | Total |
|---|---|---|---|---|---|
| Convertible senior notes | $ 64,418 | $ — | $ 443,282 | $ — | $ 507,700 |
| Interest on convertible senior notes | 11,338 | 20,396 | 8,789 | — | 40,523 |
| Financing agreement (principal and interest) | — | 50,025 | 94,259 | 55,227 | 199,511 |
| Operating lease commitments | 5,796 | 10,167 | 9,893 | 9,938 | 35,794 |
| Finance lease commitments | 2,287 | 4,574 | 4,574 | — | 11,435 |
| Purchase and other commitments (a) | 13,616 | 27,232 | 27,232 | — | 68,080 |
| Total | $ 97,455 | $ 112,394 | $ 588,029 | $ 65,165 | $ 863,043 |

(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.

In April 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.

In May 2020, Rubraca received a third FDA approval for Rubraca as a monotherapy treatment of adult patients with *BRCA1/2*-mutant recurrent, metastatic castrate-resistant prostate cancer. This approval resulted in an obligation to pay an $8.0 million milestone payment, which we paid in June 2020.

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 $8.0 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.

***Lucitanib.*** On November 19, 2013, we acquired all of the issued and outstanding capital stock of EOS pursuant to the terms set forth in that certain Stock Purchase Agreement, dated as of November 19, 2013 (the "Stock Purchase Agreement"), by and among the Company, EOS, its shareholders (the "Sellers") and Sofinnova Capital V FCPR, acting in its capacity as the Sellers' representative. Following the acquisition, EOS became a wholly-owned subsidiary of the Company. Under the terms of the Stock Purchase Agreement, in addition to the initial purchase price paid at the time of the closing of the acquisition and other license fees due to Advenchen described below, we will also be obligated to pay to the Sellers a milestone payment of $65.0 million upon obtaining the first NDA approval from the FDA with respect to 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.

***FAP.*** 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 discovery collaboration 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.

**Impact of COVID-19 Pandemic**

Our ability to generate product revenue for the year ended December 31, 2020 was negatively affected by the COVID-19 pandemic due to fewer diagnoses and fewer patients going to in-person office visits as oncology practices and patients continue to adapt to the impact of the virus. As a result of the COVID-19 pandemic, our U.S. and European sales forces have had physical access to hospitals, clinics, doctors and pharmacies curtailed and/or have been limited. Our European launches in Italy, Spain and France occurred in an environment in which our field-based personnel in those countries have not been allowed to visit hospitals since as early as late February. Similarly, we launched Rubraca for prostate cancer in the U.S. beginning in May 2020, but our physical access to hospitals, clinics, doctors and pharmacies has been limited. It is difficult to discern or predict any trend in new patient starts due to the unpredictability of the COVID-19 situation and the changing competitive landscape.

This curtailment of and/or limited physical access has decreased sales and marketing expenses during 2020 and will likely extend to 2021. In addition, due to increased travel restrictions, quarantines, “work-at-home” and “shelter-in-place” orders and extended shutdown of certain non-essential business in the United States, and European and Asia-

Pacific countries, in-person conferences and meetings requiring travel will decrease, resulting in a decrease of our selling, general and administrative expenses. We believe that we have sufficient supply of Rubraca and our product candidates to continue our commercial and clinical operations as planned.

The COVID-19 pandemic has accelerated a preference by oncology practices for more digital programming, including digital, peer-to-peer interactions and reduced in-person promotion. In order to meet these changing preferences, we are adopting a hybrid commercial strategy combining increased digital promotion activities, greater online resources and more peer-to-peer interactions with reduced and more targeted in-person promotion. Accordingly, new tools and performance indicators based on this hybrid approach were rolled out beginning in the fourth quarter, and the U.S. commercial organization was reduced in size by approximately 45 employees. Despite increased investment in digital promotion, we anticipate an effect of adopting this hybrid model will result in annual cost-savings of approximately $10.0 million. We are adopting this strategy in order to better reach customers in the way they want to be reached with the goal of returning to growth, especially as the ongoing impact of COVID-19 is reduced.

We did not see material disruption to our clinical trials as a result of the COVID-19 pandemic for the year ended December 31, 2020 as we completed target enrollment of ATHENA, our largest clinical trial, during the second quarter. However, we may see disruption during 2021. For example, new patient recruitment in certain clinical studies may be affected and the conduct of clinical trials may vary by geography as some regions are more adversely affected. Additionally, we may slow or delay enrollment in certain trials to manage expenses.

On March 18, 2020, the Families First Coronavirus Response Act ("FFCR Act"), and on March 27, 2020, the Coronavirus Aid, Relief and Economic Security ("CARES") Act were each enacted in response to the COVID-19 pandemic. The FFCR Act and the CARES Act contain numerous income tax provisions, such as relaxing limitations on the deductibility of interest and the use of net operating losses arising in taxable years beginning after December 31, 2017. We evaluated the impact of this legislation and the income tax provisions did not result in a material cash benefit to us. Future regulatory guidance under the FFCR Act and the CARES Act (as well as under the Tax Cuts and Jobs Act) remains forthcoming, and such guidance could ultimately increase or lessen their impact on our business and financial condition. It is also highly possible that Congress will enact additional legislation in connection with the COVID-19 pandemic, some of which could impact us.

The trading prices for our common stock and of other biopharmaceutical companies have been highly volatile as a result of the coronavirus pandemic. As a result of this volatility and uncertainties regarding future impact of COVID-19 on our business and operations, we may face difficulties raising capital or may only be able to raise capital on unfavorable terms.

**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, 2020, we have net operating loss ("NOL") carryforwards of approximately $1.7 billion to offset future federal income taxes. We also have research and development and orphan drug tax credit carryforwards of $254.5 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 2040.

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, 2020, we recorded a 100% valuation allowance against our net deferred tax assets in the U.S. of $801.5 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, 2020, we had cash, cash equivalents of $240.2 million, consisting of bank demand deposits and money market funds. 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, 2020, $68.1 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, 2020, it would decrease the total US dollar purchase commitment under the Swiss Manufacturing and Services Agreement by approximately $20.0 million. Similarly, a 10% weakening of the US dollar compared to the Swiss franc would increase the total US dollar purchase commitment by approximately $9.3 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, 2020, and 2019, approximately 3% and 4%, 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, 2020, 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, 2020, 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, 2020, 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, 2020, 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, 2020 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, 2020 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, 2020, 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, 2020, 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, 2020 and 2019, 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, 2020, and the related notes and our report dated February 24, 2021 expressed an 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 24, 2021

## 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 2020 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 30, 2021.

## 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 2021 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 2021 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 2021 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 2021 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. |
| 3.4(22) | Amendment No. 1 to the 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(21) | Description of the Registrant's Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934. |
| 4.7(26) | Indenture dated as of November 17, 2020, by and between Clovis Oncology, Inc. and The Bank of New York Mellon Trust Company, N.A., as trustee, relating to the 2024 Notes (2020 Issuance). |
| 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+(24) | Clovis Oncology, Inc. 2020 Stock Incentive Plan. |
| 10.5+(1) | Form of Clovis Oncology, Inc. 2009 Equity Incentive Plan Stock Option Agreement. |
| 10.6+(4) | Form of Clovis Oncology, Inc. 2011 Stock Incentive Plan Stock Option Agreement. |
| 10.7+(23) | Form of Clovis Oncology, Inc. 2020 Stock Incentive Plan Option Agreement. |
| 10.8+(23) | Form of Clovis Oncology, Inc. 2020 Stock Incentive Plan Restricted Stock Unit Agreement. |
| 10.9+(3) | Employment Agreement, dated as of August 24, 2011, by and between Clovis Oncology, Inc. and Patrick J. Mahaffy. |
| 10.10+(3) | Employment Agreement, dated as of August 24, 2011, by and between Clovis Oncology, Inc. and Gillian C. Ivers-Read. |
| 10.11+(1) | Indemnification Agreement, dated as of May 15, 2009, between Clovis Oncology, Inc. and Paul Klingenstein. |

| Exhibit Number | Exhibit Description |
|---|---|
| 10.12+(1) | Indemnification Agreement, dated as of May 15, 2009, between Clovis Oncology, Inc. and James C. Blair. |
| 10.13+(1) | Indemnification Agreement, dated as of May 15, 2009, between Clovis Oncology, Inc. and Edward J. McKinley. |
| 10.14+(1) | Indemnification Agreement, dated as of May 15, 2009, between Clovis Oncology, Inc. and Thorlef Spickschen. |
| 10.15+(1) | Indemnification Agreement, dated as of May 15, 2009, between Clovis Oncology, Inc. and M. James Barrett. |
| 10.16+(1) | Indemnification Agreement, dated as of May 15, 2009, between Clovis Oncology, Inc. and Brian G. Atwood. |
| 10.17+(1) | Indemnification Agreement, dated as of May 12, 2009, between Clovis Oncology, Inc. and Patrick J. Mahaffy. |
| 10.18(25) | Exchange and Purchase Agreement dated as of November 4, 2020, by and among Clovis Oncology, Inc. and a holder of its outstanding 2024 Notes (2019 Issuance). |
| 10.19+(1) | Indemnification Agreement, dated as of May 12, 2009, between Clovis Oncology, Inc. and Gillian C. Ivers-Read. |
| 10.20+(15) | Clovis Oncology, Inc. 2011 Employee Stock Purchase Plan, as amended. |
| 10.21+(4) | Clovis Oncology, Inc. 2011 Cash Bonus Plan. |
| 10.22+(2) | Indemnification Agreement, dated as of June 13, 2013, between Clovis Oncology, Inc. and Ginger L. Graham. |
| 10.23+(2) | Indemnification Agreement, dated as of June 13, 2013, between Clovis Oncology, Inc. and Keith Flaherty. |
| 10.24(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. |
| 10.25*(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. |
| 10.26+(10) | Indemnification Agreement, effective as of August 3, 2015, between Clovis Oncology, Inc. and Lindsey Rolfe. |
| 10.27+(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. |
| 10.28+(8) | Indemnification Agreement, dated as of February 17, 2016, between Clovis Oncology, Inc. and Daniel W. Muehl. |
| 10.29+(13) | Employment Agreement, dated as of July 6, 2017, by and between Clovis Oncology, Inc. and Daniel Muehl. |
| 10.30*(9) | First Amendment to License Agreement, between Clovis Oncology, Inc. and Pfizer Inc., dated as of August 30, 2016. |
| 10.31+(11) | Form of Clovis Oncology, Inc. 2011 Stock Incentive Plan RSU Agreement. |

| Exhibit Number | Exhibit Description |
|---|---|
| 10.32*(11) | Manufacturing Services Agreement, by and between Clovis Oncology, Inc. and Lonza Ltd, dated as of October 3, 2016. |
| 10.33*(12) | Strata Trial Collaboration Agreement, by and between Clovis Oncology, Inc. and Strata Oncology, Inc., dated as of January 30, 2017. |
| 10.34+(16) | Indemnification Agreement, dated as of October 11, 2018, between Clovis Oncology, Inc. and Robert W. Azelby. |
| 10.35+(16) | Indemnification Agreement, dated as of October 11, 2018, between Clovis Oncology, Inc. and Richard A. Fair. |
| 10.36+(17) | Employment Agreement, dated as of July 6, 2017, by and between Clovis Oncology, Inc. and Paul Gross. |
| 10.37+(17) | Indemnification Agreement, dated as of September 9, 2016, between Clovis Oncology, Inc. and Paul E. Gross. |
| 10.38 (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. |
| 10.39(18) | Pledge and Security Agreement, dated as of May 1, 2019 among each of the Grantors party thereto and the Administrative Agent party thereto. |
| 10.40# | License and Collaboration Agreement, dated September 20, 2019 by and between 3B Pharmaceuticals GmbH and Clovis Oncology, Inc. |
| 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, 2020 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, 2020 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.
(21) Filed as an exhibit with the Registrant's Annual Report on Form 10-K on February 26, 2020.
(22) Filed as an exhibit with the Registrant's Current Report on Form 8-K (File No. 001-35347) on April 16, 2020.
(23) Filed as an exhibit with the Registrant's Current Report on Form 8-K (File No. 001-35347) on June 4, 2020.
(24) Filed as an exhibit with the Registrant's Quarterly Report on Form 10-Q on August 7, 2020.
(25) Filed as an exhibit with the Registrant's Current Report on Form 8-K (File No. 001-35347) on November 5, 2020.
(26) Filed as an exhibit with the Registrant's Current Report on Form 8-K (File No. 001-35347) on November 17, 2020.
+ 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.
# Confidential portions of this Exhibit were redacted pursuant to Item 601(b)(10) of Regulation S-K and Clovis Oncology, Inc. agrees to furnish supplementary to the Securities and Exchange Commission a copy of any redacted information or omitted schedule and/or exhibit upon request.

## 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, 2020 and 2019, 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, 2020, 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, 2020 and 2019, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2020, 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, 2020, 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 24, 2021 expressed an unqualified opinion thereon.

**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 critical audit matters 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, 2020, the Company accrued $43.5 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.<br><br>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.

*Sixth Street Financing Agreement*

Description of the Matter

At December 31, 2020, the Company has drawn $99.8 million in principal and incurred $12.6 million in interest expense in relation to the Sixth Street Financing Arrangement. As discussed in Note 10 to 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 clinical trials 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 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 probabilities of certain conditions or events and certain other 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, 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 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, 2020. 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 24, 2021

**CLOVIS ONCOLOGY, INC.**

**Consolidated Statements of Operations and Comprehensive Loss**

| | Year ended December 31, | | |
|---|---|---|---|
| | 2020 | 2019 | 2018 |
| | (in thousands, except per share amounts) | | |
| Revenues: | | | |
| Product revenue | $ 164,522 | $ 143,006 | $ 95,388 |
| Operating expenses: | | | |
| Cost of sales - product | 36,128 | 29,926 | 19,444 |
| Cost of sales - intangible asset amortization | 5,177 | 4,760 | 2,630 |
| Research and development | 257,707 | 283,146 | 231,347 |
| Selling, general and administrative | 163,894 | 182,769 | 175,781 |
| Acquired in-process research and development | — | 9,440 | — |
| Other operating expenses | 3,804 | 9,711 | — |
| Total expenses | 466,710 | 519,752 | 429,202 |
| Operating loss | (302,188) | (376,746) | (333,814) |
| Other income (expense): | | | |
| Interest expense | (30,508) | (19,405) | (13,183) |
| Foreign currency loss | (72) | (547) | (346) |
| (Loss) gain on extinguishment of debt | (3,277) | 18,480 | — |
| Loss on convertible senior notes conversion | (35,075) | — | — |
| Legal settlement loss | — | (26,750) | (27,975) |
| Other income | 1,361 | 6,342 | 7,917 |
| Other income (expense), net | (67,571) | (21,880) | (33,587) |
| Loss before income taxes | (369,759) | (398,626) | (367,401) |
| Income tax benefit (expense) | 547 | (1,798) | (608) |
| Net loss | (369,212) | (400,424) | (368,009) |
| Other comprehensive income (loss): | | | |
| Foreign currency translation adjustments, net of tax | 567 | (272) | (2,543) |
| Net unrealized (loss) gain on available-for-sale securities, net of tax | (6) | 41 | 82 |
| Other comprehensive income (loss): | 561 | (231) | (2,461) |
| Comprehensive loss | $ (368,651) | $ (400,655) | $ (370,470) |
| | | | |
| Loss per basic and diluted common share: | | | |
| Basic and diluted net loss per common share | $ (4.38) | $ (7.43) | $ (7.07) |
| Basic and diluted weighted average common shares outstanding | 84,307 | 53,873 | 52,066 |

See accompanying Notes to Consolidated Financial Statements.

**CLOVIS ONCOLOGY, INC.**

**Consolidated Balance Sheets**

| | December 31, 2020 | December 31, 2019 |
|---|---|---|
| **ASSETS** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 240,229 | $ 161,833 |
| Accounts receivable, net | 26,511 | 20,562 |
| Inventories, net | 30,714 | 26,519 |
| Available-for-sale securities | — | 134,826 |
| Prepaid research and development expenses | 4,245 | 3,881 |
| Other current assets | 9,130 | 18,847 |
| Total current assets | 310,829 | 366,468 |
| Inventories | 104,123 | 98,053 |
| Deposit on inventory | — | 12,350 |
| Property and equipment, net | 12,085 | 15,287 |
| Right-of-use assets, net | 30,438 | 28,141 |
| Intangible assets, net | 65,743 | 62,920 |
| Goodwill | 63,074 | 63,074 |
| Other assets | 19,262 | 23,311 |
| Total assets | $ 605,554 | $ 669,604 |
| **LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)** | | |
| Current liabilities: | | |
| Accounts payable | $ 26,692 | $ 32,237 |
| Accrued research and development expenses | 43,500 | 53,214 |
| Lease liabilities | 5,330 | 5,405 |
| Convertible senior notes | 64,198 | — |
| Other accrued expenses | 45,208 | 42,228 |
| Total current liabilities | 184,928 | 133,084 |
| Long-term lease liabilities - less current portion | 31,640 | 29,479 |
| Convertible senior notes - less current portion | 434,846 | 644,751 |
| Borrowings under financing agreement | 110,917 | 34,991 |
| Other long-term liabilities | 1,971 | 1,556 |
| Total liabilities | 764,302 | 843,861 |
| 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, 2020 and December 31, 2019 | — | — |
| Common stock, $0.001 par value per share, 200,000,000 shares authorized at December 31, 2020 and December 31, 2019, respectively; 103,699,109 and 54,956,341 shares issued and outstanding at December 31, 2020 and December 31, 2019, respectively | 104 | 55 |
| Additional paid-in capital | 2,498,179 | 2,114,068 |
| Accumulated other comprehensive loss | (44,304) | (44,865) |
| Accumulated deficit | (2,612,727) | (2,243,515) |
| Total stockholders' deficit | (158,748) | (174,257) |
| Total liabilities and stockholders' equity (deficit) | $ 605,554 | $ 669,604 |

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, 2018 | 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) |
| Issuance of common stock, net of issuance costs | 11,090,000 | 11 | 83,416 | — | — | 83,427 |
| Issuance of common stock under employee stock purchase plan | 283,588 | 1 | 1,419 | — | — | 1,420 |
| Exercise of stock options | 34,599 | — | (57) | — | — | (57) |
| Issuance of common stock from vesting of restricted stock units | 1,012,699 | 1 | (1) | — | — | — |
| Share-based compensation expense | — | — | 50,794 | — | — | 50,794 |
| Net unrealized loss on available-for-sale securities | — | — | — | (6) | — | (6) |
| Foreign currency translation adjustments | — | — | — | 567 | — | 567 |
| Convertible senior notes conversion | 36,321,882 | 36 | 248,599 | — | — | 248,635 |
| Other financing costs | — | — | (59) | — | — | (59) |
| Net loss | — | — | — | — | (369,212) | (369,212) |
| Balance at December 31, 2020 | 103,699,109 | $ 104 | $ 2,498,179 | $ (44,304) | $ (2,612,727) | $ (158,748) |

See accompanying Notes to Consolidated Financial Statements.

**CLOVIS ONCOLOGY, INC.**

**Consolidated Statements of Cash Flows**

| | Year ended December 31, | | |
|---|---|---|---|
| | 2020 | 2019 | 2018 |
| | | (in thousands) | |
| **Operating activities** | | | |
| Net loss | $ (369,212) | $ (400,424) | $ (368,009) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | | |
| Share-based compensation expense | 50,794 | 54,304 | 49,090 |
| Depreciation and amortization | 8,198 | 7,768 | 4,601 |
| Amortization of premiums and discounts on available-for-sale securities | (174) | (1,521) | 1,345 |
| Amortization of debt issuance costs | 2,672 | 2,858 | 2,178 |
| Write-off of debt issuance costs related to convertible senior notes transactions | 4,345 | — | — |
| Loss (gain) on extinguishment of debt | 3,277 | (18,480) | — |
| Loss on convertible senior notes conversion | 35,075 | — | — |
| Legal settlement loss | — | 22,747 | — |
| Acquired in-process research and development | — | — | — |
| Other | 340 | 804 | — |
| Changes in operating assets and liabilities: | | | |
| Accounts receivable | (5,407) | (7,518) | (3,371) |
| Inventory | 5,321 | (26,160) | (49,936) |
| Prepaid and accrued research and development expenses | (8,313) | 23,233 | 9,145 |
| Deposit on inventory | — | — | (12,350) |
| Other operating assets and liabilities | 10,831 | (6,837) | (8,750) |
| Accounts payable | (5,852) | 12,289 | 5,770 |
| Other accrued expenses | 15,377 | 13,322 | 4,290 |
| Net cash used in operating activities | (252,728) | (323,615) | (365,997) |
| **Investing activities** | | | |
| Purchases of property and equipment | (354) | (3,290) | (9,242) |
| Proceeds from sale of property and equipment | — | 275 | — |
| Purchases of available-for-sale securities | (9,962) | (459,835) | (500,000) |
| Sales of available-for-sale securities | 144,644 | 621,998 | 300,000 |
| Acquired in-process research and development - milestone payment | (8,000) | (15,750) | (55,000) |
| Net cash provided by (used in) investing activities | 126,328 | 143,398 | (264,242) |
| **Financing activities** | | | |
| Proceeds from sale of common stock, net of issuance costs | 246,668 | — | 93,890 |
| Proceeds from issuance of convertible senior notes, net of issuance costs | 56,619 | 254,879 | 290,887 |
| Payment of convertible senior notes | (164,443) | — | — |
| Extinguishment of convertible senior notes | — | (169,853) | — |
| Proceeds from borrowings under ATHENA financing agreement | 65,119 | 32,871 | — |
| Proceeds from the exercise of stock options and employee stock purchases | 1,362 | 3,266 | 3,967 |
| Payments on finance leases | (1,470) | (1,115) | (245) |
| Payments on other long-term liabilities | (211) | (160) | (35) |
| Net cash provided by financing activities | 203,644 | 119,888 | 388,464 |
| Effect of exchange rate changes on cash and cash equivalents | 1,152 | 286 | (547) |
| Increase (decrease) in cash and cash equivalents | 78,396 | (60,043) | (242,322) |
| Cash and cash equivalents at beginning of period | 161,833 | 221,876 | 464,198 |
| Cash and cash equivalents at end of period | $ 240,229 | $ 161,833 | $ 221,876 |
| Supplemental disclosure of cash flow information: | | | |
| Cash paid for interest | $ 12,075 | $ 10,515 | $ 9,188 |
| Non-cash investing and financing activities: | | | |
| Vesting of restricted stock units | $ 7,493 | $ 5,442 | $ 10,808 |

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 and also an indication specific to metastatic castration-resistant prostate cancer ("mCRPC"). 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 2020, the FDA approved Rubraca for the treatment of adult patients with mCRPC associated with a deleterious BRCA mutation (germline and/or somatic) who have been treated previously with androgen receptor-directed therapy and a taxane-based chemotherapy. The FDA approved this third indication under accelerated approval based on objective response rate and duration of response data from the TRITON2 clinical trial. We launched Rubraca for this indication in the U.S. following receipt of the approval. As an accelerated approval, continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials. The TRITON3 clinical trial is expected to serve as the confirmatory study for Rubraca's approval in mCRPC. In August 2020, the FDA approved the use of Foundation Medicine's blood-based diagnostic test, FoundationOne Liquid CDx, as a companion diagnostic for the detection of deleterious BRCA mutation (germline and/or somatic) to select mCRPC patients for treatment with Rubraca.

In Europe, the European Commission granted a conditional marketing authorization in May 2018 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. 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 authorized in Europe for certain patients in the recurrent ovarian cancer maintenance setting regardless of their *BRCA* mutation status. Following successful reimbursement negotiations, Rubraca has been launched in each of Germany, United Kingdom, Italy, France, Spain and the Netherlands, and reimbursement is pending in Switzerland.

In December 2020, Rubraca met the primary study endpoint of significantly improving PFS versus chemotherapy in the ARIEL4 confirmatory study. Additional ARIEL4 study results are expected to be submitted for presentation at a medical congress meeting in 2021. ARIEL4 is a Phase 3 multicenter, randomized study of Rubraca versus chemotherapy, which enrolled relapsed ovarian cancer patients with *BRCA* mutations (inclusive of germline and/or somatic) who had received two or more prior lines of chemotherapy. Completion of ARIEL4 is a post-marketing commitment in the U.S. and Europe.

Beyond our labeled indications, 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 to evaluate its immunotherapy Opdivo (nivolumab) in combination with Rubraca. We anticipate initial data of Rubraca monotherapy versus placebo from our ATHENA study in the second half of 2021, with the results of Rubraca versus Opdivo in all study populations a year or more later. However, the timing of the ATHENA data readouts is dependent on the timing of data maturity driven by PFS events.

We initiated the Phase 2 LODESTAR study in December 2019 to evaluate Rubraca as monotherapy treatment in patients with recurrent solid tumors associated with a deleterious mutation in homologous recombination repair genes. Based on our interactions with the FDA, we believe that this study may be registration-enabling for a targeted gene- and tumor-agnostic label, if data from the trial support the potential for an accelerated approval. Assuming enrollment in this study continues as planned, and subject to the data, we may potentially file an sNDA with the FDA for this indication in the second half of 2021 or the first half of 2022.

We hold worldwide rights to Rubraca.

Pursuant to our license and collaboration agreement with 3BP, entered into in September 2019, we have initiated development of a peptide-targeted radionuclide therapy ("PTRT") and imaging agent targeting fibroblast-activating protein ("FAP"). We have completed sufficient preclinical work to support an IND for the lead candidate under our license and collaboration agreement, designated internally as FAP-2286. Accordingly, we submitted two INDs for FAP-2286 for use as imaging and treatment agents in December 2020 to support an initial 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. The INDs are expected to become effective following receipt and submission, and acceptance by the FDA, of satisfactory chemistry, manufacturing and controls ("CMC") data for the imaging agent from clinical sites. The FAP-targeting imaging agent will be utilized to identify tumors that contain FAP for treatment in the Phase 1 LuMIERE clinical study, which we anticipate initiating in the first half of 2021.

We hold U.S. and global rights to FAP-2286, excluding Europe (defined to include Russia, Turkey and Israel), where 3BP retains rights. We are also collaborating with 3BP on a discovery program directed to up to three additional, undisclosed targets for targeted radionuclide therapy, to which we would obtain global rights for any resulting product candidates.

Lucitanib, our second product candidate currently in clinical development, is an investigational, oral, potent angiogenesis inhibitor which inhibits 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"). Lucitanib inhibits the same three pathways as Lenvima® (lenvatinib), which has received an FDA approval for use in endometrial cancer in combination with Keytruda® (pembrolizumab), a PD-1 inhibitor. This, together with preclinical data for lucitanib in combination with a PD-1 inhibitor that demonstrated enhanced anti-tumor activity compared to that of single agents, 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 Bristol Myers Squibb. The Clovis-sponsored LIO-1 study of lucitanib in combination with nivolumab in advanced solid tumors and gynecologic cancers is currently enrolling patients in the Phase 2 part of the study. We expect to present interim data from this study at medical meetings in 2021, which are expected to include interim results from the ovarian and endometrial cancer expansion cohorts. We hold the global (excluding China) development and commercialization rights for lucitanib.

**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.

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 Europe 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.

We 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.

**Accounts Receivable**

We provide an allowance for credit losses based on experience and specifically identified risks. Accounts receivable are charged off against the allowance 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 begin capitalizing incurred inventory related costs upon regulatory approval. Prior to regulatory approval, incurred costs for the manufacture of drugs that could potentially be available to support the commercial launch of our products are 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 seven 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 was recorded as a result of the EOS acquisition in November 2013. 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 two reporting units based on our operating segments, U.S. and ex-U.S. We determined that our goodwill was allocated to the U.S. reporting unit and performed impairment testing by assessing qualitative factors to determine whether it is more likely than not (that is, a likelihood of more than 50 percent) that the fair value of a reporting unit is less than its carrying amount. Based on our qualitative assessment, we determined that it is not more likely than not that the fair value of a reporting unit is less than its carrying amount. Therefore, the quantitative goodwill impairment test is not necessary. There is no goodwill impairment as of December 31, 2020.

**Other Current Assets**

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

| | December 31, 2020 | December 31, 2019 |
|---|---|---|
| Prepaid insurance | $ 782 | $ 505 |
| Prepaid IT | 753 | 698 |
| Prepaid variable considerations | 1,191 | 550 |
| Prepaid expenses - other | 2,193 | 2,821 |
| Value-added tax ("VAT") receivable | 2,202 | 11,920 |
| Receivable - other | 1,884 | 2,176 |
| Other | 125 | 177 |
| Total | $ 9,130 | $ 18,847 |

**Other Accrued Expenses**

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

| | December 31, 2020 | December 31, 2019 |
|---|---|---|
| Accrued personnel costs | $ 18,334 | $ 16,915 |
| Accrued interest payable for convertible senior notes | 2,991 | 5,903 |
| Income tax payable | 907 | 3,505 |
| Accrued corporate legal fees and professional services | 459 | 310 |
| Accrued royalties | 6,617 | 6,038 |
| Accrued variable considerations | 11,701 | 5,748 |
| Accrued expenses - other | 4,199 | 3,809 |
| Total | $ 45,208 | $ 42,228 |

**Segment Information**

As of December 31, 2020, we determined that we have two operating and reportable segments, U.S. and ex-U.S., based on product revenue by geographic areas since our product revenue outside of the United States represented 11% of total product revenue. We designated our reporting segments based on the internal reporting used by the Chief Operating Decision Maker ("CODM"), which is our Chief Executive Officer, for making decisions and assessing performance as the source of our reportable segments. The CODM allocates resources and assesses the performance of each operating segment based on product revenue by geographic areas. Accordingly, we view our business as two reportable operating segments to evaluate performance, allocate resources, set operational targets and forecast our future period financial results.

We manage our assets on a company basis, not by segments, as many of our assets are shared or commingled. Our CODM does not regularly review asset information by reportable segment. The majority of long-lived assets for both segments are located in the United States.

**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 $17.0 million, $21.2 million and $15.9 million in expense for the years ended December 31, 2020, 2019 and 2018, 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. 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, 2020, and 2019, approximately 3% and 4%, 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**

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 adopted ASU 2016-13 as of January 1, 2020. 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, no impairment was recognized for the year ended December 31, 2020. We recognized a minimal allowance for credit losses related to our accounts receivable at December 31, 2020. The adoption of ASU 2016-13 did not materially impact our consolidated financial statements and disclosures.

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 adopted ASU 2018-13 as of January 1, 2020 and there was no material impact on our consolidated financial statements and related disclosures.

**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 August 2020, the FASB issued guidance that simplifies an issuer's accounting for debt and equity instruments. The guidance is effective for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. Early application is permitted. We plan to adopt this guidance on January 1, 2022. We will evaluate the impact this guidance may have on our consolidated financial statements and related disclosures as the adoption date approaches.

**3. Revenue Recognition**

We are currently approved to sell Rubraca in the United States and Europe 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 or a current liability. 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.

*Government Rebates*. Rebates include mandated discounts under the Medicaid Drug Rebate Program, the Medicare coverage gap program, the Tricare health program and various European National Health Service, Sick Fund and Clawback programs. 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. Our rebate estimates are based upon a range of possible outcomes that are probability-weighted for the estimated payor mix. The accrual for rebates is based on the expected utilization from historical data we have accumulated since the Rubraca product launch.

*GPO and Payor Rebates*. We contract with various private payor organizations and group purchasing organizations ("GPO"), primarily insurance companies, pharmacy benefit managers and hospitals, for the payment of rebates with respect to utilization of our products. We estimate these rebates and record such estimates in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability.

*Chargebacks*. Chargebacks are discounts that occur when contracted customers, which currently consist primarily of group purchasing organizations, Public Health Service ("PHS") 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 based on additional historical experience.

For the year ended December 31, 2020, and 2019, we recognized $164.5 million and $143.0 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, which were all customers in the U.S. segment, consisted of the following:

| | December 31, 2020 | December 31, 2019 |
|---|---|---|
| Customer A | 21% | 25% |
| Customer B | 14% | 20% |
| Customer C | 18% | 15% |
| Customer D | 11% | 12% |
| Customer E | 10% | 10% |

**4. Property and Equipment**

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

| | December 31, | |
|---|---|---|
| | 2020 | 2019 |
| Laboratory, manufacturing and office equipment | $ 1,267 | $ 1,290 |
| Leasehold improvements | 17,256 | 16,946 |
| Furniture and fixtures | 2,782 | 2,805 |
| Computer hardware and software | 1,835 | 1,699 |
| Total property and equipment | 23,140 | 22,740 |
| Less: accumulated depreciation | (11,055) | (7,453) |
| Total property and equipment, net | $ 12,085 | $15,287 |

Depreciation expense related to property and equipment was approximately $3.0 million, $3.0 million and $2.0 million for the years ended December 31, 2020, 2019 and 2018, 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, 2020** | | | | |
| Assets: | | | | |
| Money market | $147,921 | $147,921 | $ — | $ — |
| U.S. treasury securities | — | — | — | — |
| Total assets at fair value | $147,921 | $147,921 | $ — | $ — |
| **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 | $ — |

There were no liabilities that were measured at fair value on a recurring basis as of December 31, 2020.

Financial instruments not recorded at fair value include our convertible senior notes. At December 31, 2020, the carrying amount of the 2021 Notes was $64.2 million, which represents the aggregate principal amount net of remaining debt issuance costs, and the fair value was $59.8 million. At December 31, 2020, the carrying amount of the 2024 Notes (2019 Issuance) was $83.9 million, which represents the aggregate principal amount net of remaining debt issuance costs, and the fair value was $75.4 million. At December 31, 2020, the carrying amount of the 2024 Notes (2020 Issuance) was $56.6 million, which represents the aggregate principal amount net of remaining debt issuance costs, and the fair value was $49.1 million. At December 31, 2020, the carrying amount of the 2025 Notes was $294.3 million, which represents the aggregate principal amount net of remaining debt issuance costs, and the fair value was $211.1 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, *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**

We did not have available-for-sale securities as of December 31, 2020.

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 |

**7. Inventories**

The following table presents inventories as of December 31, 2020 and December 31, 2019 (in thousands):

| | December 31, 2020 | December 31, 2019 |
|---|---|---|
| Work-in-process | $ 102,507 | $ 104,139 |
| Finished goods, net | 32,330 | 20,433 |
| Total inventories | $ 134,837 | $ 124,572 |

At December 31, 2020, we had $30.7 million of current inventory and $104.1 million of long-term inventory.

**8. Intangible Assets**

At December 31, 2020 and 2019, intangible assets related to capitalized milestones under license agreements consisted of the following (in thousands):

| | December 31, 2020 | December 31, 2019 |
|---|---|---|
| Intangible asset - milestones | $ 79,850 | $ 71,850 |
| Accumulated amortization | (14,107) | (8,930) |
| Total intangible asset, net | $ 65,743 | $ 62,920 |

The increase in our intangible asset – milestones since December 31, 2019 is due to an $8.0 million milestone payment to Pfizer related to the May 2020 FDA approval. See Note 14, *License Agreements* for further discussion of this approval.

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 amortization expense of $5.2 million and $4.8 million related to capitalized milestone payments during the year ended December 31, 2020 and December 31, 2019, 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, 2020 is as follows (in thousands):

| | |
|---|---|
| 2021 | $ 5,371 |
| 2022 | 5,371 |
| 2023 | 5,371 |
| 2024 | 5,371 |
| 2025 | 5,371 |
| Thereafter | 38,888 |
| | $ 65,743 |

**9. Leases**

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, 2020 | Year ended December 31, 2019 |
|---|---|---|
| **Lease cost** | | |
| Finance lease cost: | | |
| Amortization of right-of-use assets | $ 1,895 | $ 1,898 |
| Interest on lease liabilities | 816 | 759 |
| Operating lease cost | 4,649 | 4,003 |
| Short-term lease cost | 401 | 301 |
| Variable lease cost | 2,071 | 2,261 |
| **Total lease cost** | $ 9,832 | $ 9,222 |
| | | |
| Operating cash flows from finance leases | $ 816 | $ 759 |
| Operating cash flows from operating leases | $ 4,649 | $ 4,003 |
| Financing cash flows from finance leases | $ 1,470 | $ 1,115 |

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

| | December 31, 2020 | December 31, 2019 |
|---|---|---|
| Weighted-average remaining lease term (years) | | |
| Operating leases | 6.6 | 6.9 |
| Finance leases | 5.0 | 6.0 |
| Weighted-average discount rate | | |
| Operating leases | 8% | 8% |
| Finance leases | 8% | 8% |

Future minimum commitments due under these lease agreements as of December 31, 2020 are as follows (in thousands):

| | Operating Leases | Finance Leases | Total |
|---|---|---|---|
| 2021 | 5,796 | 2,287 | 8,083 |
| 2022 | 5,308 | 2,287 | 7,595 |
| 2023 | 4,859 | 2,287 | 7,146 |
| 2024 | 4,868 | 2,287 | 7,155 |
| 2025 | 5,025 | 2,287 | 7,312 |
| Thereafter | 9,938 | — | 9,938 |
| Present value adjustment | (8,223) | (2,036) | (10,259) |
| Present value of lease payments | $ 27,571 | $ 9,399 | $ 36,970 |

**10. Debt**

The following is a summary of our convertible senior notes at December 31, 2020 and 2019 (principal amount in thousands):

| | Principal Amount December 31, 2020 | Principal Amount December 31, 2019 | Interest Rate | Due Date |
|---|---|---|---|---|
| 2021 Notes | $ 64,418 | $ 97,188 | 2.50% | September 15, 2021 |
| 2024 Notes (2019 Issuance) | 85,782 | 263,000 | 4.50% | August 1, 2024 |
| 2024 Notes (2020 Issuance) | 57,500 | — | 4.50% | August 1, 2024 |
| 2025 Notes | 300,000 | 300,000 | 1.25% | May 1, 2025 |
| Total | $ 507,700 | $ 660,188 | | |

***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.

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.

In August 2019, we entered into privately negotiated transactions with a limited number of holders to repurchase $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 April 2020, we entered into a privately negotiated exchange agreement with a holder ("Holder") of our 2021 Notes, pursuant to which we issued to such Holder of the 2021 Notes approximately $36.1 million in aggregate principal amount of our currently outstanding 2024 Notes (2019 Issuance) in exchange for approximately $32.8 million in aggregate principal of 2021 Notes held by such Holder (the "Exchange Transaction"), which resulted in a $3.3 million loss on extinguishment of debt. We did not receive any cash proceeds from the Exchange Transaction.

***2024 Notes (2019 Issuance)***

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 (2019 Issuance)") 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 (2019 Issuance) 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 (2019 Issuance) 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 (2019 Issuance) will mature on August 1, 2024, unless earlier repurchased or converted.

Holders may convert all or any portion of the 2024 Notes (2019 Issuance) 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 (2019 Issuance), 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 (2019 Issuance) 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 (2019 Issuance) prior to their maturity. If we undergo a fundamental change, as defined in the indenture, prior to the maturity date of the 2024 Notes (2019 Issuance), holders may require us to repurchase for cash all or any portion of the 2024 Notes (2019 Issuance) at a fundamental change repurchase price equal to 100% of the principal amount of the 2024 Notes (2019 Issuance) 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 (2019 Issuance).

The 2024 Notes (2019 Issuance) rank senior in right of payment to any of our indebtedness that is expressly subordinated in right of payment to the 2024 Notes (2019 Issuance); 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 Sixth Street 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 (2019 Issuance), 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 (2019 Issuance) using the effective interest method. We determined the expected life of the debt was equal to the five-year term of the 2024 Notes (2019 Issuance).

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 (2019 Issuance). We used the proceeds of the share offering to repurchase from such holders an aggregate of $123.4 million principal amount of 2024 Notes (2019 Issue) in privately negotiated transactions. In addition, we paid customary fees and expenses in connection with the

transactions. As a result, $3.6 million of unamortized debt issuance costs were derecognized and we recognized a $7.8 million loss on the transactions.

In April 2020, we completed the Exchange Transaction discussed in the 2021 Notes section above.

The additional 2024 Notes (2019 Issuance) issued in the Exchange Transaction were issued as additional notes under that certain Indenture, dated as of August 13, 2019 (the "Indenture"), by and between the Company and The Bank of New York Mellon Trust Company, N.A., as trustee, and have substantially identical terms to our currently outstanding 2024 Notes (2019 Issuance), except that the additional 2024 Notes (2019 Issuance) will accrue interest from February 1, 2020 and the initial interest payment date on the additional 2024 Notes (2019 Issuance) was August 1, 2020. The Holder paid to the Company accrued interest on the additional 2024 Notes (2019 Issue) from February 1, 2020 to and including April 20, 2020. The additional 2024 Notes (2019 Issuance) will be treated as a single series of securities with the currently outstanding 2024 Notes (2019 Issuance).

In April and May 2020, approximately $24.3 million in principal amount of 2024 Notes (2019 Issuance) were converted into 3,331,870 shares of our common stock at the conversion rate of 137.2213 shares per $1,000 in principal amount of 2024 Notes (2019 Issuance).

In November 2020, we entered into a privately negotiated exchange and purchase agreement with a holder of our 2024 Notes (2019 Issuance). Pursuant to the agreement, in exchange for approximately $64.8 million aggregate principal amount of 2024 Notes (2019 Issuance) held by the holder, we agreed to issue to the holder a number shares of our common stock (the "Exchanged Shares") utilizing an exchange ratio that is based in part on the daily volume-weighted average prices ("VWAPs") per share of our common stock during a seven-day pricing period following execution of the agreement.

In addition, pursuant to the agreement, we sold to the holder $57.5 million aggregate principal amount of a new series of 4.50% Convertible Senior Notes due 2024 (the "2024 Notes (2020 Issuance)") at a purchase price of $1,000 per $1,000 principal amount thereof.

The number of Exchanged Shares was calculated utilizing an exchange ratio that is based in part on the average VWAPs of our common stock (subject to a floor) during a seven-day pricing period beginning on November 5, 2020 and ending on, and including, November 13, 2020. In November 2020, we issued 15,112,848 Exchanged Shares pursuant to the debt exchange transaction. As a result, $1.4 million of unamortized debt issuance costs were derecognized and we recognized a $27.3 million loss on the transactions.

***2024 Notes (2020 Issuance)***

The 2024 Notes (2020 Issuance) 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 (2020 Issuance) 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 (2020 Issuance) will mature on August 1, 2024, unless earlier repurchased or converted.

Holders may convert all or any portion of the 2024 Notes (2020 Issuance) 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 160.3334 shares per $1,000 in principal amount of 2024 Notes (2020 Issuance), equivalent to a conversion price of approximately $6.24 per share. The initial conversion price represents a premium of approximately 10% to the last reported sale price of $5.67 per share on November 4, 2020. 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 (2020 Issuance) 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 (2020 Issuance) prior to their maturity. If we undergo a fundamental change, as defined in the indenture, prior to the maturity date of the 2024 Notes (2020 Issuance), holders may require us to repurchase for cash all or any portion of the 2024 Notes (2020 Issuance) at a fundamental change repurchase price equal to 100% of the principal amount of the 2024 Notes (2020 Issuance) 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 (2020 Issuance).

The 2024 Notes (2020 Issuance) rank senior in right of payment to any of our indebtedness that is expressly subordinated in right of payment to the 2024 Notes (2020 Issuance); equal in right of payment to all of our liabilities that are not so subordinated, including the 2021 Notes, 2024 Notes (2019 Issuance) 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 Sixth Street 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 (2020 Issuance), we incurred $0.9 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 (2020 Issuance) using the effective interest method. We determined the expected life of the debt was equal to the four-year term of the 2024 Notes (2020 Issuance).

***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.

As of December 31, 2020, and 2019, the balance of unamortized debt issuance costs related to the convertible senior notes was $8.7 million and $15.4 million, respectively.

Maturities of our convertible notes consisted of the following as of December 31, 2020 (in thousands):

| | |
|---|---|
| 2021 | $ 64,418 |
| 2022 | — |
| 2023 | — |
| 2024 | 143,282 |
| 2025 | 300,000 |
| Thereafter | — |
| | 507,700 |
| Less debt issuance costs | (8,656) |
| Current portion | (64,198) |
| Long-term portion | $ 434,846 |

***Sixth Street Financing Agreement***

On May 1, 2019, we entered into a financing agreement (the "Financing Agreement") with certain affiliates of Sixth Street Partners, LLC ("Sixth Street") in which we plan to borrow from Sixth Street 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 completed enrollment during the second quarter of 2020.

We 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 are 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 are 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, $35.0 million or (ii) if such date is during calendar year 2020 or thereafter, $50.0 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, 2020, we recorded $110.9 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 Sixth Street 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, 2020, the balance of unamortized debt issuance costs was $1.5 million.

For the year ended December 31, 2020, we used an effective interest rate of 14.6%. 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.

Expected maturities of our Financing Agreement consisted of the following as of December 31, 2020 (in thousands):

| | |
|---|---|
| 2021 | $ — |
| 2022 | 8,934 |
| 2023 | 41,091 |
| 2024 | 45,532 |
| 2025 | 16,820 |
| Thereafter | — |
| | 112,377 |
| Less debt issuance costs | (1,460) |
| Current portion | — |
| Long-term portion | $ 110,917 |

The following table sets forth total interest expense recognized during the years ended December 31, 2020, 2019 and 2018 (in thousands):

| | Year ended December 31, | | |
|---|---|---|---|
| | 2020 | 2019 | 2018 |
| Interest on convertible notes | $ 11,934 | $ 13,680 | $ 9,812 |
| Amortization of debt issuance costs | 2,672 | 2,858 | 2,178 |
| Debt issuance cost derecognized related to convertible debt transactions | 4,345 | — | — |
| Interest on finance lease | 816 | 759 | — |
| Interest on borrowings under ATHENA financing agreement | 10,624 | 1,997 | — |
| Accretion of interest on milestone liability | — | — | 977 |
| Interest on capital lease liability | — | — | 216 |
| Other interest | 117 | 111 | — |
| Total interest expense | $ 30,508 | $ 19,405 | $ 13,183 |

**11. Stockholders' Equity**

**Common Stock**

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.

In May 2020, we sold 11,090,000 shares of our common stock in a public offering at $8.05 per share. The net proceeds from the offering were $82.8 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, 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) |
| Other comprehensive income (loss) | 567 | (6) | 561 |
| Total before tax | (44,165) | (139) | (44,304) |
| Tax effect | — | — | — |
| Balance at December 31, 2020 | $ (44,165) | $ (139) | $ (44,304) |

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, 2020, 2019 and 2018.

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 April 2020, our board of directors approved the 2020 Stock Incentive Plan (the "2020 Plan"), which became effective upon approval. The 2020 Plan provides for the grant of nonqualified stock options, stock appreciation rights, restricted stock, restricted stock units, performance awards and other share-based awards to our employees and directors (collectively, "awards"). Common shares authorized for issuance under the 2020 Plan were 6,470,00 at December 31, 2020, which represents the initial reserve. 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 three- or four-year period with 33% or 25%, respectively, 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.

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 and directors. 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.

The adoption of the 2020 Plan did not affect the terms and conditions of any outstanding awards granted under the 2011 Plan. Upon the adoption of the 2020 Plan, no future grants will be granted under the 2011 Plan, but the 2011 Plan will remain in effect with respect to outstanding awards granted thereunder.

Share-based compensation expense for the years ended December 31, 2020, 2019 and 2018, respectively, was recognized in the accompanying Consolidated Statements of Operations and Comprehensive Loss as follows (in thousands):

| | Year ended December 31, | | |
|---|---|---|---|
| | 2020 | 2019 | 2018 |
| Research and development | $25,577 | $25,838 | $ 20,489 |
| Selling, general and administrative | 25,217 | 28,466 | 28,601 |
| Total share-based compensation expense | $50,794 | $54,304 | $ 49,090 |

We did not recognize a tax benefit related to share-based compensation expense during the years ended December 31, 2020, 2019 and 2018 as we maintain net operating loss carryforwards and have established a valuation allowance against the entire net deferred tax asset as of December 31, 2020.

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, 2019 | 6,287,025 | $ 42.24 | | |
| Granted | 980,592 | 7.35 | | |
| Exercised | (117,932) | 3.23 | | |
| Forfeited | (649,016) | 41.15 | | |
| Outstanding at December 31, 2020 | 6,500,669 | $ 37.79 | 5.6 | $ 127 |
| Vested and expected to vest at December 31, 2020 | 6,371,758 | $ 38.24 | 5.5 | $ 118 |
| Vested and exercisable at December 31, 2020 | 5,026,455 | $ 43.87 | 4.7 | $ 31 |

The aggregate intrinsic value in the table above represents the pretax intrinsic value, based on our closing stock price of $4.80 as of December 31, 2020, 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, 2020, 2019 and 2018 (in thousands, except weighted-average grant date fair value per share):

| | Year ended December 31, | | |
|---|---|---|---|
| | 2020 | 2019 | 2018 |
| Weighted-average grant date fair value per share | $ 5.67 | $ 13.53 | $ 32.09 |
| Intrinsic value of options exercised | $ 381 | $ 1,525 | $ 1,714 |
| Cash received from stock option exercises | $ 236 | $ 1,361 | $ 1,869 |

As of December 31, 2020, the unrecognized share-based compensation expense related to unvested options, adjusted for expected forfeitures, was $18.1 million and the estimated weighted-average remaining vesting period was 1.5 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, | | |
|---|---|---|---|
| | 2020 | 2019 | 2018 |
| Dividend yield | — | — | — |
| Volatility (a) | 99 % | 93 % | 88 % |
| Risk-free interest rate (b) | 0.49 % | 1.67 % | 2.92 % |
| Expected term (years) (c) | 6.0 | 5.9 | 5.9 |

(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, 2020, 2019 and 2018 was $22.4 million, $32.8 million and $43.3 million, respectively.

**Restricted Stock**

Beginning in 2016, we issued restricted stock units ("RSUs") to certain employees under the 2011 Plan and 2020 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, 2019 | 2,171,347 | $ 28.37 |
| Granted | 2,441,804 | 8.21 |
| Vested | (1,012,699) | 28.85 |
| Forfeited | (636,905) | 15.51 |
| Unvested at December 31, 2020 | 2,963,547 | $ 14.36 |
| Expected to vest after December 31, 2020 | 2,862,148 | $ 14.09 |

As of December 31, 2020, the unrecognized share-based compensation expense related to RSUs, adjusted for expected forfeitures, was $33.6 million and the estimated weighted-average remaining vesting period was 2.2 years.

**Common Stock Reserved for Issuance**

As of December 31, 2020, 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 | 64,522 | — | 64,522 |
| 2011 Stock Incentive Plan | 8,878,976 | — | 8,878,976 |
| 2020 Stock Incentive Plan | 520,718 | 5,949,282 | 6,470,000 |
| 2011 Employee Stock Purchase Plan | — | 361,656 | 361,656 |
| Total | 9,464,216 | 6,310,938 | 15,775,154 |

**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 283,588 and 175,634 shares to employees in 2020 and 2019, respectively. There were 361,656 shares available for sale under the Purchase Plan as of December 31, 2020. The weighted-average estimated grant date fair value of purchase awards under the Purchase Plan during the years ended December 31, 2020 and 2019 was $4.63 and $6.60 per share, respectively. The total share-based compensation expense recorded as a result of the Purchase Plan was approximately $1.1 million, $1.0 million and $0.9 million during the years ended December 31, 2020, 2019 and 2018, respectively.

The fair value of purchase awards granted to our employees during the years ended December 31, 2020, 2019 and 2018 was estimated using the Black-Scholes option pricing model based upon the weighted-average assumptions provided in the following table:

| | Year ended December 31, | | |
|---|---|---|---|
| | 2020 | 2019 | 2018 |
| Dividend yield | — | — | — |
| Volatility (a) | 138 % | 79 % | 51 % |
| Risk-free interest rate (b) | 0.90 % | 2.20 % | 1.90 % |
| 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 has constructed, in its existing facility, a production train that will be exclusively dedicated to the manufacture of the Rubraca active ingredient. We made scheduled capital program fee payments toward capital equipment and other costs associated with the construction of the dedicated production train. Beginning in the fourth quarter of 2018, once the facility was operational, we were 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, 2020, $68.1 million of purchase commitments remain 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. Plaintiffs filed their opposition to the motion to stay on March 3, 2020 and the SLC filed its reply on March 13, 2020. On May 12, 2020, after hearing oral argument, Vice Chancellor Slights granted the SLC's motion to stay proceedings until September 18, 2020 so that the SLC may complete its investigation. On September 11, 2020, Vice Chancellor Slights granted the parties' request to extend the stay until October 31, 2020, to allow the SLC further time to complete its investigation. On October 26, 2020, Vice Chancellor Slights granted the parties' request to further extend the stay until November 15, 2020. On November 13, 2020, vice Chancellor Slights granted the parties' request to further extend the stay until December 15, 2020.

On December 16, 2020, the SLC filed a report (the "SLC Report") containing the findings of its investigation. The SLC Report concludes that the claims asserted in the Consolidated Derivative Action lack merit. Specifically, the SLC Report finds that the defendants did not breach their fiduciary duties in connection with the Company's TIGER-X clinical trial. Accordingly, on the same date that the SLC Report was filed, the SLC filed a motion to terminate the Consolidated Derivative Action in Delaware Chancery Court. A briefing schedule on the motion to terminate has not yet been set.

While the motion to terminate remains pending before Vice Chancellor Slights, the Company does not believe this litigation will have a material impact on its financial position or results of operations.

***European Patent Opposition***

Two European patents in the rucaparib camsylate salt/polymorph patent family (European Patent 2534153 and its divisional European Patent 3150610) were opposed. In particular, opposition notices against European Patent 2534153 were filed by two parties on June 20, 2017. During an oral hearing that took place on December 4, 2018, the European Patent Office's Opposition Division maintained European Patent 2534153 in amended and narrowed form with claims 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 AG, appealed the written decision of the European Opposition Division and filed reply appeal briefs in early November 2019. An opposition against European Patent 3150610 was filed by Generics (UK) Limited on April 30, 2020 on grounds similar to those raised in the opposition notices against European Patent 2534153, which grounds are common in such proceedings. Moreover, these grounds of opposition, as well as documents based on which lack of patentability has been alleged, were considered by the European Patent Office during the examination stage, and the claims were deemed to comply with the applicable law when granting the patent. Clovis responded to the opposition notice in European Patent 3150610 on January 8, 2021, amending the claims to be directed to the use of rucaparib maleate in a method of inhibiting PARP activity or treating cancer. A preliminary opinion and summons to oral proceedings were issued on January 26, 2021. The oral hearing is scheduled for November 18, 2021. The preliminary opinion provides a non-binding indication of the Opposition Division's initial view based on the documents that have thus far been submitted, which agrees with our positions on a number of grounds of opposition and agrees with an objection made by the opponent, but only with respect to some of the claims. As part of the opposition proceedings, we have the opportunity to submit further arguments and pursue alternative claims in the form of auxiliary requests. While the ultimate results of patent challenges can be difficult to predict, it is our view that a number of factors support patentability, and we believe a successful challenge of all claims would be difficult.

**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) 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.

In April 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.

In May 2020, Rubraca received a third FDA approval for Rubraca as a monotherapy treatment of adult patients with *BRCA1/2*-mutant recurrent, metastatic castrate-resistant prostate cancer. This approval resulted in an obligation to pay an $8.0 million milestone payment, which we paid in June 2020.

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 $8.0 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**

On November 19, 2013, we acquired all of the issued and outstanding capital stock of EOS pursuant to the terms set forth in that certain Stock Purchase Agreement, dated as of November 19, 2013 (the "Stock Purchase Agreement"), by and among the Company, EOS, its shareholders (the "Sellers") and Sofinnova Capital V FCPR, acting in its capacity as the Sellers' representative. Following the acquisition, EOS became a wholly-owned subsidiary of the Company. Under the terms of the Stock Purchase Agreement, in addition to the initial purchase price paid at the time of the closing of the acquisition and other license fees due to Advenchen described below, we will also be obligated to pay to the Sellers a milestone payment of $65.0 million upon obtaining the first NDA approval from the FDA with respect to 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.

**FAP-2286 and the Radionuclide Therapy Development 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 discovery collaboration 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 discovery collaboration 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.

**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, | | |
|---|---|---|---|
| | 2020 | 2019 | 2018 |
| Common shares under stock incentive plans | 3,095 | 2,480 | 1,319 |
| Convertible senior notes | 25,969 | 41,598 | 8,584 |
| Total potential dilutive shares | 29,064 | 44,078 | 9,903 |

**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, | | |
|---|---|---|---|
| | 2020 | 2019 | 2018 |
| Domestic | $(370,839) | $(399,497) | $(368,402) |
| Foreign | 1,080 | 871 | 1,001 |
| Total loss before income taxes | $(369,759) | $(398,626) | $(367,401) |

The income tax provision consists of the following current and deferred tax expense (benefit) amounts (in thousands):

| | Year ended December 31, | | |
|---|---|---|---|
| | 2020 | 2019 | 2018 |
| Current tax: | | | |
| U.S. Federal & State | $ 50 | $ 3 | $ 15 |
| Foreign | (597) | 1,795 | 593 |
| Total current expense (benefit) | (547) | 1,798 | 608 |
| Deferred tax: | | | |
| U.S. Federal & State | — | — | — |
| Foreign | — | — | — |
| Total deferred (benefit) | — | — | — |
| Total income tax expense (benefit) | $ (547) | $ 1,798 | $ 608 |

A reconciliation of the U.S. federal statutory income tax rate to our effective tax rate is provided below:

| | Year ended December 31, | | |
|---|---|---|---|
| | 2020 | 2019 | 2018 |
| Federal income tax benefit at statutory rate | (21.0)% | (21.0)% | (21.0)% |
| State income tax benefit, net of federal benefit | (1.6) | (2.9) | (3.1) |
| Tax credits | (1.5) | (1.1) | (1.3) |
| Change in uncertain tax positions | 0.1 | (4.3) | 0.1 |
| SEC settlement costs | — | — | 1.1 |
| Convertible debt transactions | 2.2 | — | — |
| Prior year true ups | 0.9 | 0.1 | (0.8) |
| Share based compensation | 2.6 | 2.3 | 0.8 |
| Tax rate changes | 1.4 | 0.1 | 0.3 |
| Change in valuation allowance | 16.1 | 26.5 | 23.2 |
| Other | 0.6 | 0.8 | 0.9 |
| Effective income tax rate | (0.2)% | 0.5 % | 0.2 % |

The significant components of our deferred tax assets and liabilities are as follows (in thousands):

| | December 31, | |
|---|---|---|
| | 2020 | 2019 |
| Deferred tax assets: | | |
| Net operating loss carryforward | $ 414,932 | $ 396,100 |
| Tax credit carryforwards | 247,064 | 243,901 |
| Interest expense limitation carryforward | 5,371 | 4,449 |
| Intangible assets | 94,558 | 61,459 |
| Share-based compensation expense | 33,169 | 34,006 |
| Product acquisition costs | 4,992 | 6,288 |
| Lease liabilities | 6,122 | 5,317 |
| Accrued liabilities and other | 7,488 | 5,817 |
| Total deferred tax assets | 813,696 | 757,337 |
| Valuation allowance | (806,622) | (750,508) |
| Deferred tax assets, net of valuation allowance | 7,074 | 6,829 |
| Deferred tax liabilities: | | |
| Right-of-use assets | (6,799) | (6,337) |
| Prepaid expenses and fixed assets | (275) | (492) |
| Total deferred tax liabilities | (7,074) | (6,829) |
| Net deferred tax liability | $ — | $ — |

The Tax Cuts and Jobs 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 $56.1 million and $102.6 million for the years ended December 31, 2020 and 2019, respectively, primarily due to the growth in net operating losses and amortizable research and development expenses incurred 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, 2020 of $8.0 million, if recognized, would not impact the Company's effective tax rate as long as we remain subject to a full valuation allowance. The following table summarizes the gross amounts of unrecognized tax benefits (in thousands):

| | Year ended December 31, | |
|---|---|---|
| | 2020 | 2019 |
| Balance at beginning of year | $ 7,525 | $ 24,775 |
| Changes related to prior period tax positions | 64 | (35) |
| Additions related to current period tax positions | 415 | 398 |
| Settlements with tax authorities | — | (17,613) |
| Expiration of statute of limitations | — | — |
| Balance at end of year | $ 8,004 | $ 7,525 |

As of December 31, 2020, we had approximately $1.7 billion, $1.6 billion and $2.0 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, totaling $1.1 billion, will expire from 2029 to 2037 if not utilized and the U.S. federal net operating losses generated after the enactment of the Act, totaling $0.6 billion, do not expire and are carried forward

indefinitely. U.S. state net operating losses will expire from 2024 to 2040 if not utilized. We have research and development and orphan drug tax credit carryforwards of $254.5 million that will expire from 2030 through 2040 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 ("UTP") of $17.6 million and a decrease to the U.S. federal net operating loss carryforward due to the release of the UTP recorded against the credit. 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, 2020 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, 2016 to December 31, 2020.

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 $2.1 million, $2.2 million and $2.0 million for the years ended December 31, 2020, 2019 and 2018, 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 $1.5 million, $1.1 million and $0.9 million for the years ended December 31, 2020, 2019 and 2018, respectively.

**18. Segment Information**

The following table presents information about our reportable segments for the year months ended December 31, 2020, 2019 and 2018 (in thousands):

| | Year ended December 31, | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | 2020 | | | 2019 | | | 2018 | | |
| | U.S. | Ex-U.S. | Total | U.S. | Ex-U.S. | Total | U.S. | Ex-U.S. | Total |
| Product revenue | $ 146,259 | $ 18,263 | $ 164,522 | $ 137,187 | $ 5,819 | $ 143,006 | $ 95,388 | $ — | $ 95,388 |
| Operating expenses: | | | | | | | | | |
| Cost of sales - product | 29,526 | 6,602 | 36,128 | 28,179 | 1,747 | 29,926 | 19,444 | — | 19,444 |
| Cost of sales - intangible asset amortization | 2,287 | 2,890 | 5,177 | 1,956 | 2,804 | 4,760 | 1,954 | 676 | 2,630 |
| Research and development | 249,444 | 8,263 | 257,707 | 275,518 | 7,628 | 283,146 | 226,925 | 4,422 | 231,347 |
| Selling, general and administrative | 139,455 | 24,439 | 163,894 | 161,132 | 21,637 | 182,769 | 161,743 | 14,038 | 175,781 |
| Acquired in-process research and development | — | — | — | 9,440 | — | 9,440 | — | — | — |
| Other operating expenses | 3,804 | — | 3,804 | 9,711 | — | 9,711 | — | — | — |
| Total expenses | 424,516 | 42,194 | 466,710 | 485,936 | 33,816 | 519,752 | 410,066 | 19,136 | 429,202 |
| Operating loss | (278,257) | (23,931) | (302,188) | (348,749) | (27,997) | (376,746) | (314,678) | (19,136) | (333,814) |

**19. Quarterly Information (Unaudited)**

The results of operations on a quarterly basis for the years ended December 31, 2020 and 2019 were as follows (in thousands):

| | March 31, 2020 | June 30, 2020 | September 30, 2020 | December 31, 2020 | March 31, 2019 | June 30, 2019 | September 30, 2019 | December 31, 2019 |
|---|---|---|---|---|---|---|---|---|
| Revenues: | | | | | | | | |
| Product revenue | $ 42,564 | $ 39,887 | $ 38,772 | $ 43,299 | $ 33,118 | $ 32,978 | $ 37,603 | $ 39,307 |
| Operating expenses: | | | | | | | | |
| Cost of sales - product | 9,096 | 9,120 | 8,438 | 9,474 | 7,405 | 6,445 | 8,134 | 7,942 |
| Cost of sales - intangible asset amortization | 1,212 | 1,280 | 1,343 | 1,342 | 1,120 | 1,217 | 1,212 | 1,211 |
| Research and development | 68,221 | 69,878 | 62,902 | 56,706 | 62,031 | 70,746 | 77,896 | 72,473 |
| Selling, general and administrative | 42,598 | 41,902 | 38,636 | 40,758 | 47,761 | 48,029 | 41,811 | 45,168 |
| Acquired in-process research and development | — | — | — | — | — | — | 9,440 | — |
| Other operating expenses | 3,449 | 355 | — | — | — | — | 5,539 | 4,172 |
| Total expenses | 124,576 | 122,535 | 111,319 | 108,280 | 118,317 | 126,437 | 144,032 | 130,966 |
| Operating loss | (82,012) | (82,648) | (72,547) | (64,981) | (85,199) | (93,459) | (106,429) | (91,659) |
| Other income (expense): | | | | | | | | |
| Interest expense | (9,561) | (6,739) | (6,859) | (7,349) | (3,590) | (3,817) | (5,278) | (6,720) |
| Foreign currency (loss) gain | (877) | 142 | 633 | 30 | (192) | (226) | (229) | 100 |
| (Loss) gain on extinguishment of debt | — | (3,277) | — | — | — | — | 18,480 | — |
| Loss on convertible senior notes conversion | (7,791) | — | — | (27,284) | — | — | — | — |
| Legal settlement loss | — | — | — | — | — | (25,000) | (1,750) | — |
| Other income | 841 | 239 | 79 | 202 | 2,400 | 1,899 | 781 | 1,262 |
| Other income (expense), net | (17,388) | (9,635) | (6,147) | (34,401) | (1,382) | (27,144) | 12,004 | (5,358) |
| Loss before income taxes | (99,400) | (92,283) | (78,694) | (99,382) | (86,581) | (120,603) | (94,425) | (97,017) |
| Income tax benefit (expense) | 68 | 36 | 18 | 425 | 160 | 176 | 350 | (2,484) |
| Net loss | $ (99,332) | $ (92,247) | $ (78,676) | $ (98,957) | $ (86,421) | $ (120,427) | $ (94,075) | $ (99,501) |
| Basic and diluted net loss per common share | $ (1.39) | $ (1.15) | $ (0.89) | $ (1.02) | $ (1.63) | $ (2.27) | $ (1.72) | $ (1.81) |
| Basic and diluted weighted average common shares outstanding | 71,662 | 80,453 | 88,255 | 96,681 | 52,891 | 53,028 | 54,707 | 54,834 |

**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 24, 2021

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 24, 2021 |
| /S/ DANIEL W. MUEHL<br>**Daniel W. Muehl** | Executive Vice President and Chief Finance Officer<br>*(Principal Financial Officer and Principal Accounting Officer)* | February 24, 2021 |
| /S/ BRIAN G. ATWOOD<br>**Brian G. Atwood** | Director | February 24, 2021 |
| /S/ ROBERT W. AZELBY<br>**Robert W. Azelby** | Director | February 24, 2021 |
| /S/ JAMES C. BLAIR<br>**James C. Blair** | Director | February 24, 2021 |
| /S/ RICHARD A. FAIR<br>**Richard A. Fair** | Director | February 24, 2021 |
| /S/ KEITH FLAHERTY<br>**Keith Flaherty** | Director | February 24, 2021 |
| /S/ GINGER L. GRAHAM<br>**Ginger L. Graham** | Director | February 24, 2021 |
| /S/ PAUL KLINGENSTEIN<br>**Paul Klingenstein** | Director | February 24, 2021 |
| /S/ EDWARD J. MCKINLEY<br>**Edward J. McKinley** | Director | February 24, 2021 |
| /S/ THORLEF SPICKSCHEN<br>**Thorlef Spickschen** | Director | February 24, 2021 |

**Exhibit 10.40**

**Execution Copy**

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT HAVE BEEN OMITTED AND REPLACED WITH "[***]". SUCH IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS (I) NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE COMPANY IF PUBLICLY DISCLOSED.

# LICENSE AND COLLABORATION AGREEMENT

**THIS LICENSE AND COLLABORATION AGREEMENT** (the "**Agreement**") is made and entered into as of 20 September, 2019 (the "**Effective Date**") by and between **3B PHARMACEUTICALS GMBH**, a limited liability company organized and existing under the laws of Germany, with registered offices at Magnusstraße 11, D-12489 Berlin, Germany ("**3BP**") and **CLOVIS ONCOLOGY, INC.**, a corporation organized and existing under the laws of the State of Delaware, USA, having offices at 5500 Flatiron Parkway, Suite 100, Boulder, Colorado 80301 USA ("**Clovis**"). 3BP and Clovis are sometimes referred to herein individually as a "**Party**" and collectively as the "**Parties**."

## BACKGROUND

**WHEREAS**, Clovis is a biopharmaceutical company focused on acquiring, developing, and commercializing innovative anti-cancer agents;

**WHEREAS**, 3BP is a biotechnology company developing targeted radiopharmaceutical drugs and diagnostics for oncology indications with a high unmet medical need;

**WHEREAS**, 3BP has developed proprietary radionuclide conjugated substances and intellectual property covering those substances targeting fibroblast activation protein alpha (FAP);

**WHEREAS**, Clovis is interested in licensing from 3BP certain rights to the aforementioned substances and intellectual property in order to further develop those substances and manufacture and commercialize products that include those substances for certain territories, all in accordance with the terms and conditions set forth herein;

**WHEREAS**, 3BP is willing to grant Clovis the license described above;

**WHEREAS**, 3BP will retain the rights to the substances and intellectual property for certain territories and the right to further develop the substances and manufacture and commercialize products that include those substances in certain territories;

**WHEREAS**, Clovis is willing to grant 3BP the right to use the data and results arising from the development and manufacture activities conducted by Clovis, for the development, manufacture and commercialization activities of 3BP in its retained territories;

**WHEREAS,** both Parties' development activities shall be coordinated in a joint global development plan as well as both Parties' manufacture activities shall be coordinated in a joint manufacture plan and the Parties will establish joint bodies in order to coordinate their activities and foster the collaboration.

**NOW, THEREFORE,** in consideration of the foregoing premises and the mutual promises, covenants and conditions contained in this Agreement, the Parties agree as follows:

## 1. DEFINITIONS

Capitalized terms used in this Agreement (other than the headings of the Sections or Articles) have the following meanings set forth in this **Article 1**, or, if not listed in this **Article 1**, the meanings as designated in the text of this Agreement.

**1.1 "3BP Indemnitees"** has the meaning set forth in **Section 13.1**.

**1.2 "3BP Know-How"** means (a) all Know-How that is Controlled by 3BP or its Affiliates as of the Effective Date or during the Term and are necessary or useful for the Development, Manufacture or Commercialization of a Product, and (b) any Development Data, Manufacturing Data, and Regulatory Documentation generated by or on behalf of 3BP and its Affiliates (including generated by contract research organizations or Contract Manufacturers).

**1.3 "3BP Patents"** means any Patent that is Controlled by 3BP or its Affiliates as of the Effective Date or during the Term that (a) Covers a FAP-Targeting Compound, and/or (b) is necessary or useful for the Development, Manufacture or Commercialization of a Product, including (i) the [***] and the [***], and (ii) Patents that Cover Sole Inventions solely owned by 3BP pursuant to **Section 9.2(a)**. The 3BP Patents existing as of the Effective Date are listed on Exhibit 1.3.

**1.4 "3BP Technology"** means the 3BP Patents, 3BP Know-How, and 3BP's interest in any Joint Patents.

**1.5 "Acquiror"** has the meaning set forth in **Section 1.13**.

**1.6 "Affiliate"** means, with respect to a Party, a person, corporation, partnership, or other entity that controls, is controlled by or is under common control with such Party. For the purposes of the definition in this **Section 1.6**, the word "control" (including, with correlative meaning, the terms "controlled by" or "under the common control with") means the actual power, either directly or indirectly through one (1) or more intermediaries, to direct or cause the direction of the management and policies of such entity either by the ownership of at least fifty percent (50%) of the voting stock of such entity or the ability to otherwise control the management of the entity.

**1.7 "Alliance Manager"** has the meaning set forth in **Section 2.3**.

**1.8 "Applicable Law"** means all laws, statutes, rules, regulations, ordinances and other pronouncements having the effect of law of any federal, national, multinational, supranational, state, provincial, county, city or other political subdivision, domestic or foreign, which may be in effect from time to time and applicable to conduct under this Agreement.

**1.9 "Applicable CoC Party"** means, the Acquiror, Clovis or Clovis' successor, whatever is applicable after the respective Change of Control transaction has occurred.

**1.10 "Backup Candidates"** means, as of the Effective Date, the FAP-Targeting Product identified on Exhibit 1.10, and/ or any other FAP-Targeting Product identified and agreed by the Parties during the Term pursuant to the process described in **Section 3.1** as a candidate for further Pre-Clinical Development, either as a potential future replacement for a Lead Candidate or a potential future additional Lead Candidate.

**1.11 "Business Day"** means a day other than Saturday, Sunday or any day on which commercial banks located in either Denver, Colorado or Berlin, Germany are authorized or obligated by Applicable Law to close.

**1.12 "Calendar Year"** means any twelve (12) month period commencing on January 1.

**1.13 "Change of Control"** means a transaction in which a Party: (a) sells, conveys or otherwise disposes of all or substantially all of its property or business (with the acquiror of the property or business being referred to as the "**Acquiror**"); or (b) (i) merges or consolidates with any other entity or person (other than a wholly-owned subsidiary of such Party); or (ii) effects any other transaction or series of transactions; in each case of clause (i) or (ii), such that the stockholders of such Party immediately prior thereto, in the aggregate, no longer own, directly or indirectly, beneficially or legally, at least fifty percent (50%) of the outstanding voting securities or capital stock of the surviving entity following the closing of such merger, consolidation, other transaction or series of transactions. Notwithstanding the foregoing subsection (b), a Change of Control will not include any transaction or series of related transactions principally conducted for bona fide equity financing purposes in which cash is received, or indebtedness is cancelled or converted, or a combination thereof occurs; *provided* such equity financing is made solely by non-strategic investors (including venture capitalist entities, investment banks, and their Affiliates) who are not in the business of Developing or Commercializing pharmaceutical or biological products.

**1.14 "Change of Control Closing"** means the completion of the Change of Control transaction.

**1.15 "Claims"** has the meaning set forth in **Section 13.1**.

**1.16 "Clovis Indemnitees"** has the meaning set forth in **Section 13.2**.

**1.17 "Clovis Know-How"** means (a) all Know-How that is Controlled by Clovis or its Affiliates as of the Effective Date or during the Term and are or were necessary or useful for the Development, Manufacture or Commercialization of a Product and (b) any Development Data, Manufacturing Data, Manufacturing Documentation and Regulatory Documentation generated by or on behalf of Clovis and its Affiliates (including generated by contract research organizations and Contract Manufacturers).

**1.18 "Clovis Patents"** means any Patent that is Controlled by Clovis or its Affiliates as of the Effective Date or during the Term that (a) Covers a FAP-Targeting Compound and/or (b) is or was necessary or useful for the Development, Manufacture or Commercialization of a Product, including Patents that Cover Sole Inventions solely owned by Clovis pursuant to **Section 9.2(a)**.

**1.19 "Clovis Technology"** means the Clovis Patents, the Clovis Know-How, and Clovis' interest in any Joint Patents.

**1.20** "**CMC Activities**" means the chemistry, manufacturing and controls activities necessary or useful for generating the CMC Information required for Regulatory Approval of a Product, including Manufacture of commercial and/or clinical trial materials, process and method validation, and all other related activities that are necessary or useful to obtain or maintain Regulatory Approval of a Product.

**1.21 "CMC Information"** means information related to the chemistry, manufacturing and controls of a Product required for approval to commence clinical studies and/ or Regulatory Approval of a Product, as specified by FDA or other applicable Regulatory Authority.

**1.22 "Collaboration"** has the meaning set forth in **Section 2.1**.

**1.23 "Combination Product"** has the meaning set forth in **Section 1.78**.

**1.24 "Commercialize"** means to promote, market, distribute, sell (and offer for sale or contract to sell), import, export, provide product support for a Product, and interacting with Regulatory Authorities regarding the foregoing, and includes post-approval commitments and pharmacovigilance. For clarity, **"Commercializing"** and **"Commercialization"** have a correlative meaning.

**1.25 "Committee"** means the JSC or any other committee established by the Parties pursuant to **Section 2.1**, as the case may be.

**1.26 "Competing Product"** means any therapeutic pharmaceutical product comprising a binding moiety that deliberately targets and primarily binds to FAP, and is or can be linked to an anticancer payload as its primary mechanism of action, other than a Product.

**1.27 "Confidential Information"** of a Party means all information of such Party that is disclosed to the other Party under this Agreement or of which the other Party otherwise obtains knowledge under or in connection with this Agreement, whether in oral, written, graphic, or electronic form. The terms of this Agreement will be Confidential Information of each Party.

**1.28 "Contract Manufacturer"** means any Third Party engaged by a Party to Manufacture a Product (or any component of a Product).

**1.29 "Controlled"** means, with respect to any compound, material, Know-How or other Intellectual Property Right, that the applicable Party owns or has a license to such compound, material, Know-How or other Intellectual Property Right and has the ability to grant to the other Party access, a license or a sublicense (as applicable) to such compound, material, Know-How or other Intellectual Property Right as provided for herein without violating the terms of any agreement or other arrangements with any Third Party existing at the time such Party would be first required hereunder to grant the other Party such access, license or sublicense.

**1.30 "Cover," "Covered"** or **"Covering"** means, with reference to a Patent, that the making, using, selling, offering for sale or importing of a composition of matter or practice of a method would infringe a Valid Claim of such Patent in the country in which such activity occurs.

**1.31 "Current Good Manufacturing Practice"** or **"cGMP"** means the then-current standards for the manufacture of pharmaceutical products officially published and interpreted by EMA, FDA and/ or other applicable Regulatory Authorities that may be in effect from time to time and are applicable to the Manufacture of the Products.

**1.32 "Data Exclusivity"** means, with respect to any country or other jurisdiction in the Licensed Territory, a market protection, granted by a Regulatory Authority in such country or other jurisdiction, during which Clovis, its Affiliates or Sublicensees have the exclusive right to Commercialize the Product in such country or other jurisdiction through a regulatory exclusivity right, including orphan drug designation.

**1.33 "Develop"** or **"Development"** means, with respect to a Product, all research, preclinical, clinical, and regulatory activities (*e.g.,* preparation of regulatory applications), including synthesis of compounds, target validation activities (*e.g*., expression analysis), preparation and conduct of pre-clinical and clinical studies, test method development and stability testing, assay development, toxicology, formulation, quality assurance/quality control development, statistical analysis, process development, pharmacokinetic studies, regulatory affairs, and drug safety surveillance activities, in each case prior to Regulatory Approval or thereafter, and obtaining Regulatory Approvals.

**1.34** "**Development Costs**" means all costs incurred by or on behalf of either Party after the Effective Date that are reasonably and directly allocable to the Development of Products and/ or Backup Candidates pursuant to the Global Development Plan. Development Costs will include but not be limited to FTE Costs, out-of-pocket costs actually incurred by each Party, costs of any Products and comparator drug supplied for use in clinical studies, ethics committee fees, investigator fees, investigator meeting costs, hospital fees and contract (including clinical) research organization's fees. Development Costs shall include FTE Costs relating to regulatory activities involving preparation, submission of documents related to, and review of clinical trials with any Regulatory Authority.

**1.35** "**Development Data**" means all research data, preclinical data, pharmacology data, clinical data, and/or all regulatory documentation, information and submissions and communications pertaining to, or made in association with an IND, Marketing Authorization application and other marketing approval applications, Regulatory Approval or the like for the Products and/ or Backup Candidates, in each case that are generated in the conduct of activities conducted under the Global Development Plan or otherwise under this Agreement.

**1.36 "Diligent Efforts"** means, with respect to the efforts to be expended by a Party with respect to any objective under this Agreement, the reasonable, diligent, good faith efforts to accomplish such objective as a reasonable company would normally use to accomplish a similar objective under similar circumstances. It is understood and agreed that with respect to the Development and Commercialization of a Product by either Party, such efforts will be substantially equivalent to those efforts and resources commonly used by a reasonable company for pharmaceutical products owned by it or to which it has rights, which product is at a similar stage in its development or product life and is of similar market potential taking into account efficacy, safety, approved labeling, the competitiveness of alternative products in the marketplace, the patent and other proprietary position of the product, the likelihood of regulatory approval given the Regulatory Authority involved, the profitability of the product including the amounts payable to licensors of Patent or other Intellectual Property Rights, alternative products and other relevant factors. Diligent Efforts will be determined on a market-by-market or country-by-country basis, and indication-by-indication basis, and it is anticipated that the level of efforts required will be different for different markets and indications and will change over time, reflecting changes in the status of the Product and markets involved.

**1.37 "Distributor"** means a Third Party that (a) purchases any Products in finished form from or at the direction of Clovis or any of its Affiliates or Sublicensees, and (b) has the

right to Commercialize such Products in one or more regions, or has an option to do the foregoing. A Distributor will not be considered a Sublicensee hereunder. For the avoidance of doubt, any Third Party that actually requires a sublicense from Clovis under the 3BP Technology in order not to infringe the 3BP Technology by its activities, shall be deemed to be a Sublicensee even if it is designated as a Distributor.

**1.38 "Dollars"** or **"$"** means the lawful currency of the U.S.

**1.39 "Due Diligence Data"** has the meaning set forth in **Section 12.2(i)**.

**1.40 "Effective Date"** has the meaning set forth in the first paragraph of this Agreement.

**1.41 "EMA"** means the European Medicines Agency or any successor entity.

**1.42 "EU"** means the European Union, as its membership may be altered from time to time, and any successor thereto.

**1.43 "Euros"** or **"€"** means the lawful currency of the Eurozone.

**1.44 "Executive Officers"** means the Chief Executive Officer of Clovis and the Managing Director of 3BP (or their respective designees).

**1.45 "External Patent Costs"** means fees charged by any national or regional patent office and the reasonable costs of any external patent counsel engaged by a Party that are attributable to the filing, prosecution, maintenance and defense of a FAP Patent and are incurred by a Party pursuant to the terms of this Agreement.

**1.46 "FAP"** means a fibroblast activation protein.

**1.47 "FAP Patents"** means the 3BP Patents, Clovis Patents and Joint Patents.

**1.48 "FAP-Targeting Compound"** means a molecule identified using the 3BP Technology, [***].

**1.49 "FAP-Targeting Product"** means any molecule that comprises a FAP-Targeting Compound that is or can be labeled with a radioactive isotope for use as a therapeutic, diagnostic or theranostic radiopharmaceutical, and which the Parties Develop pursuant to the Collaboration. [***].

**1.50 "FDA"** means the United States Food and Drug Administration or any successor entity.

**1.51 "First Commercial Sale"** means, with respect to a Product in a particular country, the first commercial sale of such Product by a Selling Party to an unaffiliated Third Party in such country after all necessary Regulatory Approvals have been obtained in such country.

**1.52 "FTE"** means a full time equivalent of work devoted to or in support of the Development or Manufacture of the Product in accordance with the Global Development Plan

or pursuant to this Agreement, which is carried out by one or more qualified scientific or technical employees or contract personnel of a Party or its Affiliates, as measured in accordance with such Party's normal time allocation practices. For the avoidance of doubt, employees who work fewer than such full time equivalent of work (whether via working a partial year or part-time) are included in an FTE, provided their hours are combined to complete one FTE. By way of example, but not limitation, if the full time equivalent of work is [***] ([***]) hours, an employee working [***] ([***]) hours in a given Calendar Year would be combined with an employee working [***] ([***]) hours in the same Calendar Year to form one FTE. Similarly, in such example, any employee can be allocated at a percentage of time equaling less than one hundred percent (100%) of their work in a Calendar Year; *provided* that FTEs are calculated in [***] ([***]) hour increments.

**1.53 "FTE Cost"** means, for any period, the FTE Rate multiplied by the number of FTEs in such period.

**1.54 "FTE Rate"** means the rate set forth in Exhibit 1.54 per Calendar Year (pro-rated (a) for the period beginning on the Effective Date and ending at the end of the first Calendar Year and (b) for the period beginning on the beginning of a Calendar Year and ending at the end of the Pre-Clinical Program Term). The FTE Rate is "fully burdened" and will cover employee salaries and such facilities and equipment and other materials and services including ordinary laboratory and manufacturing consumables procured from distributors of relevant products as they may use.

**1.55 "GAAP"** means U.S. generally accepted accounting principles, consistently applied.

**1.56 "Generic Product"** means, on a country-by-country and Therapeutic Product-by-Therapeutic Product basis, any pharmaceutical product that (a) is sold by a Third Party that is not an Affiliate or Sublicensee of Clovis under a Regulatory Approval granted by a Regulatory Authority to such Third Party, (b) contains the identical or substantially similar (as determined by the applicable Regulatory Authority) active ingredient(s) as the approved Therapeutic Product, and (c) is labeled, advertised, marketed, promoted or intended for use in such country for an Indication that is also an Indication for which the Therapeutic Product is labeled, advertised, marketed, promoted or intended for use in such country.

**1.57 "Global Development Plan"** has the meaning set forth in **Section 3.2(a)**.

**1.58 "Imaging Agent"** means a Lead Candidate containing a diagnostic radioisotope, including a positron and/ or gamma-ray emitting radioisotope, which has been selected for Development, Manufacture and Commercialization by the Parties under the terms of this Agreement for in vivo diagnostic imaging purposes, and for the avoidance of doubt, not as a therapy for one or more Indications.

**1.59 "IND"** means any investigational new drug application filed with the FDA for authorization to commence clinical studies, and any comparable filings with any Regulatory Authority in any other jurisdiction.

**1.60 "IND Acceptance"** means the date upon which the first IND filing for the Lead Candidate becomes effective in accordance with FDA regulations.

**1.61 "Indemnified Party"** has the meaning set forth in **Section 13.3**.

**1.62** "**Indemnifying Party"** has the meaning set forth in **Section 13.3**.

**1.63** **"Indication"** means a discrete clinically recognized form of a disease or any precursor condition thereof defined histologically or biologically. For the avoidance of doubt, the treatment or prevention of separate varieties of the same disease or precursor condition will not be a separate Indication, the treatment or prevention of different stages of the same disease or precursor condition (e.g., lines of therapy) will not be a separate Indication, and the treatment or prevention of the same disease or medical condition in a different population will not be a separate Indication (e.g., adult and pediatric).

**1.64** **"Intellectual Property Right"** or **"IPR"** means all now known or hereafter existing (a) rights associated with works of authorship throughout the world, including exclusive exploitation rights, copyrights, moral rights and mask works, (b) internet domain name, trademark, trade dress, and trade name and similar rights, (c) trade secret rights, (d) Patents, designs, algorithms and other industrial property rights, (e) other intellectual and industrial property and proprietary rights of every kind and nature throughout the world, arising by operation of law, and (f) all registrations, applications, renewals, extensions, combinations, divisions or reissues of the foregoing.

**1.65** **"Joint Inventions"** has the meaning set forth in **Section 9.2(a)**.

**1.66** **"Joint Patents"** means a Patent that Covers a Joint Invention.

**1.67** **"Joint Steering Committee"** or **"JSC"** has the meaning set forth in **Section 2.2(a)**.

**1.68** **"Know-How"** means all confidential and proprietary: commercial, technical, scientific and other information, trade secrets, knowledge, technology, methods, processes, practices, formulae, instructions, skills, techniques, procedures, experiences, ideas, inventions, technical assistance, designs, drawings, assembly procedures, computer programs, specifications, data and results (including biological, chemical, pharmacological, toxicological, pharmaceutical, physical and analytical, preclinical, clinical, safety, manufacturing and quality control data and know-how, including study designs and protocols), in all cases, whether or not patented or patentable, in written, electronic or any other form now known or hereafter developed.

**1.69** **"Lead Candidate"** means, as of the Effective Date, the FAP-Targeting Product identified on Exhibit 1.69, and/ or any other FAP-Targeting Product identified and agreed by the Parties pursuant to the process described in **Section 3.1**. For the avoidance of doubt, the Parties may identify more than one Lead Candidate.

**1.70** **"Licensed Territory"** means all countries in the world other than those in the Retained Territory.

**1.71** **"Manufacturing"** means all activities related to the production, manufacture, processing, filling, finishing, packaging, labeling, storing and holding of Products or any intermediate thereof, sourcing of any raw materials or packaging materials with respect to manufacture of Products, qualification and validation, equipment and facility qualification and validation, commercial manufacture, stability and release testing, quality assurance and quality control. For clarity, **"Manufacture"** and **"Manufactured"** have correlative meanings.

**1.72 "Manufacturing Data"** means any and all data, documentation, information and submissions and communications pertaining to, or made in association with any CMC Activities and/ or Manufacture of the Products and/ or Backup Candidates (*e.g.*, master batch records, batch records, in-process controls records, drug master file, Manufacturing process descriptions, release documents, release specifications, release data, process control data, CMC submission documents and communication with Regulatory Authorities relating thereto), including all CMC Information, in each case that are generated in the conduct of activities conducted under the Global Development Plan or otherwise under this Agreement.

**1.73 "Manufacturing Documentation"** means any and all records and other documentation and documents which contain Manufacturing Data or are necessary or useful to assume or conduct Manufacture of the Products and/ or Backup Candidates.

**1.74 "Manufacturing Plan"** has the meaning set forth in **Section 6.2**.

**1.75 "Marketing Authorization"** means approval of an NDA by the FDA or approval of any corresponding foreign application by the relevant Regulatory Authority in the Licensed Territory.

**1.76 "NDA"** means a New Drug Application or Supplemental New Drug Application filed with the FDA (including amendments and supplements thereto).

**1.77 "Necessary"** means, in relation to Patents, [***]. **"Necessity"** shall have a correlative meaning.

**1.78 "Net Sales"** means the gross amount invoiced by or on behalf of Clovis, its Affiliates and their respective Sublicensees (each, a **"Selling Party"**) for sales of Product to unaffiliated Third Parties, less the following deductions if and to the extent they are included in the invoiced gross price of the Product or otherwise directly incurred by the Selling Party with respect to such sales:

**(a)** reasonable credits or allowances, if any, on account of price adjustments, recalls, rejection or return of Product previously sold;

**(b)** import taxes, export taxes, excises, sales taxes, value added taxes, consumption taxes, duties or other taxes imposed upon and paid with respect to such sales (excluding income or franchise taxes of any kind) but only to the extent included in the invoiced sales price;

**(c)** rebates, trade, quantity and cash discounts;

**(d)** charges included in the gross sales price for freight, insurance, transportation, postage, handling and any other charges relating to the sale, transportation, delivery or return of Product to/from (as applicable) non-Selling Parties; and

**(e)** any mandatory discounts, rebates or other payments required by Applicable Law, including any governmental medical assistance programs,

all as determined from the books and records of the Selling Party, maintained in accordance with GAAP or IFRS (as applicable).

Product will be considered "sold" when a sale by a Selling Party is recognized in accordance with revenue recognition policies mandated by GAAP or IFRS (as applicable).

Nothing herein will prevent a Selling Party from selling, distributing or invoicing Product at a discounted price for shipments to Third Parties in connection with clinical studies, compassionate sales, or an indigent program or similar bona fide arrangements in which the Selling Party agrees to forego a normal profit margin for good faith business reasons.

Sale or transfer of Product between any of the Selling Parties will not result in any Net Sales, and Net Sales instead will be based on subsequent sales or distribution to a non-Selling Party, unless such Product is consumed by a Selling Party. Sales to Distributors will be treated identically to any other sales to Third Parties.

To the extent that any Selling Party receives consideration other than or in addition to cash upon the sale or distribution of Product, Net Sales will include the fair market value of such additional consideration.

In the event the Product is sold in a finished dosage form containing the Product in combination with one or more other active ingredients (a **"Combination Product"**), the Net Sales of the Product, for the purposes of this Agreement, will be determined by multiplying the Net Sales (as defined above) of the Combination Product by the fraction, A/(A+B) where A is the weighted (by sales volume) average sale price in a particular country of the Product when sold separately in finished form and B is the weighted average sale price in that country of the other product(s) sold separately in finished form. If such average sale price cannot be determined for both the Product and the other product(s) in combination, Net Sales for purposes of determining royalty payments will be agreed by the Parties in good faith based on the relative value contributed by each component.

**1.79** [***]

**1.80** **"Patent"** means all: (a) unexpired patents (including inventor's certificates), including any substitution, extension, registration, confirmation, reissue, re-examination, supplementary protection certificates, utility models, petty patents, confirmation patents, patent of additions, renewal or any like filing thereof; (b) pending applications for patents; and (c) any international counterparts to (a) and (b) above.

**1.81** **"Patent Challenge"** means any proceeding brought by a Third Party that challenges the validity or enforceability of any Patent, including a Patent Opposition, any other opposition, action for declaratory judgment, nullity action, interference or other similar attack.

**1.82** **"Patent Opposition"** means, with respect to a Patent in a particular jurisdiction, a proceeding brought by a Third Party before a patent administrative body (such as the European Patent Office in the EU or the Patent Trial and Appeal Board in the U.S.) that has authority over such Patent, which is initiated within the first year after the Patent is granted and that challenges the validity of the Patent.

**1.83** **"Phase 1 Study"** means a clinical study in humans, the principal purpose of which is a preliminary determination of the safety of the Therapeutic Product in healthy individuals or subjects, as further described in 21 CFR § 312.21(a) (as may be amended), or a similar clinical study in a country other than the U.S.

**1.84 "Phase 2 Study"** means a clinical study in humans, the principal purpose of which is a determination of safety and efficacy of the Therapeutic Product in subjects with the disease or condition under study, as further described in 21 CFR. § 312.21(b) (as may be amended), or a similar clinical study in a country other than the U.S.

**1.85 "Phase 3 Study"** means a clinical study in humans evaluating or confirming the safety and efficacy of the Therapeutic Product that is prospectively designed, statistically powered and conducted to provide an adequate basis for obtaining regular regulatory approval to market the Therapeutic Product for the treatment of patients with the disease or condition under study, as further described in 21 CFR § 312.21(c) (as may be amended), or a similar clinical study in a country other than the U.S.

**1.86 "Pre-Clinical Development**" means those Development activities performed prior to the filing of an IND.

**1.87 "Pre-Clinical Program Term"** means the period from the Effective Date until first IND Acceptance.

**1.88** "**Product**" means one or more Imaging Agents, one or more Therapeutic Products, or both forms as the context may require. For the avoidance of doubt, the use of the term 'Product' in this Agreement does not preclude that more than one Product is Developed, Manufactured and/ or Commercialized under this Agreement and each Imaging Agent and/ or Therapeutic Product which includes a different FAP-Targeting Product or a different radioisotope shall be considered a separate 'Product' for the purposes of this Agreement.

**1.89 "Product Infringement"** has the meaning set forth in **Section 9.6(a)**.

**1.90 "Product Marks"** has the meaning set forth in **Section 5.3**.

**1.91 "Quality Agreement"** has the meaning set forth in **Section 6.1**.

**1.92 "Regulatory Approval"** means, with respect to a country or supra-national territory, any and all approvals, licenses, registrations or authorizations of any Regulatory Authority necessary in order to commercially distribute, sell or market a product in such country or some or all of such supra-national territory, including Marketing Authorizations.

**1.93 "Regulatory Authority"** means any national, multi-national, supranational, federal, state, local, municipal, provincial or other government authority of any nature (including any governmental division, prefecture, subdivision, department, agency, bureau, branch, office, commission, council, court or other tribunal) as well as any ethics committees/ IRBs.

**1.94 "Regulatory Documentation"** means regulatory applications, submissions, notifications, registrations, Regulatory Approvals, or other approvals granted by, and/or filings made to or written communication with a Regulatory Authority that are necessary or useful to Develop, Manufacture, market, sell or otherwise Commercialize a Product in a country or regulatory jurisdiction.

**1.95 "Retained Territory"** means (a) all countries within the geographical area of Europe, which ends in the west at the Atlantic ocean and in the east at the border to the Republic of Turkey, (*e.g.*, the EU, the United Kingdom (in the event it is no longer a member of the EU),

Norway, Switzerland, Island, Liechtenstein), (b) the Russian Federation, (c) the Republic of Turkey, and (d) the State of Israel, in each case (a) to (d) including its territories and possessions.

**1.96 "Retained Territory Additional Studies"** has the meaning set forth in **Section 3.3(a)**.

**1.97 "Retained Territory-Specific Study Elements"** has the meaning set forth in **Section 3.3(b)**.

**1.98 "Royalty Term"** means, on a country-by-country basis, the period commencing on the First Commercial Sale of a Product in a country in the Licensed Territory by Clovis, its Affiliates or Sublicensees and expiring on the later of: (a) [***] ([***]) years following such date in such country; or (b) the later of expiration of (i) the last Valid Claim of any 3BP Patent, and (ii) Data Exclusivity relating to the Product.

**1.99** "**Safety Data Exchange Agreement**" has the meaning set forth in **Section 4.6**.

**1.100** "**Selling Party**" has the meaning set forth in **Section 1.78**.

**1.101 "Sole Inventions"** has the meaning set forth in **Section 9.2(a)**.

**1.102** [***]

**1.103** [***]

**1.104 "Study Initiation"** means the first visit of the first patient enrolled in a given clinical study during which the Therapeutic Product is administered in accordance with the protocol.

**1.105 "Sublicense"** has the meaning set forth in **Section 7.1(c)**.

**1.106 "Sublicensee"** means any Third Party that is granted a Sublicense, either directly by Clovis or its Affiliates or indirectly by any other Sublicensee hereunder; *provided, however*, that the term "Sublicensee" does not include Distributors.

**1.107 "Sublicense Revenue"** means license fees, upfront fees, access fees, option fees, milestone payments (only amounts tied to events not defined as Milestone Events or in excess of Milestone Payments hereunder) and any other consideration (including non-monetary consideration as valued at the fair market value cash equivalent) paid to, or otherwise received by, Clovis or any of its Affiliates from a Sublicensee in consideration for the grant of a Sublicense; [***]. For the avoidance of doubt, in contrast to (ii) above, royalties measured on Net Sales of Imaging Agents by a Sublicensee as a Selling Party that are payable to Clovis or its Affiliates under a Sublicense are included in the definition of Sublicense Revenues.

**1.108 "Supply Agreement"** has the meaning set forth in **Section 6.1**.

**1.109 "Term"** has the meaning set forth in **Section 11.1**.

**1.110 "Therapeutic Product"** means a Lead Candidate containing a therapeutic radioisotope, including an electron and/ or alpha-particle emitting radioisotope, which has been selected for Development, Manufacture and Commercialization by the Parties under the terms of this Agreement as a therapy for one or more Indications.

**1.111 "Third Party"** means any person or entity other than: (a) 3BP; (b) Clovis; or (c) an Affiliate of either Party.

**1.112 "Transfer Price"** means (i) the fully-burdened cost charged by a Contract Manufacturer of Clovis to Clovis or its Affiliates for the Manufacture and supply to Clovis or its Affiliates of a Product (or component thereof), plus [***] percent ([***]%), or (ii) in the event of Manufacture of the Product by Clovis or its Affiliates, the internal, arm's length transfer price charged between Clovis and its Affiliates for supply from Clovis to its Affiliate (or vice versa) or if no transfer between Clovis and its Affiliates is made, a price that would be charged if such internal transfer was made.

**1.113** "**U.S.**" means the United States of America, including all possessions and territories thereof.

**1.114** "**Valid Claim**" means any claim of (a) any issued and unexpired patent that has not been (i) revoked or held unenforceable, unpatentable or invalid by a government authority or court of competent jurisdiction in a decision that is not appealable or that has not been appealed within the time allowed for appeal or (ii) abandoned, disclaimed, denied or admitted to be invalid or unenforceable through reissue, re-examination or disclaimer or otherwise; or (b) any patent application that has not been (i) cancelled, withdrawn or abandoned without being refiled in another application in the applicable jurisdiction or (ii) finally rejected by an administrative agency or government authority or court of competent jurisdiction in a decision that is not appealable or that has not been appealed within the time allowed for appeal.

## 2. SUBJECT-MATTER; GOVERNANCE

**2.1 Subject-Matter; Overview.** Subject-matter of this Agreement is the grant of rights by 3BP to Clovis to Develop and Manufacture Products in or for and Commercialize Products in the Licensed Territory and the collaboration with respect to the Development, Manufacture and Commercialization of Products globally, with 3BP retaining rights to Develop and Manufacture the Products in or for and Commercialize the Products in the Retained Territory (the "**Collaboration**"). The Parties will establish a Joint Steering Committee as described in this **Article 2** and may from time-to-time establish other committees or sub-committees to report to the Joint Steering Committee to effectively implement the Collaboration as jointly agreed by the Parties.

**2.2 Joint Steering Committee.**

**(a) Establishment.** Within thirty (30) days after the Effective Date, the Parties will establish a joint steering committee (the "**Joint Steering Committee**" or "**JSC**") to monitor, coordinate, and oversee the Development and Manufacture of Products under this Agreement. The JSC membership and procedures are further described in **Section 2.4**.

**(b) Specific Responsibilities of the JSC.** The JSC will in particular, in accordance with the decision-making principles set forth in **Section 2.5**:

**(i)** provide a forum for and facilitate communications between the Parties with respect to the Development and Manufacture of the Products, including any additional Indications proposed by either Party to be pursued;

**(ii)** coordinate the activities of the Parties under and oversee the implementation of the Global Development Plan agreed to by the Parties;

**(iii)** approve the selection of one or more Lead Candidates and one or more Backup Candidates and the designation of any Backup Candidate as a new Lead Candidate for continued Development, the de-ranking of a Lead Candidate to a Backup Candidate or the complete abandonment of a Lead Candidate or Backup Candidate;

**(iv)** review and approve annual and interim updates to the Global Development Plan;

**(v)** review and approve the Manufacturing Plan and any annual or interim updates and proposed amendments thereto;

**(vi)** review and approve the budget for Development Costs associated with Pre-Clinical Development to be performed by Third Party subcontractors and the scope of work assigned to such Third Parties;

**(vii)** review Development Data generated in the conduct of activities under the Global Development Plan as it becomes available, and establish plans for the periodic sharing of Development Data between the Parties;

**(viii)** monitor and coordinate all regulatory actions, communications and submissions for Products under the Global Development Plan;

**(ix)** establish a process for considering compassionate use proposals and investigator initiated research involving the Products;

**(x)** discuss and agree upon the details of the Development by the Parties of an Imaging Agent;

**(xi)** establish other Committees delegated to carry out specific tasks assigned to them by the JSC within the scope of the JSC's authorities;

**(xii)** attempt to resolve issues presented to it by, and disputes within, the other Committees in accordance with **Section 2.5**; and

**(xiii)** perform such other duties as are expressly assigned to the JSC in this Agreement and perform such other functions as appropriate to further the purposes of this Agreement as may be allocated to it by written agreement of the Parties.

**2.3 Alliance Manager.** Within thirty (30) after the Effective Date, each Party will appoint and notify the other Party of the identity of a representative to act as its alliance manager under this Agreement (the "**Alliance Manager**"). The Alliance Managers will serve as the primary contact points between the Parties for providing each Party with information on the progress of each Party's Development and business-related activities under this Agreement. The Alliance Managers will also be primarily responsible for facilitating the flow of information and otherwise promoting communication, coordination and collaboration between

the Parties. The Alliance Managers (or their designees for a particular meeting) will attend all JSC meetings, have the right to attend all other Committee meetings, and support the co-chairpersons of each Committee in the discharge of their responsibilities. An Alliance Manager may also bring any matter in relation to the Development or Manufacture to the attention of any Committee if such Alliance Manager reasonably believes that such matter warrants such attention. Each Party may replace its Alliance Manager at any time upon written notice to the other Party.

**2.4 General Committee Membership and Procedures.**

**(a) Membership.** Each of Clovis and 3BP will designate representatives to serve as members of each Committee, and each representative may serve on more than one Committee as appropriate. Each Party will have an equal number of representatives on each Committee. Each Party may replace its Committee representatives at any time upon written notice to the other Party. Each Committee will have co-chairpersons. Clovis and 3BP will each select from their representatives a co-chairperson for each of the Committees, and each Party may change its designated co-chairpersons from time to time upon written notice to the other Party. The co-chairpersons of each Committee will be responsible for calling meetings and preparing and circulating meeting agendas and minutes, but the co-chairpersons will have no additional powers or rights beyond those held by other Committee members.

**(b) Meetings.** Each Committee will hold meetings at such times as it elects to do so, provided that unless the Parties otherwise agree in writing to a different frequency for such meetings, the JSC will meet at least [***] ([***]) times each Calendar Year. Either Party may also call a special meeting of a Committee (by videoconference or teleconference) by written notice to the other Party in the event such Party reasonably believes that a significant matter must be addressed prior to the next regularly scheduled meeting. Unless a significant matter requires more urgent consideration by a Committee, the Party calling for a special meeting will provide the applicable Committee no later than [***] ([***]) Business Days prior to the special meeting with materials reasonably adequate to enable an informed decision at such meeting. No later than [***] ([***]) Business Days prior to any Committee meeting, the co-chairpersons of such Committee will prepare and circulate an agenda for such meeting; *provided*, *however*, that either Party may propose additional topics to be included on such agenda, either prior to or in the course of such meeting. Each Committee may invite non-members (including consultants and advisors of a Party who are under an obligation of confidentiality consistent with this Agreement) to participate in its meetings; *provided* that such non-member participants will have no voting authority at such meetings and may be excluded by either Party if there is an actual or potential conflict of interest. Each Committee may meet in person, by videoconference or by teleconference; *provided, however*, that at least one (1) meeting of each Committee per Calendar Year will be in person unless the Parties mutually agree in writing to waive such requirement. In-person Committee meetings will be held alternately in Boulder, Colorado or Bay Area, California and Berlin, Germany, or such other location as may be mutually agreed by the Parties. Each Party will bear the expense of its respective Committee members' participation in Committee meetings. Committee meetings will be effective only if at least one (1) representative of each Party is present or participating in such meeting. The co-chairpersons of a Committee will be responsible for preparing reasonably detailed written minutes of all meetings of such Committee that reflect all material decisions made at such meetings. The co-chairpersons will send draft meeting minutes to each member of such Committee for review and approval promptly after each Committee meeting. Such minutes will

be deemed approved unless one or more members of such Committee objects to the accuracy of such minutes within [***] ([***]) days of receipt by such member.

**2.5 Decision Making**.

**(a) Within JSC and Operating Committees.** All decisions within the JSC or any other Committee will be made by consensus, with each Party having collectively one (1) vote. If a dispute arises which cannot be resolved within any Committee other than the JSC, the representatives of either Party may cause such dispute to be referred to the JSC for resolution. If after reasonable discussion and good faith consideration of the other Party's views on a particular matter before the JSC, including any disputes referred to the JSC by another Committee, the JSC is still unable to reach a unanimous decision on such matter for a period of [***] ([***]) days from referral to the JSC (if referred by a Committee) or start of discussions within the JSC (if originally within the JSC), then either Party may upon notice to the other Party cause such dispute to be referred to the Executive Officers of the Parties for resolution as provided in **Section 2.5(b)** below.

**(b) Executive Officers.** Upon being referred a disputed matter from the JSC under **Section 2.5(a)**, the Executive Officers of each Party will consider such matter and discuss it in good faith within [***] ([***]) days after notice of such matter is received, including at least one (1) in person meeting of the Executive Officers within [***] ([***]) days after such notice is received, unless the Executive Officers agree in writing to waive such requirement. If the Executive Officers are not able to resolve such disputed matter within the afore [***] ([***]) days and either Party wishes to pursue the matter, then:

**(i)** Clovis will have the right to decide such dispute if such matter relates to: [***] and

**(ii)** 3BP will have the right to decide such dispute if such matter relates to: [***]

**(c) Exceptions.** Neither Party will be permitted to use its final decision-making authority to impose any obligations or costs on the other Party.

**(d) Limitations of Committee Authority.** Each Committee will have solely the powers expressly assigned to it in this **Article 2** and elsewhere in this Agreement or as otherwise agreed to by the Parties in writing. A Committee will not have any power to amend, modify, or waive compliance with the terms of this Agreement. It is expressly understood and agreed that the control of decision-making authority by 3BP or Clovis, as applicable, pursuant to this **Section 2.5**, so as to resolve a disagreement or deadlock on a Committee or between the Executive Officers for any matter will not authorize either Party to unilaterally modify or amend, or waive its own compliance with, the terms of this Agreement.

**(e) Good Faith.** In conducting themselves on Committees, and in exercising their rights under this **Section 2.5**, all representatives of both Parties will use reasonable efforts to consider, reasonably and in good faith, all input received from the other Party, and to reach consensus on all matters before them. Notwithstanding anything to the contrary in this Agreement, neither Party nor any of its Affiliates will be required to take, or will be penalized for not taking, any action that is not in compliance with such Party's general ethical business practices and policies to the extent reasonable and as can be demonstrated or

that such Party reasonably believes and demonstrates is not in compliance with Applicable Laws.

**2.6 Discontinuation of a Committee**.

**(a)** Each Committee, including the JSC, will continue to exist until the Parties mutually agreeing to disband the Committee.

**(b)** Once the JSC or any other Committee is disbanded in accordance with **Section 2.6(a)**, such Committee will have no further obligations under this Agreement and, thereafter, the Alliance Managers will be the contact persons for the exchange of information under this Agreement, and decisions of such Committee will be decisions of the responsible Party as specified in this Agreement, subject to any other terms of this Agreement.

**2.7 Compliance with Law.** Each Party and its Affiliates will comply in all material respects with all Applicable Laws in the Development, Manufacture, and Commercialization of Products performed under this Agreement.

## 3. DEVELOPMENT OF PRODUCTS

**3.1 General**. The Parties agree that this Agreement covers the Development of one or more Lead Candidates and, if so decided, one or more Backup Candidates, all in accordance with the Global Development Plan, including Pre-Clinical Development by 3BP of the Lead Candidate set forth in Exhibit 1.69, Development by Clovis of a Lead Candidate as a Therapeutic Product and/ or an Imaging Agent and, subject to **Section 3.6** below, if so decided by 3BP, the Development by 3BP of a Lead Candidate as an Imaging Agent. Either Party may recommend that a Backup Candidate should be designated as a replacement or additional Lead Candidate, in which case, such Party will provide the JSC with any data or publications supporting any such proposal. A Backup Candidate will become a replacement or additional Lead Candidate only with the approval of the JSC and is subject to appropriate amendments to the Global Development Plan necessary for the Development of such Backup Candidate as a replacement or additional Lead Candidate and, upon such approval by the JSC and corresponding amendment of the Global Development Plan, the Backup Candidate shall no longer be a Backup Candidate but will solely be a Lead Candidate. Clovis will be solely responsible for determining what Development activities are necessary to support Regulatory Approval for a Product in the Licensed Territory. 3BP acknowledges that Clovis' proposed clinical Development program will be primarily focused on obtaining Development Data that is sufficient to support Regulatory Approval of Products in the Licensed Territory. While 3BP will be entitled to use such Development Data to seek, at 3BP's discretion, Regulatory Approval for Products in the Retained Territory, 3BP will be solely responsible for determining what additional Development activities (*that is*, in addition to those undertaken by Clovis) may be necessary to support Regulatory Approval for each Product in the Retained Territory. Unless otherwise specified in the Global Development Plan or under this Agreement, each Party will be responsible and have the final decision-making authority and financial responsibility for all Development activities it conducts pursuant to this Agreement.

**3.2 Global Development Plan; Other Development Aspects.**

**(a) Global Development Plan.** The Development of Products under this Agreement will be conducted pursuant to a written development plan (the **"Global Development Plan"**). The Global Development Plan will set forth the specific activities

(research, pre-clinical, non-clinical, and clinical) to be conducted by each Party and the estimated timeline for Development (inclusive of Pre-Clinical Development activities) of each Lead Candidate, Therapeutic Product, Backup Candidate (including components thereof), and Imaging Agent, as the case may be, to obtain Development Data that the Parties intend will be useful, by both Parties, to obtain Regulatory Approvals of the Products by Regulatory Authorities in the Licensed Territory and Retained Territory. The Global Development Plan will also specify the plans and estimated timeline for preparing the necessary Regulatory Documentation for obtaining Regulatory Approval in such territories, subject to **Section 4.1**. The initial version of the Global Development Plan is attached as Exhibit 3.2(a) to be amended from time to time upon agreement of the Parties through the JSC.

**(b) Pre-Clinical Development.** During the Pre-Clinical Program Term, 3BP will conduct the Pre-Clinical Development activities assigned to 3BP in the Global Development Plan for the Lead Candidate set forth in Exhibit 1.69 and other Lead Candidates as agreed in accordance with the process in **Sections 2.2(b), 2.5(b)**, **2.5(c)** and **3.1** (and any Backup Candidates, as applicable) in accordance with the timelines stated therein. 3BP may utilize Third Party subcontractors to perform certain of its Pre-Clinical Development activities, in connection with which the Parties will prepare for approval by the JSC a budget for the Development Costs anticipated to be incurred by 3BP through its Third Party subcontractors. In support of 3BP's Pre-Clinical Development activities, Clovis agrees to pay 3BP in accordance with the terms of **Section 8.2** the FTE Costs for up to [***] ([***]) FTEs of 3BP who are devoted to conducting such work and agrees to pay in accordance with the terms of **Section 8.3(a)** the costs of any Third Party subcontractor engaged by 3BP in the Pre-Clinical Development activities, provided such subcontractor is expressly mentioned in the Global Development Plan and such costs are incurred in accordance the above-mentioned budget approved by the JSC.

**(c) Clinical Studies.** Each clinical study to be conducted by either Party to generate Development Data to support Regulatory Approvals for the Products will be described in the Global Development Plan. Unless otherwise agreed by the Parties pursuant to the Global Development Plan and subject to **Section 3.3**, Clovis will be the sponsor of all clinical studies and will be solely responsible for all clinical Development activities, including all activities to support Regulatory Approval for the Product in the Licensed Territory. If a Party (including through its Affiliates or sublicensees) intends to sponsor and conduct one or more additional human clinical studies (beyond what is then included in the Global Development Plan) for Development of a Product, either in an Indication already covered by the Global Development Plan or in a new Indication, such Party will notify the other of such proposed studies and provide the other Party of any data or publications supporting any such proposal. In such event, the JSC will consider such proposal and evaluate the supporting data and information in good faith, and subject to JSC's approval of the proposal, the Global Development Plan will be amended to include such additional study or studies. A clinical study may include trial sites in the other Party's territory; *provided* that the inclusion of such sites was approved by the JSC at the time such study was incorporated into the Global Development Plan or is subsequently approved by the JSC through an amendment to the Global Development Plan.

**(d) Development Costs.** Unless otherwise agreed by the Parties in writing, in particular if the Parties agree in writing to share Development Costs, (i) Clovis will be responsible for: (A) all Development Costs incurred by either Party for Development activities conducted pursuant to the Global Development Plan, including costs of clinical studies for which Clovis is the sponsor, but excluding all Development Costs for which 3BP is responsible

pursuant to (ii) below; and (B) the FTE Costs and Third Party subcontractor costs for which Clovis is responsible pursuant to **Section 3.2(b)** above, and (ii) 3BP will be solely responsible for (A) all such Development Costs incurred by or on behalf of 3BP for Pre-Clinical Development conducted by 3BP pursuant to the Global Development Plan (subject to the payment/ reimbursement set forth in **Section 3.2(b)** and **Section 8.2**); (B) all Development Costs arising from Retained Territory Additional Studies and Development Costs associated with Retained Territory-Specific Study Elements, as described in more detail in **Section 3.3**; and (C) any Development Costs for which 3BP agrees to be responsible pursuant to the Global Development Plan with respect to the Development of an Imaging Agent pursuant to **Section 3.6**.

**(e) Status Reports.** Each Party will provide the other Party and the JSC with regular written reports setting forth its Development activities under the Global Development Plan and the status and outcome of such activities, including an overview of results of such activities, at each regularly scheduled JSC meeting.

**(f) Amendments to Global Development Plan**. Beginning with the first full Calendar Year following the Effective Date, on an annual basis (no later than June 30th), or more often as the JSC deems appropriate, the JSC will review, approve, and, as required, prepare an update and amendment to the Global Development Plan. Each such updated and amended Global Development Plan will reflect, among others, any changes, additions, re-prioritization of studies and/or Indications within, and/or reallocation of resources with respect to, the Development of the Products. Once approved by the JSC, an amended Global Development Plan will become effective and supersede the previous Global Development Plan as of the date of such approval.

**3.3 Retained Territory Additional Studies and Retained Territory-Specific Study Elements**.

**(a)** 3BP will be solely responsible for seeking Regulatory Approval for Products in the Retained Territory at its sole discretion. If 3BP elects to seek Regulatory Approval of any Product in the Retained Territory, 3BP may use all Development Data generated by or on behalf Clovis, its Affiliates or Sublicensees in 3BP's Development activities, including in support of Regulatory Approvals (if any) pursued by 3BP in the Retained Territory, such that any clinical Development conducted by 3BP can or may be limited to that which relates solely to those elements of Development that are required additionally and specifically in order to support Regulatory Approval for a Product in the Retained Territory. If 3BP determines, in its sole discretion that unique data is necessary to support Regulatory Approval for any Product in the Retained Territory, 3BP will be the sponsor of those clinical studies that are conducted to obtain data which is solely and specifically necessary to support such Regulatory Approval in the Retained Territory (*that is*, which data is not necessary to support Regulatory Approval in the Licensed Territory) and which data is not obtained under the clinical studies conducted by or on behalf of Clovis (the "**Retained Territory Additional Studies"**). A Retained Territory Additional Study may be conducted at sites within the Licensed Territory if such study is agreed by the Parties to be included within the Global Development Plan; otherwise, 3BP is free to sponsor and conduct a Retained Territory Additional Study solely within the Retained Territory.

**(b)** Notwithstanding **Section 3.3(a)** above, 3BP will have the right to request that the study design of a clinical study sponsored by Clovis for a Product pursuant to **Section 3.2(c)** include elements intended to generate Development Data solely necessary and

specific to supporting Development activities of 3BP and/ or Regulatory Approval of such Product in the Retained Territory ("**Retained Territory-Specific Study Elements**"). In such event, Clovis will reasonably consider the request and generate an estimate of the Development Costs associated with the Retained Territory-Specific Study Elements. If 3BP agrees to be responsible for the associated Development Costs and Clovis agrees, which agreement shall not be unreasonably withheld, to revise its study design to include the requested protocol elements, then the study design will be revised and captured in the Global Development Plan accordingly.

**3.4 Development Diligence; Standards of Conduct.** Each Party will use Diligent Efforts to Develop the Lead Candidates and carry out the activities assigned to it under the Global Development Plan, provided that 3BP is under no obligation to conduct Retained Territory Additional Studies and/ or request the inclusion of Retained Territory-Specific Study Elements. The Parties acknowledge and agree that the Global Development Plan or any other Development activities may consist of consecutive phases or stages and that the determination that the outcome of any given phase or stage is successful may be required or commercially reasonable prior to moving to the subsequent phase or stage.

**3.5 Development Records.** Each Party will (and will cause its Affiliates and sublicensees to) maintain complete and accurate records (in the form of technical notebooks and/or electronic files where appropriate) of all work conducted by it or on its behalf (including by Affiliates and sublicensees) under the Global Development Plan. Such records, including any electronic files where such information may also be contained, will accurately reflect all work done and results achieved in the performance of the Global Development Plan in sufficient detail and in good scientific manner appropriate for Patent and regulatory purposes. Each Party will have the right to review and receive a copy of such records (including a copy of the databases) maintained by the other Party (including its Affiliates and sublicensees) at reasonable times, but no less than [***] in any one Calendar Year, and to obtain access to source documents to the extent needed for Patent or regulatory purposes, for other legal proceedings or to exercise any rights granted to a Party under this Agreement, including the right of use of Development Data. The Parties may agree to set up an electronic data room in order to manage the exchange of information in a secure manner.

**3.6 Imaging Agent**. The Parties acknowledge that the Development of a specific Imaging Agent may be beneficial or required from a commercial perspective. 3BP will prepare a concept regarding the Development of such an Imaging Agent for discussion by the JSC. If agreed by the Parties, the Global Development Plan may be amended to incorporate the agreed plan for Development of such Imaging Agent and describe each Party's responsibilities with respect to the Development and Manufacture of the agreed Imaging Agent, including responsibility for the Development Costs associated therewith.

**3.7 Subcontracts**. Each Party may perform any of its obligations under this Agreement through one or more subcontractors and consultants and will provide information in that regard to the JSC, provided that: (a) such Party remains responsible for the work allocated to, and payment to, such subcontractors and consultants as it selects to the same extent it would if it had done such work itself; (b) the subcontractors and consultants undertake in writing obligations of confidentiality and non-use regarding Confidential Information that are substantially the same as those undertaken by the Parties pursuant to **Article 10** hereof; (c) subject to **Sections 6.4(c)(ii) and 6.5(e)**, the subcontractors and consultants execute an agreement requiring the assignment of all Intellectual Property Rights relating to the Product and/ or Backup Candidates developed in the course of performing any such work to the Party

retaining such subcontractors or consultants; and (d) any subcontracting by a Party shall not diminish or limit the rights of the other Party set forth in this Agreement with respect to the use of Development Data, Regulatory Documentation, Manufacturing Data and Manufacturing Documentation generated on behalf of a Party by a Third Party subcontractor or consultant.

**3.8 Personnel**. All employees, representatives and agents of each Party and its Affiliates conducting activities under this Agreement will, prior to commencing any such activities, have executed an agreement requiring the assignment of any work-related inventions and related Intellectual Property Rights to the Party by whom they are employed or for whom they are providing services (or its designated Affiliate). The Parties acknowledge and agree that this Agreement will be deemed to be a joint research agreement under 35 U.S.C. §102(c).

## 4. REGULATORY MATTERS

**4.1 Responsible Regulatory Party.** Unless to the extent otherwise provided in the Global Development Plan and subject to **Section 2.5**, (a) Clovis will be solely responsible and have the final authority with respect to regulatory activities to obtain Regulatory Approval for Products in the Licensed Territory and (b) 3BP will be solely responsible and have the final authority with respect to all regulatory activities to obtain Regulatory Approval for Products in the Retained Territory. [***].

**4.2 Ownership of Regulatory Dossier**. Clovis will own all Regulatory Documentation for the Products in the Licensed Territory and 3BP will own all Regulatory Documentation for the Products in the Retained Territory, for all Indications.

**4.3 Regulatory Rights and Responsibilities.** For each Product it Develops hereunder, Clovis will use Diligent Efforts to prepare and file all necessary Regulatory Documentation with Regulatory Authorities in accordance with its responsibilities set forth in the Global Development Plan. In the event 3BP elects to seek Regulatory Approval of any Product in the Retained Territory, 3BP may (but is not obligated to) use Diligent Efforts to prepare and file all necessary Regulatory Documentation with Regulatory Authorities in the Retained Territory. Each Party will, unless prohibited by Applicable Law, keep the other Party informed of material regulatory developments relating to the Products in its respective territory through regular reports at the JSC meetings. Each Party will inform the other Party of any Regulatory Documentation submitted to or received from any Regulatory Authorities that may impact obtaining or maintaining Regulatory Approval for the Product in the other Party's territory.

**4.4 Know-How Transfer; Rights of Reference; Use of Data**.

**(a)** During the Term, each Party will disclose and make available to the other Party, for use by the other Party in accordance with this Agreement, all Development Data generated under the Global Development Plan in accordance with the data sharing plans established by the JSC. For the avoidance of doubt, the disclosure of Development Data shall not be deemed to be a transfer of property rights in such Development Data, and each Party shall have only those rights as are granted to it pursuant to this Agreement.

**(b)** Each Party (and its Affiliates and sublicensees) will have the right to cross reference, file or incorporate by reference any Regulatory Documentation filed by the other Party or its Affiliates for the Product in order to enable such Party (and its Affiliates and sublicensees) to Develop the Product in or for (including to obtain Regulatory Approval), Manufacture the Product in or for, and Commercialize the Product in its respective territory. Each Party will, on written request by the other Party, provide to the other Party and to any specified Regulatory Authority a letter, in the form reasonably required by the other Party, acknowledging that the other Party (or its Affiliates and sublicensees) has the above right of reference to any such Regulatory Documentation.

**4.5 Recalls.** Any decision to initiate a recall or withdrawal of a Product from the market prior to receipt of Regulatory Approval (*that is*, during clinical studies) will be made by the Party who sponsors the study and any decision to initiate a recall or withdrawal of a Product from the market after receipt of Regulatory Approval will be made by Clovis in the Licensed Territory and by 3BP in the Retained Territory; *provided* that the Parties will discuss in good faith and coordinate their efforts with respect to any such recalls. In the event of any recall or withdrawal, such Party will take all action necessary to implement such recall or withdrawal in accordance with Applicable Laws, with assistance from the other Party as reasonably requested by the deciding Party. The costs of any such recall or withdrawal will be borne solely by the deciding Party, subject to the provisions of **Article 13**.

**4.6 Safety Data Exchange Agreement.** Prior to 3BP commencing any clinical studies of Products as sponsor pursuant to the Global Development Plan or the provisions in **Section 3.3(a)**, the pharmacovigilance departments of both Parties will meet and agree on a safety data exchange agreement ("**Safety Data Exchange Agreement**").

## 5. COMMERCIALIZATION

**5.1 Overview**. Clovis will have sole control and responsibility for the Commercialization of Products in the Licensed Territory and will bear all costs and expenses associated with the Commercialization of Products in the Licensed Territory; and 3BP will have sole control and responsibility for the Commercialization of Products in the Retained Territory and will bear all costs and expenses associated with the Commercialization of Products in the Retained Territory.

**5.2 Ex-Territory Sales**. Neither Party (and their respective sublicensees or Affiliates) will engage in any advertising or promotional activities relating to the Products directed primarily to customers or other buyers or users of the Products located outside its territory or, subject to Applicable Laws, accept orders for Products from or sell Products into such other Party's territory.

**5.3 Trademarks.** Clovis will have the right to brand the Products in the Licensed Territory using trademarks and trade names it determines appropriate for the Products, which may vary by country or within a country (**"Product Marks"**). 3BP will be free to select, create and use its own trademarks for its use, in connection with the Products in the Retained Territory. 3BP will not, and will ensure that its Affiliates and sublicensees will not, make any use of the trademarks, including the Product Marks, or house marks of Clovis or its Affiliates or Sublicensees (including their corporate names) or any trademark confusingly similar thereto. Notwithstanding the foregoing, 3BP may notify Clovis in writing of 3BP's interest in using the Product Marks to Commercialize the Products in the Retained Territory; in such event, Clovis will grant to 3BP pursuant to a written agreement the royalty-free, fully

paid-up, sublicensable right to use the Product Marks to Commercialize the Products in the Retained Territory. Clovis will own all rights in the Product Marks and will register and maintain the Product Marks in the Licensed Territory as it determines reasonably necessary at its own cost and expense.

**5.4 Commercial Diligence.** During the Term, Clovis will use Diligent Efforts to Commercialize the Products in the Licensed Territory. [***].

**5.5 Reporting**. Clovis will provide 3BP with written reports, on a country-by-country and Product-by-Product basis, no less frequently than [***] following receipt of the initial Marketing Authorization summarizing Clovis' (and its Affiliates' and Sublicensees') efforts to seek Regulatory Approval for and Commercialize the Products in the Licensed Territory. All such reports will be considered Confidential Information of Clovis.

## 6. MANUFACTURING

**6.1 Overview**. In general and subject to the terms of this Agreement, (a) 3BP will be responsible for all Manufacture activities to support Development activities allocated to 3BP under the Global Development Plan or the Manufacturing Plan, including Manufacturing the Lead Candidate set forth in Exhibit 1.69 for Pre-Clinical Development activities (including CMC Activities) to the extent set forth in the Global Development Plan and/ or Manufacturing Plan, (b) Clovis will be responsible for all Manufacturing activities to support Development activities allocated to Clovis under the Global Development Plan and/ or the Manufacturing Plan; *provided* that upon completion of all transfer of technology contemplated in **Section 6.3**, but subject to 3BP's rights set forth in **Sections 6.4** and **6.5**, Clovis will be solely responsible for the Manufacture and supply of all Products for Development activities under the Global Development Plan, unless otherwise set forth in the Global Development Plan, and (c) each Party will be responsible, but subject to **Sections 6.4** and **6.5**, for Manufacturing the Product for Commercialization in its respective territory. With oversight by the JSC, the Parties will collaborate to identify Contract Manufacturers having appropriate capabilities for the Manufacture of all components of the Product; *provided* that Clovis will have the deciding vote and, upon such decision, the right and authority to appoint and enter into agreements with Contract Manufacturers as provided in **Section 6.4** to support Development activities undertaken by Clovis in or for, and/ or Commercialization of Product in, the Licensed Territory, subject however to the more detailed provisions in **Section 6.4**.

**6.2 Manufacturing Plan.** The Parties will establish a plan (the "**Manufacturing Plan**") which shall describe: (i) all CMC Activities, including process development and scale-up, and any other matters related to the Manufacture of the Products; and (ii) all activities necessary or useful to transfer the 3BP Know-How and to enable Clovis, its Affiliates, or each Contract Manufacturer (as appropriate) to Manufacture the Product, at Clovis' request, in accordance with **Section 6.3**. The Parties will make good faith efforts to establish the first Manufacturing Plan and have it approved by the JSC within ninety (90) days after the Effective Date. The Manufacturing Plan so agreed upon shall be attached as Exhibit 6.2 to this Agreement, to be amended from time to time upon agreement of the Parties through the JSC.

**6.3 Transfer of 3BP Know-How and Manufacturing Technology**. Upon Clovis' request, 3BP, at Clovis' cost and expense, will (and make Diligent Efforts to cause 3BP's

Contract Manufacturer to) promptly disclose (and provide copies, as applicable) to either Clovis or a Contract Manufacturer selected by Clovis, all 3BP Know-How existing by then and necessary or useful to enable Clovis or such Contract Manufacturer (as appropriate) to Manufacture the Lead Candidate set forth in Exhibit 1.69 and the Backup Candidate set forth in Exhibit 1.10. For clarity, nothing in this **Section 6.3** with respect to 3BP's obligation to transfer 3BP Know-How to Clovis will limit 3BP's right to use any such 3BP Know-How to fulfill 3BP's obligations under this Agreement or exercise any rights retained by or granted to 3BP under this Agreement. In addition, 3BP will (and make Diligent Efforts to cause its Contract Manufacturer to) make available to Clovis, on a reasonable consultation basis, advice of its technical personnel at Clovis' expense as may reasonably be requested by Clovis in connection with such transfer of 3BP Know-How, including that Clovis will reimburse 3BP for reasonable travel expenses incurred by personnel of 3BP and/ or Contract Manufacturers of 3BP while rendering services at the request of Clovis under this **Section 6.3**.

**6.4 Clovis Contract Manufacturers.**

**(a)** Clovis has the right to appoint one or more Contract Manufacturers for supply to Clovis and, under the conditions set forth in **Section 6.5(b)** or **6.5(c)** to 3BP, but who itself is not a "Sublicensee" hereunder and thereby exercises "have made" rights granted by 3BP to Clovis under **Section 7.1(a)(ii)**. Clovis will disclose to 3BP any agreements concluded with Contract Manufacturers.

**(b)** Clovis will be responsible for any such Contract Manufacturer hereunder and will ensure in its agreement with each Contract Manufacturer that such agreement is consistent with the relevant terms of this this Agreement.

**(c)** Notwithstanding the generality of **subclause (b)**,

**(i)** Clovis will require any such Contract Manufacturer to agree in writing to comply with the obligations of confidentiality and non-use regarding Confidential Information that are substantially the same as those undertaken by the Parties pursuant **Article 10**;

**(ii)** Clovis will require that any such Contract Manufacturer agree in writing to assign and transfer to Clovis all rights in and/ or to all Manufacturing Data generated by such Contract Manufacturer, and all Patents and other Intellectual Property Rights generated by such Contract Manufacturer that are directed specifically to any Product and/ or Backup Candidates; and

**(iii)** [***]

**6.5 3BP Demand of Products.**

**(a)** With respect to 3BP's requirements for any Product for use in Development activities undertaken by 3BP in accordance with the Global Development Plan, conduct of Retained Territory Additional Studies sponsored by 3BP and/ or Commercialization of Products in the Retained Territory, 3BP shall have the right: [***]. For the avoidance of doubt, 3BP may exercise one of these rights or several of these rights, each of those once or severally. With respect to the same Product (including any component thereof), the rights of 3BP set forth under (i) and (ii) above shall, at a given time, be exercised alternatively and not cumulatively.

**(b)** 3BP may request that Clovis supply Products (or any component thereof) that, at the time of 3BP's request, Clovis is Manufacturing itself, or through an Affiliate or Contract Manufacturer. Any such Product (or any component thereof) will be supplied to 3BP for use by 3BP in Development activities undertaken by 3BP in accordance with the Global Development Plan, conduct of Retained Territory Additional Studies sponsored by 3BP, and/ or Commercialization of Products in the Retained Territory at the applicable Transfer Price [***] and pursuant to the terms of one or more, as applicable, supply agreements to be subsequently entered into by the Parties with respect to the Product or component to be supplied (each a "**Supply Agreement**"). As part of such Supply Agreement the Parties may agree that Clovis or its Contract Manufacturer shall produce material that meets any particular cGMPs required by 3BP, in which event Clovis or its Contract Manufacturer shall Manufacture and supply Products (or Product components, as the case may be) pursuant to such particular, agreed-upon cGMP for Products manufactured for 3BP. Clovis agrees that each Supply Agreement will in any event include a right for 3BP to audit or have a designee audit, at least once per Calendar Year, any records and other documentation of Clovis in order to verify the Transfer Price invoiced by Clovis. In connection with each Supply Agreement, the Parties will enter into a separate quality agreement setting forth the responsibilities of the quality organizations of each Party with respect to the manufacture of the Product in accordance with the applicable cGMPs (the "**Quality Agreement**"). Except pursuant to a Supply Agreement concluded by the Parties pursuant to this **Section 6.5(b)**, Clovis will have no obligation to supply any Products to 3BP.

**(c)** At any time, 3BP shall have the right to conclude separate supply agreements with Contract Manufacturers then supplying Product to Clovis or its Affiliates, provided that the Manufacture by such Contract Manufacturers is restricted to supply of Products for use by 3BP in Development activities undertaken by 3BP in accordance with the Global Development Plan, conduct of Retained Territory Additional Studies sponsored by 3BP, and/ or Commercialization of Products in the Retained Territory.

**(d)** At the reasonable request of 3BP which can be made once or severally, and at 3BP's cost and expense, Clovis will (and make Diligent Efforts to cause its Contract Manufacturers to) promptly disclose (and provide copies, as applicable) to 3BP and/ or Contract Manufacturers of 3BP, all Clovis Know-How, including Manufacturing Data, and provide copies of Manufacturing Documentation existing by then, all as necessary or useful to enable 3BP, or such Contract Manufacturers as 3BP may engage, to Manufacture 3BP's requirements for Products for Development activities undertaken by 3BP in accordance with the Global Development Plan, conduct of Retained Territory Additional Studies sponsored by 3BP, and/ or Commercialization of Products in the Retained Territory. In addition, Clovis will (and make Diligent Efforts to cause its Contract Manufacturers to) make available to 3BP and/ or Contract Manufacturers selected by 3BP, on a reasonable consultation basis, advice of its technical personnel, at 3BP's expense, as may reasonably be requested by 3BP in connection with such transfer of Clovis Know-How, including that 3BP will reimburse Clovis for reasonable travel expenses incurred by personnel of Clovis and/ or Contract Manufacturers of Clovis while rendering services at the request of 3BP under this **Section 6.5(d)**;

**(e)** 3BP will have the right to grant sublicenses under the rights set forth in **Section 7.2** to its Affiliates and/ or Contract Manufacturers, provided that, with respect to any Contract Manufacturers, 3BP is under the same obligations as Clovis pursuant to **Section 6.4(c)**.

## 7. LICENSES AND RELATED RIGHTS

### 7.1 License to Clovis.

**(a) License Grants**. Subject to the terms and conditions of this Agreement, 3BP hereby grants to Clovis and its Affiliates, and Clovis hereby accepts:

**(i)** an exclusive (even as to 3BP, except as provided in **Section 7.1(b)(v)**), royalty-free license, with the right to sublicense as provided in **Section 7.1(c)**, under the 3BP Technology to Develop and have Developed the Products in the Licensed Territory during the Term;

**(ii)** an exclusive (even as to 3BP, except as provided in **Section 7.1(b)(iii)**), royalty-free license under the 3BP Technology, with the right to sublicense as provided in **Section 7.1(c)**, to Manufacture and have Manufactured the Products in the Licensed Territory during the Term;

**(iii)** an exclusive (even as to 3BP), royalty-bearing license, with the right to sublicense as provided in **Section 7.1(c)**, under the 3BP Technology to use, sell, offer for sale, distribute, import, export and otherwise Commercialize the Products in the Licensed Territory during the Term; and

**(iv)** a non-exclusive, royalty-free license, with the right to sublicense as provided in **Section 7.1(c)**, under the 3BP Technology to Develop and have Developed and Manufacture and have Manufactured the Products in the Retained Territory during the Term.

**(b) 3BP Retained Rights**. It is understood that at all times 3BP and its Affiliates retain: (i) the exclusive right to Commercialize, either itself or through Third Parties, however, subject to **Section 7.3(a)**, the Products in the Retained Territory; (ii) the right to practice the 3BP Technology as and to the extent needed in connection with its activities under this Agreement in fulfillment of its obligations hereunder or exercise of its rights hereunder; (iii) the right to Manufacture and have Manufactured the Products (including in the Licensed Territory); (iv) the right to Develop and have Developed the Products in the Retained Territory; (v) the right to Develop and have Developed the Products in the Licensed Territory in accordance with the Global Development Plan; and (vi) the right to practice the 3BP Technology for the development, manufacture, commercialization of products other than the Product, [***].

**(c) Sublicense Rights.** Subject to **Section 7.3(b)**, Clovis will have the right to grant sublicenses (through one or more tiers) of the licenses granted to it under **Section 7.1(a)** to any Third Parties (each a "**Sublicense**") without 3BP's prior written consent; *provided* that Clovis hereby covenants that:

**(i)** any such Sublicense must refer to this Agreement and will be subordinate to and consistent with the terms and conditions of this Agreement, and will and shall not limit: (A) the ability of Clovis (individually or through the activities of its Sublicensees) to fully perform all its obligations under this Agreement; or (B) 3BP's rights under this Agreement or the exercise of such rights, including the rights granted to 3BP pursuant to **Section 11.7(b)**;

**(ii)** any such Sublicense must include a right of Clovis to terminate the Sublicense for cause;

**(iii)** any Sublicenses granted by Clovis to others under this Section to sell Therapeutic Products that are subject to royalty payments under this Agreement must include an obligation for the Sublicensee to account for and report its sales of Therapeutic Products to Clovis on the same basis as if such sales were Net Sales by Clovis, and any Sublicenses granted by Clovis to others under this Section to sell Imaging Agents that are subject to royalty payments from such Sublicensee to Clovis must not include [***] and must include an obligation for the Sublicensee to account for and report to Clovis its sales of Imaging Agents on which such royalties are based in order to be able to verify the proper inclusion of such amounts as Sublicense Revenue;

**(iv)** if Clovis intends to grant a Sublicense in the first tier (*that is*, to a Sublicensee under direct Sublicense agreement with Clovis or its Affiliates), the following shall apply: [***].

**(v)** Clovis shall include into any Sublicense agreement in the first tier that also includes the right to grant further sublicenses the obligation of such Sublicensee to [***]; and

**(vi)** if Clovis grants a Sublicense to any Third Party, then Clovis will provide 3BP with a copy of each such Sublicense agreement, promptly after execution thereof.

**7.2 License to 3BP.** Subject to the terms and conditions of this Agreement, Clovis hereby grants to 3BP a worldwide, fully paid-up, royalty-free, non-exclusive license, with the right to sublicense through multiple tiers, under the Clovis Technology to use and exploit the Clovis Technology to: (a) Develop, Manufacture, and Commercialize the Products in the Retained Territory; (b) Develop the Products in the Licensed Territory in accordance with the Global Development Plan; (c) Manufacture Products in the Licensed Territory; and (d) exercise the rights retained by 3BP pursuant to **Section 7.1(b)** and the rights granted to 3BP pursuant to **Section 11.7**.

**7.3 Right of First Negotiation.**

**(a)** [***]

**(b)** [***]

**7.4 Negative Covenant.** Each Party agrees that during the Term it will not, [***].

**7.5 No Implied Licenses**. Except as explicitly set forth in this Agreement, neither Party will be deemed by estoppel or implication to have granted the other Party any license or other right to any Intellectual Property Right of such Party. Neither Party will engage in any activities that use the other Party's technology in a manner that is outside the scope of the rights granted under this Agreement.

## 8. FINANCIAL TERMS.

**8.1 Upfront Payment.** Within thirty (30) days after the Effective Date (and subject to the submission (email sufficient) of an invoice within three (3) Business Days of the Effective Date), Clovis will pay to 3BP for the licenses to Clovis and related rights as set forth in **Section 7.1** [***] a one-time, non-refundable and non-creditable upfront cash payment equal to: (a) Four Million Five Hundred Thousand Euros (€4,500,000); and (b) Four Million Five Hundred Thousand Dollars ($4,500,000).

**8.2 Collaboration FTE Support.**

**(a)** During the Pre-Clinical Program Term, as support for work performed by 3BP under the Global Development Plan and the Manufacturing Plan, Clovis will pay 3BP for up to [***] ([***]) FTEs at the proportionate share of the FTE Rate for each FTE related to the time devoted by such FTE to the Collaboration. The Parties anticipate that 3BP will devote on average (calculated on a calendar quarterly basis) up to [***] ([***]) FTEs to Pre-Clinical Development (other than CMC Activities) and up to [***] ([***]) FTEs to CMC Activities in Pre-Clinical Development during the Pre-Clinical Program Term. Any FTE support to be provided by Clovis for further Pre-Clinical Development work after the Pre-Clinical Program Term is subject to the mutual written agreement of the Parties. 3BP will establish a time tracking system for its FTEs involved in the Collaboration, under which each person for whom 3BP seeks reimbursement from Clovis will specify on an every-other-week basis what percentage of his or her working time is spent on the Collaboration.

**(b)** Within [***] ([***]) Business Days following the end of each calendar quarter during the Pre-Clinical Program Term and, subject to **Section 8.2(a)** above, thereafter, 3BP will invoice Clovis for the FTEs time at the FTE Rate devoted during such quarter to the Collaboration and will provide with each such invoice a reasonably detailed description of the proportionate share of his or her time devoted by each FTE. Clovis will pay all undisputed FTE charges to 3BP within [***] ([***]) days of receiving such invoice. **Section 8.11** will apply to 3BP and the FTE charges will be subject to audit by Clovis under the terms of that **Section 8.11**.

**8.3 Development Costs Reimbursement.**

**(a)** With respect to the costs incurred by 3BP for Third Party subcontractors engaged by 3BP to perform Pre-Clinical Development activities which are to be reimbursed by Clovis pursuant to **Section 3.2(b)**, during each calendar quarter of the Pre-Clinical Development Term, 3BP will invoice Clovis for such amounts of costs of Third Party subcontractors which have been incurred by 3BP in such calendar quarter within [***] ([***]) days following the end of each calendar quarter, and Clovis will pay each such invoice within [***] ([***]) days after receipt thereof. Each such invoice will be accompanied by appropriate documentation (e.g., the Third Party subcontractor's invoice) to support the invoiced amount to be reimbursed.

**(b)** With respect to Development Costs associated with Retained Territory-Specific Study Elements that Clovis agrees to incorporate in a clinical study for a Product and for which 3BP has agreed to be responsible pursuant to **Section 3.3(b)**, Clovis will invoice 3BP for such amounts within [***] ([***]) days following the end of each calendar quarter, and 3BP will pay each such invoice within [***] ([***]) days after receipt thereof. Each such invoice will be accompanied by appropriate documentation to support the invoiced amount to be reimbursed.

**8.4 Annual Technology Access Fee.** Commencing on December 15, 2019 Clovis will pay to 3BP each Calendar Year, a non-refundable and non-creditable technology access fee, consisting of Dollar amounts and Euro amounts, equal to the amounts set forth in the following schedule:

| Calendar Year | Dollars | Euros |
|---|---|---|
| 2019 | $[***] | €[***] |
| 2020 | $[***] | €[***] |
| 2021 | $[***] | €[***] |
| 2022 | $[***] | €[***] |

| Calendar Year | Dollars | Euros |
|---|---|---|
| 2023 | $[***] | €[***] |
| 2024 | $[***] | €[***] |
| 2025, and subsequent Calendar Years | $[***] | €[***] |

After the initial technology access fee due on December 15, 2019, the technology access fee for each subsequent Calendar Year will be due on the anniversary of such date.

Following [***], the technology access fee owed on December 15 for each Calendar Year thereafter will be an amount equal to (a) [***] and (b) [***] unless and until such Therapeutic Product achieves Net Sales equal to [***] ($[***]), at which time an annual technology access fee will no longer be due.

At least forty-five (45) days prior to December 15 of each Calendar Year in which the technology access fee is owed, 3BP will issue an invoice to Clovis specifying the corresponding amount due based on the schedule above, and Clovis will make such payment no later than December 15 of that Calendar Year.

**8.5 Development Milestone Payments.** Clovis will make milestone payments (each, a "**Milestone Payment**") to 3BP following the occurrence of each of the milestone events (each, a "**Milestone Event**") as set forth below in this **Section 8.5**. Each of the Milestone Payments will be payable by Clovis to 3BP within [***] ([***]) Business Days of the achievement of the specified Milestone Event, and such payments when owed or paid will be non-refundable and non-creditable and not subject to set-off. Each of the Milestone Payments are payable only once, regardless of the number of Therapeutic Products that achieve a specified Milestone Event. Clovis shall notify 3BP in writing promptly upon occurrence of a Milestone Event.

| Therapeutic Product Milestone Event | **Milestone Payment** (consisting of Dollar amounts and Euro amounts) | |
|---|---|---|
| | **Dollars** | **Euros** |
| [***]] | $[***] | €[***] |
| [***] | $[***] | €[***] |
| [***] | $[***] | €[***] |
| [***] | $[***] | €[***] |
| [***] | $[***] | €[***] |
| [***] | $[***] | €[***] |
| [***] | $[***] | €[***] |
| [***] | $[***] | €[***] |

[1] [***]
[2] [***]
[3] [***]

If during the Pre-Clinical Program Term, 3BP is for reasons within 3BP's control delayed in completing the Pre-Clinical Development work for which it is responsible, such that the corresponding estimated timeline for such work set forth in the Global Development Plan is delayed by more than [***] ([***]) months, then the dates associated with the Milestone Events stated in the first three rows of the table above will each be extended by a period of time equal to the actual number of months of the delay.

In the event that a Milestone Event occurs (the "**Occurred Milestone Event**") and a Milestone Payment is due but at that time one or more Milestone Events preceding the Occurred Milestone Event according to the order set forth in the table above, have not occurred, then [***].

[***].

[***].

For the avoidance of doubt, the payments set forth above shall be due regardless of whether (i) in relation to the conduct of a clinical study, the Therapeutic Product is supplied for conduct of such study in ready-to-use form or as a kit or (ii) in relation to Regulatory Approval, the Therapeutic Product receives Regulatory Approval in ready-to-use form or as a kit.

**8.6 Sublicense Revenue.** Clovis will pay to 3BP an amount equal to [***] percent ([***]%) of all Sublicense Revenue that Clovis or any of its Affiliates receives during each Calendar Year in connection with a Sublicense agreement with any Sublicensee concerning a Product for all or part of the Licensed Territory. Any such payments to 3BP will be due within [***] ([***]) days following the end of each calendar quarter in accordance with the terms of **Section 8.7(d)** hereof.

**8.7 Royalty Payments.**

**(a) Royalties in Licensed Territory for Therapeutic Products.** Subject to **Section 8.7(c)**, Clovis will pay to 3BP royalties on Net Sales of Therapeutic Products in the Licensed Territory during each calendar quarter during the Royalty Term, as calculated by multiplying the total Net Sales of the Therapeutic Products during such calendar quarter by the applicable royalty rate as determined in the following table. For purposes of determining the applicable royalty rate, all Net Sales of the Therapeutic Products in the Licensed Territory will be aggregated (including, for avoidance of doubt, sales by Affiliates of Clovis and Sublicensees). For the avoidance of doubt, the royalties shall be due regardless of whether the Therapeutic Product is sold by Clovis, its Affiliates or Sublicensees in ready-to-use form or as a kit.

| Annual Net Sales of Therapeutic Product | Royalty Rate |
|---|---|
| [***] | [***]% |
| [***] | [***]% |
| [***] | [***]% |
| [***] | [***]% |
| [***] | [***]% |
| [***] | [***]% |

**(b) Royalties in Licensed Territory for Imaging Agents.** If Clovis or any of its Affiliates is the Selling Party with respect to the sale of an Imaging Agent in the Licensed Territory, Clovis will pay to 3BP royalties at a rate of [***] ([***]%)] on Clovis' or its Affiliate's Net Sales of all Imaging Agents in the Licensed Territory during each calendar quarter during the Royalty Term, as calculated by multiplying the total Net Sales by Clovis or its Affiliate of the Imaging Agents during such calendar quarter by the royalty rate of [***]%. For the avoidance of doubt, royalties shall be due regardless of whether an Imaging Agent is sold by Clovis as a stand-

alone product or as an enabling tool for a Therapeutic Product. If an Imaging Agent is sold by Clovis or its Affiliate together with a Therapeutic Product (for the avoidance of doubt, other than as a Combination Product), then the royalty rates set forth in **Section 8.7(a)** above shall apply to the aggregate sales price of the sale of the Therapeutic Product and the Imaging Agent. For the avoidance of doubt, the royalties shall be due regardless of whether the Imaging Agent is sold by the Selling Party in ready-to-use form or as a kit.

**(c) Royalty Adjustments.**

**(i) Third Party License.** On a country-by-country and Product-by-Product basis and only in the event that the Therapeutic Product Commercialized by Clovis, its Affiliates or Sublicensees comprises a FAP-Targeting Compound that is a peptide, if, after the Effective Date, Clovis or its Affiliate or Sublicensee: (A) reasonably determines that it is Necessary to obtain a license from any Third Party under Patents controlled by such Third Party in order to make, have made, use, sell, offer for sale or import a Therapeutic Product in any country of the Licensed Territory, and pursuant to such license is required to pay a royalty to the Third Party and such Necessity is approved by 3BP and the Parties through the JSC agree that Clovis, its Affiliate or Sublicensee shall obtain the license (and not 3BP, in which event this **Section 8.7(c)(i)** shall not be applicable) and Clovis has provided to 3BP the respective license terms (including royalties and other payments) to be entered into with the Third Party and these are approved by 3BP; or (B) is held by any court of competent jurisdiction in a final, non-appealable decision, due to infringement of Patents controlled by such Third Party through making, having made, using, selling, offering for sale or importing a Therapeutic Product in any country(ies) of the Licensed Territory, to pay a royalty to such Third Party, then Clovis may deduct from the royalties that would otherwise be due to 3BP for such country [***] percent ([***]%) of any such amount paid by Clovis (or its Affiliates, Sublicensees) to such Third Party in the respective calendar quarter; *provided* that the deduction pursuant to this **Section 8.7(c)(i)** will not reduce the royalties due to 3BP for the Therapeutic Product in such country in the respective calendar quarter below [***] percent ([***]%) of the amount for such calendar quarter that otherwise would have become due for such country pro rata in such calendar quarter pursuant to **Section 8.7(a)**.

**(ii) Patent Expiry, Absence of Data Exclusivity.** On a country-by-country basis and Product-by-Product basis, if there is no Valid Claim of any 3BP Patent Covering the composition of matter of the Therapeutic Product or Data Exclusivity relating to the Therapeutic Product, then the royalty rates under **Section 8.7(a)** will be reduced by [***] percent ([***]%).

**(iii) Generic Product.** On a country-by-country and Product-by-Product basis, if, during any calendar quarter, the unit volume of sales of all Generic Product(s) in such country during such quarter are more than [***] percent ([***]%) of the total unit volume of sales of (i) all such Generic Product(s) plus (ii) the respective Therapeutic Product's unit volume of sales in such country, then the royalty rates under **Section 8.7(a)** (as adjusted pursuant to **Section 8.7(c)(ii)** if applicable) will be reduced by [***] percent ([***]%). The percentage of sales of the Generic Product relative to all sales of unlicensed products and to the sales of Therapeutic Product will be based on unit-equivalent data, calculated using data provided by IMS or, in the absence of such publication by IMS, any similar market data source, or if such data is not available, another reliable data source that is mutually acceptable to 3BP and Clovis.

**(d) Royalty Reports and Payments**. Within [***] ([***]) days following the end of each calendar quarter during the Royalty Term, Clovis will provide 3BP with a report containing the following information for the applicable calendar quarter basis broken down on a country-by-country and Product-by-Product basis: (i) gross sales and Net Sales of the Product consolidated in Dollars; (ii) a calculation (including the basis of such calculations) of the royalty payment due on such sales; (iii) if applicable, the amount of Sublicense Revenue received during the quarter and the amounts owed under **Section 8.6;** (iv) the adjustment, if any, made in accordance with the terms of **Section 8.7(c)**, as well as any other details reasonably requested by 3BP. Within [***] ([***]) days of providing the report to 3BP, Clovis will proceed to the payment of the royalties and Sublicense Revenue payment due by wire transfer of immediately available funds.

**8.8 Payment Method.** All payments due under this Agreement to 3BP will be made in the specified currency by bank wire transfer in immediately available funds to an account designated by 3BP.

**8.9 Late Payment.** If a Party fails to make any payment due to the other Party under this Agreement, then interest will accrue on a daily basis at the rate equal to one month EURIBOR plus [***] ([***]) basis points per annum, or at the maximum rate permitted by Applicable Law, whichever is the lower, provided that the interest shall in no event be less than [***]% per annum.

**8.10 Foreign Exchange.** Conversion of sales recorded in local currencies to Dollars will be performed in a manner consistent with Clovis' normal practices used to prepare its audited financial statements for internal and external reporting purposes, which uses a widely accepted source of published exchange rates.

**8.11 Records; Inspection.** During the Royalty Term, Clovis will, and will ensure that its Affiliates and Sublicensee(s) will, keep complete, true and accurate books of account and records for the purpose of determining the payments to be made under this Agreement. Such books and records will be kept for at least [***] ([***]) years following the end of the Calendar Year to which they pertain. Such records will be open for inspection during such [***] period by independent accountants reasonably acceptable to Clovis (who will agree with Clovis to keep such records confidential), solely for the purpose of verifying payment statements hereunder. Such inspections will be made no more than once each Calendar Year (except for-cause), on reasonable notice during normal business hours, and will solely relate to the [***] ([***]) preceding Calendar Years. Any underpayment or overpayment (plus interest as set forth in **Section 8.9**) that are discovered will be paid by the owing Party within [***] ([***]) days. Inspections conducted under this **Section 8.11** will be

at the expense of 3BP, unless the inspection discloses an underpayment by Clovis of [***] ([***]%) or more of the amount due for any period covered by the inspection, whereupon the reasonable fees of the independent accountant relating to the inspection for such period will be paid promptly by Clovis.

**8.12 Taxes**.

**(a) VAT**. Any amounts for payment set forth in **Sections 8.1 to 8.7** above are expressed net of VAT, which shall be paid by Clovis in addition, to the extent applicable.

**(b) Taxes on Income.** Subject to **Section 8.12(a)**, each Party will be solely responsible for the payment of all taxes imposed on its share of income arising directly or indirectly from the efforts of the Parties under this Agreement.

**(c) Withholding Taxes.** All payments due and payable under this Agreement will be made without any deduction or withholding for or on account of any tax unless such deduction or withholding is required by Applicable Laws. If the paying Party is so required to deduct or withhold, such Party will (i) promptly notify the other Party of such requirement, (ii) pay to the relevant authorities the full amount required to be deducted or withheld promptly upon the earlier of determining that such deduction or withholding is required or receiving notice that such amount has been assessed against the other Party, (iii) promptly forward to the other Party an official receipt (or certified copy) or other documentation reasonably acceptable to the other Party evidencing such payment to such authorities and (iv) assist the other Party in obtaining any redemption of such amount.

**(d) Other Taxes.** Each Party will be solely responsible for the payment of custom duties, registration duties, transfer taxes, stamp duties and any other taxes or duties imposed to it in relation with the payments made under this Agreement.

## 9. INTELLECTUAL PROPERTY

**9.1 Patent Strategy.** With respect to all Patent preparation, filing, prosecution and maintenance, defense, and enforcement activities described in this **Article 9**, the Parties will discuss, confer and cooperate in good faith with respect to the overall Patent strategy with respect to the Licensed Territory and Retained Territory. Each Party, acting reasonably and in good faith, will consider the comments of the other Party in connection with the Patent strategy.

**9.2 Ownership of Inventions**; **Right to File Patent Applications**.

**(a) Ownership of Inventions**. Each Party will own all inventions, Know-How and other Intellectual Property Rights, whether or not patentable, made solely by its or its Affiliates' own employees, agents, independent contractors or subcontractors (including Contract Manufacturers, if in accordance with the terms of the applicable agreement with such Contract Manufacturer entered into pursuant to **Section 6.4**), in the course of conducting its activities under this Agreement ("**Sole Inventions**"). The Parties will jointly own, in equal, undivided interests, any inventions, Know-How and other Intellectual Property Rights, whether or not patentable, that are made jointly by employees, agents, independent contractors or subcontractors (including Contract Manufacturers, if in accordance with the terms of the applicable agreement with such Contract Manufacturer entered into pursuant to **Section 6.4**) of each Party or its Affiliates in the course of conducting its activities under this Agreement

(including pursuant to the Global Development Plan or the Manufacturing Plan) ("**Joint Inventions**"). Inventorship will be determined in accordance with the U.S. patent laws.

**(b) Right to Prepare and File Priority and PCT Patent Applications**. As between the Parties, (i) [***] and (ii) [***]. With respect to any Patents claiming any Joint Inventions which relate to any FAP-Targeting Compound (each, a "**Joint Patent"**), (a) the Parties' patent counsels will confer in good faith to attempt to agree upon the appropriate Party to prepare the Joint Patent, and (b) if the Parties are unable to agree, then (i) [***], and (ii) [***]. All Joint Patents will be subject to each Party's rights set forth in **Sections 9.2** and **9.4 to 9.6** below. In each instance above, the Party preparing an application for any Patent will file the priority application in the jurisdiction of its choice and use outside patent counsel of that Party's choice that is reasonably acceptable to the other Party.

**9.3 Invention Disclosure.** Each Party will promptly disclose to the other Party all Sole Inventions and Joint Inventions, including any invention disclosures or other similar documents, submitted to it by its or its Affiliates' employees, agents, independent contractors or subcontractors (including Contract Manufacturers in accordance with the terms of the applicable agreement with such contract manufacturer entered into pursuant to **Section 6.4**), describing inventions that are either Sole Inventions or Joint Inventions, and all information relating to such inventions to the extent necessary for the preparation, filing and prosecution of any Patent with respect to such invention. Upon the disclosure of a Joint Invention or Sole Invention pursuant to this **Section 9.3**, the Parties will promptly discuss such Joint Invention or Sole Invention and confirm its status as either a Joint Invention or a Sole Invention in light of the ownership principles set forth in **Section 9.2**.

**9.4 Patent National and Regional Filings; Prosecution, Maintenance, and Abandonment.**

**(a) Clovis Authority.**

**(i) Prosecution and Maintenance.** Concurrent with or subsequent to the filing of a PCT Application, Clovis shall, at its own cost and expense, be responsible for the filing of any regional (including with the European Patent Office) or national application (other than a priority application) and for prosecution and maintenance of (A) all Clovis Patents in any jurisdiction world-wide, and (B) [***] and Joint Patents in the Licensed Territory, in Clovis' own name, with respect to Clovis Patents, in 3BP's name, with respect to the [***], and in the name of both Parties, with respect to Joint Patents, including the defense of any claims or conducting any proceedings relating to such Patents (including but not limited to any patent interference, derivation proceeding, reissue, re-examination, supplemental examination, post-grant review, *inter partes* review, or other Patent Challenge proceedings, subject in each case to the provisions of **Section 9.5**). Clovis shall promptly provide 3BP and 3BP's external patent counsel, (i) with respect to Clovis Patents, with all material documentation and correspondence from, sent to or filed with patent offices in the respective jurisdictions regarding the prosecution of any such Patents, and provide 3BP with a reasonable opportunity to review and comment upon all substantive filings with such patent offices in advance of submission of such filings to such patent offices and (ii) with respect to [***] and Joint Patents, with all documentation and correspondence from, sent to or filed with patent offices in the respective jurisdictions regarding the prosecution of any such Patents, and provide 3BP with a reasonable opportunity of a least [***] (or in exceptional urgent cases a lesser but reasonable period) to review and comment upon all filings with such patent offices in advance of submission of such filings to such patent offices. Clovis shall consider 3BP's comments, acting

reasonably and in good faith, including any comments regarding whether to reduce the scope of or abandon any Valid Claims within such Patents taking into account the joint patent strategy established by the Parties pursuant to **Section 9.1**.

**(ii) Abandonment**. If Clovis determines to abandon or not to further prosecute (*e.g.*, not file any further divisional or continuation applications) or not to maintain (*e.g.*, not to validate a national/ regional patent in a particular country) or otherwise abandon (*e.g.,* by not paying respective annual maintenance or other fees due) (collectively to "**Abandon**") any Patent for which it has prosecution and maintenance authority under **Section 9.4(a)(i)** in any country, then Clovis shall notify 3BP in writing of such determination at least [***] ([***]) days prior to the intended Abandonment, and (A) in the event a Joint Patent shall be Abandoned, **Section 9.4(a)(iii)** shall apply, (B) in the event a Clovis Patent shall be Abandoned, **Section 9.4(a)(iv)** shall apply, and (C) in the event a [***] shall be Abandoned, **Section 9.4(a)(v)** shall apply. In the event that the Patent to be Abandoned expires pursuant to statutory time periods (*e.g*., non-payment of fees after due date) (the "**Statutory Expiration Date**"), the aforementioned [***] ([***]) days' notice period shall be calculated such that all of [***] ([***]) days are prior to the Statutory Expiration Date.

**(iii) Abandonment of Joint Patents.** In the event Clovis notifies 3BP of its determination to Abandon a Joint Patent, it shall provide 3BP with the opportunity to request to further prosecute and maintain such Patent in such country in 3BP's own name (or the name of an Affiliate or licensee of 3BP) as assignee, at 3BP's own cost and expense, which request shall be made within [***] ([***]) days of receipt of Clovis notification. In the event that 3BP has, within the aforementioned [***] ([***]) days notified Clovis that it wishes to assume such Patent, Clovis shall promptly assign and transfer its joint interest in such Joint Patent to 3BP (or the designated Affiliate or licensee of 3BP) and shall execute any documents and undertake any other acts, reasonably necessary to vest all such rights in such Patent to 3BP and the Patent shall from such assignment be deemed to be a "3BP Patent" with all other rights and obligations of Clovis pursuant to this Agreement in relation to such 3BP Patent (including payment obligations and licenses granted to Clovis pursuant to **Section 7.1**) remaining unaffected. In the event that 3BP has not requested the assumption of the Joint Patent within the aforementioned [***] ([***]) day period, Clovis shall be free to Abandon the Patent.

**(iv) Abandonment of Clovis Patents.** In the event Clovis notifies 3BP of its determination to Abandon a Clovis Patent, it shall provide 3BP with the opportunity to request to further prosecute and maintain such Patent in such country at 3BP's own cost and expense, but, for the avoidance of doubt, with all other rights and obligations of Clovis and 3BP pursuant to this Agreement in relation to such Clovis Patent remaining unaffected, including the license pursuant to **Section 7.2**. In the event that 3BP has not notified Clovis that it wishes to assume the further prosecution and maintenance of the Clovis Patent within the [***] ([***]) days, Clovis shall be free to Abandon the Patent.

**(v) Abandonment of** [***]. In the event Clovis notifies 3BP of its determination to Abandon a [***], it shall provide 3BP with the opportunity to request to further prosecute and maintain such Patent in such country at 3BP's own cost and expense. The request shall be made within [***] ([***]) days of receipt of Clovis notification and together with and from such request, 3BP shall have the right to continue prosecution of the [***] under 3BP's authority, in accordance with and as forth in **Section 9.4(b)** and **Section 9.5(b)**, with all other rights and obligations of Clovis pursuant to this Agreement in relation to such [***] (including payment obligations and licensed granted to Clovis pursuant to **Section 7.1**) remaining unaffected. In the event that 3BP has not notified Clovis that it wishes to assume

the further prosecution and maintenance of the Patent within the aforementioned [***] ([***]) day period, Clovis shall be free to Abandon the Patent.

**(b) 3BP Authority.**

**(i) Prosecution and Maintenance.** Concurrent with or subsequent to the filing of a PCT Application, 3BP shall, at its own cost and expense, be responsible for the filing of any regional (including with the European Patent Office) or national Patent application (other than a priority application) and for the prosecution and maintenance of (A) all 3BP Patents (other than a [***] in the Licensed Territory) in any jurisdiction world-wide and (B) all Joint Patents in the Retained Territory, in its own name with respect to the 3BP Patents, and in the name of both Parties with respect to any Joint Patents, including the defense of any claims or conducting any proceedings relating to such Patents (including but not limited to any patent interference, derivation proceeding, reissue, re-examination, supplemental examination, post-grant review, *inter partes* review, or other Patent Challenge proceedings, subject in each case to the provisions of **Section 9.5**). 3BP shall promptly provide Clovis (i) with respect to 3BP Patents, with all material documentation and correspondence from, sent to or filed with patent offices in the respective jurisdictions regarding the prosecution of any such Patents, and provide Clovis with a reasonable opportunity to review and comment upon all substantive filings with such patent offices in advance of submission of such filings to such patent offices and (ii) with respect to Joint Patents, with all documentation and correspondence from, sent to or filed with patent offices in the respective jurisdictions regarding the prosecution of any such Patents, and provide Clovis with a reasonable opportunity of a least [***] (or in exceptional urgent cases a lesser but reasonable period) to review and comment upon all filings with such patent offices in advance of submission of such filings to such patent offices. 3BP shall consider Clovis' comments, acting reasonably and in good faith, including any comments regarding whether to reduce the scope of or abandon any Valid Claims within such Patents taking into account the joint patent strategy established by the Parties pursuant to **Section 9.1**.

**(ii) Abandonment**. If 3BP determines to Abandon any Patent for which it has prosecution and maintenance authority under **Section 9.4(b)(i)** in any country, then 3BP shall notify Clovis in writing of such determination at least [***] ([***]) days prior to the intended Abandonment, and (A) in the event a Joint Patent shall be Abandoned, **Section 9.4(b)(iii)** shall apply and (B) in the event a 3BP Patent shall be Abandoned, **Section 9.4(b)(iv)** shall apply. In the event that the Patent to be Abandoned expires pursuant to a Statutory Expiration Date, the aforementioned [***] ([***]) days' notice period shall be calculated such that all of these [***] ([***]) days are prior to the Statutory Expiration Date.

**(iii) Abandonment of Joint Patents**. In the event 3BP notifies Clovis of its determination to Abandon a Joint Patent, it shall provide Clovis with the opportunity to request to further prosecute and maintain such Patent in such country in Clovis' own name (or the name of an Affiliate or Sublicensee) as assignee, at Clovis' own cost and expense, which request shall be made within [***] ([***]) days of receipt of 3BP notification. In the event Clovis has, within the aforementioned [***] ([***]) days, notified 3BP that it wishes to assume the Patent, 3BP shall promptly assign and transfer its joint interest in such Joint Patent to Clovis (or the designated Affiliate or Sublicensee) and shall execute any documents and undertake any other acts, reasonably necessary to vest all such rights in such Patent to Clovis (or its designee) and such Patent shall from such assignment be deemed to be a "Clovis Patent" with all provisions under this Agreement applying to it, including the license pursuant to **Section 7.2**. In the event that Clovis has not requested the assumption of the Joint Patent within the aforementioned [***] ([***]) day period, 3BP shall be free to Abandon the Patent.

**(iv) Abandonment of 3BP Patents**. In the event 3BP notifies Clovis of its determination to Abandon a 3BP Patent, it shall provide Clovis with the opportunity to request to further prosecute

and maintain such Patent in such country at Clovis' own cost and expense, but, for the avoidance of doubt, with all other rights and obligations of Clovis and 3BP pursuant to this Agreement in relation to such 3BP Patent remaining unaffected, including the license pursuant to **Section 7.1**. In the event that Clovis has not notified 3BP that it wishes to assume the further prosecution and maintenance of the 3BP Patent within the [***] ([***]) days, 3BP shall be free to Abandon the Patent.

**(c) Patent Term Extension.** 3BP and Clovis will cooperate with each other and will use Diligent Efforts in obtaining patent term extensions, orange book listings (or equivalent), or supplemental protection certificates or their equivalents in any country to the Clovis Patents, the 3BP Patents, and the Joint Patents.

**(d) Cooperation.** Each Party will provide the other Party all reasonable assistance and cooperation in the patent prosecution efforts provided above in this **Section 9.4**, including providing any necessary information, documents, and powers of attorney, and executing any other required documents or instruments for such prosecution.

**9.5 Defense of Patent Challenges.**

**(a) Clovis Authority**. If a Clovis Patent becomes the subject of any Patent Challenge proceeding commenced by a Third Party in any jurisdiction world-wide, or if a [***] or Joint Patent becomes the subject of any Patent Challenge proceeding commenced by a Third Party in any country in the Licensed Territory, then Clovis will have the first right, but not the obligation, to control the defense of such Patent Challenge at its own expense using counsel of its own choice. Clovis will notify 3BP reasonably in advance of all applicable deadlines whether or not Clovis will defend against such Patent Challenge. If Clovis decides that it does not wish to defend against such Patent Challenge, 3BP will thereafter have the right, but not the obligation, to assume defense of such action at its own expense. If Clovis decides that it wishes to defend against such Patent Challenge, 3BP shall have the right, but not the obligation, to participate in such defense. If 3BP elects to participate in the defense against an action, 3BP will notify Clovis within [***] ([***]) Business Days, and (i) with respect to Patent Opposition, the Parties will jointly control the defense using counsel acceptable to each Party and sharing expenses equally and neither Party will have the right to settle any proceeding without the prior written consent of such other Party, such consent not to be unreasonably withheld or delayed and (ii) with respect to any Patent Challenge proceeding other than a Patent Opposition, Clovis will permit 3BP to participate in the proceedings to the extent permissible under Applicable Laws and to be represented by its own counsel at 3BP's expense and Clovis will reasonably consider comments of 3BP with respect to any defense strategy, but will have sole and final decision-making authority with respect to such defense strategy, including settlement of any such proceeding.

**(b) 3BP Authority**. If a 3BP Patent other than a [***] in the Licensed Territory becomes the subject of any Patent Challenge proceeding commenced by a Third Party in any jurisdiction world-wide, or if a [***] or a Joint Patent becomes the subject of any Patent Challenge proceeding commenced by a Third Party in any country in the Retained Territory, then 3BP will have the first right, but not the obligation, to control the defense of such Patent

Challenge at its own expense using counsel of its own choice. 3BP will notify Clovis reasonably in advance of all applicable deadlines whether or not 3BP will defend against such Patent Challenge. If 3BP decides that it does not wish to defend against such Patent Challenge, Clovis will thereafter have the right, but not the obligation, to assume defense of such Patent Challenge at its own expense. If 3BP decides that it wishes to defend against such Patent Challenge, Clovis shall have the right, but not the obligation, to participate in such defense. If Clovis elects to participate in the defense against an action, Clovis will notify 3BP within [***] ([***]) Business Days, and (i) with respect to any Patent Opposition, the Parties will jointly control the defense using counsel acceptable to each Party and sharing expenses equally and neither Party will have the right to settle any proceeding without the prior written consent of such other Party, such consent not to be unreasonably withheld or delayed and (ii) with respect to any Patent Challenge proceeding other than a Patent Opposition, 3BP will permit Clovis to participate in the proceedings to the extent permissible under Applicable Laws and to be represented by its own counsel at Clovis' expense and 3BP will reasonably consider comments of Clovis with respect to any defense strategy, but will have sole and final decision-making authority with respect to such defense strategy.

**(c) Defense Participation**. Promptly upon being notified of any proceedings which are subject to joint participation pursuant to either **Section 9.5(a)** or **Section 9.5(b)**, the Parties will agree on and enter into a "common interest agreement" as may be necessary to protect privileged communications between the Parties and wherein the Parties agree to their shared, mutual interest in the outcome of such proceeding, and thereafter the Parties will promptly meet to consider the claims or assertions in such proceedings and the appropriate course of action.

**9.6 Enforcement of FAP Patents.**

**(a) Notification and Dispute Resolution**. If either Party becomes aware of any existing or threatened infringement of any FAP Patent, which infringing activity involves the manufacture, use, import, offer for sale or sale of any Product in the Licensed Territory or Retained Territory (a "**Product Infringement**"), it will promptly notify the other Party in writing to that effect, and the Parties will consult with each other regarding any actions to be taken with respect to such Product Infringement.

**(b) Enforcement in Licensed Territory.** In the Licensed Territory, Clovis will have the sole authority and discretion to bring an infringement action against any person or entity engaged in a Product Infringement of the FAP Patents, at Clovis' cost and expense *provided*, *however*, that: (i) to the extent reasonably practicable, prior to initiating any such suit or proceeding, the Parties will discuss the extent and effect of the Product Infringement; (ii) Clovis will promptly disclose to 3BP all material information or, with respect to 3BP Patents and Joint Patents, all information, related to such action, and (iii) with respect to 3BP Patents and Joint Patents, Clovis shall discuss with 3BP any enforcement strategy and consider in good faith any reasonable comments made by 3BP in relation thereto. If Clovis elects not to bring such action, the Parties will negotiate in good faith to provide 3BP with the authority and discretion to bring such action at its own cost and expense, subject to **Sections 9.6(d)** and **9.6(e)**, provided however, that 3BP shall in any event have the right, upon its request, to bring such action, if the Product Infringement is expected to materially affect the overall amount of royalties to be payable to 3BP pursuant to this Agreement and/ or the Sublicense Revenues.

**(c) Enforcement in Retained Territory.** In the Retained Territory, 3BP will have the sole authority and discretion to bring an infringement action against any person

or entity engaged in a Product Infringement of the FAP Patents, at 3BP's cost and expense; *provided*, *however*, that: (i) to the extent reasonably practicable, prior to initiating any such suit or proceeding, the Parties will discuss the extent and effect of the Product Infringement; and (ii) 3BP will promptly disclose to Clovis all material information or, with respect to Clovis Patents and Joint Patents, all information, related to such action, and (iii) with respect to Clovis Patents and Joint Patents, 3BP shall discuss with Clovis any enforcement strategy and consider in good faith any reasonable comments made by Clovis in relation thereto . If 3BP elects not to bring such action, the Parties will negotiate in good faith to provide Clovis with the authority and discretion to bring such action at its own cost and expense, subject to **Sections 9.6(d)** and **9.6(e)**.

**(d) Cooperation.** Each Party will provide to the enforcing Party under this **Section 9.6** reasonable assistance in such enforcement, at such enforcing Party's request and expense, including joining such action as a party plaintiff if required by Applicable Laws to pursue such action. The enforcing Party will keep the other Party regularly informed of the status and progress of such enforcement efforts and will reasonably consider the other Party's comments on any such efforts. The non-enforcing Party will be entitled to separate representation in such matter by counsel of its own choice and at its own expense, but such Party will at all times cooperate fully with the enforcing Party. If 3BP is the enforcing Party, no settlement of any Product Infringement action which restricts or adversely affects the scope of the licenses granted by 3BP to Clovis under the terms of this Agreement , or which may adversely affect the Commercialization of a Product in the Licensed Territory, will be entered into by 3BP without the prior written consent of Clovis, which consent shall not be unreasonably withheld or delayed. If Clovis is the enforcing Party, no settlement of any such Product Infringement action which restricts the scope, or adversely affects the enforceability of a FAP Patent, which restricts or adversely affects the scope of the licenses granted by Clovis to 3BP under the terms of this Agreement or which may adversely affect the Commercialization of a Product (including, may adversely affect the amount of royalties to be payable to 3BP pursuant to this Agreement) shall be entered into by Clovis without the prior written consent of 3BP, which consent shall not be unreasonably withheld or delayed.

**(e) Expenses and Recoveries.** The enforcing Party bringing a claim, suit or action under this **Section 9.6** will be solely responsible for any expenses incurred by such Party as a result of such claim, suit or action and if both Parties collectively bring the claim, suit or action under this **Section 9.6**, they will be jointly responsible for any expenses incurred by them as a result of such claim, suit or action. If a Party/ies recover(s) monetary damages in a claim, suit or action under **Section 9.6**, such recovery will be allocated first to the reimbursement of any reasonable expenses incurred by the Parties in such litigation, and any remaining amounts will be allocated as follows: (i) in the case of any recovery for a Product Infringement in the Licensed Territory pursuant to an infringement action brought by Clovis or 3BP under **Section 9.6(b)**, such recoveries will be deemed Net Sales of Clovis if Clovis brings an infringement action, and will to [***] percent ([***]%) be deemed Net Sales of Clovis and to the other [***] percent ([***]%) be paid directly to 3BP if 3BP only brings an infringement action; and (ii) in the case of any recovery for a Product Infringement in the Retained Territory pursuant to an infringement action solely brought by 3BP under **Section 9.6(c)**, 3BP will be entitled to retain all such recoveries.

**9.7 New Lead Candidate; Reimbursement of External Patent Costs.**

**(a) Additional [***] Applications.** Subject to the rights in **Sections 9.2(b)**, **9.4(a)**, and **9.4(b)**, if the JSC selects a new Lead Candidate during the Term, then [***].

**(b) Costs for 3BP Patents in the Licensed Territory.** If, at any time during the Term, the [***] Covers specifically any then-current Lead Candidate and/ or Backup Candidate and the Parties agree that a [***] should not be filed in a specific jurisdiction of the Licensed Territory, then Clovis will reimburse 3BP [***] percent ([***]%) of its External Patent Costs attributable to that jurisdiction of the Licensed Territory that have been incurred by 3BP in connection with the filing, prosecution, maintenance and defense of such [***] in such jurisdiction of the Licensed Territory prior to the selection of such compound as Lead Candidate and/or Backup Candidate and [***] percent ([***]%) of all future External Patent Costs incurred by 3BP in that jurisdiction of the Licensed Territory thereafter. If such External Patent Costs incurred by 3BP cannot be specifically and exclusively allocated to activities in that jurisdiction of the Licensed Territory, Clovis shall reimburse [***] percent ([***]%) of all such previous and future External Patent Costs incurred by 3BP in both the Licensed Territory and the Retained Territory. 3BP will invoice Clovis for all such previous External Patent Costs to be reimbursed hereunder within [***] ([***]) days after the date the Parties have agreed that a [***] should not be filed, and on a calendar quarterly basis thereafter, which invoices will be accompanied by reasonably detailed documentation of such External Patent Costs. Clovis will pay any such invoices within [***] ([***]) days of the invoice date.

**9.8 Infringement of Third Party Rights**. Without prejudice to the representations and warranties and covenants, if any Product becomes the subject of a Third Party's claim or assertion of infringement of such Third Party's Intellectual Property Rights in any jurisdiction in connection with the Development, Manufacture or Commercialization of the Product, then without prejudice to any indemnification obligations, each Party will promptly notify the other Party, and the Parties will agree on and enter into a "common interest agreement" as may be necessary to protect privileged communications between the Parties and wherein the Parties agree to their shared, mutual interest in the outcome of such potential dispute, and thereafter, the Parties will promptly meet to consider the claim or assertion and the appropriate course of action. Unless agreed otherwise by the Parties (including, if it is agreed by the JSC pursuant to **Section 8.7(c)(i)** that Clovis shall obtain the Third Party license) and without prejudice to any indemnification obligations, each Party will be solely responsible for defending itself against any such claim or assertion relating to its activities, whether in its territory or for its territory (*e.g.*, Development by Clovis in the Retained Territory in support of Regulatory Approval for the Licensed Territory), at its sole expense. To the extent the other Party engages separate counsel in such defense, it will be at its own cost and expense. The defending Party will keep the other Party fully informed of such claim and its defense and will reasonably consider and seek to accommodate any timely comments of the other Party with respect thereto.

**9.9 Patent Marking**. Clovis will, and will require its Affiliates and Sublicensees to, mark Products sold by or on behalf of it hereunder with appropriate patent numbers or indicia to the extent permitted by Applicable Laws, and in those countries in which such markings or such notices impact recoveries of damages or equitable remedies available with respect to infringement of Clovis Patents or 3BP Patents or Joint Patents.

## 10. CONFIDENTIALITY

**10.1 Confidentiality Obligations.** The Parties agree that during the Term and for a period of five (5) years thereafter, a Party receiving Confidential Information of the other Party will: (a) use Diligent Efforts to maintain in confidence such Confidential Information (but not less than those efforts as such Party uses to maintain in confidence its own proprietary industrial or intellectual information of similar kind and value and in no event less than a reasonable degree of care customary in the pharmaceutical industry for those kinds of information); (b) not

disclose such Confidential Information to any Third Party without prior written consent of the other Party, except to the extent expressly authorized by this Agreement or otherwise agreed in writing by the Parties; and (c) not use such other Party's Confidential Information for any purpose except those permitted by this Agreement or in connection with exercising such Party's rights and/or fulfilling their obligations under this Agreement.

**10.2 Exceptions.** The obligations in **Section 10.1** will not apply with respect to any portion of the other Party's Confidential Information that the receiving Party can show by competent written proof:

**(a)** was known to the receiving Party, other than under an obligation of confidentiality, at the time of disclosure by the disclosing Party;

**(b)** was generally available to the public or otherwise part of the public domain, at the time of disclosure by the other Party;

**(c)** becomes generally available to the public or otherwise part of the public domain after the disclosure by the other Party, other than through any act or omission of the receiving Party in breach of this Agreement;

**(d)** is subsequently disclosed to the receiving Party by a Third Party who has a legal right to make such disclosure and who did not obtain such information directly or indirectly from the other Party; or

**(e)** is subsequently independently developed by employees or contractors of the receiving Party who had no access to or knowledge of the other Party's Confidential Information.

**10.3 Authorized Disclosure.** A Party may disclose the Confidential Information belonging to the other Party to the extent such disclosure is reasonably necessary in the following instances; *provided* that unless otherwise provided below, notice of any such disclosure will be provided as soon as practicable to the other Party:

**(a)** filing or prosecuting Patents in accordance with **Sections 9.2(b)** and **9.4**;

**(b)** complying with the requirement of Regulatory Authorities with respect to obtaining and maintaining Regulatory Approval of Products;

**(c)** prosecuting or defending litigation as contemplated by this Agreement, provided that the Party obligated to disclosure will promptly notify the other Party of such required disclosure and will, upon the other Party's request, use reasonable efforts to assist the other Party, at such other Party's expense, in obtaining a protective order preventing or limiting the required disclosure;

**(d)** disclosure to its or its Affiliates' employees, agents, consultants, contractors, licensees or sublicensees on a need-to-know basis for the sole purpose of performing its obligations or exercising its or its Affiliates' rights under this Agreement or any other agreement between the Parties or their Affiliates consistent with the terms of this Agreement; provided that in each case, prior to disclosure the disclosees are bound by written obligations of confidentiality and non-use consistent with those contained in this Agreement;

**(e)** disclosure to each Party's board of directors (or similar governing body) on a confidential basis or to any bona fide potential or actual investor, sublicensee, acquiror or merger partner or other potential or actual financial partner (including any banks, venture capital companies and public funding agencies) for the sole purpose of evaluating an actual or potential investment, sublicense, acquisition, grant of loan or funding or other business relationship; *provided* that in connection with such disclosure, the disclosing Party will inform each disclosee of the confidential nature of such Confidential Information and prior to disclosure obligate and cause each disclosee to treat such Confidential Information as confidential (unless such partner is subject to confidentiality by way of laws or mandatory professional rules); or

**(f)** complying with Applicable Laws, including regulations promulgated by applicable security exchanges, court orders or administrative subpoenas or orders, provided that the Party obligated to disclosure will promptly notify the other Party of such required disclosure and will, upon the other Party's request, use reasonable efforts to assist the other Party, at such other Party's expense, in obtaining a protective order preventing or limiting the required disclosure.

**10.4 Publicity; Terms of Agreement**.

**(a)** On or promptly after the Effective Date, the Parties will jointly issue a public announcement of the execution of this Agreement in a form mutually agreed upon. Neither Party will issue any subsequent press release or make other disclosures regarding this Agreement or the Parties' activities hereunder, or any results or data arising hereunder, except (i) with the other Party's prior written consent, such consent not to be unreasonably withheld; or (ii) in accordance with this **Article 10**. Notwithstanding the foregoing, to the extent information regarding this Agreement or the Parties' activities hereunder has already been publicly disclosed, either Party may subsequently disclose the same information to the public without the consent of the other Party and provided such information remains accurate as of such time.

**(b)** If either Party desires to make a public announcement in connection with this Agreement, such as press releases containing Development achievements made under this Agreement or presentations regarding a Product made at financial/ investment conferences (*e.g.*, on the JP Morgan conference), such Party will give reasonable prior advance notice of the proposed text of such announcement or presentation to the other Party for its prior review and approval (except as otherwise provided herein), such approval not to be unreasonably withheld, except that in the case of an ad hoc press release or governmental filing required by law, regulation or stock exchange rules, the disclosing Party will provide the other Party with such advance notice as it reasonably can and will not be required to obtain approval therefor if otherwise mandatory timelines cannot be complied with. A Party commenting on such a proposed press release or governmental filing will provide its comments, if any, within [***] ([***]) Business Days after receiving the press release or presentation for review. In addition, (i) any such press release or financial/ investor presentation by Clovis will include, and Clovis will ensure that any press release or presentation of its Affiliates will include, in each case subject to any word-count restraints, a reference to 3BP as the developer of the underlying technology, (ii) each Party shall refer in any press release or financial/ investor presentation to the collaboration of the Parties hereunder, and (iii) each Party shall be entitled to propose to display in any press release and/ or financial/ investor presentation submitted for review hereunder its logo and/ or the logo of the other Party.

**10.5 Technical Publications.** Neither Party may publish peer reviewed manuscripts or give other forms of public disclosure such as abstracts or congress presentations, of results of studies carried out under this Agreement (collectively "**Technical Publication**"), without the opportunity for prior review and coordination by the other Party, except to the extent required by Applicable Laws. A Party seeking a Technical Publication will provide the other Party the opportunity to review and comment on any such proposed publication at least [***] ([***]) days (but only [***] ([***]) Business Days for abstracts or congress presentations) prior to its intended submission for presentation or publication. The other Party will provide the Party seeking publication with its comments in writing, if any, within [***] ([***]) days (but only [***] ([***]) Business Days for abstracts or congress presentations) after receipt of such proposed publication. Shorter review timelines are acceptable so long as a Party notifies the other Party at least [***] ([***]) Business Days prior to sending the proposed publication to the other Party for review and comment of such shorter timelines and provided that the time for the other Party to review and comment the proposed publication shall in no event be less than [***] ([***]) days (or, respectively, [***] ([***]) Business Days for abstracts or congress presentations). In the event of such a shorter timeline, the other Party will provide the Party seeking publication with its comments in writing, if any, within such notified shorter timeline. The Party seeking publication will consider in good faith any comments thereto provided by the other Party, provided that it will in any event comply with the other Party's request to remove such other Party's Confidential Information from the proposed publication. In addition, the Party seeking a Technical Publication will delay the submission for a period up to [***] ([***]) days if the other Party can demonstrate reasonable need for such delay, including the preparation and filing of a Patent application. If the other Party fails to provide its comments to the Party seeking publication within the applicable review and commenting time set forth in the preceding sentences, such other Party will be deemed not to have any comments, and the Party seeking publication will be free to publish in accordance with this **Section 10.5** after the respective review timeline has elapsed. The Party seeking publication will provide the other Party with a copy of the abstract, congress presentation, or manuscript at the time of the submission. Each Party agrees to acknowledge the contributions of the other Party and its employees in all Technical Publications as scientifically appropriate, unless such other Party objects, and provided that in any event a publication by Clovis will include, and Clovis will ensure that any publication of its Affiliates or Sublicensees will include, a reference to 3BP as the developer of the underlying technology.

**10.6 Equitable Relief.** Each Party acknowledges that its breach of this **Article 10** may cause irreparable harm to the other Party, which might not be reasonably or adequately compensated in damages in an action at law. By reasons thereof, each Party agrees that the other Party may be entitled, in addition to any other remedies it may have under this Agreement or otherwise, to seek preliminary and permanent injunctive and other equitable relief to prevent or curtail any actual or threatened breach of the obligations relating to Confidential Information set forth in this **Article 10** by the other Party.

## 11. TERM AND TERMINATION

**11.1 Term.** This Agreement will become effective on the Effective Date and, unless earlier terminated pursuant to this **Article 11** or by mutual written agreement, will remain in effect on a Product-by-Product basis until the expiration of the Royalty Term in the last country of the Licensed Territory and will continue thereafter for so long as Clovis is Developing or Commercializing such Product in any country in the Licensed Territory (the "**Term**"), provided that upon expiration of the Royalty Term in a country, the licenses and rights granted to Clovis

under this Agreement will, with respect to such country, become non-exclusive, royalty-free and fully paid-up and all licenses and other rights of use granted by Clovis to 3BP hereunder, including the licenses and rights granted pursuant to **Section 7.2** and pursuant to **Section 5.3**, shall survive without change.

**11.2 Termination by 3BP for Country-Specific Non-Activity.** On a Product-by-Product basis, beginning on the [***] ([***]) anniversary of the date of receipt for a Product of its initial Marketing Authorization in the U.S. that is a full approval by the FDA (i.e., not an accelerated approval granted pursuant to 21 CFR 314, also known as 'subpart H'), 3BP shall have the right to terminate this Agreement on a country-by-country basis for the respective Product in each country of the Licensed Territory in which, at such date, Clovis is not then Developing such Product in such country(ies) with Diligent Efforts, either itself directly, or indirectly through an Affiliate or a Sublicensee.

**11.3 Discretionary Termination by Clovis; Termination for Cause by Clovis.**

**(a) Without Cause.** Clovis will be permitted to terminate this Agreement in full, without cause and subject to payment to 3BP of an amount equal to [***] Dollars ($[***]), upon [***] ([***])] days prior written notice to 3BP.

**(b) For** [***] **Reason**

**(i)** Clovis will have the right to terminate this Agreement on a Therapeutic Product-by-Therapeutic Product basis, and without payment of the amount set forth under **Section 11.3(a)** above due from Clovis to 3BP on account of such termination, if the board of directors of Clovis concludes [***]. If the board of directors of Clovis makes such a determination, Clovis will provide written notice to 3BP describing the issues upon which the board based its conclusion.

**(ii)** Within [***] ([***]) days of receipt of a notice of termination pursuant to **Section 11.3(b)(i)**, 3BP will consider the decision in good faith, and if 3BP agrees, it will so notify Clovis in writing, and the Agreement will terminate [***] ([***]) days after the date of Clovis' original termination notice. If 3BP notifies Clovis that 3BP does not agree with the determination made by the Clovis board of directors, the dispute (a "**Determination Dispute**") will be referred to an expert for resolution in accordance with Exhibit 11.3. If the expert agrees with the conclusion reached by the Clovis board of directors, the Agreement will terminate [***] ([***]) days after the date of the expert's decision; otherwise the Agreement will, at Clovis' choice, continue in full force and effect or be deemed terminated by Clovis pursuant to **Section 11.3(a)**.

**11.4 Termination for Material Breach.** If either Party believes that the other Party is in breach of its material obligations hereunder, then the non-breaching Party may deliver notice of such breach to the other Party specifying the nature of the alleged breach in reasonable detail. The allegedly breaching Party will have [***] ([***]) days from such notice to dispute or cure such breach. If the Party receiving notice of breach fails to cure such breach within

such [***] ([***]) day period, whether through specific performance or payment of money damages or through a combination of specific performance and payment of money damages, then the non-breaching Party may terminate this Agreement in its entirety, provided that, if the allegedly breaching Party in good faith disputes such material breach or disputes the failure to cure or remedy such material breach and provides written notice of that dispute to the other Party, the matter will be addressed under the dispute resolution provisions in **Article 14**, and the non-breaching Party may or, at its discretion, may not terminate this Agreement until it has been determined under **Article 14** that the conditions for termination of this **Section 11.4** are met. If the non-breaching Party has elected not to terminate until it has been determined that the conditions for termination are met and such determination is made in accordance with the dispute resolution provisions in **Article 14**, such termination will then be effective upon written notification from the non-breaching Party to the breaching Party. For clarification purpose, for Clovis' material breach of its obligations set forth in **Section 3.4** (Development Diligence; Standards of Conduct) and **Section 5.4** (Commercial Diligence), 3BP will only be permitted to terminate the Agreement with respect to those countries to which such breach relates.

**11.5 Termination for Bankruptcy Event.** Either Party may terminate this Agreement if the other Party is generally unable to meet its debts when due, or makes a general assignment for the benefit of its creditors, or there shall have been appointed a receiver, trustee or other custodian for such Party for or a substantial part of its assets, or any case or proceeding shall have been commenced or other action taken by or against such Party in bankruptcy or seeking the reorganization, liquidation, dissolution or winding-up of such Party or any other relief under any bankruptcy, insolvency, reorganization or other similar act or law, and any such event shall have continued for [***] ([***]) days undismissed, unstayed, unbonded and undischarged. In such circumstances, the other Party may, upon notice to such Party, terminate this Agreement, such termination to be effective upon such Party's receipt of such notice.

**11.6 Termination for Rejection of Performance**. Each Party shall be entitled to terminate this Agreement if an insolvency administrator of the other Party's assets rejects performance of this Agreement (*Erfüllungsablehnung*).

**11.7 Effects of Termination of the Agreement**. Upon any early termination of this Agreement (*that is*, for avoidance of doubt, not by operation of expiration pursuant to **Section 11.1**), in its entirety or on a country-by-country basis:

**(a) Termination of Licenses.**

**(i)** Other than termination by Clovis on the basis of a material breach of the Agreement by 3BP under **Section 11.4** or by Clovis pursuant to **Section 11.6** (the effects of which on the licenses are set forth in subclause (ii) or (iii), respectively, below), (A) all licenses granted to Clovis under **Section 7.1** will terminate, but in the case of termination on a country-by-country basis, solely to the extent such licenses relate to those countries so terminated; *provided* that Clovis will retain a non-exclusive license under **Section 7.1** to sell, offer for sale and import remaining inventories of the Products in terminated countries for a period not exceeding [***] ([***]) months (and make respective royalty payments in accordance with Section **8.7** for such sales and payment of Sublicense Revenues in accordance with **Section 8.6**) and *further provided* that if and to the extent such termination of Clovis' license is based upon termination by 3BP pursuant to **Section 11.2** or **Section 11.4** last sentence, the respective countries in which Clovis' license so terminates shall be deemed included in the Retained Territory with all rights of 3BP relating to the Retained Territory applying also to these countries; and (B) all licenses and other rights of use granted by Clovis

to 3BP hereunder (including the right to use Products Marks in the Retained Territory if granted pursuant to **Section 5.3**) will survive without change.

**(ii)** In the case of termination of this Agreement by Clovis pursuant to **Section 11.4** due to a material breach by 3BP, without prejudice to any other remedies of Clovis, including the right to claim damages: (A) all licenses granted to Clovis under **Section 7.1** will become perpetual, fully paid up and Clovis will no longer have any obligations pursuant to this Agreement; *provided, however*, that Clovis will pay to 3BP, for the Royalty Term, [***] percent ([***]%) of the royalty payments set forth in **Section 8.7** and [***] percent ([***]%) of the Sublicense Revenues set forth in **Section 8.6** when they would have become due if the Agreement had not been terminated and make respective reporting in accordance with **Section 8.7(d)**; and (B) all licenses and other rights of use granted by Clovis to 3BP hereunder (including the right to use Products Marks in the Retained Territory if granted pursuant to **Section 5.3**) will shall survive without change.

**(iii)** In the case of termination of this Agreement by Clovis pursuant to **Section 11.6**: (A) all licenses granted to Clovis under **Section 7.1** will become perpetual, fully paid up and Clovis will no longer have any obligations pursuant to this Agreement; *provided, however*, that Clovis will pay to 3BP any Milestone Payments set forth in **Section 8.5** when they would have become due if the Agreement had not been terminated, and Clovis will pay to 3BP, for the Royalty Term, the royalty payments set forth in **Section 8.7** and the Sublicense Revenues set forth in **Section 8.6** when they would have become due if the Agreement had not been terminated and make respective reporting in accordance with **Section 8.7(d)**; and (B) all licenses and other rights of use granted by Clovis to 3BP hereunder (including the right to use Products Marks in the Retained Territory if granted pursuant to **Section 5.3**) will shall survive without change.

**(b) Sublicense Agreements; Agreements with Contract Manufacturer.**

**(i)** Termination of this Agreement by 3BP on the basis of a material breach by Clovis under **Section 11.4** will not automatically terminate any Sublicense if the following conditions are met: (A) the Sublicense meets the requirements of **Section 7.1(c)**; (B) with respect to such Sublicense agreement the Sublicensee is at the time of termination in full compliance and further, is not in breach of any provision of this Agreement; and (C) the Sublicensee agrees to the assignment of such Sublicense to 3BP (i.e., such that 3BP will step into the role of Clovis under such Sublicense and become the Sublicensee's direct licensor). If all of the aforementioned conditions are met, the Sublicense will be assigned automatically to 3BP; however if any of the conditions under (i) to (iii) are not met, such Sublicense will automatically terminate upon termination of this Agreement.

**(ii)** Any termination of this Agreement for any reason other than termination by 3BP on the basis of a material breach of Clovis (which is regulated in subsection (i) above) or by Clovis pursuant to **Section 11.6** (which is regulated by subsection (iii) below), will automatically terminate all outstanding Sublicenses, unless (A) 3BP requests the assignment of the Sublicense agreement to 3BP, in which event it shall be automatically assigned to 3BP, provided such assignment of the Sublicense does not require the consent of the Sublicensee according to the governing laws of such Sublicense agreement, or (B) if the assignment of the Sublicense requires the consent of the Sublicensee according to the governing laws of such Sublicense agreement, the Sublicensee and 3BP agree to continue the Sublicense between them as parties.

**(iii)** Termination by Clovis pursuant to **Section 11.6** shall have no effect on any Sublicenses then outstanding, which shall remain in full force and effect.

**(iv)** Upon any termination of this Agreement other than by Clovis on the basis of a material breach by 3BP or by Clovis pursuant to **Section 11.6**, at 3BP's request, Clovis will use Diligent Efforts to procure the assignment to 3BP of Clovis' then-current agreement(s) with Contract Manufacturers for the Manufacture of Products (or components thereof).

**(c) Documentation; Data.** Other than termination by Clovis on the basis of a material breach of the Agreement by 3BP under **Section 11.4**, at 3BP's request, Clovis agrees to transfer to 3BP, at Clovis' expense, the Regulatory Documentation and Regulatory Approvals as well as any Manufacturing Documentation (including Manufacturing Documentation of any Contract Manufacturer of Clovis and its Affiliates) relating to the Products in such terminated country in the Licensed Territory.

**(d) Return of Confidential Information.** Upon termination of this Agreement each Party will surrender to the other Party, or, if so requested by the other Party, destroy and provide the other Party with a certificate signed by an Executive Officer of the first Party attesting to the destruction of, all copies of any Confidential Information provided by the other Party hereunder, provided that the first Party may retain one (1) copy of any Confidential Information in an appropriately secure location. The afore obligation of return or destruction shall not apply to the extent a Party requires the further use of the Confidential Information of the other Party for reason of exercising any licenses and/ or other rights which survive the termination of this Agreement.

**(e) Product Mark.** Other than termination by Clovis on the basis of a material breach of the Agreement by 3BP under **Section 11.4**, and except where Clovis can reasonably demonstrate that Commercializing the Product under the Product Mark in the terminated country(ies) is detrimental to Clovis' sales in any non-terminated countries, at 3BP's request, Clovis will consider in good faith or, in the event of termination of this Agreement by 3BP on the basis of a material breach of the Agreement by Clovis under **Section 11.4** Clovis will be obligated to the grant of a royalty-free, fully paid-up, license to 3BP, for a period of time allowing 3BP to switch the Product Mark, under any and all Product Marks then being used by Clovis solely and exclusively for any such Product and transfer to 3BP the right to use during the transition period any domain names containing solely such Product Marks, in each case only to the extent that such Product Mark is not also used for any product Controlled by Clovis which does not fall under this Agreement and does not make reference to any other trade name or trademark of Clovis.

**(f) Post Termination Technology Transfer**. Other than termination by Clovis on the basis of a material breach of the Agreement by 3BP under **Section 11.4**, Clovis will reasonably cooperate with 3BP, at 3BP's request, in order to enable 3BP to promptly assume the Development and/or Commercialization of all Products then being Commercialized or in Development by Clovis for Commercialization in the Licensed Territory (or in a particular country if such termination is only as to such country). Such cooperation and assistance will be provided in a timely manner (having regard to the nature of the cooperation or assistance requested). Such assistance shall be at 3BP's reasonable cost and expenses, except in the event of termination by 3BP on the basis of a material breach of the Agreement by Clovis under **Section 11.4** or termination by Clovis under **Section 11.3(a),** in which event it shall be at Clovis' cost and expense.

**11.8 Accrued Rights; Survival**. Termination or expiration of this Agreement for any reason (i) will be without prejudice to any right or obligation which will have accrued prior to such termination or expiration, including damages arising from any breach under this Agreement and (ii) will leave unaffected, the following provisions which will survive any expiration or termination of this Agreement: **Articles 1**, **10**, **13** (with respect to Third Party claims based on events occurring during the Term), **14**, and **Sections 8.11, 9.2, 11.7,** this **11.8**, **14** and **16.10**.

## 12. REPRESENTATIONS AND WARRANTIES AND COVENANTS

**12.1 Mutual Representations and Warranties.** Each Party hereby represents and warrants to the other Party by way of an independent guarantee within the meaning of Section 311 of the German Civil Code (*Selbständiges Garantieversprechen*) as follows:

**(a) Corporate Existence.** As of the Effective Date, it is a company or corporation duly organized, validly existing, and in good standing, if applicable, under the Applicable Laws of the jurisdiction in which it is incorporated.

**(b) Corporate Power, Authority and Binding Agreement.** As of the Effective Date: (i) it has the corporate power and authority and the legal right to enter into this Agreement, and to carry out and otherwise perform its obligations hereunder; (ii) it has taken all necessary corporate action on its part required to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder; (iii) this Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, and binding obligation of such Party that is enforceable against it in accordance with its terms, and (iv) the carrying out and other performance of its obligations under this Agreement by such Party (A) does not conflict with, or contravene or constitute any default under, any agreement, instrument or understanding, oral or written, to which it is a party, including its certificate of incorporation or by-laws, and (B) does not violate Applicable Law or any judgment, injunction, order or decree of any governmental authority having jurisdiction over it.

**12.2 Additional Representations and Warranties of 3BP**. 3BP represents and warrants to Clovis by way of an independent guarantee within the meaning of Section 311 of the German Civil Code (*Selbständiges Garantieversprechen*) (except for the representation and warranty pursuant to **Section 12.2(i)** in relation to which 3BP represents and guarantees by way of a simple obligation (*Verpflichtung*)) that, as of the Effective Date:

**(a) Title; Encumbrances**. [***].

**(b) Sufficiency**. **Exhibit 1.3** sets forth a complete and accurate list of all 3BP Patents in existence as of the Effective Date. [***].

**(c) Non-Infringement**. [***].

**(d) No Out-Bound Agreements**. 3BP has not granted any Third Party (including any academic organization or agency), or any Affiliate, any licenses to the Products (except for rights outside of the Licensed Territory).

**(e) Proper Assignment of Rights**. 3BP has obtained from all individuals who participated in any respect in the invention or authorship of any 3BP Technology owned by 3BP or its Affiliates effective assignments of all ownership rights of such individuals in

such 3BP Technology as are necessary to grant the licenses hereunder, either pursuant to written agreement or by operation of law.

**(f) Pending or Threatened Proceedings**. There are no actual, pending, or announced actions, suits, proceedings or formal governmental investigations involving the Products and/or the 3BP Technology relating to the Products by or against 3BP or any of its Affiliates, in or before any court, governmental or Regulatory Authority. There are no judgments against or litigation settlements entered into by 3BP relating to the 3BP Technology or the Products.

**(g) Intellectual Property Proceedings.** 3BP is not aware of any fact or circumstance which would make the 3BP Patents invalid and unenforceable in their entirety. Neither 3BP nor any of its Affiliates have received any Third Party written communication alleging that any of the 3BP Patents are unpatentable, invalid or unenforceable or are subject to interference, reexamination, reissue, revocation, opposition, appeal or other administrative proceeding. 3BP has not taken any action or failed to take any action, which action or failure reasonably could be expected to result in the abandonment, cancellation, forfeiture, relinquishment, invalidation or unenforceability of any of the 3BP Patents.

**(h) Debarment.** In the course of the development of Products, 3BP has not used any employee or consultant who has been debarred by any Regulatory Authority, or, to 3BP's knowledge, is or was the subject of debarment proceedings by a Regulatory Authority.

**(i) Due Diligence Data.** [***].

**(j) Notice of Infringement or Misappropriation.** Neither 3BP nor its Affiliates have received any written notice from any Third Party asserting or alleging that any research or development of the Products by 3BP or its Affiliates prior to the Effective Date infringed or misappropriated the Intellectual Property Rights of such Third Party.

**12.3 Mutual Covenants**.

**(a) No Debarment.** In the course of the Development of Products, neither Party nor its Affiliates will use any employee or consultant who is debarred by any Regulatory Authority, or, to such Party's knowledge, is the subject of debarment proceedings by a Regulatory Authority. Each Party will notify the other Party promptly upon becoming aware that any of its or its Affiliates' employees or consultants has been debarred or is the subject of debarment proceedings by any Regulatory Authority.

**(b) Compliance.** Each Party and its Affiliates will comply in all material respects with all Applicable Laws in the Development, Manufacture and Commercialization of the Product and performance of its obligations under this Agreement.

**12.4 Disclaimer**. EXCEPT AS EXPRESSLY STATED IN THIS AGREEMENT, NO REPRESENTATIONS OR WARRANTIES WHATSOEVER, WHETHER EXPRESS OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT, OR NON-MISAPPROPRIATION OF THIRD PARTY INTELLECTUAL PROPERTY RIGHTS, ARE MADE OR GIVEN BY OR ON BEHALF OF A PARTY, AND ALL REPRESENTATIONS AND WARRANTIES, WHETHER ARISING BY OPERATION OF LAW OR OTHERWISE, ARE HEREBY EXPRESSLY EXCLUDED. NOTWITHSTANDING ANYTHING TO THE CONTRARY IN THIS AGREEMENT, BOTH PARTIES ACKNOWLEDGE AND AGREE THAT, NOTWITHSTANDING THE DILIGENT EFFORTS OF THE PARTIES, THE ACTIVITIES TO BE CONDUCTED UNDER THE COLLABORATION AND THE GLOBAL DEVELOPMENT PLAN ARE INHERENTLY UNCERTAIN, AND THAT THERE ARE NO ASSURANCES THAT THE PARTIES WILL SUCCESSFULLY IDENTIFY A LEAD CANDIDATE OR THAT ANY SUCH CANDIDATE WILL BE SUCCESSFULLY DEVELOPED AND COMMERCIALIZED BY CLOVIS AS A PRODUCT.

## 13. INDEMNIFICATION AND LIMITATION OF LIABILITY

**13.1 Indemnification by Clovis.** Clovis will defend, indemnify, and hold 3BP and its Affiliates and their respective officers, directors, employees, and agents (the "**3BP Indemnitees**") harmless from any and all damages or other amounts payable to a Third Party claimant, as well as any reasonable attorneys' fees and costs of litigation incurred by such 3BP Indemnitees, all to the extent resulting from claims, suits, proceedings or causes of action brought by such Third Party ("**Claims**") against such 3BP Indemnitees to the extent arising from or based upon: (a) the Development, Manufacture or Commercialization of the Products by or on behalf of Clovis or its Affiliates or its or their Sublicensees (excluding in all cases 3BP or its Affiliates or sublicensees), including infringement of Third Party Intellectual Property Rights in such Development, Manufacture and/ or Commercialization; (b) the negligent or willful breach of any of Clovis' obligations under this Agreement, including (but without the requirement of negligence or willful misconduct) Clovis' representations and warranties set forth herein; (c) the willful misconduct or gross negligence of any Clovis Indemnitee or Sublicensees; or (d) the use by Clovis or its Affiliates or its or their Sublicensees in the Licensed Territory of Development Data or Regulatory Documentation supplied by 3BP to Clovis under this Agreement. Notwithstanding the foregoing, Clovis will not have any responsibility hereunder for any Claims to the extent arising from any breach of any of 3BP's obligations under this Agreement, including 3BP's representations and warranties set forth herein.

**13.2 Indemnification by 3BP**. 3BP will defend, indemnify, and hold Clovis and its Affiliates and their respective officers, directors, employees, and agents (the **"Clovis Indemnitees"**) harmless from and against any and all damages or other amounts payable to a Third Party claimant, as well as any reasonable attorneys' fees and costs of litigation incurred by such Clovis Indemnitees, all to the extent resulting from Claims against such Clovis Indemnitees to the extent arising from or based upon: (a) the Development, Manufacture or Commercialization of the Products by or on behalf of 3BP or its Affiliates or its or their sublicensees (excluding in all cases Clovis, its Affiliates or its Sublicensees); (b) the negligent or willful breach of any of 3BP's obligations under this Agreement, including (but without the

requirement of negligence or willful misconduct, except for breach of the representations and warranties given under **Section 12.2(i)** which for an indemnification obligation under this section requires negligence or willful misconduct)) 3BP's representations and warranties set forth herein; (c) the willful misconduct or gross negligence of any 3BP Indemnitee; or (d) the use by 3BP or its Affiliates or its or their sublicensees in the Retained Territory of Development Data or Regulatory Documentation supplied by Clovis to 3BP under this Agreement. Notwithstanding the foregoing, 3BP will not have any responsibility hereunder for any Claims to the extent arising from any breach of any of Clovis' obligations under this Agreement, including Clovis' representations and warranties set forth herein.

**13.3 Conditions to Indemnification.** The Party claiming indemnity under this **Article 13** (the "**Indemnified Party**") will give written notice to the Party from whom indemnity is being sought (the "**Indemnifying Party**") promptly after learning of such Claim in relation to which it wishes to claim indemnification hereunder, provided that the failure to promptly provide such notice will not relieve the Indemnifying Party of any of its indemnification obligations hereunder, except to the extent that the Indemnifying Party's defense of the relevant Claim is prejudiced by such failure. The Indemnifying Party may upon such notice assume the defense of the Claim, and the Indemnified Party will provide the Indemnifying Party, upon the Indemnifying Party's request, with reasonable assistance, at the Indemnifying Party's expense, in connection with the defense of the Claim for which indemnity is being sought. The Indemnified Party may participate in and monitor such defense with counsel of its own choosing at its sole expense. The Indemnifying Party will not settle any Claim without the prior written consent of the Indemnified Party, not to be unreasonably withheld. So long as the Indemnifying Party is actively defending the Claim in good faith, the Indemnified Party will not settle or compromise any such Claim without the prior written consent of the Indemnifying Party. If the Indemnifying Party does not assume and conduct the defense of the Claim as provided above, (i) the Indemnified Party may defend against, consent to the entry of any judgment, or enter into any settlement with respect to such Claim in any manner the Indemnified Party may deem reasonably appropriate (and the Indemnified Party need not consult with, or obtain any consent from, the Indemnifying Party in connection therewith), and (ii) the Indemnifying Party will remain responsible to indemnify the Indemnified Party as provided in this **Article 13**.

**13.4 Limitation of Liability.**

**(a)** EXCEPT FOR (I) ANY CLAIMS RELATED TO ONE PARTY'S INFRINGEMENT OF THE OTHER PARTY'S INTELLECTUAL PROPERTY OUTSIDE OF THE RIGHTS AND LICENSES GRANTED HEREUNDER, ANY BREACH OF CONFIDENTIALITY OR THE PROVISIONS OF SECTION 7.5, (II) DAMAGES OR AMOUNTS PAYABLE TO A THIRD PARTY CLAIMANT UNDER SECTIONS 13.1 OR 13.2 (INCLUDING FOR DEATH OR BODILY INJURY), AND/ OR (III) ANY SITUATION WHERE A LIMITATION OF LIABILITY IS NOT PERMISSIBLE UNDER THE GOVERNING LAWS, NEITHER PARTY WILL BE LIABLE TO THE OTHER FOR ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL, PUNITIVE, OR INDIRECT DAMAGES ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES; SUBJECT TO THAT THE TERMS 'SPECIAL, CONSEQUENTIAL, INCIDENTAL, PUNITIVE, OR INDIRECT DAMAGES' AS USED BEFORE SHALL BE UNDERSTOOD AND CONSTRUED AS THOSE DAMAGES WHICH ARE NOT THE NATURAL AND/OR PROBABLE CONSEQUENCE OF, WITH RESPECT TO (I) ABOVE, THE BREACH OR, WITH RESPECT TO (II) ABOVE, THE SITUATION GIVING RISE TO THE THIRD PARTY CLAIM.

**(b)** Clovis will not bring any claims or action against 3BP and will not exercise any rights under this Agreement for breach of this Agreement by 3BP to the extent the breach results from or relates to the facts and matters disclosed in Exhibit 12.2(a).

**13.5 Insurance.** Each Party will procure and maintain insurance, including product liability insurance, with respect to its activities hereunder and which is consistent with normal business practices of prudent companies similarly situated at all times during which any Product is being clinically tested in human subjects or commercially distributed or sold. Each Party will provide the other Party with evidence of such insurance upon request and will provide the other Party with written notice at least [***] ([***]) days prior to the cancellation, non-renewal or material changes in such insurance. It is understood that such insurance will not be construed to create a limit of either Party's liability with respect to its indemnification obligations under this **Article 13**.

## 14. DISPUTE RESOLUTION.

**14.1 Disputes.** The Parties recognize that disputes as to certain matters may from time to time arise that relate to either Party's rights and/or obligations hereunder. It is the objective of the Parties to establish procedures to facilitate the resolution of disputes arising under this Agreement in an expedient manner by mutual cooperation and without resort to litigation. To accomplish this objective, the Parties agree to follow the procedures set forth in this **Article 14** to resolve any controversy or claim arising out of, relating to or in connection with any provision of this Agreement, if and when a dispute arises under this Agreement.

**14.2 Amicable Resolution**. In the event of a dispute arising hereunder, other than a dispute referred to the Executive Officers pursuant to **Section 2.5(b)** (for which the procedure set forth in **Section 2.5(b)** shall apply), in the first place the Executive Officers of the Parties shall meet and try to amicably resolve the issue within [***] ([***]) days (or any longer period of time agreed by the Executive Officers) from such dispute being referred to them.

**14.3 Binding Arbitration.** If the Executive Officers of the Parties are unable to resolve a given dispute in accordance with the timelines set forth in **Section 14.2**, except for the non-arbitrable disputes set forth in **Section 14.4**, either Party may have the given dispute settled by binding arbitration administered by the International Chamber of Commerce ("**ICC**") and judgment on the arbitration award may be entered in any court having jurisdiction thereof. The Parties agree that:

**(a)** The place of arbitration will be [***] and all proceedings and communications will be in English.

**(b)** The ICC Rules of Arbitration ("**ICC Rules**") shall apply to the dispute, which rules are deemed incorporated by reference into this clause, provided that (i) the Emergency Arbitrator Rules of the ICC effective as of January 2012 and the ICC Rules on expedited procedure effective as of March 1, 2017 shall not apply and (ii) in the event that the ICC Rules conflict with the provisions of this **Section 14.3**, the provisions of this **Section 14.3** shall prevail.

**(c)** The dispute shall be settled by three arbitrators nominated in accordance with the Arbitration Rules of the ICC, unless the Parties agree on one arbitrator.

**(d)** Either Party may apply to the arbitrators for interim injunctive relief until the arbitration award is rendered or the controversy is otherwise resolved. Either Party also may, without waiving any remedy under this Agreement, seek from any court having jurisdiction any injunctive or provisional relief necessary to protect the rights or property of that Party pending the arbitration award. The arbitrators will have no authority to award punitive or any other type of damages not measured by a Party's compensatory damage. Except to the extent necessary to confirm an award or as may be required by applicable Laws, neither Party nor any arbitrator may disclose the existence, content, or results of an arbitration without the prior written consent of both Parties. In no event will arbitration be initiated after the date when commencement of a legal or equitable proceeding based on the dispute, controversy or claim would be barred by the applicable statute of limitations.

**14.4 Non-Arbitrable Disputes**.

**(a)** Any dispute with respect to which a Party has final decision-making authority pursuant to **Section 2.5(b)** or other provisions of this Agreement, and any Determination Dispute, will not be subject to resolution by binding arbitration under **Section 14.3.**

**(b)** Any dispute between the Parties to the extent relating to [***], will not be subject to resolution by binding arbitration under **Section 14.3** and instead will be resolved in a court or governmental agency of competent jurisdiction, which, to the extent there is no exclusive jurisdiction or exclusive decision-making authority of an agency, shall be the courts located in [***].

## 15. CONSEQUENCES OF CHANGE OF CONTROL

**15.1 Change of Control prior to** [***]**.**

**(a)** In the event of a Change of Control of Clovis that occurs prior to [***], if the Applicable CoC Party fails within [***] from the Change of Control Closing to: (i) [***]; or (ii) if applicable [***], then in either case 3BP will have the right to terminate this Agreement in full upon [***] ([***]) days written notice to the Applicable CoC Party, and the effects of termination set forth in **Sections 11.7(a)(i)**, **11.7(b)(ii)**, **11.7(b)(iv)** and **11.7(c)** to **11.7(f)** will apply.

**(b)** In the event of a Change of Control of Clovis that occurs prior to [***], unless 3BP exercises the right to terminate this Agreement pursuant to **Section 15.1(a)** above within [***] from such termination right arising pursuant to **Section 15.1(a)** above, then the Milestone Payments set forth in **Section 8.5** tied to: (i) [***]; and (ii) [***], will in each case, become due upon the [***] of: (A) [***]; and (B) [***].

**15.2 Change of Control after** [***]**.**

**(a)** In the event of a Change of Control of Clovis that occurs after the [***], if the royalty payments made to 3BP pursuant to **Section 8.7** during the first [***] ([***]) consecutive months following the Change of Control Closing do not total [***] Dollars ($[***]), then 3BP will be entitled to an additional payment in the amount equal to [***]

Dollars ($[***]) less the amount of royalties actually paid to 3BP on Net Sales during such [***] period. Thereafter, royalty payments will be based solely on the rates set forth in **Section 8.7**.

**(b)** In the event of a Change of Control of Clovis that occurs after [***], if the Applicable CoC Party fails to, if applicable [***], within [***] from the Change of Control Closing then 3BP will have the right to terminate this Agreement in full upon [***] ([***]) days written notice to the Applicable CoC Party which right of termination shall be exercised by 3BP not later than [***] ([***]) days following [***], and the effects of termination set forth in **Sections 11.7(a)(i)**, **11.7(b)(ii)**, **11.7(b)(iv)** and **11.7(c)** to **11.7(f)** will apply.

## 16. MISCELLANEOUS

**16.1 Entire Agreement; Amendments.** This Agreement, including all Exhibits attached hereto as well any Supply Agreement, Quality Agreement, and Safety Data Exchange Agreement when entered into, sets forth the complete, final and exclusive agreement and all the covenants, promises, agreements, warranties, representations, conditions and understandings between the Parties hereto with respect to the subject matter hereof, and supersedes all prior agreements and understandings between the Parties with respect to the subject matter hereof. There are no covenants, promises, agreements, warranties, representations, conditions or understandings, either oral or written, between the Parties other than as are set forth in this Agreement. No subsequent alteration, amendment, change or addition to this Agreement will be binding upon the Parties unless reduced to writing and signed by an authorized officer of each Party.

**16.2 Force Majeure.** Each Party will be excused from the performance of its obligations under this Agreement to the extent that such performance is prevented by force majeure (as defined below) and the nonperforming Party promptly provides notice of the prevention to the other Party. Such excuse will be continued so long as the condition constituting force majeure continues and the nonperforming Party takes reasonable efforts to remove the condition. For purposes of this Agreement, "**force majeure**" will mean conditions beyond the control of the Parties and occurring without the respective Party's negligence or intent, including an act of God, war, civil commotion, labor strike or lock-out, epidemic, failure or default of public utilities, destruction of production facilities or materials by earthquake, storm or like uncontrollable catastrophe. In the event that the force majeure event continues for more than six (6) months, the Party not affected by force majeure shall have the right to terminate this Agreement.

**16.3 Notices.** Any notices given under this Agreement will be in writing, addressed to the Parties at the following addresses, and delivered by person, by facsimile (with receipt confirmation), or by FedEx or other reputable courier service. Any such notice will be deemed to have been given: (a) as of the day of personal delivery; (b) one (1) day after the date sent by facsimile service; or (c) on the day of successful delivery to the other Party confirmed by the courier service. Unless otherwise specified in writing, the mailing addresses of the Parties will be as described below.

| | |
|---|---|
| If to 3BP: | 3B Pharmaceuticals GmbH<br>Magnusstr. 11<br>D-12489 Berlin<br>Germany<br>Attention: Managing Director<br>FAX: +49(0)30 63 92 43 14 |
| with copy to: | 3B Pharmaceuticals GmbH<br>Magnusstr. 11<br>D-12489 Berlin<br>Germany<br>Attention: Head of Nuclear Medicine<br>FAX: +49(0)30 63 92 43 14 |
| If to Clovis: | Clovis Oncology, Inc.<br>5500 Flatiron Parkway, Suite 100<br>Boulder, Colorado 80301<br>USA<br>Attention: Project Leadership<br>FAX: +1 303 245 0360 |
| with copy to: | Clovis Oncology, Inc.<br>5500 Flatiron Parkway, Suite 100<br>Boulder, Colorado 80301<br>USA<br>Attention: Legal Department<br>FAX: +1 303 245 0360 |

**16.4 Assignment.** Neither Party may assign or transfer this Agreement or any rights or obligations hereunder without the prior written consent of the other, except that (a) each Party may make such an assignment without the other Party's consent to an Affiliate of the assigning Party; and (b) each Party may assign this Agreement without the other Party's consent in the event of a Change of Control (subject, in the case of Clovis, to **Article 15**). The Parties agree that this Agreement is of the type described in Section 365(c)(1) of the United States Bankruptcy Code, and neither the Agreement nor any of the rights under the Agreement may be assumed or assigned in any bankruptcy proceeding (or otherwise) without the express prior written consent of the other Party. Further, nothing in this Agreement alone shall be considered consent by 3BP to the assumption or assignment of this Agreement by Clovis, a trustee, a debtor, a debtor-in-possession or any other person or entity in any bankruptcy proceeding involving Clovis. Any successor or assignee of rights and/or obligations permitted hereunder will, in writing to the other Party, expressly assume performance of such rights and/or obligations. Any permitted assignment will be binding on the successors of the assigning Party. Any assignment or attempted assignment by either Party in violation of the terms of this **Section 16.4** will be null, void and of no legal effect.

**16.5 Performance by Affiliates**. Each Party may discharge any obligations and exercise any right hereunder through any of its Affiliates. Notwithstanding the foregoing, prior to the sale by Clovis of any Affiliate that holds a Marketing Authorization for a Product (other than as part of a Change of Control of Clovis), Clovis will require the assignment or transfer of such Marketing Authorization back to Clovis. Each Party hereby guarantees the performance

by its Affiliates of such Party's obligations under this Agreement, and will cause its Affiliates to comply with the provisions of this Agreement in connection with such performance. Any breach by a Party's Affiliate of any of such Party's obligations under this Agreement will be deemed a breach by such Party, and the other Party may proceed directly against such Party without any obligation to first proceed against such Party's Affiliate. For the avoidance of doubt, the discharge through Affiliates shall leave unaffected the contracting entities hereunder and shall solely be a subcontracting.

**16.6 Further Actions.** Each Party agrees to execute, acknowledge and deliver such further instruments, and to do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.

**16.7 Severability.** If any of the provisions of this Agreement are held to be invalid or unenforceable by any court of competent jurisdiction from which no appeal can be or is taken, the provision will be considered severed from this Agreement and will not serve to invalidate any remaining provisions hereof. The Parties will make a good faith effort to replace any invalid or unenforceable provision with a valid and enforceable one such that the objectives contemplated by the Parties when entering this Agreement may be realized.

**16.8 No Waiver.** Any delay in enforcing a Party's rights under this Agreement or any waiver as to a particular default or other matter will not constitute a waiver of such Party's rights to the future enforcement of its rights under this Agreement, excepting only as to an express written and signed waiver as to a particular matter for a particular period of time.

**16.9 Independent Contractors**. Each Party will act solely as an independent contractor, and nothing in this Agreement will be construed to give either Party the power or authority to act for, bind, or commit the other Party in any way. Nothing herein will be construed to create the relationship of partners, principal and agent, or joint-venture partners between the Parties.

**16.10 Governing Law.** The construction of this Agreement as well as resolution of all disputes, controversies or claims arising out of, relating to or in connection with this Agreement or the performance, enforcement, breach or termination of this Agreement and any remedies relating thereto, will be governed by and construed under the substantive laws of [***], without regard to conflicts of law rules.

**16.11 Construction of this Agreement.** Except where the context otherwise requires, wherever used, the use of any gender will be applicable to all genders, and the word "**or**" is used in the inclusive sense. When used in this Agreement, "**including**" means "**including without limitation**". References to either Party include the successors and permitted assigns of that Party. The headings of this Agreement are for convenience of reference only and in no way define, describe, extend or limit the scope or intent of this Agreement or the intent of any provision contained in this Agreement. The Parties have each consulted counsel of their choice regarding this Agreement and have jointly prepared this Agreement, and, accordingly, no provisions of this Agreement will be construed against either Party on the basis that the Party drafted this Agreement or any provision thereof. If the terms of this Agreement conflict with the terms of any Exhibit, then the terms of this Agreement will govern. The official text of this Agreement and any Exhibits hereto, any notice given or accounts or statements required by this Agreement, and any dispute proceeding related to or arising hereunder, will be in English. In the event of any dispute concerning the construction or meaning of this Agreement, reference

will be made only to this Agreement as written in English and not to any other translation into any other language.

**16.12 Counterparts.** This Agreement may be executed in two (2) or more counterparts, each of which will be an original and all of which will constitute together the same document. Counterparts may be signed and delivered by facsimile, or electronically in PDF format, each of which will be binding when sent.

*[Signature page follows.]*

**IN WITNESS WHEREOF**, the Parties have caused this Agreement to be executed by their respective duly authorized officers as of the Effective Date.

| **CLOVIS ONCOLOGY, INC.** | **3B PHARMACEUTICALS GMBH** |
|---|---|
| By: | By: |
| Name: | Name: |
| Title: | Title: |

Exhibits



*****Confidential Treatment Requested.**

**Exhibit 1.3**

**3BP Patents**

**[***]**



*****Confidential Treatment Requested.**

**Exhibit 1.10**

**Backup Candidate**

**[***]**



*****Confidential Treatment Requested.**

**Exhibit 1.54**

**FTE Rate**

FTE Rate is fixed at a rate of [***] Euro (€[***]) per FTE per Calendar Year.

**Exhibit 1.69**

**Lead Candidate**

[***]



*****Confidential Treatment Requested.**

**Exhibit 3.2(a)**

**[***]**



***Confidential Treatment Requested.**

**Exhibit 11.3(b)**

**Determination Dispute Resolution**

Disputes regarding a determination by the board of directors of Clovis that [***] will be resolved in the following manner:

**1.** **Appointment of Expert**. Within [***] ([***])] Business Days after 3BP requests under Section 11.3 that an expert be appointed to resolve a Determination Dispute, the Parties will jointly appoint a mutually acceptable expert with experience and expertise in the subject matter of the dispute. If the Parties are unable to so agree within the [***] ([***])] Business Day period, or if there is a disclosure of a conflict by an expert under Paragraph 2 hereof that results in the Parties not confirming the appointment of the expert, then an expert (willing to act in that capacity hereunder) will be appointed by an experienced arbitrator on the roster of the International Chamber of Commerce ("ICC").

**2.** **Conflicts of Interest**. Any person appointed as an expert will be entitled to act and continue to act as an expert even if at the time of the appointment or at any time before the expert gives a determination on the Determination Dispute, the expert has or may have some interest or duty which conflicts or may conflict with the appointment; *provided* that before accepting the appointment (or as soon as practicable after the expert becomes aware of the conflict or potential conflict), the expert fully discloses the interest or duty and the Parties will, after the disclosure, have confirmed the expert's appointment.

**3.** **Not Arbitrator**. No expert will be deemed to be an arbitrator and the provisions of any Applicable Law relating to arbitration will not apply to the expert or the expert's determination or the procedure by which the expert reaches his determination under this Exhibit 11.3.

**4.** **Condition and Procedure**.

**(a)** Condition for Appointment. The expert will be appointed on condition that he/she undertakes that: (i) the expert promptly fixes a reasonable time and place for receiving representations, submissions or information from the Parties for the proper conduct of the expert's determination and any hearing; and (ii) the expert renders a decision (with full reasons) within [***] ([***]) Business Days (or another date as the Parties and the expert may agree) after receipt of all information requested by the expert under Paragraph 4(c) hereof.

**(b)** Procedure: Upon its appointment, the Parties shall ensure that the expert follows the procedure set forth under subclause (a) above.

**(c)** Disclosure of Evidence. The Parties undertake to give to the expert all the evidence and information within their respective possession or control as the expert may reasonably consider necessary for determining the Determination Dispute, and they will disclose promptly and in any event within [***] ([***])] Business Days of a written request from the expert to do so. The Parties will co-operate and seek to narrow and limit the issues to be determined.

**(d)** Advisors. Each Party may appoint any counsel, consultants and advisors as it feels appropriate to assist the expert in making a determination and to present their respective cases.

**(e)** Final and Binding. The determination of the expert will, except for fraud or manifest error, be final and binding upon the Parties.

**(f)** Costs. Each Party will bear its own costs for any matter referred to an expert hereunder and, in the absence of express provision in the Agreement to the contrary, the costs and expenses of the expert will be shared equally by the Parties.

**Exhibit 12.2(a)**

[***]



*****Confidential Treatment Requested.**

**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. 333-251120) 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, 333-226523 and 333-238936) pertaining to the 2009 Equity Incentive Plan, 2011 Stock Incentive Plan, 2020 Stock Incentive Plan and 2011 Employee Stock Purchase Plan of Clovis Oncology, Inc.;

of our reports dated February 24, 2021, 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, 2020.

/s/ Ernst & Young LLP

Denver, Colorado
February 24, 2021

**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, 2020;

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 24, 2021

/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, 2020;

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 24, 2021

/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, 2020, 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 24, 2021

/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, 2020, 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 24, 2021

/s/ DANIEL W. MUEHL
Daniel W. Muehl
Executive Vice President and Chief Finance Officer