
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

FORM 10-Q

- ☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934.**

For the quarterly period ended March 31, 2022.

- ☐ **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
(State or other jurisdiction of
incorporation or organization)

90-0475355
(I.R.S. Employer
Identification No.)

5500 Flatiron Parkway, Suite 100
Boulder, Colorado
(Address of principal executive offices)

80301
(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 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, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☒
Non-accelerated filer ☐

Accelerated filer ☐
Smaller reporting company ☐
Emerging growth company ☐

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

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

The number of outstanding shares of the registrant's common stock, par value \$0.001 per share, as of April 29, 2022 was 143,879,140.

CLOVIS ONCOLOGY, INC.

FORM 10-Q

TABLE OF CONTENTS

PART I. Financial Information	3
ITEM 1. Financial Statements (unaudited)	3
Consolidated Statements of Operations and Comprehensive Loss — for the three months ended March 31, 2022 and 2021	3
Consolidated Balance Sheets — as of March 31, 2022 and December 31, 2021	4
Consolidated Statements of Stockholders' Equity (Deficit) — for the three months ended March 31, 2022 and 2021	5
Consolidated Statements of Cash Flows — for the three months ended March 31, 2022 and 2021	6
Notes to Unaudited Consolidated Financial Statements	7
ITEM 2. Management's Discussion and Analysis of Financial Condition and Results of Operations	27
ITEM 3. Quantitative and Qualitative Disclosures About Market Risk	43
ITEM 4. Controls and Procedures	44
PART II. Other Information	45
ITEM 1. Legal Proceedings	45
ITEM 1A. Risk Factors	45
ITEM 2. Unregistered Sales of Equity Securities and Use of Proceeds	45
ITEM 3. Defaults Upon Senior Securities	45
ITEM 4. Mine Safety Disclosures	45
ITEM 5. Other Information	45
ITEM 6. Exhibits	45
SIGNATURES	50

PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

CLOVIS ONCOLOGY, INC. **Consolidated Statements of Operations and Comprehensive Loss** **(Unaudited)** **(In thousands, except per share amounts)**

	Three months ended March 31,	
	2022	2021
	(in thousands, except per share amounts)	
Revenues:		
Product revenue	\$ 34,247	\$ 38,053
Operating expenses:		
Cost of sales - product	8,070	8,268
Cost of sales - intangible asset amortization	1,343	1,343
Research and development	42,250	52,805
Selling, general and administrative	29,213	29,941
Other operating expenses	3,730	3,707
Total expenses	84,606	96,064
Operating loss	(50,359)	(58,011)
Other income (expense):		
Interest expense	(9,100)	(8,037)
Foreign currency loss	(978)	(546)
Other income	148	183
Other income (expense), net	(9,930)	(8,400)
Loss before income taxes	(60,289)	(66,411)
Income tax benefit	120	134
Net loss	(60,169)	(66,277)
Other comprehensive income (loss):		
Foreign currency translation adjustments, net of tax	435	(80)
Other comprehensive income (loss)	435	(80)
Comprehensive loss	\$ (59,734)	\$ (66,357)
Loss per basic and diluted common share:		
Basic and diluted net loss per common share	\$ (0.44)	\$ (0.64)
Basic and diluted weighted average common shares outstanding	138,205	104,246

See accompanying Notes to Unaudited Consolidated Financial Statements.

CLOVIS ONCOLOGY, INC.
Consolidated Balance Sheets
(In thousands, except for share amounts)

	March 31, 2022 (Unaudited)	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 122,241	\$ 143,428
Accounts receivable, net	27,296	26,868
Inventories, net	14,504	13,688
Prepaid research and development expenses	4,928	2,397
Other current assets	16,566	11,706
Total current assets	185,535	198,087
Inventories	106,118	109,848
Property and equipment, net	5,987	6,554
Right-of-use assets, net	18,675	19,109
Intangible assets, net	59,029	60,371
Goodwill	63,074	63,074
Other assets	13,111	15,790
Total assets	<u>\$ 451,529</u>	<u>\$ 472,833</u>
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	\$ 22,332	\$ 27,308
Accrued research and development expenses	34,314	35,121
Lease liabilities	3,556	3,414
Borrowings under financing agreement	17,000	8,500
Other accrued expenses	44,630	50,871
Total current liabilities	121,832	125,214
Long-term lease liabilities - less current portion	19,004	19,731
Convertible senior notes	437,284	436,772
Borrowings under financing agreement - less current portion	176,715	169,956
Total liabilities	754,835	751,673
Commitments and contingencies (Note 14)		
Stockholders' equity:		
Preferred stock, par value \$0.001 per share; 10,000,000 shares authorized, no shares issued and outstanding at March 31, 2022 and December 31, 2021	—	—
Common stock, \$0.001 par value per share, 200,000,000 shares authorized at March 31, 2022 and December 31, 2021, respectively; 143,869,226 and 129,109,543 shares issued and outstanding at March 31, 2022 and December 31, 2021, respectively	144	129
Additional paid-in capital	2,676,965	2,641,712
Accumulated other comprehensive loss	(42,995)	(43,430)
Accumulated deficit	(2,937,420)	(2,877,251)
Total stockholders' deficit	(303,306)	(278,840)
Total liabilities and stockholders' deficit	<u>\$ 451,529</u>	<u>\$ 472,833</u>

See accompanying Notes to Unaudited Consolidated Financial Statements.

CLOVIS ONCOLOGY, INC.
Consolidated Statements of Stockholders' Equity (Deficit)
(Unaudited)

	Common Stock		Additional	Accumulated	Accumulated	
	Shares	Amount	Paid-In	Other	Deficit	Total
			Capital	Comprehensive		
			(in thousands, except for share amounts)			
January 1, 2022	129,109,543	\$ 129	\$ 2,641,712	\$ (43,430)	\$ (2,877,251)	\$ (278,840)
Issuance of common stock, net of issuance costs	13,870,410	14	28,622	—	—	28,636
Issuance of common stock from vesting of restricted stock units	889,273	1	(1)	—	—	—
Share-based compensation expense	—	—	6,632	—	—	6,632
Foreign currency translation adjustments	—	—	—	435	—	435
Net loss	—	—	—	—	(60,169)	(60,169)
March 31, 2022	143,869,226	144	2,676,965	(42,995)	(2,937,420)	(303,306)

	Common Stock		Additional	Accumulated	Accumulated	
	Shares	Amount	Paid-In	Other	Deficit	Total
			Capital	Comprehensive		
			(in thousands, except for share amounts)			
January 1, 2021	103,699,109	\$ 104	\$ 2,498,179	\$ (44,304)	\$ (2,612,727)	\$ (158,748)
Exercise of stock options	5,609	—	27	—	—	27
Issuance of common stock from vesting of restricted stock units	853,239	1	(1)	—	—	—
Share-based compensation expense	—	—	4,039	—	—	4,039
Foreign currency translation adjustments	—	—	—	(80)	—	(80)
Net loss	—	—	—	—	(66,277)	(66,277)
March 31, 2021	104,557,957	105	2,502,244	(44,384)	(2,679,004)	(221,039)

See accompanying Notes to Unaudited Consolidated Financial Statements

CLOVIS ONCOLOGY, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)
(In thousands)

	<u>Three months ended March 31,</u>	
	<u>2022</u>	<u>2021</u>
Operating activities		
Net loss	\$ (60,169)	\$ (66,277)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation expense	6,632	4,039
Depreciation and amortization	1,923	2,241
Amortization of debt issuance costs	558	639
Other	368	877
Changes in operating assets and liabilities:		
Accounts receivable	(765)	4,732
Inventory	3,685	3,665
Prepaid and accrued research and development expenses	(1,323)	2,125
Other operating assets and liabilities	(4,879)	(5,005)
Accounts payable	(4,818)	(6,290)
Other accrued expenses	293	(2,636)
Net cash used in operating activities	(58,495)	(61,890)
Investing activities		
Purchases of property and equipment	(62)	(118)
Net cash used in investing activities	(62)	(118)
Financing activities		
Proceeds from sale of common stock, net of issuance costs	28,636	—
Proceeds from borrowings under financing agreement	9,221	13,802
Proceeds from the exercise of stock options and employee stock purchases	—	27
Payments on finance leases	—	(386)
Payments on other long-term liabilities	—	(67)
Net cash provided by financing activities	37,857	13,376
Effect of exchange rate changes on cash and cash equivalents	(487)	(675)
Decrease in cash and cash equivalents	(21,187)	(49,307)
Cash and cash equivalents at beginning of period	143,428	240,229
Cash and cash equivalents at end of period	<u>\$ 122,241</u>	<u>\$ 190,922</u>
Supplemental disclosure of cash flow information:		
Cash paid for interest	\$ 3,224	\$ 3,292
Non-cash investing and financing activities:		
Vesting of restricted stock units	\$ 1,763	\$ 7,129

See accompanying Notes to Unaudited Consolidated Financial Statements.

CLOVIS ONCOLOGY, INC.

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

1. Nature of Business

Clovis Oncology, Inc. (together with its consolidated subsidiaries, the “Company”, “Clovis”, “we”, “our”, “us”) is 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. We have and intend to continue to license or acquire rights to oncology compounds in all stages of development. In exchange for the right to develop and commercialize these compounds, we generally expect to provide the licensor with a combination of upfront payments, milestone payments and royalties on future sales. In addition, we generally expect to assume the responsibility for future drug development and commercialization costs. We currently operate in two segments. Since inception, our operations have consisted primarily of developing in-licensed compounds, evaluating new product acquisition candidates and general corporate activities and since 2016 we have also marketed and sold products.

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. Rubraca received a second approval from the FDA in April 2018 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. 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 and selected for therapy based on an FDA-approved companion diagnostic for Rubraca. The FDA approved this indication under accelerated approval based on objective response rate and duration of response data from the TRITON2 clinical trial. 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 as well as the basis for us to seek a potential second-line label expansion. We anticipate the initial data readout from TRITON3 in the third quarter of 2022.

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 now authorized in Europe for certain patients in the recurrent ovarian cancer maintenance setting regardless of their *BRCA* mutation status. Following successful reimbursement negotiations, Rubraca is marketed in each of Germany, United Kingdom, Italy, France, Spain, the Netherlands and Switzerland.

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 the ATHENA Phase 3 study 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.

[Table of Contents](#)

On March 31, 2022, we announced positive top-line data from the monotherapy portion of the ATHENA (GOG 3020/ENGOT-ov45) trial (ATHENA-MONO) demonstrating that Rubraca as maintenance treatment successfully achieved the primary endpoint of significantly improved investigator-assessed progression-free survival (“PFS”) compared with placebo. Benefit was observed in both primary efficacy analyses of newly-diagnosed patients with advanced ovarian cancer following successful treatment with platinum-based chemotherapy: those who had homologous recombination deficiency (HRD-positive), including deleterious *BRCA* mutations, as well as all patients randomized in the trial (overall intent-to-treat population (“ITT”)). Benefit in PFS was also seen in the exploratory subgroups of patients with *BRCA* mutant (*BRCAm*) tumors, *BRCA* wild type HRD-negative and *BRCA* wild type HRD-positive and in patients with unknown biomarker status. The safety of Rubraca observed in the ATHENA-MONO study was consistent with both the US and European labels.

The timing for Phase 3 data readouts from each of TRITON3 and ATHENA-COMBO is contingent upon the occurrence of the protocol-specified PFS events, and timing estimates are based on event-based projections.

We hold worldwide rights to Rubraca.

FAP-2286 is our initial product candidate to emerge from our targeted radionuclide collaboration with 3B Pharmaceuticals GmbH (“3BP”). FAP-2286 is a peptide-targeted radionuclide therapy (“PRT”) and imaging agent targeting fibroblast activation protein (“FAP”). PRT uses cancer cell-targeting peptides to deliver radiation-emitting radionuclides specifically to tumors. Following the clearance by the FDA of two INDs submitted in December 2020 to support the use of FAP-2286 as an imaging and treatment agent, we initiated the phase 1 portion of the LuMIERE clinical study in June 2021. LuMIERE is a phase 1/2 study of FAP-2286 labeled with lutetium-177 (¹⁷⁷Lu-FAP-2286) evaluating the compound in patients with advanced solid tumors to determine the dose, schedule, and tolerability of FAP-2286 as a therapeutic agent with expansion cohorts planned in multiple tumor types as part of a global development program. We are currently enrolling patients in the third dose cohort, and we plan to initiate phase 2 expansion cohorts during the fourth quarter of 2022. FAP-2286 labeled with gallium-68 (⁶⁸Ga-FAP-2286) is being utilized to identify tumors that contain FAP for treatment in this study.

We plan to present phase 1 clinical data from LuMIERE in an oral presentation at the Society of Nuclear Medicine & Molecular Imaging (“SNMMI”) Annual Meeting in June 2022. During 2022, we also anticipate additional presentations of non-clinical data for FAP-2286 and the launch of our combination study program to explore FAP-2286 in combination with other oncology compounds, and in 2023, a potential IND filing of FAP-2286 linked to a FAP-targeted alpha-emitter PRT.

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 have global rights for any resulting product candidates.

Lucitanib, our 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 certain populations of patients with 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 phase 1b/2 LIO-1 study evaluated the combination of lucitanib and Opdivo in gynecologic cancers. Interim data from the non-clear cell ovarian cancer expansion cohort were presented at the American Society of Clinical Oncology (“ASCO”) 2021 and the initial efficacy data do not support further development in non-clear cell ovarian cancer. The remaining three cohorts, which include non-clear cell endometrial, cervical and clear-cell ovarian and endometrial cancers, showed sufficient responses in stage one of each of the cohorts to advance to stage 2. The data from the cervical cohort was presented at the Society of Gynecologic Oncology (“SGO”) 2022 Annual Meeting on Women’s Cancer in March 2022 and represent encouraging data in this subset of gynecological cancers. Phase 2 LIO-1 efficacy and safety data results across the different types of gynecologic cancers will also be presented at the ASCO 2022 Annual Meeting in June. However, given the competing priorities, including development of FAP-2286, we have determined that we will not pursue further development of lucitanib in gynecological cancers at this time.

We hold the global (excluding China) development and commercialization rights for lucitanib.

Going Concern and Management Plans

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 even with Rubraca now generating revenues. Rubraca revenues have not been consistent in prior quarters, mainly as a result of the impact of COVID-19 and competition from other products on the market, including the impact on second-line maintenance that may result from an increase in first-line maintenance treatment of ovarian cancer, which has made forecasting revenues difficult. In addition to factors described, future Rubraca revenues will depend, in part, on the timing and extent of any recovery from the impacts of COVID-19, with any such recovery of revenues expected to take several quarters to have a meaningful impact on our financial results. We do not expect to generate a sufficient amount of Rubraca revenues to finance our cash requirements in the foreseeable future, and which we may never be able to do in sufficient amounts. We require significant cash resources to execute our business plans and we will need to raise additional cash to continue to fund our operating plan. We cannot be certain that additional funding will be available on acceptable terms, or at all, especially given that we will need our stockholders to approve an amendment to our certificate of incorporation to increase the number of shares of common stock that we are authorized to issue. The aforementioned factors, which are largely outside of our control, raise substantial doubt about our ability to continue as a going concern within one year from the date of filing of this quarterly report.

In the near term, we believe there is some flexibility within our operating plan, particularly with managing certain discretionary expenses, to adjust to variations in our expected Rubraca revenues and the availability and timing of potential sources of financings to meet our working capital requirements. However, based on our current cash, cash equivalents and liquidity available under our ATHENA clinical financing agreement, together with current estimates for revenues generated by sales of Rubraca, we will need to raise additional capital in the near term in order to fund our operating plan for the next 12 months and to continue as a going concern. Our ability to obtain additional financing (including through collaborating and licensing arrangements) will depend on a number of factors, including, among others, our ability to generate positive data from our clinical studies and to obtain label expansions through regulatory approvals, the condition of the capital markets and the other risks described under Risk Factors in our Annual Report on Form 10-K for the year ended December 31, 2021 ("2021 Form 10-K"). We expect to finance our operating plan through a combination of public or private equity or debt offerings, collaborations, strategic alliances and other similar licensing arrangements in both the short term and the long term.

We currently have capacity to issue approximately \$16.5 million of additional shares of common stock under our previously established ATM Program, assuming the remaining authorized but unissued shares of our common stock are sold at an offering price of \$2.03 per share, the closing price of our common stock on the Nasdaq Global Select Market on May 2, 2022. There can be no assurance that we will be able to sell any shares of our common stock under the ATM Program or regarding the price at which we will be able to sell any such shares, and any sales of shares of our common stock under the ATM Program may be at prices that result in additional dilution to existing stockholders of the Company.

We will not be able to raise sufficient additional capital through public or private equity offerings (or offerings of securities convertible into our equity securities) until our stockholders approve a proposed reverse stock split of our common stock at our 2022 Annual Meeting of Stockholders, which, when implemented by our board of directors, will have the effect of increasing the number of authorized but unissued and unreserved shares of our common stock that are available to be issued. We cannot be certain that our stockholders will approve such a proposal. In the event our stockholders do not approve such a proposal, our ability to raise capital to fund our operations beyond the next 12 months will be significantly limited.

In light of the uncertainty about our ability to raise sufficient capital through potential equity offerings (or offerings of securities convertible into equity securities), we are considering other sources of funding, potentially through incurring further indebtedness or entering into strategic partnerships or licensing arrangements for one or more of our products or product candidates in which we may have to give up certain of our future commercialization or other rights to obtain interim funding. We are exploring various partnership and licensing arrangements for our products and product candidates outside the U.S., but those will largely depend on our ability to generate positive data from our

clinical studies and to obtain label expansions through regulatory approvals. We cannot be certain that such other sources of funding will be available to us or on acceptable terms or in sufficient amounts to meet our requirements.

In the event that we are unable to raise sufficient additional capital, which is dependent on factors outside of our control, we will need to cut expenses further, including potentially delaying, scaling back or eliminating certain of our pipeline development programs, and undertake a more significant restructuring of our operations, in order to continue as a going concern and fund our committed obligations and working capital requirements. There can be no assurances that we will be able to achieve such a restructuring or that such a restructuring will be successful over the long term to allow us to fund our requirements and our plan to invest sufficient amounts to fund the development of FAP-2286 to its potential.

Basis of Presentation

All financial information presented includes the accounts of the Company and its wholly-owned subsidiaries. All significant intercompany balances and transactions have been eliminated in consolidation.

The unaudited financial statements of Clovis Oncology, Inc. included herein reflect all adjustments that, in the opinion of management, are necessary to fairly state our financial position, results of operations and cash flows for the periods presented herein. Interim results may not be indicative of the results that may be expected for the full year. Certain information and footnote disclosures normally included in audited financial statements prepared in accordance with accounting principles generally accepted in the United States (“U.S. GAAP”) have been condensed or omitted pursuant to the rules and regulations of the U.S. Securities and Exchange Commission (“SEC”). These financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto which are included in our 2021 Form 10-K for a broader discussion of our business and the opportunities and risks inherent in such business.

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.

2. Summary of Significant Accounting Policies

Recently Adopted Accounting Standards

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 adopted this guidance on January 1, 2022 and there was no material impact on our consolidated financial statements and related disclosures.

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. 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 GPOs, 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 generally range from 30 to 60 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 is considered short dated 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.

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.

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 the 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 five 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 production train at Lonza are included in Other Operating Expenses on 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.

Segment Information

We have two operating and reportable segments, U.S. and ex-U.S., based on product revenue by geographic areas. We designated our reporting segments based on the internal reporting used by the Chief Operating Decision Maker

[Table of Contents](#)

(“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.

Our other significant accounting policies are described in Note 2, *Summary of Significant Accounting Policies* of the Notes to the Consolidated Financial Statements included in our 2021 Form 10-K.

3. Financial Instruments and 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. We do not have Level 2 assets or 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 and liabilities that were measured at fair value on a recurring basis (in thousands):

	<u>Balance</u>	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>
March 31, 2022				
Assets:				
Money market investments	\$ 72,941	\$ 72,941	\$ —	\$ —
Total assets at fair value	<u>\$ 72,941</u>	<u>\$ 72,941</u>	<u>\$ —</u>	<u>\$ —</u>
December 31, 2021				
Assets:				
Money market investments	\$ 72,934	\$ 72,934	\$ —	\$ —
Total assets at fair value	<u>\$ 72,934</u>	<u>\$ 72,934</u>	<u>\$ —</u>	<u>\$ —</u>

There were no liabilities that were measured at fair value on a recurring basis as of March 31, 2022 and December 31, 2021.

Financial instruments not recorded at fair value include our convertible senior notes. At March 31, 2022, the carrying amount of the 2024 Notes (2019 Issuance) was \$84.5 million, which represents the aggregate principal amount net of remaining debt issuance costs, and the fair value was \$57.5 million. At March 31, 2022, the carrying amount of the 2024 Notes (2020 Issuance) was \$56.9 million, which represents the aggregate principal amount net of remaining debt issuance costs, and the fair value was \$44.0 million. At March 31, 2022, the carrying amount of the 2025 Notes was \$295.9 million, which represents the aggregate principal amount net of remaining debt issuance costs, and the fair value was \$205.1 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 9, *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.

4. Inventories

The following table presents inventories as of March 31, 2022 and December 31, 2021 (in thousands):

	March 31, 2022	December 31, 2021
Work-in-process	\$ 83,462	\$ 85,084
Finished goods, net	37,160	38,452
Total inventories	<u>\$ 120,622</u>	<u>\$ 123,536</u>

5. Other Current Assets

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

	March 31, 2022	December 31, 2021
Prepaid insurance	\$ 3,772	\$ 794
Prepaid IT	593	769
Prepaid variable considerations	1,483	1,336
Prepaid expenses - other	3,474	1,936
Value-added tax ("VAT") receivable	5,519	4,307
Receivable - other	1,661	2,499
Other	64	65
Total	<u>\$ 16,566</u>	<u>\$ 11,706</u>

6. Intangible Assets and Goodwill

Intangible assets related to capitalized milestones under license agreements consisted of the following (in thousands):

	March 31, 2022	December 31, 2021
Intangible asset - milestones	\$ 79,850	\$ 79,850
Accumulated amortization	(20,821)	(19,479)
Total intangible asset, net	<u>\$ 59,029</u>	<u>\$ 60,371</u>

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 \$1.3 million related to capitalized milestone payments during the three months ended March 31, 2022 and March 31, 2021. Amortization expense is included in cost of sales – intangible asset amortization on the Consolidated Statements of Operations and Comprehensive Loss.

Estimated future amortization expense associated with intangibles is expected to be as follows (in thousands):

2022 (remaining nine months)	\$ 4,028
2023	5,371
2024	5,371
2025	5,371
2026	5,371
Thereafter	33,517
	<u>\$ 59,029</u>

7. Other Accrued Expenses

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

	March 31, 2022	December 31, 2021
Accrued personnel costs	\$ 10,459	\$ 15,714
Accrued interest payable for convertible senior notes	2,609	3,283
Income tax payable	871	1,579
Accrued corporate legal fees and professional services	185	141
Accrued royalties	5,226	5,463
Accrued variable considerations	17,907	17,211
Accrued legal settlement loss	2,325	2,325
Accrued expenses - other	5,048	5,155
Total	<u>\$ 44,630</u>	<u>\$ 50,871</u>

8. Leases

At the inception of an arrangement, we determine whether the arrangement is or contains a lease based on the unique facts and circumstances. 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.

Prior to June 30, 2021, we had a finance lease and operating lease for certain equipment at the production train at Lonza, our non-exclusive manufacturer of the Rubraca API. Pursuant to the terms of Amendment 2 discussed in Note

[Table of Contents](#)

14, *Commitments and Contingencies*, we derecognized the lease components recognized under the original agreement with Lonza. This includes the operating lease liabilities and right-of-use (“ROU”) assets, finance lease liabilities and ROU assets and leasehold improvement assets and liability.

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

	Three months ended March 31,		Three months ended March 31,	
	2022		2021	
Lease cost				
Finance lease cost:				
Amortization of right-of-use assets	\$	—	\$	474
Interest on lease liabilities		—		185
Operating lease cost		1,215		1,253
Short-term lease cost		77		80
Variable lease cost		639		523
Total lease cost	\$	1,931	\$	2,515
Operating cash flows from finance leases	\$	—	\$	185
Operating cash flows from operating leases	\$	1,215	\$	1,253
Financing cash flows from finance leases	\$	—	\$	386

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

	March 31, 2022	March 31, 2021
Weighted-average remaining lease term (years)		
Operating leases	5.6	6.4
Finance leases	N/A	4.8
Weighted-average discount rate		
Operating leases	8%	8%
Finance leases	N/A	8%

Future minimum commitments due under these lease agreements as of March 31, 2022 are as follows (in thousands):

	Operating Leases
2022 (remaining nine months)	4,076
2023	4,906
2024	4,650
2025	4,805
2026	4,934
Thereafter	4,899
Present value adjustment	(5,710)
Present value of lease payments	\$ 22,560

9. Debt

The following is a summary of our convertible senior notes at March 31, 2022 and December 31, 2021 (principal amount in thousands):

	Principal Amount March 31, 2022	Principal Amount December 31, 2021	Interest Rate	Maturity Date	Conversion rate per \$1,000 principal amount (shares)
2024 Notes (2019 Issuance)	85,782	85,782	4.50%	August 1, 2024	137.2213
2024 Notes (2020 Issuance)	57,500	57,500	4.50%	August 1, 2024	160.3334
2025 Notes	300,000	300,000	1.25%	May 1, 2025	13.1278
Total	443,282	443,282			
Unamortized debt issuance costs	(5,998)	(6,510)			
Convertible senior notes	<u>\$ 437,284</u>	<u>\$ 436,772</u>			

Our convertible senior notes are governed by the terms of their respective indentures between the Company, as issuer, and The Bank of New York Mellon Trust Company, N.A., as trustee. Holders may convert all or any portion of the senior 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 as noted above. The conversion rate is subject to adjustment upon the occurrence of certain events described in the indentures.

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

The senior notes rank senior in right of payment to any of our indebtedness that is expressly subordinated in right of payment to the senior 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.

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 convertible senior notes using the effective interest method.

Maturities of our convertible notes consisted of the following as of March 31, 2022 (in thousands):

2022 (remaining nine months)	\$ —
2023	—
2024	143,282
2025	300,000
2026	—
Thereafter	—
	<u>443,282</u>
Less debt issuance costs	(5,998)
Current portion	—
Long-term portion	<u>\$ 437,284</u>

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 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 in 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 completed enrollment during the second quarter of 2020, and top-line data from

[Table of Contents](#)

the ATHENA-MONO study was announced during the first quarter of 2022. Top-line data readout from the ATHENA-COMBO study is anticipated in the first quarter of 2023, contingent upon the occurrence of the protocol-specified PFS events.

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, 30 days after the end of the quarter, 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”). We expect to make the first payment by October 30, 2022, unless one of the other events occurs prior to September 30, 2022.

- 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 on 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 \$8.9 million and \$14.2 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. Quarterly payments are due within 30 days after each calendar quarter. Our first quarterly payment is estimated to be due on October 30, 2022, 30 days after the Repayment Start Date.

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.

[Table of Contents](#)

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) (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.

If an event of default were to occur under the Financing Agreement, or if an event of default were to be determined to be probable, we would classify all our obligations that become due and payable thereunder as current liabilities.

For the three months ended March 31, 2022, we used an effective interest rate of 13.7%, which is based on the estimate of remaining cash flows. 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.

Amounts reflected on the balance sheet and in the table below in respect of the Financing Agreement represent the maximum amounts payable by us to the lenders during the periods indicated. Payments due under our Financing Agreement are based, for the most part, on net sales of Rubraca by us and our licensees. Rubraca sales have not been consistent historically and sales in future periods are difficult to predict. Therefore, expected maturities of our Financing Agreement as of March 31, 2022 (in thousands) are shown below based on the quarterly capped amount described above and certain other mandatory payments set forth in the Financing Agreement. Actual payments may fluctuate and may be less than the amounts reflected in the table below. See above for a full description of the Financing Agreement and our payment obligations thereunder.

2022 (remaining nine months)	\$	8,500
2023		34,000
2024		34,000
2025		79,939
2026		34,000
Thereafter		122,438
		<u>312,877</u>
Less debt issuance costs		(1,232)
Less unrecognized interest		(117,930)
Current portion		(17,000)
Long-term portion	\$	<u>176,715</u>

The following table sets forth total interest expense recognized during the three months ended March 31, 2022 and 2021 (in thousands):

	Three months ended March 31,	
	2022	2021
Interest on convertible notes	\$ 2,549	\$ 2,977
Amortization of debt issuance costs	558	639
Interest on finance lease	—	185
Interest on borrowings under financing agreement	5,993	4,210
Other interest	—	26
Total interest expense	<u>\$ 9,100</u>	<u>\$ 8,037</u>

10. Stockholders' Equity

Common Stock

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.

On May 17, 2021, we entered into a distribution agreement (the "Distribution Agreement") with J.P. Morgan Securities LLC and BofA Securities, Inc., as agents (the "Agents"), pursuant to which we may offer and sell, from time to time, through the Agents, shares of our common stock having an aggregate offering price of up to \$75.0 million in transactions that are deemed to be "at the market" offerings as defined in Rule 415(a)(4) under the Securities Act of 1933, as amended, including sales made by means of ordinary brokers' transactions, including directly on the Nasdaq Global Select Market or into any other existing trading market for the Shares, or sales made to or through a market maker, in block transactions or by any other method permitted by law, including negotiated transactions. Sales may be made at market prices prevailing at the time of a sale or at prices related to prevailing market prices or at negotiated prices. During the period between May 18, 2021 and June 9, 2021, we sold an aggregate of 13,492,231 shares of our common stock under the Distribution Agreement resulting gross proceeds of \$75.0 million and net proceeds to us of \$72.5 million, after deducting commissions and offering expenses, effectively closing out sales we may make pursuant to the Distribution Agreement. We have used and intend to use the net proceeds of this offering for general corporate purposes, including funding of our development programs, sales and marketing expenses associated with Rubraca, repayment, repurchase or refinance of our debt obligations, payment of milestones pursuant to our license agreements, general and administrative expenses, acquisition or licensing of additional product candidates or businesses and working capital.

On August 16, 2021, we entered into a distribution agreement (the "August Distribution Agreement") with the Agents, pursuant to which we may offer and sell, from time to time, through the Agents, shares of our common stock, having an aggregate offering price of up to \$125.0 million in transactions that are deemed to be "at the market" offerings as defined in Rule 415(a)(4) under the Securities Act of 1933, as amended, including sales made by means of ordinary brokers' transactions, including directly on the Nasdaq Global Select Market or into any other existing trading market for the shares, or sales made to or through a market maker, in block transactions or by any other method permitted by law, including privately negotiated transactions. Sales may be made at market prices prevailing at the time of a sale or at prices related to prevailing market prices or at negotiated prices. During the period between August 17, 2021 and September 15, 2021, we sold an aggregate of 9,379,976 shares of our common stock under the August Distribution Agreement resulting in gross proceeds of \$43.0 million and net proceeds to us of \$41.5 million, after deducting commissions and offering expenses. During the period between November 5, 2021 and November 16, 2021, we sold an aggregate of 731,292 shares of our common stock resulting in gross proceeds of \$3.1 million and net proceeds to us of \$3.0 million, after deducting commissions and offering expenses.

During the period between January 18, 2022 and March 3, 2022, we sold an aggregate of 13,870,410 shares of our common stock resulting in gross proceeds of \$29.8 million and net proceeds to us of \$28.6 million, after deducting commissions and offering expenses.

We have used and intend to use the net proceeds of this offering for general corporate purposes, including funding of our development programs, sales and marketing expenses associated with Rubraca, repayment, repurchase or refinance of our debt obligations, payment of milestones pursuant to our license agreements, general and administrative expenses, acquisition or licensing of additional product candidates or businesses and working capital.

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 for the three months ended March 31, 2022 and 2021, as follows (in thousands):

	Foreign Currency Translation Adjustments		Unrealized Losses		Total Accumulated Other Comprehensive Loss	
	2022	2021	2022	2021	2022	2021
Balance at Jan 1,	\$ (43,291)	\$ (44,165)	\$ (139)	\$ (139)	\$ (43,430)	\$ (44,304)
Other comprehensive income	435	(80)	—	—	435	(80)
Total before tax	(42,856)	(44,245)	(139)	(139)	(42,995)	(44,384)
Tax effect	—	—	—	—	—	—
Balance at March 31,	<u>\$ (42,856)</u>	<u>\$ (44,245)</u>	<u>\$ (139)</u>	<u>\$ (139)</u>	<u>\$ (42,995)</u>	<u>\$ (44,384)</u>

There were no reclassifications out of accumulated other comprehensive loss in each of the three months ended March 30, 2022 and 2021.

11. Share-Based Compensation

Share-based compensation expense for all equity-based programs, including stock options, restricted stock units and the employee stock purchase plan, for the three months ended March 31, 2022 and 2021 was recognized in the accompanying Consolidated Statements of Operations and Comprehensive Loss as follows (in thousands):

	Three months ended March 31,	
	2022	2021
Research and development	\$ 3,229	\$ 2,876
Selling, general and administrative	3,403	1,163
Total share-based compensation expense	<u>\$ 6,632</u>	<u>\$ 4,039</u>

We did not recognize a tax benefit related to share-based compensation expense during the three months ended March 31, 2022 and 2021, as we maintain net operating loss carryforwards and have established a valuation allowance against the entire net deferred tax asset as of March 31, 2022 and 2021.

Stock Options

The following table summarizes the activity relating to our options to purchase common stock for the three months ended March 31, 2022:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (Thousands)
Outstanding at December 31, 2021	7,010,039	\$ 33.36		
Granted	516,250	1.96		
Exercised	—	—		
Forfeited	(342,217)	26.30		
Outstanding at March 31, 2022	<u>7,184,072</u>	\$ 31.44	5.7	\$ 35
Vested and expected to vest at March 31, 2022	<u>6,963,967</u>	\$ 32.29	5.6	\$ 28
Vested and exercisable at March 31, 2022	<u>5,384,051</u>	\$ 39.88	4.6	\$ —

The aggregate intrinsic value in the table above represents the pretax intrinsic value, based on our closing stock price of \$2.02 as of March 31, 2022, 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.

[Table of Contents](#)

The following table summarizes information about our stock options as of and for the three months ended March 31, 2022 and 2021 (in thousands, except per share amounts):

	Three months ended March 31,	
	2022	2021
Weighted-average grant date fair value per share	\$ 1.47	\$ 4.94
Intrinsic value of options exercised	\$ —	\$ 14
Cash received from stock option exercises	\$ —	\$ 27

As of March 31, 2022, the unrecognized share-based compensation expense related to unvested options, adjusted for expected forfeitures, was \$6.2 million and the estimated weighted-average remaining vesting period was 1.7 years.

Restricted Stock

The following table summarizes the activity relating to our unvested restricted stock units (“RSUs”) for the three months ended March 31, 2022:

	Number of Units	Weighted Average Grant Date Fair Value
Unvested at December 31, 2021	3,683,422	\$ 8.36
Granted	2,749,649	1.95
Vested	(889,273)	8.43
Forfeited	(70,411)	6.96
Unvested at March 31, 2022	<u>5,473,387</u>	\$ 5.15
Expected to vest after March 31, 2022	<u>4,537,263</u>	\$ 5.47

As of March 31, 2022, the unrecognized share-based compensation expense related to unvested RSUs, adjusted for expected forfeitures, was \$25.6 million and the estimated weighted-average remaining vesting period was 2.0 years.

12. License Agreements

Rucaparib

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.

During 2016 through 2020, we paid Pfizer a total of \$82.5 million in milestone payments related to the FDA and European Commission approvals received for Rubraca. 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.

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.

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. In April 2021, we made a milestone payment to 3BP under the license and collaboration agreement of \$2.2 million as a result of the FDA's acceptance of the IND for the treatment agent. In September 2021, we made a \$3.3 million milestone payment to 3BP under the license and collaboration agreement.

In February 2020, we finalized the terms of a drug discovery collaboration agreement with 3BP to identify up to three additional, undisclosed targets for PTRT, 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.

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 Srl) 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.

13. 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):

	Three months ended March 31,	
	2022	2021
Common shares under stock incentive plans	5,971	5,719
Convertible senior notes	24,928	25,969
Total potential dilutive shares	30,899	31,688

14. Commitments and Contingencies

Royalty and License Fee Commitments

We have entered into certain license agreements, as identified in Note 12, *License Agreements*, with third parties that include the payment of development and regulatory milestones, as well as royalty payments, upon the achievement

of pre-established development, regulatory and commercial targets. Our payment obligation related to these license agreements is contingent upon the successful development, regulatory approval and commercialization of the licensed products. Due to the nature of these arrangements, the future potential payments are inherently uncertain, and accordingly, we only recognize payment obligations which are probable and estimable as of the balance sheet date.

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 manufacture the Rubraca active ingredient. We made scheduled capital program fee payments toward capital equipment and other costs associated with the construction of the 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 March 31, 2022, \$39.6 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, financial lease of equipment, purchase of leasehold improvements and prepaid 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.

On June 16, 2021, we entered into amendment no. 2 of the Agreement with Lonza (“Amendment 2”). Pursuant to the terms of Amendment 2, we paid Lonza \$1.1 million to repurpose the production train so that Lonza will be able to use the facility to manufacture other products for third parties in addition to API for Clovis. Lonza is guaranteeing a minimum percentage usage of this production train for third parties and Lonza would reduce our fixed facility fee starting in 2023 based on this minimum percentage usage. If Lonza is able to utilize greater than the minimum guaranteed percentage, it will increase the reduction to our fixed facility fee. We evaluated Amendment 2 and determined that we no longer have a lease with Lonza at June 30, 2021 because Amendment 2 modified the terms of the Agreement in that Lonza will use a portion of the production train for third parties. The Agreement no longer conveys the right to direct the use of the identified asset and Clovis no longer has the right to obtain substantially all the economic benefit from the asset. As a result, the arrangement is no longer in scope of ASC 842, “Leases”, resulting in the derecognition of the lease components recognized under the original agreement. This includes the operating lease liabilities and ROU assets, finance lease liabilities and ROU assets and leasehold improvement assets and liability.

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

In March 2017, two putative shareholders of the Company, Macalinao and McKenry (“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, 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 for rociletinib 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. Following supplementation of the complaint by Plaintiffs (the “Supplemental Derivative Complaint”) and additional briefing, the Court held oral arguments on the motion to dismiss on June 19, 2019.

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.

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. Pursuant to subsequent requests by the parties, Vice Chancellor Slights ultimately granted extensions of the stay through and 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.

Following certain discovery on January 7, 2022, the Plaintiffs, the Company and the SLC participated in a mediation, which resulted in the parties reaching an agreement in principle to settle the pending litigation. While the defendants continue to dispute the allegations, on March 4, 2022, the parties executed a stipulation and agreement of settlement to fully resolve the Consolidated Derivative Action without admitting any liability. The settlement is subject to, among other things, approval by the Court. As part of the settlement, the Company agreed to adopt certain corporate governance reforms, including, among other things, the election of one new independent director to the Clovis Board of Directors by the 2023 Annual Meeting of Stockholders and the creation of a management-level Disclosure Committee. Neither the Company nor any of the defendants would make a financial contribution towards the principal terms of the settlement. Moreover, under the terms of the agreement in principle, the Company agreed not to oppose or object to Plaintiffs’ application for an award of attorneys’ fees and expenses not to exceed \$2.325 million in the aggregate, which amount, as ultimately awarded by the Court, is payable by the Company and included in Other accrued expenses on the Consolidated Balance Sheets at March 31, 2022 and December 31, 2021.

On April 13, 2022, the SLC filed a brief in support of the settlement and Plaintiffs filed their opening brief in support of the settlement and award for attorneys’ fees and expenses. Pursuant to the Scheduling Order entered on March 10, 2022, any objections to the settlement were due on or before April 20, 2022, and no objections were received. On May 4, 2022, after a final hearing, the Delaware Chancery Court entered an order and final judgment approving the settlement. The judgment found that notice to the Company’s stockholders was adequate and sufficient, that the settlement is fair, reasonable and adequate in all respects, and releases claims on behalf of the Company’s stockholders that were brought or could have been brought in the Consolidated Derivative Action and forever bars and enjoins them from prosecuting such claims.

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

[Table of Contents](#)

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 oral hearing in the appeal is scheduled on December 8, 2022.

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. Clovis responded to the opposition notice in European Patent 3150610 by amending the claims to be directed to the use of rucaparib maleate in a method of inhibiting PARP activity or treating cancer. That is, the amended claims do not cover Rubraca. During an oral hearing that took place on November 18, 2021, European Patent 3150610 was revoked and the written decision of the European Patent Office was dated December 15, 2021. Clovis filed its appeal on April 20, 2022. During the appeal, the effect of the Opposition Division's decision is suspended, and the patent remains in force until a Technical Board of Appeals issues its own decision.

In Europe, regulatory exclusivity is available for ten years, plus one year for a new indication; therefore, we have regulatory exclusivity for Rubraca, including all forms of rucaparib, in Europe until 2028, and if the EMA approves a subsequent indication that brings significant clinical benefit in comparison with existing therapies, until 2029.

15. Segment Information

The following table presents information about our reportable segments for the three months ended March 31, 2022 and 2021 (in thousands):

	Three months ended March 31,					
	2022			2021		
	U.S.	Ex-U.S.	Total	U.S.	Ex-U.S.	Total
Product revenue	\$ 24,509	\$ 9,738	\$ 34,247	\$ 31,701	\$ 6,352	\$ 38,053
Operating expenses:						
Cost of sales - product	4,835	3,235	8,070	6,157	2,111	8,268
Cost of sales - intangible asset amortization	620	723	1,343	620	723	1,343
Research and development	40,465	1,785	42,250	50,830	1,975	52,805
Selling, general and administrative	23,919	5,294	29,213	24,321	5,620	29,941
Other operating expenses	3,730	—	3,730	3,707	—	3,707
Total expenses	73,569	11,037	84,606	85,635	10,429	96,064
Operating loss	\$ (49,060)	\$ (1,299)	(50,359)	\$ (53,934)	\$ (4,077)	(58,011)
Other income (expense):						
Interest expense			(9,100)			(8,037)
Foreign currency loss			(978)			(546)
Other income			148			183
Other income (expense), net			(9,930)			(8,400)
Loss before income taxes			(60,289)			(66,411)
Income tax (expense) benefit			120			134
Net loss			\$ (60,169)			\$ (66,277)

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Forward-Looking Information

This Quarterly Report on Form 10-Q 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 Quarterly Report on Form 10-Q 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, our ability to raise capital, 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 Quarterly Report on Form 10-Q 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 Quarterly Report on Form 10-Q or to reflect the occurrence of unanticipated events.

You should also read carefully the factors described in the “Risk Factors” in Part I, Item 1A in our most recent Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission (“SEC”) as supplemented by the risk factors set forth herein, as updated from time to time in our subsequent SEC filings, 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.

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, 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. Rubraca received a second approval from the FDA in April 2018 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. 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 and selected for therapy based on an FDA-approved companion diagnostic for Rubraca. The FDA approved this indication under accelerated approval based on objective response rate and duration of response data from the TRITON2 clinical trial. 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 as well as the basis for us to seek a potential second-line label expansion. We anticipate the initial data readout from TRITON3 in the third quarter of 2022.

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 now authorized in Europe for certain patients in the recurrent ovarian cancer maintenance setting regardless of their *BRCA* mutation status. Following successful reimbursement negotiations, Rubraca is marketed in each of Germany, United Kingdom, Italy, France, Spain, the Netherlands and Switzerland.

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 the ATHENA Phase 3 study as part of our ongoing clinical collaboration with Bristol Myers Squibb to evaluate its immunotherapy OPDIVO® (nivolumab) in combination with Rubraca.

On March 31, 2022, we announced positive top-line data from the monotherapy portion of the ATHENA (GOG 3020/ENGOT-ov45) trial (ATHENA-MONO) demonstrating that Rubraca as maintenance treatment successfully achieved the primary endpoint of significantly improved investigator-assessed PFS compared with placebo. Benefit was observed in both primary efficacy analyses of newly-diagnosed patients with advanced ovarian cancer following successful treatment with platinum-based chemotherapy: those who had homologous recombination deficiency (HRD-positive), including deleterious *BRCA* mutations, as well as all patients randomized in the trial (overall intent-to-treat population (“ITT”). Benefit in PFS was also seen in the exploratory subgroups of patients with *BRCA* mutant (*BRCAm*) tumors, *BRCA* wild type HRD-negative and *BRCA* wild type HRD-positive and in patients with unknown biomarker status. The safety of Rubraca observed in the ATHENA-MONO study was consistent with both the US and European labels.

Based on these results, we plan to prepare an sNDA for submission to the FDA and, subject to EMA agreement, a Type II variation for submission to the EMA for a first-line maintenance treatment indication for women with advanced ovarian cancer who have responded to first-line platinum-based chemotherapy. These approvals, if and when obtained, would provide the potential to reach a significantly two to three times larger patient population in an earlier line of therapy for ovarian cancer, in which Rubraca is currently approved in later-line indications.

We are currently evaluating the timing of our planned sNDA and Type II variation submissions. As suggested by the recent Oncologic Drugs Advisory Committee (“ODAC”) involving PI3K inhibitors, and our recent discussions with the FDA on May 3 and 4, 2022, the FDA is placing increasing emphasis on overall survival (“OS”) in oncology trials. Despite the fact that the ATHENA-MONO trial met its primary endpoint, and OS is a secondary endpoint, the FDA advised us that we should not submit the first line maintenance sNDA until OS data from the ATHENA-MONO trial are as much as 50% mature, and if we do choose to submit prior to that, we should expect the FDA to require a discussion at an ODAC meeting in connection with its review of such sNDA submission. This recommendation by the FDA was also influenced by their interpretation of the ARIEL4 survival data. Currently, the OS data are approximately 25% mature and our initial estimates suggest we would reach 50% maturity in approximately 2 years. We have not yet initiated discussions with EMA.

At the current maturity, the hazard ratios of the OS in ATHENA-MONO in the HRD-positive and ITT populations are 0.96 and 0.97, respectively. As reported in the *New England Journal of Medicine*, the OS in the PRIMA first line maintenance trial of niraparib was only 11% mature at the time it reported its primary endpoint. Hazard ratios in the HRD and ITT populations of PRIMA were 0.61 and 0.71, respectively. At the time the primary results of the PAOLA-1 first line maintenance trial of olaparib+bevacizumab primary endpoint were reported, OS was 26% mature and the HR in the ITT population was 1.01 as described in the European Public Assessment Report. As reported in the *New England Journal of Medicine*, at the time the SOLO-1 first line maintenance trial of olaparib primary endpoint was reported, OS was 21% mature and the HR in the ITT population was 0.95.

In light of this unexpected recommendation from the FDA, we are developing our strategy for next steps and potential timing of our sNDA submission in consultation with clinical advisors and outside counsel.

ATHENA is a double-blind, placebo-controlled, Phase 3 trial of rucaparib in first-line ovarian cancer maintenance treatment. It has two parts which are statistically independent. The top-line results reported were from the ATHENA-MONO part (rucaparib vs. placebo), with results from the ATHENA-COMBO part (rucaparib+nivolumab vs. rucaparib) expected in the first quarter of 2023 based on a slower than expected event count.

ATHENA-MONO enrolled 538 women with high-grade ovarian, fallopian tube, or primary peritoneal cancer. The primary efficacy analysis evaluated two prospectively defined molecular sub-groups in a step-down manner: 1) HRD-positive (inclusive of *BRCAm* tumors), and 2) all patients randomized (ITT) in ATHENA-MONO.

Following is a summary of the primary efficacy analyses by investigator review, the primary analysis of ATHENA-MONO.

Significant Improvement in PFS in the HRD-positive Patient Population

The rucaparib arm (n=185) successfully achieved statistical significance over the placebo arm (n=49) for the primary endpoint of PFS with a hazard ratio of 0.47 (95% CI: 0.31-0.72). The median PFS for the HRD-positive patient population treated with rucaparib was 28.7 months vs. 11.3 months among those who received placebo (p=0.0004).

Significant Improvement in PFS in All Patients Studied (ITT or all comers)

Rucaparib also showed statistical significance in all 538 patients randomized in the ATHENA-MONO comparison. The rucaparib arm (n=427) successfully achieved statistical significance over the placebo arm (n=111) for the primary endpoint of PFS with a hazard ratio of 0.52 (95% CI: 0.40-0.68). The median PFS for all patients enrolled in ATHENA-MONO and treated with rucaparib was 20.2 months vs. 9.2 months among those who received placebo (p<0.0001).

Benefit in PFS was also observed in the exploratory subgroups of patients with *BRCAm* tumors, those with *BRCA* wild-type, HRD-positive and HRD-negative tumors, and those whose biomarker status could not be determined.

Treatment Benefit in PFS Endpoint for Exploratory BRCA wild type HRD-negative Subgroup

The PFS endpoint in the exploratory subgroup of HRD-negative demonstrated a hazard ratio of 0.65 (95% CI: 0.45-0.95). The median PFS for these patients treated with rucaparib (n=189) was 12.1 months vs. 9.1 months for those who received placebo (n=49) (p=0.0284).

Treatment Benefit in PFS Endpoint for Exploratory BRCA wild type HRD-positive Subgroup

The PFS endpoint in the exploratory subgroup of HRD-positive demonstrated a hazard ratio of 0.58 (95% CI: 0.33-1.01). The median PFS for these patients treated with rucaparib (n=94) was 20.3 months vs. 9.2 months for those who received placebo (n=25) (p=0.0584).

Treatment Benefit in PFS Endpoint for Exploratory BRCAm Subgroup

The PFS endpoint in the exploratory subgroup of *BRCAm* demonstrated a hazard ratio of 0.40 (95% CI: 0.21-0.75). The median PFS for these patients treated with rucaparib (n=91) was Not Reached vs 14.7 months for those who received placebo (n=24) (p=0.0041). Results were consistent for the germline *BRCA* (n=68) and somatic *BRCA* (n=33) and unknown (n=14) populations.

Treatment Benefit in PFS Endpoint for Exploratory Biomarker Status Unknown Subgroup

The PFS endpoint in the exploratory subgroup of patients whose biomarker status could not be determined demonstrated a hazard ratio of 0.39 (95% CI: 0.20-0.78). The median PFS for these patients treated with rucaparib (n=53) was 17.5 months vs. 8.9 months for those who received placebo (n=13) (p=0.0068).

Summary of ATHENA-MONO Safety Data

The safety of Rubraca observed in ATHENA-MONO was consistent with both the current US and European labels. The most common (≥5%) treatment-emergent grade 3/4 adverse events (TEAEs) among all patients treated with rucaparib in the monotherapy portion of the ATHENA study were anemia/decreased hemoglobin (28.7%), neutropenia (14.6%), ALT/AST increase (10.6%), and thrombocytopenia (7.1%). The discontinuation rate for TEAEs was 11.8% for rucaparib-treated patients and 5.5% for the placebo arm. The rate of treatment-emergent myelodysplastic syndrome

(MDS)/acute myeloid leukemia (AML) in the rucaparib arm was 0.2%, and no patients on the placebo arm experienced treatment-emergent MDS/AML.

These data have been accepted for oral presentation at the ASCO Annual Meeting in June 2022.

About Ovarian Cancer

Ovarian cancer is the eighth leading cause of cancer-related death among women worldwide. In 2020, GLOBOCAN estimated 314,000 women received a new diagnosis of ovarian cancer and approximately 207,200 women died from ovarian cancer. According to the American Cancer Society, an estimated more than 19,000 women will be diagnosed with ovarian cancer in the United States and there will be an estimated nearly 13,000 deaths from ovarian cancer in 2022. According to GLOBOCAN, 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 NIH National Cancer Institute, more than 75% of women are diagnosed with ovarian cancer at an advanced stage.

Despite recent advances in the therapeutic landscape of newly diagnosed ovarian cancer, advanced ovarian cancer is still considered incurable for the majority of patients and the optimal treatment strategy has yet to be determined, according to a 2021 report in the *International Journal of Gynecological Cancer*. Although most respond initially to this treatment, 80% of patients with advanced ovarian cancer will have a recurrence and require subsequent therapies, according to a 2012 study published in the *Annals of Oncology*.

About Biomarkers in Ovarian Cancer

In the high-grade epithelial ovarian cancer setting, a patient's tumor can be classified based on the genetic biomarker status: those with homologous recombination deficiencies, or HRD-positive, include those with a mutation of the *BRCA* gene (*BRCAm*), inclusive of germline and somatic mutations of *BRCA*, which represent approximately 25 percent of patients, according to studies published in Cancer and Clinical Cancer Research, and those with a range of genetic abnormalities other than *BRCAm*, which result in other homologous recombination deficiencies that represent an additional estimated 25 percent of patients (HRD-positive, *BRCAwt*), according to a 2015 study published in Cancer Discovery; in addition, those whose test results show no deficiencies in homologous recombination repair (HRD-negative) represent the remaining approximate 50 percent of patients, according to a 2022 study published in Cancers. HRD-positive may also be referred to as HR-deficient, HRD, HRD+, HRd, or biomarker positive. HRD-negative may also be referred to as HR-proficient, HRD-, HRp, or biomarker negative.

The timing for Phase 3 data readouts from each of TRITON3 and ATHENA-COMBO is contingent upon the occurrence of the protocol-specified PFS events, and timing estimates are based on event-based projections.

We previously announced top line data from ARIEL4, a Phase 3 multicenter, randomized study of Rubraca versus chemotherapy, which enrolled 349 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.

In December 2020, we announced that Rubraca met the primary study endpoint of significantly improving InvPFS versus chemotherapy in the primary efficacy population with a hazard ratio ("HR") of 0.64 (p=0.001). The median PFS for the patients in the efficacy population treated with rucaparib was 7.4 months versus 5.7 months among those who received chemotherapy. Additionally, in the ITT population, the rucaparib arm achieved statistical significance over the chemotherapy arm for the primary endpoint of PFS with an HR of 0.67 (p=0.002). The median PFS for the patients in the ITT population treated with rucaparib was 7.4 months versus 5.7 months among those who received chemotherapy. Adverse events were consistent with the known safety profiles of Rubraca and 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. In December 2020, we also announced that an interim analysis of OS, a secondary endpoint in the study in which 51% of events had occurred in the intent-to-treat population, showed a trend toward an OS 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.

In April 2022, we read out the final OS data from ARIEL4, and in the ITT population, the HR is 1.313 with a nominal p of 0.0507. In the platinum resistant subgroup, the HR is 1.511 with a nominal p of 0.0251. In the platinum sensitive subgroup, the HR is 1.071 with a nominal p of 0.7455. We believe that ARIEL4 is the only randomized phase 3 trial of a PARP inhibitor in the advanced ovarian cancer treatment setting that has included both platinum resistant and platinum sensitive cohorts in its study design. The results of the randomized phase 3 trial of olaparib, SOLO-3, which included platinum sensitive patients only, were presented at the SGO 2022 Annual Meeting on Women's Cancer in March 2022, and reported a HR of 1.07, which is exactly the same as the HR of the platinum sensitive subgroup in ARIEL4. In ARIEL4, patients randomized to chemotherapy were allowed to cross over and receive Rubraca at the time of disease progression. 69% of the chemotherapy patients did cross over and overall, 90% of all ARIEL4 participants received Rubraca within the clinical trial. The survival outcomes in the rucaparib arm are within the expected range for standard of care therapy. Statistical analyses that adjust for the effect of crossover suggest no difference in OS outcomes between the two arms. Therefore, these data are not straightforward to interpret and highlight the complexity of OS analyses in clinical trials where crossover is a mandated component of study design. We expect to present the final ARIEL4 OS data at a medical meeting later this year.

Data from ARIEL4, including the interim OS data, were initially submitted to the EMA in August 2021 and the FDA in September 2021. In April 2022, we submitted the final OS data to both the FDA and the EMA. The EMA has begun an Article 20 referral procedure to review the ARIEL4 dataset, specifically to evaluate the risk:benefit of Rubraca in the third-line and later treatment indication. An Article 20 referral is a procedure used to resolve issues such as concerns around benefit-risk balance of a medicine or a class of medicines. In a referral, the EMA is requested to conduct a scientific assessment of a particular medicine or class of medicines on behalf of the European Union ("EU"). EMA has explicitly stated that there are no new safety concerns with Rubraca, and this review does not include the use of Rubraca as maintenance treatment following chemotherapy in the second-line setting. While the Article 20 procedure is ongoing, EMA has asked physicians not to start new patients on the treatment indication. We will distribute a Dear Healthcare Professional ("DHCP") letter in Europe communicating EMA's recommendation, which we expect to occur in May 2022. We expect the Article 20 procedure to last 3-6 months. We also plan to distribute a DHCP letter in the United States recommending that physicians not start new patients in the treatment indication.

On May 4, 2022 we had discussions with the FDA regarding the impact of the ARIEL4 OS data on the treatment indication in the Rubraca prescribing information, which may ultimately lead us to withdraw the treatment indication in the U.S., and possibly in Europe. The treatment indication currently represents a very small portion of our total sales in both the U.S. and Europe, and with respect to Europe, this indication is currently only reimbursed in Germany and the Netherlands. Although these regulatory actions do not affect our broader maintenance indication in the U.S. or Europe, we cannot be certain there will be no commercial impact on overall Rubraca sales.

We hold worldwide rights to Rubraca.

FAP-2286 is our initial product candidate to emerge from our targeted radionuclide collaboration with 3B Pharmaceuticals GmbH ("3BP"). FAP-2286 is a peptide-targeted radionuclide therapy ("PRT") and imaging agent targeting fibroblast activation protein ("FAP"). PRT uses cancer cell-targeting peptides to deliver radiation-emitting radionuclides specifically to tumors. Following the clearance by the FDA of two INDs submitted in December 2020 to support the use of FAP-2286 as an imaging and treatment agent, we initiated the phase 1 portion of the LuMIERE clinical study in June 2021. LuMIERE is a phase 1/2 study of FAP-2286 labeled with lutetium-177 (¹⁷⁷Lu-FAP-2286) evaluating the compound in patients with advanced solid tumors to determine the dose, schedule, and tolerability of FAP-2286 as a therapeutic agent with expansion cohorts planned in multiple tumor types as part of a global development program. We are currently enrolling patients in the third dose cohort, and we plan to initiate phase 2 expansion cohorts during the fourth quarter of 2022. FAP-2286 labeled with gallium-68 (⁶⁸Ga-FAP-2286) is being utilized to identify tumors that contain FAP for treatment in this study.

We plan to present phase 1 clinical data from LuMIERE in an oral presentation at the SNMMI 2022 Annual Meeting in June. During 2022, we also anticipate additional presentations of non-clinical data for FAP-2286 and the launch of our combination study program to explore FAP-2286 in combination with other oncology compounds, and in 2023, a potential IND filing of FAP-2286 linked to a FAP-targeted alpha-emitter PRT.

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 have global rights for any resulting product candidates.

Lucitanib, our 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 certain populations of patients with 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 phase 1b/2 LIO-1 study evaluated the combination of lucitanib and Opdivo in gynecologic cancers. Interim data from the non-clear cell ovarian cancer expansion cohort were presented at ASCO 2021 and the initial efficacy data do not support further development in non-clear cell ovarian cancer. The remaining three cohorts, which include non-clear cell endometrial, cervical and clear-cell ovarian and endometrial cancers, showed sufficient responses in stage one of each of the cohorts to advance to stage 2. The data from the cervical cohort was presented at the SGO 2022 Annual Meeting on Women’s Cancer in March 2022 and represent encouraging data in this subset of gynecological cancers. Phase 2 LIO-1 efficacy and safety data results across the different types of gynecologic cancers will also be presented at the ASCO 2022 Annual Meeting in June. However, given the competing priorities, including development of FAP-2286, we have determined that we will not pursue further development of lucitanib in gynecological cancers at this time.

We hold the global (excluding China) development and commercialization rights for lucitanib.

We have three key strategies on which we remain focused: first, we seek to drive Rubraca revenue growth; second, we intend to be an emerging leader in targeted radionuclide therapy, which includes the LuMIERE phase 1/2 clinical study of FAP-2286, which is the first peptide-targeted radionuclide therapy targeting FAP and is now enrolling; and third, we seek to achieve long-term financial stability.

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 three months ended March 31, 2022 and 2021, we have generated \$34.2 million and \$38.1 million, respectively, in product revenue related to sales of Rubraca.

We have never been profitable and, as of March 31, 2021, we had an accumulated deficit of \$2,937.4 million. We incurred net losses of \$60.2 million and \$66.3 million for the three months ended March 31, 2022 and 2021, respectively. We had cash and cash equivalents totaling \$122.2 million at March 31, 2022.

We have incurred significant net losses since inception and we expect operating losses and negative cash flows to continue for the foreseeable future.

License Agreements

Rucaparib

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.

During 2016 through 2020, we paid Pfizer a total of \$82.5 million in milestone payments related to the FDA and European Commission approvals received for Rubraca. 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.

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.

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. In April 2021, we made a milestone payment to 3BP under the license and collaboration agreement of \$2.2 million as a result of the FDA's acceptance of the IND for the treatment agent. In September 2021, we made a \$3.3 million milestone payment to 3BP under the license and collaboration agreement.

In February 2020, we finalized the terms of a drug discovery collaboration agreement with 3BP to identify up to three additional, undisclosed targets for PTRT, 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

[Table of Contents](#)

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.

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 Srl) 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.

Financial Operations Overview

Revenue

Product revenue is derived from sales of our product, Rubraca, in the United States and Europe. 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 healthcare providers. Separately, we have arrangements with certain payors and other third parties that provide for government-mandated and privately-negotiated rebates, chargebacks and other discounts. Revenue is recorded net of estimated rebates, chargebacks, discounts and other deductions as well as estimated product returns (collectively, “variable considerations”). Revenue from product sales are recognized when customers obtain control of our product, which occurs at a point in time, typically upon delivery to the customers. For further discussion of our revenue recognition policy, see Note 2, *Summary of Significant Accounting Policies* in the Revenue Recognition section.

In the three months ended March 31, 2022, we recorded product revenue of \$34.2 million related to sales of Rubraca. 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 three months ended March 31, 2022, the supply of this free drug was approximately 19% of the overall commercial supply or the equivalent of \$5.9 million in commercial value.

Our ability to generate product revenue for the quarter ended March 31, 2022 continued to be negatively affected by the COVID-19 pandemic, primarily due to the ongoing effect the pandemic has had on oncology treatment and practice, and in particular, in ovarian cancer, resulting in fewer diagnoses and fewer patients going to in-person office visits in the U.S. 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 occurred in an environment in which our field-based personnel have not been allowed to visit hospitals since as early as 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.

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 the FDA approval of Rubraca. Milestone payments are amortized on a straight-line basis over the estimated remaining patent life of Rubraca.

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 contract research organizations (“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 during the three months ended March 31, 2022 compared to the same period in the prior year. We expect research and development costs in the full year 2022 to be comparable to 2021.

We did not see material disruption to our clinical trials as a result of the COVID-19 pandemic for the three months ended March 31, 2022. However, we may see disruption during the remainder of 2022. For example, new patient

[Table of Contents](#)

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 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 (in thousands):

	Three months ended March 31,	
	2022	2021
Rucaparib Expenses		
Research and development	\$ 17,992	\$ 29,010
Rucaparib Total	17,992	29,010
FAP Expenses		
Research and development	2,452	2,214
FAP Total	2,452	2,214
Lucitanib Expenses		
Research and development	1,685	2,498
Lucitanib Total	1,685	2,498
Rociletinib Expenses		
Research and development	19	17
Rociletinib Total	19	17
Personnel and other expenses	20,102	19,066
Total	\$ 42,250	\$ 52,805

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.

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 adopted 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. New tools and performance indicators based on this hybrid approach were rolled out during the fourth quarter of 2020. We adopted 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 expect selling, general and administrative expenses in the full year 2022 to be comparable to 2021.

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 intangible asset amortization cost of sales.

Other Income and Expense

Other income and expense is primarily comprised of foreign currency gains and losses resulting from transactions with CROs, investigative 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.

For a description of our critical accounting policies, please see Management's Discussion and Analysis of Financial Condition and Results of Operations included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2021. There have not been any material changes to our critical accounting policies since December 31, 2021.

New Accounting Standards

From time to time, the FASB or other standards-setting bodies issue new accounting pronouncements. Updates to the FASB Accounting Standards Codification are communicated through the issuance of an Accounting Standards Update. To understand the impact of recently issued guidance, whether adopted or to be adopted, please review the information provided in Note 2, *Summary of Significant Accounting Policies*, in the Notes to the Unaudited Consolidated Financial Statements included in Part I, Item 1 of this Form 10-Q.

Results of Operations

Comparison of Three Months Ended March 31, 2022 and 2021 (in thousands):

	Three months ended March 31,					
	2022			2021		
	U.S.	ex-U.S.	Total	U.S.	ex-U.S.	Total
Transaction price	\$ 30,810	\$ 17,096	\$ 47,906	\$ 40,062	\$ 11,077	\$ 51,139
Sales deductions:						
Government rebates and chargebacks	(3,984)	(6,661)	(10,645)	(5,086)	(4,124)	(9,210)
Discounts and fees	(2,317)	(697)	(3,014)	(3,275)	(601)	(3,876)
Total sales deductions	(6,301)	(7,358)	(13,659)	(8,361)	(4,725)	(13,086)
Product revenue	24,509	9,738	34,247	31,701	6,352	38,053
Operating expenses:						
External cost of sales - product	4,835	3,235	8,070	6,157	2,111	8,268
Cost of sales - intangible asset amortization	620	723	1,343	620	723	1,343
Research and development	40,465	1,785	42,250	50,830	1,975	52,805
Selling, general and administrative	23,919	5,294	29,213	24,321	5,620	29,941
Other operating expenses	3,730	—	3,730	3,707	—	3,707
Total expenses	73,569	11,037	84,606	85,635	10,429	96,064
Operating loss	\$ (49,060)	\$ (1,299)	\$ (50,359)	\$ (53,934)	\$ (4,077)	\$ (58,011)
Other income (expense):						
Interest expense			(9,100)			(8,037)
Foreign currency loss			(978)			(546)
Other income			148			183
Other income (expense), net			(9,930)			(8,400)
Loss before income taxes			(60,289)			(66,411)
Income tax benefit			120			134
Net loss			\$ (60,169)			\$ (66,277)

Product revenue. Total product revenue for the three months ended March 31, 2022 decreased compared to the same period in the prior year primarily due to fewer diagnoses and fewer patient starts in the U.S., primarily caused by the ongoing COVID-19 pandemic as there have been fewer patients going to in-person office visits as oncology practices and patients continue to adapt to the impact of the virus and competition from other products on the market, including

the impact on second-line maintenance that may result from an increase in first-line maintenance treatment of ovarian cancer.

U.S. product revenue for the three months ended March 31, 2022 decreased \$7.2 million compared to the same period in the prior year while ex-U.S. product revenue for the three months ended March 31, 2022 increased \$3.4 million compared to the same period in the prior year. The increase in ex-U.S. product revenue is due to Rubraca being launched in countries in Europe throughout 2019 and 2020.

Product revenue is recorded net of variable considerations comprised of rebates, chargebacks and other discounts. Product revenue for the three months ended March 31, 2022 was \$24.5 million in the United States and \$9.7 million outside of the United States. Total variable considerations increased during the three months ended March 31, 2022 compared to the three months ended March 31, 2021 at 28.5% and 25.6% of the transaction price, respectively.

External cost of sales – product. Product cost of sales for the three months ended March 31, 2022 remained consistent compared to the same period in the prior year. 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 three months ended March 31, 2022 decreased \$1.3 million compared to the same period in the prior year due to the decrease in product revenue.

Ex-U.S. product cost of sales for the three months ended March 31, 2022 increased \$1.1 million compared to the same period in the prior year due to the increase in product revenue.

Cost of sales – intangible asset amortization. In the three months ended March 31, 2022 and 2021, we recognized cost of sales of \$1.3 million 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 three months ended March 31, 2022 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 and our ARIEL and ATHENA studies for ovarian cancer.

Selling, general and administrative expenses. Selling, general and administrative expenses for the three months ended March 31, 2022 remained consistent compared to the same period in the prior year.

Other operating expenses. During the three months ended March 31, 2022 and 2021, we recognized other operating expenses related to our production train at Lonza. We expect these expenses to remain consistent during the remainder of 2022 due to our fixed facility fee each quarter since we expect to have sufficient inventory and do not plan to produce inventory at Lonza during the remainder of 2022.

Interest expense. Interest expense increased during the three months ended March 31, 2022 compared to the same period in the prior year primarily due to interest expense under our financing agreement related to our ATHENA trial.

Liquidity and Capital Resources

Going Concern and Management Plans

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 even with Rubraca now generating revenues. Rubraca revenues have not been consistent in prior quarters, mainly as a result of the impact of COVID-19 and competition from other products on the market, including the impact on second-line maintenance that may result from an increase in first-line maintenance treatment of ovarian cancer, which has made forecasting revenues difficult. In addition to factors described, future Rubraca revenues will depend, in part, on the timing and extent of any recovery from the impacts of COVID-19, with any such recovery of revenues expected to take several quarters to have a meaningful impact on our financial results. We do not expect to generate a sufficient amount of Rubraca revenues to finance our cash requirements in the foreseeable future, and which we may never be able to do in sufficient amounts. We require significant cash resources to execute our business plans and we will need to raise

[Table of Contents](#)

additional cash to continue to fund our operating plan. We cannot be certain that additional funding will be available on acceptable terms, or at all, especially given that we will need our stockholders to approve an amendment to our certificate of incorporation to increase the number of shares of common stock that we are authorized to issue. The aforementioned factors, which are largely outside of our control, raise substantial doubt about our ability to continue as a going concern within one year from the date of filing of this quarterly report.

In the near term, we believe there is some flexibility within our operating plan, particularly with managing certain discretionary expenses, to adjust to variations in our expected Rubraca revenues and the availability and timing of potential sources of financings to meet our working capital requirements. However, based on our current cash, cash equivalents and liquidity available under our ATHENA clinical financing agreement, together with current estimates for revenues generated by sales of Rubraca, we will need to raise additional capital in the near term in order to fund our operating plan for the next 12 months and to continue as a going concern. Our ability to obtain additional financing (including through collaborating and licensing arrangements) will depend on a number of factors, including, among others, our ability to generate positive data from our clinical studies and to obtain label expansions through regulatory approvals, the condition of the capital markets and the other risks described under Risk Factors in our Annual Report on Form 10-K for the year ended December 31, 2021 (“2021 Form 10-K”). We expect to finance our operating plan through a combination of public or private equity or debt offerings, collaborations, strategic alliances and other similar licensing arrangements in both the short term and the long term.

We currently have capacity to issue approximately \$16.5 million of additional shares of common stock under our previously established ATM Program, assuming the remaining authorized but unissued shares of our common stock are sold at an offering price of \$2.03 per share, the closing price of our common stock on the Nasdaq Global Select Market on May 2, 2022. There can be no assurance that we will be able to sell any shares of our common stock under the ATM Program or regarding the price at which we will be able to sell any such shares, and any sales of shares of our common stock under the ATM Program may be at prices that result in additional dilution to existing stockholders of the Company.

We will not be able to raise sufficient additional capital through public or private equity offerings (or offerings of securities convertible into our equity securities) until our stockholders approve a proposed reverse stock split of our common stock at our 2022 Annual Meeting of Stockholders, which, when implemented by our board of directors, will have the effect of increasing the number of authorized but unissued and unreserved shares of our common stock that are available to be issued. We cannot be certain that our stockholders will approve such a proposal. In the event our stockholders do not approve such a proposal, our ability to raise capital to fund our operations beyond the next 12 months will be significantly limited.

In light of the uncertainty about our ability to raise sufficient capital through potential equity offerings (or offerings of securities convertible into equity securities), we are considering other sources of funding, potentially through incurring further indebtedness or entering into strategic partnerships or licensing arrangements for one or more of our products or product candidates in which we may have to give up certain of our future commercialization or other rights to obtain interim funding. We are exploring various partnership and licensing arrangements for our products and product candidates outside the U.S., but those will largely depend on our ability to generate positive data from our clinical studies and to obtain label expansions through regulatory approvals. We cannot be certain that such other sources of funding will be available to us or on acceptable terms or in sufficient amounts to meet our requirements.

In the event that we are unable to raise sufficient additional capital, which is dependent on factors outside of our control, we will need to cut expenses further, including potentially delaying, scaling back or eliminating certain of our pipeline development programs, and undertake a more significant restructuring of our operations, in order to continue as a going concern and fund our committed obligations and working capital requirements. There can be no assurances that we will be able to achieve such a restructuring or that such a restructuring will be successful over the long term to allow us to fund our requirements and our plan to invest sufficient amounts to fund the development of FAP-2286 to its potential.

Sources and Uses of Cash

The following table sets forth the primary sources and uses of cash for the three months ended March 31, 2022 and 2021 (in thousands):

	Three months ended March 31,	
	2022	2021
Net cash used in operating activities	\$ (58,495)	\$ (61,890)
Net cash used in investing activities	(62)	(118)
Net cash provided by financing activities	37,857	13,376
Effect of exchange rate changes on cash and cash equivalents	(487)	(675)
Net decrease in cash and cash equivalents	<u>\$ (21,187)</u>	<u>\$ (49,307)</u>

Operating Activities

Net cash used in operating activities was lower during the three months ended March 31, 2022 compared to the same period in the prior year primarily due to a lower net loss.

Investing Activities

There were no significant investing activities during the three months ended March 31, 2022 and 2021.

Financing Activities

Net cash provided by financing activities for the three months ended March 31, 2022 included \$28.6 million net proceeds resulting from our “at the market” offerings that occurred during January through March 2022 and \$9.2 million proceeds from borrowings under our financing agreement related to our ATHENA trial.

Net cash provided by financing activities for the three months ended March 31, 2021 included proceeds of \$13.8 million proceeds from borrowings under our financing agreement.

On May 17, 2021, we entered into a distribution agreement (the “Distribution Agreement”) with J.P. Morgan Securities LLC and BofA Securities, Inc., as agents (the “Agents”), pursuant to which we may offer and sell, from time to time, through the Agents, shares of our common stock having an aggregate offering price of up to \$75.0 million in transactions that are deemed to be “at the market” offerings as defined in Rule 415(a)(4) under the Securities Act of 1933, as amended, including sales made by means of ordinary brokers’ transactions, including directly on the Nasdaq Global Select Market or into any other existing trading market for the shares, or sales made to or through a market maker, in block transactions or by any other method permitted by law, including negotiated transactions. Sales may be made at market prices prevailing at the time of a sale or at prices related to prevailing market prices or at negotiated prices. During the period between May 18, 2021 and June 9, 2021, we sold an aggregate of 13,492,231 shares of our common stock under the Distribution Agreement resulting in gross proceeds of \$75.0 million and net proceeds to us of \$72.5 million, after deducting commissions and offering expenses, effectively closing out sales we may make pursuant to the Distribution Agreement.

The issuance and sale of the shares under the Distribution Agreement were made pursuant to our effective registration statement on Form S-3 filed with the U.S. Securities and Exchange Commission (the “SEC”) on February 25, 2021 (File No. 333-253485) as amended by pre-effective Amendment No. 1 thereto filed with the SEC on May 5, 2021. The offering is described in the Company’s prospectus dated May 7, 2021, as supplemented by a prospectus supplement dated May 17, 2021, as filed with the SEC on May 17, 2021. We have used and intend to use the net proceeds of this offering for general corporate purposes, including funding of our development programs, sales and marketing expenses associated with Rubraca, repayment, repurchase or refinance of our debt obligations, payment of milestones pursuant to our license agreements, general and administrative expenses, acquisition or licensing of additional product candidates or businesses and working capital.

On August 16, 2021, we entered into a distribution agreement (the “August Distribution Agreement”) with the Agents, pursuant to which we may offer and sell, from time to time, through the Agents, shares of our common stock, having an aggregate offering price of up to \$125.0 million in transactions that are deemed to be “at the market” offerings as defined in Rule 415(a)(4) under the Securities Act of 1933, as amended, including sales made by means of ordinary brokers’ transactions, including directly on the Nasdaq Global Select Market or into any other existing trading market

for the shares, or sales made to or through a market maker, in block transactions or by any other method permitted by law, including privately negotiated transactions. Sales may be made at market prices prevailing at the time of a sale or at prices related to prevailing market prices or at negotiated prices. During the period between August 17, 2021 and September 15, 2021, we sold an aggregate of 9,379,976 shares of our common stock under the August Distribution Agreement resulting in gross proceeds of \$43.0 million and net proceeds to us of \$41.5 million, after deducting commissions and offering expenses. During the period between November 5, 2021 and November 16, 2021, we sold an aggregate of 731,292 shares of our common stock resulting in gross proceeds of \$3.1 million and net proceeds to us of \$3.0 million, after deducting commissions and offering expenses. During the period between January 18, 2022 and March 3, 2022, we sold an aggregate of 13,870,410 shares of our common stock resulting in gross proceeds of \$29.8 million and net proceeds to us of \$28.6 million, after deducting commissions and offering expenses.

The issuance and sale of the shares under the August Distribution Agreement will be made pursuant to our effective registration statement on Form S-3 filed with the SEC on February 25, 2021 (File No. 333-253485) as amended by pre-effective Amendment No. 1 thereto filed with the SEC on May 5, 2021. The offering is described in the Company's prospectus dated May 7, 2021, as supplemented by a prospectus supplement dated August 16, 2021, as filed with the SEC on August 16, 2021. We have used and intend to use the net proceeds of this offering for general corporate purposes, including funding of our development programs, sales and marketing expenses associated with Rubraca, repayment, repurchase or refinancing of our debt obligations, payment of milestones pursuant to our license agreements, general and administrative expenses, acquisition or licensing of additional product candidates or businesses and working capital.

Cash Requirements

We expect to incur significant losses for the foreseeable future, as we commercialize Rubraca and expand our selling, general and administrative functions to support the growth in our commercial organization.

As of March 31, 2022, we had cash and cash equivalents totaling \$122.2 million and total current liabilities of \$121.8 million.

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

- revenues from the sale of our Rubraca product;
- 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 product candidates.

For a discussion of our contractual obligations, see "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations" in our 2021 Annual Report on Form 10-K. For further information regarding our contractual obligations and commitments, see Note 14, *Commitments and Contingencies* to our unaudited consolidated financial statements included elsewhere in this report.

Impact of COVID-19 Pandemic

Our ability to generate product revenues for the three months ended March 31, 2022 was negatively affected by the COVID-19 pandemic, primarily due to the ongoing effect the pandemic has had on oncology treatment and practice, and in particular, in ovarian cancer, resulting in fewer diagnoses and fewer patients going to in-person office visits in the U.S. As recently reported by a competitor, ovarian cancer diagnoses are down approximately 29% from pre-pandemic

levels and in the fourth quarter of 2021, new patient starts for PARP inhibitors across all indications were down 19% compared to the first quarter of 2021 and down 26% compared to the first quarter of 2020. 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 occurred in an environment in which our field-based personnel were not allowed to visit hospitals beginning as early as 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 remains 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.

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 adopted 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. New tools and performance indicators based on this hybrid approach were rolled out during the fourth quarter of 2020. We adopted 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 three months ended March 31, 2022. However, we may see disruption during the remainder of 2022. 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. We believe that we have sufficient supply of Rubraca and our product candidates to continue our commercial and clinical operations as planned.

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. On March 11, 2021, President Biden signed an additional coronavirus relief package entitled the American Rescue Plan Act of 2021 (“ARPA”), which included, among other things, provisions relating to stimulus payments to some Americans, extension of several CARES Act relief programs, expansion of the child tax credit, funding for vaccinations and other COVID-19 related assistance programs. The CARES Act, FFCR Act, and the ARPA have not had a material impact on the Company; however, we will continue to examine the impacts that these Acts, as well as any future economic relief legislation, may have on our business.

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.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to market risk related to changes in interest rates. As of March 31, 2022, we had cash and cash equivalents of \$122.2 million, consisting of bank demand deposits, money market funds and U.S. treasury securities. The primary objectives of our investment policy are to preserve principal and maintain proper liquidity to meet operating needs. Our investment policy specifies credit quality standards for our investments and limits the amount of credit exposure to any single issue, issuer or type of investment. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our investments are in short-term securities. 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, investigative 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 Lonza, a Swiss company, for the long-term manufacture and supply of the API 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 production train were made in Swiss Francs. Once the production train became operational in October 2018, we were obligated to pay a fixed facility fee each quarter for the duration of the agreement, which expires on December 31,

2025. As discussed in Note 14, *Commitments and Contingencies*, we amended this agreement in June 2021, resulting in the derecognition of the lease components recognized under the original agreement.

As of March 31, 2022, \$39.6 million of purchase commitments exist under the Manufacturing and Services Agreement, which includes the fixed facility fee noted above, 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 March 31, 2022, it would decrease the total US dollar purchase commitment under the Manufacturing and Services Agreement by \$3.6 million. Similarly, a 10% weakening of the US dollar compared to the Swiss franc would increase the total US dollar purchase commitment by \$4.4 million.

While we periodically hold foreign currencies, primarily Euro, Swiss Franc and Pound Sterling, 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 March 31, 2022 and December 31, 2021, approximately 4% of our total liabilities were denominated in currencies other than the functional currency.

ITEM 4. CONTROLS AND PROCEDURES

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 Chief Financial 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. With the participation of our Chief Executive Officer and Chief Financial Officer, management performed an evaluation as of March 31, 2022 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 Financial Officer concluded that, as of March 31, 2022, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended March 31, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

See Note 14, *Commitments and Contingencies*.

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 risk factors described under the heading “Risk Factors” in Part I, Item 1A of our most recent Annual Report on Form 10-K, in addition to other information contained in or incorporated by reference into this Quarterly Report on Form 10-Q 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.

There were no material changes to the risk factors included in our previously filed Annual Report on Form 10-K for the year ended December 31, 2021.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not Applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

INDEX TO EXHIBITS

Exhibit Number	Exhibit Description
3.1(5)	Amended and Restated Certificate of Incorporation of Clovis Oncology, Inc.
3.2(17)	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(20)	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(13)	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.

[Table of Contents](#)

- 4.3(13) [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.](#)
- 4.4(18) [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.](#)
- 4.5(19) [Description of the Registrant's Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934.](#)
- 4.6(22) [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+(26) [Clovis Oncology, Inc. Amended and Restated 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+(21) [Form of Clovis Oncology, Inc. 2020 Stock Incentive Plan Option Agreement.](#)
- 10.8+(21) [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.](#)
- 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.](#)

Table of Contents

- 10.17+(1) [Indemnification Agreement, dated as of May 12, 2009, between Clovis Oncology, Inc. and Patrick J. Mahaffy.](#)
- 10.18+(1) [Indemnification Agreement, dated as of May 12, 2009, between Clovis Oncology, Inc. and Gillian C. Ivers-Read.](#)
- 10.19+(4) [Clovis Oncology, Inc. 2011 Cash Bonus Plan.](#)
- 10.20+(2) [Indemnification Agreement, dated as of June 13, 2013, between Clovis Oncology, Inc. and Ginger L. Graham.](#)
- 10.21+(2) [Indemnification Agreement, dated as of June 13, 2013, between Clovis Oncology, Inc. and Keith Flaherty.](#)
- 10.22(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.](#)
- 10.23*(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.](#)
- 10.24+(9) [Indemnification Agreement, effective as of August 3, 2015, between Clovis Oncology, Inc. and Lindsey Rolfe.](#)
- 10.25+(15) [Amended and Restated Employment Agreement, dated as of February 27, 2019, by and between Clovis Oncology, Inc. and Clovis Oncology UK Limited and Dr. Lindsey Rolfe.](#)
- 10.26+(7) [Indemnification Agreement, dated as of February 17, 2016, between Clovis Oncology, Inc. and Daniel W. Muehl.](#)
- 10.27+(12) [Employment Agreement, dated as of July 6, 2017, by and between Clovis Oncology, Inc. and Daniel W. Muehl.](#)
- 10.28*(8) [First Amendment to License Agreement, between Clovis Oncology, Inc. and Pfizer Inc., dated as of August 30, 2016.](#)
- 10.29+(10) [Form of Clovis Oncology, Inc. 2011 Stock Incentive Plan RSU Agreement.](#)
- 10.30*(10) [Manufacturing Services Agreement, by and between Clovis Oncology, Inc. and Lonza Ltd, dated as of October 3, 2016.](#)
- 10.31*(11) [Strata Trial Collaboration Agreement, by and between Clovis Oncology, Inc. and Strata Oncology, Inc., dated as of January 30, 2017.](#)
- 10.32+(14) [Indemnification Agreement, dated as of October 11, 2018, between Clovis Oncology, Inc. and Robert W. Azelby.](#)
- 10.33+(14) [Indemnification Agreement, dated as of October 11, 2018, between Clovis Oncology, Inc. and Richard A. Fair.](#)

[Table of Contents](#)

10.34+(15)	<u>Employment Agreement, dated as of July 6, 2017, by and between Clovis Oncology, Inc. and Paul Gross.</u>
10.35+(15)	<u>Indemnification Agreement, dated as of September 9, 2016, by and between Clovis Oncology, Inc. and Paul Gross.</u>
10.36(16)	<u>Financing Agreement, dated as of May 1, 2019 among Clovis Oncology, Inc., certain subsidiaries of its subsidiaries named therein, as Guarantors, the Lenders from time to time party thereto, and the Administrative Agent party thereto.</u>
10.37(16)	<u>Pledge and Security Agreement, dated as of May 1, 2019 among each of the Grantors party thereto and the Administrative Agent party thereto.</u>
10.38#(23)	<u>License and Collaboration Agreement, dated September 20, 2019 by and between 3B Pharmaceuticals GmbH and Clovis Oncology, Inc.</u>
10.39+(24)	<u>Employment Agreement, dated as of May 4, 2021, by and between Clovis Oncology, Inc. and Thomas C. Harding.</u>
10.40+(24)	<u>Indemnification Agreement, dated as of May 3, 2021, by and between Clovis Oncology, Inc. and Thomas C. Harding.</u>
10.41+(25)	<u>Indemnification Agreement, dated as of July 12, 2021, by and between Clovis Oncology, Inc. and Ronit Simantov.</u>
10.42+(26)	<u>Clovis Oncology, Inc. 2021 Employee Stock Purchase Plan.</u>
21.1(27)	<u>List of Subsidiaries of Clovis Oncology, Inc.</u>
31.1	<u>Certification of principal executive officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as amended.</u>
31.2	<u>Certification of principal financial officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as amended.</u>
32.1	<u>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.</u>
32.2	<u>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.</u>
101	The following materials from Clovis Oncology, Inc.'s Quarterly Report on Form 10-Q for the period ended March 31, 2022 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 Statements of Cash Flows and (v) Notes to Unaudited Consolidated Financial Statements.
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

- (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.

[Table of Contents](#)

- (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 April 1, 2016.
- (8) Filed as an exhibit with the Registrant's Quarterly Report on Form 10-Q on November 4, 2016.
- (9) Filed as an exhibit with the Registrant's Annual Report on Form 10-K on February 29, 2016.
- (10) Filed as an exhibit with the Registrant's Annual Report on Form 10-K on February 23, 2017.
- (11) Filed as an exhibit with the Registrant's Quarterly Report on Form 10-Q on May 4, 2017.
- (12) Filed as an exhibit with the Registrant's Current Report on Form 8-K (File No. 001-35347) on July 7, 2017.
- (13) Filed as an exhibit with the Registrant's Current Report on Form 8-K (File No. 001-35347) on April 19, 2018.
- (14) Filed as an exhibit with the Registrant's Current Report on Form 8-K (File No. 001-35347) on October 12, 2018.
- (15) Filed as an exhibit with the Registrant's Annual Report on Form 10-K on February 28, 2019.
- (16) Filed as an exhibit with the Registrant's Current Report on Form 8-K (File No. 001-35347) on May 2, 2019.
- (17) Filed as an exhibit with the Registrant's Current Report on Form 8-K (File No. 001-35347) on June 6, 2019.
- (18) Filed as an exhibit with the Registrant's Current Report on Form 8-K (File No. 001-35347) on August 13, 2019.
- (19) Filed as an exhibit with the Registrant's Annual Report on Form 10-K on February 26, 2020.
- (20) Filed as an exhibit with the Registrant's Current Report on Form 8-K (File No. 001-35347) on April 16, 2020.
- (21) Filed as an exhibit with the Registrant's Current Report on Form 8-K (File No. 001-35347) on June 4, 2020.
- (22) Filed as an exhibit with the Registrant's Current Report on Form 8-K (File No. 001-35347) on November 17, 2020.
- (23) Filed as an exhibit with the Registrant's Current Report on Form 10-K (File No. 001-35347) on February 25, 2021.
- (24) Filed as an exhibit with the Registrant's Current Report on Form 10-Q on May 5, 2021.
- (25) Filed as an exhibit with the Registrant's Current Report on Form 8-K (File No. 001-35347) on July 13, 2021.
- (26) Filed as an exhibit with the Registrant's Current Report on Form 10-Q on August 4, 2021.
- (27) Filed as an exhibit with the Registrant's Current Report on Form 10-Q on November 3, 2021.
- + Indicates management contract or compensatory plan.
- * Confidential treatment has been 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.

SIGNATURES

Pursuant to the requirements 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.

Date: May 5, 2022

CLOVIS ONCOLOGY, INC.

By: /s/ PATRICK J. MAHAFFY

Patrick J. Mahaffy
President and Chief Executive Officer

By: /s/ DANIEL W. MUEHL

Daniel W. Muehl
Executive Vice President and Chief Financial Officer

I, Patrick J. Mahaffy, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Clovis Oncology, Inc. for the quarter ended March 31, 2022;
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: May 5, 2022

/s/ PATRICK J. MAHAFFY

Patrick J. Mahaffy
President and Chief Executive Officer

I, Daniel W. Muehl, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Clovis Oncology, Inc. for the quarter ended March 31, 2022;
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: May 5, 2022

/s/ DANIEL W. MUEHL

Daniel W. Muehl

Executive Vice President and Chief Financial Officer

**CERTIFICATIONS PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002
(18 U.S.C. SECTION 1350)**

In connection with the Quarterly Report of Clovis Oncology, Inc., a Delaware corporation (the “Company”), on Form 10-Q for the quarter ended March 31, 2022, as filed with the Securities and Exchange Commission (the “Report”), Patrick J. Mahaffy, as 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: May 5, 2022

/s/ PATRICK J. MAHAFFY

Patrick J. Mahaffy
President and Chief Executive Officer

**CERTIFICATIONS PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002
(18 U.S.C. SECTION 1350)**

In connection with the Quarterly Report of Clovis Oncology, Inc., a Delaware corporation (the “Company”), on Form 10-Q for the quarter ended March 31, 2022, as filed with the Securities and Exchange Commission (the “Report”), Daniel W. Muehl, as Executive Vice President and Principal Financial and Accounting 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: May 5, 2022

/s/ DANIEL W. MUEHL

Daniel W. Muehl

Executive Vice President and Chief Financial Officer
