Clovis Oncology, Inc.
Form 10-Q
May 09, 2016

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934.
For the quarterly period ended March 31, 2016.

¨ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934.
For the transition period from to .

Commission file number: 001-35347

Clovis Oncology, Inc.

(Exact name of Registrant as specified in its charter)

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

(303) 625-5000

(Registrant’s telephone number, including area code)

Not Applicable

(Former name, former address and former fiscal year, if changed since last report)

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 x No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post such files). Yes x 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	x	Accelerated filer	o
Non-accelerated filer	o (Do not check if a smaller reporting company)	Smaller reporting company	o

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

The number of outstanding shares of the registrant’s common stock, par value $0.001 per share, as of April 29, 2016 was 38,385,660.

CLOVIS ONCOLOGY, INC.

FORM 10-Q

TABLE OF CONTENTS

PART I. Financial Information		3
ITEM 1.	Financial Statements (unaudited)	3
	Consolidated Statements of Operations — for the three months ended March 31, 2016 and 2015	3
	Consolidated Statements of Comprehensive Loss — for the three months ended March 31, 2016 and 2015	4
	Consolidated Balance Sheets — as of March 31, 2016 and December 31, 2015	5
	Consolidated Statements of Cash Flows — for the three months ended March 31, 2016 and 2015	6
	Notes to Unaudited Consolidated Financial Statements	7
ITEM 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	19
ITEM 3.	Quantitative and Qualitative Disclosures About Market Risk	27
ITEM 4.	Controls and Procedures	27
PART II. Other Information		28
ITEM 1.	Legal Proceedings	28
ITEM 1A.	Risk Factors	29
ITEM 2.	Unregistered Sales of Equity Securities and Use of Proceeds	49
ITEM 3.	Defaults Upon Senior Securities	49
ITEM 4.	Mine Safety Disclosures	49
ITEM 5.	Other Information	49
ITEM 6.	Exhibits	49
SIGNATURES		52

2

PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS
CLOVIS ONCOLOGY, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

(In thousands, except per share amounts)

	Three Months Ended March 31,	
	2016	2015
Revenues:		
License and milestone revenue	$—	$—
Operating expenses:		
Research and development	74,608	56,750
General and administrative	9,827	6,751
Change in fair value of contingent purchase consideration	516	724
Total expenses	84,951	64,225
Operating loss	(84,951)	(64,225)
Other income (expense):		
Interest expense	(2,104)	(2,075)
Foreign currency gains (losses)	(551)	3,247
Other income	25	11
Other income (expense), net	(2,630)	1,183
Loss before income taxes	(87,581)	(63,042)
Income tax benefit (expense)	4,181	(102)
Net loss	$(83,400)	$(63,144)
Basic and diluted net loss per common share	$(2.17)	$(1.86)
Basic and diluted weighted-average common shares outstanding	38,360	34,011

See accompanying Notes to Unaudited Consolidated Financial Statements.

CLOVIS ONCOLOGY, INC.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(Unaudited)

(In thousands)

	Three Months Ended March 31,	
	2016	2015
Net loss	$(83,400)	$(63,144)
Other comprehensive income (loss)		
Foreign currency translation adjustments, net of tax	3,513	(25,915)
Net unrealized gain on available-for-sale securities, net of tax	230	88
Other comprehensive income (loss)	3,743	(25,827)
Comprehensive loss	$(79,657)	$(88,971)

See accompanying Notes to Unaudited Consolidated Financial Statements.

CLOVIS ONCOLOGY, INC.

CONSOLIDATED BALANCE SHEETS

(Unaudited)

(In thousands, except for share amounts)

	March 31, 2016	December 31, 2015
ASSETS		
Current assets:		
Cash and cash equivalents	$220,373	$278,756
Available-for-sale securities	225,117	249,832
Prepaid research and development expenses	10,391	3,377
Other current assets	8,090	7,736
Total current assets	463,971	539,701
Property and equipment, net	5,108	4,946
Intangible assets	105,689	101,500
Goodwill	61,775	59,327
Other assets	8,031	7,912
Total assets	$644,574	$713,386
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$14,100	$11,260
Accrued research and development expenses	52,642	53,011
Other accrued expenses	7,199	11,305
Total current liabilities	73,941	75,576
Contingent purchase consideration	25,710	24,661
Deferred income taxes, net	30,476	31,133
Convertible senior notes	280,192	279,885
Deferred rent, long-term	1,592	1,481
Total liabilities	411,911	412,736
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, 2016 and December 31, 2015	—	—
Common stock, $0.001 par value per share, 100,000,000 shares authorized at March 31, 2016 and December 31, 2015; 38,364,454 and 38,359,454 shares issued and outstanding at March 31, 2016 and December 31, 2015, respectively	38	38
Additional paid-in capital	1,141,648	1,129,978
Accumulated other comprehensive loss	(43,717)	(47,460)
Accumulated deficit	(865,306)	(781,906)

Total stockholders' equity	232,663	300,650
Total liabilities and stockholders' equity	$644,574	$713,386

See accompanying Notes to Unaudited Consolidated Financial Statements.

CLOVIS ONCOLOGY, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

(In thousands)

	Three Months Ended March 31,	
	2016	2015
Operating activities		
Net loss	$(83,400)	$(63,144)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation expense	10,965	8,682
Depreciation and amortization	270	169
Amortization of premiums and discounts on available-for-sale securities	80	471
Amortization of debt issuance costs	307	298
Change in fair value of contingent purchase consideration	1,049	(2,794)
Loss on disposal of property and equipment	169	—
Deferred income taxes	(4,145)	—
Changes in operating assets and liabilities:		
Prepaid and accrued research and development expenses	(7,601)	7,776
Other operating assets	(130)	(805)
Accounts payable	2,682	4,228
Other accrued expenses	(3,984)	(3,286)
Net cash used in operating activities	(83,738)	(48,405)
Investing activities		
Purchases of property and equipment	(604)	(816)
Purchases of available-for-sale securities	—	(142,216)
Maturities of available-for-sale securities	25,000	—
Net cash provided by (used in) investing activities	24,396	(143,032)
Financing activities		
Proceeds from the exercise of stock options and employee stock purchases	705	1,193
Net cash provided by financing activities	705	1,193
Effect of exchange rate changes on cash and cash equivalents	254	(891)
Decrease in cash and cash equivalents	(58,383)	(191,135)
Cash and cash equivalents at beginning of period	278,756	482,677
Cash and cash equivalents at end of period	$220,373	$291,542
Supplemental disclosure of cash flow information:		
Cash paid for interest	$3,594	$3,714

See accompanying Notes to Unaudited Consolidated Financial Statements.

6

CLOVIS ONCOLOGY, INC.

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

1. Nature of Business and Basis of Presentation

Clovis Oncology, Inc. (the "Company") is a biopharmaceutical company focused on acquiring, developing and commercializing innovative anti-cancer agents in the United States, Europe and other international markets. The Company has and intends 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, the Company generally expects to provide the licensor with a combination of upfront payments, milestone payments and royalties on future sales. In addition, the Company generally expects to assume the responsibility for future drug development and commercialization costs. The Company currently operates in one segment. Since inception, the Company's operations have consisted primarily of developing in-licensed compounds, evaluating new product acquisition candidates and general corporate activities.

In July 2015, the Company submitted a New Drug Application ("NDA") regulatory filing and a Marketing Authorization Application ("MAA") for rociletinib to the U.S. Food and Drug Administration ("FDA") and the European Medicines Agency ("EMA"), respectively. Both the FDA and EMA subsequently accepted the respective filings.

On April 12, 2016, the Oncologic Drugs Advisory Committee ("ODAC") met to discuss approval of the NDA for rociletinib. The ODAC reviews and evaluates data concerning the safety and effectiveness of marketed and investigational human drug products used in the treatment of cancer and makes recommendations to the FDA. The Committee recommended that the FDA wait to see results from TIGER-3, the Company's ongoing Phase III, randomized, controlled trial of rociletinib, before making a decision on approval of the treatment.

On May 5, 2016, the Company announced that it was notified by the FDA that it could expect to receive a Complete Response Letter ("CRL") for the rociletinib NDA on or before the Prescription Drug User Fee Act date of June 28, 2016. The FDA issues a CRL to indicate that their review of an application is complete and that the application is not ready for approval. In anticipation of receiving the CRL, the Company terminated enrollment in all ongoing sponsored clinical studies of rociletinib. The Company will continue to provide drug to patients whose clinicians recommend continuing rociletinib therapy. In addition, the Company has withdrawn its MAA for rociletinib currently on file with the EMA.

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, consisting only of normal recurring adjustments, which in the opinion of management are necessary to fairly state our financial position, results of operations and cash flows for the periods presented. 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 Annual Report on Form 10-K for the year ended December 31, 2015 for a broader discussion of our business and the opportunities and risks inherent in such business.

Reclassifications

Certain reclassifications have been made to prior year amounts to conform to the current year presentation. These reclassifications had no effect on the Company's previously reported results of operations, financial position or cash flows.

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, management evaluates its estimates, including estimates related to contingent purchase consideration, the allocation of purchase consideration, intangible asset impairment, clinical trial accruals and share-based compensation expense. The Company bases its estimates on historical experience and other market-specific or other relevant assumptions that it believes to be reasonable under the circumstances. Actual results may differ from those estimates or assumptions.

Liquidity

The Company has incurred significant net losses since inception and has relied on its ability to fund its operations through debt and equity financings. Management expects operating losses and negative cash flows to continue for the foreseeable future. As the Company continues to incur losses, transition to profitability is dependent upon the successful development, approval and commercialization of its product candidates and achieving a level of revenues adequate to support the Company's cost structure. The Company may never achieve profitability, and unless or until it does, the Company will continue to need to raise additional cash.

Management intends to fund future operations through additional private or public debt or equity offerings and may seek additional capital through arrangements with strategic partners or from other sources. Based on current estimates, management believes that existing working capital at March 31, 2016 is sufficient to meet the cash requirements to fund planned operations through at least the next 12 months, although there can be no assurance that this can, in fact, be accomplished.

2. Summary of Significant Accounting Policies

The Company's significant accounting policies are described in Note 2 of the Notes to the Consolidated Financial Statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2015.

Recently Issued Accounting Standards

In March 2016, the Financial Accounting Standards Board issued Accounting Standards Update ("ASU") No. 2016-09, "Compensation – Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting." ASU No. 2016-09 requires all income tax effects of awards to be recognized in the income statement when the awards vest or are settled. The guidance also requires the presentation of excess tax benefits as an operating activity on the statement of cash flows rather than as a financing activity. This update is effective for annual periods beginning after December 15, 2016, including interim periods within those annual periods. Early adoption is permitted. Amendments related to the timing of when excess tax benefits are recognized should be applied using a modified retrospective transition method. An entity may elect to apply the amendments related to the presentation of excess tax benefits on the statement of cash flows using either a prospective transition method or a retrospective transition method. The Company is currently evaluating its planned method of adoption and the impact the standard may have on its consolidated financial statements and related disclosures.

3. EOS Acquisition

On November 19, 2013, the Company acquired all of the outstanding common and preferred stock of Ethical Oncology Science, S.p.A. (“EOS”) (now known as Clovis Oncology Italy S.r.l.). The Company paid $11.8 million in cash and issued $173.7 million of common stock at the acquisition date and may make additional future cash payments if certain lucitanib regulatory and sales milestones are achieved. The potential contingent milestone payments range from a zero payment, which assumes lucitanib fails to achieve any of the regulatory milestones, to approximately $195.7 million ($65.0 million and €115.0 million) if all regulatory and sales milestones are met, utilizing the translation rate at March 31, 2016. The Company recorded a liability for the estimated fair value of these payments, which totaled $25.7 million and $24.7 million at March 31, 2016 and December 31, 2015, respectively.

4. Financial Instruments and Fair Value Measurements

Cash, Cash Equivalents and Available-for-Sale Securities

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

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

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

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. The Company's Level 1 assets consist of money market investments. The Company does 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. The Company's Level 2 assets consist of U.S. treasury securities. The Company does not have Level 2 liabilities.

Level 3: Unobservable inputs that are supported by little or no market activity. The Company does not have Level 3 assets. The contingent purchase consideration related to the undeveloped lucitanib product rights acquired with the purchase of EOS is a Level 3 liability. The fair value of this liability is based on unobservable inputs and includes valuations for which there is little, if any, market activity. See Note 3 of the Company's 2015 Form 10-K for further discussion of the unobservable inputs and valuation techniques related to the contingent purchase consideration liability.

The following table identifies the Company's assets and liabilities that were measured at fair value on a recurring basis (in thousands):

	Balance	Level 1	Level 2	Level 3
March 31, 2016				
Assets:				
Money market	$201,467	$201,467	$—	$—
U.S. treasury securities	225,117	—	225,117	—
Total assets at fair value	$426,584	$201,467	$225,117	$—
Liabilities:				
Contingent purchase consideration	$25,710	$—	$—	$25,710
Total liabilities at fair value	$25,710	$—	$—	$25,710
December 31, 2015				
Assets:				

Money market	$251,037	$251,037	$—	$