Clovis Oncology, Inc.
Form 10-Q
November 04, 2016

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 September 30, 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 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 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 Accelerated filer
Non-accelerated filer (Do not check if a smaller reporting company) Smaller reporting company

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 October 28, 2016 was 38,585,662.

CLOVIS ONCOLOGY, INC.

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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 September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Revenues:				
License and milestone revenue	$ —	$ —	$—	$—
Operating expenses:				
Research and development	54,338	76,138	196,675	193,256
General and administrative	9,162	8,331	28,541	22,286
Acquired in-process research and development	500	12,000	800	12,000
Impairment of intangible asset	—	—	104,517	—
Change in fair value of contingent purchase consideration	—	783	(24,936)	2,271
Total expenses	64,000	97,252	305,597	229,813
Operating loss	(64,000)	(97,252)	(305,597)	(229,813)
Other income (expense):				
Interest expense	(2,108)	(2,099)	(6,318)	(6,271)
Foreign currency gains (losses)	(66)	(101)	(434)	2,004
Other income	252	179	473	252
Other expense, net	(1,922)	(2,021)	(6,279)	(4,015)
Loss before income taxes	(65,922)	(99,273)	(311,876)	(233,828)
Income tax benefit	227	628	33,467	508
Net loss	$ (65,695)	$ (98,645)	$(278,409)	$(233,320)
Basic and diluted net loss per common share	$ (1.70)	$ (2.62)	$(7.24)	$(6.62)
Basic and diluted weighted-average common shares outstanding	38,538	37,613	38,429	35,252

See accompanying Notes to Unaudited Consolidated Financial Statements.

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CLOVIS ONCOLOGY, INC.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(Unaudited)

(In thousands)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Net loss	$ (65,695)	$ (98,645)	$(278,409)	$(233,320)
Other comprehensive income (loss)				
Foreign currency translation adjustments, net of tax	58	416	2,190	(17,186)
Net unrealized gain (loss) on available-for-sale securities, net of tax	(18)	7	260	148
Other comprehensive income (loss)	40	423	2,450	(17,038)
Comprehensive loss	$ (65,655)	$ (98,222)	$(275,959)	$(250,358)

See accompanying Notes to Unaudited Consolidated Financial Statements.

CLOVIS ONCOLOGY, INC.

CONSOLIDATED BALANCE SHEETS

(Unaudited)

(In thousands, except for share amounts)

	September 30, 2016	December 31, 2015
ASSETS		
Current assets:		
Cash and cash equivalents	$243,724	$278,756
Available-for-sale securities	75,054	249,832
Prepaid research and development expenses	7,376	3,377
Other current assets	5,194	7,736
Total current assets	331,348	539,701
Property and equipment, net	4,707	4,946
Intangible assets	—	101,500
Goodwill	60,748	59,327
Other assets	1,821	7,912
Total assets	$398,624	$713,386
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$11,076	$11,260
Accrued research and development expenses	36,088	53,011
Other accrued expenses	11,906	11,305
Total current liabilities	59,070	75,576
Contingent purchase consideration	—	24,661
Deferred income taxes, net	266	31,133
Convertible senior notes	280,813	279,885
Deferred rent, long-term	1,437	1,481
Total liabilities	341,586	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 September 30, 2016 and December 31, 2015	—	—
Common stock, $0.001 par value per share, 100,000,000 shares authorized at September 30, 2016 and December 31, 2015; 38,582,755 and 38,359,454 shares issued and outstanding at September 30, 2016 and December 31, 2015, respectively	39	38
Additional paid-in capital	1,162,324	1,129,978
Accumulated other comprehensive loss	(45,010)	(47,460)

Accumulated deficit	(1,060,315)	(781,906)
Total stockholders' equity	57,038	300,650
Total liabilities and stockholders' equity	$398,624	$713,386

See accompanying Notes to Unaudited Consolidated Financial Statements.

CLOVIS ONCOLOGY, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

(In thousands)

	Nine Months Ended September 30,	
	2016	2015
Operating activities		
Net loss	$(278,409)	$(233,320)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation expense	29,744	29,458
Depreciation and amortization	819	548
Amortization of premiums and discounts on available-for-sale securities	190	1,319
Amortization of debt issuance costs	928	900
Impairment of intangible asset	104,517	—
Change in fair value of contingent purchase consideration	(24,661)	(32)
Loss on disposal of property and equipment	105	—
Deferred income taxes	(33,320)	(529)
Changes in operating assets and liabilities:		
Prepaid and accrued research and development expenses	(14,877)	21,046
Other operating assets	2,358	(3,500)
Accounts payable	(322)	6,124
Other accrued expenses	923	609
Net cash used in operating activities	(212,005)	(177,377)
Investing activities		
Purchases of property and equipment	(761)	(1,175)
Proceeds from sale of property and equipment	65	-
Purchases of available-for-sale securities	—	(392,540)
Maturities of available-for-sale securities	175,000	—
Sales of available-for-sale securities	—	140,996
Net cash provided by (used in) investing activities	174,304	(252,719)
Financing activities		
Proceeds from the sale of common stock, net of issuance costs	—	298,509
Proceeds from the exercise of stock options and employee stock purchases	2,602	5,027
Net cash provided by financing activities	2,602	303,536
Effect of exchange rate changes on cash and cash equivalents	67	(674)
Decrease in cash and cash equivalents	(35,032)	(127,234)
Cash and cash equivalents at beginning of period	278,756	482,677
Cash and cash equivalents at end of period	$243,724	$355,443
Supplemental disclosure of cash flow information:		
Cash paid for interest	$7,188	$7,307

See accompanying Notes to Unaudited Consolidated Financial Statements.

CLOVIS ONCOLOGY, INC.

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

1. Nature of Business and Basis of Presentation

Clovis Oncology, Inc. (the “Company”, “Clovis”, “we”, “our”, “us”) is a biopharmaceutical company focused on acquiring, developing and commercializing cancer treatments in the United States, Europe and other international markets. 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 one segment. Since inception, our operations have consisted primarily of developing in-licensed compounds, evaluating new product acquisition candidates and general corporate activities.

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, except for those discussed in the following footnotes, 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 our 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, we evaluate our estimates, including estimates related to contingent purchase consideration, the allocation of purchase consideration, 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.

Liquidity

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

We intend 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 our current estimates, we believe that our cash, cash equivalents and available-for-sale securities as of September 30, 2016 will allow us to fund activities through at least the next 12 months.

2. Summary of Significant Accounting Policies

Our 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 ("2015 Form 10-K").

Recently Issued Accounting Standards

In March 2016, the Financial Accounting Standards Board ("FASB") 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. We are currently evaluating our planned method of adoption and the impact the standard may have on our consolidated financial statements and related disclosures.

3. EOS Acquisition

On November 19, 2013, we 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.). We paid $11.8 million in cash and issued $173.7 million of common stock at the acquisition date and are obligated to pay 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 $193.5 million ($65.0 million and €115.0 million) if all regulatory and sales milestones are met, utilizing the translation rate at September 30, 2016.

During the second quarter of 2016, we recorded a $25.5 million reduction in the fair value of the contingent purchase consideration liability due to our and our development partner's decision to discontinue the development of lucitanib for breast cancer (see Note 4). At September 30, 2016, the contingent purchase consideration liability recorded on the Consolidated Balance Sheets was zero due to the uncertainty of achieving any of the lucitanib regulatory milestones. At December 31, 2015, the liability for the estimated fair value of the payments recorded on the Consolidated Balance Sheets was $24.7 million.

4. Financial Instruments and Fair Value Measurements

Cash, Cash Equivalents and Available-for-Sale Securities

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

Marketable securities are considered to be available-for-sale securities and consist of U.S. Treasury securities. Available-for-sale securities are reported at fair value on the Consolidated Balance Sheets and unrealized gains and losses are included in accumulated other comprehensive income (loss) on the Consolidated Balance Sheets. Realized gains and losses, amortization of premiums and discounts and interest and dividends earned are included in other income (expense) on the Consolidated Statements of Operations. The cost of investments for purposes of computing realized and unrealized gains and losses is based on the specific identification method. Investments with maturities

beyond one year are classified as short-term based on our intent to fund current operations with these securities or to make them available for current operations.

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

Fair Value Measurements

Fair value is defined as the exchange price that would be received to sell an asset or paid to transfer a liability (at exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date.

The three levels of inputs that may be used to measure fair value include:

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

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

Level 3: Unobservable inputs that are supported by little or no market activity. We do not have Level 3 assets that are measured at fair value on a recurring basis. 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 our 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 our assets and liabilities that were measured at fair value on a recurring basis (in thousands):

	Balance	Level 1	Level 2	Level 3
September 30, 2016				
Assets:				
Money market	$227,182	$227,182	$—	$ —
U.S. treasury securities	75,054	—	75,054	—
Total assets at fair value	$302,236	$227,182	$75,054	$ —
Liabilities:				
Contingent purchase consideration	$—	$—	$—	$ —
Total liabilities at fair value	$—	$—	$—	$ —
December 31, 2015				
Assets:				
Money market	$251,037	$251,037	$—	$ —
U.S. treasury securities	249,832	—	249,832	—
Total assets at fair value	$500,869	$251,037	$249,832	$ —
Liabilities:				
Contingent purchase consideration				