Clovis Oncology, Inc.
Form 10-Q
November 06, 2015

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 September 30, 2015.

¨ 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.)
2525 28th Street, 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 October 30, 2015 was 38,320,649.

CLOVIS ONCOLOGY, INC.

FORM 10-Q

TABLE OF CONTENTS

2

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 September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Revenues:				
License and milestone revenue	$—	$—	$—	$13,625
Operating expenses:				
Research and development	76,138	34,965	193,256	87,556
General and administrative	8,331	5,267	22,286	15,852
Acquired in-process research and development	12,000	—	12,000	8,806
Amortization of intangible asset	—	—	—	3,409
Accretion of contingent purchase consideration	783	888	2,271	2,571
Total expenses	97,252	41,120	229,813	118,194
Operating loss	(97,252)	(41,120)	(229,813)	(104,569)
Other income (expense):				
Interest expense	(2,099)	(511)	(6,271)	(511)
Foreign currency gains (losses)	(101)	2,323	2,004	2,579
Other income (expense)	179	(42)	252	(134)
Other income (expense), net	(2,021)	1,770	(4,015)	1,934
Loss before income taxes	(99,273)	(39,350)	(233,828)	(102,635)
Income tax benefit (expense)	628	(292)	508	(2,489)
Net loss	$(98,645)	$(39,642)	$(233,320)	$(105,124)
Basic and diluted net loss per common share	$(2.62)	$(1.17)	$(6.62)	$(3.10)
Basic and diluted weighted average common shares outstanding	37,613	33,921	35,252	33,871
Comprehensive loss	$(98,222)	$(58,809)	$(250,358)	$(126,126)

See accompanying Notes to Unaudited Consolidated Financial Statements.

CLOVIS ONCOLOGY, INC.

CONSOLIDATED BALANCE SHEETS

(Unaudited)

(In thousands, except for share amounts)

	September 30, 2015	December 31, 2014
ASSETS		
Current assets:		
Cash and cash equivalents	$355,443	$482,677
Available-for-sale securities	250,444	—
Prepaid research and development expenses	2,394	3,765
Other current assets	7,159	4,730
Total current assets	615,440	491,172
Property and equipment, net	3,303	2,718
Intangible assets	196,390	212,900
Goodwill	60,932	66,055
Other assets	15,624	13,361
Total assets	$891,689	$786,206
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$9,316	$2,917
Accrued research and development expenses	58,954	37,257
Other accrued expenses	7,667	7,598
Total current liabilities	75,937	47,772
Contingent purchase consideration	52,421	52,453
Deferred income taxes, net	61,138	66,851
Convertible senior notes	287,500	287,500
Deferred rent, long-term	371	—
Total liabilities	477,367	454,576
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, 2015 and December 31, 2014	—	—
Common stock, $0.001 par value per share, 100,000,000 shares authorized at September 30, 2015 and December 31, 2014; 38,280,996 and 33,977,187 shares issued and outstanding at September 30, 2015 and December 31, 2014, respectively	38	34
Additional paid-in capital	1,118,135	785,089
Accumulated other comprehensive loss	(41,486)	(24,448)
Accumulated deficit	(662,365)	(429,045)

Total stockholders' equity	414,322	331,630
Total liabilities and stockholders' equity	$891,689	$786,206

See accompanying Notes to Unaudited Consolidated Financial Statements.

CLOVIS ONCOLOGY, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

(In thousands)

	Nine Months Ended September 30,	
	2015	2014
Operating activities		
Net loss	$(233,320)	$(105,124)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	548	3,700
Share-based compensation expense	29,458	15,585
Amortization of premiums and discounts on available-for-sale securities	1,319	—
Amortization of debt issuance costs	900	72
Change in value of contingent purchase consideration	(32)	(309)
Deferred income taxes	(529)	761
Changes in operating assets and liabilities:		
Prepaid and accrued research and development expenses	21,046	7,152
Other operating assets	(3,500)	(3,941)
Accounts payable	6,124	(1,889)
Other accrued expenses	609	892
Net cash used in operating activities	(177,377)	(83,101)
Investing activities		
Purchases of property and equipment	(1,175)	(2,191)
Purchases of available-for-sale securities	(392,540)	—
Sales of available-for-sale securities	140,996	—
Net cash used in investing activities	(252,719)	(2,191)
Financing activities		
Proceeds from the sale of common stock, net of issuance costs	298,509	—
Proceeds from the issuance of convertible senior notes, net of issuance costs	—	278,335
Proceeds from the exercise of stock options and employee stock purchases	5,027	763
Net cash provided by financing activities	303,536	279,098
Effect of exchange rate changes on cash and cash equivalents	(674)	(449)
(Decrease) increase in cash and cash equivalents	(127,234)	193,357
Cash and cash equivalents at beginning of period	482,677	323,228
Cash and cash equivalents at end of period	$355,443	$516,585
Supplemental disclosure of cash flow information:		
Cash paid for interest	$7,307	$—

See accompanying Notes to Unaudited Consolidated Financial Statements.

5

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 up-front 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 for review. The FDA granted the rociletinib NDA priority review status with a Prescription Drug User Fee Act action date of March 30, 2016.

Basis of Presentation

All financial information presented includes the accounts of the Company and its wholly-owned subsidiaries, Clovis Oncology UK Limited and Clovis Oncology Italy S.r.l. 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, 2014 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, 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. See Note 10 for discussion of our recent common stock offering.

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, 2014.

Recent Accounting Pronouncements

In April 2015, the Financial Accounting Standards Board issued Accounting Standards Update ("ASU") No. 2015-03, "Interest – Imputation of Interest (Subtopic 835-30) – Simplifying the Presentation of Debt Issuance Costs." ASU No. 2015-03 requires debt issuance costs to be presented as a deduction from the corresponding debt liability, rather than as an asset. This update is effective for fiscal years beginning after December 15, 2015, including interim periods within those years. Early adoption is permitted. Upon adoption, the guidance must be applied retrospectively to all periods presented in the financial statements. The Company has elected not to early adopt this standard. Adoption of the standard will impact the presentation of the Company's debt issuance costs on the Consolidated Balance Sheets and the 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 initial purchase consideration was comprised of an $11.8 million cash payment and the issuance of $173.7 million of the Company's common stock to the former EOS shareholders. The Company may make additional purchase payments to the previous EOS shareholders 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 $193.9 million ($65.0 million and €115.0 million) if all regulatory and sales milestones are met, utilizing the translation rate at September 30, 2015. The Company recorded a liability for the estimated fair value of these payments, which totaled $52.4 million and $52.5 million at September 30, 2015 and December 31, 2014, 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 with original maturities greater than three months are considered to be available-for-sale securities. Available-for-sale securities are reported at fair value and unrealized gains and losses are included in accumulated other comprehensive loss on the Consolidated Balance Sheets. Realized gains and losses, amortization of premiums and discounts and interest and dividends earned are included in other income (expense) on the Consolidated Statements of Operations and Comprehensive Loss. The cost of investments for purposes of computing realized and unrealized gains and losses is based on the specific identification method. Investments with maturities beyond one

year are classified as short-term based on 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 value 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.

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 include 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 2014 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
September 30, 2015				
Assets:				
Money market	$325,843	$325,843	$—	$—
U.S. treasury securities	250,444	—	250,444	—
Total assets at fair value	$576,287	$325,843	$250,444	$—
Liabilities:				
Contingent purchase consideration	$52,421	$—	$—	$52,421
Total liabilities at fair value	$52,421	$—	$—	$52,421
December 31, 2014				
Assets:				
Money market	$447,994	$447,994	$—	$—
Total assets at fair value	$447,994	$447,994	$—	$—
Liabilities:				
Contingent purchase consideration	$52,453	$—	$—	$52,453
Total liabilities at fair value	$52,453	$—	$—	$52,453

The following table rolls forward the fair value of Level 3 instruments (significant unobservable inputs) (in thousands):

	For the Nine Months Ended September 30, 2015
Liabilities:	
Balance at beginning of period	$ 52,453
Accretion	2,271
Change in foreign currency gains and losses	(2,303)
Balance at end of period	$ 52,421

The change in the fair value of Level 3 instruments is included in accretion of contingent purchase consideration and foreign currency gains (losses) for changes in the foreign currency translation rate on the Consolidated Statements of Operations and Comprehensive Loss.

Financial instruments not recorded at fair value include the Company's convertible senior notes. At September 30, 2015, the carrying amount of the convertible senior notes was $287.5 million, which represents the aggregate principal amount, and the fair value was $480.1 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 Notes, which are not listed on any securities exchange or quoted on an inter-dealer automated quotation system. See Note 9 for discussion of the convertible senior notes.

5. Available-for-Sale Securities

As of September 30, 2015, available-for-sale securities consisted of the following (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Aggregate Fair Value
U.S. treasury securities	$ 250,296	$ 148	$ —	$ 250,444

As of September 30, 2015, the amortized cost and fair value of available-for-sale securities by contractual maturity were (in thousands):

	Amortized Cost	Fair Value
Due in one year or less	$175,171	$175,246
Due in one year to two years	75,125	75,198
Total	$250,296	$250,444

6. Other Current Assets

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

	September 30, 2015	December 31, 2014
Receivable from partners	$ 3,836	$ 1,991
Prepaid expenses- other	1,915	1,168
Prepaid insurance	491	1,190
Other	917	381
Total	$ 7,159	$ 4,730

7. Intangible Assets and Goodwill

Intangible acquired in-process research and development ("IPR&D") assets and goodwill were established as part of the purchase accounting of EOS in November 2013.

IPR&D assets and goodwill consisted of the following (in thousands):

	September 30, 2015	December 31, 2014	
IPR&D assets:			
Balance at beginning of period	$212,900	$244,518	
Change in foreign currency gains and losses	(16,510)	(28,209)	
Amortization of intangible asset	—	(3,409)	(a)
Balance at end of period	$196,390	$212,900	
Goodwill:			
Balance at beginning of period	$66,055	$74,811	
Change in foreign currency gains and losses	(5,123)	(8,756)	

Balance at end of period	$60,932	$66,055

(a) During the first quarter of 2014, the Company recorded a $3.4 million reduction in the intangible assets driven by lower expected future milestone revenue from the lucitanib development activities due to the receipt of a lucitanib milestone payment from Servier (see Note 12). This reduction was reported as amortization of intangible asset on the Consolidated Statements of Operations and Comprehensive Loss.

Recurring amortization of the IPR&D assets will commence when the useful lives of the intangible assets have been determined. IPR&D intangible assets are evaluated for impairment at least annually or more frequently if impairment indicators exist and any reduction in fair value will be recognized as an expense in the Consolidated Statements of Operations and Comprehensive Loss.

8. Other Accrued Expenses

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

	September 30, 2015	December 31, 2014
Accrued personnel costs	$ 6,972	$ 4,726
Accrued interest payable	299	2,236
Income tax payable	125	411
Accrued expenses - other	271	225
Total	$ 7,667	$ 7,598

9. Convertible Senior Notes

On September 9, 2014, we completed a private placement of $287.5 million aggregate principal amount of 2.5% convertible senior notes due 2021 (the “Notes”) resulting in net proceeds to the Company of $278.3 million after deducting offering expenses. In accordance with the accounting guidance, the conversion feature did not meet the criteria for bifurcation, and the entire principal amount was recorded as a long-term liability on the Consolidated Balance Sheets.

The Notes are governed by the terms of the indenture between the Company, as issuer, and The Bank of New York Mellon Trust Company, N.A., as trustee. The Notes are senior unsecured obligations and bear interest at a rate of 2.5% per year, payable semi-annually in arrears on March 15 and September 15 of each year, beginning March 15, 2015. The Notes will mature on September 15, 2021, unless earlier converted, redeemed or repurchased.

Holders may convert all or any portion of the Notes at any time prior to the close of business on the business day immediately preceding the maturity date. Upon conversion, the holders will receive shares of our common stock at an initial conversion rate of 16.1616 shares per $1,000 in principal amount of Notes, equivalent to a conversion price of approximately $61.88 per share. The conversion rate is subject to adjustment upon the occurrence of certain events described in the indenture, but will not be adjusted for any accrued and unpaid interest. In addition, following certain corporate events that occur prior to the maturity date or upon our issuance of a notice of redemption, we will increase the conversion rate for holders who elect to convert the Notes in connection with such a corporate event or during the related redemption period in certain circumstances.

On or after September 15, 2018, we may redeem the Notes, at our option, in whole or in part, if the last reported sale price of our common stock has been at least 150% of the conversion price then in effect for at least 20 trading days (whether or not consecutive) during any 30 consecutive trading day period ending not more than two trading days preceding the date on which we provide written notice of redemption at a redemption price equal to 100% of the principal amount of the Notes to be redeemed plus accrued and unpaid interest to, but excluding, the redemption date. No sinking fund is provided for the Notes.

If we undergo a fundamental change, as defined in the indenture, prior to the maturity date of the Notes, holders may require us to repurchase for cash all or any portion of the Notes at a fundamental change repurchase price equal to

100% of the principal amount of the Notes to be repurchased, plus accrued and unpaid interest to, but excluding, the fundamental change repurchase date.

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

In connection with the issuance of the Notes, the Company incurred $9.2 million of debt issuance costs, which is included in other assets on the Consolidated Balance Sheets. The debt issuance costs are amortized as interest expense over the expected life of the Notes using the effective interest method. The Company determined the expected life of the debt was equal to the seven-year term of the Notes. As of September 30, 2015, the balance of unamortized debt issuance costs was $7.9 million.

The following table sets forth total interest expense recognized related to the Notes during the three and nine months ended September 30, 2015 and 2014 (in thousands):

	Three Months Ended September 30,		Nine Month Ended September 30,	
	2015	2014	2015	2014
Contractual interest expense	$1,797	$439	$5,371	$439