Clovis Oncology, Inc.
Form 10-Q
November 07, 2013
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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, 2013.

¨ **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 ¨	Accelerated filer x
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 x

The number of outstanding shares of the registrant s common stock, par value $0.001 per share, as of November 1, 2013 was 30,171,432.

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CLOVIS ONCOLOGY, INC.

FORM 10-Q

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PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

CLOVIS ONCOLOGY, INC.

(A Development Stage Enterprise)

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(Unaudited)

(In thousands, except per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,		Cumulative from April 20, 2009 (Inception) to September 30,
	2013	2012	2013	2012	2013
Revenues	$	$	$	$	$
Operating Expenses:					
Research and development	16,063	15,458	44,001	40,610	167,706
General and administrative	4,312	2,762	11,022	7,867	35,031
Acquired in-process research and development			250	4,250	36,585
Operating loss	(20,375)	(18,220)	(55,273)	(52,727)	(239,322)
Other income (expense), net	55	(48)	(56)	(224)	(489)
Loss before income taxes	(20,320)	(18,268)	(55,329)	(52,951)	(239,811)
Income taxes				27	
Net loss	$ (20,320)	$ (18,268)	$ (55,329)	$ (52,924)	$ (239,811)
Basic and diluted net loss per common share	$ (0.68)	$ (0.71)	$ (2.00)	$ (2.15)	$ (20.73)
Basic and diluted weighted average common shares outstanding	30,047	25,906	27,614	24,568	11,570

Comprehensive loss	$ (20,299)	$ (18,261)	$ (55,314)	$ (52,919)	$ (239,743)

See accompanying notes.

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CLOVIS ONCOLOGY, INC.

(A Development Stage Enterprise)

CONSOLIDATED BALANCE SHEETS

(Unaudited)

(In thousands, except for share amounts)

	September 30, 2013	December 31, 2012
Assets		
Current assets:		
Cash and cash equivalents	$ 356,624	$ 144,097
Prepaid research and development expenses	1,167	116
Other current assets	727	659
Total current assets	358,518	144,872
Property and equipment, net	988	1,084
Other assets	753	38
Total assets	$ 360,259	$ 145,994
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable	$ 880	$ 2,297
Accrued research and development expenses	10,916	7,161
Other accrued expenses	2,783	2,702
Total current liabilities	14,579	12,160
Non-current liabilities	150	338
Commitments and contingencies (Note 10)		
Stockholders equity:		
Preferred stock, par value $0.001 per share; 10,000,000 shares authorized, no shares issued and outstanding at September 30, 2013 and December 31, 2012		
Common stock, $0.001 par value per share, 100,000,000 shares authorized at September 30, 2013 and December 31, 2012; 30,171,432 and 26,207,190 shares issued and outstanding at September 30, 2013 and December 31, 2012, respectively	30	26
Additional paid-in capital	585,243	317,899
Accumulated other comprehensive income	68	53
Deficit accumulated during development stage	(239,811)	(184,482)
Total stockholders equity	345,530	133,496

Total liabilities and stockholders equity	$ 360,259	$ 145,994

See accompanying notes.

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CLOVIS ONCOLOGY, INC.

(A Development Stage Enterprise)

CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

(Dollars in thousands)

	Nine Months Ended September 30,		Cumulative from April 20, 2009 (Inception) to September 30,
	2013	2012	2013
Operating activities			
Net loss	$ (55,329)	$ (52,924)	$ (239,811)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	185	269	812
Share-based compensation expense	6,663	3,608	13,009
Amortization of premiums and discounts on available for sale securities		11	471
Loss on disposal of equipment			1,162
Gain on sale of available for sale securities			(34)
Non-cash acquired in-process research and development			7,000
Changes in operating assets and liabilities:			
Prepaid and accrued research and development expenses	1,990	3,083	9,034
Other operating assets	(5)	573	(222)
Accounts payable	(1,463)	(933)	835
Other accrued expenses	81	(438)	2,688
Net cash used in operating activities	(47,878)	(46,751)	(205,056)
Investing activities			
Purchases of property and equipment	(80)	(1,038)	(2,624)
Purchases of available for sale securities			(27,008)
Maturities and sales of available for sale securities		2,000	26,571
Net cash provided by (used in) investing activities	(80)	962	(3,061)
Financing activities			

Proceeds from sale of convertible preferred stock, net of issuance costs			75,499
Proceeds from sale of common stock, net of issuance costs	259,071	69,976	458,406
Proceeds from exercise of stock options and employee stock purchase plan	1,403	42	2,869
Proceeds from issuance of convertible promissory notes, net of issuance costs			27,902
Net cash provided by financing activities	260,474	70,018	564,676
Effect of exchange rate changes on cash and cash equivalents	11	14	65
Increase in cash and cash equivalents	212,527	24,243	356,624
Cash and cash equivalents at beginning of period	144,097	138,236	
Cash and cash equivalents at end of period	$ 356,624	$ 162,479	$ 356,624
Non-cash items:			
Conversion of convertible preferred stock to common stock	$	$	$ 75,499
Conversion of convertible promissory notes and accrued interest to common stock	$	$	$ 35,851
Assets recorded for which payment (has)/has not yet occurred	$ (34)	$ (684)	$ 29

See accompanying notes.

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CLOVIS ONCOLOGY, INC.

(A Development Stage Enterprise)

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

1. Nature of Business and Basis of Presentation

Clovis Oncology, Inc. (the Company), a corporation in the development stage, was incorporated in Delaware on April 20, 2009, and commenced operations in May 2009. 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 and their companion diagnostics, evaluating new product acquisition candidates, raising capital and corporate organization activities. The Company has never earned revenue from these activities, and accordingly, the Company is considered to be in the development stage as of September 30, 2013.

Basis of Presentation

The information reported within the Company s financial statements from April 20, 2009 to December 31, 2010 was based solely on the accounts of Clovis Oncology, Inc. Effective January 1, 2011, Clovis Oncology UK Limited, a wholly owned subsidiary of the Company, commenced operations. All financial information presented after December 31, 2010 was consolidated and includes the accounts of the Company and its wholly owned subsidiary. 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. Changes in accumulated other comprehensive loss are not disclosed in our notes to the unaudited financial statements due to the insignificance of the activity. 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 information prepared in accordance with accounting principles generally accepted in the United States of America, or U.S. GAAP, have been condensed or omitted pursuant to the rules and regulations of the Securities and Exchange Commission, or SEC. The Company evaluates subsequent events up to the time of filing with the 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, 2012 for a broader discussion of our business and the opportunities and risks inherent in such business.

Use of Estimates

The preparation of these unaudited consolidated financial statements requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, expenses, other comprehensive loss and related disclosures. On an ongoing basis, management evaluates its estimates, including estimates related to 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 public and private equity financings, and management expects operating losses and negative cash flows to continue for at least the next several years. 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 cash and investments on hand and additional private or public debt or equity offerings, and may seek additional capital through arrangements with strategic partners or from other sources.

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, 2012.

3. Financial Instruments and Fair Value Measurement

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. Cash equivalents are reported at fair value.

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Marketable securities with original maturities greater than three months are considered to be available for sale securities and historically consisted of U.S. agency obligations, U.S. government obligations and corporate debt obligations. Available for sale securities are reported at fair market value and unrealized gains and losses are included as a separate component of stockholders equity. Realized gains, realized losses, the amortization of premiums and discounts, interest earned and dividends earned are included in other income (expense). 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 of Financial Instruments

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 and liabilities consist of money market investments.

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 does not have Level 2 assets and liabilities.

Level 3: Unobservable inputs that are supported by little or no market activity. The Company does not have any Level 3 assets and liabilities.

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

	Balance	Level 1	Level 2	Level 3
September 30, 2013				
Money market	$ 352,885	$ 352,885	$	$
Total assets at fair value	$ 352,885	$ 352,885	$	$
December 31, 2012				
Money market	$ 135,385	$ 135,385	$	$
Total assets at fair value	$ 135,385	$ 135,385	$	$

There were no security transfers between Levels 1 and 2 during the nine month period ended September 30, 2013.

4. Other Accrued Expenses

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

	September 30, 2013	December 31, 2012
Accrued personnel costs	$ 2,205	$ 2,441
Accrued corporate legal fees and professional services	365	63
Accrued expenses other	213	198
Other accrued expenses	$ 2,783	$ 2,702

5. Convertible Promissory Notes

In May 2011, the Company issued $20.0 million of 5% Convertible Promissory Notes to existing investors for cash. In June 2011, the Company issued $15.0 million of 5% Convertible Promissory Notes to Pfizer, which was comprised of a $7.0 million note issued to acquire the global rights to develop and market rucaparib and an $8.0 million note issued for cash (the Notes). The Notes accrued interest at an annual rate of 5% and had a maturity date of May 25, 2012. In connection with the completion of the Company s initial public offering in November 2011, the principal balance and all accrued and unpaid interest due on the Notes was converted into 2,757,788 shares of the Company s common stock.

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6. Convertible Preferred Stock and Stockholders Equity

Common Stock

In May 2009, the Company issued 1,206,899 shares of its common stock to the original founders at a purchase price of $.0029 per share. The shares were issued under restricted stock purchase agreements, which allowed the Company, at its discretion, to repurchase unvested shares if the founders terminated their employment with the Company. All common stock shares issued to the founders under the restricted stock purchase agreements became fully vested in May 2013.

In November 2011, the Company sold 10,700,000 shares of its common stock in an initial public offering at a price of $13.00 per share. The Company received net proceeds from the offering of $129.4 million, after deduction of $6.9 million of underwriting commissions and $2.8 million of offering expenses.

In April 2012, the Company sold 3,750,000 shares of its common stock in a public offering at $20.00 per share. The net offering proceeds realized after deducting offering expenses and underwriters discounts and commissions was $70.0 million.

In June 2013, the Company sold 3,819,444 shares of its common stock in a public offering at $72.00 per share. The net offering proceeds realized after deducting offering expenses and underwriters discounts and commissions was $259.1 million.

The holders of common stock are entitled to one vote per share on all matters to be voted upon by the stockholders of the Company. 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 the Company s Board of Directors.

Preferred Stock

In May 2009, the Company entered into the Series A-1, A-2, B and C Preferred Stock Purchase Agreement with various investors (the Preferred Stock Purchase Agreement). The Preferred Stock Purchase Agreement provided for the issuance of up to $146.3 million of the Company s convertible preferred stock, subject to various terms and conditions. During 2009, the Company issued shares of Series A-1, Series A-2 and Series B convertible preferred stock resulting in total aggregate cash proceeds to the Company of $75.5 million, net of $174,000 related stock issuance costs.

In connection with the completion of the Company s initial public offering in November 2011, all of the outstanding shares of convertible preferred stock were automatically converted into 7,244,523 shares of the Company s common stock. The Series A-1, A-2 and B convertible preferred stock converted at a rate of 2.9 for 1 into common stock based upon the election of the convertible preferred stock holders immediately prior to the closing of the initial public offering.

7. Share-Based Compensation

Share-based compensation expense for all equity based programs, including stock options and the employee stock purchase plan, for the three and nine months ended September 30, 2013 and 2012, respectively, was recognized in the accompanying Consolidated Statements of Operations and Comprehensive Loss as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Research and development	$ 1,138	$ 687	$ 3,095	$ 1,719
General and administrative	1,653	807	3,568	1,889
Total share-based compensation expense	$ 2,791	$ 1,494	$ 6,663	$ 3,608

The Company did not recognize a tax benefit related to share-based compensation expense during the three and nine months ended September 30, 2013 and 2012, respectively, as the Company maintains net operating loss carryforwards and has established a valuation allowance against the entire net deferred tax asset as of September 30, 2013. No share-based compensation expense was capitalized on our Consolidated Balance Sheets as of September 30, 2013 and December 31, 2012.

The following table summarizes the activity relating to the Company s options to purchase common stock for the nine month period ended September 30, 2013:

	Option Shares Outstanding	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Balance at December 31, 2012	1,599,044	$ 14.05		
Granted	1,080,658	29.83		
Exercised	(132,349)	9.24		
Forfeited	(29,400)	16.75		
Balance at September 30, 2013	2,517,953	$ 21.04	8.55	$ 101,885,010
Vested and expected to vest at September 30, 2013	2,325,710	$ 20.59	8.50	$ 95,108,922
Vested at September 30, 2013	824,748	$ 12.72	7.66	$ 39,848,593

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The aggregate intrinsic value in the table above represents the pretax intrinsic value, based on our closing stock price of $60.80 as of September 30, 2013, 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.

Presented in the table below are financial details associated with our stock options during the three and nine months ended September 30, 2013 and 2012.

	Three Months Ended September 30,	
	2013	2012
Weighted-average grant-date fair value per share	$ 43.43	$ 14.32
Intrinsic value of options exercised	$ 85,589	$
Cash received from stock option exercises	$ 34,711	$

	Nine Months Ended September 30,	
	2013	2012
Weighted-average grant-date fair value per share	$ 18.43	$ 15.01
Intrinsic value of options exercised	$ 5,801,963	$ 223,319
Cash received from stock option exercises	$ 1,223,023	$ 42,149

As of September 30, 2013, the unrecognized share-based compensation expense related to nonvested options, adjusted for expected forfeitures, was $22.2 million and the estimated weighted-average remaining vesting period was 2.7 years.

8. License Agreements

CO-1686

In May 2010, the Company entered into a worldwide license agreement with Avila Therapeutics, Inc. (Avila) to discover, develop and commercialize a covalent inhibitor of mutant forms of the epidermal growth factor receptor gene product. In March 2012, Avila was acquired by Celgene Corporation (Celgene). CO-1686 was identified as the lead drug candidate to be developed under the license agreement. The Company is responsible for all preclinical, clinical, regulatory and other activities necessary to develop and commercialize CO-1686. The Company made an up-front payment of $2.0 million upon execution of the license agreement which was recognized as acquired in-process research and development expense. The Company is obligated to pay royalties on net sales of CO-1686, based on the volume of annual net sales achieved. Celgene has the option to increase royalty rates by electing to reimburse a portion of the development expenses incurred by the Company. This option must be exercised within a limited period of time after Celgene is notified of our intent to pursue regulatory approval of CO-1686 in the United States or European Union as a first line therapy.

In January 2012, the U.S. Food and Drug Administration (FDA) accepted our investigational new drug (IND) application to begin clinical investigation of CO-1686. Following the FDA s acceptance of the IND application, the Company made a milestone payment of $4.0 million to Avila as required by the license agreement and recognized the payment as acquired in-process research and development expense. The Company may be required to pay up to an additional aggregate of $115.0 million in development and regulatory milestone payments if certain clinical study objectives and regulatory filings, acceptances and approvals are achieved. In addition, the Company may be required to pay up to an aggregate of $120.0 million in sales milestones if certain annual sales targets are achieved.

In January 2013, the Company entered into an exclusive license agreement with Gatekeeper Pharmaceuticals, Inc. (Gatekeeper) to acquire exclusive rights under patent applications associated with mutant epidermal growth factor receptor (EGFR) inhibitors and methods of treatment. Pursuant to the terms of the license agreement, the Company made an up-front payment of $250,000 upon execution of the agreement, which was recognized as acquired in-process research and development expense. If CO-1686 is approved for commercial sale, the Company will pay royalties to Gatekeeper on future net sales.

Rucaparib

In June 2011, the Company entered into a worldwide license agreement with Pfizer Inc. to acquire exclusive development and commercialization rights to Pfizer s drug candidate known as rucaparib. This drug candidate is a small molecule inhibitor of poly (ADP-ribose) polymerase, or PARP, which the Company is developing for the treatment of selected solid tumors. Pursuant to the terms of the license agreement, the Company made an up-front payment by issuing to Pfizer a $7.0 million convertible promissory note with a 5% annual interest rate, due in 2012. Upon completion of the Company s initial public offering in November 2011, the principal balance and all accrued and unpaid interest due on this note of $7.2 million was converted into 551,222 shares of common stock. The Company is responsible for all development and commercialization costs of rucaparib and, if approved, Pfizer will receive royalties on the net sales of the product. In addition, Pfizer is eligible to receive up to $259 million of further payments, in aggregate, if certain development, regulatory and sales milestones are achieved.

In April 2012, the Company entered into a license agreement with AstraZeneca UK Limited to acquire exclusive rights associated with rucaparib 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 rucaparib for the uses claimed by these patents. Pursuant to the terms of the license agreement, the Company made an up-front payment of $250,000 upon execution of the agreement, which was recognized as acquired in-process research and development expense. The Company may be required to pay up to an aggregate of $0.7 million in milestone payments if certain regulatory filings, acceptances and approvals are achieved. If approved, AstraZeneca will also receive royalties on any net sales of rucaparib.

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CO-101

In November 2009, the Company entered into a license agreement with Clavis Pharma ASA (Clavis) to develop and commercialize CO-101 in North America, Central America, South America and Europe. Under terms of the license agreement, the Company made an up-front payment to Clavis in the amount of $15.0 million, which was comprised of $13.1 million for development costs incurred prior to the execution of the agreement that was recognized as acquired in-process research and development and $1.9 million for the prepayment of preclinical activities to be performed by Clavis. In November 2010, the license agreement was amended to expand the license territory to include Asia and other international markets. The Company made a payment of $10.0 million to Clavis for the territory expansion and recognized the payment as acquired in-process research and development. As part of the amended license agreement, Clavis also agreed to reimburse up to $3.0 million of the Company s research and development costs for certain CO-101 development activities subject to the Company incurring such costs, all of which was completed in 2011.

On November 12, 2012, the Company reported results from a pivotal study for CO-101 as compared to gemcitabine in metastatic pancreatic cancer. The study results failed to demonstrate a difference in overall survival between the two study arms. Based on the results of the study, the Company has ceased development of CO-101 and terminated the license agreement.

Drug Discovery Collaboration Agreement

In July 2012, the Company entered into a drug discovery collaboration agreement with Array BioPharma Inc. for the discovery of a novel cKIT inhibitor targeting resistance mutations for the treatment of GIST, a gastrointestinal cancer. Under the terms of the agreement, the Company is responsible to fund all costs of the discovery program, as well as costs to develop and commercialize any clinical candidates discovered. If any clinical candidates are discovered and the Company seeks to pursue clinical development of such clinical candidates, the Company may be required to pay Array up to an aggregate of $192.0 million in milestone payments if certain development and regulatory objectives and annual net sales targets are achieved.

9. Net Loss Per Share

Basic net loss per share is calculated by dividing net loss by the weighted-average number of common shares outstanding during the period, without consideration for common stock equivalents. Diluted net loss per share is computed by dividing net loss by the weighted-average number of common share equivalents outstanding for the period determined using the treasury-stock method. For purposes of this calculation, stock options are considered to be common stock equivalents and are only included in the calculation of diluted net loss per share when their effect is dilutive.

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 and Nine Months Ended September 30,	
	2013	2012
Common shares under option	2,341	1,067
Total potential dilutive shares	2,341	1,067

10. Commitments and Contingencies

Royalty and License Fee Commitments

The Company has entered into certain license agreements, as identified in Note 8, 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. The Company s 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 no amounts have been recorded in the Company s accompanying Consolidated Balance Sheets at September 30, 2013 and December 31, 2012.

Development and Manufacturing Agreement Commitments

In February 2013, the Company entered into a development and manufacturing agreement with a third-party supplier for the production of the active ingredient for rucaparib. Under the Development and Manufacturing Agreement, the Company will provide the third-party supplier a rolling 24-month forecast that will be updated by the Company on a quarterly basis. The Company is obligated to order the quantity specified in the first twelve months of any forecast. As of September 30, 2013, $6.8 million of purchase commitments were established under this agreement.

11. Subsequent Events

The Company evaluated events up to the filing date of these interim financial statements and determined that no subsequent activity required disclosure.

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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, our ongoing and planned preclinical studies and clinical trials, the timing of and our ability to make regulatory filings and obtain and maintain regulatory approvals for our product candidates, the degree of clinical utility of our products, particularly in specific patient populations, expectations regarding clinical trial data, our results of operations, financial condition, liquidity, prospects, growth and strategies, the industry in which we operate 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 section of this Quarterly Report on Form 10-Q 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 other reports filed with the SEC and on our website.

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 seek to simultaneously develop, with partners, companion diagnostics that direct our product candidates to the patients that are most likely to benefit from their use. We are currently developing two product candidates for which we hold global marketing rights: CO-1686, an orally available, small molecule epidermal growth factor receptor, or EGFR, covalent inhibitor that is in Phase I/II clinical development for the treatment of non-small cell lung cancer, or NSCLC, in patients with activating EGFR mutations, including the initial activating mutations, as well as the primary resistance mutation, T790M; and rucaparib, an orally available, small molecule poly (ADP-ribose) polymerase, or PARP, inhibitor being developed for various solid tumors that is currently in Phase I/II clinical trials. We have also entered into a drug discovery agreement for the discovery of a novel cKIT inhibitor targeting resistance mutations for the treatment of GIST, a gastrointestinal cancer. If any clinical candidates are discovered, we would seek to pursue clinical development of such clinical candidates.

We were incorporated in Delaware in April 2009 and commenced operations in May 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. We have generated no revenues and, through September 30, 2013, have principally funded our operations using the $75.5 million of net proceeds from the sale of convertible preferred stock, the issuance of $35.0 million aggregate principal amount of convertible promissory notes, and $458.4 million of net proceeds from public offerings of our common stock completed in November 2011, April 2012 and June 2013. The convertible preferred stock and outstanding principal amount of the convertible promissory notes and all accrued and unpaid interest converted into shares of our common stock immediately prior to the closing of our initial public offering in November 2011.

We have never been profitable and, as of September 30, 2013, we had an accumulated deficit of $239.8 million. We expect to incur significant and increasing losses for the foreseeable future as we advance our product candidates through clinical development to seek regulatory approval and, if approved, commercialize such product candidates. We will need additional financing to support our operating activities. We will seek to fund our operations through public or private equity or debt financings or other sources. Adequate additional financing may not be available to us on acceptable terms, or at all. Our failure to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategy. We expect that research and development expenses will increase as we continue the development of our product candidates. We will need to generate significant revenues to achieve profitability and we may never do so.

In October 2013, we provided an update on the progress toward the clinical, regulatory, and development objectives for 2013 for each of our programs. Data from the ongoing CO-1686 Phase I dose escalation study was presented at the World Conference on Lung Cancer. These data showed that six RECIST partial responses (PR) had been observed to date in nine evaluable patients dosed at 900mg twice daily (BID) of the free base formulation of CO-1686, for a 67 percent objective response rate. Eight of the nine evaluable patients experienced PRs or tumor shrinkage greater than 10 percent. These patients were heavily pretreated prior to receiving CO-1686. Fifty-six patients have been treated to date across all dosing cohorts in the Phase I study, with no evidence of dose-related wild-type EGFR-driven toxicities.

In August, we commenced enrollment in the Phase I study using the hydrobromide (HBr) formulation of CO-1686. Pharmacokinetic data from the initial cohort receiving 500 mg BID of the HBr formulation demonstrated substantially increased exposures over those seen in patients dosed with the free base formulation at 900mg BID. There has been no evidence of skin or gastrointestinal toxicity in the 500mg BID cohort, and no dose limiting toxicity. Dose escalation is ongoing with the HBr formulation, currently dosing at 750mg BID, as the maximum tolerated dose has not yet been reached. We expect to establish the Phase 2 dose for CO-1686 by year-end 2013, and to initiate Phase 2 studies to assess efficacy in second line NSCLC patients with the T790M mutation as well as first line NSCLC patients with activating EGFR mutations. In addition, we expect to commence our initial registration study with CO-1686 in the first half of 2014 in second line NSCLC patients with the T790M mutation.

In October 2013, we announced the signing of an agreement with QIAGEN to develop a companion diagnostic test to identify the T790M mutation in patients with EGFR driven NSCLC. The diagnostic will build on QIAGEN s *therascreen* EGFR RGQ PCR Kit, which was approved by the U.S. Food and Drug Administration in July 2013 as a companion diagnostic used in the treatment of metastatic NSCLC patients whose tumors have certain EGFR mutations. Analytical performance of the *therascreen* EGFR test has been established for 21 EGFR mutations, including T790M.

During the third quarter of 2013, a dose of 600 BID was selected as the recommended Phase 2/3 dose for rucaparib. Safety data to date shows rucaparib to be well-tolerated, which is important for a drug intended to be used in a maintenance setting. In data presented at recent medical meetings, rucaparib demonstrated durable objective responses in heavily pre-treated patients. To date, eight RECIST responses have been observed during the Phase 1 study. In ovarian cancer patients with a germline BRCA mutation, one RESIST complete response, two PRs, and two biomarker assessed responses have been observed to date. Responses have been observed in both ovarian cancer

patients who responded to prior treatment with a platinum-based chemotherapy and patients who did not. Overall, seven of ten ovarian cancer patients with germline BRCA mutations treated with rucaparib at all doses achieved disease control, defined as a complete response, partial response, or stable disease for a period greater than 24 weeks. Responses have also been achieved for rucaparib patients with breast and pancreatic cancers with a germline BRCA mutation.

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Finally, we recently announced the enrollment of the first patient in the global ARIEL (Assessment of Rucaparib in Ovarian Cancer Phase 2 Trial) study. ARIEL2 is a single-arm, open-label, Phase 2 study designed to identify tumor characteristics that predict sensitivity to rucaparib using DNA sequencing to evaluate each patient s tumor. Tumor samples from study participants will be evaluated for BRCA1 and BRCA2 mutations, as well as other genes that are expected to confer sensitivity to PARP inhibitor therapy when mutated. In late 2013, we intend to initiate our pivotal study ARIEL3, a randomized, double-blind, Phase 3 study that will compare the effects of rucaparib against placebo. The study will evaluate whether maintenance rucaparib given to ovarian cancer patients who responded to a platinum based chemotherapy can extend the period of time for which the disease is controlled after successful chemotherapy.

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Product License Agreements

CO-1686

In May 2010, we entered into a worldwide license agreement with Avila (now part of Celgene Corporation) to discover, develop and commercialize a covalent inhibitor of mutant forms of the EGFR gene product. CO-1686 was identified as the lead inhibitor candidate under the license agreement. We are responsible for all preclinical, clinical, regulatory and other activities necessary to develop and commercialize CO-1686. We made an up-front payment of $2.0 million to Avila upon execution of the license agreement and an additional $4.0 million milestone payment in the first quarter of 2012 upon the acceptance by the U.S. Food and Drug Administration, or FDA, of our investigational new drug, or IND, application for CO-1686. We recognized both payments as acquired in-process research and development expense. We are obligated to pay royalties on net sales of CO-1686, based on the volume of annual net sales achieved. Celgene has the option to increase royalty rates by electing to reimburse a portion of our development expenses. This option must be exercised within a limited period of time after Celgene is notified by us of our intent to pursue regulatory approval of CO-1686 in the United States or the European Union as a first-line treatment. We may be required to pay up to an additional aggregate of $115.0 million in additional development and regulatory milestone payments if certain clinical study objectives and regulatory filings, acceptances and approvals are achieved. In addition, we may be required to pay up to an aggregate of $120.0 million in sales milestone payments if certain annual sales targets are achieved.

In January 2013, the Company entered into an exclusive license agreement with Gatekeeper Pharmaceuticals, Inc. (Gatekeeper) to acquire exclusive rights under patent applications associated with mutant EGFR inhibitors and methods of treatment. Pursuant to the terms of the license agreement, the Company made an up-front payment of $250,000 upon execution of the agreement, which was recognized as acquired in-process research and development expense. If CO-1686 is approved for commercial sale, the Company will pay royalties to Gatekeeper on future net sales.

Rucaparib

In June 2011, we entered into a license agreement with Pfizer to acquire exclusive global development and commercialization rights to Pfizer s drug candidate known as rucaparib. This drug candidate is a small molecule PARP inhibitor which we are developing for the treatment of selected solid tumors. Pursuant to the terms of the license agreement, we made an up-front payment by issuing Pfizer $7.0 million principal amount of a 5% convertible promissory note due in 2012, which was subsequently converted to common stock immediately prior to our initial public offering. We are responsible for all development and commercialization costs of rucaparib and, if approved, we will be required to pay Pfizer royalties on sales of the product. In addition, we may be required to pay Pfizer up to an aggregate of $259.0 million in milestone payments if certain development, regulatory and sales milestones are achieved.

In April 2012, the Company entered into a license agreement with AstraZeneca UK Limited to acquire exclusive rights associated with rucaparib 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 rucaparib for the uses claimed by these patents. Pursuant to the terms of the license agreement, the Company made an up-front payment of $250,000 upon execution of the agreement, which was recognized as acquired in-process research and development expense. The Company may be required to pay up to an aggregate of $0.7 million in milestone payments if certain regulatory filings, acceptances and approvals are achieved. If approved, AstraZeneca will also receive royalties on any sales of rucaparib.

Drug Discovery Collaboration Agreement

In July 2012, the Company entered into a drug discovery collaboration agreement with Array BioPharma Inc. for the discovery of a novel cKIT inhibitor targeting resistance mutations for the treatment of GIST, a gastrointestinal cancer. Under the terms of the agreement, the Company is responsible to fund all costs of the discovery program, as well as costs to develop and commercialize any clinical candidates discovered. If any clinical candidates are discovered and the Company seeks to pursue clinical development of such clinical candidates, the Company may be required to pay Array up to an aggregate of $192.0 million in milestone payments if certain development and regulatory objectives and annual net sales targets are achieved.

CO-101

In November 2009, we entered into a license agreement with Clavis to develop and commercialize CO-101 in North America, Central America, South America and Europe. Under the terms of the license agreement, we made an up-front payment to Clavis in the amount of $15.0 million, which was comprised of $13.1 million for development costs incurred prior to the execution of the agreement, which we recognized as acquired in-process research and development and $1.9 million for the prepayment of preclinical activities to be performed by Clavis. In November 2010, the license agreement was amended to expand the license territory to include Asia and other international markets. We paid Clavis $10.0 million for the territory expansion and recognized that payment as acquired in-process research and development expense. As part of the amendment to the license agreement, Clavis agreed to reimburse up to $3.0 million of our research and development costs for certain CO-101 development activities subject to our incurring such costs.

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On November 12, 2012, the Company reported results from a pivotal study of CO-101 versus gemcitabine in metastatic pancreatic cancer, which failed to demonstrate a difference in overall survival between the two study arms. Based on the results of the study, the Company has ceased development of CO-101 and terminated the license agreement.

Financial Operations Overview

Revenue

To date, we have not generated any revenues. In the future, we may generate revenue from the sales of product candidates that are currently under development. Based on our current development plans, we do not expect to generate significant revenues for the foreseeable future. If we fail to complete the development of our product candidates and, together with our partners, companion diagnostics or obtain regulatory approval for them, our ability to generate future revenue, and our results of operations and financial position, will be adversely affected.

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 statements of operations as acquired in-process research and development;
- employee-related expenses, including salaries, benefits, travel and share-based compensation expense;
- expenses incurred under agreements with CROs and investigative sites that conduct our clinical trials and preclinical studies;
- the cost of acquiring, developing and manufacturing clinical trial materials;
- costs associated with preclinical activities and regulatory operations; 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, 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.

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily

due to the increased size and duration of later stage clinical trials. We plan to increase our research and development expenses for the foreseeable future as we seek to expand our clinical and companion diagnostic development activities for our CO-1686 and rucaparib product candidates and perform drug discovery activities for a cKIT inhibitor targeting resistance mutations for the treatment of GIST.

The following table identifies research and development costs and acquired in-process research and development costs on a program-specific basis for our product candidates in-licensed through September 30, 2013, their companion diagnostics, and the cKIT inhibitor drug discovery program. 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.

	Three Months Ended September 30,		Nine Months Ended September 30,		Cumulative from April 20, 2009 (Inception) to September 30,
	2013	2012	2013	2012	2013
	(in thousands)				
CO-101 Expenses					
Acquired in-process R&D	$	$	$	$	$ 23,085
Research and development	(20)	4,774	946	16,119	61,447
CO-101 Total	(20)	4,774	946	16,119	84,532
CO-1686 Expenses					
Acquired in-process R&D			250	4,000	6,250
Research and development	4,133	2,350	11,509	4,678	27,878
CO-1686 Total	4,133	2,350	11,759	8,678	34,128
Rucaparib Expenses					
Acquired in-process R&D				250	7,250
Research and development	6,441	2,944	13,746	6,531	25,560
Rucaparib Total	6,441	2,944	13,746	6,781	32,810
cKIT Inhibitor Expenses					
Acquired in-process R&D					
Research and development	1,135	812	3,398	812	5,495
cKIT Inhibitor Total	1,135	812	3,398	812	5,495
Personnel and other expenses	4,374	4,578	14,402	12,470	47,326
Total	$ 16,063	$ 15,458	$ 44,251	$ 44,860	$ 204,291

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General and Administrative Expenses

General and administrative expenses consist principally of salaries and related costs for personnel in executive, finance, business development, legal, investor relations and information technology functions. Other general and administrative expenses include facility costs, communication expenses, corporate insurance, and professional fees for legal, consulting and accounting services.

Other Income and Expense

Other income is comprised of interest income earned on cash, cash equivalents and available for sale securities, gain on the sale of available for sale securities, and a federal grant awarded to us under the Qualifying Therapeutic Discovery Project Program in 2010. Other expense includes interest expense associated with the convertible notes payable outstanding during 2011. In addition, we hold cash balances at financial institutions denominated in currencies other than the U.S. dollar to fund research and development activities performed by various third-party vendors. The translation of these currencies into U.S. dollars results in foreign currency gains or losses, depending on the change in value of these currencies against the U.S. dollar. These gains and losses are included in Other Income and Expense.

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 and expenses and the disclosure of contingent assets and liabilities in our financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to accrued expenses and share-based compensation. 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, 2012. There have not been any material changes to our critical accounting policies since December 31, 2012.

Results of Operations

Comparison of Three Months Ended September 30, 2013 and 2012:

The following table summarizes the results of our operations for the three months ended September 30, 2013 and 2012:

	Three Months Ended			
	September 30,			
	2013	2012	Increase (Decrease)	Percent Change

		(in thousands)		
Revenues	$	$	$	
Operating Expenses:				
Research and development	16,063	15,458	605	3.9%
General and administrative	4,312	2,762	1,550	56.1%
Acquired in-process research and development				0.0%
Operating loss	(20,375)	(18,220)	2,155	11.8%
Other income (expense), net	55	(48)	(103)	(214.6%)
Loss before income taxes	(20,320)	(18,268)	2,052	11.2%
Income taxes				0.0%
Net loss	$ (20,320)	$ (18,268)	$ 2,052	11.2%

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Research and Development Expenses. The increase in research and development expenses for the three months ended September 30, 2013 compared to the three months ended September 30, 2012 was due to development expenses associated with our CO-1686 and rucaparib product candidates, less a reduction of $4.8 million in CO-101 development expenses associated with the termination of this program. Research and development expenses for CO-1686 increased by $1.7 million due primarily to expenses incurred for clinical supply manufacturing activities, as well as increased enrollment in the ongoing Phase I study for CO-1686. Research and development expenses for rucaparib increased by $3.5 million due primarily to clinical supply manufacturing activities, the initiation of two new clinical studies during the second quarter of 2013 and continued enrollment in existing clinical studies. We also initiated a drug discovery program for cKIT inhibitors during the third quarter of 2012, which resulted in an increase of $0.3 million over the third quarter of 2012.

General and Administrative Expenses. The increase in general and administrative expenses for the three months ended September 30, 2013 compared to the three months ended September 30, 2012 was primarily attributable to an increase in share-based compensation expense of $0.8 million. The increase was also due to larger professional services costs in 2013.

Other Income (Expense), Net. The decrease in other income (expense), net for the three months ended September 30, 2013 compared to the three months ended September 30, 2012 was due to an increase in foreign currency gains. The gain increased in the third quarter of the current year in comparison to the same quarter of the prior year due to the strengthening of foreign currencies in relation to the U.S. dollar and the timing and size of the foreign currency balance maintained during each period.

Comparison of Nine Months Ended September 30, 2013 and 2012:

The following table summarizes the results of our operations for the nine months ended September 30, 2013 and 2012:

	Nine Months Ended September 30,			
	2013	2012	Increase (Decrease)	Percent Change
			(in thousands)	
Revenues	$	$	$	
Operating Expenses:				
Research and development	44,001	40,610	3,391	8.4%
General and administrative	11,022	7,867	3,155	40.1%
Acquired in-process research and development	250	4,250	(4,000)	(94.1%)
Operating loss	(55,273)	(52,727)	2,546	4.8%
Other income (expense), net	(56)	(224)	(168)	(75.0%)
Loss before income taxes	(55,329)	(52,951)	2,378	4.5%
Income taxes		27	27	100.0%
Net loss	$ (55,329)	$ (52,924)	$ 2,405	4.5%

Research and Development Expenses. The increase in research and development expenses for the nine months ended September 30, 2013 compared to the nine months ended September 30, 2012 was due to an increase in development expenses associated with our CO-1686 and rucaparib product candidates, offset by a reduction of $15.1 million in CO-101 development expenses associated with the termination of this program. Research and development expenses for CO-1686 increased by $6.9 million due primarily to drug formulation development activities, clinical supply manufacturing activities, and increased clinical trial costs as we initiated clinical development activities for this program in March 2012. Research and development expenses for rucaparib increased by $7.2 million due primarily to the initiation of two new clinical studies during the second quarter of 2013 and clinical supply manufacturing activities. In the third quarter of 2012, we also initiated a drug discovery program for cKIT inhibitors, resulting in an increase of $2.6 million over the first nine months of 2012. The remaining increase is attributable to personnel costs, including a $1.4 million increase in share-based compensation expense for research and development personnel.

General and Administrative Expenses. The increase in general and administrative expenses for the nine months ended September 30, 2013 compared to the nine months ended September 30, 2012 was primarily attributable to an increase in share-based compensation expense of $1.7 million. The increase was also due to larger personnel, professional services and facilities costs in 2013 to support the Company s growth.

Acquired In-Process Research and Development Expenses. The decrease in acquired in-process research and development expenses for the nine months ended September 30, 2013 compared to the nine months ended September 30, 2012 was due to a reduction in payments made to partners related to in-licensing agreements. In January 2012, we made a regulatory milestone payment of $4.0 million to Avila Therapeutics, Inc. for the FDA s acceptance of our IND application to begin clinical investigation of CO-1686.

Other Income (Expense), Net. The decrease in other income (expense), net for the nine months ended September 30, 2013 compared to the nine months ended September 30, 2012 was due to an increase in foreign currency gains. The gains increased over the prior year due to the strengthening of the foreign currencies denominated in Euros and British Pounds in relation to the U.S. dollar and the timing and size of the foreign currency balances maintained during each period.

Liquidity and Capital Resources

Through September 30, 2013, we funded our operations through the private placement of preferred stock and convertible debt securities and the public offering of our common stock. As of September 30, 2013, we have received $75.5 million in net proceeds from the issuance of convertible preferred stock, $27.9 million through the issuance of convertible promissory notes, $458.4 million in net proceeds from the issuance of common stock and $2.9 million in proceeds from stock option exercises. The outstanding principal amount and all accrued and unpaid interest associated with the convertible promissory notes were converted into shares of our common stock immediately prior to the closing of our initial public offering at the initial public offering price of $13.00 per share, in November 2011. As of September 30, 2013, we had cash and cash equivalents totaling $356.6 million.

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The following table sets forth the primary sources and uses of cash for the nine months ended September 30, 2013 and 2012:

	Nine Months Ended September 30,	
	2013	2012
	(in thousands)	
Net cash used in operating activities	$ (47,878)	$ (46,751)
Net cash provided by (used in) investing activities	(80)	962
Net cash provided by financing activities	260,474	70,018
Effect of exchange rate changes on cash and cash equivalents	11	14
Net increase in cash and cash equivalents	$ 212,527	$ 24,243

Operating Activities

The cash used in operating activities for all periods resulted primarily from our net losses adjusted for non-cash charges and changes in components of working capital. The cash used in operating activities for all periods reflects the continued development of our product candidates as described in Results of Operations above.

Investing Activities

The cash provided by (used in) investing activities for all periods primarily reflects the maturities and sales of available for sale securities, offset by the purchase of property and equipment. The decrease of $1.0 million in cash provided by (used in) investing activities for the nine months ended September 30, 2013 compared to the prior year s respective period was due to a reduction in available for sale security sales and maturities of $2.0 million, offset by a decrease of $1.0 million used for the purchase of property and equipment.

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Financing Activities

The cash provided by financing activities for the nine months ended September 30, 2013 represents the receipt of $1.4 million in proceeds from the exercise of stock options and employee stock purchase plan and the receipt of $259.1 million in net proceeds from the sale of our common stock in June 2013. The cash provided by financing activities for the nine months ended September 30, 2012 reflects the receipt of $70.0 million in net proceeds from the sale of our common stock in April 2012.

Operating Capital Requirements

We anticipate that we will continue to generate significant losses for the foreseeable future as we incur expenses to complete our development activities for each of our programs, including clinical trial activities, companion diagnostic development, drug development, establishing our commercial capabilities, and expanding our general and administrative functions to support the growth in our research and development and commercial organizations.

The net proceeds raised from the sale of securities to date will not be sufficient to fund our operations through successful development and commercialization of our product candidates. As a result, we will need to raise additional capital to fund our operations and continue to conduct clinical trials to support additional development and potential regulatory approval, make milestone payments to our licensors and commercialize our product candidates.

We believe that our existing cash and cash equivalents, will allow us to fund our operating plan through at least the next 12 months. If our available cash and cash equivalents are insufficient to satisfy our liquidity requirements, we may seek to sell additional equity or debt securities or obtain a credit facility. The sale of additional equity and debt securities may result in additional dilution to our shareholders.

In addition, if we raise additional funds through the issuance of debt securities or preferred stock, these securities may have rights senior to those of our common stock and could contain covenants that would restrict our operations. Furthermore, any such required additional capital may not be available on reasonable terms, if at all. If we were unable to obtain additional financing, we may be required to reduce the scope of, delay, or eliminate some or all of our planned development and commercialization activities, which could harm our business.

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

- the number and characteristics of the product candidates, companion diagnostics, and indications we pursue;
- the achievement of various development, regulatory and commercial milestones resulting in required payments to partners pursuant to the terms of our license agreements;
- the scope, progress, results and costs of researching and developing our product candidates and related companion diagnostics and conducting clinical and preclinical trials;

the timing of, and the costs involved in, obtaining regulatory approvals for our product candidates and companion diagnostics;

the cost of manufacturing any of our product candidates; and

the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims

Contractual Obligations and Commitments

For a discussion of our contractual obligations, see Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operations in our 2012 Annual Report on Form 10-K. There have not been any material changes to such contractual obligations or potential milestone payments since December 31, 2012 aside from those disclosed in Note 10 to the Notes to Unaudited Consolidated Financial Statements included elsewhere in this report.

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ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to market risk related to changes in interest rates. As of September 30, 2013, we had cash and cash equivalents of $356.6 million, consisting of bank demand deposits and money market funds that primarily invest in U.S. government obligations. 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 market value of our portfolio.

We contract with CROs, investigational sites, and contract manufacturers globally. We may be subject to fluctuations in foreign currency rates in connection with these agreements. While we periodically hold foreign currencies, primarily Euro 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 September 30, 2013 and December 31, 2012, approximately 11% and 26%, respectively, of our total liabilities were denominated in currencies other than our 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, or 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 September 30, 2013 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 September 30, 2013, 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 September 30, 2013 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

We are not currently a party to any material legal proceedings.

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 carefully consider the risk factors described under the heading Risk Factors in our Annual Report on Form 10-K for the fiscal year ended December 31, 2012 and in 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 have been no material changes to the risk factors included in our previously filed Annual Report on Form 10-K for the year ended December 31, 2012, except as described in the updated risk factor provided below. Additional risks and uncertainties not presently known to us or that we currently believe are immaterial also may negatively impact our business.

We face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively.

The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. In addition, the competition in the oncology market is intense. We have competitors both in the United States and internationally, including major multinational pharmaceutical companies, biotechnology companies and universities and other research institutions. For example, Tarceva®, Iressa®, and Gilotrif (afatanib) are three of the currently approved drugs that are used to treat EGFR mutant NSCLC, and in addition, we are aware of four products in development targeting EGFR for the treatment of NSCLC: Pfizer s PF-299804 (dacomitinib), Ariad s AP26113, Taiho s TAS-2913, and Hanmi Pharmaceutical s HM61713. In addition, AstraZeneca is developing AZD9291, which has been shown to have activity against both the activating EGFR mutations, as well as the T790M resistance mutation targeted by CO-1686. Also, we believe the products in development targeting the PARP pathway consist of Abbott s ABT-888 (velaparib), Tesaro, Inc. s niraparib, Eisai s E-7016, Teva s CEP-9722, Biomarin s BMN-673, and AstraZeneca s olaprib.

Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff and experienced marketing and manufacturing organizations. Additional mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. As a result, these companies may obtain regulatory approval more rapidly than we are able and may be more effective in selling and marketing their products as well. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors may succeed in developing, acquiring or licensing on an exclusive basis drug products that are more effective or less costly than any drug candidate that we are currently developing or that we may develop. If approved, our product candidates will face competition from commercially available drugs as well as drugs that are in the development pipelines of our competitors and later enter

the market.

Established pharmaceutical companies may invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make our product candidates less competitive. In addition, any new product that competes with an approved product must demonstrate compelling advantages in efficacy, convenience, tolerability and safety in order to overcome price competition and to be commercially successful. Accordingly, our competitors may succeed in obtaining patent protection, receiving FDA, EMA or other regulatory approval or discovering, developing and commercializing medicines before we do, which would have a material adverse impact on our business.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS
Use of Proceeds from Sales of Registered Securities

Our initial public offering of common stock was effected through a Registration Statement on Form S-1 (File No. 333-175080) that was declared effective by the Securities and Exchange Commission on November 15, 2011 and registered an aggregate of 11,500,000 shares of our common stock. On November 21, 2011, 10,000,000 shares of common stock were sold on our behalf at an initial public offering price of $13.00 per share, for aggregate gross proceeds of $130.0 million. On November 30, 2011, in connection with the exercise of the underwriters over-allotment option, 700,000 additional shares of common stock were sold on our behalf at the initial public offering price of $13.00 per share, for aggregate gross proceeds of $9.1 million. Following the sale of the 10,700,000 shares of common stock, the offering terminated.

We paid to the underwriters underwriting discounts and commissions of approximately $6.9 million in connection with the offering. In addition, we incurred expenses of approximately $2.8 million in connection with the offering, which when added to the underwriting discounts and commissions paid by us, amounts to total expenses of approximately $9.7 million. Thus, the net offering proceeds to us, after deducting underwriting discounts and commissions and offering expenses, were approximately $129.4 million. No offering expenses were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning ten percent or more of any class of our equity securities or to any other affiliates.

As of September 30, 2013, we had used $115.9 million of the net proceeds from our initial public offering to fund operations, capital expenditures, working capital and other general corporate purposes. The remainder of the proceeds have been invested into money market funds.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES
None.

ITEM 4. MINE SAFETY DISCLOSURES
Not Applicable.

ITEM 5. OTHER INFORMATION
None.

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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(5)	Amended and Restated Bylaws of Clovis Oncology, Inc.
4.1(3)	Form of Common Stock Certificate of Clovis Oncology, Inc.
4.2(1)	Clovis Oncology Inc. Investor Rights Agreement, dated as of May 15, 2009, between Clovis Oncology, Inc. and certain investors named therein.
10.1*(4)	Amended and Restated Strategic License Agreement, dated as of June 16, 2011, by and between Clovis Oncology, Inc. and Avila Therapeutics, Inc.

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Exhibit

Number	Exhibit Description
10.2*(4)	License Agreement, dated as of June 2, 2011, by and between Clovis Oncology, Inc. and Pfizer Inc.
10.3+(1)	Clovis Oncology, Inc. 2009 Equity Incentive Plan.
10.4+(4)	Clovis Oncology, Inc. 2011 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+(3)	Employment Agreement, dated as of August 24, 2011, between Clovis Oncology, Inc. and Patrick J. Mahaffy.
10.8+(3)	Employment Agreement, dated as of August 24, 2011, between Clovis Oncology, Inc. and Erle T. Mast.
10.9+(3)	Employment Agreement, dated as of August 24, 2011, between Clovis Oncology, Inc. and Gillian C. Ivers-Read.
10.10+(3)	Employment Agreement, dated as of August 24, 2011, between Clovis Oncology, Inc. and Andrew R. Allen.
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.
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 Erle T. Mast.
10.19+(1)	Indemnification Agreement, dated as of May 12, 2009, between Clovis Oncology, Inc. and Gillian C. Ivers-Read.
10.20+(1)	Indemnification Agreement, dated as of May 13, 2009, between Clovis Oncology, Inc. and Andrew R. Allen.
10.21+(1)	Restricted Stock Purchase Agreement, dated as of May 12, 2009, between Clovis Oncology, Inc. and Patrick J. Mahaffy.

10.22+(1)	Restricted Stock Purchase Agreement, dated as of May 12, 2009, between Clovis Oncology, Inc. and Erle T. Mast.
10.23+(1)	Restricted Stock Purchase Agreement, dated as of May 12, 2009, between Clovis Oncology, Inc. and Gillian C. Ivers-Read.
10.24+(1)	Restricted Stock Purchase Agreement, dated as of May 12, 2009, between Clovis Oncology, Inc. and Andrew R. Allen.
10.25+(4)	Clovis Oncology, Inc. 2011 Employee Stock Purchase Plan.
10.26+(4)	Clovis Oncology, Inc. 2011 Cash Bonus Plan.
10.27+(6)	Employment Agreement, dated as of March 22, 2012, by and between Clovis Oncology, Inc. and Steven L. Hoerter.
10.28+(6)	Indemnification Agreement, dated as of March 22, 2012, by and between Clovis Oncology, Inc. and Steven L. Hoerter.
10.29+(2)	Indemnification Agreement, dated as of June 13, 2013, between Clovis Oncology, Inc. and Ginger L. Graham.
10.30+(2)	Indemnification Agreement, dated as of June 13, 2013, between Clovis Oncology, Inc. and Keith Flaherty.
31.1	Certification of principal executive officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as amended.
31.2	Certification of principal financial officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as amended.
32.1	Certification of principal executive officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of principal financial officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101	The following materials from Clovis Oncology, Inc. s Quarterly Report on Form 10-Q for the period ended September 30, 2013, formatted in XBRL (eXtensible Business Reporting Language): (i) the Consolidated Statements of Operations, (ii) the Consolidated Balance Sheets, (iii) the Consolidated Statements of Cash Flows and (iv) Notes to Unaudited Consolidated Financial Statements.

(1) Filed as an exhibit with the Registrant s Registration Statement on Form S-1 (File No. 333-175080) on June 23, 2011.
(2) Filed as an exhibit with the Registrant s Current Report on Form 8-K (File No. 001-35347) on June 14, 2013.
(3) Filed as an exhibit with Amendment No. 2 to the Registrant s Registration Statement on Form S-1 (File No. 333-175080) on August 31, 2011.
(4) Filed as an exhibit with Amendment No. 3 to the Registrant s Registration Statement on Form S-1 (File No. 333-175080) on October 31, 2011.
(5) Filed as an exhibit with the Registrant s Annual Report on Form 10-K on March 15, 2012.
(6) Filed as an exhibit with the Registrant s Registration Statement on Form S-1 (File No. 333-180293) on March 23, 2012.
+ 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.

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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: November 7, 2013

CLOVIS ONCOLOGY, INC.

By: /s/ Patrick J. Mahaffy
Patrick J. Mahaffy
President and Chief Executive Officer; Director

By: /s/ Erle T. Mast
Erle T. Mast
Executive Vice President and Chief Financial Officer