Clovis Oncology, Inc.
Form 10-Q
May 11, 2012

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended March 31, 2012.

¨ **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 ¨
Non-accelerated filer x (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 May 7, 2012 was 26,128,989.

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 March 31,		Cumulative from April 20, 2009 (Inception) to
	2012	2011	March 31, 2012
Revenues	$	$	$
Operating Expenses:			
Research and development	12,562	7,041	77,373
General and administrative	2,425	1,405	15,796
Acquired in-process research and development	4,000		36,085
Operating loss	(18,987)	(8,446)	(129,254)
Other income (expense), net	(4)	118	(209)
Loss before income taxes	(18,991)	(8,328)	(129,463)
Income taxes	(8)		(35)
Net loss	$ (18,999)	$ (8,328)	$ (129,498)
Basic and diluted net loss per common share	$ (0.86)	$ (6.64)	$ (33.68)
Basic and diluted weighted average common shares outstanding	22,041	1,254	3,845
Comprehensive loss	$ (18,997)	$ (8,334)	$ (129,447)

See accompanying notes.

CLOVIS ONCOLOGY, INC.

(A Development Stage Enterprise)

CONSOLIDATED BALANCE SHEETS

(Unaudited)

(In thousands, except for share amounts)

	March 31, 2012	December 31, 2011
Assets		
Current assets:		
Cash and cash equivalents	$ 120,983	$ 138,236
Available for sale securities		2,012
Prepaid research and development expenses	542	1,020
Other current assets	650	247
Total current assets	122,175	141,515
Property and equipment, net	2,003	1,896
Other assets	35	34
Total assets	$ 124,213	$ 143,445
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable	$ 2,477	$ 3,036
Accrued research and development expenses	5,857	5,071
Other accrued expenses	1,341	2,889
Total current liabilities	9,675	10,996
Non-current liabilities	555	656
Commitments and contingencies (Note 11)		
Stockholders equity:		
Preferred stock, par value $0.001 per share; 10,000,000 shares authorized, no shares issued and outstanding at March 31, 2012 and December 31, 2011		
Common stock, $0.001 par value per share, 100,000,000 shares authorized at March 31, 2012 and December 31, 2011; 22,378,989 and 22,375,757 shares issued and outstanding at March 31, 2012 and December 31, 2011, respectively	22	22
Additional paid-in capital	243,408	242,221
Accumulated other comprehensive income	51	49
Deficit accumulated during development stage	(129,498)	(110,499)
Total stockholders equity	113,983	131,793
Total liabilities and stockholders equity	$ 124,213	$ 143,445

See accompanying notes.

CLOVIS ONCOLOGY, INC.

(A Development Stage Enterprise)

CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

(Dollars in thousands)

	Three Months Ended March 31,		Cumulative from April 20, 2009 (Inception) to March 31,
	2012	2011	2012
Operating activities			
Net loss	$ (18,999)	$ (8,328)	$ (129,498)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	84	42	358
Share-based compensation expense	946	59	2,343
Amortization of premiums and discounts on available for sale securities	10	61	471
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	1,264	797	5,315
Other operating assets	321	(371)	121
Accounts payable	(580)	(294)	2,476
Other accrued expenses	(1,599)	(155)	1,101
Net cash used in operating activities	(18,553)	(8,189)	(110,347)
Investing activities			
Purchases of property and equipment	(701)	(120)	(2,187)
Purchases of available for sale securities			(27,008)
Maturities and sales of available for sale securities	2,000	2,400	26,571
Net cash provided by (used in) investing activities	1,299	2,280	(2,624)
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	(19)		129,340
Proceeds from stock option exercises	10	2	1,161
Proceeds from issuance of convertible promissory notes, net of issuance costs			27,902
Net cash provided by (used in) financing activities	(9)	2	233,902
Effect of exchange rate changes on cash and cash equivalents	10	1	52
Increase (decrease) in cash and cash equivalents	(17,253)	(5,906)	120,983
Cash and cash equivalents at beginning of period	138,236	10,508	
Cash and cash equivalents at end of period	$ 120,983	$ 4,602	$ 120,983

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 not yet occurred	$ 291		$ 291

See accompanying notes.

CLOVIS ONCOLOGY, INC.

(A Development Stage Enterprise)

NOTES TO UNAUDITED 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 clinical 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 three 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 March 31, 2012.

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. 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. 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, 2011 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 private equity financings and its initial public offering, 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 additional private or public debt or equity offerings, and may seek additional capital through arrangements with strategic partners or from other sources. Based on the Company s operating plan, existing working capital at March 31, 2012 and the Company s sale of common stock in April 2012 (see Note 12) is sufficient to meet the cash requirements to fund planned operations through at least the next twelve months without additional sources of cash, although there can be no assurance that this can, in fact, be accomplished.

Recently Adopted Accounting Updates

On January 1, 2012, the Company adopted Accounting Standards Update (ASU) No. 2011-05, Presentation of Comprehensive Income. The standard eliminates the current option to report other comprehensive income and its components in the statement of changes in equity. An entity may present items of net income and other comprehensive income in one continuous statement, or in two separate, but consecutive statements. The Company adopted this standard on January 1, 2012.

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, 2011.

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. Marketable securities with original maturities greater than three months are considered to be available for sale securities and consist 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 s Level 2 assets and liabilities include U.S. government obligations, U.S. government agency obligations and corporate debt securities.

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

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

Description	Balance	Level 1	Level 2	Level 3
March 31, 2012				
Money market	$ 115,885	$ 115,885	$	$
Total assets at fair value	$ 115,885	$ 115,885	$	$
December 31, 2011				
Money market	$ 136,273	$ 136,273	$	$
U.S. agency obligations	2,012		2,012	
Total assets at fair value	$ 138,285	$ 136,273	$ 2,012	$

There were no security transfers between Levels 1 and 2 in the three month period ended March 31, 2012.

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4. Available for Sale Securities

The Company s available for sale securities at cost or amortized cost value and fair market value by contractual maturity were (in thousands):

	Cost or Amortized Cost Value	Fair Market Value
March 31, 2012		
Due in one year or less	$	$
Total	$	$
December 31, 2011		
Due in one year or less	$ 2,010	$ 2,012
Total	$ 2,010	$ 2,012

The types of securities included in the Company s available for sale investments at March 31, 2012 and December 31, 2011 were (in thousands):

	Cost or Amortized Cost Value	Gross Unrealized Gains	Gross Unrealized (Losses)	Fair Market Value
March 31, 2012				
U.S. government agencies	$	$	$	$
December 31, 2011				
U.S. government agencies	$ 2,010	$ 2	$	$ 2,012

No securities have been in a continuous unrealized loss position for more than 12 months at March 31, 2012 and December 31, 2011, respectively, and no impairments have been recorded for the periods presented.

5. Other Accrued Expenses

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

	March 31, 2012	December 31, 2011
Accrued personnel costs	$ 1,082	$ 2,373
Accrued corporate legal fees and professional services	25	231
Accrued expenses other	234	285
Other accrued expenses	$ 1,341	$ 2,889

6. 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.

7. Convertible 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. Holders of the Series A-1, A-2 and B convertible preferred stock had the right to convert the convertible preferred stock, at any time, into shares of common stock, during the period in which they were outstanding.

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 was 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. The preferred shares also contained beneficial liquidation and dividend preferences, none of which were realized due to the conversion of the shares into common stock.

8. Share-Based Compensation

Share-based compensation expense for the three months ended March 31, 2012 and 2011, respectively, was recognized in the accompanying Consolidated Statements of Operations and Comprehensive Loss as follows:

	Three Months Ended March 31,		Cumulative from April 20, 2009 (Inception) to March 31,
	2012	2011	2012
Research and development	$ 440	$ 34	$ 1,101
General and administrative	506	25	1,242
Total share-based compensation expense	$ 946	$ 59	$ 2,343

The Company did not recognize a tax benefit related to share-based compensation expense during the three months ended March 31, 2012 and 2011, respectively, as the Company maintains net operating loss carryforwards and has established a valuation allowance against the entire tax benefit as of March 31, 2012. No share-based compensation expense was capitalized on our Consolidated Balance Sheets as of March 31, 2012 and December 31, 2011.

The following table summarizes the activity relating to the Company s options to purchase common stock:

	Option Shares Outstanding	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Balance at December 31, 2011	934,816	$ 4.88		
Granted	656,800	24.57		
Exercised	(3,232)	3.11		
Forfeited				
Balance at March 31, 2012	1,588,384	$ 13.02	9.20	$ 19,739,859
Vested and expected to vest at March 31, 2012	1,399,519	$ 12.25	9.14	$ 18,476,164
Vested at March 31, 2012	278,711	$ 1.76	8.06	$ 6,601,994

The aggregate intrinsic value in the table above represents the pretax intrinsic value, based on our closing stock price of $25.45 as of March 31, 2012, 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.

	Three Months Ended March 31,	
	2012	2011
Weighted-average grant-date fair value per share	$ 15.58	$ 9.25
Intrinsic value of options exercised	$ 60,474	$
Cash received from stock option exercises	$ 10,041	$ 2,378

The 2009 Equity Incentive Plan allows for the option holder to exercise stock option shares prior to the vesting of the option. The shares acquired from an early exercise are subject to repurchase if the option holder terminates employment or service with the Company. The number of unvested common shares at the point of termination will be repurchased by the Company at the stated exercise price of the option. The number of common shares exercised prior to vesting was 277,968 and 81,206 at March 31, 2012 and 2011, respectively. The number of early exercised shares expected to vest using estimated forfeiture rates over the remaining service period of the option term was 273,102 and 80,922 at

March 31, 2012 and 2011, respectively.

As of March 31, 2012, the unrecognized share-based compensation expense related to nonvested options, adjusted for expected forfeitures, and estimated weighted-average remaining vesting period was as follows:

Unrecognized share-based compensation expense (in millions)	Weighted-average remaining vesting period (in years)
$ 14.1	3.5

9. License Agreements

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 has 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. For the three months ended March 31, 2012 and 2011 and the cumulative period from April 20, 2009 (Inception) to March 31, 2012, the Company incurred expenses eligible for reimbursement of approximately $0, $1.0 million and $3.0 million, respectively, which were recorded as a reduction to research and development expenses. The Company is responsible for all remaining development and commercialization costs of the compound and, if approved, Clavis will be eligible to receive royalties based on the volume of annual net sales achieved. The Company may be required to pay Clavis up to an 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 Clavis up to an aggregate of $445.0 million in sales milestone payments if certain annual sales targets are met for the CO-101 compound.

Subject to certain conditions set forth in the license agreement, Clavis may elect to co-develop and co-promote CO-101 in Europe. If Clavis were to make this election, it would be required to reimburse the Company for a portion of both past and future development costs. In addition, the milestone payments described above would be reduced, and Clavis would not be entitled to royalties on the net sales in Europe, but would instead share equally in the pretax profits or losses resulting from commercialization activities in Europe.

CO-1686

In May 2010, the Company entered into a worldwide license agreement with Avila Therapeutics, Inc. (Avila) to discover, develop and commercialize preclinical covalent inhibitors of mutant forms of the epidermal growth factor receptor gene. CO-1686 was identified as the lead inhibitor candidate developed by Avila 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 to Avila upon execution of the license agreement, which was recognized as acquired in-process research and development expense. The Company is obligated to pay Avila royalties on net sales of CO-1686, based on the volume of annual net sales achieved. Avila 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 of Avila s being notified of our intent to pursue regulatory approval of CO-1686 in the United States or European Union as a first line therapy. The Company may be required to pay to Avila up to an aggregate of $119.0 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 Avila up to an aggregate of $120.0 million in sales milestones if certain annual sales targets are achieved. In March 2012, Avila was acquired by Celgene Corporation.

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, we 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.

Rucaparib

In June 2011, the Company entered into a license agreement with Pfizer Inc. to acquire exclusive global development and commercialization rights to Pfizer s drug candidate PF-01367338, also 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.

10. 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, convertible preferred stock and 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 Months Ended March 31,	
	2012	2011
Common shares under option	1,588	947
Convertible preferred stock		7,245
Total potential dilutive shares	1,588	8,192

11. Commitments and Contingencies

The Company has entered into certain license agreements, as identified in Note 9, with third parties that include the payment of certain 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 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 March 31, 2012 and December 31, 2011.

12. Subsequent Events

The Company evaluated subsequent events through the filing date of these interim financial statements.

Follow-on Offering

In April 2012, the Company raised $75.0 million in gross proceeds from the sale of 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 approximately $70.5 million.

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 three product candidates for which we hold global marketing rights: CO-101, a lipid-conjugated form of the anti-cancer drug gemcitabine, which is in a pivotal study in a specific patient population for the treatment of metastatic pancreatic cancer; 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. As our product candidates mature, we intend to build commercial organizations of our own in major global markets and contract with local distributors in smaller markets.

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 March 31, 2012, 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 $129.4 million of net proceeds from our initial public offering completed in November 2011. 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 April 2012, we raised an additional $70.5 million of net proceeds through a public offering of our common stock.

We have never been profitable and, as of March 31, 2012, we had an accumulated deficit of $129.5 million. We incurred losses of $129.5 million, $19.0 million, and $8.3 million for the cumulative period from April 20, 2009 (inception) through March 31, 2012 and for the three months ended March 31, 2012, and 2011, respectively. 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 and general and

administrative costs will increase as we grow and operate as a public company. We will need to generate significant revenues to achieve profitability and we may never do so.

The financial information presented from April 20, 2009 (inception) to December 31, 2010 was based solely on the results of Clovis Oncology, Inc. Subsequent to January 1, 2011, the financial information is consolidated and includes the results of our wholly owned subsidiary in the United Kingdom. All intercompany transactions and balances are eliminated in this consolidation.

Product License Agreements

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 $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 has also 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. We are responsible for all remaining development and commercialization costs of the compound and, if approved, Clavis will be entitled to receive royalties based on the volume of annual net sales achieved. We may be required to pay Clavis an aggregate of up to $115.0 million in 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 Clavis an aggregate of up to $445.0 million in sales milestone payments if certain annual sales targets are met for CO-101.

Subject to certain conditions set forth in the license agreement, Clavis may elect to co-develop and co-promote CO-101 in Europe. If Clavis were to make this election, it would be required to reimburse us for a portion of both past and future development costs. In addition, our milestone payment obligations described above would be reduced. Clavis would not be entitled to royalties on the net sales in Europe, but would instead share equally in the pretax profits or losses resulting from commercialization activities in Europe.

CO-1686

In May 2010, we entered into a worldwide license agreement with Avila to discover, develop and commercialize preclinical covalent inhibitors of mutant forms of EGFR. CO-1686 was identified as the lead inhibitor candidate developed by Avila 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 Avila royalties on net sales of CO-1686, based on the volume of annual net sales achieved. Avila 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 of Avila s being 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 Avila up to an 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 Avila up to an aggregate of $120.0 million in sales milestone payments if certain annual sales targets are achieved.

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 PF-01367338, also 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 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.

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 until 2014 at the earliest. 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 complete development of our most advanced product candidate, CO-101, and its companion diagnostic, transition our CO-1686 product candidate into human clinical trials, and continue the development of rucaparib including the cost of ongoing clinical trials.

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 March 31, 2012 and their companion diagnostics. 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 March 31,		Cumulative from April 20, 2009 (Inception) to March 31,
	2012	2011	2012
	(in thousands)		
CO-101 Expenses			
Acquired in-process R&D	$	$	$ 23,085
Research and development	5,881	3,762	42,416
CO-101 Total	5,881	3,762	65,501
CO-1686 Expenses			
Acquired in-process R&D	4,000		6,000
Research and development	1,012	1,289	9,640
CO-1686 Total	5,012	1,289	15,640
Rucaparib Expenses			
Acquired in-process R&D			7,000
Research and development	1,932		4,793
Rucaparib Total	1,932		11,793
Personnel and other expenses	3,737	1,990	20,524
Total	$ 16,562	$ 7,041	$ 113,458

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, and professional fees for legal, consulting and accounting services.

We anticipate that our general and administrative expenses will increase due to many factors and the most significant of these factors include:

- increased personnel expenses to support the growth in research and development activities; and
- increased expenses related to becoming a publicly traded company, including increased legal and accounting services, addition of new headcount to support compliance and communication needs, and increased insurance premiums.

Other Income and Expense

Other income is primarily comprised of interest income earned on cash, cash equivalents and available for sale securities. 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, 2011. There have not been any material changes to our critical accounting policies since December 31, 2011.

Results of Operations

Comparison of Three Months Ended March 31, 2012 and 2011:

Research and Development Expenses. Research and development expenses for the three months ended March 31, 2012 and 2011 were as follows:

	Three Months Ended March 31,			
	2012	2011	Increase (Decrease)	Percent Change
	(in thousands)			
Research and development expenses	$ 12,562	$ 7,041	$ 5,521	78.4%

The increase in research and development expenses for the three months ended March 31, 2012 compared to the three months ended March 31, 2011 was due to the growth in CO-101 development expenses of $2.1 million associated with the expansion of clinical trials, the development of companion diagnostics and drug formulation and manufacturing costs. In addition, for rucaparib, which we in-licensed in the second quarter of 2011, research and development expenses increased by $1.9 million, due to our assumption of clinical development responsibility and associated costs for this product candidate. The remaining increase of $1.8 million was due primarily to an increase in our internal salaries, benefits and personnel related costs resulting from additional headcount hired to support the expanding development activities of CO-101, CO-1686 and rucaparib.

General and Administrative Expenses. General and administrative expenses for the three months ended March 31, 2012 and 2011 were as follows:

	Three Months Ended March 31,			
	2012	2011	Increase (Decrease)	Percent Change
	(in thousands)			
General and administrative expenses	$ 2,425	$ 1,405	$ 1,020	72.6%

The increase in general and administrative expenses for the three months ended March 31, 2012 compared to the three months ended March 31, 2011 was primarily attributable to increased personnel, professional services, travel and information system costs associated with being a publicly traded company. Additionally, share-based compensation expense increased by $0.5 million due to the increase in value of the options granted in the first quarter of 2012.

Acquired In-Process Research and Development Expenses. Acquired in-process research and development expenses for the three months ended March 31, 2012 and 2011 were as follows:

	Three Months Ended March 31,			
	2012	2011	Increase (Decrease)	Percent Change
	(in thousands)			
Acquired in-process research and development	$ 4,000	$	$ 4,000	100.0%

The increase in acquired in-process research and development expenses for the three months ended March 31, 2012 compared to the three months ended March 31, 2011 was due to the payment of a $4.0 million regulatory milestone to Avila Therapeutics, Inc. for the FDA s acceptance in January 2012 of our IND application to begin clinical investigation of CO-1686.

Other Income (Expense), Net. Other income (expense), net for the three months ended March 31, 2012 and 2011 were as follows:

	Three Months Ended March 31,			
	2012	2011	Increase (Decrease)	Percent Change
	(in thousands)			
Other income (expense), net	$ (4)	$ 118	$ (122)	(103.4%)

The decrease in other income (expense), net for the three months ended March 31, 2012 compared to March 31, 2011 was due to an $113,000 reduction in foreign currency transaction gains related primarily to a change in the value of the Euro in relation to the U.S. Dollar.

Liquidity and Capital Resources

Through March 31, 2012, we funded our operations through the private placement of equity, convertible debt securities and our initial public offering completed in November 2011. As of March 31, 2012, we have received $75.5 million in net proceeds from the issuance of convertible preferred stock, $28.0 million through the issuance of convertible promissory notes, and $129.4 million in net proceeds from the issuance of common stock through our initial public offering. 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 March 31, 2012, we had cash and cash equivalents totaling $121.0 million. In April 2012, we raised an additional $70.5 million of net proceeds through a public offering of our common stock.

The following table sets forth the primary sources and uses of cash for the three months ended March 31, 2012 and 2011:

	Three Months Ended March 31,	
	2012	2011
	(in thousands)	
Net cash used in operating activities	$ (18,553)	$ (8,189)
Net cash provided by investing activities	1,299	2,280
Net cash provided by (used in) financing activities	(9)	2
Effect of exchange rate changes on cash and cash equivalents	10	1
Net decrease in cash and cash equivalents	$ (17,253)	$ (5,906)

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 increase of $10.4 million to cash used in operating activities for the three months ended March 31, 2012 in comparison to the prior year s respective period was due to the payment of a $4.0 million regulatory milestone to Avila Therapeutics, Inc. in January 2012 and an increase in research and development expenses as described in Results of Operations above.

Investing Activities

The cash provided by investing activities for all periods primarily reflects the purchase of available for sale securities offset by maturities and sales of available for sale securities. The decrease of $1.0 million in cash provided by investing activities for the three months ended March 31, 2012 compared to the prior year s respective period was due to a reduction in available for sale security maturities of $0.4 million and an increase of $0.6 million for the purchase of property and equipment.

Financing Activities

The cash provided by (used in) financing activities for all periods was not significant.

Operating Capital Requirements

Assuming we successfully complete clinical trials and obtain requisite regulatory approvals, we do not anticipate commercializing any of our product candidates until 2014 at the earliest. As such, we anticipate that we will continue to generate significant losses for the next several years 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 sales 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 and the additional $70.5 million raised in April 2012 through the sale of common stock, 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, 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 commercialization activities, if any, of our product candidates are approved for sale, including marketing and distribution costs;
- the cost of manufacturing any of our product candidates we successfully commercialize;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, including litigation costs and outcome of such litigation; and
- the timing, receipt and amount of sales, if any, of our product candidates.

Contractual Obligations and Commitments

There have been no material changes to our contractual obligations and commitments since December 31, 2011 disclosed in the Annual Report on Form 10-K.

We have certain obligations under licensing agreements with third parties contingent upon achieving various development, regulatory and commercial milestones. Pursuant to our license agreement with Clavis for the development and commercialization of CO-101, we may be required to pay Clavis an aggregate of up to $115.0 million if certain clinical study objectives and regulatory filings and approvals are achieved. Further, we may be required to pay Clavis up to an aggregate of $445.0 million in sales milestone payments if certain annual sales targets are met for CO-101. Subject to certain conditions set forth in the license agreement, Clavis may elect to co-develop and co-promote CO-101 in Europe. If Clavis were to make this election, it would be required to reimburse us for a portion of both past and future development costs. In addition, the milestone payments described above would be reduced. Pursuant to our license agreement with Avila for the development and commercialization of CO-1686, we may be required to pay Avila an aggregate of up to $115.0 million if certain clinical study objectives and regulatory approvals are achieved. Further, we may be required to pay Avila an aggregate of up to $120.0 million in sales milestone payments if certain annual sales targets are met for CO-1686. Pursuant to our license agreement with Pfizer for the development of rucaparib, we may be required to pay Pfizer up to an aggregate $259.0 million in milestone payments upon the successful attainment of development, regulatory and sales milestones. Finally, pursuant to terms of each of these license agreements, we will pay royalties to our licensors on sales, if any, of the respective products.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to market risk related to changes in interest rates. As of March 31, 2012, we had cash and cash equivalents of $121.0 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 March 31, 2012 and December 31, 2011, approximately 27% and 31%, respectively, of our total liabilities were denominated in currencies other than the functional currency.

ITEM 4. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

Our disclosure controls and procedures are designed to ensure that information required to be disclosed in the reports we file or submit under the Securities Exchange Act of 1934, as amended, 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 March 31, 2012 of the effectiveness of the design and operation of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of March 31, 2012, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended March 31, 2012 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 consider the following discussion of risk factors, in its entirety, in addition to other information contained in or incorporated by reference into this Quarterly Report on Form 10-Q and our other public filings with the SEC. Other events that we do not currently anticipate or that we currently deem immaterial may also affect our business, prospects, financial condition and results of operations.

We have marked with an asterisk (*) those risk factors that reflect substantive changes from the risk factors included in our previously filed Annual Report on Form 10-K for the year ended December 31, 2011.

Risks Related to Our Financial Position and Capital Requirements

We have incurred significant losses since our inception and anticipate that we will continue to incur losses for the foreseeable future. We are a clinical-stage company with no approved products, and no historical revenues, which makes it difficult to assess our future viability.*

We are a clinical-stage biopharmaceutical company with a limited operating history. Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. We have focused primarily on in-licensing and developing our product candidates, CO-101, CO-1686 and rucaparib. We are not profitable and have incurred losses in each year since our inception in April 2009. Because we were only recently formed, we have only a limited operating history upon which you can evaluate our business and prospects. In addition, as an early stage company, we have limited experience and have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the biopharmaceutical area. We have not generated any revenue from product sales to date. We continue to incur significant research and development and other expenses related to our ongoing operations. Our net loss for the three months ended March 31, 2012 was approximately $19.0 million. As of March 31, 2012, we had an accumulated deficit of $129.5 million. We expect to continue to incur losses for the foreseeable future, and we expect these losses to increase as we continue our development of, and seek regulatory approvals for, our product candidates, and begin to commercialize any approved products. As such, we are subject to all of the risks incident in the development of new biopharmaceutical products and related companion diagnostics, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. If any of our product candidates fail in clinical trials or do not gain regulatory approval, or if any of our product candidates, if approved, fail to achieve market acceptance, we may never become profitable. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders equity and working capital.

We will require substantial additional funding which may not be available to us on acceptable terms, or at all. If we fail to obtain additional financing, we may be unable to complete the development and commercialization of our product candidates, or continue our development programs.

Our operations have consumed substantial amounts of cash since inception. We expect to continue to spend substantial amounts to advance the clinical development of our product candidates and launch and commercialize any product candidates for which we receive regulatory approval, including building our own commercial organizations to address certain markets.

We will require additional capital for the further development and commercialization of our product candidates and may also need to raise additional funds sooner if we choose to expand more rapidly than we presently anticipate. We will also require funding for our other operating expenses as well as capital expenditures to maintain and improve our facilities, equipment and systems.

We cannot be certain that additional funding will be available on acceptable terms, or at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our product candidates. We may also seek collaborators for one or more of our current or future product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available. Any of these events could significantly harm our business, financial condition and prospects.

Risks Related to Our Business and Industry

We are heavily dependent on the success of our three product candidates, and we cannot give any assurance that any of our product candidates will receive regulatory approval, which is necessary before they can be commercialized.

To date, we have invested a significant portion of our efforts and financial resources in the acquisition and development of our product candidates. Our future success is substantially dependent on our ability to successfully develop, obtain regulatory approval for, and then successfully commercialize such product candidates. Our product candidates, CO-101, CO-1686 and rucaparib, are currently in clinical trials. Our business depends entirely on the successful development and commercialization of our product candidates, which may never occur. We currently generate no revenues from sales of any drugs, and we may never be able to develop or commercialize a marketable drug.

Each of our product candidates will require additional clinical development, management of clinical, preclinical and manufacturing activities, regulatory approval in multiple jurisdictions, obtaining manufacturing supply, building of a commercial organization, substantial investment and significant marketing efforts before we generate any revenues from product sales. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the FDA or comparable foreign regulatory authorities, and we may never receive such regulatory approval for any of our product candidates. We believe that, depending on the result of our current CO-101 clinical trial, this trial may serve as a pivotal trial to support our application for approval of CO-101. To the extent that the results of the trial are not satisfactory to the Food and Drug Administration, or FDA, or the European Medicines Agency, or EMA, for support of a New Drug Application, or NDA, or Marketing Approval Application, or MAA, respectively, with respect to CO-101, we will be required to expend significant additional resources to conduct additional clinical trials in support of approval of CO-101. In addition, our product development programs contemplate the development of companion diagnostics by our third-party collaborators. Companion diagnostics are subject to regulation as medical devices and must themselves be approved for marketing by the FDA or certain other foreign regulatory agencies before we may commercialize our product candidates.

We have not previously submitted an NDA to the FDA, or similar drug approval filings to comparable foreign authorities, for any product candidate, and we cannot be certain that any of our product candidates will be successful in clinical trials or receive regulatory approval. Further, our product candidates may not receive regulatory approval even if they are successful in clinical trials. If we do not receive regulatory approvals for our product candidates, we may not be able to continue our operations. Even if we successfully obtain regulatory approvals to market one or more of our product candidates, our revenues will be dependent, in part, upon our collaborators ability to obtain regulatory approval of the companion diagnostics to be used with our product candidates, as well as the size of the markets in the territories for which we gain regulatory approval and have commercial rights. If the markets for patient subsets that we are targeting are not as significant as we estimate, we may not generate significant revenues from sales of such products, if approved.

We plan to seek regulatory approval to commercialize our product candidates both in the United States, the European Union and in additional foreign countries. While the scope of regulatory approval is similar in other countries, to obtain separate regulatory approval in many other countries we must comply with numerous and varying regulatory requirements of such countries regarding safety and efficacy and governing, among other things, clinical trials and commercial sales, pricing and distribution of our product candidates, and we cannot predict success in these jurisdictions.

Clinical drug development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. For example, the positive results generated to date in clinical trials for CO-101 and rucaparib do not ensure that later clinical trials will demonstrate similar results. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Our future clinical trial results may not be successful.

Although we have clinical trials ongoing for CO-101, CO-1686 and rucaparib, we may experience delays in our ongoing clinical trials and we do not know whether planned clinical trials will begin on time, need to be redesigned, enroll patients on time or be completed on schedule, if at all. Clinical trials can be delayed for a variety of reasons, including delays related to:

- obtaining regulatory approval to commence a trial;
- reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtaining institutional review board, or IRB, approval at each site;
- recruiting suitable patients to participate in a trial;
- developing and validating companion diagnostics on a timely basis;
- having patients complete a trial or return for post-treatment follow-up;
- clinical sites deviating from trial protocol or dropping out of a trial;
- adding new clinical trial sites; or
- manufacturing sufficient quantities of product candidate for use in clinical trials.

Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors including the size and nature of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the design of the clinical trial, competing clinical trials and clinicians and patients perceptions as to the potential advantages of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating. Furthermore, we rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials and while we have agreements governing their committed activities, we have limited influence over their actual performance.

We could encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by the Data Safety Monitoring Board, or DSMB, for such trial or by the FDA or other regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. If we experience delays in the

completion of, or termination of, any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may harm our business, financial condition and prospects significantly. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.

The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate s clinical development and may vary among jurisdictions. We have not obtained regulatory approval for any product candidate and it is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval.

Our product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate s clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of an NDA or other submission or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies;
- the FDA or comparable foreign regulatory authorities may fail to approve the companion diagnostics we contemplate developing with partners; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

This lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market CO-101, rucaparib and CO-1686, which would significantly harm our business, results of operations and prospects.

In addition, even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our products, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

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Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.

Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign authorities. To date, patients treated with CO-101 have experienced drug-related side effects including nausea, vomiting, anorexia, fatigue, myelosuppression (an impairment of bone marrow function), neutropenia (a reduction in white blood cells), and thrombocytopenia (a reduction in blood platelet cells) and those treated with rucaparib have experienced drug-related side effects such as nausea and vomiting. While we have only recently initiated clinical trials for CO-1686, as is the case with all oncology drugs, it is likely that there may be side effects associated with its use. Results of our trials could reveal a high and unacceptable severity and prevalence of these or other side effects. In such an event, our trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

Additionally if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approvals of such product;
- regulatory authorities may require additional warnings on the label;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could significantly harm our business, results of operations and prospects.

Failure to successfully validate, develop and obtain regulatory approval for companion diagnostics could harm our drug development strategy.

As one of the key elements of our clinical development strategy, we seek to identify patient subsets within a disease category who may derive selective and meaningful benefit from the product candidates we are developing. In collaboration with partners, we plan to develop companion diagnostics to help us to more accurately identify patients within a particular subset, both during our clinical trials and in connection with the commercialization of our product candidates. Companion diagnostics are subject to regulation by the FDA and comparable foreign regulatory authorities as medical devices and require separate regulatory approval prior to commercialization. We do not develop companion diagnostics internally and thus we are dependent on the sustained cooperation and effort of our third-party collaborators in developing and obtaining approval for these companion diagnostics. We and our collaborators may encounter difficulties in developing and obtaining approval for the companion diagnostics, including issues relating to selectivity/specificity, analytical validation, reproducibility, or clinical validation. Any delay or failure by our collaborators to develop or obtain regulatory approval of the companion diagnostics could delay or prevent approval of our product candidates. In addition, our collaborators may encounter production difficulties that could constrain the supply of the companion diagnostics, and both they and we may have difficulties gaining acceptance of the use of the companion diagnostics in the clinical community. If such companion diagnostics fail to gain market acceptance, it would have an adverse effect on our ability to derive revenues from sales of our products. In addition, the diagnostic company with whom we contract may decide to discontinue selling or manufacturing the companion diagnostic that we anticipate using in connection with development and commercialization of our product candidates or our

relationship with such diagnostic company may otherwise terminate. We may not be able to enter into arrangements with another diagnostic company to obtain supplies of an alternative diagnostic test for use in connection with the development and commercialization of our product candidates or do so on commercially reasonable terms, which could adversely affect and/or delay the development or commercialization of our product candidates.

If we established the hENT1 cut-off improperly, or if our LEAP trial results do not support the hENT1 hypothesis, we could jeopardize our potential for success with CO-101.

Retrospective analysis of tissue samples has shown a correlation between hENT1 expression levels and response to gemcitabine therapy such that patients with low levels of hENT1 expression are believed to derive little or no benefit from the drug. Our ongoing pivotal trial will, to our knowledge, be the first clinical trial to prospectively identify patients as hENT1-low and to then correlate their response to CO-101 versus gemcitabine. We utilized both previously published research data, as well as the data we derived from our own retrospective analysis of tissue samples, to reach a judgment as to those pancreatic cancer patients whose level of hENT1 expression we characterize as hENT1-low . Using this definition of hENT1-high and hENT1-low, 64% of the 360 patients enrolled in the LEAP trial have been classified as hENT1-low. If we have set the cut-off too high (to cover a broader range of patients), we may reduce our chances of being able to show a statistically significant improvement in the rate of survival in the patients classified as hENT1-low, and thereby fail to meet the pre-defined endpoint of the trial. Conversely, if we were overly conservative in our judgment of classifying patients as hENT1-low, we may improve our chance of success in achieving the pre-defined endpoint, but at the cost of limiting the prescribing label on CO-101 to such a small subset of potential patients as to significantly constrain the commercial potential for this product candidate, if approved. Finally, we have established our hENT1 cut-off based on tissue samples that came from primary pancreatic tumors, but are using tissue samples from metastatic cancer sites to define the hENT1 status of the patients in the trial. While there are limited data that suggest that the hENT1 status is generally consistent between metastatic and primary tumors, this may not be the case in the clinical setting, which could adversely affect the outcome of the trial.

There have been multiple publications addressing the relationship between hENT1 levels and gemcitabine treatment outcomes. To date, all of these publications have suggested the same relationship, namely that hENT1-high patients tend to respond better to gemcitabine therapy than hENT1-low patients. For example, in 2009, a study published in *Gastroenterology* reported the results of a retrospective analysis of randomized samples collected from 198 pancreatic cancer patients between 1998 and 2002 comparing treatment with gemcitabine versus 5-FU. Patients in this study treated with gemcitabine who had a high level of hENT1 expression had a median overall survival of 21 months, compared to a median overall survival of 16 months for gemcitabine-treated patients with low hENT1 expression and 12 months for gemcitabine-treated patients with no hENT1 expression. Importantly, the results of this study also demonstrated that there was no correlation between overall survival and hENT1 expression for patients treated with 5-FU. It is possible that other retrospective analyses of tissue samples may be published that do not reflect this correlation. Moreover, none of such studies have attempted to do what our LEAP trial is designed to do, which is to seek to prospectively prove this hENT1 hypothesis. Accordingly, we bear the risk that in a prospective, well controlled clinical trial, we may not be able to prove the hENT1 hypothesis. Our failure to achieve the predefined endpoints of the LEAP trial that support this hENT1 hypothesis would have an adverse impact on our ability to obtain approval for CO-101 and on our business, financial condition and prospects.

We rely on third parties to conduct our preclinical and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.

We have relied upon and plan to continue to rely upon third-party CROs to monitor and manage data for our ongoing preclinical and clinical programs. We rely on these parties for execution of our preclinical and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards and our reliance on the CROs does not relieve us of our regulatory responsibilities. We and our CROs are

required to comply with current good clinical practices, or cGCP, which are regulations and guidelines enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area, or EEA, and comparable foreign regulatory authorities for all of our products in clinical development. Regulatory authorities enforce these cGCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs fail to comply with applicable cGCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, EMA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with cGCP regulations. In addition, our clinical trials must be conducted with product produced under cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

Our CROs have the right to terminate their agreements with us in the event of an uncured material breach. In addition, some of our CROs have an ability to terminate their respective agreements with us if it can be reasonably demonstrated that the safety of the subjects participating in our clinical trials warrants such termination, if we make a general assignment for the benefit of our creditors or if we are liquidated.

If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. In addition, our CROs are not our employees, and except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our on-going clinical, nonclinical and preclinical programs. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed.

Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

We rely completely on third parties to manufacture our clinical drug supplies and we intend to rely on third parties to produce commercial supplies of any approved product candidate, and our commercialization of any of our product candidates could be stopped, delayed or made less profitable if those third parties fail to obtain approval of the FDA, Competent Authorities of the Member States of the EEA or comparable regulatory authorities, fail to provide us with sufficient quantities of drug product or fail to do so at acceptable quality levels or prices.

We do not currently have nor do we plan to acquire the infrastructure or capability internally to manufacture our clinical drug supplies for use in the conduct of our clinical trials, and we lack the resources and the capability to manufacture any of our product candidates on a clinical or commercial scale. The facilities used by our contract manufacturers to manufacture our product candidates must be approved by the FDA pursuant to inspections that will be conducted after we submit our NDA to the FDA. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with the regulatory requirements, known as current good manufacturing practices, or cGMPs, for manufacture of both active drug substances and finished drug products. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved.

We rely on our manufacturers to purchase from third-party suppliers the materials necessary to produce our product candidates for our clinical trials. There are a limited number of suppliers for raw materials that we use to manufacture our drugs and there may be a need to assess alternate suppliers to prevent a possible disruption of the manufacture of the materials necessary to produce our product candidates for our clinical trials, and if approved, ultimately for commercial sale. We do not have any control over the process or timing of the acquisition of these raw materials by our manufacturers. Moreover, we currently do not have any agreements for the commercial production of these raw materials. Although we generally do not begin a clinical trial unless we believe we have a sufficient supply of a product candidate to complete the clinical trial, any significant delay in the supply of a product candidate, or the raw material components thereof, for an ongoing clinical trial due to the need to replace a third-party manufacturer could considerably delay completion of our clinical trials, product testing and potential regulatory approval of our product candidates. If our manufacturers or we are unable to purchase these raw materials after regulatory approval has been obtained for our product candidates, the commercial launch of our product candidates would be delayed or there would be a shortage in supply, which would impair our ability to generate revenues from the sale of our product candidates.

We expect to continue to depend on third-party contract manufacturers for the foreseeable future. We have not entered into long-term agreements with our current contract manufacturers or with any alternate fill/finish suppliers, and though we intend to do so prior to commercial launch in order to ensure that we maintain adequate supplies of finished drug product, we may be unable to enter into such an agreement or do so on commercially reasonable terms, which could have a material adverse impact upon our business. We currently obtain our supplies of finished drug product through individual purchase orders.

Even if we receive regulatory approval for any of our product candidates, we will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense. Additionally, our product candidates, if approved, could be subject to labeling and other restrictions and market withdrawal and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products.

Any regulatory approvals that we receive for our product candidates may also be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase IV clinical trials, and surveillance to monitor the safety and efficacy of the product candidate. In addition, if the FDA or a comparable foreign regulatory authority approves any of our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs and cGCPs for any clinical trials that we conduct post-approval. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- fines, warning letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; and
- injunctions or the imposition of civil or criminal penalties.

The FDA s policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

We currently have no marketing and sales organization. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our product candidates, we may not be able to effectively market and sell our product candidates, if approved, or generate product revenues.

We currently do not have a marketing or sales organization for the marketing, sales and distribution of pharmaceutical products. In order to commercialize any product candidates, we must build our marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services, and we may not be successful in doing so. If our product candidates receive regulatory approval, we intend to establish our sales and marketing organization with technical expertise and supporting distribution capabilities to commercialize our product candidates, which will be expensive and time consuming. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of these products. With respect to our product candidates, we may choose to collaborate with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. If we are unable to enter into such arrangements on acceptable terms or at all, we may not be able to successfully commercialize any of our product candidates that receive regulatory approval. If we are not successful in commercializing our product candidates, either on our own or through collaborations with one or more third parties, our future product revenue will suffer and we may incur significant additional losses.

Our commercial success depends upon attaining significant market acceptance of our product candidates, if approved, among physicians, patients, healthcare payors and major operators of cancer clinics.

Even if we obtain regulatory approval for our product candidates, the product may not gain market acceptance among physicians, health care payors, patients and the medical community, which are critical to commercial success. Market acceptance of any product candidate for which we receive approval depends on a number of factors, including:

- the efficacy and safety as demonstrated in clinical trials;
- the timing of market introduction of such product candidate as well as competitive products;
- the clinical indications for which the drug is approved;
- the approval, availability, market acceptance and reimbursement for the companion diagnostic;
- acceptance by physicians, major operators of cancer clinics and patients of the drug as a safe and effective treatment;
- the potential and perceived advantages of such product candidate over alternative treatments, especially with respect to patient subsets that we are targeting with such product candidate;
- the safety of such product candidate seen in a broader patient group, including its use outside the approved indications;
- the cost of treatment in relation to alternative treatments;

the availability of adequate reimbursement and pricing by third-party payors and government authorities;

relative convenience and ease of administration;

the prevalence and severity of adverse side effects; and

the effectiveness of our sales and marketing efforts.

If our product candidates are approved but fail to achieve an adequate level of acceptance by physicians, health care payors and patients, we will not be able to generate significant revenues, and we may not become or remain profitable.

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, there are currently two agents approved for the treatment of metastatic pancreatic cancer: Gemzar®/gemcitabine marketed by Eli Lilly, Teva Pharmaceutical Industries and APP Pharmaceuticals, and Tarceva® (erlotinib) marketed by Astellas Pharma. In addition, although not an approved therapy, the National Comprehensive Cancer Network includes FOLFIRINOX (5FU/leucovorin plus oxaliplatin and irinotecan) in its recommended first-line treatment options for good performance status patients with metastatic pancreatic cancer. There also are a number of active clinical trials ongoing in pancreatic cancer, including by AB Science SA, Amgen Inc., Astellas Pharma, BioSante Pharmaceuticals, Inc., Celgene Corporation, Immunomedics, Inc., Lorus Therapeutics, Merrimack Pharmaceuticals, Inc., NewLink Genetics Corporation and Threshold Pharmaceuticals, Inc. Tarceva® and Iressa® are two of the currently approved drugs that are used to treat EGFR mutant NSCLC, and in addition, we are aware of two products in development targeting EGFR for the treatment of NSCLC: Boehringer Ingelheim s BIBW-2992 (afatinib) and Pfizer s PF-299804. Finally, we believe the products in development targeting the PARP pathway consist of Abbott s ABT-888 (velaparib), Merck s MK-4827, Eisai s E-7016, Cephalon s CEP-9722 and Biomarin s BMN-673.

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.

Reimbursement may be limited or unavailable in certain market segments for our product candidates, which could make it difficult for us to sell our products profitably.

There is significant uncertainty related to the third-party coverage and reimbursement of newly approved drugs. We intend to seek approval to market our product candidates in the United States, Europe and other selected foreign jurisdictions. Market acceptance and sales of our product candidates in both domestic and international markets will depend significantly on the availability of adequate coverage and reimbursement from third-party payors for any of our product candidates and may be affected by existing and future health care reform measures.

Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which drugs they will pay for and establish reimbursement levels. Reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor s determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Obtaining coverage and reimbursement approval for a product from a government or other third-party payor is a time consuming and costly process that could require us to provide supporting scientific, clinical and cost-effectiveness data for the use of our products to the payor. We may not be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement. If reimbursement of our future products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, we may be unable to achieve or sustain profitability.

In both the United States and certain foreign jurisdictions, there have been and we expect there will continue to be a number of legislative and regulatory changes to the health care system that could impact our ability to sell our products profitably. In particular, the Medicare Modernization Act of 2003 revised the payment methodology for many products under the Medicare program in the United States. This has resulted in lower rates of reimbursement. In 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively, the Healthcare Reform Law, was enacted. The Healthcare Reform Law substantially changes the way healthcare is financed by both governmental and private insurers and significantly affects the pharmaceutical industry. Among the provisions of the Healthcare Reform Law of greatest importance to the pharmaceutical industry are the following:

- an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, beginning in 2011;
- an increase in the minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- a new Medicare Part D coverage gap discount program, under which manufacturers must agree to offer 50 percent point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer s outpatient drugs to be covered under Medicare Part D, beginning in 2011;
- extension of manufacturers Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations, effective March 23, 2010;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program, effective January 2010;

a licensure framework for follow-on biologic products; and

a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research.

There have been, and likely will continue to be, legislative and regulatory proposals at the federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare may adversely affect:

the demand for any drug products for which we may obtain regulatory approval;

our ability to set a price for our products;

our ability to generate revenues and achieve or maintain profitability;

the level of taxes that we are required to pay; and

the availability of capital.

In addition, governments may impose price controls, which may adversely affect our future profitability.

In some foreign countries, particularly in the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product candidate. To obtain reimbursement or pricing approval in some countries, we may be required to conduct additional clinical trials that compare the cost-effectiveness of our product candidates to other available therapies. If reimbursement of our product candidates is unavailable or limited in scope or amount in a particular country, or if pricing is set at unsatisfactory levels, we may be unable to achieve or sustain profitability of our products in such country.

If we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.

Our industry has experienced a high rate of turnover of management personnel in recent years. Our ability to compete in the highly competitive biotechnology and pharmaceuticals industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on our management, scientific and medical personnel, especially Patrick J. Mahaffy, our President and Chief Executive Officer, Erle T. Mast, our Executive Vice President and Chief Financial Officer, Andrew R. Allen, our Executive Vice President of Clinical and Pre-Clinical Development and Chief Medical Officer, Steven L. Hoerter, our Senior Vice President of Commercial, and Gillian C. Ivers-Read, our Executive Vice President of Technical Operations and Chief Regulatory Officer, whose services are critical to the successful implementation of our product candidate acquisition, development and regulatory strategies. We are not aware of any present intention of any of these individuals to leave our company. In order to induce valuable employees to continue their employment with us, we have provided stock options that vest over time. The value to employees of stock options that vest over time is significantly affected by movements in our stock price that are beyond our control, and may at any time be insufficient to counteract more lucrative offers from other companies.

Despite our efforts to retain valuable employees, members of our management, scientific and development teams may terminate their employment with us on short notice. Pursuant to their employment arrangements, each of our executive officers may voluntarily terminate their employment at any time by providing as little as thirty days advance notice. Our employment arrangements, other than those with our executive officers, provide for at-will employment, which means that any of our employees (other than our executive officers) could leave our employment at any time, with or without notice. The loss of the services of any of our executive officers or other key employees and our inability to find suitable replacements could potentially harm our business, financial condition and prospects. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level, and senior managers as well as junior, mid-level, and senior scientific and medical personnel.

We may not be able to attract or retain qualified management and scientific personnel in the future due to the intense competition for a limited number of qualified personnel among biopharmaceutical, biotechnology, pharmaceutical and other businesses. Many of the other pharmaceutical companies that we compete against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high quality candidates than what we have to offer. If we are unable to continue to attract and retain high quality personnel, the rate and success at which we can develop and commercialize product candidates will be limited.

We will need to grow the size of our organization, and we may experience difficulties in managing this growth.

As of May 1, 2012, we had 57 full-time employees. As our development and commercialization plans and strategies develop, we expect to need additional managerial, operational, sales, marketing, financial and other resources. Future growth would impose significant added responsibilities on members of management, including:

- managing our clinical trials effectively;
- identifying, recruiting, maintaining, motivating and integrating additional employees;
- managing our internal development efforts effectively while complying with our contractual obligations to licensors, licensees, contractors and other third parties;
- improving our managerial, development, operational and finance systems; and
- expanding our facilities.

As our operations expand, we expect that we will need to manage additional relationships with various strategic partners, suppliers and other third parties. Our future financial performance and our ability to commercialize our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to manage our development efforts and clinical trials effectively and hire, train and integrate additional management, administrative and sales and marketing personnel. We may not be able to accomplish these tasks, and our failure to accomplish any of them could prevent us from successfully growing our company.

Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have a material adverse effect on our business.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with FDA regulations, provide accurate information to the FDA, comply with manufacturing standards we have established, comply with federal and state health-care fraud and abuse laws and regulations, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a Code of Business Ethics, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant fines or other sanctions.

We may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws and health information privacy and security laws. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

If we obtain FDA approval for any of our product candidates and begin commercializing those products in the United States, our operations may be directly, or indirectly through our customers, subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act. These laws may impact, among other things, our proposed sales, marketing and education programs. In addition, we may be subject to patient privacy regulation by both the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include:

the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs;

federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payers that are false or fraudulent;

the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters;

HIPAA, as amended by the Health Information Technology and Clinical Health Act, or HITECH, and its implementing regulations, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information; and

state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payer, including commercial insurers, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.

We face an inherent risk of product liability as a result of the clinical testing of our product candidates and will face an even greater risk if we commercialize any products. For example, we may be sued if any product we develop allegedly causes injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability, and a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates, if approved. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

decreased demand for our product candidates or products that we may develop;

injury to our reputation;

withdrawal of clinical trial participants;

initiation of investigations by regulators;

costs to defend the related litigation;

a diversion of management s time and our resources;

substantial monetary awards to trial participants or patients;

product recalls, withdrawals or labeling, marketing or promotional restrictions;

loss of revenues from product sales; and

the inability to commercialize our product candidates.

Our inability to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop.

We currently carry $10.0 million of product liability insurance, which we believe is adequate for our clinical trials. Although we maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We will have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts.

Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited.

We have incurred substantial losses during our history and do not expect to become profitable in 2012 and may never achieve profitability. To the extent that we continue to generate taxable losses, unused losses will carry forward to offset future taxable income, if any, until such unused losses expire. Under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, if a corporation undergoes an ownership change (generally defined as a greater than 50% change (by value) in its equity ownership over a three year period), the corporation s ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income may be limited. We may experience ownership changes in the future as a result of subsequent shifts in our stock ownership. As of December 31, 2011, we had federal net operating loss carryforwards of approximately $63.6 million that could be limited if we experience an ownership change, which could have an adverse effect on our results of operations.

Our business and operations would suffer in the event of system failures.

Despite the implementation of security measures, our internal computer systems and those of our CROs and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we have not experienced any such system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our drug development programs. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development of our product candidates could be delayed.

We will incur increased costs and demands upon management as a result of complying with the laws and regulations affecting public companies.

As a public company, we are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, the Sarbanes-Oxley Act of 2002, or the Sarbanes Oxley Act, as well as rules subsequently adopted by the SEC and the NASDAQ Stock Market, or NASDAQ. The Exchange Act requires, among other things, that we file annual, quarterly and current reports with respect to our business and financial condition. In addition, on July 21, 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive compensation-related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas such as say on pay and proxy access, and the SEC has since issued final rules implementing say on pay measures. We expect these rules and regulations to substantially increase our legal and financial compliance costs, to make some activities more time-consuming and costly, to result in increased general and administrative expenses and to divert management time and attention from revenue-generating activities. The increased costs will decrease our net income or increase our consolidated net loss, and may require us to reduce costs in other areas of our business or increase the prices of our products or services. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal controls for financial reporting and disclosure controls and procedures. In particular, we are required to perform system and

process evaluation and testing of our internal controls over financial reporting to allow management to report, commencing in our Annual Report on Form 10-K for the year ending December 31, 2012, on the effectiveness of our internal controls over financial reporting, if then required by Section 404 of the Sarbanes-Oxley Act. Our testing, or the subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses. Our compliance with Section 404 will require that we incur substantial accounting expense and expend significant management efforts. We currently do not have an internal audit group, and we will need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge. Moreover, if we are not able to comply with the requirements of Section 404 in a timely manner or if we identify or our independent registered public accounting firm identifies deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses, the market price of our stock could decline and we could be subject to sanctions or investigations by NASDAQ, the SEC or other regulatory authorities, which would require additional financial and management resources.

New laws and regulations as well as changes to existing laws and regulations affecting public companies, including the provisions of the Sarbanes-Oxley Act and rules adopted by the SEC and by NASDAQ, would likely result in increased costs to us as we respond to their requirements.

Risks Related to Our Intellectual Property

If our efforts to protect the proprietary nature of the intellectual property related to our technologies are not adequate, we may not be able to compete effectively in our market.

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our technologies. Any disclosure to or misappropriation by third parties of our confidential proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in our market.

The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. The patent applications that we own or license may fail to result in issued patents in the United States or in other foreign countries. Even if the patents do successfully issue, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing around our claims. If the breadth or strength of protection provided by the patent applications we hold or pursue with respect to our product candidates is threatened, it could threaten our ability to commercialize our product candidates. Further, if we encounter delays in our clinical trials, the period of time during which we could market our product candidates under patent protection would be reduced. Since patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain that we were the first to file any patent application related to our product candidates. Furthermore, an interference proceeding can be provoked by a third-party or instituted by the United States Patent and Trademark Office, or the U.S. PTO, to determine who was the first to invent any of the subject matter covered by the patent claims of our applications.

With respect to CO-101, we have an exclusive, worldwide license from Clavis to a portfolio of patents directed to the CO-101 composition of matter that expire in 2018. With respect to rucaparib, we have an exclusive, worldwide license from Pfizer to a portfolio of patents and patent applications directed to the rucaparib composition of matter that expire in 2020. While patent term extensions under the Hatch-Waxman Act in the United States and under supplementary protection certificates in Europe may be available to extend our patent exclusivity for either CO-101 or rucaparib, we cannot provide any assurances that any such patent term extension will be obtained.

In addition to the protection afforded by patents, we seek to rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable, processes for which patents are difficult to enforce and any other elements of our drug development processes that involve proprietary know-how, information or technology that is not covered by patents. Although we require all of our employees to assign their inventions to us, and all of our employees, consultants, advisors and any third parties who have

access to our proprietary know-how, information or technology to enter into confidentiality agreements, we cannot be certain that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Further, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent material disclosure of the intellectual property related to our technologies to third parties, we will not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, results of operations and financial condition.

Third-party claims of intellectual property infringement may prevent or delay our drug discovery and development efforts. *

Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. There is a substantial amount of litigation involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including interference and reexamination proceedings before the U.S. PTO or oppositions and other comparable proceedings in foreign jurisdictions. Numerous United States and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may give rise to claims of infringement of the patent rights of others.

Third parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents of which we are currently unaware with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our product candidates, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtain a license under the applicable patents, or until such patents expire or they are finally determined to be held invalid or unenforceable. Similarly, if any third-party patent were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy or patient selection methods, the holders of any such patent may be able to block our ability to develop and commercialize the applicable product candidate unless we obtain a license, limit our uses, or until such patent expires or is finally determined to be held invalid or unenforceable. In either case, such a license may not be available on commercially reasonable terms or at all.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us,

we may have to pay substantial damages, including treble damages and attorneys fees for willful infringement, obtain one or more licenses from third parties, limit our uses, pay royalties or redesign our infringing product candidates, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize one or more of our product candidates, which could harm our business significantly.

The patent protection and patent prosecution for some of our product candidates is dependent on third parties.

While we normally seek and gain the right to fully prosecute the patents relating to our product candidates, there may be times when platform technology patents that relate to our product candidates are controlled by our licensors. This is the case with our license of CO-1686 from Avila Therapeutics, Inc., in which Avila retained the right to prosecute and maintain the patents and patent applications covering its core discovery technology, including molecular backbones, building blocks and classes of compounds generated by that technology, aspects of which relate to CO-1686. While we have the right to prosecute and maintain the patent rights for the composition of matter for CO-1686, if Avila or any of our future licensing partners fail to appropriately prosecute and maintain patent protection for patents covering any of our product candidates, our ability to develop and commercialize those product candidates may be adversely affected and we may not be able to prevent competitors from making, using and selling competing products.

We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time consuming and unsuccessful.

Competitors may infringe our patents or the patents of our licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated, held unenforceable, or interpreted narrowly and could put our patent applications at risk of not issuing.

Interference proceedings provoked by third parties or brought by the U.S. PTO may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our licensors. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees.

We may not be able to prevent, alone or with our licensors, misappropriation of our trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as in the United States. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on all of our product candidates throughout the world would be prohibitively expensive. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products in jurisdictions where we do not have any issued patents and our patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business.

If we breach any of the agreements under which we license commercialization rights to our product candidates from third parties, we could lose license rights that are important to our business.

We license the use, development and commercialization rights for all of our product candidates, and may enter into similar licenses in the future. Under each of our existing license agreements with Clavis (CO-101), Avila (CO-1686) and Pfizer (rucaparib), we are subject to commercialization and development, diligence obligations, milestone payment obligations, royalty payments and other obligations. If we fail to comply with any of these obligations or otherwise breach our license agreements, our licensing partners may have the right to terminate the license in whole or in part. Generally, the loss of any one of our three current licenses or other licenses in the future could materially harm our business, prospects, financial condition and results of operations.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, or permit us to maintain our competitive advantage. The following examples are illustrative:

- Others may be able to make compounds that are similar to our product candidates but that are not covered by the claims of the patents that we own or have exclusively licensed.
- We or our licensors or strategic partners might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed.
- We or our licensors or strategic partners might not have been the first to file patent applications covering certain of our inventions.
- Others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights.
- It is possible that our pending patent applications will not lead to issued patents.
- Issued patents that we own or have exclusively licensed may not provide us with any competitive advantages, or may be held invalid or unenforceable, as a result of legal challenges by our competitors.
- Our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets.
- We may not develop additional proprietary technologies that are patentable.
- The patents of others may have an adverse effect on our business.

Should any of these events occur, they could significantly harm our business, results of operations and prospects.

Risks Related to Ownership of our Common Stock

There may not be a viable public market for our common stock and as a result it may be difficult for you to sell your shares of our common stock. *

Our common stock had not been publicly traded prior to our initial public offering in November 2011. The trading market for our common stock on The NASDAQ Global Select Market has been limited and an active

trading market for our shares may not be sustained. As a result of these and other factors, you may be unable to resell your shares at a price that is attractive to you or at all. Further, an inactive market may also impair our ability to raise capital by selling shares of our common stock and may impair our ability to enter into strategic partnerships or acquire companies or products by using our shares of common stock as consideration.

The price of our stock has been, and may continue to be, volatile, and you could lose all or part of your investment. *

The trading price of our common stock has been, and may continue to be, volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. Since our initial public offering in November 2011 the price of our common stock on the NASDAQ Global Select Market has ranged from $11.45 per share to $27.55 per share. In addition to the factors discussed in this Risk Factors section and elsewhere in this report, these factors include:

- our failure to commercialize our product candidates, if approved;
- actual or anticipated adverse results or delays in our clinical trials;
- unanticipated serious safety concerns related to the use of any of our product candidates;
- adverse regulatory decisions;
- changes in laws or regulations applicable to our product candidates, including but not limited to clinical trial requirements for approvals;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our product candidates;
- our decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial;
- our dependence on third parties, including CROs as well as our partners that provide us with companion diagnostic products;
- additions or departures of key scientific or management personnel;
- failure to meet or exceed any financial guidance or expectations regarding development milestones that we may provide to the public;
- actual or anticipated variations in quarterly operating results;
- failure to meet or exceed the estimates and projections of the investment community;

overall performance of the equity markets and other factors that may be unrelated to our operating performance or the operating performance of our competitors, including changes in market valuations of similar companies;

conditions or trends in the biotechnology and biopharmaceutical industries;

introduction of new products offered by us or our competitors;

announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;

our ability to maintain an adequate rate of growth and manage such growth;

issuances of debt or equity securities;

significant lawsuits, including patent or stockholder litigation;

sales of our common stock by us or our stockholders in the future;

trading volume of our common stock;

publication of research reports about us or our industry or positive or negative recommendations or withdrawal of research coverage by securities analysts;

ineffectiveness of our internal controls;

general political and economic conditions;

effects of natural or man-made catastrophic events; and

other events or factors, many of which are beyond our control.

In addition, the stock market in general, and the NASDAQ Global Select Market and biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. The realization of any of the above risks or any of a broad range of other risks, including those described in these Risk Factors, could have a dramatic and material adverse impact on the market price of our common stock.

Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval. *

Our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates known to us beneficially own approximately 62.1% of our voting stock. These stockholders have the ability to influence us through this ownership position. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders.

Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall. *

Persons who were our stockholders prior to our initial public offering continue to hold a substantial number of shares of our common stock. If such persons sell, or indicate an intention to sell, substantial amounts of our common stock in the public market after the lapse of lock-up restrictions on resale resulting from our initial public offering and any other legal restrictions on resale, the trading price of our common stock could decline.

We expect that the lock-up agreements pertaining to our initial public offering signed by our directors, officers and substantially all of our stockholders prior to our initial public offering will expire on May 29, 2012 (subject to extension upon the occurrence of specified events). The lock-up agreements pertaining to our follow-on public offering in April 2012 signed by our directors and executive officers will expire 60 days from April 3, 2012 (subject to extension upon the occurrence of specified events). After these lock-up periods expire, up to an additional 15,930,534 shares of common stock will be eligible for sale in the public market, 11,888,685 of which shares are held by directors, executive officers and other affiliates, subject to vesting schedules, volume limitations under Rule 144 under the Securities Act of 1933, as amended, or the Securities Act. Our underwriters, however, may, in their sole discretion, permit our officers, directors and other stockholders who are subject to the lock-up agreements to sell shares prior to the expiration of the lock-up agreements.

In addition, shares of common stock that are either subject to outstanding options or reserved for future issuance under our equity incentive plans will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, the lock-up agreements and Rule 144 and Rule 701 under the Securities Act. If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

Furthermore, 15,714,252 shares of our common stock, or approximately 60.1% of our total outstanding common stock as of April 20, 2012 (and holders of 297,237 shares of our common stock issuable upon exercise of options to purchase our common stock), are entitled to rights with respect to the registration of their shares under the Securities Act, subject to vesting schedules and to the lock-up agreements described above). Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares purchased by affiliates. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock.

Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall. *

We expect that significant additional capital will be needed in the future to continue our planned operations. To raise capital, we may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights, preferences and privileges senior to those of holders of our common stock.

Pursuant to our equity incentive plan(s), our compensation committee (or a subset thereof) is authorized to grant equity-based incentive awards to our employees, directors and consultants. As of March 31, 2012, the number of shares of our common stock available for future grant under our 2011 Stock Incentive Plan, or the 2011 Plan, is 700,458, which includes 138,258 shares of our common stock that were reserved for future issuance under our the 2009 Equity Incentive Plan, or the 2009 Plan, and were transferred to the 2011 Plan for future issuance. The number of shares of our common stock reserved for issuance under our 2011 Plan will be increased (i) from time to time by the number of shares of our common stock forfeited upon the expiration, cancellation, forfeiture, cash settlement or other termination of awards under our 2009 Plan, and (ii) at the discretion of our board of directors, on the date

of each annual meeting of our stockholders, by up to the lesser of (x) a number of additional shares of our common stock representing 4% of our then-outstanding shares of common stock on such date and (y) 2,758,621 shares of our common stock. Future option grants and issuances of common stock under our 2011 Plan may have an adverse effect on the market price of our common stock.

Some provisions of our charter documents and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our amended and restated certificate of incorporation and bylaws, as well as provisions of Delaware law, could make it more difficult for a third-party to acquire us or increase the cost of acquiring us, even if doing so would benefit our stockholders or remove our current management. These provisions include:

- authorizing the issuance of blank check preferred stock, the terms of which may be established and shares of which may be issued without stockholder approval;
- limiting the removal of directors by the stockholders;
- creating a staggered board of directors;
- prohibiting stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders;
- eliminating the ability of stockholders to call a special meeting of stockholders;
- permitting our board of directors to accelerate the vesting of outstanding option grants upon certain transactions that result in a change of control; and
- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings.

These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management. Because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which may discourage, delay or prevent someone from acquiring us or merging with us whether or not it is desired by or beneficial to our stockholders. Under Delaware law, a corporation may not, in general, engage in a business combination with any holder of 15% or more of its capital stock unless the holder has held the stock for three years or, among other things, the board of directors has approved the transaction. Any provision of our certificate of incorporation or bylaws or Delaware law that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock, and could also affect the price that some investors are willing to pay for our common stock.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. If one or more of the analysts who cover us downgrade our stock or publish inaccurate or unfavorable research about our business, our stock price would likely decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

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 March 31, 2012, we had used approximately $22.4 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.

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., certain investors named therein.
10.1*(1)	Amended and Restated License Agreement, dated as of November 10, 2010, by and between Clovis Oncology, Inc. and Clavis Pharma ASA.
10.2*(4)	Amended and Restated Strategic License Agreement, dated as of June 16, 2011, by and between Clovis Oncology, Inc. and Avila Therapeutics, Inc.
10.3*(4)	License Agreement, dated as of June 2, 2011, by and between Clovis Oncology, Inc. and Pfizer Inc.
10.4+(1)	Clovis Oncology, Inc. 2009 Equity Incentive Plan.
10.5+(4)	Clovis Oncology, Inc. 2011 Stock Incentive Plan.
10.6+(1)	Form of Clovis Oncology, Inc. 2009 Equity Incentive Plan Stock Option Agreement.
10.7+(4)	Form of Clovis Oncology, Inc. 2011 Stock Incentive Plan Stock Option Agreement.
10.8+(3)	Employment Agreement, dated as of August 24, 2011, between Clovis Oncology, Inc. and Patrick J. Mahaffy.
10.9+(3)	Employment Agreement, dated as of August 24, 2011, between Clovis Oncology, Inc. and Erle T. Mast.
10.10+(3)	Employment Agreement, dated as of August 24, 2011, between Clovis Oncology, Inc. and Gillian C. Ivers-Read.
10.11+(3)	Employment Agreement, dated as of August 24, 2011, between Clovis Oncology, Inc. and Andrew R. Allen.
10.12+(1)	Indemnification Agreement, dated as of May 15, 2009, between Clovis Oncology, Inc. and John C. Reed.
10.13+(1)	Indemnification Agreement, dated as of May 15, 2009, between Clovis Oncology, Inc. and Paul Klingenstein.
10.14+(1)	Indemnification Agreement, dated as of May 15, 2009, between Clovis Oncology, Inc. and James C. Blair.
10.15+(1)	Indemnification Agreement, dated as of May 15, 2009, between Clovis Oncology, Inc. and Edward J. McKinley.
10.16+(1)	Indemnification Agreement, dated as of May 15, 2009, between Clovis Oncology, Inc. and Thorlef Spickschen.
10.17+(1)	Indemnification Agreement, dated as of May 15, 2009, between Clovis Oncology, Inc. and M. James Barrett.
10.18+(1)	Indemnification Agreement, dated as of May 15, 2009, between Clovis Oncology, Inc. and Brian G. Atwood.
10.19+(1)	Indemnification Agreement, dated as of May 12, 2009, between Clovis Oncology, Inc. and Patrick J. Mahaffy.
10.20+(1)	Indemnification Agreement, dated as of May 12, 2009, between Clovis Oncology, Inc. and Erle T. Mast.
10.21+(1)	Indemnification Agreement, dated as of May 12, 2009, between Clovis Oncology, Inc. and Gillian C. Ivers-Read.
10.22+(1)	Indemnification Agreement, dated as of May 13, 2009, between Clovis Oncology, Inc. and Andrew R. Allen.
10.23+(1)	Restricted Stock Purchase Agreement, dated as of May 12, 2009, between Clovis Oncology, Inc. and Patrick J. Mahaffy.
10.24+(1)	Restricted Stock Purchase Agreement, dated as of May 12, 2009, between Clovis Oncology, Inc. and Erle T. Mast.
10.25+(1)	Restricted Stock Purchase Agreement, dated as of May 12, 2009, between Clovis Oncology, Inc. and Gillian C. Ivers-Read.
10.26+(1)	Restricted Stock Purchase Agreement, dated as of May 12, 2009, between Clovis Oncology, Inc. and Andrew R. Allen.
10.27*(4)	Companion Diagnostics Agreement, dated as of April 19, 2011, by and between Clovis Oncology, Inc. and Roche Molecular Systems, Inc.

10.28*(4)	Master Service Agreement, dated as of March 23, 2010, by and between Clovis Oncology, Inc. and Ventana Medical Systems, Inc., together with the related Individual Project Agreement, dated as of March 25, 2010.
10.29+(4)	Clovis Oncology, Inc. 2011 Employee Stock Purchase Plan.
10.30+(4)	Clovis Oncology, Inc. 2011 Cash Bonus Plan.
10.31+(6)	Employment Agreement, dated as of March 22, 2012, by and between Clovis Oncology, Inc. and Steven L. Hoerter.
10.32+(6)	Indemnification Agreement, dated as of March 22, 2012, by and between Clovis Oncology, Inc. and Steven L. Hoerter.
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.
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.
101	The following materials from Clovis Oncology, Inc. s Quarterly Report on Form 10-Q for the three months ended March 31, 2012, 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 Amendment No. 1 to the Registrant s Registration Statement on Form S-1 (File No. 333-175080) on August 5, 2011.
(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.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: May 11, 2012

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