Loxo Oncology, Inc.
Form 10-Q
September 12, 2014
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2014

Or

o TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Commission File Number 001-36562

LOXO ONCOLOGY, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**46-2996673**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
One Landmark Square, Suite 1122	
Stamford, CT	
(Address of Principal Executive Offices)	**06901** (Zip Code)

Registrant s telephone number, including area code: **(203) 653-3880**

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Name of each exchange on which registered**
Common Stock, par value $0.0001 per share	NASDAQ Global Market

Securities registered pursuant to Section 12(g) of the Act: **None**

(Title of Class)

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 o No x

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 o

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 o	Accelerated filer o
Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company x

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

Common Stock, $0.0001 par value | Shares outstanding as of September 12, 2014: 16,629,590

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PART I

ITEM 1. FINANCIAL STATEMENTS

LOXO ONCOLOGY, INC.

Condensed Balance Sheets

(in thousands, except share and per share amounts)

	December 31, 2013	June 30, 2014 (unaudited)
Assets		
Current assets:		
Cash and cash equivalents	$ 14,994	$ 51,304
Prepaid expenses with related party and other current assets	17	651
Total current assets	15,011	51,955
Property and equipment		7
Deferred initial public offering costs		927
Security deposit	11	23
Total assets	$ 15,022	$ 52,912
Liabilities, redeemable convertible preferred stock and stockholders deficit		
Current liabilities:		
Accounts payable	$ 221	$ 652
Accrued expenses	189	581
Total liabilities	410	1,233
Commitments and contingencies		
Redeemable convertible preferred stock:		
Series A, $0.0001 par value; 5,156,250 shares authorized at December 31, 2013 and June 30, 2014; 2,812,497 and 5,156,250 shares issued and outstanding at December 31, 2013 and June 30, 2014, respectively; (liquidation preference of $18,000 at December 31, 2013 and $33,000 at June 30, 2014)	17,799	32,821
Series A-1, $0.0001 par value; 500,704 shares authorized at December 31, 2013 and June 30, 2014; 500,704 shares issued and outstanding at December 31, 2013 and June 30, 2014, respectively; (liquidation preference of $12,000 at December 31, 2013 and June 30, 2014)	7,044	7,044
Series B, $0.0001 par value; 0 and 3,166,237 shares authorized at December 31, 2013 and June 30, 2014, respectively; 0 and 3,166,233 shares issued and outstanding at December 31, 2013 and June 30, 2014, respectively; (liquidation preference of $0 at December 31, 2013 and $28,389 at June 30, 2014)		28,184
Total redeemable convertible preferred stock	24,843	68,049
Stockholders deficit:		
Common stock, $0.0001 par value; 9,375,000 and 12,187,500 shares authorized at December 31, 2013 and June 30, 2014, respectively; 452,896 and 577,874 shares issued and 452,896 and 561,008 outstanding at December 31, 2013 and June 30, 2014, respectively		
Additional paid-in capital	59	727
Accumulated deficit	(10,290)	(17,097)
Total stockholders deficit	(10,231)	(16,370)
Total liabilities, redeemable convertible preferred stock and stockholders deficit	$ 15,022	$ 52,912

See accompanying notes to unaudited condensed financial statements.

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LOXO ONCOLOGY, INC.

Condensed Statements of Operations (Unaudited)

(in thousands, except share and per share amounts)

	Period From May 9, 2013 (Date of Inception) to June 30, 2013	Three Months Ended June 30, 2014	Six Months Ended June 30, 2014
Operating expenses:			
Research and development with a related party	$ 53	$ 1,717	$ 2,992
Research and development	6	855	1,566
General and administrative	31	1,333	2,249
Total operating expenses and net loss	(90)	(3,905)	(6,807)
Accretion of redeemable convertible preferred stock		(17)	(28)
Net loss attributable to common stockholders	$ (90)	$ (3,922)	$ (6,835)
Per share information:			
Net loss per share of common stock, basic and diluted	$	$ (14.46)	$ (28.69)
Weighted average shares outstanding, basic and diluted		271,317	238,246

See accompanying notes to unaudited condensed financial statements.

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LOXO ONCOLOGY, INC.

Condensed Statements of Redeemable Convertible Preferred Stock and Stockholders Deficit (Unaudited)

For the period from January 1, 2014 to June 30, 2014

(in thousands except share and per share amounts)

	Preferred stock							Stockholders deficit				
	Series A		Series A-1		Series B			Common stock $0.0001 Par Value		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders Deficit
	Shares	Amount	Shares	Amount	Shares	Amount	Total	Shares	$	$	$	$
Balance at January 1, 2014	2,812,497	$ 17,799	500,704	$ 7,044		$	$ 24,843	452,896	$	$ 59	$ (10,290)	$ (10,231)
Issuance of common stock due to exercise of vested options								108,112		159		159
Issuance of Series A redeemable convertible preferred stock - March 2014 at $6.40 per share	2,343,753	15,000					15,000					
Issuance of Series B redeemable convertible preferred stock - April 2014 and June 2014 at $8.9661 per share					3,166,233	28,178	28,178					
Accretion of redeemable convertible preferred stock to redemption value		22				6	28			(28)		(28)
Stock-based compensation expense										537		537
Net loss											(6,807)	(6,807)
Balance at June 30, 2014	5,156,250	$ 32,821	500,704	$ 7,044	3,166,233	$ 28,184	$ 68,049	561,008	$	$ 727	$ (17,097)	$ (16,370)

See accompanying notes to unaudited condensed financial statements.

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LOXO ONCOLOGY, INC.

Condensed Statements of Cash Flows

(unaudited)

(in thousands)

	Period From May 9, 2013 (Date of Inception) to June 30, 2013	Six Months Ended June 30, 2014
Operating activities:		
Net loss	$ (90)	$ (6,807)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation		537
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(79)	(634)
Security deposits		(12)
Accounts payable	55	355
Accrued expenses	114	118
Net cash used in operating activities		(6,443)
Investing activities:		
Purchase of property		(7)
Net cash used in investing activities		(7)
Financing activities:		
Proceeds from issuance of redeemable convertible preferred stock, net		43,223
Proceeds from the exercise of stock options		159
Payment of deferred financing fees		(622)
Net cash provided by financing activities		42,760
Net increase in cash and cash equivalents		36,310
Cash and cash equivalents beginning of period		14,994
Cash and cash equivalents end of period	$	$ 51,304
Supplemental schedule of noncash financing activities:		
Accounts payable and accrued expenses related to financing fees	$	$ 350

See accompanying notes to unaudited condensed financial statements.

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LOXO ONCOLOGY, INC.

Notes to Unaudited Financial Statements

June 30, 2014

1. Organization and Description of the Business

Loxo Oncology, Inc. (the Company) is a development-stage company that was incorporated on May 9, 2013 in the State of Delaware. The Company develops targeted small molecule therapeutics for the treatment of cancer in genetically defined patient populations. The Company s development approach translates key scientific insights relating to the oncogenic drivers of cancer into drugs that are potent and highly selective for their intended targets. Such drugs typically achieve high target engagement, which has been correlated with improved tumor response. The Company is also building a pipeline of additional product candidates targeting cancers driven by genetic alterations. The Company operates in one segment and has its principal office in Stamford, Connecticut. As of June 30, 2014, the Company was financed by venture capital investors.

Initial Public Offering

On July 31, 2014, the Company s registration statements on Form S-1 (File Nos. 333-197123 and 333-197779) relating to its initial public offering of its common stock were declared effective by the Securities and Exchange Commission (SEC). The shares began trading on The NASDAQ Global Select Market on August 1, 2014. The initial public offering closed on August 6, 2014, and 5,261,538 shares of common stock were sold at an initial public offering price of $13.00 per share, for aggregate gross proceeds to the Company of $68.4 million. Concurrent with the close of the offering, New Enterprise Associates 14, L.P., or NEA, an existing stockholder, purchased 230,769 shares of common stock at the initial public offering price in a private placement and the Company received gross proceeds of $3.0 million. In addition, upon the closing of the initial public offering, all of the Company s outstanding convertible preferred stock was converted into an aggregate total of 9,932,042 shares of common stock.

On August 29, 2014, the underwriters of the Company s initial public offering gave notification that they would partially exercise the over-allotment option granted to them and on September 4, 2014, 642,000 additional shares of common stock were sold on the Company s behalf at the initial public offering price of $13.00 per share, for aggregate gross proceeds of approximately $8.3 million.

The Company paid to the underwriters underwriting discounts and commissions of approximately $5.6 million in connection with the offering, including the private placement and over-allotment. In addition, the Company incurred expenses of approximately $1.7 million in connection with the offering. Thus, the net offering proceeds to the Company, after deducting underwriting discounts and commissions and offering expenses, were approximately $72.4 million.

Stock Splits

In July 2013, the Company s Board of Directors (the Board) and stockholders approved a 2.07 to 1 reverse stock split of the Company s common stock. The reverse stock split became effective on July 2, 2013. Subsequently, in July 2014, the Board and stockholders approved a 1.5625-for-1 forward stock split of the Company s common stock. The forward stock split became effective on July 21, 2014. All share and per share amounts in the financial statements and notes thereto have been adjusted to give effect to this reverse stock split.

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Liquidity

At June 30, 2014, the Company had working capital of $50.7 million, an accumulated deficit of $17.1 million, and cash and cash equivalents of $51.3 million. Upon consummation of its initial public offering and the concurrent private placement on August 6, 2014, the Company received cash proceeds, net of underwriting discounts and commissions, of approximately $72.4 million. The Company has not generated any product revenues and has not achieved profitable operations. There is no assurance that profitable operations will ever be achieved, and, if achieved, could be sustained on a continuing basis. In addition, development activities, clinical and pre-clinical testing, and commercialization of the Company s products will require significant additional financing.

The Company believes that its existing cash and cash equivalents, in conjunction with the proceeds received in connection with its initial public offering and concurrent private placement in August 2014, will be sufficient to enable the Company to continue as a going concern for a reasonable period of time beyond June 30, 2014. However, the Company will need to secure additional funding in the future, from one or more equity or debt financings, collaborations, or other sources, in order to carry out all of its planned research and development activities. If the Company is unable to obtain additional financing or generate license or product revenue, the lack of liquidity could have a material adverse effect on the Company s future prospects.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America (GAAP). Any reference in these notes to applicable guidance is meant to refer to GAAP as found in the Accounting Standards Codification (ASC) and Accounting Standards Update (ASU) of the Financial Accounting Standards Board (FASB).

Unaudited Interim Financial Information

The accompanying balance sheet as of December 31, 2013, the statement of operations, statement of redeemable convertible preferred stock and stockholders deficit and the statement of cash flows for the period from May 9, 2013 (date of inception) to December 31, 2013 was derived from the Company s audited financial statements included in Form S-1 filed on July 30, 2014 with the SEC that was declared effective on July 31, 2014.

The accompanying balance sheet as of June 30, 2014, the statements of operations for the three and six months ended June 30, 2014 and the period from May 9, 2013 (Date of Inception) to June 30, 2013, the statements of redeemable convertible preferred stock and stockholders deficit for the six months ended June 30, 2014 and the statements of cash flows for the six months ended June 30, 2014 and the period from May 9, 2013 (Date of Inception) to June 30, 2013 are unaudited. The interim unaudited financial statements have been prepared on the same basis as the annual audited financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary for the fair presentation of the Company s financial position as of June 30, 2014 and the results of its operations, and its cash flows for

the three and six months ended June 30, 2014 and the period from May 9, 2013 (date of inception) to June 30, 2013. The financial data and other information disclosed in these notes related to the three and six months ended June 30, 2014 and for the period from May 9, 2013 (date of inception) to June 30, 2013 are unaudited. The results for the six months ended June 30, 2014 are not necessarily indicative of results to be expected for the year ending December 31, 2014, any other interim periods or any future year or period. These unaudited financial statements should be read in conjunction with the audited financial statements and the notes thereto for the year ended December 31, 2013 included in the Company s Form S-1 filed July 30, 2014 with the SEC.

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Significant Accounting Policies

The Company s significant accounting policies are disclosed in the audited financial statements for the year ended December 31, 2013 included in the Company s Form S-1 filed on July 30, 2014 with the SEC. Since the date of such financial statements, there have been no changes to the Company s significant accounting policies, other than those detailed below.

Property and Equipment

Property and equipment are depreciated using the straight-line method over the estimated useful lives of the assets which are generally three to five years. Maintenance and repairs are expensed as incurred. Upon disposal, retirement, or sale, the related cost and accumulated depreciation is removed from the accounts and any resulting gain or loss is included in the results of operations. Due to the timing in which property and equipment was placed into service, there was no depreciation expense during the three or six months ended June 30, 2014.

Deferred Initial Public Offering Costs

Deferred IPO costs as of June 30, 2014, consisting of legal, accounting, printing and filing fees incurred in the preparation of the Company s Registration Statement on Form S-1 were capitalized. The deferred costs are included in deferred initial public offering costs on the unaudited condensed balance sheet as of June 30, 2014. The deferred offering costs were offset against the IPO proceeds upon the completion of the offering in August 2014.

Recent Accounting Pronouncements

On June 10, 2014, the FASB issued ASU No. 2014-10, *Development Stage Entities (Topic 915): Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entities Guidance in Topic 810, Consolidation*. The guidance is intended to reduce the overall cost and complexity associated with financial reporting for development stage entities without reducing the availability of relevant information. The Board also believes the changes will simplify the consolidation accounting guidance by removing the differential accounting requirements for development stage entities. As a result of these changes, there no longer will be any accounting or reporting differences in GAAP between development stage entities and other operating entities. For organizations defined as public business entities the presentation and disclosure requirements in Topic 915 will no longer be required starting with the first annual period beginning after December 15, 2014, including interim periods therein. Early application is permitted for any annual reporting period or interim period for which the entity s financial statements have not yet been issued (public business entities) or made available for issuance (other entities). The Company early adopted this guidance during the three months ended June 30, 2014 and, as a result, the Company no longer presents inception-to-date information about the statements of operations, cash flows, and stockholders deficit.

In June 2014, the FASB issued ASU No. 2014-12, *Compensation - Stock Compensation (Topic 718): Accounting for Share-Based Payments When the Terms of an Award Provide that a Performance Target Could be Achieved after the Requisite Service Period*, (ASU 2014-12). ASU 2014-12 requires that a performance target that affects vesting, and that could be achieved after the requisite service period, be treated as a

performance condition. As such, the performance target should not be reflected in estimating the grant date fair value of the award. This update further clarifies that compensation cost should be recognized in the period in which it becomes probable that the performance target will be achieved and should represent the compensation cost attributable to the period(s) for which the requisite service has already been rendered. The Company does not anticipate that the adoption of this standard will have a material impact on its financial statements.

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3. Net Loss Per Common Share

The following table sets forth the computation of basic and diluted net loss per share for the periods indicated (in thousands, except share and per share data):

	Three Months Ended June 30, 2014	Six Months Ended June 30, 2014
Basic and diluted net loss per common share calculation:		
Net loss	$ (3,905)	$ (6,807)
Accretion of redeemable convertible preferred stock	(17)	(28)
Net loss attributable to common stockholders	$ (3,922)	$ (6,835)
Weighted average common shares outstanding	271,317	238,246
Net loss per share of common stock basic and diluted	$ (14.46)	$ (28.69)

The following outstanding securities at June 30, 2014 have been excluded from the computation of diluted weighted average shares outstanding, as they would have been anti-dilutive:

Convertible preferred stock	8,823,187
Unvested restricted stock	264,190
Stock options	1,231,706
Total	10,319,083

4. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	December 31, 2013	June 30, 2014
Research and development expenses	$ 81	$ 92
General and administrative expenses	108	104
Share repurchase obligation		45
Financing costs and other		340
	$ 189	$ 581

5. Redeemable Convertible Preferred Stock and Stockholders Deficit

Capitalization

As of December 31, 2013, the Company s amended and restated certificate of incorporation reflected the following authorized shares: 15,031,954 shares of capital stock, consisting of 9,375,000 shares of common stock, par value of $0.0001 per share, and 5,656,954 shares of preferred stock, par value of $0.0001 per share of which (i) 5,156,250 shares are designated Series A Redeemable Convertible Preferred Stock (Series A) and (ii) 500,704 shares are designated Series A-1 Redeemable Convertible Preferred Stock (Series A-1).

As of June 30, 2014, the Company s amended and restated certificate of incorporation reflected the following authorized shares: 21,010,691 shares of capital stock, consisting of 12,187,500 shares of common stock, par value of $0.0001 per share, and 8,823,191 shares of preferred stock, par value of $0.0001 per share of which (i) 5,156,250 shares are designated Series A, (ii) 500,704 shares are designated Series A-1 and (iii) 3,166,237 shares are designated Series B.

On June 28, 2013 and July 3, 2013, the Company issued 452,896 shares of common stock to its co-founders. The shares of common stock issued to two of these co-founders, aggregating 264,190 shares, were subject to vesting pursuant to restricted stock agreements, with 25% of such shares vesting on July 3, 2014 and the remaining 75% vesting in equal monthly installments over a three-year period thereafter. The estimated grant-date fair value of these restricted shares was de minimis.

On July 3, 2013, the Company entered into a stock purchase agreement, which was subsequently amended on September 19, 2013, pursuant to which the Company agreed to sell to certain investors, upon the satisfaction of certain conditions, up to 2,812,497 shares of Series A. The initial closing occurred on July 3, 2013 and 1,562,500 shares of Series A were issued. The remaining

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1,249,997 shares were issued on September 19, 2013. Upon completing the July and September closings, the Company received net proceeds of approximately $17.8 million. Additionally on July 3, 2013, the Company issued 500,704 shares, with an estimated fair value of approximately $7.0 million, of Series A-1 to Array in connection with entering into a collaboration agreement (see Note 6). The estimated fair value of these shares has been recognized as research and development expense-related party in the accompanying statements of operations.

On February 28, 2014, the Company filed with the United States Food and Drug Administration an Investigational New Drug Application for a tyrosine kinase inhibitor targeted to the TRK family of receptors. As a result and in accordance with the provisions of the stock purchase agreement entered into on July 3, 2013, the Company issued 2,343,753 shares of Series A at a price of $6.40 per share and received net proceeds of $15.0 million on March 18, 2014.

On April 24, 2014 and June 24, 2014, the Company entered into stock purchase agreements pursuant to which the Company agreed to sell 2,664,343 and 501,890 shares, respectively, of Series B, $0.0001 par value, at a purchase price of $8.9661 per share. Upon completing the April and June offerings, the Company received gross proceeds of approximately $28.4 million.

As previously discussed in Note 1, the Company completed its initial public offering in August 2014. As part of that offering, all of the Company s outstanding convertible preferred stock was converted into an aggregate total of 9,932,042 shares of common stock.

2013 Equity Incentive Plan

Effective July 2, 2013, the Company adopted the 2013 Equity Incentive Plan, which was amended in November 2013 (the 2013 Plan). The 2013 Plan provides for the granting of incentive stock options, non-statutory stock options and the issuance of restricted stock awards. As of December 31, 2013 and June 30, 2014, there were 905,796 and 1,491,895 shares, respectively, of common stock authorized for issuance in connection with the Plan, of which there were 224,734 and 135,211 shares available for future issuance, respectively.

Incentive options may be granted to employees, including members of the Board. Non-statutory stock options and purchase rights are granted to employees and consultants of the Company, including members of the Board and advisory board members. The terms of the stock option agreements, including the purchase price per share payable upon exercise of the non-statutory options, are determined by the Board. The exercise price of the incentive options shall not be less than the fair market value per share of common stock on the date of grant. The maximum term of the options granted is ten years, unless an employee owns more than 10% of the total combined voting power of all classes of stock of the Company.

Certain options are eligible for exercise prior to vesting. Exercised but unvested shares are subject to repurchase by the Company at the initial exercise price. The proceeds from the shares subject to repurchase are classified as a liability and reclassified to equity as the shares vest. Under the 2013 Plan s early exercise feature, the Company could be required to repurchase 16,866 shares as of June 30, 2014. The Company records cash received from early exercised shares as a liability. As of June 30, 2014, $45,000 has been recorded as a liability and included in accrued expenses. In connection with the Company s initial public offering, no further grants will be made under this plan and all remaining shares available for grant were transferred to the 2014 Incentive Plan (see Note 8).

The following table summarizes stock option activity under the 2013 Plan for the period from December 31, 2013 through June 30, 2014:

	Number of Shares	Weighted-Average Exercise Price
Outstanding at December 31, 2013	681,056	$ 1.1840
Granted	658,762	3.3818
Exercised	(108,112)	1.4689
Cancelled		
Forfeited		
Outstanding at June 30, 2014	1,231,706	$ 2.3055
Vested and expected to vest at June 30, 2014	1,231,706	$ 2.3055
Exercisable at June 30, 2014	89,483	$ 1.5282
Weighted-average grant date fair value of options granted during the six months ended June 30, 2014	$ 10.53	

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The 1,231,706 shares of common stock issuable upon the exercise of options outstanding as of June 30, 2014 in the table above includes 16,866 shares of common stock that have been issued upon exercise prior to vesting and are subject to repurchase by the Company.

The weighted-average remaining contractual term of the outstanding options at December 31, 2013 and June 30, 2014 was 9.92 and 9.68 years, respectively.

As of June 30, 2014, there was $9,539,479 of total unrecognized compensation expense related to options granted but not yet vested. This amount will be recognized as expense over a weighted-average period of 3.28 years.

The Company uses the Black-Scholes option pricing model to estimate the fair value of option awards with the following weighted-average assumptions, which are based on industry comparative information, for the period indicated:

	Six Months Ended June 30, 2014
Risk-free interest rate	2.15%
Expected dividend yield	0%
Expected stock price volatility	89.76%
Expected term of options (in years)	7.07
Expected forfeiture rate	0%

The weighted-average valuation assumptions were determined as follows:

- Risk-free interest rate: The Company bases the risk-free interest rate on the interest rate payable on U.S. Treasury securities in effect at the time of grant for a period that is commensurate with the assumed expected option term.

- Expected annual dividends: The estimate for annual dividends is 0%, because the Company has not historically paid, and does not expect for the foreseeable future to pay, a dividend.

- Expected stock price volatility: The expected volatility used is based on historical volatilities of similar entities within the Company s industry which were commensurate with the Company s expected term assumption.

- Expected term of options: The expected term of options represents the period of time options are expected to be outstanding. The expected term of the options granted to employees is derived from the simplified method as described in SAB 107 relating to stock-based compensation. The expected term for options granted to non-employees is equal to the contractual term of the awards.

- Expected forfeiture rate: The Company s estimated annual forfeiture rate was 0%, based on historical forfeiture experience of various employee groups.

- Fair value of common stock: The fair values of common stock of $1.1840 per share, and $3.6480 per share in March 2014 and $13.00 per share June of 2014, were determined with the assistance of a third-party valuation firm in connection with the Company s initial Series A, A-1, and B convertible preferred stock issuances.

- The estimated fair value of the Company s stock-based awards is amortized on a straight-line basis over the awards service period. Share-based compensation expense recognized was as follows (in thousands):

	Three Months Ended June 30, 2014	Six Months Ended June 30, 2014
Research and development	$ 281	$ 325
General and administrative	192	212
	$ 473	$ 537

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6. Commitments and Contingencies

Array Collaboration Agreement

On July 3, 2013, the Company signed a multi-year strategic collaboration agreement with Array, and this agreement was subsequently amended on November 26, 2013 and April 10, 2014. Under the terms of the collaboration agreement, the Company obtained certain rights to Array s TRK inhibitor program, as well as additional novel oncology targets. The Company has worldwide commercial rights to each product candidate from the collaboration and Array participates in any potential successes through milestones, royalties, and an equity ownership in the Company.

With respect to the discovery and preclinical program, the collaboration agreement runs through July 3, 2016, and the Company has the option to extend the term for up to two additional one-year renewal periods by providing written notice to Array at least three months before the end of the initial discovery and preclinical development programs or the renewal period, if applicable.

As part of the agreement the Company agreed to pay Array a fixed amount per month, based on Array s commitment to provide full-time equivalents and other support relating to the conduct of the discovery and preclinical development programs. The Company recorded related-party research and development expenses for the three and six months ended June 30, 2014 of $1.7 million and $3.0 million, respectively, related to the conduct of the discovery preclinical development programs by Array.

On April 10, 2014, the Company and Array entered into an amendment to the collaboration agreement. Pursuant to the amendment, in addition to LOXO-101, the parties designated 12 discovery targets, of which six are to be selected for additional study on or before January 2015, which will be reduced to four on or before October 2015. The Company has the option to increase the total candidate selection number to five for a modest additional payment. The Company also agreed to provide additional headcount support for Array s research activities on the agreed-upon targets.

Milestones

With respect to product candidates directed to TRK, including LOXO-101 and its back-up compounds, the Company could be required to pay Array up to $222 million in milestone payments, the substantial majority of which are due upon the achievement of commercial milestones. With respect to product candidates directed to targets other than TRK, the Company could be required to pay Array up to $213 million in milestone payments, the substantial majority of which are due upon the achievement of commercial milestones.

Royalties

The Company is required to pay Array mid-single digit royalties on worldwide net sales of products directed to TRK and directed to targets. With respect to the royalty on products directed to targets, the Company has the right to credit certain milestone payments against royalties on sales of products directed to such target.

Convertible preferred stock issuance

In connection with this agreement, the Company issued Array 500,704 shares of Series A-1 convertible preferred stock, par value $0.0001. The Company recognized, as a component of research and development expense with related party approximately $7.0 million related to the estimated fair value of the shares issued during the period from May 9, 2013 (date of inception) to December 31, 2013.

Legal Proceedings

The Company is not involved in any legal proceeding that it expects to have a material effect on its business, financial condition, results of operations and cash flows.

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7. Related Party Transactions

The Company recorded expenses for the three and six months ended June 30, 2014 of approximately $1.7 million and $3.0 million, respectively, as a component of research and development with a related party for services provided by Array under the collaboration agreement as described in further detail above in Note 6. As of June 30, 2014, the Company had $0.7 million in prepaid expenses to Array under the collaboration agreement for services that will be provided in subsequent periods.

8. Subsequent Events

Stock Option Grant

On July 9, 2014, the Board granted 204,780 options with an exercise price of $7.1360 per share pursuant to the Plan. The vesting terms of each award may vest immediately, over a four-year period or upon the achievement of certain milestones as defined in each award.

Capital Stock

On July 21, 2014, the Company amended and restated its certificate of incorporation to reflect the following authorized share increases: 31,010,691 shares of capital stock, consisting of 22,187,500 shares of common stock, par value of $0.0001 per share, and 8,823,191 shares of preferred stock, par value of $0.0001 per share of which (i) 5,156,250 shares are designated Series A Redeemable Convertible Preferred Stock, (ii) 500,704 shares are designated Series A-1 Redeemable Convertible Preferred Stock and (iii) 3,166,237 shares are designated Series B Redeemable Convertible Preferred Stock.

On August 7, 2014, in connection with its initial public offering, the Company amended and restated its certificate of incorporation to reflect the following authorized share increases: 130,000,000 shares of capital stock, consisting of 125,000,000 shares of common stock, par value $0.0001 per share and 5,000,000 shares of preferred stock, par value $0.0001 per share.

2014 Equity Incentive Plan

The Company adopted a 2014 Equity Incentive Plan that became effective on July 30, 2014 and serves as the successor to the 2013 Equity Incentive Plan. The 2014 Equity Incentive Plan provides for the grant of awards to employees, directors, consultants, independent contractors and advisors, provided the consultants, independent contractors, directors and advisors are natural persons that render services not in connection with the offer and sale of securities in a capital-raising transaction. The exercise price of stock options must be at least equal to the fair market value of our common stock on the date of grant.

The Company has reserved 1,092,085 shares of its common stock to be issued under the 2014 Equity Incentive Plan and will increase automatically on January 1 of each of 2015 through 2024 by the number of shares equal to 3.0% of the aggregate number of outstanding shares of our common stock as of the immediately preceding December 31. The Company s Board may reduce the amount of the increase in any particular year.

The 2014 Equity Incentive Plan authorizes the award of stock options, restricted stock awards, or RSAs, stock appreciation rights, or SARs, restricted stock units, or RSUs, performance awards and stock bonuses.

2014 Employee Stock Purchase Plan

The Company adopted a 2014 Employee Stock Purchase Plan (ESPP) that became effective on July 31, 2014 which was the effective date of the Company s registration statement. The ESPP provides employees of the Company, including any parent or subsidiary companies that the Board designates from time to time as a corporation that shall participate in the plan, with a means of acquiring an equity interest in the Company and to provide an incentive for continued employment.

There are 149,600 shares of common stock reserved for future issuances under the ESPP. Any employee regularly employed by the Company for six months or more on a full-time or part-time basis (20 hours or more per week on a regular schedule) will be eligible to participate in the plan. The ESPP will operate in successive six month offering periods. Each eligible employee who has elected to participate may purchase up to 1,000 shares or $25,000 during each offering period. The purchase price will be the lower of (i) 85% of the fair market value of a share of common stock on the first trading day of the offering period or (ii) 85% of the fair market value of a share of common stock on the last trading day of the offering period. The ESPP will continue for a period of ten years from the first purchase date under the plan unless otherwise terminated by the Board. As of September 12, 2014, no commencement date for the first offering period has been approved by the Board or compensation committee and no shares have been issued under the ESPP.

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Forward Stock Split

In July 2014, the Board approved a 1.5625-for-1 forward stock split of the Company s common stock (see Note 1).

Initial Public Offering

On August 6, 2014, the Company closed its initial public offering and private placement and 5,492,307 shares of common stock were sold at an initial public offering price of $13.00 per share, for aggregate gross proceeds to the Company of $71.4 million (see Note 1).

On August 29, 2014, the underwriters of the Company s initial public offering gave notification that they would partially exercise the over-allotment option granted to them and on September 4, 2014, 642,000 additional shares of common stock were sold on the Company s behalf at the initial public offering price of $13.00 per share, for aggregate gross proceeds of approximately $8.3 million (see Note 1).

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ITEM 2. MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our interim unaudited condensed financial statements and related notes included in this Quarterly Report on Form 10-Q and the audited financial statements and notes thereto as of and for the year ended December 31, 2013 and the related Management s Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our final prospectus dated July 31, 2014 filed pursuant to Rule 424(b)(4) of the Securities Act with the SEC on August 1, 2014. As used in this report, unless the context suggests otherwise, we, us, our, the Company or Loxo refer to Loxo Oncology, Inc.

Forward Looking Statements

The information in this discussion contains forward-looking statements and information within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, which are subject to the safe harbor created by those sections. This Quarterly Report on Form 10-Q contains forward-looking statements that involve substantial risks and uncertainties. In some cases, you can identify forward-looking statements by the words may, might, will, could, would, should, expect, intend, plan, objective, anticipate, believe, estimate, predict, project, potential, continue and ongoing, terms, or other comparable terminology intended to identify statements about the future. These statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. Although we believe that we have a reasonable basis for each forward-looking statement contained in this prospectus, we caution you that these statements are based on a combination of facts and factors currently known by us and our expectations of the future, about which we cannot be certain. You should refer to the risks set forth in Part II, Item 1A, Risk Factors in this Quarterly Report on Form 10-Q for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. Furthermore, such forward-looking statements speak only as of the date of this report. We undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

Overview

Loxo Oncology develops targeted small molecule therapeutics for the treatment of cancer in genetically defined patient populations. Our development approach translates key scientific insights relating to the oncogenic drivers of cancer into drugs that are potent and highly selective for their intended targets. Such drugs typically achieve high target engagement, which has been correlated with improved tumor response. We believe our approach will allow us to develop drugs with a high probability of clinical success while reducing the time, costs and risks of drug development. Our lead product candidate, LOXO-101, is a potent and selective inhibitor of tropomyosin receptor kinase, or TRK, a family of signaling molecules that appear to play an important role in the development and perpetuation of many cancers. We are evaluating LOXO-101 in a Phase 1 dose escalation trial for patients with advanced solid tumors, and we anticipate reporting data by early 2015. We are also building a pipeline of additional product candidates targeting cancers driven by genetic alterations.

Our Phase 1 clinical trial of LOXO-101 is an open label, multicenter trial that has two stages: dose escalation and expansion. The primary objectives of the dose escalation stage are to determine the maximum tolerated dose and the appropriate dose for further clinical investigation, as well as to determine the safety, tolerability and pharmacokinetic profile of orally administered LOXO-101. Inclusion criteria is for patients with (1) locally advanced or metastatic adult solid tumor that has progressed or was nonresponsive to available therapies and for which no standard or available curative therapy exists, (2) an ECOG score, which measures disease progression, of 0 or 1 and (3) adequate hematologic, hepatic and

renal function. Dosing cohorts are expected to include three to six patients in up to six cohorts. Initial human pharmacokinetic data from the first cohort of this Phase 1 trial demonstrate LOXO-101 was absorbed with good exposure. In addition, no limiting toxicities were reported and dose escalation is proceeding. We expect the dose escalation stage to be completed by early 2015. The primary objective of the expansion phase is to assess preliminary evidence of antitumor activity across multiple tumor types in preselected patients with TRK alterations who meet the inclusion criteria listed above. During the expansion phase, the LOXO-101 dose selected from the dose escalation phase will be explored in up to 33 patients per cohort.

We were incorporated in May 2013 and commenced operations in the third quarter of 2013. Our operations to date have included organizing and staffing our company, business planning, raising capital, developing LOXO-101, engaging in other discovery and preclinical activities, and initiating our first clinical trial. We have financed our operations to date primarily through private placements of our convertible preferred stock and through proceeds from our initial public offering. As of June 30, 2014, we had received aggregate gross proceeds of $33.0 million from the sale of our Series A convertible preferred stock. In addition, in July 2013,

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we received certain rights under the Array Agreement, which, in part, were granted in exchange for our issuance of shares of Series A-1 convertible preferred stock. Subsequently, in April and June 2014, we received gross proceeds of approximately $23.9 million and $4.5 million, respectively, through issuances of Series B convertible preferred stock. Our ability to become profitable depends on our ability to generate revenue. We do not expect to generate significant revenue unless and until we or collaborators obtain marketing approval for and commercialize LOXO-101 or one of our other future product candidates.

Since inception, we have incurred significant operating losses. Our net losses from May 9, 2013 (date of inception) to June 30, 2014 were $17.1 million, including approximately $14.2 million of total research and development expenses, and approximately $2.8 million of total general and administrative expenses. We expect to incur significant expenses and increasing operating losses for the foreseeable future as we continue the discovery, development and clinical trials of, and seek regulatory approval for and pursue potential commercialization of, our product candidates. In addition, we will also incur additional expenses if and as we enter into additional collaboration agreements, acquire or in-license products and technologies, expand our collaboration with Array, establish sales, marketing and distribution infrastructure and/or expand and protect our intellectual property portfolio.

We will need to obtain substantial additional funding in connection with our continuing operations. We will seek to fund our operations through the sale of equity, debt financings or other sources, including potential collaborations. We may be unable to raise additional funds or enter into such other agreements when needed on favorable terms, or at all. If we fail to raise capital or enter into such other arrangements as, and when, needed, we may have to significantly delay, scale back or discontinue the development and commercialization of one or more of our product candidates.

On July 3, 2013, we signed the Array Agreement, which was subsequently amended in November 2013 and April 2014. For further information on the Array Agreement, see below under Contractual Obligations and Commitments Array Collaboration Agreement. Concurrent with entering into this collaboration agreement, we also issued Array 500,704 shares of Series A-1 convertible preferred stock. We recognized related-party research and development expense of $7.0 million related to the estimated fair value of the shares issued, at $14.07 per share. The shares of Series A-1 convertible preferred stock issued to Array were subject to an antidilution protection feature, which provided that the rate at which such Series A-1 convertible preferred stock would be convertible into common stock would increase as a result of certain new issuances of our stock, as further specified in our certificate of incorporation. As of April 2014, this antidilution feature had expired and the 500,704 shares of Series A-1 convertible preferred stock held by Array were converted into 1,609,560 shares of our common stock in connection with the closing of our initial public offering.

Liquidity

Our financial statements and related disclosures have been prepared on a going-concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. Accordingly, the financial statements do not include any adjustments that might be necessary should we be unable to continue in existence. We have not generated any revenues and have not yet achieved profitable operations. There is no assurance that profitable operations, if ever achieved, could be sustained on a continuing basis. In addition, development activities, clinical and preclinical testing, and commercialization of our products will require significant additional financing. Our accumulated deficit at June 30, 2014 was approximately $17.1 million, and management expects to incur substantial and increasing losses in future periods. Our ability to successfully pursue our business is subject to certain risks and uncertainties, including among others, uncertainty of product development, competition from third parties, uncertainty of capital availability, uncertainty in our ability to enter into agreements with collaborative partners, dependence on third parties, and dependence on key personnel. We plan to finance future operations with a combination of proceeds from the issuance of equity, debt, licensing fees, and revenues from future product sales, if any. We have not generated positive cash flows from operations, and there are no assurances that we will be successful in obtaining an adequate level of financing for the development and commercialization of our planned products. We believe that our existing cash and cash equivalents as of June 30, 2014, in conjunction with the

proceeds received in connection with our initial public offering and concurrent private placement in August 2014, will be sufficient to enable us to continue as a going concern for a reasonable period of time beyond June 30, 2014.

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Components of Operating Results

Revenue

To date, we have not generated any revenues. Our ability to generate product revenues, which we do not expect will occur for many years, if ever, will depend heavily on the successful development and eventual commercialization of our product candidates.

Research and Development Expenses with Related Party

Our research and development expenses with a related party for the three and six months ended June 30, 2014 consisted primarily of $1.7 and $3.0 million related to the conduct of the discovery and preclinical development programs by Array.

Research and Development Expenses

Research and development costs are charged to expense as incurred. These costs include, but are not limited to, employee-related expenses, including salaries, benefits, stock-based compensation and travel as well as expenses related to third-party collaborations and contract research arrangements.

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. As we advance our product candidates, we expect the amount of research and development will continue to increase for the foreseeable future, while our internal spending should increase at a slower and more controlled pace.

It is difficult to determine with certainty the duration and completion costs of our current or future preclinical programs and clinical trials of our product candidates, or if, when or to what extent we will generate revenue from the commercialization and sale of any of our product candidates that obtain regulatory approval. We may never succeed in achieving regulatory approval for any of our product candidates. The duration, costs and timing of clinical trials and development of our product candidates will depend on a variety of factors, including the uncertainties of future clinical and preclinical studies, uncertainties in clinical trial enrollment rate and significant and changing government regulation. In addition, the probability of success for each product candidate will depend on numerous factors, including competition, manufacturing capability and commercial viability. We will determine which programs to pursue and how much to fund each program in response to the scientific and clinical success of each product candidate, as well as an assessment of each product candidate s commercial potential.

General and Administrative Expenses

General and administrative expenses consist principally of salaries and related costs for executive and other personnel, including stock-based compensation and travel expenses. Other general and administrative expenses include facility-related costs, communication expenses and professional fees for legal, patent prosecution and maintenance consulting and accounting services.

Accretion of Redeemable Convertible Preferred Stock

We account for the discount due to issuance costs on our convertible preferred stock using the straight-line method, which approximates the effective interest method, accreting such amounts to convertible preferred stock from the date of issuance to the earliest date the holder can demand redemption.

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Critical Accounting Policies and Significant Judgments and Estimates

This management s discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues 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, revenue recognition, deferred revenue and stock-based compensation. We base our estimates on historical experience, known trends and events and various other factors that we believe 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. We believe there have been no significant changes in our critical accounting policies as discussed in our Form S-1 filed on July 30, 2014 with the SEC.

Recent Accounting Pronouncements

On June 10, 2014, FASB issued ASU No. 2014-10, *Development Stage Entities (Topic 915): Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entities Guidance in Topic 810, Consolidation.* The guidance is intended to reduce the overall cost and complexity associated with financial reporting for development stage entities without reducing the availability of relevant information. The Board also believes the changes will simplify the consolidation accounting guidance by removing the differential accounting requirements for development stage entities. As a result of these changes, there no longer will be any accounting or reporting differences in GAAP between development stage entities and other operating entities. For organizations defined as public business entities the presentation and disclosure requirements in Topic 915 will no longer be required starting with the first annual period beginning after December 15, 2014, including interim periods therein. Early application is permitted for any annual reporting period or interim period for which the entity s financial statements have not yet been issued (public business entities) or made available for issuance (other entities). We have early adopted this guidance during the three months ended June 30, 2014 and, as a result, we will no longer present inception-to-date information about income statement line items, cash flows, and equity transactions.

In June 2014, the FASB issued ASU No. 2014-12, *Compensation - Stock Compensation (Topic 718): Accounting for Share-Based Payments When the Terms of an Award Provide that a Performance Target Could be Achieved after the Requisite Service Period*, (ASU 2014-12). ASU 2014-12 requires that a performance target that affects vesting, and that could be achieved after the requisite service period, be treated as a performance condition. As such, the performance target should not be reflected in estimating the grant date fair value of the award. This update further clarifies that compensation cost should be recognized in the period in which it becomes probable that the performance target will be achieved and should represent the compensation cost attributable to the period(s) for which the requisite service has already been rendered. We do not anticipate that the adoption of this standard will have a material impact on our financial statements.

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Results of Operations

Comparison of the Period from May 9, 2013 (Date of Inception) to June 30, 2013 and the Three Months Ended June 30, 2014 (in thousands)

	Three Months Ended June 30, 2014	Period from May 9, 2013 (Date of Inception) to June 30, 2013	Change
Operating expenses:			
Research and development with related party	$ 1,717	$ 53	$ 1,664
Research and development	855	6	849
General and administrative	1,333	31	1,302
Total operating expenses and net loss	(3,905)	(90)	(3,815)
Accretion of redeemable convertible preferred stock	(17)		(17)
Net loss attributable to common stockholders	$ (3,922)	$ (90)	$ (3,832)

Research and development expense

Research and development expenses increased by $2.5 million, from $59,000 for the period from May 9, 2013 (Date of Inception) through June 30, 2013 to $2.6 million for the three months ended June 30, 2014. The increase was primarily due to the timing in which we entered into our Array Agreement which did not occur until July of 2013. The expense for the three months ended June 30, 2014 relate primarily to $1.7 million in monthly advances paid in connection with the Array Agreement, $0.4 million of stock-based compensation expenses, and $0.5 million in consulting expenses. Substantially all of our cash research and development expenses for the three months ended June 30, 2014 have been directed toward our TRK program, including LOXO-101.

General and administrative expense

General and administrative expenses increased by $1.3 million for the three months ended June 30, 2014 compared to the period from May 9, 2013 (Date of Inception) through June 30, 2013 primarily due to the timing in which we commenced a substantial portion of our operations in the third quarter of 2013. For the three months ended June 30, 2014, these expenses consisted primarily of $0.2 million of legal expenses, $0.6 million of employee salaries and benefits, $0.3 million of professional fees, and $0.2 million of office and miscellaneous expenses. We expect our general and administrative expenses to continue to increase during 2014 due the increase in headcount, compensation expense associated with stock options granted and increased insurance, professional fees and other operating costs as a result of becoming a public company.

Comparison of the Period from May 9, 2013 (Date of Inception) to June 30, 2013 and the Six Months Ended June 30, 2014 (in thousands)

	Six Months Ended June 30, 2014	Period from May 9, 2013 (Date of Inception) to June 30, 2013	Change
Operating expenses:			
Research and development with related party	$ 2,992	$ 53	$ 2,939
Research and development	1,566	6	1,560
General and administrative	2,249	31	2,218
Total operating expenses and net loss	(6,807)	(90)	(6,717)
Accretion of redeemable convertible preferred stock	(28)		(28)
Net loss attributable to common stockholders	$ (6,835)	$ (90)	$ (6,745)

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Research and development expense

Research and development expenses increased by $4.5 million, from $59,000 for the period from May 9, 2013 (Date of Inception) through June 30, 2013 to $4.6 million for the six months ended June 30, 2014. The increase was primarily due to the timing in which we entered into our Array Agreement which did not occur until July of 2013. The expenses for the six months ended June 30, 2014 relate primarily to $3.0 million in monthly advances paid in connection with the Array Agreement, $1.0 million in consulting expenses, $0.4 million of stock-based compensation expenses, and $0.2 million in clinical and preclinical expenses.

General and administrative expense

General and administrative expenses increased by $2.2 million for the six months ended June 30, 2014 compared to the period from May 9, 2013 (Date of Inception) through June 30, 2013 primarily due to the timing in which we commenced a substantial portion of our operations in the third quarter of 2013. For the six months ended June 30, 2014, these expenses consisted primarily of $0.6 million of legal expenses, $0.9 million of employee salaries and benefits, $0.4 million of professional fees, and $0.3 million of office and miscellaneous expenses.

Liquidity and Capital Resources

Since our inception, we have incurred net losses and negative cash flows from our operations. We incurred net losses of $6.8 million for the six months ended June 30, 2014. Net cash used in operating activities was $6.4 million during the six months ended June 30, 2014. At June 30, 2014, we had an accumulated deficit of $17.1 million, working capital of $50.7 million and cash and cash equivalents of $51.3 million. Historically, we have financed our operations principally through private placements of preferred stock. In August 2014, we completed our initial public offering. Through June 30, 2014, we have received net proceeds of $61.2 million from the issuance of preferred and common stock.

Cash Flows

Due to the timing in which we commenced our operations during the third quarter of 2013, net cash used in or provided by operating, investing, and financing activities for the period from May 9, 2013 (Date of Inception) through June 30, 2013 was zero.

The following table summarizes our cash flows for the six months ended June 30, 2014 (in thousands):

Net cash (used in) provided by:		
Operating activities	$	(6,443)
Investing activities		(7)

Financing activities		42,760
Net increase in cash and cash equivalents	$	36,310

Net cash used in operating activities

Net cash used in operating activities was $6.4 million for the six months ended June 30, 2014 and consisted primarily of a net loss of $6.8 million and changes in operating assets and liabilities of $0.2 million partially offset by noncash stock compensation expense of $0.5 million. The significant factors that contributed to the change in operating assets and liabilities included $0.6 million prepayment made under our Array agreement offset by the increases in accounts payable and accrued expenses of $0.5 million as a result of our increase in legal and professional fees incurred in connection with our initial public offering.

Net cash used in investing activities

Net cash used in investing activities for the six months ended June 30, 2014 totaled $7,000 and consisted primarily of the purchase of office furniture related to our new offices in South San Francisco, California.

Net cash provided by financing activities

Net cash provided by financing activities was $42.8 million for the six months ended June 30, 2014, which was primarily due to $43.4 million in net proceeds from the issuance of our redeemable convertible preferred stock and common stock that was offset by $0.6 million in financing fees related to completing our initial public offering in August 2014.

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Operating and Capital Expenditure Requirements

We have not achieved profitability since our inception and we expect to continue to incur net losses for the foreseeable future. We expect our cash expenditures to increase in the near term as we fund future clinical trials of LOXO-101, as well as clinical trials of our other preclinical product candidates and continuing preclinical activities.

As a publicly traded company, we will incur significant legal, accounting and other expenses that we were not required to incur as a private company. In addition, the Sarbanes-Oxley Act of 2002, as well as rules adopted by the SEC and The NASDAQ Stock Market, requires public companies to implement specified corporate governance practices that are currently inapplicable to us as a private company. We expect these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly.

We believe that, based upon our current operating plan, our existing capital resources, together with the net proceeds from our offering and the concurrent private placement, will be sufficient to fund our anticipated operations until at least July 2016, including development of LOXO-101 through our planned Phase 1 expansion trial, as well as discovery and development activities through IND for one additional product candidate, with additional resources available for other discovery and development activities. However, we anticipate that we will need to raise substantial additional financing in the future to fund our operations. In order to meet these additional cash requirements, we may incur debt, license certain intellectual property and seek to sell additional equity or convertible securities that may result in dilution to our stockholders. If we raise additional funds through the issuance of equity or convertible securities, these securities could have rights or preferences senior to those of our common stock and could contain covenants that restrict our operations. There can be no assurance that we will be able to obtain additional equity or debt financing on terms acceptable to us, if at all. Our future capital requirements will depend on many factors, including:

- the progress and results of the Phase 1 clinical program for LOXO-101;
- our ability to enter into collaborative agreements for the development and commercialization of our product candidates;
- the number and development requirements of any other product candidates that we pursue;
- the scope, progress, results and costs of researching and developing our product candidates or any future product candidates, both in the United States and outside the United States;
- the costs, timing and outcome of regulatory review of our product candidates or any future product candidates, both in the United States and outside the United States;

- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive marketing approval;

- any product liability or other lawsuits related to our products;

- the expenses needed to attract and retain skilled personnel;

- the general and administrative expenses related to being a public company, including developing an internal accounting function;

- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval; and

- the costs involved in preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending our intellectual property-related claims, both in the United States and outside the United States.

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If we are unable to successfully raise sufficient additional capital, through future debt or equity financings, product sales, or through strategic and collaborative ventures with third parties, we will not have sufficient cash flows and liquidity to fund our planned business operations. In that event, we might be forced to limit many, if not all, of our programs and consider other means of creating value for our stockholders, such as licensing to others the development and commercialization of products that we consider valuable and would otherwise likely develop internally. To the extent that we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our product candidates, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. If we do raise additional capital through public or private equity offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

Contractual Obligations and Commitments

Purchase Commitments

Other than amounts due for the lease of our Stamford, CT and South San Francisco, CA offices and under the Array collaboration agreement, as described below, we have no material non-cancelable purchase commitments with contract manufacturers or service providers as we have generally contracted on a cancelable basis.

Operating Lease

On May 15, 2014, we entered into an operating lease agreement to occupy office space in South San Francisco, CA. The lease commenced in May 2014 and will continue through June 2017, with the option for us to extend the lease for one additional period of three years. The total of the estimated base payments over the term of the lease are approximately $211,000. In addition to the base rent payments, we will be obligated to pay a pro rata share of operating expenses, utilities, and taxes.

Array Collaboration Agreement

On July 3, 2013, we signed the Array Agreement, which was subsequently amended on November 26, 2013 and April 10, 2014. Under the terms of the Array Agreement, we obtained certain rights to Array s TRK inhibitor program, as well as additional novel oncology targets. We have worldwide commercial rights to each product candidate from the collaboration and Array participates in any potential successes through milestones, royalties, and equity ownership.

With respect to the discovery and preclinical program, the collaboration agreement runs through July 3, 2016, and we have the option to extend the term for up to two additional one-year renewal periods by providing written notice to Array at least three months before the end of the initial discovery and preclinical development programs or the renewal period, if applicable.

As part of the Array Agreement we agreed to pay Array a fixed amount per month, based on Array s commitment to provide full-time equivalents and other support relating to the conduct of the discovery and preclinical development programs. We recorded related-party research and development expenses for the three and six months ended June 30, 2014 of $1.7 million and $3.0 million, respectively, related to the conduct of the discovery preclinical development programs by Array.

Milestones

With respect to product candidates directed to TRK, including LOXO-101 and its back-up compounds, we could be required to pay Array up to $222 million in milestone payments, the substantial majority of which are due upon the achievement of commercial milestones. With respect to product candidates directed to targets other than TRK, we could be required to pay Array up to $213 million in milestone payments, the substantial majority of which are due upon the achievement of commercial milestones.

Royalties

We will pay Array a mid-single digit royalty on worldwide net sales of products developed through the collaboration. With respect to the royalty on products directed to targets, we have the right to credit certain milestone payments against royalties on sales of products directed to such target.

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Other Commitments

In addition, in the course of normal business operations, we have agreements with contract service providers to assist in the performance of our research and development and manufacturing activities. We can generally elect to discontinue the work under these agreements. We could also enter into additional collaborative research, contract research, manufacturing and supplier agreements in the future, which may require upfront payments and even long-term commitments of cash.

Off-Balance Sheet Arrangements

Through June 30, 2014, we do not have any off-balance sheet arrangements, as defined by applicable SEC regulations.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

As a smaller reporting company as defined by Item 10 of Regulation S-K, we are not required to provide the information required by Item 3.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of June 30, 2014, the end of the period covered by this Quarterly Report on Form 10-Q.

Based on our evaluation, we believe that our disclosure controls and procedures as of June 30, 2014 are effective to provide reasonable assurance that the information required to be disclosed by us in reports filed under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported within the time periods specified in the SEC s rules and forms, and that such information is accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate, to allow timely decisions regarding required disclosure. We believe that a controls system, no matter how well designed and operated, cannot provide absolute assurance that the objectives of the controls system are met, and no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within a company have been detected.

Neither we nor our independent registered public accounting firm has performed an evaluation of our internal control over financial reporting during any period in accordance with the provisions of the Sarbanes-Oxley Act. As a result it is possible that, had we and our independent

registered public accounting firm performed an evaluation of our internal control over financial reporting in accordance with the provisions of the Sarbanes-Oxley Act, material weaknesses and significant control deficiencies may have been identified. However, for as long as we remain an emerging growth company as defined in the JOBS Act, we intend to take advantage of the exemption permitting us not to comply with the requirement that our independent registered public accounting firm provide an attestation on the effectiveness of our internal control over financial reporting.

Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting during our second fiscal quarter ended June 30, 2014 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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PART II

ITEM 1. LEGAL PROCEEDINGS

None.

ITEM 1A. RISK FACTORS

This Quarterly Report on Form 10-Q contains forward-looking information based on our current expectations. Because our actual results may differ materially from any forward-looking statements that we make or that are made on our behalf, this section includes a discussion of important factors that could affect our actual future results, including, but not limited to, our capital resources, the progress and timing of our clinical programs, the safety and efficacy of our product candidates, risks associated with regulatory filings, risks associated with determinations made by regulatory agencies, the potential clinical benefits and market potential of our product candidates, commercial market estimates, future development efforts, patent protection, effects of healthcare reform, reliance on third parties, and other risks set forth below.

Risks Related to Our Financial Position and Need For Additional Capital

We have incurred significant losses since our inception. We expect to incur losses over the next several years and may never achieve or maintain profitability.

Since inception, we have incurred significant operating losses. Our cumulative net losses were $17.1 million for the period from May 9, 2013 (date of inception) to June 30, 2014. As of June 30, 2014, we had a cumulative deficit of $17.1 million. We have focused primarily on our discovery collaboration with Array and developing our product candidates. We have recently initiated clinical development of our lead product candidate, LOXO-101, and expect that it will be many years, if ever, before we have a product candidate ready for commercialization. To date, we have financed our operations primarily through private placements of our convertible preferred stock and our initial public offering. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. The net losses we incur may fluctuate significantly from quarter to quarter. We anticipate that our expenses will increase substantially if and as we:

- continue development of our product candidates;
- seek to identify additional product candidates;

- maintain and leverage our collaboration with Array;

- continue and initiate clinical trials for our product candidates;

- enter into additional collaboration arrangements with regards to product discovery or acquire or in-license other products and technologies;

- seek marketing approvals for our product candidates that successfully complete clinical trials;

- establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval;

- maintain, expand and protect our intellectual property portfolio;

- hire additional personnel;

- add operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts; and

- incur increased costs as a result of operating as a public company.

To become and remain profitable, we must develop and eventually commercialize a product or products with significant market potential. This will require us to be successful in a range of challenging activities, including completing clinical trials of our product

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candidates, obtaining marketing approval for these product candidates and manufacturing, marketing and selling those products for which we may obtain marketing approval. We may never succeed in these activities and, even if we do, may never generate revenues that are significant or large enough to achieve profitability. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of the company and could impair our ability to raise capital, maintain our discovery and preclinical development efforts, expand our business or continue our operations and may require us to raise additional capital that may dilute your ownership interest. A decline in the value of our company could also cause you to lose all or part of your investment.

Our limited operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability.

We are an early-stage clinical development company. We were incorporated in May 2013 and commenced operations in the third quarter of 2013 and rely on our collaboration with Array and other third parties to provide discovery and preclinical development capability. Our operations to date have been limited to organizing and staffing our company, business planning, raising capital, acquiring and developing our technology, identifying potential product candidates, undertaking preclinical studies and preparing to undertake clinical studies of our most advanced product candidate, LOXO-101, which we recently advanced into clinical trials. We have not yet demonstrated our ability to successfully complete any clinical trials, including large-scale, pivotal clinical trials, obtain marketing approvals, manufacture a commercial scale product, or arrange for a third-party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Medicines, on average, take ten to 15 years to be developed from the time they are discovered to the time they are available for treating patients. Consequently, any predictions you make about our future success or viability based on our short operating history to date may not be as accurate as they could be if we had a longer operating history.

In addition, as a new business, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. We will need to transition from a company with a research focus to a company capable of supporting commercial activities. We may not be successful in such a transition.

We will need substantial additional funding. If we are unable to raise capital when needed, we would be compelled to delay, reduce or eliminate our product development programs or commercialization efforts.

We expect our expenses to increase in parallel with our ongoing activities, particularly as we continue our discovery and preclinical development collaborations to identify new clinical candidates and initiate clinical trials of, and seek marketing approval for, our product candidates. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. Furthermore, we expect to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our discovery and preclinical development programs or any future commercialization efforts.

We believe that, based upon our current operating plan, our existing capital resources will be sufficient to fund our anticipated operations until at least July 2016, including development of LOXO-101 through our planned Phase 1 expansion trial, as well as discovery and development activities through IND for one additional product candidate, with additional resources available for other discovery and clinical development activities. Our future capital requirements will depend on many factors, including:

- the scope, progress, results and costs of compound discovery, preclinical development, laboratory testing and clinical trials for our product candidates;

- the extent to which we enter into additional collaboration arrangements with regard to product discovery or acquire or in-license products or technologies;

- our ability to establish additional discovery collaborations on favorable terms, if at all;

- the costs, timing and outcome of regulatory review of our product candidates;

- the costs of future commercialization activities, including product sales, marketing, manufacturing and distribution, for any of our product candidates for which we receive marketing approval;

- revenue, if any, received from commercial sales of our product candidates, should any of our product candidates receive

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marketing approval; and

- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims.

Identifying potential product candidates and conducting preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of products that we do not expect to be commercially available for many years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings and debt financings. We do not have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

We cannot be certain that additional funding will be available on acceptable terms, or at all. If we are unable to raise additional funds when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts.

Risks Related to the Discovery and Development of Our Product Candidates

Our discovery and preclinical development is focused on the development of targeted therapeutics for patients with genetically defined cancers, which is a rapidly evolving area of science, and the approach we are taking to discover and develop drugs is novel and may never lead to marketable products.

The discovery and development of targeted drug therapeutics for patients with genetically defined cancers is an emerging field, and the scientific discoveries that form the basis for our efforts to discover and develop product candidates are relatively new. The scientific evidence to support the feasibility of developing product candidates based on these discoveries is both preliminary and limited. The patient populations for our product candidates are not completely defined but are substantially smaller than the general treated cancer population, and we will need to screen and identify these patients. Successful identification of patients is dependent on several factors, including achieving certainty as to how specific genetic alterations respond to our product candidates and developing companion diagnostics to identify such genetic alterations. Furthermore,

even if we are successful in identifying patients, we cannot be certain that the resulting patient populations will be large enough to allow us to successfully commercialize our products and achieve profitability. Therefore, we do not know if our approach of treating patients with genetically defined cancers will be successful, and if our approach is unsuccessful, our business will suffer.

We are very early in our development efforts and are substantially dependent on our lead product candidate, LOXO-101. If we or our collaborators are unable to successfully develop and commercialize LOXO-101 or experience significant delays in doing so, our business will be materially harmed.

We currently do not have any products that have gained regulatory approval. We have invested substantially all of our efforts and financial resources in identifying potential drug candidates and funding our collaboration agreement with Array to conduct preclinical studies. Our ability to generate product revenues, which we do not expect will occur for many years, if ever, will depend heavily on the successful development and eventual commercialization of LOXO-101, for which we have recently initiated a Phase 1 clinical trial in patients in advanced solid tumors. As a result, our business is substantially dependent on our ability to complete the development of and obtain regulatory approval for LOXO-101.

We 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. For example, to execute our business plan, we will need to successfully:

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- execute LOXO-101 development activities;

- obtain required regulatory approvals for the development and commercialization of LOXO-101;

- maintain, leverage and expand our intellectual property portfolio;

- build and maintain robust sales, distribution and marketing capabilities, either on our own or in collaboration with strategic partners;

- gain market acceptance for LOXO-101;

- develop and maintain any strategic relationships we elect to enter into, including our collaboration with Array; and

- manage our spending as costs and expenses increase due to drug discovery, preclinical development, clinical trials, regulatory approvals and commercialization.

If we are unsuccessful in accomplishing these objectives, we may not be able to successfully develop and commercialize LOXO-101, and our business will suffer.

Difficulty in enrolling patients could delay or prevent clinical trials of our product candidates. We may find it difficult to enroll patients in our Phase 1 expansion trial for LOXO-101 given that we do not know how many patients share the TRK alterations LOXO-101 is designed to inhibit.

Identifying and qualifying patients to participate in clinical studies of our product candidates is critical to our success. The timing of our clinical studies depends in part on the speed at which we can recruit patients to participate in testing our product candidates, and we may experience delays in our clinical trials if we encounter difficulties in enrollment. The patient population for our product candidates is not completely defined, but is substantially smaller than other cancer indications, because we are looking for the same type of genetic alterations across different tumor types and the number of patients with these alterations may be small. For example, with respect to LOXO-101, we do not know how many patients will have the target LOXO-101 is designed to inhibit.

In addition to the potentially small populations, the eligibility criteria of our clinical trials will further limit the pool of available study participants as we will require that patients have specific characteristics that we can measure or to assure their disease is either severe enough or not too advanced to include them in a study. Additionally, the process of finding and diagnosing patients may prove costly. We also may not be able to identify, recruit, and enroll a sufficient number of patients to complete our clinical studies because of the perceived risks and benefits of the product candidate under study, the availability and efficacy of competing therapies and clinical trials, the proximity and availability of clinical study sites for prospective patients, and the patient referral practices of physicians. If patients are unwilling to participate in our studies for any reason, the timeline for recruiting patients, conducting studies, and obtaining regulatory approval of potential products may be delayed.

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 revenue from any of these product candidates could be delayed or prevented. 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 revenue. 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, including:

- unforeseen safety issues or adverse side effects;
- failure of our companion diagnostics in identifying patients;
- modifications to protocols of our clinical trials resulting from FDA or institutional review board, or IRB, decisions; and
- ambiguous or negative interim results of our clinical trials, or results that are inconsistent with earlier results.

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Clinical drug development involves a lengthy and expensive process, with an uncertain outcome. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

We have only recently commenced clinical development of our lead product candidate LOXO-101 and the risk of failure for all of our product candidates is high. Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Clinical testing is expensive, difficult to design and implement and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. Further, 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, and interim results of a clinical trial do not necessarily predict final results. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products. It is impossible to predict when or if any of our product candidates will prove effective or safe in humans or will receive regulatory approval.

We may experience delays in our clinical trials and we do not know whether planned clinical trials will begin or enroll subjects on time, need to be redesigned or be completed on schedule, if at all. For example, we may not be permitted to initiate the expansion phase of our LOXO-101 Phase 1 trial if our methods of selecting patients for treatment are not accepted by FDA. There can be no assurance that FDA will not put any of our product candidates on clinical hold in the future. We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our product candidates. Clinical trials may be delayed, suspended or prematurely terminated because costs are greater than we anticipate or for a variety of reasons, such as:

- delay or failure in reaching agreement with FDA or a comparable foreign regulatory authority on a trial design that we are able to execute;

- delay or failure in obtaining authorization to commence a trial or inability to comply with conditions imposed by a regulatory authority regarding the scope or design of a clinical trial;

- delays in reaching, or failure to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;

- inability, delay, or failure in identifying and maintaining a sufficient number of trial sites, many of which may already be engaged in other clinical programs;

- delay or failure in recruiting and enrolling suitable subjects to participate in a trial;

- delay or failure in having subjects complete a trial or return for post-treatment follow-up;

- clinical sites and investigators deviating from trial protocol, failing to conduct the trial in accordance with regulatory requirements, or dropping out of a trial;

- lack of adequate funding to continue the clinical trial, including the incurrence of unforeseen costs due to enrollment delays, requirements to conduct additional clinical studies and increased expenses associated with the services of our clinical research organizations (CROs) and other third parties;

- clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;

- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials at a higher rate than we anticipate;

- we may experience delays or difficulties in the enrollment of patients whose tumors harbor the specific genetic alterations that our product candidates are designed to target;

- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;

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- we may have difficulty partnering with experienced CROs that can screen for patients whose tumors harbor the applicable genetic alterations and run our clinical trials effectively;

- regulators or IRBs may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;

- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate; or

- there may be changes in governmental regulations or administrative actions.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may:

- be delayed in obtaining marketing approval for our product candidates;

- not obtain marketing approval at all;

- obtain approval for indications or patient populations that are not as broad as intended or desired;

- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings that would reduce the potential market for our products or inhibit our ability to successfully commercialize our products;

- be subject to additional post-marketing restrictions and/or testing requirements; or

- have the product removed from the market after obtaining marketing approval.

Our product development costs will also increase if we experience delays in testing or marketing approvals. We do not know whether any of our preclinical studies or clinical trials will need to be restructured or will be completed on schedule, or at all. Significant preclinical or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our product candidates and may harm our business and results of operations.

We may not be successful in advancing the clinical development of our product candidates, including LOXO-101.

In order to execute on our strategy of advancing the clinical development of our product candidates, we have designed our existing Phase 1 clinical trial of LOXO-101, and expect to design future trials, to include patients whose tumors harbor the applicable genetic alterations that we believe contribute to cancer. Our goal in doing this is to enroll patients who have the highest probability of responding to the drug, in order to show early evidence of clinical efficacy. If we are unable to include patients whose tumors harbor the applicable genetic alterations, or if our product fails to work as we expect, our ability to assess the therapeutic effect, seek participation in FDA expedited review and approval programs, including Breakthrough Therapy, Fast Track Designation, Priority Review and Accelerated Approval, or otherwise to seek to accelerate clinical development and regulatory timelines, could be compromised, resulting in longer development times, larger trials and a greater likelihood of not obtaining regulatory approval. In addition, because the natural history of different tumor types is variable, we will need to study our product candidates, including LOXO-101, in clinical trials specific for a given tumor type and this may result in increased time and cost. Even if our product candidate demonstrates efficacy in a particular tumor type, we cannot guarantee that any product candidate, including LOXO-101, will behave similarly in all tumor types, and we will be required to obtain separate regulatory approvals for each tumor type we intend a product candidate to treat. If any of our clinical trials are unsuccessful, our business will suffer.

If serious adverse events or unacceptable side effects are identified during the development of our product candidates, we may need to abandon or limit our development of some of our product candidates.

If our product candidates are associated with undesirable side effects in preclinical or clinical trials or have characteristics that are unexpected, we may need to interrupt, delay or abandon their development or limit development to more narrow uses or

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subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. LOXO-101 toxicology studies in rats and monkeys demonstrated reversible increases in liver enzymes, and this may occur in humans. Testing in animals may not uncover all expected side effects or side effects in humans may be more severe. The TRK receptor family targeted by LOXO-101 plays an important role in the nervous system in general and the central nervous system, or CNS, in particular. In animal models no adverse CNS effects were observed. However, no assurance can be given that LOXO-101 will not cause unwanted, and potentially unacceptable, nervous system or CNS side effects when tested in the clinic. Additional or more severe side effects may be identified in our ongoing Phase 1 dose escalation trial or through further clinical studies. These or other drug-related side effects could affect patient recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims. Many compounds developed in the biopharmaceutical industry that initially showed promise in early-stage testing for treating cancer have later been found to cause side effects that prevented further development of the compound. Any of these occurrences may harm our business, financial condition and prospects significantly.

We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we must focus on a limited number of research programs and product candidates and on specific indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future discovery and preclinical development programs and product candidates for specific indications may not yield any commercially viable products.

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

As one of the central elements of our business strategy and clinical development approach, we seek to screen and identify subsets of patients with a genetic alteration who may derive meaningful benefit from our development product candidates. To achieve this, our product development program is dependent on the development and commercialization of a companion diagnostic by us or by third party collaborators. Companion diagnostics are developed in conjunction with clinical programs for the associated product and are subject to regulation as medical devices. Each agency that approves a product will independently need to approve the companion diagnostic before or concurrently with its approval of the product candidate, and before a product can be commercialized. The approval of a companion diagnostic as part of the product label will limit the use of the product candidate to only those patients who express the specific genetic alteration it was developed to detect. We may also experience delays in developing a sustainable, reproducible and scalable manufacturing process or transferring that process to commercial partners or negotiating insurance reimbursement plans, all of which may prevent us from completing our clinical trials or commercializing our products on a timely or profitable basis, if at all.

Companion diagnostics are subject to regulation by FDA and comparable foreign regulatory authorities as medical devices and require separate clearance or approval prior to their commercialization. To date, FDA has required premarket approval of all companion diagnostics for cancer therapies. We and our third-party collaborators may encounter difficulties in developing and obtaining approval for these companion diagnostics. Any delay or failure by us or third- party collaborators to develop or obtain regulatory approval of a companion diagnostic could delay or prevent approval of our related product candidates.

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Failure by us or our third-party collaborators to successfully commercialize companion diagnostics developed for use with our product candidates could harm our ability to commercialize these product candidates.

Even if we or our companion diagnostic collaborators successfully obtain regulatory approval for the companion diagnostics for our product candidates, our collaborators:

- may not perform their obligations as expected;
- may not pursue commercialization of companion diagnostics for our therapeutic product candidates that achieve regulatory approval;
- may elect not to continue or renew commercialization programs based on changes in the collaborators strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities;
- may not commit sufficient resources to the marketing and distribution of such product or products; and
- may terminate their relationship with us.

Additionally, we or our collaborators may encounter production difficulties that could constrain the supply of the companion diagnostics, affect the ease of use, affect the price or have difficulties gaining acceptance of the use of the companion diagnostics in the clinical community.

If companion diagnostics for use with our product candidates fail to gain market acceptance, our ability to derive revenues from sales of our product candidates could be harmed. If we or our collaborators fail to commercialize these companion diagnostics, 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 our product candidates or do so on commercially reasonable terms, which could adversely affect and delay the development or commercialization of our product candidates.

Risks Related to Regulatory Approval of Our Product Candidates and Other Legal Compliance Matters

If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals, we will not be able to commercialize our product candidates, and our ability to generate revenue will be materially impaired.

Our product candidates must be approved by FDA pursuant to a new drug application, or NDA, in the United States and by the European Medicines Agency, or EMA, and similar regulatory authorities outside the United States prior to commercialization. The process of obtaining marketing approvals, both in the United States and abroad, is expensive and takes many years, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate. We have not received approval to market any of our product candidates from regulatory authorities in any jurisdiction. We have no experience in filing and supporting the applications necessary to gain marketing approvals and expect to rely on third-party CROs to assist us in this process. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate s safety and efficacy. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. Our product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of a product candidate. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may also cause delays in or prevent the approval of an application.

New cancer drugs frequently are indicated only for patient populations that have not responded to an existing therapy or have relapsed. If any of our product candidates receives marketing approval, the accompanying labeling may limit the approved use of our drug in this way, which could limit sales of the product.

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Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

If we experience delays in obtaining approval or if we fail to obtain approval of our product candidates, the commercial prospects for our product candidates may be harmed and our ability to generate revenues will be materially impaired.

We may seek Orphan Drug Exclusivity for some of our product candidates, and we may be unsuccessful.

Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, FDA may designate a product as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a disease with a patient population of fewer than 200,000 individuals in the United States.

Generally, if a product with an Orphan Drug Designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the EMA or FDA from approving another marketing application for the same drug for the same indication during the period of exclusivity. The applicable period is seven years in the United States and ten years in Europe. The European exclusivity period can be reduced to six years if a drug no longer meets the criteria for Orphan Drug Designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified. Orphan Drug Exclusivity may be lost if FDA or EMA determines that the request for designation was materially defective, if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition.

Even if we obtain Orphan Drug Exclusivity for a product candidate, that exclusivity may not effectively protect the product candidate from competition because different drugs can be approved for the same condition. Even after an orphan drug is approved, FDA can subsequently approve a different drug for the same condition if FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care.

A Fast Track Designation by FDA, even if granted for any of our product candidates, may not lead to a faster development or regulatory review or approval process and does not increase the likelihood that our product candidates will receive marketing approval.

We do not currently have Fast Track Designation for any of our product candidates but intend to seek such designation. If a drug is intended for the treatment of a serious or life-threatening condition and the drug demonstrates the potential to address unmet medical needs for this condition, the drug sponsor may apply for FDA Fast Track Designation. FDA has broad discretion whether or not to grant this designation. Even if we believe a particular product candidate is eligible for this designation, we cannot assure you that FDA would decide to grant it. Even if we do receive Fast Track Designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. FDA may withdraw Fast Track Designation if it believes that the designation is no longer supported by data from our clinical development program. Many drugs that have received Fast Track Designation have failed to obtain drug approval.

A Breakthrough Therapy Designation by FDA, even if granted for any of our product candidates, may not lead to a faster development or regulatory review or approval process, and does not increase the likelihood that our product candidates will receive marketing approval.

We do not currently have Breakthrough Therapy Designation for any of our product candidates but may seek such designation. A Breakthrough Therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drugs that have been designated as Breakthrough Therapies, interaction and communication between FDA and the sponsor can help to identify the most efficient path for development.

Designation as a Breakthrough Therapy is within the discretion of FDA. Accordingly, even if we believe, after completing early clinical trials, that one of our product candidates meets the criteria for designation as a Breakthrough Therapy, FDA may disagree and instead determine not to make such designation. In any event, the receipt of a Breakthrough Therapy designation for a product candidate may not result in a faster development process, review or approval compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate approval by FDA. In addition, even if one or more of our product

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candidates qualify as Breakthrough Therapies, FDA may later decide that such product candidates no longer meet the conditions for qualification.

Failure to obtain marketing approval in international jurisdictions would prevent our product candidates from being marketed abroad.

In order to market and sell our products in the European Union and many other jurisdictions, we or our third-party collaborators must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, it is required that the product be approved for reimbursement before the product can be approved for sale in that country. We or these third parties may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all. Approval by FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by FDA. We may not be able to file for marketing approvals and may not receive necessary approvals to commercialize our products in any market.

Any product candidate for which we obtain marketing approval will be subject to extensive post-marketing regulatory requirements and could be subject to post-marketing restrictions or withdrawal from the market, and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our products, when and if any of them are approved.

Our product candidates and the activities associated with their development and commercialization, including their testing, manufacture, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, current good manufacturing practices, or cGMP, requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, including periodic inspections by FDA and other regulatory authority, requirements regarding the distribution of samples to physicians and recordkeeping.

FDA may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of the product. FDA closely regulates the post-approval marketing and promotion of drugs to ensure drugs are marketed only for the approved indications and in accordance with the provisions of the approved labeling. FDA imposes stringent restrictions on manufacturers communications regarding use of their products and if we promote our products beyond their approved indications, we may be subject to enforcement action for off-label promotion. Violations of the Federal Food, Drug, and Cosmetic Act relating to the promotion of prescription drugs may lead to investigations alleging violations of federal and state healthcare fraud and abuse laws, as well as state consumer protection laws.

In addition, later discovery of previously unknown adverse events or other problems with our products, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may yield various results, including:

- restrictions on such products, manufacturers or manufacturing processes;

- restrictions on the labeling or marketing of a product;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning or untitled letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;

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- fines, restitution or disgorgement of profits or revenues;

- suspension or withdrawal of marketing approvals;

- refusal to permit the import or export of our products;

- product seizure; or

- injunctions or the imposition of civil or criminal penalties.

Non-compliance with European Union requirements regarding safety monitoring or pharmacovigilance, and with requirements related to the development of products for the pediatric population, can also result in significant financial penalties. Similarly, failure to comply with the European Union s requirements regarding the protection of personal information can also lead to significant penalties and sanctions.

Our relationships with customers and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, physicians and third-party payors will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our future arrangements with third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute any products for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations include the following:

- the federal Anti-Kickback Statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid;

- the federal False Claims Act imposes criminal and civil penalties, including civil whistleblower or *qui tam* actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

- federal law requires applicable manufacturers of covered drugs to report payments and other transfers of value to physicians and teaching hospitals, which includes data collection and reporting obligations. The information is to be made publicly available on a searchable website in September 2014; and

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers.

Some state laws require pharmaceutical companies to comply with the pharmaceutical industry s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

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Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion of products from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

Recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and affect the prices we may obtain.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidates for which we obtain marketing approval.

In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or the MMA, changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and introduced a new reimbursement methodology based on average sales prices for physician-administered drugs. In addition, this legislation provided authority for limiting the number of drugs that will be covered in any therapeutic class. Cost reduction initiatives and other provisions of this legislation could decrease the coverage and price that we receive for any approved products. While the MMA only applies to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment

limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from the MMA may result in a similar reduction in payments from private payors.

More recently, in March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively the PPACA, a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms.

Among the provisions of the PPACA of importance to our potential product candidates are the following:

- an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents;

- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;

- expansion of healthcare fraud and abuse laws, including the False Claims Act and the Anti-Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance;

- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices;

- extension of manufacturers Medicaid rebate liability;

- expansion of eligibility criteria for Medicaid programs;

- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;

- new requirements to report financial arrangements with physicians and teaching hospitals;

- a new requirement to annually report drug samples that manufacturers and distributors provide to physicians; and

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

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effectiveness research, along with funding for such research.

In addition, other legislative changes have been proposed and adopted since the PPACA was enacted. These changes included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, starting in 2013. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding.

We expect that the PPACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by the U.S. Congress of FDA s approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

Governments outside the United States tend to impose strict price controls, which may adversely affect our revenues, if any.

In some countries, particularly the countries of 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. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed, possibly materially.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could harm our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

Although we maintain workers compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our discovery, preclinical development or production efforts. Our failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

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Risks Related to Our Dependence on Third Parties

Our existing discovery collaboration with Array is important to our business. If we are unable to maintain this collaboration, or if this collaboration is not successful, our business could be adversely affected.

On July 3, 2013, we entered into a Drug Discovery Collaboration Agreement with Array, which was subsequently amended on November 26, 2013 and April 10, 2014, or the Array Agreement. Pursuant to the Array Agreement, Array agreed to design, conduct and perform research and preclinical testing for certain compounds that we select, including LOXO-101, targeted at TRKA, TRKB and TRKC, and identify IND candidates for TRK and other targets, while undertaking manufacturing activities sufficient to conduct Phase 1 clinical trials for a subset of these programs.

Array granted us exclusive licenses worldwide, for clinical and commercial development of these compounds. Array has an obligation to test targets during our discovery phase, but we cannot be certain that our collaboration will lead to the discovery of any additional product candidates beyond LOXO-101 or that any of these product candidates will be successfully commercialized and developed. We and Array jointly own the intellectual property developed by the combined efforts of both our employees, and we each retain ownership of intellectual property that we develop independently pursuant to the collaboration. Array has granted us an exclusive license under all intellectual property for our product candidates.

Because we currently rely on Array for a substantial portion of our discovery and preclinical capabilities, including reliance on employees of Array whom we fund to conduct preclinical development of our product candidates pursuant to the Array Agreement, if Array delays or fails to perform its obligations under the Array Agreement, disagrees with our interpretation of the terms of the collaboration or our discovery plan or terminates the Array Agreement, our pipeline of product candidates would be adversely affected. In addition, we rely on Array s expertise in drug discovery and preclinical testing, and our results will suffer if the Array employees who conduct work on our behalf lack expertise in this area. In some cases, Array subcontracts and hires consultants to conduct work on our program. If these subcontractors or consultants fail to perform their obligations as agreed, our program could suffer. Array may also fail to properly maintain or defend the intellectual property we have licensed from them, or even infringe upon, our intellectual property rights, leading to the potential invalidation of our intellectual property or subjecting us to litigation or arbitration, any of which would be time-consuming and expensive. Additionally, in the event that Array commits a material breach of the Array Agreement, our only recourse is to terminate the collaboration. If we terminate our collaboration with Array, especially during our discovery phase, the development of our product candidates would be materially delayed or harmed. Furthermore, we are dependent on the success of Array s business. If Array continues to be unprofitable and if it is unsuccessful in retaining employees or obtaining future financing, we would need to identify a new collaboration partner for discovery and preclinical development. If we are unsuccessful or significantly delayed in identifying a new collaboration partner, or unable to reach an agreement with such a partner on commercially reasonable terms, development for our pipeline of products will suffer and our business would be materially harmed.

Furthermore, if Array changes its strategic focus, or if external factors cause it to divert resources from our collaboration, or if it independently develops products that compete directly or indirectly with our product candidates using resources it acquires from our collaboration, our business and results of operations could suffer. For example, while Array has granted us a license for compounds designed to target at least two of the three known TRK kinases. Array has retained ownership and rights to development of compounds targeting only one TRK kinase. If Array develops such compounds in direct competition with our product candidates, our business would be adversely impacted.

Future discovery and preclinical development collaborations may be important to us. If we are unable to maintain these collaborations, or if these collaborations are not successful, our business could be adversely affected.

For some of our product candidates, we may in the future determine to collaborate with pharmaceutical and biotechnology companies for development of products. We face significant competition in seeking appropriate collaborators. Our ability to reach a definitive agreement for any collaboration will depend, among other things, upon our assessment of the collaborator s resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator s evaluation of a number of factors. If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a product candidate, reduce or delay its development program or one or more of our other development

programs, delay its potential development schedule or reduce the scope of research activities, or increase our expenditures and undertake discovery or preclinical development activities at our own expense. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development activities, we may not be able to further develop our product candidates or continue to develop our product candidates and our business may be materially and adversely affected.

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Future collaborations we may enter into may involve the following risks:

- collaborators may have significant discretion in determining the efforts and resources that they will apply to these collaborations;

- collaborators may not perform their obligations as expected;

- changes in the collaborators strategic focus or available funding, or external factors, such as an acquisition, may divert resources or create competing priorities;

- collaborators may delay discovery and preclinical development, provide insufficient funding for product development of targets selected by us, stop or abandon discovery and preclinical development for a product candidate, repeat or conduct new discovery and preclinical development for a product candidate;

- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates if the collaborators believe that competitive products are more likely to be successfully developed than ours;

- product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the development of our product candidates;

- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or termination of the discovery, preclinical development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;

- collaborators may not properly maintain or defend our intellectual property rights or intellectual property rights licensed to us or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;

- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; and

- collaborations may be terminated for the convenience of the collaborator and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates.

Additionally, subject to its contractual obligations to us, if a collaborator of ours is involved in a business combination, the collaborator might deemphasize or terminate the development of any of our product candidates. If one of our collaborators terminates its agreement with us, we may find it more difficult to attract new collaborators and our perception in the business and financial communities could be adversely affected.

If we are unable to maintain our collaborations, development of our product candidates could be delayed and we may need additional resources to develop them. All of the risks relating to product

development, regulatory approval and commercialization described in this prospectus also apply to the activities of our collaborators.

We expect to rely on third-party contractors and organizations to conduct our clinical trials, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials.

We will rely on third-party clinical research contractors and organizations, to conduct our ongoing Phase 1 clinical trial of LOXO-101; and we will rely on third party contractors, clinical data management organizations, independent contractors, medical institutions and clinical investigators to conduct our clinical trials beyond Phase 1. These agreements may terminate for a variety of reasons, including a failure to perform by the third parties. If we needed to enter into alternative arrangements, our product development activities would be delayed.

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We compete with many other companies, some of which may be our competitors, for the resources of these third parties. Large pharmaceutical companies often have significantly more extensive agreements and relationships with such third-party providers, and such third-party providers may prioritize the requirements of such large pharmaceutical companies over ours. The third parties on whom we rely may terminate their engagements with us at any time, which may cause delay in the development and commercialization of our product candidates. If any such third party terminates its engagement with us or fails to perform as agreed, we may be required to enter into alternative arrangements, which would result in significant cost and delay to our product development program. Moreover, our agreements with such third parties generally do not provide assurances regarding employee turnover and availability, which may cause interruptions in the research on our product candidates by such third parties.

Our reliance on these third parties to conduct our clinical trials will reduce our control over these activities but will not relieve us of our responsibilities. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, FDA and other regulatory authorities require us to comply with standards, commonly referred to as good clinical practices, or GCPs, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. We are also required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within specified timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

Additionally, we expect to rely substantially on third-party data managers for our clinical trial data. There is no assurance that these third parties will not make errors in the design, management or retention of our data or data systems. There is no assurance that these third parties will pass FDA or other regulatory audits, which could delay or prevent regulatory approval.

If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates.

We contract with third parties for the manufacture of our product candidates for preclinical and clinical testing and expect to continue to do so for commercialization. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or products at an acceptable cost and quality, which could delay, prevent or impair our development or commercialization efforts.

We do not own or operate facilities for the manufacture of our product candidates, and we do not have any manufacturing personnel. We currently have no plans to build our own clinical or commercial scale manufacturing capabilities. We rely, and expect to continue to rely, on third parties, including Array, for the manufacture of our product candidates for preclinical and clinical testing. We will rely on third parties as well for commercial manufacture if any of our product candidates receive marketing approval. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts.

Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval. We do not currently have arrangements in place for redundant supply or a source for bulk drug substance. Array currently supplies all of our drug product requirements for our Phase 1 dose escalation trial for LOXO-101. If Array cannot supply us with our Phase 1 dose escalation drug product requirements as agreed, we may be required to identify alternative manufacturers, which would lead us to incur added costs and delays in identifying and qualifying any such replacement.

The formulation used in early studies is not a final formulation for commercialization. Additional, changes may be required by FDA or other regulatory authorities on specifications and storage conditions. These may require additional studies, and may delay our clinical trials.

We expect to rely on third-party manufacturers or third-party collaborators for the manufacture of commercial supply of any other product candidates for which our collaborators or we obtain marketing approval.

We also expect to rely on other third parties to store and distribute drug supplies for our clinical trials. Any performance failure on the part of our distributors could delay clinical development or marketing approval of our product candidates or commercialization of our products, producing additional losses and depriving us of potential product revenue.

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We may be unable to establish any agreements with third-party manufacturers or to do so on acceptable terms. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- reliance on the third party for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreement by the third party;
- the possible misappropriation of our proprietary information, including our trade secrets and know-how; and
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us.

Third-party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside the United States. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products.

Our product candidates and any products that we may develop may compete with other product candidates and products for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us.

Our current and anticipated future dependence upon others for the manufacture of our product candidates or products may adversely affect our future profit margins and our ability to commercialize any products that receive marketing approval on a timely and competitive basis.

Risks Related to the Commercialization of Our Product Candidates

Even if any of our product candidates receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.

If any of our product candidates receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. For example, current cancer treatments like chemotherapy and radiation

therapy are well established in the medical community, and doctors may continue to rely on these treatments to the exclusion of our product candidates. In addition, physicians, patients and third-party payors may prefer other novel products to ours. If our product candidates do not achieve an adequate level of acceptance, we may not generate significant product revenues and we may not become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy and safety and potential advantages and disadvantages compared to alternative treatments;
- our ability to offer our products for sale at competitive prices;
- the convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of our marketing and distribution support;
- the availability of third-party coverage and adequate reimbursement, including patient cost-sharing programs such as copays and deductibles;
- our ability to develop or partner with third-party collaborators to develop companion diagnostics;
- the prevalence and severity of any side effects; and
- any restrictions on the use of our products together with other medications.

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

We currently do not have a marketing or sales team for the marketing, sales and distribution of any of our product candidates that are able to obtain regulatory approval. In order to commercialize any product candidates, we must build on a territory-by-territory basis 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 an internal sales or marketing team with technical expertise and supporting distribution capabilities to commercialize our product candidates, which will be expensive and time consuming and will require significant attention of our executive officers to manage. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of any of our products that we obtain approval to market. With respect to the commercialization of all or certain of our product candidates, we may choose to collaborate, either globally or on a territory-by-territory basis, 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 when needed on acceptable terms or at all, we may not be able to successfully commercialize any of our product candidates that receive regulatory approval or any such commercialization may experience delays or limitations. 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.

We face substantial competition, which may result in others discovering, developing or commercializing competing products before or more successfully than we do.

The development and commercialization of new drug products is highly competitive. We face competition with respect to our current product candidates, and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. There are a number of large pharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of products for the treatment of the disease indications for which we are developing our product candidates. Some of these competitive products and therapies are based on scientific approaches that are the same as or similar to our approach, and others are based on entirely different approaches. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

Specifically, there are a large number of companies developing or marketing treatments for cancer, including many major pharmaceutical and biotechnology companies. In addition, many companies are developing cancer therapeutics that work by inhibiting multiple kinases, that may directly compete with our lead product candidate and future product candidates, including Plexxikon s (subsidiary of Daiichi Sankyo) PLX-7486, Tesaro s TSR-011, Ignyta s RXDX-101 and Novartis AG s dovitinib.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market and or slow our regulatory approval. In addition, our ability to compete may be affected in many cases by insurers or other third-party payors seeking to encourage the use of generic products. Generic products are currently on the market for the indications that we are pursuing, and additional products are expected to become available on a generic basis over the coming years. If our product candidates achieve marketing approval, we expect that they will be priced at a significant premium over competitive generic products.

Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

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The insurance coverage and reimbursement status of newly approved products is uncertain. Failure to obtain or maintain adequate coverage and reimbursement for new or current products could limit our ability to market those products and decrease our ability to generate revenue.

The availability and extent of reimbursement by governmental and private payors is essential for most patients to be able to afford expensive treatments. Sales of our product candidates will depend substantially, both domestically and abroad, on the extent to which the costs of our product candidates will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third-party payors. If reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the United States, the principal decisions about reimbursement for new medicines are typically made by the Centers for Medicare & Medicaid Services, or CMS, an agency within the U.S. Department of Health and Human Services, as CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare. Private payors tend to follow CMS to a substantial degree. It is difficult to predict what CMS will decide with respect to reimbursement for fundamentally novel products such as ours, as there is no body of established practices and precedents for these new products. Reimbursement agencies in Europe may be more conservative than CMS. For example, a number of cancer drugs have been approved for reimbursement in the United States and have not been approved for reimbursement in certain European countries. Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe, Canada, and other countries has and will continue to put pressure on the pricing and usage of our product candidates. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. In general, the prices of medicines under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for medicines, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for our products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenues and profits.

Moreover, increasing efforts by governmental and third-party payors, in the United States and abroad, to cap or reduce healthcare costs may cause such organizations to limit both coverage and level of reimbursement for new products approved and, as a result, they may not cover or provide adequate payment for our product candidates. We expect to experience pricing pressures in connection with the sale of any of our product candidates, due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products into the healthcare market.

In addition to CMS and private payors, professional organizations such as the National Comprehensive Cancer Network and the American Society of Clinical Oncology can influence decisions about reimbursement for new medicines by determining standards for care. In addition, many private payors contract with commercial vendors who sell software that provide guidelines that attempt to limit utilization of, and therefore reimbursement for, certain products deemed to provide limited benefit to existing alternatives. Such organizations may set guidelines that limit reimbursement or utilization of our products.

Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop.

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and will face an even greater risk if we commercially sell any products that we may develop. If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or products that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;

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- significant costs to defend the related litigation;
- substantial monetary awards to trial participants or patients;
- loss of revenue;
- reduced resources of our management to pursue our business strategy; and
- the inability to commercialize any products that we may develop.

We currently hold $5 million in product liability insurance coverage in the aggregate, with a per incident limit of $5 million, which may not be adequate to cover all liabilities that we may incur. We may need to increase our insurance coverage as we expand our clinical trials or if we commence commercialization of our product candidates. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain intellectual property protection for our technology and products, or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully commercialize our technology and products may be impaired.

Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to our proprietary technology and products, including any companion diagnostic developed by us or a third-party collaborator. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our novel technologies and product candidates. Our patent portfolio includes patents and patent applications we exclusively licensed from Array as well as exclusive worldwide licenses for all therapeutic indications for new intellectual property developed in our Array collaboration. This patent portfolio includes issued patents and pending patent applications covering compositions of matter and methods of use.

The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. We may choose not to seek patent protection for certain innovations and may choose not to pursue patent protection in certain jurisdictions, and under the laws of certain jurisdictions, patents or other intellectual property rights may be unavailable or limited in scope. It is also possible that we will fail to identify patentable aspects of our discovery and preclinical development output before it is too late to obtain patent protection. Moreover, in some circumstances, we do not have the right to control the preparation,

filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from third parties. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. For example, India and China do not allow patents for methods of treating the human body. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection.

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. The U.S. Patent and Trademark Office, or U.S. PTO, recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, only became

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effective on March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

Moreover, we may be subject to a third-party preissuance submission of prior art to the U.S. PTO, or become involved in opposition, derivation, reexamination, inter partes review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Even if our owned and licensed patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our owned or licensed patents by developing similar or alternative technologies or products in a non-infringing manner.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

The risks described elsewhere pertaining to our patents and other intellectual property rights also apply to the intellectual property rights that we license, and any failure to obtain, maintain and enforce these rights could have a material adverse effect on our business. In some cases we may not have control over the prosecution, maintenance or enforcement of the patents that we license, and our licensors may fail to take the steps that we believe are necessary or desirable in order to obtain, maintain and enforce the licensed patents. Any inability on our part to protect adequately our intellectual property may have a material adverse effect on our business, operating results and financial position.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to be paid to the U.S. PTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and/or applications. We have systems in place to remind us to pay these fees, and we employ an outside firm and rely on our outside counsel to pay these fees due to non-U.S. patent agencies. The U.S. PTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which non-compliance can result in abandonment or lapse of the patent or

patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors might be able to enter the market and this circumstance would have a material adverse effect on our business.

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We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time consuming and unsuccessful.

Because competition in our industry is intense, competitors may infringe or otherwise violate our issued patents, patents of our licensors or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents. In addition, in a patent infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable, in whole or in part, construe the patent s claims narrowly or 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 proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly. We may also elect to enter into license agreements in order to settle patent infringement claims or to resolve disputes prior to litigation, and any such license agreements may require us to pay royalties and other fees that could be significant. 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.

We may need to license certain intellectual property from third parties, and such licenses may not be available or may not be available on commercially reasonable terms.

A third party may hold intellectual property, including patent rights, that are important or necessary to the development of our products. It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our products, in which case we would be required to obtain a license from these third parties on commercially reasonable terms, or our business could be harmed, possibly materially. Although we believe that licenses to these patents are available from these third parties on commercially reasonable terms, if we were not able to obtain a license, or were not able to obtain a license on commercially reasonable terms, our business could be harmed, possibly materially.

Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business.

Our commercial success depends upon our ability, and the ability of our collaborators, to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. There is considerable intellectual property litigation in the biotechnology and pharmaceutical industries. We may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our products and technology, including interference or derivation proceedings before the U.S. PTO. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future.

If we are found to infringe a third party s intellectual property rights, we could be required to obtain a license from such third party to continue developing and marketing our products and technology. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. We could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, we could be found liable for monetary damages, including treble damages and attorneys fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

We may not be successful in obtaining or maintaining necessary rights for our development pipeline through acquisitions and in-licenses.

Presently we have rights to intellectual property to develop our product candidates, including patents and patent applications we exclusively licensed from Array as well as exclusive worldwide licenses for all therapeutic indications for new intellectual property developed in our Array collaboration. Because our programs may involve additional product candidates that may require the use of proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire, in-license or use these proprietary rights. Additionally, a companion diagnostic may require that we or a third-party collaborator developing the diagnostic acquire use or proprietary rights held by third parties. We may be unable to acquire or in-license any compositions, methods of use, or other third-party intellectual property rights from third parties that we identify. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire

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third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities.

For example, we may collaborate with U.S. and foreign academic institutions to accelerate our discovery and preclinical development work under written agreements with these institutions. Typically, these institutions provide us with an option to negotiate a license to any of the institution s rights in technology resulting from the collaboration. Regardless of such right of first negotiation for intellectual property, we may be unable to negotiate a license within the specified time frame or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to other parties, potentially blocking our ability to pursue our program.

In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment. If we are unable to successfully obtain rights to required third-party intellectual property rights, our business, financial condition and prospects for growth could suffer.

We may be subject to claims by third parties asserting that our employees or we have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property.

Many of our employees were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that these employees or we have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee s former employer. Litigation may be necessary to defend against these claims.

In addition, while it is our policy to require our employees and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own. Our and their assignment agreements may not be self-executing or may be breached, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property.

If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to management.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking patents for some of our technology and product candidates, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside

scientific collaborators, contract manufacturers, consultants, advisors and other third parties. We seek to protect our confidential proprietary information, in part, by entering into confidentiality and invention or patent assignment agreements with our employees and consultants, however, we cannot be certain that such agreements have been entered into with all relevant parties. Moreover, to the extent we enter into such agreements, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

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Risks Related to Employee Matters, Managing Growth and Macroeconomic Conditions

We currently have a limited number of employees, are highly dependent on our Chief Executive Officer and our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.

We are an early-stage clinical development company with a limited operating history, and, as of July 30, 2014, had only five employees and four executive officers. We are highly dependent on the research and development, clinical and business development expertise of Joshua H. Bilenker, M.D. our President and Chief Executive Officer, as well as the other principal members of our management, scientific and clinical team. Although we have entered into employment letter agreements with our executive officers, each of them may terminate their employment with us at any time. We do not maintain key person insurance for any of our executives or other employees.

Recruiting and retaining qualified scientific, clinical, manufacturing and sales and marketing personnel or consultants will also be critical to our success. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our discovery and preclinical development and commercialization strategy. The loss of the services of our executive officers or other key employees and consultants could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees or consultants may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize products. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel or consultants on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

We expect to expand our development and regulatory capabilities and potentially implement sales, marketing and distribution capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

We expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of drug development, regulatory affairs and, if any of our product candidates receives marketing approval, sales, marketing and distribution. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

Unfavorable global economic conditions could adversely affect our business, financial condition or results of operations.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. The recent global financial crisis caused extreme volatility and disruptions in the capital and credit markets. A severe or prolonged economic downturn, such as the recent global financial crisis, could result in a variety of risks to our business, including our ability to raise additional capital when needed on acceptable terms, if at all. This is particularly true in Europe, which is undergoing a continued severe economic crisis. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

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, collaborators and third-parties on whom we rely are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Furthermore, we have little or no control over the security measures and computer systems of our third-party collaborators, including Array. While we and, to our knowledge, our third-party collaborators 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, or the operations of Array or our other third-party collaborators, it could result in a material disruption of our drug development

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programs. For example, the loss of research data by Array could delay development of our product candidates and the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and we may incur substantial costs to attempt to recover or reproduce the data. If any disruption or security breach resulted in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and/or the further development of our product candidates could be delayed.

Risks Related to Our Common Stock

Our executive officers, directors and principal stockholders, if they choose to act together, will continue to have the ability to control all matters submitted to stockholders for approval.

Following our initial public offering, our executive officers and directors, combined with our stockholders who individually own more than 5% of our outstanding common stock, in the aggregate, beneficially owned shares representing approximately [66.6]% of our capital stock, or [72.6]%. As a result, if these stockholders were to choose to act together, they would be able to control all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these persons, if they choose to act together, would control the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. This concentration of ownership control may:

- delay, defer or prevent a change in control;
- entrench our management and the board of directors; or
- impede a merger, consolidation, takeover or other business combination involving us that other stockholders may desire.

Provisions in our corporate charter documents and under Delaware law could make an acquisition of our company, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our certificate of incorporation and our may discourage, delay or prevent a merger, acquisition or other change in control of our company that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, 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. Among other things, these provisions:

- establish a classified board of directors such that only one of three classes of directors is elected each year;

- allow the authorized number of our directors to be changed only by resolution of our board of directors;

- limit the manner in which stockholders can remove directors from our board of directors;

- establish advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to our board of directors;

- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent;

- limit who may call stockholder meetings;

- authorize our board of directors to issue preferred stock without stockholder approval, which could be used to institute a poison pill that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors; and

- require the approval of the holders of at least two-thirds of the voting power of all of the then-outstanding shares of capital stock that would be entitled to vote generally in the election of directors to amend or repeal specified provisions of our certificate of incorporation or bylaws.

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Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans or otherwise, could result in dilution to 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 additional common stock, convertible securities or other equity securities, investors in a prior transaction may be materially diluted. Additionally, new investors could gain rights, preferences and privileges senior to those of existing holders of our common stock. Further, any future sales of our common stock by us or resales of our common stock by our existing stockholders could cause the market price of our common stock to decline.

As of the closing of the initial public offering there were 1,013,960 shares of our common stock available for future grant under our 2014 Equity Incentive Plan, or the 2014 Plan. Additionally, as of June 30, 2014, there were outstanding options to purchase up to 1,214,839 shares of our common stock. Any future grants of options, warrants or other securities exercisable or convertible into our common stock, or the exercise or conversion of such shares, and any sales of such shares in the market, could have an adverse effect on the market price of our common stock.

The price of our common stock may be volatile and fluctuate substantially,.

Our stock price is likely to be volatile. The stock market in general and the market for smaller biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, the market price of our common stock may experience material adverse impacts. The market price for our common stock may be influenced by many factors, including:

- the success of competitive products or technologies;
- results of clinical trials of our product candidates or those of our competitors;
- events affecting our collaboration partners, including Array;
- regulatory or legal developments in the United States and other countries;

- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to any of our product candidates or clinical development programs;
- the results of our efforts to discover, develop, acquire or in-license additional product candidates or products;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions; and
- the other factors described in this Risk Factors section.

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We may be subject to securities litigation, which is expensive and could divert management attention.

Our share price may be volatile, and in the past companies that have experienced volatility in the market price of their stock have been subject to an increased incidence of securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management s attention from other business concerns, which could seriously harm our business.

If securities or industry analysts do not publish research or reports about our business, or publish negative reports 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. We do not have any control over these analysts. There can be no assurance that analysts will cover us or provide favorable coverage. If one or more of the analysts who cover us downgrade our stock or change their opinion of our stock, our stock price would likely decline. If one or more of these analysts cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which could cause our stock price or trading volume to decline.

A significant portion of our total outstanding shares are eligible to be sold into the market in the near future, which could cause the market price of our common stock to drop significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. Sales of a substantial number of shares of our common stock in the public market could occur at any time.

We are an emerging growth company, and the reduced disclosure requirements applicable to emerging growth companies may make our common stock less attractive to investors.

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and may remain an emerging growth company for up to five years. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced Management s Discussion and Analysis of Financial Condition and Results of Operations disclosure;

- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;

- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor s report providing additional information about the audit and the financial statements;

- reduced disclosure obligations regarding executive compensation; and

- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We have taken advantage of reduced reporting burdens in this prospectus. In particular, in this prospectus, we have not included all of the executive compensation-related information that would be required if we were not an emerging growth company. We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of these accounting standards until they would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this exemption and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

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We will incur increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives and corporate governance practices.

As a public company, and particularly after we are no longer an emerging growth company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of The NASDAQ Stock Market and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance, which in turn could make it more difficult for us to attract and retain qualified members of our board of directors.

We are evaluating these rules and regulations, and cannot predict or estimate the amount of additional costs we may incur or the timing of such costs. These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, we will first be required to furnish a report by our management on our internal control over financial reporting for the year ending December 31, 2015. However, while we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by Section 404. If we identify one or more material weaknesses, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

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

Under Section 382 of the Internal Revenue Code of 1986, as amended, 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, or NOLs, and other pre-change tax attributes (such as research tax credits) to offset its post-change income or taxes may be limited. It is possible that we may have triggered an ownership change limitation. We may also experience ownership changes in the future as a result of subsequent shifts in our stock ownership (some of which are outside our control). As a result, if we earn net taxable income, our ability to use our pre-change NOL carryforwards to offset U.S. federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed.

Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain.

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, the terms of any future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

There have been no material changes from our risk factors as previously reported in our final prospectus filed on August 1, 2014 with the SEC pursuant to Rule 424(b)(4) of the Securities Act.

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ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

(a) Sales of Unregistered Securities

From April 1, 2014 through August 1, 2014 (the date of the filing of our registration statement on Form S-8) we issued and sold to an employee 22,656 shares of common stock upon the exercise of options under the 2013 Equity Incentive Plan at an exercise price of $7.14 per share, for an aggregate exercise price of approximately $161,764. This issuance was undertaken in reliance upon the exemption from registration requirements of Rule 701 of the Securities Act.

On April 24, 2014 and June 24, 2014, we entered into stock purchase agreements pursuant to which we agreed to sell 2,664,343 and 501,890 shares, respectively, of Series B convertible preferred stock at a purchase price of $8.9661 per share to nine purchasers that represented to us that they were sophisticated accredited investors and qualified institutional buyers. The securities issued in this transaction were exempt from the registration requirements of the Securities Act in reliance on Rule 506 promulgated under the Securities Act.

Concurrent with the close of our initial public offering on August 6, 2014, New Enterprise Associates 14, L.P., or NEA, an existing stockholder, purchased 230,769 shares of our common stock at the initial public offering price in a private placement and we received gross proceeds of $3.0 million. The securities were issued in this transaction in reliance upon the exemption from the registration requirements of the Securities Act, as set forth in Section 4(2) under the Securities Act.

(b) Use of Proceeds from Sales of Registered Securities

On August 6, 2014, we closed our initial public offering, in which we sold 5,261,538 shares of common stock at a price to the public of $13.00 per share. The aggregate offering price for shares sold in the offering was approximately $68.4 million. The offer and sale of all of the shares in the initial public offering were registered under the Securities Act pursuant to a registration statements on Form S-1 (File Nos. 333-197123 and 333-197779), which were declared effective by the SEC on July 31, 2014. The offering commenced on July 31, 2014 and did not terminate before all of the shares that were registered in the registration statements were sold. Cowen and Company, LLC and Stifel, Nicolaus & Company, Incorporated acted as the managing underwriters. On August 29, 2014, the underwriters of the Company s initial public offering gave notification that they would partially exercise the over-allotment option granted to them and on September 4, 2014, 642,000 additional shares of common stock were sold on the Company s behalf at the initial public offering price of $13.00 per share, for aggregate gross proceeds of approximately $7.8 million.

We paid to the underwriters underwriting discounts and commissions of approximately $5.6 million in connection with the offering and private placement with NEA and over-allotment. In addition, we incurred expenses of approximately $1.7 million in connection with the offering. Thus, the net offering proceeds to us for the initial public offering, private placement and exercise of the over-allotment, after deducting underwriting discounts and commissions and offering expenses, were approximately $72.4 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.

There has been no material change in the expected use of the net proceeds from our initial public offering as described in our final prospectus filed with the SEC pursuant to Rule 424(b) on August 1, 2014. Pending the uses described in our final prospectus, we have invested the net proceeds in short-term, interest-bearing obligations, investment-grade instruments, certificates of deposit or direct or guaranteed obligations of the U.S. government.

ITEM 4. MINE SAFETY DISCLOSURES

None.

ITEM 5. OTHER INFORMATION

None.

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ITEM 6. EXHIBITS

The following is a list of exhibits filed as part of this Quarterly Report on Form 10-Q. Where so indicated by footnote, exhibits that were previously filed are incorporated by reference. For exhibits incorporated by reference, the location of the exhibit in the previous filing is indicated.

Exhibit Number	Description
31.1*	Certification of the Principal Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934.
31.2*	Certification of the Principal Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934.
32.1*(1)	Certification of the Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*(1)	Certification of the Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS (2)	XBRL Report Instance Document
101.SCH (2)	XBRL Taxonomy Extension Schema Document
101.CAL (2)	XBRL Taxonomy Calculation Linkbase Document
101.LAB (2)	XBRL Taxonomy Label Linkbase Document
101.PRE (2)	XBRL Presentation Linkbase Document
101.DEF (2)	XBRL Taxonomy Extension Definition Linkbase Document

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* Filed herewith.

To be filed by amendment during the 30-day grace period provided by Rule 405(a)(2) of Regulation S-T.

(1) The certifications on Exhibit 32 hereto are deemed not filed for purposes of Section 18 of the Exchange Act or otherwise subject to the liability of that Section. Such certifications will not be deemed incorporated by reference into any filing under the Securities Act or the Exchange Act.

(2) In accordance with Rule 406T of Regulation S-T, the information in these exhibits is furnished and deemed not filed or part of a registration statement or prospectus for purposes of sections 11 or 12 of the Securities Act, is deemed not filed for purposes of section 18 of the Exchange Act, and otherwise is not subject to liability under these sections.

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) 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: September 12, 2014

LOXO ONCOLOGY, INC.

By: /s/ DOV A. GOLDSTEIN, M.D.
Dov A. Goldstein, M.D.
Chief Financial Officer and Director
(Principal Accounting Officer and Principal Financial Officer and duly Authorized Signatory)

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