Loxo Oncology, Inc.
Form 10-Q
August 05, 2015
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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, 2015

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**

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No o

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 July 31, 2015: 16,687,436

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PART I

ITEM 1. FINANCIAL STATEMENTS

LOXO ONCOLOGY, INC.

Condensed Balance Sheets

(in thousands, except share and per share amounts)

	June 30, 2015 (unaudited)	December 31, 2014 (Note 2)
Assets		
Current assets:		
Cash and cash equivalents	$ 36,635	$ 43,930
Short-term investments	65,165	62,362
Prepaid expenses with related party	972	663
Other prepaid expenses and current assets	410	821
Total current assets	103,182	107,776
Long-term investments		6,648
Property and equipment, net	78	12
Security deposit	23	23
Total assets	$ 103,283	$ 114,459
Liabilities and Stockholders Equity		
Current liabilities:		
Accounts payable	$ 415	$ 239
Accrued expenses and other current liabilities	1,403	1,548
Total liabilities	1,818	1,787
Commitments and contingencies		
Stockholders equity:		
Common stock, $0.0001 par value; 125,000,000 shares authorized; 16,687,436 shares issued and outstanding at June 30, 2015; 16,644,219 shares issued and 16,634,063 shares outstanding at December 31, 2014	2	2
Additional paid-in capital	146,660	143,660
Accumulated deficit	(45,200)	(30,962)
Accumulated other comprehensive income (loss)	3	(28)
Total stockholders equity	101,465	112,672
Total liabilities and stockholders equity	$ 103,283	$ 114,459

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)

	Three Months Ended June 30, 2015	Three Months Ended June 30, 2014	Six Months Ended June 30, 2015	Six Months Ended June 30, 2014
Operating expenses:				
Research and development with related party	$ 2,919	$ 1,717	$ 4,837	$ 2,992
Research and development	2,793	1,020	4,708	1,789
General and administrative	2,387	1,168	4,779	2,026
Total operating expenses and loss from operations	(8,099)	(3,905)	(14,324)	(6,807)
Interest income, net	43		86	
Net loss	(8,056)	(3,905)	(14,238)	(6,807)
Accretion of redeemable convertible preferred stock		(17)		(28)
Net loss attributable to common stockholders	$ (8,056)	$ (3,922)	$ (14,238)	$ (6,835)
Share information:				
Net loss per share of common stock, basic and diluted	$ (0.49)	$ (14.46)	$ (0.86)	$ (28.69)
Weighted average shares outstanding, basic and diluted	16,540,764	271,317	16,507,700	238,246

See accompanying notes to unaudited condensed financial statements.

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LOXO ONCOLOGY, INC.

Condensed Statements of Comprehensive Loss

(unaudited)

(in thousands)

	Three Months Ended June 30, 2015	Three Months Ended June 30, 2014	Six Months Ended June 30, 2015	Six Months Ended June 30, 2014
Net loss	$ (8,056)	$ (3,905)	$ (14,238)	$ (6,807)
Other comprehensive income:				
Unrealized gain on available for sale securities	10		31	
Comprehensive loss	$ (8,046)	$ (3,905)	$ (14,207)	$ (6,807)

See accompanying notes to unaudited condensed financial statements.

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LOXO ONCOLOGY, INC.

Condensed Statement of Stockholders Equity

(unaudited)

For the period from January 1, 2015 to June 30, 2015

(in thousands, except share and per share amounts)

	Stockholders equity					
	Common stock				Accumulated Other	
	Shares	$0.0001 Par Value	Additional Paid-in Capital	Accumulated Deficit	Comprehensive Income (Loss)	Total Stockholders Equity
Balance at January 1, 2015	16,634,063	$ 2	$ 143,660	$ (30,962)	$ (28)	$ 112,672
Stock-based compensation expense			2,684			2,684
Stock option exercises	43,217		279			279
Reclassification of shares issued and previously subject to repurchase	10,156		37			37
Other comprehensive income					31	31
Net loss				(14,238)		(14,238)
Balance at June 30, 2015	16,687,436	$ 2	$ 146,660	$ (45,200)	$ 3	$ 101,465

See accompanying notes to unaudited condensed financial statements.

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LOXO ONCOLOGY, INC.

Condensed Statements of Cash Flows

(unaudited)

(in thousands)

	Six Months Ended June 30, 2015	Six Months Ended June 30, 2014
Operating activities:		
Net loss	$ (14,238)	$ (6,807)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization of premium and discounts on investments, net	157	
Stock-based compensation	2,684	537
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	102	(646)
Accounts payable	176	355
Accrued expenses and other current liabilities	(108)	118
Net cash used in operating activities	(11,227)	(6,443)
Investing activities:		
Purchases of available-for-sale securities	(36,676)	
Proceeds from maturing available-for-sale securities	40,400	
Purchase of property, plant and equipment	(71)	(7)
Net cash provided by (used in) investing activities	3,653	(7)
Financing activities:		
Proceeds from issuance of redeemable convertible preferred stock, net		43,223
Proceeds from the exercise of stock options	279	159
Payment of deferred financing fees		(622)
Net cash provided by financing activities	279	42,760
Net (decrease) increase in cash and cash equivalents	(7,295)	36,310
Cash and cash equivalents beginning of period	43,930	14,994
Cash and cash equivalents end of period	$ 36,635	$ 51,304
Supplemental schedule of noncash investing activities:		
Unrealized gain on available for sale securities	$ 31	$
Supplemental schedule of noncash financing activities:		
Accretion of redeemable convertible preferred stock	$	$ 350
Reclassification of share repurchase obligation	$ 37	$

See accompanying notes to unaudited condensed financial statements.

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LOXO ONCOLOGY, INC.

Notes to Unaudited Condensed Financial Statements

June 30, 2015

1. Organization and Description of the Business

Loxo Oncology, Inc. (the Company) was incorporated on May 9, 2013 in the State of Delaware. The Company is committed to the discovery, development, and commercialization of targeted cancer therapies with best-in-class potential. Loxo Oncology, Inc. s diverse pipeline reflects the convergence of proven therapeutic technologies with emerging insights into the underlying susceptibilities of cancer and drug resistance. The Company operates in one segment and has its principal office in Stamford, Connecticut.

Liquidity

At June 30, 2015, the Company had working capital of $101.4 million and an accumulated deficit of $45.2 million. The Company had cash, cash equivalents and investments of $101.8 million at June 30, 2015. 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 capital.

The Company believes that its existing cash, cash equivalents, and investments, will be sufficient to enable the Company to continue as a going-concern for a reasonable period of time beyond June 30, 2016. 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, 2014, was derived from the Company s audited financial statements included in Form 10-K filed on March 27, 2015. It is suggested that the interim unaudited condensed financial statements be read in conjunction with the annual financial statements and the notes thereto included in the Company s Annual Report on Form 10-K.

The accompanying balance sheet as of June 30, 2015, the statements of operations for the three and six months ended June 30, 2015 and 2014, the statements of comprehensive loss for the three and six months ended June 30, 2015 and 2014, the statement of stockholders equity for the six months ended June 30, 2015 and the statements of cash flows for the six months ended June 30, 2015 and 2014 are unaudited.

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The interim unaudited condensed 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, 2015 and the results of its operations for the three and six months ended June 30, 2015 and 2014 as well as its cash flows for the six months ended June 30, 2015 and 2014.

The interim unaudited condensed financial statements have been prepared pursuant to the rules and regulations of the Securities and Exchange Commission. Certain information and note disclosures normally included in annual financial statements prepared in accordance with GAAP have been condensed or omitted pursuant to those rules and regulations, although the Company believes that the disclosures made are adequate to make the information not misleading.

Significant Accounting Policies

The Company s significant accounting policies are disclosed in the audited financial statements for the year ended December 31, 2014 included in the Company s Form 10-K filed on March 27, 2015 with the United States Securities and Exchange Commission on the SEC. Since the date of such financial statements, there have been no changes to the Company s significant accounting policies.

Reclassifications

Certain reclassifications were made to prior period amounts to correct the previous presentation. During the three and six months ended June 30, 2014, $165,000 and $223,000, respectively, of certain expenses that had been previously classified as general and administrative were reclassified into research and development.

3. Net Loss Per Common Share

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

	Three Months Ended June 30, 2015	Three Months Ended June 30, 2014	Six Months Ended June 30, 2015	Six Months Ended June 30, 2014
Basic and diluted net loss per common share calculation:				
Net loss	$ (8,056)	$ (3,905)	$ (14,238)	$ (6,807)
Accretion of redeemable convertible preferred stock		(17)		(28)
Net loss attributable to common stockholders	$ (8,056)	$ (3,922)	$ (14,238)	$ (6,835)
	16,540,764	271,317	16,507,700	238,246

Weighted average common shares outstanding basic and diluted								
Net loss per share of common stock basic and diluted	$	(0.49)	$	(14.46)	$	(0.86)	$	(28.69)

The following outstanding securities at June 30, 2015 and 2014 have been excluded from the computation of diluted weighted average shares outstanding, as they would have been anti-dilutive:

	2015	2014
Redeemable convertible preferred stock		8,823,187
Unvested restricted stock	137,598	264,190
Stock options	1,977,773	1,231,706
	2,115,371	10,319,083

4. Fair Value Investments

Financial Instruments

The financial instruments recorded in the Company s balance sheets include cash and cash equivalents, investments, and accounts payable.

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Included in cash and cash equivalents are money market funds representing a type of mutual fund required by law to invest in low-risk securities (for example, U.S. government bonds, U.S. Treasury Bills and commercial paper) and overnight repurchase agreements. Money market funds are structured to maintain the fund s net asset value at $1.00 per unit, which assists in providing adequate liquidity upon demand by the holder. Money market funds pay dividends that generally reflect short-term interest rates. Thus, only the dividend yield fluctuates. Also included in cash and cash equivalents are U.S. government sponsored enterprise debt securities that have a maturity of 3 months or less from their original acquisition date. Due to their short-term maturity, the carrying amounts of cash and cash equivalents (including money market funds), and accounts payable approximate their fair values. The Company classifies its remaining investments as available-for-sale. Gains or losses on securities sold are based on the specific identification method.

For investments classified as available-for-sale, the Company records unrealized gains or losses resulting from changes in fair value between measurement dates as a component of other comprehensive income (loss).

(amounts in thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized (Losses)	Fair Value
June 30, 2015				
Overnight repurchase agreements	$ 18,500	$	$	$ 18,500
Money market funds	11,268			11,268
Total included in cash and cash equivalents	29,768			29,768
Government enterprise debt securities				
Short-term available-for-sale securities	64,162	3		64,165
Total	64,162	3		64,165
US Government debt securities				
Short-term available-for-sale securities	1,000			1,000
Total	1,000			1,000
Total fair value financial instruments	$ 94,930	$ 3	$	$ 94,933
December 31, 2014				
Government enterprise debt securities	$ 17,009	$	$	$ 17,009
Money market funds	8,846			8,846
Total included in cash and cash equivalents	25,855			25,855
Government enterprise debt securities				
Short-term available-for-sale securities	62,387		(25)	62,362
Long-term available-for-sale securities	6,651		(3)	6,648
Total	69,038		(28)	69,010
Total fair value financial instruments	$ 94,893	$	$ (28)	$ 94,865

Fair value guidance establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value. These tiers include:

- Level 1 Quoted prices in active markets for identical assets or liabilities.

- Level 2 Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

- Level 3 Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

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The Company s financial assets measured at fair value on a recurring basis at June 30, 2015 were as follows (in thousands):

	Fair Value Measurements at Measurement Date:			
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total As Of June 30, 2015
Assets:				
Government enterprise debt securities	$	$ 64,165	$	$ 64,165
Overnight repurchase agreements	18,500			18,500
Money market funds	11,268			11,268
US Government debt securities	1,000			1,000
Totals	$ 30,768	$ 64,165	$	$ 94,933

The Company s financial assets measured at fair value on a recurring basis at December 31, 2014 were as follows (in thousands):

	Fair Value Measurements at Measurement Date:			
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total As Of December 31, 2014
Assets:				
Government enterprise debt securities	$	$ 86,019	$	$ 86,019
Money market funds	8,846			8,846
Totals	$ 8,846	$ 86,019	$	$ 94,865

There were no items that were accounted for at fair value on a non-recurring basis for the six months ended June 30, 2015 and 2014.

Financial instruments that potentially subject the Company to a concentration of credit risk consist of cash and cash equivalents and investments. At June 30, 2015 and December 31, 2014, the Company s cash and cash equivalents were held by two financial institutions and the amounts on deposit were in excess of FDIC insurance limits. The Company mitigates this risk by depositing its uninsured cash in major well capitalized financial institutions, and by investing excess operating cash in overnight repurchase agreements which are 100% collateralized by U.S. Government backed securities with the Company s bank. The Company has not recognized any losses on its cash and cash equivalents.

5. Accrued Expenses

Accrued expenses and other current liabilities consisted of the following (in thousands):

	June 30, 2015	December 31, 2014
Research and development expenses	$ 912	$ 742
General and administrative expenses	491	769
Share repurchase obligation		37
	$ 1,403	$ 1,548

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6. Stock-Based Compensation

Effective July 2013, the Company adopted the 2013 Equity Incentive Plan, which was amended in November 2013 (the 2013 Plan). The 2013 Plan provided for the granting of incentive stock options, non-statutory stock options and the issuance of restricted stock awards. As of June 30, 2015, the Company reserved 1,544,615 shares of common stock authorized for issuance in connection with the 2013 Plan. 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. 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 Equity Incentive Plan.

The Company adopted the 2014 Equity Incentive Plan (the 2014 Plan) that became effective on July 30, 2014 and serves as the successor to the 2013 Plan. The 2014 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 other than 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 the Company s common stock on the date of grant.

The Company has reserved 1,591,106 shares of its common stock to be issued under the 2014 Plan of which 989,743 shares were available for future issuance as of June 30, 2015. Shares authorized 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 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.

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.

The following table summarizes stock option activity under the 2014 Plan for the period from January 1, 2015 through June 30, 2015:

	Number of Shares	Weighted-Average Exercise Price	Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at January 1, 2015	2,011,005	$ 6.75	9.5	$ 11,375
Granted	99,725	11.87		
Exercised	(53,373)	5.92		
Cancelled				
Forfeited	(79,584)	7.50		
Outstanding at June 30, 2015	1,977,773	$ 7.00	9.0	$ 21,813
Vested and expected to vest at June 30, 2015	1,906,654	$ 6.94	9.0	$ 21,137
Exercisable at June 30, 2015	689,660	$ 3.66	8.7	$ 9,910
Weighted-average grant date fair value of options granted during the six months ended June 30, 2015	$ 7.98			

As of June 30, 2015, there was $12.4 million of total unrecognized compensation expense related to options granted but not yet vested of which $3.4 million is attributable to non-employee awards and subject to re-measurement until vested. The total unrecognized compensation expense of $12.4 million will be recognized as expense over a weighted-average period of 3.0 years.

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

	Six Months Ended June 30, 2015
Risk-free interest rate	1.62%
Expected dividend yield	0.0%
Expected stock price volatility	76.80%
Expected term of options (in years)	6.04
Expected forfeiture rate	6.59%

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 Staff Accounting Bulletin 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 6.59%, based on historical forfeiture experience of its various employee groups.

- Estimated fair value of the Company s stock-based awards: The estimated fair value of the Company s stock-based awards is amortized on a straight-line basis over the awards service period for those awards with graded vesting and which contain only a service condition. For awards with graded vesting and a performance and service

condition, when achievement of the performance condition is deemed probable, the Company recognizes compensation cost using the accelerated recognition method over the awards service period.

Share-based compensation expense recognized was as follows (in thousands):

	Three Months Ended June 30, 2015	Three Months Ended June 30, 2014	Six Months Ended June 30, 2015	Six Months Ended June 30, 2014
Research and development	$ 882	$ 281	$ 1,344	$ 325
General and administrative	753	192	1,340	212
	$ 1,635	$ 473	$ 2,684	$ 537

The stock-based compensation expense for restricted stock is determined based on the estimated fair value of the Company s common stock on the grant date of the awards applied to the total number of awards that are anticipated to vest. During 2013, the Company granted 264,189 restricted stock awards and as of December 31, 2014 there were 170,622 shares expected to vest over the next 3 years. During the six months ended June 30, 2015, 33,024 restricted shares vested and the remaining 137,598 shares are expected to vest over the next 2.5 years. Stock-based compensation for restricted stock was de minimis at their original grant date.

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7. Commitments and Contingencies

Array Collaboration Agreement

On July 3, 2013, the Company signed a multi-year strategic collaboration agreement with Array BioPharma, Inc. (Array), and this agreement was subsequently amended on November 26, 2013, April 10, 2014, October 13, 2014 and March 31, 2015. The March 31, 2015 amendment was to provide additional full-time equivalents and other support dedicated to the conduct of the discovery, preclinical and clinical development programs for the remainder of 2015.

Under the terms of the collaboration agreement, the Company obtained certain rights to Array s tropomyosin receptor kinase (TRK) inhibitor program, as well as additional novel oncology targets, including rearranged during transfection (RET), fibroblast growth factor receptor (FGFR) and FMS-like tyrosine kinase 3 (FLT3). 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. In addition to LOXO-101, the parties designated 12 discovery targets, of which seven were selected for additional study in January 2015, which will be reduced to four on or before January 2016. The Company has the option to increase the total candidate selection number to five for a modest additional payment.

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. See Note 8 for amounts the Company recorded in related-party research and development expenses.

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. With respect to the royalty on products directed to targets other than TRK, the Company has the right to credit certain milestone payments against royalties on sales of products directed to such target.

Research and Development Arrangements

In the course of normal business operations, the Company enters into agreements with clinical research organizations, or CROs, to assist in the performance of research and development and preclinical activities. Expenditures to CROs may represent a significant portion of development costs for the Company in future periods. The Company can elect to discontinue the work under these agreements at any time. The Company 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.

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 or cash flows.

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8. Related Party Transactions

The Company recorded related-party research and development expenses of $4.8 million and $3.0 million for the six months ended June 30, 2015 and 2014, respectively, for services provided by Array under a collaboration agreement. The Company recorded related-party research and development expenses of $2.9 million and $1.7 million for the three months ended June 30, 2015 and 2014, respectively, for services provided by Array under a collaboration agreement. As of June 30, 2015, the Company had $1.0 million in prepaid expenses to Array under the collaboration agreement for services that will be provided in subsequent periods and $48,000 in accrued expenses already incurred.

Dr. Lori Kunkel, a board member, has a consulting agreement with the Company to assist in the Company s drug development process. Dr. Kunkel is eligible to receive a maximum of $15,000 monthly for her consulting work. Payments are expensed as incurred and recorded as a component of research and development expenses. During the three and six months ended June 30, 2015, the Company recognized expenses of $ 45,000 and $90,000, respectively, in accordance with the terms of the consulting agreement. As of June 30, 2015, there was $15,000 included in accrued expenses to Dr. Kunkel.

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

The interim unaudited condensed financial statements and this Management s Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with the financial statements and notes thereto for the year ended December 31, 2014 and the related Management s Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our Annual Report on Form 10-K filed with the SEC on March 27, 2015. 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, predict, project, potential, continue and ongoing, or the negative of these 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, Inc. is committed to the discovery, development, and commercialization of targeted cancer therapies with best-in-class potential. Our diverse pipeline reflects the convergence of proven therapeutic technologies with emerging insights into the underlying susceptibilities of cancer and drug resistance. We leverage the expertise of our partners in academia and industry and our management team s deep clinical-regulatory experience to deploy focused clinical development strategies in well-defined patient populations. Our goal is to create important new cancer therapies as efficiently as possible to substantially benefit patients.

LOXO-101

Pre-clinical research indicates that 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 certain cancers. We are evaluating LOXO-101 in a Phase 1 dose escalation trial for patients with advanced solid tumors, and we reported interim data at the American Association of Cancer Research (AACR) Annual Meeting in Philadelphia in April 2015. We are also building a pipeline of additional targeted cancer therapies with best-in-class potential.

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. We began enrolling patients in our Phase 1 trial in May of 2014. Initial safety and pharmacokinetic data were presented at the American Association for Cancer Research (AACR) Annual Meeting in April 2015. As of the data cut-off for the AACR poster, March 26, 2015, 15 patients had been enrolled across three dose cohorts, including one soft tissue sarcoma patient with an NTRK1 fusion. Pharmacokinetic data were consistent with good systemic exposure of LOXO-101 after oral dosing, with actual exposures exceeding those predicted by nonclinical studies.

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A research brief published in July 2015 in Cancer Discovery provided early clinical validation of LOXO-101 against TRK fusion cancer. As discussed in the publication, with four months of treatment, CT scans demonstrated almost complete tumor disappearance of the largest tumors and the patient did not have any adverse events that were attributed to LOXO-101.

We plan to initiate a Phase 2 trial in the second half of 2015, earlier than previously anticipated. The trial will be a multicenter, international Phase 2 open label study in adult cancer patients whose tumors harbor TRK fusions. We believe that a wide variety of tumor types harbor TRK fusions, and plans to work creatively with clinical partners to identify patients with these genetic alterations.

Pre-clinical Programs

We are working on several pipeline programs in conjunction with our collaboration with Array BioPharma. We have identified RET and FGFR as our next likely IND candidates. Activating fusions and mutations in RET have been identified across a range of cancer histologies. We are designing a highly specific RET inhibitor that optimizes on-target potency for RET fusions, activating mutations, and anticipated resistance mutations.

Activating fusions and mutations in FGFR3 and FGFR2 have also been identified across a range of cancer histologies. However, most small molecule FGFR inhibitors are functionally equipotent against isoforms FGFR1, FGFR2 and FGFR3, and are associated with metabolic and systemic toxicities that limit dose, duration of therapy and target engagement. We are designing an FGFR1-sparing inhibitor that has the potential to avoid many of the side effects that have been endemic to the FGFR class. We have submitted preclinical data abstracts for presentation at the AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics meeting in November 2015 in Boston, MA, and will provide IND guidance for one of these programs by the end of 2015.

Since inception, we have incurred significant operating losses. Our net loss for the six months ended June 30, 2015 was $14.2 million, including approximately $9.5 million of total research and development expenses, and approximately $4.8 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.

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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, 2015 was approximately $45.2 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, 2015 will be sufficient to enable us to continue as a going concern for a reasonable period of time beyond June 30, 2016.

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 Array, a related party, relate to discovery, preclinical and manufacturing activities as defined within our collaboration agreement with 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.

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It is difficult to determine with certainty the duration and completion costs of our current or future preclinical and clinical studies 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 costs relating to the development of our product candidates will depend on a variety of factors, including the uncertainties of future clinical and preclinical study requirements, uncertainties in clinical trial enrollment rate 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.

Interest Income (Expense), net

Interest income and expense consist principally of the interest earned from our short-term and long-term investments offset by the amortization of discounts recorded in connection with the purchase of certain investments.

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 10-K filed on March 27, 2015 with the SEC.

Results of Operations

Comparison of the Three Months Ended June 30, 2015 and 2014 (in thousands)

	Three Months Ended June 30, 2015 (unaudited)	Three Months Ended June 30, 2014 (unaudited)	Change
Operating expenses:			
Research and development with related party	$ 2,919	$ 1,717	$ 1,202
Research and development	2,793	1,020	1,773
General and administrative	2,387	1,168	1,219
Total operating expenses and loss from operations	$ (8,099)	$ (3,905)	$ (4,194)

Research and development expense with related party

Research and development expenses with related party were $2.9 million for the three months ended June 30, 2015, compared to $1.7 million for the three months ended June 30, 2014. This increase was primarily related to additional full-time equivalents and other support dedicated to discovery, preclinical, and manufacturing activities at Array.

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Research and development expense

Research and development expenses were $2.8 million for the three months ended June 30, 2015, compared to $1.0 million for the three months ended June 30, 2014. The increase was primarily due to timing in which our clinical development efforts expanded during 2014 and into 2015 including site and patient enrollment in our Phase 1a clinical trial for LOXO-101. We also increased our internal headcount during 2014 and into 2015. As a result, we had increases in our clinical and preclinical costs, employment costs and stock-based compensation expense of $0.6 million, $0.6 million, and $0.6 million, respectively.

General and administrative expense

General and administrative expenses were $2.4 million for the three months ended June 30, 2015, compared to $1.2 million for the three months ended June 30, 2014. The increase was primarily due to increased costs associated with operating as a public company, including increases in our employment costs, stock-based compensation expense and other operating expense of $0.3 million, $0.6 million and $0.3 million, respectively.

Comparison of the Six Months Ended June 30, 2015 and 2014 (in thousands)

	Six Months Ended June 30, 2015 (unaudited)	Six Months Ended June 30, 2014 (unaudited)	Change
Operating expenses:			
Research and development with related party	$ 4,837	$ 2,992	$ 1,845
Research and development	4,708	1,789	2,919
General and administrative	4,779	2,026	2,753
Total operating expenses and loss from operations	$ (14,324)	$ (6,807)	$ (7,517)

Research and development expense with related party

Research and development expenses with related party were $4.8 million for the six months ended June 30, 2015, compared to $3.0 million for the six months ended June 30, 2014. This increase was primarily related to additional full-time equivalents and other support dedicated to discovery, preclinical, and manufacturing activities at Array.

Research and development expense

Research and development expenses were $4.7 million for the six months ended June 30, 2015, compared to $1.8 million for the six months ended June 30, 2014. The increase was primarily due to timing in which our clinical development efforts expanded during 2014 and into 2015 including site and patient enrollment in our Phase 1a clinical trial for LOXO-101. We also increased our internal headcount during 2014 and into 2015. As a result we had increases in our clinical and preclinical costs, employment costs and stock-based compensation expense of $0.7 million, $1.2 million, and $1.0 million, respectively.

General and administrative expense

General and administrative expenses were $4.8 million for the six months ended June 30, 2015, compared to $2.0 million for the six months ended June 30, 2014. The increase was primarily due to increased costs associated with operating as a public company including increases in our employment costs, stock-based compensation expense and other operating costs of $0.6 million, $1.1 million and $1.1 million, respectively.

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Liquidity and Capital Resources

Since our inception, we have incurred net losses and negative cash flows from our operations. We incurred a net loss of $14.2 million for the six months ended June 30, 2015. Net cash used in operating activities was $11.2 million during the six months ended June 30, 2015. At June 30, 2015, we had an accumulated deficit of $45.2 million, and working capital of $101.4 million. We had cash, cash equivalents and investments of $101.8 million at June 30, 2015. Historically, we have financed our operations principally through private placements of preferred stock and our initial public offering of common stock.

Cash Flows

The following table summarizes our cash flows for the six months ended June 30, 2015 and 2014 (in thousands):

	Six Months Ended June 30, 2015 (unaudited)	Six Months Ended June 30, 2014 (unaudited)
Net cash (used in) provided by:		
Operating activities	$ (11,227)	$ (6,443)
Investing activities	3,653	(7)
Financing activities	279	42,760
Net increase (decrease) in cash and cash equivalents	$ (7,295)	$ 36,310

Net cash used in operating activities

Net cash used in operating activities was $11.2 million for the six months ended June 30, 2015 and consisted primarily of a net loss of $14.2 million and a $0.2 million increase in our net operating assets. The increase in our net operating assets was primarily due to the timing of payments related to our clinical and preclinical activities. These decreases were offset by noncash expenses of $2.8 million, primarily attributable to stock-based-compensation expense.

Net cash used in operating activities was $6.4 million during the six months ended June 30, 2014 and consisted primarily of a net loss of $6.8 million and a $0.2 million decrease in net operating assets. These decreases were offset by noncash expenses of $0.5 million and attributable to stock-based-compensation expense.

Net cash provided by (used in) investing activities

Net cash provided by investing activities for the six months ended June 30, 2015 totaled $3.7 million and consisted primarily of $36.7 million of available-for-sale security purchases offset by $40.4 million proceeds from maturing available-for-sale securities.

Net cash used in investing activities for the six months ended June 30, 2014 totaled $7,000.

Net cash provided by financing activities

Net cash provided by financing activities was $0.3 million for the six months ended June 30, 2015, which was primarily due to the proceeds from the exercise of stock options.

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 and option exercises that was offset by $0.6 million in financing fees related to 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 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 were 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 into 2017 including the development of LOXO-101 through our planned Phase 1 expansion trial, as well as discovery and development activities through Investigational New Drug (IND) application 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 capital 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;
- the number and development requirements of any other product candidates that we pursue;
- our ability to enter into collaborative agreements for the development and commercialization of our product candidates;
- 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;

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- 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.

Please see Risk Factors for additional risks associated with our substantial capital requirements.

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

On July 3, 2013, we signed a multi-year strategic collaboration agreement with Array, and this agreement was subsequently amended on November 26, 2013, April 10, 2014, October 13, 2014 and March 31, 2015. Under the terms of the collaboration agreement, we obtained certain rights to Array s TRK inhibitor program, as well as additional novel oncology targets, including RET, FGFR, and FLT3. We have 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 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. In addition to LOXO-101, the parties designated 12 discovery targets, of which seven were selected for additional study in January 2015, which will be reduced to four on or before January 2016. We have the option to increase the total candidate selection number to five for a modest additional payment.

As part of the 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 of $4.8 million and $3.0 million for the six months ended June 30, 2015 and 2014, respectively for services provided by Array under a collaboration agreement.

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.

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Royalties

We are required to pay Array mid-single digit royalties on worldwide net sales of products. With respect to the royalty on products directed to targets other than TRK, we have the right to credit certain milestone payments against royalties on sales of products directed to such target.

Off-Balance Sheet Arrangements

Through June 30, 2015, 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 principal financial officer, evaluated the effectiveness of our disclosure controls and procedures as of June 30, 2015, the end of the period covered by this Quarterly Report on Form 10-Q.

Based on our evaluation, we concluded that our disclosure controls and procedures as of June 30, 2015 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 principal financial officer, as appropriate, to allow timely decisions regarding required disclosure. We believe that a control 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. We will perform an evaluation of our internal control over financial reporting as of December 31, 2015.

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, 2015 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 Capital Needs

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 net loss was $20.7 million and $14.2 million for the year ended December 31, 2014 and the six months ended June 30, 2015, respectively. As of June 30, 2015, we had an accumulated deficit of $45.2 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;

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

- maintain and leverage our collaboration with Array;

- continue and initiate clinical trials for our product candidates;

- 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.

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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 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 into 2017, 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;

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- 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 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 well defined patient populations, which is a rapidly evolving area of science, and the approach we are taking to discover and develop drugs is relatively new and may never lead to marketable products.

The discovery and development of targeted therapeutics for well defined patient populations 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 as appropriate. 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 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 significant financial resources in identifying potential drug candidates and funding our collaboration agreement with Array to conduct preclinical studies.

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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 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:

- 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 onto our clinical trials for LOXO-101 given that we do not know how many patients harbor 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 often 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, the adoption of genetic testing across large populations of patients with cancer will be required for us to identify patients appropriate for our trials that are restricted to genetically defined populations. The sensitivity of these genetic tests may vary with respect to their ability to detect the target of interest.

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 and/or that 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.

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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.

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 difficult to accurately 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. There can be no assurance that the 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 the 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;

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- 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;

- 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.

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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 may 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 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 in future 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 often 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 programs can be 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 the FDA and comparable foreign regulatory authorities as medical devices and require separate clearance or approval prior to their commercialization. To date, the 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 the 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 little 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, among other requirements. 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.

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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.

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, the 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 the 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 the 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, the FDA can subsequently approve a different drug for the same condition if the 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 the 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 may seek such designation if we believe such a designation may be warranted. 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 the FDA Fast Track Designation. The 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 the 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. The 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.

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A Breakthrough Therapy Designation by the 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 if we believe such a designation may be warranted. 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 the FDA and the sponsor can help to identify the most efficient path for development.

Designation as a Breakthrough Therapy is within the discretion of the 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, the 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 the FDA. In addition, even if one or more of our product candidates qualify as Breakthrough Therapies, the 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 and different criteria for approval. 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 the 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 the FDA. In addition, failure to obtain approval in some countries or jurisdictions may prevent marketing authorizations from being considered in some other countries or jurisdictions. 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 the 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 the FDA and other regulatory authority, requirements regarding the distribution of samples to physicians and recordkeeping.

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The FDA may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of the product. The 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. The 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;
- 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.

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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.

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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.

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;

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- 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 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 the 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 the 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.

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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.

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, April 10, 2014, October 13, 2014, and March 31, 2015 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. We were notified by Array regarding their efforts and use of third parties for the development and/or commercialization of compounds that selectively modulate TRKA for oncology indications. We have not elected to be a third party partner for such efforts, as permitted under our collaboration agreement with Array. If Array or its partners develop such compounds in direct competition with our product candidates, our business would be adversely impacted.

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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.

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.

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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, and for our clinical trials for other development molecules. 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 could be delayed.

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, the 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.

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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.

The formulation used in early studies is not a final formulation for commercialization. Additional, changes may be required by the 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.

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.

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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.

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.

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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. For LOXO-101, examples of such potential competitors include, Daiichi Sankyo and its subsidiary Plexxikon (PLX-7486), Tesaro (TSR-011), Ignyta (RXDX-101), Novartis AG (dovitinib), and Mirati (MGDC516). For RET, competitors may include Eisai (lenvatinib), Exelixis (cabozantinib), AstraZeneca (vandetanib), Ariad (ponatinib), Novartis (dovitinib), Roche (alectinib), Blueprint Medicines (no name yet), Pfizer (sunitinib). For FGFR, competitors may include J&J (JNJ-42756493), Novartis (BGJ-398, dovitinib), AstraZeneca (AZD4547), Clovis Oncology (lucitinib), Chugai (CH5183284), Bayer (BAY 1163877, BAY 1179470), Lilly (LY2874455), Eisai (E7090), Taiho (TAS-120), BI (Nintedanib), Ariad (ponatinib), FivePrime (FP-1039, FPA144), Incyte (INCB54828), ArQule (ARQ087), BioClinica (MFGR1877S), Principia (PRN1371), Blueprint Medicines (BLU-554). For FLT3 competitors may include, Daiichi Sankyo (quizartinib, PLX3397), Arog (crenolanib), Novartis (midostaurin), CTI BioPharma (pacritinib), Takeda (TAK-659), Flexus (FLX925), Astellas (ASP2215).

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 payers 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:

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- 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;
- 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.

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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 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.

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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.

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.

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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 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 June 30, 2015, had only twelve employees and three 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, Jennifer Low, M.D. our Executive Vice President of Research and Development and Chief Medical 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 will also be critical to our success. The loss of the services of our executive officers or other key employees 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 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 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. 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. 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.

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Failure to protect our information technology infrastructure against cyber-based attacks, network security breaches, service interruptions, or data corruption could significantly disrupt our operations and adversely affect our business and operating results.

We rely on information technology and telephone networks and systems, including the Internet, to process and transmit sensitive electronic information and to manage or support a variety of business processes and activities. We use enterprise information technology systems to record, process, and summarize financial information and results of operations for internal reporting purposes and to comply with regulatory financial reporting, legal, and tax requirements. Our information technology systems, some of which are managed by third-parties, such as those of our CROs, may be susceptible to damage, disruptions or shutdowns due to computer viruses, attacks by computer hackers, failures during the process of upgrading or replacing software, databases or components thereof, power outages, hardware failures, telecommunication failures, user errors or catastrophic events. Although we have developed systems and processes that are designed to protect proprietary or confidential information and prevent data loss and other security breaches, including systems and processes designed to reduce the impact of a security breach at a third party vendor, such measures cannot provide absolute security. If our systems are breached or suffer severe damage, disruption or shutdown and we are unable to effectively resolve the issues in a timely manner, our business and operating results may significantly suffer and we may be subject to litigation, government enforcement actions or potential liability. Security breaches could also cause us to incur significant remediation costs, result in product development delays, disrupt key business operations, including development of our product candidates, and divert attention of management and key information technology resources.

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.

As of June 30, 2015, 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 70.4% of our capital stock. 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.

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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 bylaws 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.

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 resale of our common stock by our existing stockholders could cause the market price of our common stock to decline.

As of June 30, 2015, there were 989,743 shares of our common stock available for future grant under our 2014 Equity Incentive Plan. Additionally, as of June 30, 2015, there were outstanding options to purchase up to 1,977,773 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.

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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, 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.

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We have taken advantage of reduced reporting burdens. In particular, 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.

We will continue to incur increased costs as a result of operating as a public company, and our management is 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.

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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.

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

(a) Sales of Unregistered Securities

None.

(b) Use of Proceeds from Sales of Registered Securities

On July 31, 2014, our registration statements on Form S-1 (File Nos. 333-197123 and 333-197779) were declared effective by the SEC for our initial public offering pursuant to which we sold an aggregate of 5,903,538 shares of our common stock, including shares subject to the underwriters overallotment, at a price to the public of $13.00 per share. There has been no material change in the planned use of proceeds from our initial public offering as described in our final prospectus filed with the SEC on August 1, 2014 pursuant to Rule 424(b).

ITEM 3: DEFAULTS UPON SENIOR SECURITIES

Not applicable.

ITEM 4: MINE SAFETY DISCLOSURES

Not applicable

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	XBRL Report Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Calculation Linkbase Document
101.LAB	XBRL Taxonomy Label Linkbase Document
101.PRE	XBRL Presentation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document

* Filed herewith.

(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.

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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: August 5, 2015

LOXO ONCOLOGY, INC.

By: /s/ JOSHUA H. BILENKER, M.D.
Joshua H. Bilenker, M.D.
President, Chief Executive Officer and Director
(Principal Executive Officer)

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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: August 5, 2015

LOXO ONCOLOGY, INC.

By: /s/ JENNIFER BURSTEIN
Jennifer Burstein
Vice President of Finance
(Principal Accounting Officer and Principal Financial Officer)

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EXHIBIT INDEX

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