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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2017

Or

☐ **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.)
281 Tresser Blvd., 9th Floor Stamford, CT	**06901**
(Address of Principal Executive Offices)	(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 ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.:

Large accelerated filer ☐	Accelerated filer ☒
Non-accelerated filer ☐	Smaller reporting company ☐
Emerging growth company ☒	
(Do not check if a smaller reporting company)	

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒

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

Common Stock, $0.0001 par value	Shares outstanding as of October 31, 2017: 29,937,504

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PART I

ITEM 1. FINANCIAL STATEMENTS

LOXO ONCOLOGY, INC.
Condensed Consolidated Balance Sheets
(in thousands, except share and per share amounts)

	September 30, 2017 (unaudited)	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	$ 80,419	$ 30,376
Short-term investments	291,250	108,935
Other prepaid expenses and current assets	4,942	2,483
Total current assets	376,611	141,794
Long term investments	33,606	2,499
Property and equipment, net	566	248
Other assets	723	771
Total assets	$ 411,506	$ 145,312
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,829	$ 1,061
Accrued expenses and other current liabilities	15,641	14,083
Total liabilities	17,470	15,144
Commitments and contingencies		
Stockholders' equity:		
Common stock, $0.0001 par value; 125,000,000 shares authorized; 29,915,722 and 21,681,236 shares issued and outstanding at September 30, 2017 and December 31, 2016, respectively	3	2
Additional paid-in capital	661,613	269,423
Accumulated deficit	(267,484)	(139,236)
Accumulated other comprehensive loss	(96)	(21)
Total stockholders' equity	394,036	130,168
Total liabilities and stockholders' equity	$ 411,506	$ 145,312

See accompanying notes to unaudited condensed consolidated financial statements.

LOXO ONCOLOGY, INC.
Condensed Consolidated Statements of Operations
(unaudited)
(in thousands, except share and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Operating expenses:				
Research and development	$ 64,754	$ 14,230	$ 109,321	$ 34,917
General and administrative	9,680	3,679	20,968	10,859
Total operating expenses and loss from operations	(74,434)	(17,909)	(130,289)	(45,776)
Interest income, net	1,115	218	2,041	572
Net loss	$ (73,319)	$ (17,691)	$ (128,248)	$ (45,204)
Per share information:				
Net loss per share of common stock, basic and diluted	$ (2.45)	$ (0.82)	$ (4.68)	$ (2.19)
Weighted average shares outstanding, basic and diluted	29,872,198	21,609,424	27,391,020	20,659,829

See accompanying notes to unaudited condensed consolidated financial statements.

LOXO ONCOLOGY, INC.
Condensed Consolidated Statements of Comprehensive Loss
(unaudited)
(in thousands)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Net loss	$ (73,319)	$ (17,691)	$ (128,248)	$ (45,204)
Other comprehensive income (loss):				
Unrealized gain (loss) on available for sale securities	69	(38)	(75)	72
Comprehensive loss	$ (73,250)	$ (17,729)	$ (128,323)	$ (45,132)

See accompanying notes to unaudited condensed consolidated financial statements.

LOXO ONCOLOGY, INC.
Condensed Consolidated Statement of Stockholders' Equity
(unaudited)
For the period from January 1, 2017 to September 30, 2017
(in thousands except share and per share amounts)

	Stockholders' equity					
	Common stock					
	Shares	$0.0001 Par Value	Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity
Balance at January 1, 2017	21,681,236	$ 2	$ 269,423	$ (139,236)	$ (21)	$ 130,168
Stock-based compensation expense	—	—	14,677	—	—	14,677
Stock option exercises	161,486	—	2,207	—	—	2,207
Issuance of common stock, net of offering costs	8,073,000	1	375,306	—	—	375,307
Other comprehensive loss	—	—	—	—	(75)	(75)
Net loss	—	—	—	(128,248)	—	(128,248)
Balance at September 30, 2017	29,915,722	$ 3	$ 661,613	$ (267,484)	$ (96)	$ 394,036

See accompanying notes to unaudited condensed consolidated financial statements.

LOXO ONCOLOGY, INC.
Condensed Consolidated Statements of Cash Flows
(unaudited)
(in thousands)

	Nine Months Ended September 30, 2017	Nine Months Ended September 30, 2016
Operating activities:		
Net loss	$ (128,248)	$ (45,204)
Adjustments to reconcile net loss to net cash used in operating activities:		
Amortization of premium and discounts on investments	142	408
Depreciation of property and equipment	80	44
Stock-based compensation	14,677	5,394
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(2,411)	(1,182)
Accounts payable	768	752
Accrued expenses and other current liabilities	1,558	3,049
Net cash used in operating activities	(113,434)	(36,739)
Investing activities:		
Purchases of available-for-sale securities	(359,694)	(121,592)
Proceeds from maturing available-for-sale securities	146,055	102,361
Purchase of property and equipment	(398)	(225)
Net cash used in investing activities	(214,037)	(19,456)
Financing activities:		
Proceeds from issuance of common stock, net	375,307	38,733
Proceeds from the exercise of stock options	2,207	1,214
Net cash provided by financing activities	377,514	39,947
Net increase (decrease) in cash and cash equivalents	50,043	(16,248)
Cash and cash equivalents—beginning of period	30,376	68,177
Cash and cash equivalents—end of period	$ 80,419	$ 51,929

See accompanying notes to unaudited condensed consolidated financial statements.

LOXO ONCOLOGY, INC.

Notes to Unaudited Condensed Consolidated Financial Statements

September 30, 2017

1. Organization and Description of the Business

Loxo Oncology, Inc. (the "Company") is a biopharmaceutical company innovating the development of highly selective medicines for patients with genetically defined cancers. Its pipeline focuses on cancers that are uniquely dependent on single gene abnormalities, such that a single drug has the potential to treat the cancer with dramatic effect. The Company operates in one segment and has its principal office in Stamford, Connecticut.

Liquidity

At September 30, 2017, the Company had working capital of $359.1 million, an accumulated deficit of $267.5 million and cash, cash equivalents and investments of $405.3 million. The Company has not generated any product revenues and has not achieved profitable operations. There is no assurance that profitable operations will ever be achieved, and, if achieved, could be sustained on a continuing basis. In addition, development activities, clinical and preclinical testing, and commercialization of the Company's products will require significant additional financing.

The Company believes that its existing cash, cash equivalents and investments, will be sufficient to enable the Company to continue as a going concern through at least November 2, 2018. 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 and commercialization 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 consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP") and include the results of operations of the Company and its wholly owned subsidiary. All intercompany accounts and transactions have been eliminated in consolidation. 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, 2016, was derived from the Company's audited financial statements included in Form 10-K filed with the Securities and Exchange Commission ("SEC") on March 7, 2017. It is suggested that the interim unaudited condensed consolidated 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 September 30, 2017, the statements of operations for the three and nine months ended September 30, 2017 and 2016, the statements of comprehensive loss for the three and nine months ended September 30, 2017 and 2016, the statements of stockholders' equity for the period from January 1, 2017 to September 30, 2017 and the statements of cash flows for the nine months ended September 30, 2017 and 2016 are unaudited.

The interim unaudited condensed consolidated 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 September 30, 2017, the results of its operations for the three and nine months ended September 30, 2017 and 2016 and its cash flows for the nine months ended September 30, 2017 and 2016.

The interim unaudited condensed consolidated financial statements have been prepared pursuant to the rules and regulations of the SEC. 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, 2016 included in the Company's Form 10-K filed with the SEC on March 7, 2017. Since the date of such financial statements, there have been no changes to the Company's significant accounting policies, except as it relates to principles of consolidation, the impact of the adoption of ASU No. 2017-01, *Business Combinations (Topic 805): Clarifying the Definition of a Business* ("ASU 2017-01"), ASU No. 2016-09, *Improvements to Employee Share-Based Payment Accounting* ("ASU 2016-09") and ASU No. 2015-17, *Balance Sheet Classification of Deferred Taxes* ("ASU 2015-17"), as described below.

Principles of Consolidation

The consolidated financial statements include the accounts of Loxo Oncology, Inc. and its wholly owned subsidiary. All intercompany balances and transactions have been eliminated in consolidation.

Recently Adopted Accounting Pronouncements

In January 2017, the FASB issued ASU 2017-01, which provides additional guidance on evaluating whether transactions should be accounted for as acquisitions of assets or businesses. ASU 2017-01 requires an entity to evaluate if substantially all of the fair value of the assets acquired is concentrated in a single identifiable asset or a group of similar identifiable assets. If this threshold is met, the new guidance would define this as an asset acquisition; otherwise, the entity then evaluates whether the asset meets the requirement that a business include, at a minimum, an input and substantive process that together significantly contribute to the ability to create outputs. The Company has early adopted ASU 2017-01 in the third quarter of 2017. Refer to Note 9 for discussion on the Company's acquisition of in process research and development ("IPR&D") from Redx Pharma Plc and Redx Oncology Limited (collectively, "Redx"), which was accounted for as an asset acquisition under this new guidance.

In March 2016, the FASB issued ASU 2016-09, which provides for simplification of certain aspects of employee share-based payment accounting including income taxes, classification of awards as either equity or liabilities, accounting for forfeitures and classification on the statement of cash flows. ASU 2016-09 was effective for the Company in the first quarter of 2017. The standard requires the recognition of any pre-adoption date net operating loss ("NOL") carryforwards from share-based compensation arrangements to be recognized on a modified retrospective basis, through an opening retained earnings adjustment on January 1, 2017. Any income tax effects from share-based compensation arrangements arising after January 1, 2017 will be recognized prospectively in the income statement. Upon adoption, the Company recognized all previously unrecognized tax benefits. These previously unrecognized tax benefits were recorded as a deferred tax asset, which was fully offset by a valuation allowance on January 1, 2017, thus there was no net impact from the adoption of ASU 2016-09 as of the same date. The Company's adoption of the standard did not have any impact to the consolidated statements of cash flows as no NOL carryforwards from share-based compensation arrangements were recognized prior to January 1, 2017. The Company has elected to continue to estimate forfeitures under the true-up provision of ASC 718.

In November 2015, the FASB issued ASU 2015-17, which eliminates the current requirement to present deferred tax liabilities and assets as current and noncurrent in a classified balance sheet. Instead, entities will be required to classify all deferred tax assets and liabilities as noncurrent. ASU 2015-17 was effective for the Company in the first quarter of 2017. The adoption of the ASU 2015-17 did not have a material impact on the Company's financial statements.

Recent Accounting Pronouncements Not Yet Adopted

In November 2016, the FASB issued ASU No. 2016-18*, Statement of Cash Flows (Topic 230): Restricted Cash* ("ASU 2016-18"), which amended the existing accounting standards for the statement of cash flows by requiring restricted cash to be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. ASU 2016-18 will be effective in fiscal years beginning after December 15, 2017, including interim periods within those fiscal years, and early adoption is permitted. The amendments should be applied retrospectively to all periods presented. The Company is currently in the process of assessing the impact of ASU 2016-18 on the Company's financial statements and related disclosures.

In August 2016, the FASB issued ASU No. 2016-15*, Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments* ("ASU 2016-15"), which amended the existing accounting standards for the statement of cash flows by providing guidance on eight classification issues related to the statement of cash flows. ASU 2016-15 will be effective in fiscal years beginning after December 15, 2017, including interim periods within those fiscal years, and early adoption is permitted. The amendments should be applied retrospectively to all periods presented. For issues that are impracticable to apply retrospectively, the

amendments may be applied prospectively as of the earliest date practicable. The Company is currently in the process of assessing the impact of ASU 2016-15 on the Company's financial statements and related disclosures.

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)* ("ASU 2016-02"), which requires lessees to recognize assets and liabilities for the rights and obligations created by most leases on their balance sheet. The guidance is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. Early application is permitted. ASU 2016-02 requires modified retrospective adoption for all leases existing at, or entered into after, the date of initial application, with an option to use certain transition relief. The Company is currently evaluating the impact the standard may have on the Company's financial statements and related disclosures.

In January 2016, the FASB issued ASU No. 2016-01, *Financial Instruments - Overall (Subtopic 825-10), Recognition and Measurement of Financial Assets and Financial Liabilities* ("ASU 2016-01"), which addresses certain aspects of recognition, measurement, presentation, and disclosure of financial instruments. ASU 2016-01 will be effective for annual periods and interim periods within those annual periods beginning after December 15, 2017 and early adoption is not permitted. The Company is currently evaluating the impact that the standard will have on the Company's financial statements and related disclosures.

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 September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Basic and diluted net loss per common share calculation:				
Net loss	$ (73,319)	$ (17,691)	$ (128,248)	$ (45,204)
Weighted average common shares outstanding — basic and diluted	29,872,198	21,609,424	27,391,020	20,659,829
Net loss per share of common stock — basic and diluted	$ (2.45)	$ (0.82)	$ (4.68)	$ (2.19)

The following outstanding securities at September 30, 2017 and 2016 have been excluded from the computation of diluted weighted average shares outstanding, as they are anti-dilutive:

	September 30, 2017	September 30, 2016
Unvested restricted stock	—	55,038
Stock options	3,246,018	2,297,494
Total	3,246,018	2,352,532

4. Fair Value Measurements

Financial Instruments

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

(amounts in thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
September 30, 2017				
Overnight repurchase agreements	$ 40,000	$ —	$ —	$ 40,000
Money market funds	33,079	—	—	33,079
Total included in cash and cash equivalents	73,079	—	—	73,079
U.S. Government debt securities	81,208	—	(18)	81,190
Government enterprise debt securities	210,127	11	(78)	210,060
Short-term available-for-sale securities	291,335	11	(96)	291,250
U.S. Government debt securities	33,617	4	(15)	33,606
Long-term available-for-sale securities	33,617	4	(15)	33,606
Total fair value financial instruments	$ 398,031	$ 15	$ (111)	$ 397,935
December 31, 2016				
Overnight repurchase agreements	$ 10,000	$ —	$ —	$ 10,000
Money market funds	12,146	—	—	12,146
Total included in cash and cash equivalents	22,146	—	—	22,146
U.S. Government debt securities	12,769	995	—	13,764
Government enterprise debt securities	96,184	—	(1,013)	95,171
Short-term available-for-sale securities	108,953	995	(1,013)	108,935
U.S. Government debt securities	2,502	—	(3)	2,499
Long-term available-for-sale securities	2,502	—	(3)	2,499
Total fair value financial instruments	$ 133,601	$ 995	$ (1,016)	$ 133,580

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.

The Company's financial assets measured at fair value on a recurring basis at September 30, 2017 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 September 30, 2017
Assets:				
Cash and cash equivalents				
Cash	$ 7,340	$ —	$ —	$ 7,340
Overnight repurchase agreements	40,000	—	—	40,000
Money market funds	33,079	—	—	33,079
Total cash and cash equivalents	80,419	—	—	80,419
Short-term investments				
U.S. Government debt securities	81,190	—	—	81,190
Government enterprise debt securities	—	210,060	—	210,060
Total short-term investments	81,190	210,060	—	291,250
Long-term investments				
Government enterprise debt securities		33,606	—	33,606
Total long-term investments		33,606	—	33,606
Totals	$ 161,609	$ 243,666	$ —	$ 405,275

The Company's financial assets measured at fair value on a recurring basis at December 31, 2016 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, 2016
Assets:				
Cash and cash equivalents				
Cash	$ 8,230	$ —	$ —	$ 8,230
Overnight repurchase agreements	10,000	—	—	10,000
Money market funds	12,146	—	—	12,146
Total cash and cash equivalents	30,376	—	—	30,376
Short-term investments				
U.S. Government debt securities	13,764	—	—	13,764
Government enterprise debt securities	—	95,171	—	95,171
Total short-term investments	13,764	95,171	—	108,935
Long-term investments				
U.S. Government debt securities	2,499	—	—	2,499
Total long-term investments	2,499	—	—	2,499
Totals	$ 46,639	$ 95,171	$ —	$ 141,810

There were no items that were accounted for at fair value on a non-recurring basis for the nine months ended September 30, 2017 and 2016.

Financial instruments that potentially subject the Company to a concentration of credit risk consist of cash and cash equivalents. At September 30, 2017 and December 31, 2016, the Company's cash and cash equivalents were held by two financial institutions and the amounts on deposit were in excess of Federal Deposit Insurance Company 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 and Other Current Liabilities

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

	September 30, 2017	December 31, 2016
Research and development accrued expenses	$ 11,694	$ 12,120
General and administrative accrued expenses	3,947	1,963
	$ 15,641	$ 14,083

Included in the above amounts is $1.3 million and $1.5 million of accrued bonuses at September 30, 2017 and December 31, 2016, respectively.

6. Stock-Based Compensation

Equity Incentive Plan (the "Plan")

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 September 30, 2017, 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 2,828,874 shares of its common stock to be issued under the 2014 Plan of which 605,226 shares were available for future issuance as of September 30, 2017. 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 the Company's 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.

The following table summarizes stock option activity under the Plan for the period from January 1, 2017 through September 30, 2017:

	Number of Shares	Weighted-Average Exercise Price	Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at January 1, 2017	2,825,851	$ 15.35	8.34	$ 47,364
Granted	639,500	61.51		
Exercised	(161,486)	13.66		
Forfeited and expired	(57,847)	27.47		
Outstanding at September 30, 2017	3,246,018	$ 24.32	7.99	$ 220,092
Vested and expected to vest at September 30, 2017	3,111,991	$ 23.59	7.95	$ 213,259
Exercisable at September 30, 2017	1,646,023	$ 12.25	7.17	$ 131,462
Weighted-average grant date fair value of options granted during the nine months ended September 30, 2017	$ 41.69			

As of September 30, 2017, there was $42.6 million of total unrecognized compensation expense related to options granted but not yet vested of which $5.1 million is attributable to non-employee awards and subject to re-measurement until vested. The total unrecognized compensation expense of $42.6 million will be recognized as expense over a weighted-average period of 2.9 years.

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:

	Nine Months Ended September 30, 2017
Risk-free interest rate	1.99%
Expected dividend yield	0%
Expected stock price volatility	77.95%
Expected term of options (in years)	6.1
Expected forfeiture rate	11.58%

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 forfeiture rate is 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 September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Research and development	$ 2,148	$ 1,595	$ 8,010	$ 2,102
General and administrative	3,120	1,170	6,667	3,292
	$ 5,268	$ 2,765	$ 14,677	$ 5,394

7. Commitments and Contingencies

Operating Leases

The Company leases office space under operating leases for its locations in South San Francisco, California, Boulder, Colorado and in Stamford, Connecticut. The Company's lease agreements contain escalation clauses; accordingly, the Company straight-lines the rent expense over the lease term. Rent expense under operating leases for the three months ended September 30, 2017 and 2016 was $247,812 and $166,236, respectively. Rent expense under operating leases for the nine months ended September 30, 2017 and 2016 was $645,860 and $520,882, respectively.

Future minimum lease payments as of September 30, 2017 are as follows (in thousands):

	Operating Leases
2017	$ 240
2018	1,369
2019	1,392
2020	1,427
2021	1,464
Thereafter	1,515
	$ 7,407

In January 2017, the Company entered into an office lease agreement to replace its existing leased space in South San Francisco, CA. The Company's previous lease expired June 30, 2017. The new lease provided for a term of 51 months, commencing when the landlord delivered the premise to the Company on May 1, 2017. In August 2017, the Company signed the First Amendment to the San Francisco office space lease, extending the end of the original lease term to January 31, 2023. In addition to extending the lease term, the First Amendment provides for additional space, beginning in November 2017. The Company expects to incur approximately $418,000 of annual rent expense associated with the lease.

In May 2017, the Company entered into a lease agreement in Boulder, CO. The lease commencement date is October 1, 2017. The lease had a termination option, where the Company had the option to terminate the lease on or prior to September 30, 2017 in exchange for consideration of $10,000 per month. The Company did not exercise the termination option and the lease commenced

October 1, 2017. The lease has a term of 63 months, ending December 31, 2022, after which the lease shall continue on a month to month basis. The Company has an option to renew the primary lease term for two additional periods of five years and has the one-time right to terminate the lease effective at the end of the 39th month following the commencement date by delivering six months prior written notice of such termination and upon payment of a termination fee equal to $30,000. The Company expects to incur approximately $296,000 of annual rent expense associated with the lease.

Array Bio Pharma ("Array") Collaboration

On July 3, 2013, the Company signed a multi-year strategic collaboration agreement with Array, and this agreement was subsequently amended on November 26, 2013, April 10, 2014, October 13, 2014, March 31, 2015 and February 18, 2016. 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"), and fibroblast growth factor receptor ("FGFR"). The Company has worldwide commercial rights to each product candidate from the collaboration and Array participates in any potential successes through milestones and royalties.

With respect to the discovery and preclinical program, the collaboration agreement, as amended, runs through September 30, 2017, and the Company has the option to extend the term for up to one additional one-year renewal period by providing written notice to Array at least three months before the end of the initial discovery and preclinical development programs term. This option was exercised during the three-month period ended June 30, 2017.

Before the February 2016 amendment, in addition to larotrectinib, formerly referred to as LOXO-101, the parties designated 12 discovery targets, of which seven were selected for additional study in January 2015, which was to be reduced to four on or before January 2016. The Company had the option to maintain the total target number at five for an additional payment, and the Company exercised this option to maintain five discovery programs in January 2016. In the February 2016 amendment, the parties designated a total of six discovery targets. An additional payment was due at contract signing, satisfying a prior obligation of the April 2014 amendment.

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. For the three months ended September 30, 2017 and 2016, the Company recorded $2.2 million and $2.9 million of research and development expenses related to the collaboration agreement, respectively. For the nine months ended September 30, 2017 and 2016, the Company recorded $6.1 million and $9.2 million of research and development expenses related to the collaboration agreement, respectively.

Milestones

With respect to product candidates directed to TRK, including larotrectinib and LOXO-195, the Company could be required to pay Array up to $223 million in milestone payments for each compound, the substantial majority of which are due upon the achievement of commercial milestones. The Company has made or accrued $7.0 million and $1.3 million in larotrectinib and LOXO-195 milestone payments, respectively, from inception through September 30, 2017, of which $1.0 million relating to LOXO-195 was recognized as Research and Development expense in the three and nine months ended September 30, 2017.

With respect to product candidates directed to targets other than TRK, including LOXO-292, 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. The Company has made or accrued $1.3 million in LOXO-292 milestone payments from inception through September 30, 2017, of which $1.0 million was recognized as Research and Development expense in the nine months ended September 30, 2017.

Royalties

The Company is required to pay Array mid-single digit royalties on worldwide net sales of products that were discovered under the agreement. 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 contract research organizations, or CROs, to assist in the performance of research and development and preclinical activities. Expenditures to CROs may represent a significant cost in preclinical and clinical development for the Company in future periods. The Company can elect to discontinue the work under these agreements at any time. The Company has also entered into an agreement with Roche, to develop and commercialize a companion diagnostic. The Company could also enter into additional collaborative research, contract research, manufacturing, and supplier agreements in the future, which may require upfront payments and 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 and cash flows.

8. Related Party Transactions

Dr. Lori Kunkel, a board member, had a consulting agreement with the Company to assist in the Company's drug development process which was modified effective as of October 31, 2015, to provide that she receives only the standard director compensation for her services. Dr. Kunkel also received stock option grants in 2013 and 2014 as compensation for her consulting services which continue to vest. During the three and nine months ended September 30, 2017, the Company recognized stock-based compensation expense of $0.3 million and $1.7 million, respectively, in accordance with the terms of the consulting agreement, which are included as a component of research and development expenses. The Company recognized stock-based compensation expense of $0.8 million in the three and nine months ended September 30, 2016.

Dr. Keith Flaherty, a board member, has an agreement with the Company to serve as Scientific Advisor Board ("SAB") Chair for which he receives cash compensation. Dr. Flaherty also received stock option grants in 2013 and 2014 as compensation for his SAB services which continue to vest. Both cash compensation that was expensed as incurred and stock-based compensation are recorded as a component of research and development expenses. During the three months ended September 30, 2017 and 2016, the Company recognized cash compensation expense of $15,000 and $15,000, respectively, and stock-based compensation expense of $0.5 million and $0.3 million, respectively, in accordance with the terms of the SAB agreement. During the nine months ended September 30, 2017 and 2016, the Company recognized cash compensation expense of $45,000 and $51,000 and stock-based compensation expense of $2.3 million and $0.4 million in accordance with the terms of the SAB agreement, respectively.

9. Asset Acquisition

On July 28, 2017, the Company entered into and closed on an Agreement for the Assignment of Patents and other Rights and for the Novation of Certain Agreements, including for Product Manufacturing, with Redx Pharma Plc and Redx Oncology Limited (acting by the joint administrators of those companies, Mr. Jason Baker and Mr. Miles Needham of FRP Advisory LLP) (collectively "Redx"), pursuant to which the Company paid $40.0 million in cash to acquire IPR&D, including patents and other rights related to the Redx Bruton's tyrosine kinase ("BTK") inhibitor discovery program, including lead product candidate LOXO-305. The Company is not subject to any future milestone or royalty payments related to this transaction. The transaction was accounted for as an asset acquisition pursuant to ASU 2017-01 as the majority of the fair value of the assets acquired was concentrated in a group of similar assets. The total cost of $40.0 million was included in research and development expense in the Company's condensed consolidated statements of operations for the three and nine months ended September 30, 2017 because the IPR&D acquired did not have an alternative future use.

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

The interim unaudited condensed consolidated 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, 2016 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 7, 2017. As used in this report, unless the context suggests otherwise, "we," "us," "our," "the Company" or "Loxo" refer to Loxo Oncology, Inc.

Forward Looking Statements

The information in this discussion contains forward-looking statements and information within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, which are subject to the "safe harbor" created by those sections. This Quarterly Report on Form 10-Q contains forward-looking statements that involve substantial risks and uncertainties. In some cases, you can identify forward-looking statements by the words "may," "might," "will," "could," "would," "should," "expect," "intend," "plan," "objective," "anticipate," "believe," "estimate," "predict," "project," "potential," "continue" and "ongoing," 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 Form 10-Q, 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 is a biopharmaceutical company innovating the development of highly selective medicines for patients with genetically defined cancers. Our pipeline focuses on cancers that are uniquely dependent on single gene abnormalities, such that a single drug has the potential to treat the cancer with dramatic effect. We believe that the most selective, purpose-built medicines have the highest probability of maximally inhibiting the intended target, thereby delivering best-in-class disease control and safety. Our management team seeks out experienced industry partners, world-class scientific advisors and innovative clinical-regulatory approaches to deliver new cancer therapies to patients as quickly and efficiently as possible.

With our scientific knowledge, collaborative partnerships and targeted approach, we are developing multiple small molecule therapeutics utilizing focused clinical development strategies in well-defined patient populations. Larotrectinib, formerly referred to as LOXO-101, a highly selective TRK inhibitor, is being evaluated in three ongoing multi-center studies that include patients with solid tumors that harbor TRK gene fusions. We are also in clinical development for LOXO-292, a highly selective RET inhibitor, and LOXO-195, a highly selective TRK inhibitor designed to address anticipated mechanisms of acquired resistance in cancers exposed to a prior TRK inhibitor. We have preclinical programs in development for BTK ("LOXO-305"), FGFR and other targets.

In July 2017, we entered into a definitive agreement to purchase the BTK inhibitor program from Redx. Under the terms of the agreement, we made a $40 million payment to Redx for the full acquisition of the BTK discovery program, including lead candidate LOXO-305 (formerly RXC005). The lead candidate from this program is expected to enter clinical development in 2018. We are not subject to any milestone or royalty payments in connection with the acquisition.

In October 2017, we announced top-line overall response rate (ORR) results from the independent review committee assessment of the larotrectinib dataset. Consistent with global written regulatory correspondence, this dataset includes adult and pediatric TRK fusion patients enrolled in our Phase 1 adult trial, Phase 2 trial (NAVIGATE), and Phase 1/2 pediatric trial (SCOUT). The dataset is based on the intent to treat (ITT) principle, using the first 55 TRK fusion patients with RECIST-evaluable disease enrolled to the three clinical trials, regardless of prior therapy or tumor tissue diagnostic method. The primary endpoint for the integrated analysis of efficacy is ORR according to the independent review committee assessment, as measured by RECIST v1.1. A key secondary endpoint is ORR according to local investigator assessment, as measured by RECIST v1.1. As of a July 17, 2017 data cut-off date, the ORR was 75% by independent review and 80% by investigator assessment.

In October 2017, LOXO-292 trial investigators presented initial clinical data from the program at the International Association for the Study of Lung Cancer (IASLC) World Conference on Lung Cancer. This presentation primarily described the first two patients with RET-fusion lung cancer with and without brain metastases treated with LOXO-292. Both patients had disease progression while receiving

prior multi-kinase inhibitors. On single agent LOXO-292, both patients achieved RECIST confirmed partial responses and remain on LOXO-292 as of the September 27, 2017 data cut-off of the presentation. In this early, two-patient dataset, LOXO-292 has been well-tolerated, with no adverse events attributed to LOXO-292. Additionally, the presentation included pharmacology evidence that the Phase 1 dose level of 60mg twice daily provides IC90 RET target coverage in patients. We plan to present additional clinical data from this program in the first half of 2018.

Since inception, we have incurred significant operating losses. Our net loss for the three and nine months ended September 30, 2017 was $73.3 million and $128.2 million, respectively, including approximately $64.8 million and $109.3 million, respectively, of total research and development expenses, and approximately $9.7 million and $21.0 million, respectively, 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, enter into companion diagnostics collaborations, 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.

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 September 30, 2017 was approximately $267.5 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, cash equivalents and investments as of September 30, 2017 will be sufficient to enable us to continue as a going concern through at least November 2, 2018.

Components of Operating Results

Revenue

To date, we have not generated any revenues. Our ability to generate product revenues will depend heavily on the successful development and eventual commercialization of our product candidates.

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 asset acquisitions of IPR&D, third-party collaborations, contract research arrangements and activities associated with the development of companion diagnostics for our product candidates.

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 external research and development will continue to increase for the foreseeable future, while our internal spending should increase at a slower and more controlled pace.

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

General and Administrative Expenses

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

Interest Income, net

Interest income, net consists 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 discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States of America, or GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses and the disclosure of contingent assets and liabilities in our financial statements. In accordance with GAAP, we base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances. 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 7, 2017 with the SEC.

Results of Operations

Comparison of the Three Months Ended September 30, 2017 and 2016 (in thousands)

	Three Months Ended September 30, 2017 (unaudited)	Three Months Ended September 30, 2016 (unaudited)	Change
Operating expenses:			
Research and development	$ 64,754	$ 14,230	$ 50,524
General and administrative	9,680	3,679	6,001
Total operating expenses and loss from operations	$ (74,434)	$ (17,909)	$ (56,525)

Research and development expenses

Research and development expenses were $64.8 million for the three months ended September 30, 2017, compared to $14.2 million for the three months ended September 30, 2016. The increase was primarily due to the $40.0 million asset acquisition of the BTK inhibitor program from Redx, expanded larotrectinib development activities including clinical costs and costs related to the companion diagnostics agreement with Roche that commenced in the first quarter of 2017, as well as additional expenses related to our other programs. We also had higher headcount and employment-related costs, as well as higher stock-based compensation costs. As a result, we had increases in larotrectinib development expenses of $5.6 million, LOXO-292 development expenses of $1.7 million, LOXO-305 development expenses of $0.9 million, LOXO-195 development expenses of $0.2 million, Array milestones of $1.0 million, employment costs of $0.9 million and stock-based compensation of $0.6 million.

General and administrative expenses

General and administrative expenses were $9.7 million for the three months ended September 30, 2017, compared to $3.7 million for the three months ended September 30, 2016. The increase was primarily due to increases in preparation activities for the

potential commercialization of larotrectinib of $1.5 million, general and administrative professional fees of $1.1 million, stock-based compensation expense of $1.9 million, and employment costs of $1.0 million.

Comparison of the Nine Months Ended September 30, 2017 and 2016 (in thousands)

	Nine Months Ended September 30, 2017 (unaudited)	Nine Months Ended September 30, 2016 (unaudited)	Change
Operating expenses:			
Research and development	$ 109,321	$ 34,917	$ 74,404
General and administrative	20,968	10,859	10,109
Total operating expenses and loss from operations	$ (130,289)	$ (45,776)	$ (84,513)

Research and development expense

Research and development expenses were $109.3 million for the nine months ended September 30, 2017, compared to $34.9 million for the nine months ended September 30, 2016. The increase was primarily due to the $40.0 million asset acquisition of the BTK inhibitor program from Redx, expanded larotrectinib development activities including clinical costs and costs related to the companion diagnostics agreement with Roche that commenced in the first quarter of 2017, as well as additional expenses related to our other programs. We also had higher headcount and employment-related costs, as well as higher stock-based compensation costs. As a result, we had increases in larotrectinib development expenses of $21.1 million, LOXO-292 development expenses of $3.8 million, LOXO-195 development expenses of $0.9 million, LOXO-305 development costs of $0.9 million, stock-based compensation of $5.9 million and employment and other costs of $3.1 million. This was offset by a net decrease in Array full-time equivalents and milestones of $1.2 million.

General and administrative expense

General and administrative expenses were $21.0 million for the nine months ended September 30, 2017, compared to $10.9 million for the nine months ended September 30, 2016. The increase was primarily due to increases in preparation activities for the potential commercialization of larotrectinib of $2.2 million, general and administrative professional fees of $2.2 million, stock-based compensation expense of $3.4 million and employment costs of $1.5 million.

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 $128.2 million for the nine months ended September 30, 2017. Net cash used in operating activities was $113.4 million during the nine months ended September 30, 2017. At September 30, 2017, we had an accumulated deficit of $267.5 million, and working capital of $359.1 million. We had cash, cash equivalents and investments of $405.3 million at September 30, 2017. Historically, we have financed our operations principally through private placements of preferred stock, our initial public offering of common stock and follow-on offerings of common stock.

Cash Flows

The following table summarizes our cash flows for the nine months ended September 30, 2017 and 2016 (in thousands):

	Nine Months Ended September 30, 2017 (unaudited)	Nine Months Ended September 30, 2016 (unaudited)
Net cash (used in) provided by:		
Operating activities	$ (113,434)	$ (36,739)
Investing activities	(214,037)	(19,456)
Financing activities	377,514	39,947
Net increase (decrease) in cash and cash equivalents	$ 50,043	$ (16,248)

Net cash used in operating activities

Net cash used in operating activities was $113.4 million for the nine months ended September 30, 2017 and consisted primarily of a net loss of $128.2 million, which included the $40.0 million cash asset acquisition of the BTK inhibitor program from

Redx, a decrease in prepaid expenses and other current assets of $2.4 million, an increase in accrued expenses and other current liabilities of $1.6 million and an increase in accounts payable of $0.8 million. This was offset by noncash expenses of $14.9 million, primarily attributable to stock-based compensation expense.

Net cash used in operating activities was $36.7 million for the nine months ended September 30, 2016 and consisted primarily of a net loss of $45.2 million. This was offset by noncash expenses of $5.8 million, primarily attributable to stock-based-compensation expense and a $2.6 million increase in our net operating assets, related to the timing of payments for our clinical and preclinical activities.

Net cash used in investing activities

Net cash used in investing activities for the nine months ended September 30, 2017 totaled $214.0 million and consisted primarily of $359.7 million of available for sale security purchases offset by $146.0 million of proceeds from maturing available-for-sale securities.

Net cash used in investing activities for the nine months ended September 30, 2016 totaled $19.5 million and consisted primarily of $121.6 million of available-for-sale security purchases offset by $102.4 million of proceeds from maturing available-for-sale securities.

Net cash provided by financing activities

Net cash provided by financing activities was $377.5 million for the nine months ended September 30, 2017, which was primarily due to $375.3 million in net proceeds from the sale and issuance of our common stock in January 2017 and September 2017. We also received $2.2 million in proceeds from the exercise of employee stock options.

Net cash provided by financing activities was $39.9 million for the nine months ended September 30, 2016, which was primarily due to $38.7 million in net proceeds from the issuance of our common stock in May 2016. We also received $1.2 million in proceeds from the exercise of employee stock options.

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 the larotrectinib, LOXO-292 and LOXO-195 clinical trials, prepare for potential larotrectinib commercialization, establish companion diagnostics collaborations, fund clinical trials of our other preclinical product candidates and continue other 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 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 clinical programs for larotrectinib, LOXO-292 and LOXO-195;
- 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 U.S. and outside the U.S.;
- the costs, timing and outcome of regulatory review of our product candidates or any future product candidates, both in the U.S. and outside the U.S.;

- 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;
- the costs, timing and outcome of our companion diagnostics collaborations;
- any product liability or other lawsuits related to our products;
- the expenses needed to attract and retain skilled personnel;
- the general and administrative expenses related to being a public company, including developing an internal accounting function;
- the revenue, if any, received from the commercialization 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 U.S. and outside the U.S.

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 or restrict our operations. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

Contractual Obligations and Commitments

Purchase Commitments

Other than amounts due for the leases of our locations in Stamford, CT, Boulder, CO and South San Francisco, CA offices (see Note 7 to the financial statements) and under the Array collaboration agreement, as described below, we have no material non-cancelable purchase commitments with contract manufacturers or service providers as we have generally contracted on a cancelable basis.

Array Collaboration Agreement

On July 3, 2013, we signed the Array Agreement, which was subsequently amended on November 26, 2013, April 10, 2014, October 13, 2014, March 31, 2015 and February 18, 2016. Under the terms of the Array Agreement, we obtained certain rights to Array's TRK inhibitor program, as well as the right to develop product candidates against additional novel oncology targets, including but not limited to RET and FGFR. We have worldwide commercial rights to each product candidate from the collaboration and Array participates in any potential successes through milestones and royalties.

With respect to the discovery and preclinical program, the collaboration agreement, as amended, runs through September 30, 2017, and we have the option to extend the term for up to one additional one-year renewal period by providing written notice to Array at least three months before the end of the discovery and preclinical development program's term. This option was exercised during the three-month period ended June 30, 2017.

Before the February 2016 amendment, in addition to larotrectinib the parties designated 12 discovery targets, of which seven were selected for additional study in January 2015, which was to be reduced to four on or before January 2016. We had the option to maintain the total target number at five for an additional payment, and we exercised this option to maintain five discovery

programs in January 2016. In the February 2016 amendment, the parties designated a total of six discovery targets. An additional payment was due at contract signing, satisfying a prior obligation from the April 2014 amendment.

As part of the Array Agreement, as amended, 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. For the three months ended September 30, 2017 and 2016, we recorded $2.2 million and $2.9 million of research and development expenses related to the collaboration agreement, respectively. For the nine months ended September 30, 2017 and 2016, we recorded $6.1 million and $9.2 million of research and development expenses related to the collaboration agreement, respectively.

Milestones

With respect to product candidates directed to TRK, including larotrectinib and LOXO-195, we could be required to pay Array up to $223 million in milestone payments for each compound, the substantial majority of which are due upon the achievement of commercial milestones. We have made or accrued $7.0 million and $1.3 million in larotrectinib and LOXO-195 milestone payments, respectively, from inception through September 30, 2017, of which $1.0 million relating to LOXO-195 was recognized as Research and Development expense in the three and nine months ended September 30, 2017.

With respect to product candidates directed to targets other than TRK, including LOXO-292, 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. The February 2016 amendment allowed Array to be eligible for similar milestones on any back-up compounds developed through the collaboration. We have made or accrued $1.3 million in LOXO-292 milestone payments from inception through September 30, 2017, of which $1.0 million was recognized as Research and Development expense in the nine months ended September 30, 2017.

Royalties

We are required to pay Array mid-single digit royalties on worldwide net sales of products developed through the collaboration that were discovered under the agreement. 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 September 30, 2017, we do not have any off-balance sheet arrangements, as defined by applicable SEC regulations.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to market risk related to changes in interest rates. As of September 30, 2017 and December 31, 2016, we had cash and cash equivalents and investments of $405.3 million and $141.8 million, respectively, consisting of money market funds, certificates of deposit, overnight repurchase agreements, government enterprise debt securities and U.S. government debt securities. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our investments are in marketable debt securities. Our available-for-sale securities are subject to interest rate risk and will fall in value if market interest rates increase. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, an immediate 10% change in interest rates would not have a material effect on the fair market value of our portfolio. We have the ability to hold our available-for-sale-securities until maturity, and therefore, we would not expect our operating results or cash flows to be affected to any significant degree by the effect of a change in market interest rates on our investments. We do not currently have any auction rate securities.

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 September 30, 2017, the end of the period covered by this Quarterly Report on Form 10-Q.

Based on our evaluation, we believe that our disclosure controls and procedures as of September 30, 2017 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 controls system, no matter how well designed and operated, cannot provide absolute assurance that the objectives of the controls system are met, and no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within a company have been detected.

Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting during our fiscal quarter ended September 30, 2017 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II

ITEM 1. LEGAL PROCEEDINGS

We are not currently a party to any material legal proceedings and we are not aware of any pending or threatened legal proceeding against us that we believe could have a material adverse effect on our business, operating results or financial condition.

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 $73.3 and $128.2 million, respectively, for the three and nine months ended September 30, 2017. As of September 30, 2017, we had an accumulated deficit of $267.5 million. We have focused primarily on our drug discovery efforts and developing our product candidates. We have initiated clinical development of larotrectinib, LOXO-292 and LOXO-195, and it could 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, our initial public offering and our follow-on public offerings in November 2015, May 2016, January 2017 and June 2017. 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, acquire or in-license other products and technologies, or develop internal drug discovery capabilities;
- enter into collaboration arrangements for companion diagnostics for our cancer therapies;
- 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.

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, successfully developing companion diagnostics, 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 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 Loxo Oncology could also cause you to lose all or part of your investment.

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

We are a clinical development company. We were incorporated in May 2013 and commenced operations in the third quarter of 2013. We 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 and acquiring potential product candidates and conducting product development activities for larotrectinib, LOXO-292 and LOXO-195, which we have advanced into clinical trials, and other product candidates. We have not yet demonstrated our ability to successfully complete any clinical trials, including large-scale, pivotal clinical trials, develop companion diagnostics, 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 fifteen years to be developed from the time they are discovered to the time they are available for treating patients. Consequently, any predictions about our future success or viability based on our short operating history to date may not be as accurate as 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, diagnostics, manufacturing and distribution. Furthermore, we continue to incur 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.

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;
- the extent to which we enter into collaboration arrangements for companion diagnostics for our cancer therapies;
- our ability to establish additional discovery collaborations on favorable terms, if at all;
- the extent to which we develop or expand internal drug discovery and development capabilities;
- the costs, timing and outcome of regulatory review of our product candidates;
- the costs of future commercialization activities, including product sales, marketing, manufacturing and distribution, for any of our product candidates for which we receive marketing approval;

- revenue, if any, received from commercial sales of our product candidates, should any of our product candidates receive 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. In addition, public policy around drug pricing, in the U.S, and outside of the U.S., may affect the commercial success of our product candidates. 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. Our estimates of the potential market opportunities for our products are informed by work that is not definitive and future analyses may lead to estimates that are higher or lower than these estimates than those provided at any given time, with respect to addressable patient populations. Therefore, we do not know if our approach will be successful, and if our approach is unsuccessful, our business will suffer.

We are early in our development efforts and are substantially dependent on the development of our product candidates. If we or our collaborators are unable to successfully develop and commercialize our product candidates 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 product candidates, funding our collaboration agreement with Array to conduct preclinical studies, conducting clinical development of our product candidates, and acquiring the Redx Pharma Plc BTK program.

Our ability to generate product revenues will depend heavily on the successful development and eventual commercialization of our product candidates. As a result, our business is substantially dependent on our ability to complete the development of, and obtain regulatory approval for, larotrectinib.

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 and complete development activities;
- obtain required regulatory approvals for the development and commercialization of our product candidates;
- 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;
- establish successful companion diagnostics collaborations;
- gain market acceptance;
- 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 larotrectinib or our other product candidates, and our business will suffer.

Difficulty in enrolling patients could delay or prevent clinical trials of our product candidates. We may find it difficult to enroll patients in our clinical trials for larotrectinib or our other product candidates given that we do not know how many patients harbor the relevant alteration each product candidate 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 populations for our product candidates are not completely defined, but are 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 larotrectinib, we do not know exactly how many patients will have the target larotrectinib 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 number of patients suitable for trial enrollment and potential commercialization depends on a series of risks that are difficult to quantify based on available information. For example, in the case of TRK, there is significant uncertainty around the true number of patients with advanced cancer and a TRK fusion, the number of these patients who are referred for comprehensive genomic profiling, the sensitivity of the chosen comprehensive genomic assay for detecting TRK fusions, the ability of healthcare providers to recognize the importance of the presence of a TRK fusion, patient interest in seeking out a TRK inhibitor, and patient interest in larotrectinib instead of a competing program. Nevertheless, in the case of TRK fusion cancers, incidence appears to be low in the more common tumor types. Our proprietary work suggests that there are approximately 1,500-5,000 eligible advanced cancer patients addressable each year in the United States. However, the work that informed this estimate is not definitive and future analyses may lead to estimates that are higher or lower than this estimate. In addition, the broad utilization of sensitive diagnostic tests in routine clinical practice capable of identifying TRK fusion patients is as important to successful commercialization as the actual number of addressable patients.

In addition to 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. 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 ("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 commenced the clinical development of larotrectinib, LOXO-292, and LOXO-195, and there is significant risk that one or more of our product candidates will fail to reach commercialization. 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;
- 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 larotrectinib, LOXO-292 and LOXO-195.

In order to execute on our strategy of advancing the clinical development of our product candidates, we have designed clinical trials for larotrectinib, LOXO-292, and LOXO-195, and expect to design future trials, to include patients whose tumors harbor the applicable genetic alterations that we believe contribute to cancer. Our goal 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.

We plan to seek marketing approval of larotrectinib for the treatment of unresectable or metastatic solid tumors with NTRK-fusion proteins in adult and pediatric patients who require systemic therapy and who have either progressed following prior treatment or who have no acceptable alternative treatments. However, in order to obtain marketing approval from FDA, we may need to study our product candidates, including larotrectinib, in clinical trials specific for a given tumor type and this may result in increased time and cost. Even if our product candidate demonstrates efficacy in a particular tumor type, we cannot guarantee that any product candidate, including larotrectinib, 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.

Larotrectinib 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 larotrectinib plays an important role in the nervous system in general and the central nervous system ("CNS") in particular. In animal models no adverse CNS effects were observed. However, no assurance can be given that larotrectinib will not cause unwanted, and potentially unacceptable, nervous system or CNS side effects in humans. Toxicology studies for LOXO-292 and LOXO-195 have also demonstrated potential side effects that could affect humans, but also may have failed to uncover additional side effects that could affect humans.

Additional or more severe side effects may be identified in our ongoing clinical trials 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.

Investors should not place undue reliance on the results of preclinical experiments or our ongoing clinical trials since they are not necessarily predictive of the results that will form the basis of our global regulatory approval packages, and larotrectinib and our other product candidates may not receive regulatory approval.

Investors should not place undue reliance on the results from completed preclinical studies or data from our ongoing clinical trials since they do not ensure that other clinical trial data will be comparable, in terms of safety, overall response rate ("ORR"), durability of response ("DOR"), or other factors the FDA and other regulators will consider in determining whether to approve an NDA for larotrectinib or our other product candidates.

Final datasets, upon which global regulatory decisions will be based, will differ from interim datasets previously disclosed. Potential reasons for these differences include, but are not limited to:

- not all patients will demonstrate tumor regression, experience tumor regression that meets the measurement thresholds required under RECIST v1.1 for a partial response, or remain on study long enough for an initial or confirmatory response assessment;

- patients will discontinue our product candidates for a number of reasons, including an adverse event, tumor progression following a response, or a lack of tumor regression or clinical benefit and discontinuations will impact our product candidates' reported duration of therapy and DOR;

- additional time and patient accrual provide new opportunities to capture new adverse events and further characterize the ORR and DOR;

- patient accrual beyond interim disclosed data will likely include study subjects with new tumor types, demographics (e.g. pediatric patients), and exposures to varying prior therapies. Thus, the inclusion of these subpopulations in the final dataset may alter the characterization of our product candidates' overall safety, ORR and DOR; and

- the precise composition of the final dataset is subject to additional regulatory feedback, which is expected closer to the time of an NDA, or equivalent, and the advice may vary by regulatory authority.

As a result, the final efficacy and safety datasets for our product candidates have not been fully populated or established, and are expected to differ from any interim dataset publicly disclosed. Moreover, regulatory approvals will be based on the final efficacy and safety databases, and as such, we can give no assurance that our product candidates will receive regulatory approval.

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.

We may expand our business through the acquisition of companies or businesses or by entering into collaborations or in-licensing product candidates that could disrupt our business and harm our financial condition.

We have in the past and may in the future seek to expand our pipeline and capabilities by acquiring one or more companies, businesses or assets, entering into collaborations or in-licensing one or more product candidates. For example, in July 2017, we acquired a patent portfolio from Redx Pharma Plc and Redx Oncology Limited in connection with our acquisition of the Redx BTK discovery program. Any difficulties we experience in transitioning and integrating such product candidate into our operations may result in delays in clinical trials as well as problems in our development efforts and regulatory filings, particularly if we do not receive all of the necessary drug product, information, reports and data from third parties in a timely manner. More particularly, we have had no involvement with or control over the preclinical development of LOXO-305 prior to acquiring the rights to it. Furthermore, we did not get any representations or warranties with regards to the patents or associated rights.

Acquisitions, collaborations and in-licenses involve numerous risks, including:

- substantial cash expenditures;

- potentially dilutive issuance of equity securities;

- incurrence of debt and contingent liabilities, some of which may be difficult or impossible to identify at the time of acquisition;

- potential adverse consequences if the acquired assets are worth less than we anticipated or we are unable to successfully develop and commercialize the acquired assets for any reason;

- difficulties in assimilating the operations and technology of the acquired companies;

- potential disputes, including litigation, regarding contingent consideration for the acquired assets;

- the assumption of unknown liabilities of the acquired businesses;

- diverting our management's attention away from other business concerns;

- entering markets in which we have limited or no direct experience; and

- potential loss of our key employees or key employees of the acquired companies or businesses.

Our experience in making acquisitions, entering collaborations and in-licensing product candidates is limited. We cannot assure you that any acquisition, collaboration or in-license will result in short-term or long-term benefits to us. We may incorrectly judge the value or worth of an acquired company or business or in-licensed product candidate. In addition, our future success may depend in part on our ability to manage the growth and technology integration associated with any of these acquisitions, collaborations and in-licenses. We cannot assure you that we will be able to successfully combine our business with that of acquired businesses, manage collaborations or integrate in-licensed product candidates or that such efforts would be successful. Furthermore, the development or expansion of our business or any acquired business or company or any collaboration or in-licensed product candidate may require a substantial capital investment by us. We may also seek to raise funds by selling shares of our capital stock, which could dilute our current stockholders' ownership interest, or securities convertible into our capital stock, which could dilute current stockholders' ownership interest upon conversion. We may also incur debt obligations, which could require us to comply with covenants which could restrict our ability to operate our business and negatively impact the value of our common stock.

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 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. For example, for larotrectinib, we are working with collaborators to develop appropriate companion diagnostics to identify patients with tumors that harbor TRK fusions. The approval of a companion diagnostic as part of the product labeling may 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.

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 insurance reimbursement to the laboratories who perform the companion diagnostic tests is inadequate, utilization may be low, and patient tumors may not be comprehensively screened for the presence of the genetic markers that predict response to our product candidates. 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 ("NDA") in the United States and by the European Medicines Agency ("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, may not have an acceptable durability of response, may not have an acceptable risk-benefit profile, 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. For example, development programs that span many tumor types are relatively novel, and to date, the FDA has not approved a therapy to treat multiple tumor types based on a basket trial. We cannot be sure that the FDA will accept our NDA for larotrectinib, including the basket trial design, for registration or that we will be able to obtain broad approval for larotrectinib across cancers with TRK fusions on the basis of the ongoing trials, if at all. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of a product candidate. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may also cause delays in or prevent the approval of an application.

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

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.

The FDA has granted rare pediatric disease designation to larotrectinib for the treatment of infantile fibrosarcoma; however, an NDA for larotrectinib may not meet the eligibility criteria for a priority review voucher upon approval.

The FDA has granted rare pediatric disease designation to larotrectinib for the treatment of infantile fibrosarcoma, a rare pediatric cancer under section 529(d) of the FDC Act. Designation of a drug as a drug for a rare pediatric disease does not guarantee that an NDA for such drug will meet the eligibility criteria for a rare pediatric disease priority review voucher at the time the application is approved. Under the FDC Act, we will need to request a rare pediatric disease priority review voucher in our original NDA for larotrectinib. The FDA may determine that an NDA for larotrectinib does not meet the eligibility criteria for a priority review voucher upon approval, including for the following reasons:

- infantile fibrosarcoma no longer meets the definition of rare pediatric disease;
- the NDA contains an active ingredient (including any ester or salt of the active ingredient) that has been previously approved in an NDA;
- the NDA is not deemed eligible for priority review;

- the NDA does not rely on clinical data derived from studies examining a pediatric population and dosages of the drug intended for that population (i.e., if the NDA does not contain sufficient clinical data to allow for adequate labeling for use by the full range of affected pediatric patients); or

- the NDA seeks approval for a different adult indication than the rare pediatric disease (for example, if the FDA were to determine that the current larotrectinib breakthrough therapy designation indication that includes adult and pediatric patients is a different indication than the infantile fibrosarcoma indication).

The authority for the FDA to award rare pediatric disease priority review vouchers for drugs that have received rare pediatric disease designation prior to September 30, 2020 currently expires on September 30, 2022. If the NDA for larotrectinib is not approved prior to September 30, 2022 for any reason, regardless of whether it meets the criteria for a rare pediatric disease priority review voucher, it will not be eligible for a priority review voucher. However, it is also possible the authority for FDA to award rare pediatric disease priority review vouchers will be further extended through Federal lawmaking.

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. In September 2015, we announced that the United States Food and Drug Administration, or the FDA, granted larotrectinib orphan drug designation for the treatment of soft tissue sarcoma. In January 2016, we announced that the European Commission designated larotrectinib as an orphan medicinal product for treatment of patients with soft tissue sarcoma. In May 2017, we announced that the FDA granted orphan drug designation to larotrectinib for the "treatment of solid tumors with NTRK-fusion proteins." There can be no assurance that any of our other product candidates will be designated as an orphan drug.

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, or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition.

Orphan Drug Exclusivity of larotrectinib or other product candidates, may not effectively protect the product candidate from competition because different drugs can be approved for the same orphan condition. In addition, after an orphan drug is approved and granted exclusivity, the FDA can subsequently approve a different drug containing the same active moiety 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. The FDA can also approve drugs containing the same active moiety for different indications.

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 we may seek such designation, if we believe such a designation is 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 to the FDA for 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.

A Breakthrough Therapy Designation by the FDA 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.

In July 2016, we announced that the FDA granted Breakthrough Therapy Designation to larotrectinib "for the treatment of unresectable or metastatic solid tumors with NTRK-fusion proteins in adult and pediatric patients who require systemic therapy and who have either progressed following prior treatment or who have no acceptable alternative treatments." There can be no assurance

that larotrectinib will be approved by the FDA with this indication or at all. There can be no assurance that any of our other product candidates will receive Breakthrough Therapy Designation. A Breakthrough Therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drugs that have received a Breakthrough Therapy Designation, interaction and communication between the FDA and the sponsor can help to identify the most efficient path for development.

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 our product candidates receive a Breakthrough Therapy Designation, 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 our third party collaborators, 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. However, failure to obtain approval in some countries or jurisdictions may compromise our ability to obtain approval elsewhere. 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-approval regulatory requirements and could be subject to post-approval 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-approval information and reports, registration and listing requirements, current good manufacturing practices ("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, restrictions or requirements regarding the distribution of samples to physicians and recordkeeping requirements.

The FDA may also impose requirements for costly post-marketing studies or clinical trials, diagnostic approval, 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 FDC 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-approval 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.

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

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

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

- the federal Anti-Kickback Statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid;
- the federal False Claims Act imposes criminal and civil penalties, including civil whistleblower or *qui tam* actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996 ("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 was to be made publicly available on a searchable website in September 2014; and

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

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

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 ("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.

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

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

- an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- expansion of healthcare fraud and abuse laws, including the False Claims Act and the Anti-Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices;
- extension of manufacturers' Medicaid rebate liability;
- expansion of eligibility criteria for Medicaid programs;

- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- new requirements to report financial arrangements with physicians and teaching hospitals;
- a new requirement to annually report drug samples that manufacturers and distributors provide to physicians; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical 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, former 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. In 2016, the U.S. Congress held hearings on the rising costs of prescription drugs and in October 2017, President Trump issued the Executive Order Promoting Healthcare Choice and Competition, directing certain federal agencies to modify their implementation of the PPACA. Future legislation could potentially change drug pricing dynamics.

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.

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 ("the Array Agreement") which was subsequently amended on November 26, 2013, April 10, 2014, October 13, 2014, March 31, 2015 and February 18, 2016. The statutory end of the Array Agreement is scheduled for September 30, 2017, with a one-year extension at our option. This option was exercised during the three-month period ended June 30, 2017. Pursuant to the Array Agreement, Array agreed to design, conduct and perform research and preclinical testing for certain compounds that we select, including larotrectinib, targeted at TRKA, TRKB and TRKC, and identify Investigational New Drug 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. See "Business—Array Collaboration."

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 larotrectinib, LOXO-292, and LOXO-195, 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 the third-party partner for such efforts, as permitted under our collaboration agreement with Array. If Array or its partners were to develop such compounds in direct competition with our product candidates, our business could be adversely impacted.

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

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

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

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 the perception of our company by the business and financial communities could be adversely affected.

If we are unable to maintain our collaborations, development of our product candidates could be delayed and we may need additional resources to develop them. All of the risks relating to product development, regulatory approval and commercialization described in this filing 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 clinical trials of larotrectinib, LOXO-292, and LOXO-195, 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 our current trials, and for clinical trials for programs other than larotrectinib, LOXO-292, and LOXO-195. 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 business 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 reduces our control over these activities but does not relieve us of our responsibilities. For example, we 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 ("GCPs") for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. We are also required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within specified timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

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

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

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

We do not own or operate facilities for the manufacture of our product candidates, and we rely on outside manufacturing personnel to operate these third party facilities. 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 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. Arrangements for redundant supply or a source for bulk drug product may be infeasible, too costly, unavailable or inadequate to prevent a delay in clinical development or marketing approval should our existing or future manufacturers experience performance failure. The formulation used in early studies is not necessarily 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. In addition, if, during a preapproval inspection or other inspection of our third-party manufacturers' facility or facilities, FDA determines that the facility is not in compliance with cGMP, any of our marketing applications that lists such facility as a manufacturer may not be approved or approval may be delayed until the facility comes into compliance with cGMP and completes a successful reinspection by FDA

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

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

Risks Related to the Commercialization of Our Product Candidates

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

If any of our product candidates receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. For example, current cancer treatments like chemotherapy and radiation therapy are well established in the medical community, and doctors may continue to rely on these treatments to the exclusion of our product candidates. In addition, physicians, patients and third-party payors may prefer other novel products to ours. If our product candidates do not achieve an adequate level of acceptance, we may not generate significant product revenues and we may not become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

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

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. Patient identification will be important in the commercial setting, much as it has been important in the clinical trial setting. For example, our proprietary work suggests that there are approximately 1,500-5,000 eligible advanced cancer patients addressable each year in the United States for larotrectinib. Estimates for addressable patient populations relevant to our other product candidates are also uncertain. The work that informs these estimates is not definitive and future analyses may lead to estimates that are higher or lower than these estimates, making difficult the tasks of sizing of a marketing and sales force or evaluating the attractiveness of a commercial partnership. The utilization of sensitive diagnostic testing in routine clinical practice is likely an important variable in identifying all of the eligible patients that may truly exist. This requirement may cause the potential launch of larotrectinib to be slower than other commercialized oncology products.

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. Capable managers with commercial experience will need to be identified and successfully recruited to the company. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of any of our products that we obtain approval to market. With respect to the commercialization of all or certain of our product candidates, we may choose to collaborate, either globally or on a territory-by-territory basis, with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. If we are unable to enter into such arrangements when needed on acceptable terms or at all, we may not be able to successfully commercialize any of our product candidates that receive regulatory approval or any such commercialization may experience delays or limitations. If we are not successful in commercializing our product candidates, either on our own or through collaborations with one or more third parties, our future product revenue will suffer and we may incur significant additional losses.

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

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

Specifically, there are a large number of companies developing or marketing treatments for cancer, including many major pharmaceutical and biotechnology companies. In addition, many companies are developing cancer therapeutics that work by inhibiting multiple kinases that may directly compete with larotrectinib and our other product candidates.

For larotrectinib and LOXO-195, examples of such potential competitors include Daiichi Sankyo and its subsidiary Plexxikon (PLX-7486), Tesaro (TSR-011), Ignyta (entrectinib), Novartis AG (dovitinib), Mirati (MGDC516), Ono Pharmaceutical (ONO-4474 and ONO-5390556), Chugai Pharmaceutical, a member of the Roche Group (CH7057288), Blueprint Medicines, TP Therapeutics (TPX-0005) and Deciphera.

For LOXO-292, examples of such potential competitors include Eisai (lenvatinib), Exelixis (cabozantinib), AstraZeneca (vandetanib), Ariad (ponatinib), Novartis (dovitinib), Roche (alectinib), Pfizer (sunitinib), Ignyta (RXDX-105) and Blueprint Medicines (BLU-667).

For LOXO-305, examples of such potential competitors include Abbvie/Pharmacyclics (ibrutinib), AstraZeneca/Acerta (acalabrutinib), Beigene (BGB-3111), Gilead/Ono (GS-4059), ArQule (ARQ-531), Sunesis (SNS-062), Biogen (BIIB-068), Celgene (CC-292), Principia (PRN1008, PRN2246), Bristol-Myers Squibb (BMS-986142), Genentech (GDC-0853), Roche (RN983) and Impetis (PNQ-154).

For the FGFR program, examples of such potential competitors 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) and Principia (PRN1371).

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 or slow our regulatory approval. In addition, our ability to compete may be affected in many cases by insurers or other third-party payors seeking to encourage the use of generic products. Generic products are currently on the market for the indications that we are pursuing, and additional products are expected to become available on a generic basis over the coming years. If our product candidates achieve marketing approval, we expect that they will be priced at a significant premium over competitive generic products.

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

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 (“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. In 2016, the U.S. Congress held hearings on the rising costs of prescription drugs, and there is increased media attention on the issue. Future legislation could potentially change drug pricing dynamics. 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.

If insurance reimbursement to the laboratories who purchase the companion diagnostic tests is inadequate, utilization may be low, and patient tumors may not be comprehensively screened for the presence of the genetic markers that predict response to our product candidates.

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

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

- decreased demand for any product candidates or products that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- 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, exclusive worldwide licenses for all therapeutic indications for new intellectual property developed in our Array collaboration, and patents that we purchased from Redx. This patent portfolio includes issued patents and pending patent applications covering compositions of matter and methods of use.

The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. We may choose not to seek patent protection for certain

innovations and may choose not to pursue patent protection in certain jurisdictions, and under the laws of certain jurisdictions, patents or other intellectual property rights may be unavailable or limited in scope. It is also possible that we will fail to identify patentable aspects of our discovery and preclinical development output before it is too late to obtain patent protection. Moreover, in some circumstances, we do not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from third parties. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business.

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

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 (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 ("U.S. PTO") 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. 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, which 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, exclusive worldwide licenses for all therapeutic indications for new intellectual property developed in our Array collaboration, and patents that we purchased from Redx. 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.

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 September 30, 2017, had 47 full-time employees. We are highly dependent on the research and development, clinical and business development expertise of Joshua H. Bilenker, M.D., our President and Chief Executive Officer, as well as the other principal members of our management, scientific and clinical team. Although we have entered into employment letter agreements with our executive officers, each of them may terminate their employment with us at any time. We do not maintain "key person" insurance for any of our executives or other employees.

Recruiting and retaining qualified scientific, clinical, manufacturing and sales and marketing personnel will also be critical to our success as we scale. 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 development or commercialization strategies. 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. A severe or prolonged economic downturn 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.

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 September 30, 2017, 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 slightly less than a majority 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.

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 September 30, 2017, there were 605,226 shares of our common stock available for future grant under our 2014 Equity Incentive Plan. Additionally, as of September 30, 2017, there were outstanding options to purchase up to 3,246,018 shares of our common stock. Any future grants of options, warrants or other securities exercisable or convertible into our common stock, or the exercise or conversion of such shares, and any sales of such shares in the market, could have an adverse effect on the market price of our common stock.

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

Our stock price is likely to be volatile. The stock market in general and the market for smaller biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of the underlying companies. As a result of this volatility, the market price of our common stock may fall. 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.

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 ("the JOBS Act") and may remain an emerging growth company for up to five years. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure;
- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We have taken advantage of reduced reporting burdens. In 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 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 ("Section 404") we are required to furnish a report by our management on our internal control over financial reporting at the end of each fiscal year. This assessment includes disclosure of any material weaknesses identified by our management in our internal control over financial reporting. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting that results in more than a reasonable possibility that a material misstatement of annual or interim financial statements will not be prevented or detected on a timely basis. However, because we are an emerging growth company, we have not been required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. We will be required to include this attestation report in our Annual Report on Form 10-K the year ended December 31, 2017.

To achieve compliance with Section 404, we have been engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we have dedicated and 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, 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 ("NOLs") and other pre-change tax attributes (such as research tax credits) to offset its post-change income or taxes may be limited. It is possible that we may have triggered an "ownership change" limitation. We may also experience ownership changes in the future as a result of subsequent shifts in our stock ownership (some of which are outside our control). As a result, if we earn net taxable income, our ability to use our pre-change NOL carryforwards to offset U.S. federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed.

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

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

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

Not applicable.

ITEM 3: DEFAULTS UPON SENIOR SECURITIES

Not applicable.

ITEM 4: MINE SAFETY DISCLOSURES

Not applicable

ITEM 5. OTHER INFORMATION

None.

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
10.1*†	Agreement for the Assignment of Patents and other Rights and for the Novation of Certain Agreements, including for Product Manufacturing by and among the Registrant, Redx Pharma Plc and Redx Oncology Limited, dated July 28, 2017.
10.2*†	Assignment by and among the Registrant, Redx Pharma Plc and Redx Oncology Limited, and the individuals acting as Administrators, dated July 29, 2017.
31.1*	Certification of the Principal Executive Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of the Principal Financial Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
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.

† Portions of this exhibit have been omitted based on an application for confidential treatment submitted to the SEC. The omitted portions of this exhibit have been filed separately with the SEC.

(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.

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: November 2, 2017

LOXO ONCOLOGY, INC.

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

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: November 2, 2017

LOXO ONCOLOGY, INC.

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

Exhibit 10.1

EXECUTION VERSION

Date: 28 July 2017

REDX PHARMA PLC and REDX ONCOLOGY LIMITED (both in administration)
c/o FRP Advisory LLP

AND

JASON BAKER and **MILES NEEDHAM** both of FRP Advisory LLP

AND

LOXO ONCOLOGY, INC.

Agreement for the Assignment of Patents and other Rights and for the Novation of certain Agreements, including for Product Manufacturing

Fieldfisher Riverbank House 2 Swan Lane London EC4R 3TT

Contents

THIS AGREEMENT made the 28 day of July 2017

BETWEEN:

(1) **REDX PHARMA PLC** and **REDX ONCOLOGY LIMITED** (both in administration) c/o FRP Advisory LLP, 110 Cannon Street, London, EC4N 6EU, UK (together "**REDX**");

(2) **JASON BAKER** and **MILES NEEDHAM** both of FRP Advisory LLP, 110 Cannon Street, London, EC4N 6EU, UK (together "**Administrators**"); and

(3) **LOXO ONCOLOGY, INC.** a corporation whose offices are at 281 Tresser Boulevard, 9th Floor Stamford, CT 06901, USA ("**LOXO**");

together the "**Parties**" and each a "**Party**".

BACKGROUND:

(A) On 24 May 2017, the Administrators were appointed as administrators of REDX.

(B) REDX is willing to assign the rights it has in its BTK program, which rights are defined below as "**Assigned Rights**".

(C) LOXO is interested in acquiring Assigned Rights and REDX and the Administrators have agreed to assign the Assigned Rights in consideration of the sum of US$40M, on the terms of this Agreement.

(D) LOXO have also agreed to novate certain agreements entered into by REDX on the terms of certain novation agreements attached hereto.

IT IS AGREED:

1. **Definitions and Interpretation**

1.1 Unless the context otherwise requires, the following words and expressions shall have the following meanings in this agreement ("**Agreement**") and in any Recitals and Schedules to it:

Expression	Meaning
Asset Information	means any Confidential Information relating to the Assigned Rights and/or the Data Package.
Assigned Rights	means such of the following rights as are held by REDX: (a) the Patents; and (b) Intellectual Property Rights in the Data Package;
BTK	Bruton's tyrosine kinase (Uniprot # Q06187)
Confidential Information	all commercial, financial, technical or other information of a confidential or proprietary nature (including know-how, trade

	secrets, formulae, processes, ideas and inventions, specifications, designs, financial or business information, customer details, market research and pricing strategies) in any form whatever, whether or not: (a) labelled or otherwise identified as confidential; and/or (b) belonging to a Party or any Third Party.
Data Package	means documents, product samples and other materials identified as categories 1 to 4 in Schedule 2, each a "**Category**" identified in this Agreement as "**Category 1**" etc., where "documents", as used in this definition, shall include the following types of documents in each case solely to the extent they exist and their content relates to the REDX BTK Program, as noted in Schedule 2 (it being understood that, if documents include content which is not created solely in relation to the REDX BTK Program, then the latter shall be redacted before they are made available to LOXO, where reasonably possible): • the results of all trials or tests undertaken by or on behalf of REDX and analyses of those results; • pre-clinical test reports and all clinical or other test or trial results; • laboratory notebooks; • regulatory documents; and • documentation related to the Patents;
Effective Date	means the date of this Agreement, as stated above;
Intellectual Property	means all intellectual property of whatever nature including all patents, utility models, database rights, copyright (including copyright in software and computer algorithms), trade secrets and other confidential information, know-how, and all other intellectual and industrial property and rights of a similar or corresponding nature in any part of the world, whether registered or not or capable of registration or not and including the right to apply for and all applications for any of the foregoing rights, the right to claim priority, the right to sue for past infringements and common law or equitable remedies in respect of any of the foregoing rights, and any renewals, extensions or restorations, and divisional, continuation and reissued applications of the foregoing rights, together with rights to sue for unfair competition or for passing off, including in respect of past activities (and "**Intellectual Property Rights**" means rights, title and interest in such Intellectual Property);

Novated Contracts	means the [***] Agreement, the [***] Agreement and the [***] Agreement, and associated Purchase Orders, as each are identified in schedule 1 to each of the Novation Agreements included in Schedule 3.
Novation Agreements	means the novation agreements or any of them in the form set out in Schedule 3;
Patents	any and all of the patents and patent applications (including applications in draft form, if any, and any and all rights to file patent applications) existing as of the Effective Date and relating to the REDX BTK Program, including those referred to in Schedule 1, including any PCT applications (including national phases thereof), divisionals, continuations, continuations in part, patents issuing therefrom, including extensions (such as patent term extensions), reissues, re-examinations, and any supplementary protection certificates allowed on the foregoing;
Product	means the product to be manufactured pursuant to the Novated Contracts;
Purchase Price	shall have the meaning given in Clause 5.1; and
REDX BTK Program	means REDX's research program for the development of small molecules each of which has an intended primary mode of action as a BTK inhibitor, including the drug candidate known as "RXC005".

1.2 In this Agreement (except where the context otherwise requires):

(a) any reference to "REDX" shall be construed as a reference to each entity comprising REDX and any obligation, undertaking or liability of REDX shall be an obligation, undertaking or liability of each such entity on a joint and several basis;

(b) any phrase introduced by the terms "including", "include", "in particular" or any similar expression will be construed as illustrative and the words following any of those terms will not limit the sense of the words preceding those terms;

(c) the headings are included for convenience only and will not affect the construction and interpretation of this Agreement;

(d) references to a company shall include any company, corporation or other body corporate, wherever and however incorporated or established;

(e) use of the singular includes the plural and vice versa;

(f) reference to a Party includes its successors and permitted assigns;

(g) any reference to "persons" includes natural persons, firms, partnerships, bodies corporate and corporations, associations, organisations, governments, states, foundations, trusts and other unincorporated bodies (in each case whether or not incorporated and whether or not having a separate legal personality);

(h) any reference to a Recital, Clause or Schedule is to the relevant recital or clause of or schedule to this Agreement and any reference to a sub-clause or paragraph is to the relevant sub-clause or paragraph of the Clause or Schedule in which it appears; and

(i) the Schedules form part of this Agreement and will have effect as if set out in full in the body of this Agreement.

2. **Intellectual Property Rights Assignment; Delivery**

2.1 In consideration for the sums payable in accordance with Clause 5.1, REDX hereby assigns to LOXO absolutely whatever rights, title and interest it has in and to the Assigned Rights including:

(a) in respect of any and each application in the Patents:

(i) the right to claim priority from and to prosecute and obtain grant of patent; and

(ii) the right to file divisional applications based thereon and to prosecute and obtain the grant of patent on each and any such divisional application;

(b) in respect of each and any invention disclosed in the Patents, the right to file an application, claim priority from such application, and prosecute and obtain grant of patent or similar protection in or in respect of any country or territory in the world, including supplementary protection certificates and patent term extensions;

(c) the right to extend to or register in or in respect of any country or territory in the world each and any of the Patents, and each and any of the applications comprised in the Patents or filed as aforesaid, and to extend to or register in, or in respect of, any country or territory in the world any patent or like protection granted on any of such applications;

(d) the absolute entitlement to any Patents granted pursuant to any of the applications comprised in the Patents or filed as aforesaid;

(e) the right to bring, make, oppose, defend, appeal proceedings, claims or actions and obtain relief (and to retain any damages recovered) in respect of any infringement, or any other cause of action arising from ownership, of any of the Patents or any Patents granted on any of the applications in the Patents or filed as aforesaid, whether occurring before on or after the date of this Agreement;

(f) the unfettered right to use or allow others to use in any manner the Data Package and/or any components thereof.

2.2 REDX hereby undertakes to provide the Data Package in stages, within the due dates set forth in the applicable column of Schedule 2, and otherwise as follows, subject to LOXO meeting its obligations in sub-clauses (c) and (d) below, as applicable:

(a) unrestricted access to the documents in Category 1 shall be provided by changing the access controls in the data room to allow LOXO to download copies (redacted copies will remain redacted, provided that the redacted information which relates to the REDX BTK Program is readily available in other documents in Category 1 provided to LOXO as set forth in this Clause 2.2(a));

(b) unrestricted access to the documents in Category 3 and 4 shall be provided electronically via a system agreed between LOXO and REDX;

(c) product samples and materials in Categories 2, 3 and 4 shall be supplied at the cost of LOXO to an address or addresses supplied by LOXO and via a courier arranged by LOXO. LOXO may alternatively request that samples or some of them be destroyed, again, at the cost of LOXO. If LOXO fails to elect for delivery or destruction of samples or to provide the courier and appropriate address instructions, REDX shall destroy the samples by the date that is sixty (60) days from the Effective Date for Categories 2 and 3, and eight (8) months from the Effective Date for Category 4 and shall invoice LOXO the reasonable costs of that destruction. All invoices payable by LOXO in respect of delivery or destruction of samples shall be paid within thirty (30) days of their date;

(d) REDX and LOXO shall engage in discussions on the content and provision of documents and materials in Category 4. LOXO shall indicate a list of priorities for granting access of documents and supply of materials included in Category 4, and REDX shall use commercially reasonable endeavors to supply documents and materials in Category 4 in accordance with the terms of this Agreement and in accordance with the discussions with LOXO. If despite REDX's endeavours in accordance with this Clause 2.2(d), the making available of documents or provision or destruction of materials in Category 4 are not completed within six (6) months of the Effective Date, the Parties may agree by mutual consent (both parties acting reasonably) a further long stop date by which REDX shall complete this task. For the avoidance of doubt, LOXO may take such action as it considers necessary to protect or enforce its rights under this Agreement (including, in respect to REDX's breach of the delivery obligations set out in this Clause 2).

2.3 At Loxo's request, a director of REDX, (with, if REDX remains in administration, consent to exercise such a management power from the Administrators (such consent hereby granted and acknowledged)), shall confirm in writing when REDX believes (acting reasonably) that it has completed its obligations in relation to the supply or making available (as applicable) of any and all assets included in the Data Package in the form set out in Schedule 5 ("**Confirmation**"), and separately will provide a confirmation in writing at the expiry of 8 (eight) months that it has complied with its destruction obligations, it being understood that REDX shall not retain (and shall destroy) any and all copies of such assets except as provided in the next sentence. Notwithstanding the foregoing, the Parties acknowledge and agree that REDX shall retain any laboratory notebooks included in the Data Package in their original form, provided that (i) REDX shall implement commercially reasonable measures to restrict access to the foregoing to REDX's then-current CEO and CSO and IT manager, (ii) REDX shall cause its CEO and CSO and IT manager to (a) use the foregoing solely to the extent necessary to respond to LOXO's requests and (b) not to disclose the foregoing to any other person (whether within the members of its group our outside such group) for any reason (save as required to do so by law, regulation or order of a competent authority, in which case REDX shall use reasonable endeavours to give

LOXO reasonable advance notice of such required disclosure in order to enable LOXO to prevent or limit such disclosure to the extent legally permissible).

2.4 On the Effective Date, REDX shall deliver to LOXO a release of the Assigned Rights (in a form previously agreed with LOXO) from the security registered in favour of Liverpool City Council.

3. **Assigned Rights Obligations, Further Assurance and Wrong Pockets**

3.1 REDX and the Administrators (whilst they remain in office) shall, at LOXO's cost (such costs to be reasonable), perform (or procure the performance of) all further acts and things, and execute and deliver (or procure the execution or delivery of) all further documents required by law or which LOXO reasonably requests to vest in LOXO the full benefit of the right, title and interest which are assigned to LOXO under this Agreement, including:

(a) executing immediately after exchange and completion of this Agreement a confirmatory patent assignment for the Patents (to the extent LOXO has rights in them) in the form attached as Schedule 4, it being understood that Clause 6 and Clauses 7.2 and 7.3 of this Agreement shall apply to such patent assignment, notwithstanding anything to the contrary set forth therein; and

(b) assisting LOXO in obtaining, defending and enforcing the Intellectual Property Rights, to the extent REDX has rights in them, and assisting with any other proceedings which may be brought by or against LOXO against or by any third party relating to the rights assigned by this Agreement, in each case if REDX's assistance is reasonably necessary.

3.2 If, after the Effective Date, LOXO and REDX (acting reasonably) both believe that there is an asset owned or used by REDX that was intended to be included in the Data Package and therefore to be assigned to LOXO on or after the Effective Date under this Agreement (a "**Wrong Pockets Asset**"), REDX shall (and shall procure that the other members of its group shall), at LOXO's cost (such costs to be reasonable), as soon as reasonably practicable:

(a) do all such reasonable things and/or execute all such documents as necessary to transfer the Wrong Pockets Asset to LOXO (and REDX does hereby transfer to LOXO) for no further consideration and pending such transfer, the Wrong Pockets Asset shall be held on trust for LOXO; or

(b) if the relevant Wrong Pockets Asset cannot lawfully be so transferred, do all such reasonable things and/or execute all such documents as reasonably necessary to grant to LOXO (and REDX does hereby grant to LOXO) a royalty free, perpetual, assignable, irrevocable, worldwide licence (with a right to sub-licence through multiple tiers) to use the Wrong Pockets Asset.

4. **Novation**

4.1 Insofar as any Novated Contracts cannot effectively be assigned by REDX to LOXO except by a novation agreement or with the agreement or consent of any third party and such novation, agreement or consent has not taken place or been obtained at or prior to completion of this Agreement:

(a) LOXO and REDX shall, at LOXO's expense, use all reasonable endeavours to procure that such agreement or consent is obtained as promptly as reasonably practicable, and that agreements novating any Assumed Contract are entered into on the terms set out in the Novation Agreements set out in Schedule 3.

4.2 Unless and until such Novated Contracts shall be novated or assigned, REDX shall, at LOXO's option:

(a) hold them in trust, insofar as it is legally able to do so, for LOXO absolutely and LOXO shall (if sub-contracting is permissible and lawful) as REDX's sub-contractor perform all REDX's obligations under them.

(b) give LOXO the benefit of them to the same extent as if they had been novated or assigned and act under the reasonable direction of LOXO and account to LOXO accordingly, provided that REDX and the Administrators shall have no liability to LOXO in respect of any of them arising out of or in connection with their performance, termination, variation or amendment by LOXO after completion of this Agreement, and any acts undertaken by REDX shall be at LOXO's reasonable expense.

4.3 In addition, REDX shall at Loxo's expense and where requested by Loxo make introductions to specified past suppliers of goods and services to REDX in relation to the REDX BTK Program and, where REDX has contractual rights to the requested information or assistance, use reasonable endeavours to leverage such rights to obtain and otherwise facilitate the flow of information between LOXO and the applicable supplier.

4.4 REDX shall execute novation agreements substantially in the form of the novation agreements in Schedule 3 and which are notified by LOXO in writing and are in respect of other contracts with third party suppliers which relate solely to the REDX BTK Program. The provisions of Clauses 4.1 and 4.2 shall apply mutatis mutandis to contracts so notified by LOXO from time to time.

5. **Purchase Price**

5.1 Upon the Effective Date, LOXO's English solicitors shall pay to REDX's English solicitors the sum of $US40M (forty million US dollars) plus any applicable VAT and stamp duty taxes ("**Purchase Price**") in immediately available funds to the following account, in consideration for the assignment of REDX's interest in the Assigned Rights:

Bank	[***]
Branch	[***]
Address	[***]
Sort code	[***]
Swift code (for Clients abroad)	[***]
Account Number	[***]
Bank Identifier code (BIC)	[***]

International Bank A/C no (IBAN)	[***]
Account name	[***]

6. **No Representations or Warranties etc**

6.1 All representations (whether made innocently, negligently or otherwise but not fraudulently), warranties, undertakings, conditions and stipulations, express or implied, statutory, customary or otherwise in respect of the Assigned Rights or Novated Contracts, or any of the rights, title and interests transferred or agreed to be transferred or novated pursuant to this Agreement are expressly excluded (including warranties and conditions as to title, quiet possession, freedom from third party rights or claims, and freedom to manufacture, import, market, promote and sell any product including the Products or any other activity in relation to the Products or any other product, and the likelihood of patent applications proceeding to grant and freedom of patent applications from opposition proceedings and any patents from invalidity proceedings, and as to the enforceability of any contractual obligations).

6.2 Unless otherwise required by law (and then only to that extent) REDX and the Administrators and each of them shall not be liable for any loss or damage of any kind whatever, consequential or otherwise arising out of or due to or caused by any defect or deficiencies in any of the Assigned Rights or Novated Contracts.

6.3 LOXO agrees that the terms and conditions of this Agreement and the exclusions and limitations contained in it are fair and reasonable having regard to the following:

(a) that this is a sale by an insolvent company in circumstances where it is usual that no representations and warranties can be given by or on behalf of REDX or the Administrators;

(b) that LOXO has relied solely upon LOXO's own opinion and/or professional advice concerning the Assigned Rights and the Novated Contracts, including as to the enforceability of any of the rights in, under or pursuant to them, freedom from third party rights or claims, and freedom to manufacture, import, market, promote or sell any product including the Products or any other activity in relation to the Products or any other product, and the likelihood of patent applications proceeding to grant and freedom of patent applications from opposition proceedings and any patents from invalidity proceedings, and as to the enforceability of any contractual obligations;

(c) that LOXO has agreed to purchase the rights of REDX in the Assigned Rights and to enter into the Novation Agreements in respect of the Novated Contracts "as seen" in their present state and condition for a consideration which takes into account the risk to LOXO represented by the parties' belief that the exclusions and limitations contained in this Agreement are or would be recognised by the courts; and

(d) that LOXO, its servants, employees, agents, representatives and advisers have been given every opportunity it or they may wish to have to give all due consideration to all or any of the rights of REDX in the Assigned Rights and the Novated Contracts and all

relevant documents relating to them and to obtain information from REDX and/or the Administrators relating to the Assigned Rights and the Novated Contracts.

6.4 LOXO agrees that neither REDX nor the Administrators shall incur any liability to it by reason of any fault or defect in or in title or otherwise of any or all of the Assigned Rights or the Novated Contracts.

6.5 LOXO acknowledges for the avoidance of doubt that if REDX does not have title or unencumbered title to any or all of the Assigned Rights or rights under the Novated Contracts or if LOXO cannot exercise any right conferred or purported to be conferred on it by this Agreement or the Novation Agreements, this shall not be a ground or grounds for rescinding, avoiding or varying any or all of the provisions of this Agreement or the Novation Agreements and shall not give rise to any claim to compensation or damages or a reduction in or repayment of the Purchase Price or sums payable by LOXO pursuant to the Novation Agreements.

6.6 In respect of claims against REDX only, and not the Administrators, the exclusions and limitations set out in clause 6.1, 6.2, 6.3 and 6.4 shall not apply to clause 2.3 of this Agreement or to the Confirmation issued pursuant to that clause.

7. **Relationship of the Parties**

7.1 Nothing in this Agreement, and no action taken by the Parties pursuant to this Agreement, shall constitute, or be deemed to constitute, a partnership between the Parties, or shall constitute either Party as the agent, employee or representative of the other.

7.2 The Administrators are a party to this Agreement in their own capacity solely for receiving and enforcing the obligations, undertakings and waivers on the part of LOXO. The Administrators have entered into and signed this Agreement as agent for and on behalf of REDX and the Administrators, their firm, employees and agents shall incur no personal liability whatsoever whether on their own part or in respect of any failure on the part of REDX to observe perform or comply with any such obligations hereunder (including the provision of the Confirmation) or under or in relation to any associated arrangements or negotiations whether such liability would arise under the Insolvency Act 1986 or otherwise.

7.3 The Parties acknowledge that the liability (i) under this Agreement of REDX and that of the Administrators; and (ii) under the Confirmation of REDX, (whether given during or after the period of administration), shall constitute an expense of the administration (within the meaning of rule 3.51 of the Insolvency Rules 2016) and shall have the ranking conferred by paragraph 99(4) of Schedule B1 of the Insolvency Act 1986. However, as to ranking, LOXO agrees that any claim it may make in respect of any such liability will be subordinated to and will rank in order of priority below each of the expenses of the administration listed in Rule 3.51(2) of the Insolvency Rules 2016 and for sake of clarity LOXO agrees that the Administrators may, no earlier than 30 calendar days from the Effective Date (such restriction shall not apply in respect of the payment of secured, preferential and administration expense creditors), pay ahead of LOXO (and with no recourse from LOXO) all unsecured creditors of REDX that exist on the Effective Date and owe no duty to LOXO to protect the value of the charged assets after their appointment ceases.

7.4 The Parties acknowledge that following the Effective Date, the Administrators intend to exit administration and return REDX to the control of its directors. The Administrators agree that prior to the earlier of (i) the date on which the Confirmation (as defined in Clause 2.3) is given

pursuant to Clause 2.3 above; and (ii) the date falling 12 (twelve) weeks from the Effective Date, they shall not file the appropriate form with Companies House and/or the court to terminate the administration. The Parties further agree that the terms of this Agreement shall be binding on REDX following its exit from administration and (to the extent necessary) on any and all successors to the Administrators (including any subsequently appointed liquidators).

7.5 The rights and remedies of LOXO, REDX and the Administrators under this Agreement are cumulative and not exclusive of any rights and remedies provided by law, and all such rights and remedies may be enforced separately or concurrently with any other right or remedy. No failure to exercise or delay in exercising any right or remedy shall constitute a waiver of that right or remedy. No single or partial exercise of any right or remedy, and no waiver of any right or remedy, shall prevent or restrict the further exercise of that or any other right or remedy. Any waiver of any right or remedy shall be effective only if it is made in writing, expressly states that it is a waiver of the relevant right or remedy and is duly executed by or on behalf of LOXO, REDX and/ or the Administrators (as applicable) by an authorised representative.

8. **Notices**

8.1 Any notice or other communication required to be given under this Agreement or in connection with the matters contemplated by it shall, except where otherwise specifically provided, be in writing in the English language and shall be addressed as provided in Clause 8.2 and may be:

(a) personally delivered, in which case it shall be deemed to have been given upon delivery at the relevant address; or

(b) if within the United Kingdom, sent by pre-paid and registered or recorded post, in which case it shall be deemed to have been given on the date of signed receipt at the relevant address; or

(c) sent by a recognised courier service, when it shall be deemed to have been given on the date of the signed receipt at the relevant address;

8.2 The relevant addresses of each of the Parties for the purposes of Clause 8.1 shall be the following, subject to Clause 8.3:

LOXO

Position/ Name: Jacob S. Van Naarden (Chief Business Officer)

Address: 281 Tresser Boulevard, 9th Floor, Stamford, CT 06901, USA

REDX

Position/ Name: [***] (Head of Research & Operations) & [***] (Non-Executive Chairman)

Address: Block 33, Mereside, Alderley Park, Macclesfield, SK10 4TG

ADMINISTRATORS

Position/ Name: Jason Baker & Miles Needham (Administrators)

Address: FRP Advisory LLP, 110 Cannon Street, London, EC4N 6EU

8.3 Any Party to this Agreement may notify the other Parties in accordance with this Clause of any change to its address specified in Clause 8.2 or other details, provided that such notification shall only be effective on the date specified in such notice or five days after the notice is given, whichever is later.

9. **Confidentiality**

9.1 Each Party (the "**Receiving Party**") undertakes to keep confidential any Confidential Information directly or indirectly belonging or relating to any other Party (the "**Disclosing Party**") and disclosed by or on behalf of the Disclosing Party to the Receiving Party.

9.2 The obligations contained in this Clause 9 shall survive the expiry or termination of this Agreement for any reason, but shall not apply to any Confidential Information, other than Asset Information, which Disclosing Party and/or received or learned by the Receiving Party pursuant to or in the course of this Agreement (including through their presence at the other Parties premises) and which:

(a) is publicly known at the time of disclosure to the receiving Party; or

(b) becomes publicly known otherwise than through a breach of this Agreement by the receiving Party, its officers, employees or professional advisers or any other person to whom the receiving Party discloses Confidential Information (whether or not in breach of this Agreement); or

(c) can be proved by the Receiving Party to have reached it otherwise than by being communicated by or at the request of the Disclosing Party including:

(i) being known to it prior to disclosure; or

(ii) having been developed by or for it wholly independently of the other Party; or

(iii) having been obtained from a Third Party without any restriction on disclosure on such Third Party; or

(d) is required by law, regulation or order of a competent authority (including any regulatory or governmental body or securities exchange) to be disclosed by the receiving Party, provided that, where permitted by law and regulation, the Disclosing Party is given reasonable advance notice of time, place and content of the intended disclosure, giving the opportunity to the Disclosing Party to object to the necessity of the disclosure or any of it. The receiving Party shall, to the extent permitted by law and regulation, comply with any reasonable request of the Disclosing Party in connection with any such disclosure.

9.3 Notwithstanding any other provision of this Clause 9, the Parties agree that on and from the Effective Date LOXO shall not have any confidentiality obligations with respect to Asset Information, which Asset Information shall be deemed LOXO's Confidential Information.

10. **Non-Compete**

10.1 During the period commencing on the Effective Date and ending on the third (3rd) anniversary thereof, REDX and its affiliates will not, directly or indirectly, either alone or with a third party or by assisting any third party, (i) conduct research or development of Competing Products, or manufacture or commercialize, a pharmaceutical product that is known by REDX and its affiliates to be a Competing Product, or (ii) conduct a drug discovery or other research program the goal of which is to identify Competing Products. "Competing Product" means any product that includes, as an active pharmaceutical ingredient, a small molecule agent that is developed with an intended primary mode of action as a BTK inhibitor.

10.2 If REDX shall breach the provisions of Clause 10.1 and applies for patents resulting from the activities comprised in the breach or for patents of any Competing Product and which arise from the use of information comprised in the Data Package then REDX shall assign all rights, title and interest that it has to those patent applications to LOXO.

10.3 The Parties acknowledge that damages may not be an adequate remedy for any breach of this Agreement and LOXO shall be entitled to seek the remedies of injunction, specific performance and any other equitable remedy for any threatened or actual breach of this Agreement.

11. **Variation**

11.1 No variation of or amendment to this Agreement shall bind any Party unless made in writing and signed by all Parties.

12. **Announcements**

12.1 The Parties shall not make any press statement, circular or other public announcement in connection with this Agreement without the prior written approval of the text of such statement or announcement by each other (such consent not to be unreasonably withheld or delayed). Once any such statement, circular or announcement is so approved, either Party may make subsequent public disclosure of the content thereof without the further approval of the other Party. Notwithstanding the foregoing, to the extent a public disclosure is required by law (including the requirements of any nationally recognized securities exchange, quotation system or over-the-counter market on which such Party has its securities listed or traded or pursuant to the Insolvency Act 1986) the disclosing Party may make such disclosure without consent of the other Party, provided that (to the extent such disclosure was not previously approved by the other Party) the disclosing Party shall make good faith efforts to provide the other Party with notice beforehand and to coordinate with the other Party with respect to the wording and timing of any such disclosure.

12.2 The Parties covenant and undertake not to make any derogatory or disparaging comments or remarks (verbally or in writing, publicly or otherwise) with respect to any other Party, the Assigned Rights or the subject matter of this Agreement.

13. **Law and Jurisdiction**

13.1 This Agreement and any dispute or claim arising out of or in connection with it or its subject matter or formation, including any question regarding its existence, validity or termination, (including non-contractual disputes or claims) (**"Dispute"**) shall be governed by and construed in accordance with the laws of England.

13.2 Disputes shall be referred to the courts of England and which shall have exclusive jurisdiction to settle any Dispute.

13.3 This Clause 13 shall be without prejudice to either Party's rights to at any time seek interim relief from the courts to protect their confidential information, or their rights or assets.

13.4 LOXO irrevocably appoints TMF Global Services (UK) Limited of 6 St. Andrew Street, 5th Floor, London, EC4A 3AE as its agent for service of process in any proceedings in the courts of England arising out of or in connection with this Agreement and agrees that failure by its process agent to notify it of such service shall not affect the validity of such service. If its process agent is or becomes unable or unwilling for any reason to act as agent for service of process in England, LOXO shall promptly appoint another process agent who is able and willing so to act and notify the other Parties in writing of the new process agent's name and address. If its process agent moves to a new address within England, LOXO shall promptly notify the other Parties of its process agent's new address.

14. **Entire Agreement**

14.1 This Agreement and the Novation Agreements constitute the entire agreement between the Parties relating to their subject matter and supersede any and all previous agreements (whether written or oral) between the Parties or any of them relating to that subject matter, including, for the avoidance of doubt, the confidentiality agreements entered into between (i) the Parties dated on or around 2 June 2017; (ii) the Parties and Fish & Richardson P.C. dated on or around 21 June 2017; and (iii) the Parties and [***] dated on or around 17 July 2017. Each Party agrees that all representations made (innocently or negligently) by or on behalf of any other Party (or relied on by it) in relation to the subject matter of this Agreement are excluded. Each Party agrees that it shall have no claim for innocent or negligent misrepresentation or negligent misstatement based on any statement expressly set out in this Agreement. Nothing in this Clause 14 however, shall limit or reduce any liability of any person except to the extent permitted by law.

14.2 If any provision of this Agreement is void or unenforceable by reason of any provision of applicable law, such provision will be deemed to be modified to the extent necessary to render it legal, valid and enforceable. If no such modification is possible, it will be deleted and the remaining provisions of this Agreement will continue in full force and effect and, if necessary, be so amended as is necessary to give effect to the spirit of this Agreement so far as possible.

14.3 This Agreement may be executed in any number of counterparts, and by the Parties on separate counterparts, but will not be effective until all the Parties have executed at least one counterpart. All the counterparts will together constitute one and the same instrument and each counterpart will constitute an original of this Agreement.

15. **Rights of third parties**

15.1 Other than the Administrators' firm and its employees and agents enforcing their rights pursuant to Clause 7.2, no term of this Agreement shall be enforceable by a person who is not a Party to this Agreement.

THIS AGREEMENT has been entered into on the date stated at the beginning of this Agreement.

SIGNED for and on behalf of **REDX PHARMA PLC** (in administration):

/s/ Jason D. Baker
Signature

Jason D. Baker
Printed name

Administrator
Title

28.7.17
Date

SIGNED for and on behalf of **REDX ONCOLOGY LIMITED** (in administration):

/s/ Jason D. Baker
Signature

Jason D. Baker
Printed name

Administrator
Title

28.7.17
Date

SIGNED by one **ADMINISTRATOR** for and on behalf of both of them:

/s/ Jason D. Baker
Signature

Jason D. Baker
Printed name

Administrator
Title

28.7.17
Date

SIGNED for and on behalf of **LOXO ONCOLOGY, INC.**:

/s/ Joshua H. Bilenker
Signature

Joshua H. Bilenker
Printed name

CEO
Title

July 28, 2017
Date

Schedule 1: Patents

Subject	Country	Application Number	Filing date	Status	Grant date	Expiry date*	Publication Number
[***]	[***]	[***]	[***]	[***]			
[***]	[***]	[***]	[***]	[***]			
	[***]	[***]	[***]	[***]			[***]
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[***]	[***]	[***]	[***]	[***]			
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	[***]	[***]	[***]	[***]	[***]

* Expiry date does not take into account any potential extension or termination of term (e.g., patent term adjustment or the filing of terminal disclaimers)

Schedule 2: Data Package

	Category 1 RXC005 specific Due Date: [***]	Category 2 RXC005 specific Due Date: [***] from the Effective Date	Category 3 RXC005 specific Due Date: [***] from the Effective Date	Category 4 Other BTK inhibitors Due Date: [***]from the Effective Date	N/A Does not exist
• [***]					
○ [***]	[***]				
○ [***]	[***]				
• [***]					
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Schedule 3: Novation Agreements

Schedule 3A

[***] Novation Agreement

THIS DEED is made the [ ] day of [ ] 2017

BETWEEN:

(1) **REDX PHARMA PLC** and **REDX ONCOLOGY LIMITED** (both in administration) c/o FRP Advisory LLP, 110 Cannon Street, London, EC4N 6EU, UK (together "**REDX**");

(2) **LOXO ONCOLOGY INC** a corporation whose offices are at 281 Tresser Boulevard, 9th Floor Stamford, CT 06901, USA ("**LOXO**"); and

(3) **JASON BAKER** and **MILES NEEDHAM** both of FRP Advisory LLP, 110 Cannon Street, London, EC4N 6EU, UK (together "**Administrators**"); and

(4) **[***]** (trading as **[***]**), a company registered in England and Wales with company number [***], whose offices are at [***] (**"[***]"**) (the "**Continuing Party**").

together the **"Parties**" and each a "**Party**".

BACKGROUND:

(A) On 24 May 2017, the Administrators were appointed as administrators of REDX.

(B) This deed (also "**Novation Agreements**") is supplemental to an agreement for [***] dated 13 April 2017 and made between the REDX and the Continuing Party and certain Services Plans entered into pursuant to that agreement as particularised in Schedule 1 (the "**Contract**"). Copies of the Contract and Services Plans are annexed hereto at Schedule 2 and initialled by the Parties for the purpose of identification.

(C) Pursuant to an agreement dated the same date as this Agreement, REDX and LOXO have completed the sale to LOXO of specific assets.

(D) In relation to those assets, REDX wishes to be released and discharged from the Contract as from [DATE] ("**Effective Date**") and the Continuing Party has agreed to release and discharge REDX from the Effective Date upon the terms of LOXO's undertaking to perform the Contract and be bound by the terms of the Contract in place of REDX.

IT IS AGREED:

1. Novation

1.1 As from the Effective Date, LOXO undertakes to each of REDX and the Continuing Party to perform the Contract and be bound by its terms in every way as if LOXO had been a party to it in place of REDX.

1.2 With effect from the Effective Date, REDX transfers all its rights and obligations under the Contract to LOXO. LOXO shall enjoy all the rights and benefits of REDX under the Contract, and

all references to REDX in the Contract shall be read and construed as references to LOXO. The Continuing Party agrees to perform the Contract and be bound by its terms in every way as if LOXO were the original party to it in place of REDX.

2. Release

2.1 REDX and the Continuing Party hereby mutually release each other from their obligations under the Contract as from the Effective Date.

2.2 The Continuing Party releases and discharges REDX from all future claims and demands whatsoever in respect of the Contract, whether arising before or on the Effective Date, and accepts the liability of LOXO under the Contract from the Effective Date.

2.3 LOXO and the Continuing Party shall have the right to enforce the Contract and pursue any claims and demands under the Contract against the other with respect to matters arising before, on or after the Effective Date as though LOXO were the original party Contract instead of REDX.

3. Intellectual Property

3.1 The Continuing Party hereby confirms that it has assigned under the Contract, all of its right, title and interest in and to the Intellectual Property Rights arising, or to arise, from work and research carried out in or in connection with the services it has provided to REDX ("Project IP").

3.2 To the extent any Project IP is not properly vested in REDX, the Continuing Party hereby jointly and severally assigns to LOXO with effect from the Effective Date, by way of present and future assignment, absolutely and with full title guarantee free from encumbrances all its right, title and interest in and to the Project IP, including the right to bring, make, oppose, defend, appeal proceedings, claims or actions and obtain relief (and to retain any damages recovered) in respect of any infringement, or any other cause of action arising from ownership, of any of such rights whether occurring before, on, or after the date of this Deed.

3.3 The Continuing Party shall provide all assistance reasonably required by LOXO in relation to the registration, enforcement or protection of the Project IP.

4. Payments

4.1 LOXO shall pay the invoices set out at Schedule 1 to the Novation Agreement. The Parties hereby confirm that there are no other invoices outstanding as of the Effective Date.

5. Confidentiality

5.1 Each Party (the "**Receiving Party**") undertakes to keep confidential any Confidential Information directly or indirectly belonging or relating to any other Party (the "**Disclosing Party**") and disclosed by or on behalf of the Disclosing Party to the Receiving Party.

5.2 The obligations contained in this Clause 5 shall survive the expiry or termination of this Deed for any reason, but shall not apply to any Confidential Information which Disclosing Party and/or received or learned by the Receiving Party pursuant to or in the course of this Deed (including through their presence at the other Parties premises) and which:

(a) is publicly known at the time of disclosure to the receiving Party; or

(b) becomes publicly known otherwise than through a breach of this Deed by the receiving Party, its officers, employees or professional advisers or any other person to whom the receiving Party discloses Confidential Information (whether or not in breach of this Deed); or

(c) can be proved by the Receiving Party to have reached it otherwise than by being communicated by or at the request of the Disclosing Party including:

(d) being known to it prior to disclosure; or

(e) having been developed by or for it wholly independently of the other Party; or

(f) having been obtained from a Third Party without any restriction on disclosure on such Third Party; or

(g) is required by law, regulation or order of a competent authority (including any regulatory or governmental body or securities exchange) to be disclosed by the receiving Party, provided that, where permitted by law and regulation, the Disclosing Party is given reasonable advance notice of time, place and content of the intended disclosure, giving the opportunity to the Disclosing Party to object to the necessity of the disclosure or any of it. The receiving Party shall, to the extent permitted by law and regulation, comply with any reasonable request of the Disclosing Party in connection with any such disclosure.

6. Variation

6.1 No variation of or amendment to this Deed shall bind any Party unless made in writing and signed by all Parties.

7. Announcements

7.1 The Parties shall not make any press statement, circular or other public announcement in connection with this Agreement without the prior written approval of the text of such statement or announcement by each other (such consent not to be unreasonably withheld or delayed). Once any such statement, circular or announcement is so approved, either Party may make subsequent public disclosure of the content thereof without the further approval of the other Party. Notwithstanding the foregoing, to the extent a public disclosure is required by law (including the requirements of any nationally recognized securities exchange, quotation system or over-the-counter market on which such Party has its securities listed or traded or pursuant to the Insolvency Act 1986) the disclosing Party may make such disclosure without consent of the other Party, provided that (to the extent such disclosure was not previously approved by the other Party) the disclosing Party shall make good faith efforts to provide the other Party with notice beforehand and to coordinate with the other Party with respect to the wording and timing of any such disclosure.

8. General

8.1 The Administrators are a party to this Agreement in their own capacity solely for receiving and enforcing the obligations, undertakings and waivers on the part of LOXO. The Administrators have entered into and signed this Agreement as agent for and on behalf of REDX and the Administrators, their firm, employees and agents shall incur no personal liability whatsoever whether on their own part or in respect of any failure on the part of REDX to observe perform or comply with any such obligations hereunder or under or in relation to any associated arrangements or negotiations whether such liability would arise under the Insolvency Act 1986 or otherwise.

8.2 The Parties acknowledge that the liability under this Agreement of REDX and that of the Administrators shall constitute an expense of the administration (within the meaning of rule 3.51 of the Insolvency Rules 2016) and shall have the ranking conferred by paragraph 99(4) of Schedule B1 of the Insolvency Act 1986. However, as to ranking, LOXO agrees that any claim it may make in respect of any such liability will be subordinated to and will rank in order of priority below each of the expenses of the administration listed in Rule 3.51(2) of the Insolvency Rules 2016 and for sake of clarity LOXO agrees that that the Administrators may, no earlier than 30 calendar days from the Effective Date (such restriction shall not apply in respect of the payment of secured, preferential and administration expense creditors), pay ahead of LOXO (and with no recourse from LOXO) all creditors of REDX that exist on the Effective Date and owe no duty to LOXO to protect the value of the charged assets after their appointment ceases.

8.3 The rights and remedies of LOXO, REDX and the Administrators under this Agreement are cumulative and not exclusive of any rights and remedies provided by law, and all such rights and remedies may be enforced separately or concurrently with any other right or remedy. No failure to exercise or delay in exercising any right or remedy shall constitute a waiver of that right or remedy. No single or partial exercise of any right or remedy, and no waiver of any right or remedy, shall prevent or restrict the further exercise of that or any other right or remedy. Any waiver of any right or remedy shall be effective only if it is made in writing, expressly states that it is a waiver of the relevant right or remedy and is duly executed by or on behalf of LOXO, REDX and/ or the Administrators (as applicable) by an authorised representative.

8.4 No term of this deed shall be enforceable by a person who is not a Party to this deed.

8.5 The Contract and this deed constitute the entire agreement between the Parties relating to its subject matter and supersede any and all previous agreements (whether written or oral) between the Parties or any of them relating to that subject matter. Each Party agrees that no representation has been made (innocently or negligently) by or on behalf of any other Party (or relied on by it) in relation to the subject matter of this deed. Each Party agrees that it shall have no claim for innocent or negligent misrepresentation or negligent misstatement based on any statement expressly set out in this deed. Nothing in this Clause 8.5 however, shall limit or reduce any liability of any person except to the extent permitted by law.

8.6 The Parties shall deliver or cause to be delivered such instruments and other documents at such times and places as are reasonably necessary or desirable, and shall take any other action reasonably requested by the other Party for the purpose of putting this deed into effect.

9. Law and Jurisdiction

9.1 This Agreement and any dispute or claim arising out of or in connection with it or its subject matter or formation, including any question regarding its existence, validity or termination,

(including non-contractual disputes or claims) (**"Dispute"**) shall be governed by and construed in accordance with the laws of England.

9.2 Disputes shall be referred to the courts of England and which shall have exclusive jurisdiction to settle any Dispute.

9.3 This Clause 9 shall be without prejudice to either Party's rights to at any time seek interim relief from the courts to protect their confidential information, or their rights or assets.

9.4 LOXO irrevocably appoints TMF Global Services (UK) Limited of 6 St. Andrew Street, 5th Floor, London, EC4A 3AE as its agent for service of process in any proceedings in the courts of England arising out of or in connection with this Agreement and agrees that failure by its process agent to notify it of such service shall not affect the validity of such service. If its process agent is or becomes unable or unwilling for any reason to act as agent for service of process in England, LOXO shall promptly appoint another process agent who is able and willing so to act and notify the other Parties in writing of the new process agent's name and address. If its process agent moves to a new address within England, LOXO shall promptly notify the other Parties of its process agent's new address.

IN WITNESS THEREOF this deed was executed and delivered by the Parties on the date stated at the beginning of this document.

EXECUTED AND DELIVERED
for and on behalf of **REDX PHARMA PLC**
(in administration)
by as its deed in the presence of

Signature

Print name

EXECUTED AND DELIVERED
for and on behalf of by one **ADMINISTRATOR** for
and on behalf of both of them
by as its deed in the presence of

Signature

Print name

EXECUTED AND DELIVERED for and on behalf of **REDX ONCOLOGY LIMITED (in administration)**
by as its deed in the presence of

Signature

Print name
EXECUTED AND DELIVERED
for and on behalf of **LOXO ONCOLOGY, INC.**
by as its deed in the presence of

Signature

Print name

EXECUTED AND DELIVERED
for and on behalf of **[***]**
by as its deed in the presence of

Signature

Print name

Schedule 1

Services Plans to be Novated pursuant to this Deed

SP number	Description	SP value (net)	Invoiced Net	Invoiced VAT	Invoiced Gross	Invoice Nos	Paid	Outstanding (Gross)
[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]
	Total	[***]	[***]	[***]	[***]		[***]	[***]

Schedule 2

Executed copy of the Contract and relevant Services Plans

(1) "[***] Terms of Supply" between [***] and RedX Pharma plc, dated April 13, 2017; and (2) Quotation Prepared For RedX Pharma with issue date of April 13th 2017, Quotation Reference: [***].

Schedule 3B

[***] Novation Agreement

THIS DEED is made the [ ] day of [ ] 2017

BETWEEN:

(1) **REDX PHARMA PLC** and **REDX ONCOLOGY LIMITED** (both in administration) c/o FRP Advisory LLP, 110 Cannon Street, London, EC4N 6EU, UK (together "**REDX**");

(2) **LOXO ONCOLOGY INC** a corporation whose offices are at 281 Tresser Boulevard, 9th Floor Stamford, CT 06901, USA ("**LOXO**"); and

(3) **JASON BAKER** and **MILES NEEDHAM** both of FRP Advisory LLP, 110 Cannon Street, London, EC4N 6EU, UK (together "**Administrators**"); and

(4) **[***]** whose offices are at [***], **[***]**, whose offices are at [***];**[***]**, whose offices are at [***]; and [***], whose offices are at [***] (collectively **"[***]")** (the "**Continuing Party**").

together the **"Parties**" and each a "**Party**".

BACKGROUND:

(A) On 24 May 2017, the Administrators were appointed as administrators of REDX.

(B) This deed (also "**Novation Agreements**") is supplemental to a Master Services Agreement dated 17 March 2016 and made between the REDX and the Continuing Party and certain Work Orders entered into pursuant to the Master Services Agreement as particularised in Schedule 1 (the "**Contract**"). Copies of the Contract and Work Orders are annexed hereto at Schedule 2 and initialled by the Parties for the purpose of identification.

(C) Pursuant to an agreement dated the same date as this Agreement, REDX and LOXO have completed the sale to LOXO of specific assets.

(D) In relation to those assets, REDX wishes to be released and discharged from the Contract as from [DATE] ("**Effective Date**") and the Continuing Party has agreed to release and discharge REDX from the Effective Date upon the terms of LOXO's undertaking to perform the Contract and be bound by the terms of the Contract in place of REDX.

IT IS AGREED:

1. Novation

1.1 As from the Effective Date, LOXO undertakes to each of REDX and the Continuing Party to perform the Contract and be bound by its terms in every way as if LOXO had been a party to it in place of REDX.

1.2 With effect from the Effective Date, REDX transfers all its rights and obligations under the Contract to LOXO. LOXO shall enjoy all the rights and benefits of REDX under the Contract, and

all references to REDX in the Contract shall be read and construed as references to LOXO. The Continuing Party agrees to perform the Contract and be bound by its terms in every way as if LOXO were the original party to it in place of REDX.

2. Release

2.1 REDX and the Continuing Party hereby mutually release each other from their obligations under the Contract as from the Effective Date.

2.2 The Continuing Party releases and discharges REDX from all future claims and demands whatsoever in respect of the Contract, whether arising before or on the Effective Date, and accepts the liability of LOXO under the Contract from the Effective Date.

2.3 LOXO and the Continuing Party shall have the right to enforce the Contract and pursue any claims and demands under the Contract against the other with respect to matters arising before, on or after the Effective Date as though LOXO were the original party Contract instead of REDX.

3. Intellectual Property

3.1 The Continuing Party hereby confirms that it has assigned under the Contract, all of its right, title and interest in and to the Intellectual Property Rights arising, or to arise, from work and research carried out in or in connection with the services it has provided to REDX ("Project IP").

3.2 To the extent any Project IP is not properly vested in REDX, the Continuing Party hereby jointly and severally assigns to LOXO with effect from the Effective Date, by way of present and future assignment, absolutely and with full title guarantee free from encumbrances all its right, title and interest in and to the Project IP, including the right to bring, make, oppose, defend, appeal proceedings, claims or actions and obtain relief (and to retain any damages recovered) in respect of any infringement, or any other cause of action arising from ownership, of any of such rights whether occurring before, on, or after the date of this Deed.

3.3 The Continuing Party shall provide all assistance reasonably required by LOXO in relation to the registration, enforcement or protection of the Project IP.

4. Payments

LOXO shall pay the invoices set out at Schedule 1 to the Novation Agreements. The Parties hereby confirm that there are no other invoices outstanding as of the Effective Date.

5. **Confidentiality**

5.1 Each Party (the "**Receiving Party**") undertakes to keep confidential any Confidential Information directly or indirectly belonging or relating to any other Party (the "**Disclosing Party**") and disclosed by or on behalf of the Disclosing Party to the Receiving Party.

5.2 The obligations contained in this Clause 5 shall survive the expiry or termination of this Deed for any reason, but shall not apply to any Confidential Information which Disclosing Party and/or received or learned by the Receiving Party pursuant to or in the course of this Deed (including through their presence at the other Parties premises) and which:

5.2.1 is publicly known at the time of disclosure to the receiving Party; or

5.2.2 becomes publicly known otherwise than through a breach of this Deed by the receiving Party, its officers, employees or professional advisers or any other person to whom the receiving Party discloses Confidential Information (whether or not in breach of this Deed); or

5.2.3 can be proved by the Receiving Party to have reached it otherwise than by being communicated by or at the request of the Disclosing Party including:

(a) being known to it prior to disclosure; or

(b) having been developed by or for it wholly independently of the other Party; or

(c) having been obtained from a Third Party without any restriction on disclosure on such Third Party; or

(d) is required by law, regulation or order of a competent authority (including any regulatory or governmental body or securities exchange) to be disclosed by the receiving Party, provided that, where permitted by law and regulation, the Disclosing Party is given reasonable advance notice of time, place and content of the intended disclosure, giving the opportunity to the Disclosing Party to object to the necessity of the disclosure or any of it. The receiving Party shall, to the extent permitted by law and regulation, comply with any reasonable request of the Disclosing Party in connection with any such disclosure.

6. Variation

No variation of or amendment to this Deed shall bind any Party unless made in writing and signed by all Parties.

7. Announcements

The Parties shall not make any press statement, circular or other public announcement in connection with this Agreement without the prior written approval of the text of such statement or announcement by each other (such consent not to be unreasonably withheld or delayed). Once any such statement, circular or announcement is so approved, either Party may make subsequent public disclosure of the content thereof without the further approval of the other Party. Notwithstanding the foregoing, to the extent a public disclosure is required by law (including the requirements of any nationally recognized securities exchange, quotation system or over-the-counter market on which such Party has its securities listed or traded or pursuant to the Insolvency Act 1986) the disclosing Party may make such disclosure without consent of the other Party, provided that (to the extent such disclosure was not previously approved by the other Party) the disclosing Party shall make good faith efforts to provide the other Party with notice beforehand and to coordinate with the other Party with respect to the wording and timing of any such disclosure.

8. General

8.1 The Administrators are a party to this Agreement in their own capacity solely for receiving and enforcing the obligations, undertakings and waivers on the part of LOXO. The Administrators

have entered into and signed this Agreement as agent for and on behalf of REDX and the Administrators, their firm, employees and agents shall incur no personal liability whatsoever whether on their own part or in respect of any failure on the part of REDX to observe perform or comply with any such obligations hereunder or under or in relation to any associated arrangements or negotiations whether such liability would arise under the Insolvency Act 1986 or otherwise.

8.2 The Parties acknowledge that the liability under this Agreement of REDX and that of the Administrators shall constitute an expense of the administration (within the meaning of rule 3.51 of the Insolvency Rules 2016) and shall have the ranking conferred by paragraph 99(4) of Schedule B1 of the Insolvency Act 1986. However, as to ranking, LOXO agrees that any claim it may make in respect of any such liability will be subordinated to and will rank in order of priority below each of the expenses of the administration listed in Rule 3.51(2) of the Insolvency Rules 2016 and for sake of clarity LOXO agrees that that the Administrators may, no earlier than 30 calendar days from the Effective Date (such restriction shall not apply in respect of the payment of secured, preferential and administration expense creditors), pay ahead of LOXO (and with no recourse from LOXO) all creditors of REDX that exist on the Effective Date and owe no duty to LOXO to protect the value of the charged assets after their appointment ceases.

8.3 The rights and remedies of LOXO, REDX and the Administrators under this Agreement are cumulative and not exclusive of any rights and remedies provided by law, and all such rights and remedies may be enforced separately or concurrently with any other right or remedy. No failure to exercise or delay in exercising any right or remedy shall constitute a waiver of that right or remedy. No single or partial exercise of any right or remedy, and no waiver of any right or remedy, shall prevent or restrict the further exercise of that or any other right or remedy. Any waiver of any right or remedy shall be effective only if it is made in writing, expressly states that it is a waiver of the relevant right or remedy and is duly executed by or on behalf of LOXO, REDX and/ or the Administrators (as applicable) by an authorised representative.

8.4 No term of this deed shall be enforceable by a person who is not a Party to this deed.

8.5 The Contract and this deed constitute the entire agreement between the Parties relating to its subject matter and supersede any and all previous agreements (whether written or oral) between the Parties or any of them relating to that subject matter. Each Party agrees that no representation has been made (innocently or negligently) by or on behalf of any other Party (or relied on by it) in relation to the subject matter of this deed. Each Party agrees that it shall have no claim for innocent or negligent misrepresentation or negligent misstatement based on any statement expressly set out in this deed. Nothing in this Clause 8.5 however, shall limit or reduce any liability of any person except to the extent permitted by law.

8.6 The Parties shall deliver or cause to be delivered such instruments and other documents at such times and places as are reasonably necessary or desirable, and shall take any other action reasonably requested by the other Party for the purpose of putting this deed into effect.

9. Law and Jurisdiction

9.1 This Agreement and any dispute or claim arising out of or in connection with it or its subject matter or formation, including any question regarding its existence, validity or termination, (including non-contractual disputes or claims) (**"Dispute"**) shall be governed by and construed in accordance with the laws of England.

9.2 Disputes shall be referred to the courts of England and which shall have exclusive jurisdiction to settle any Dispute.

9.3 This Clause 9 shall be without prejudice to either Party's rights to at any time seek interim relief from the courts to protect their confidential information, or their rights or assets.

9.4 LOXO irrevocably appoints TMF Global Services (UK) Limited of 6 St. Andrew Street, 5th Floor, London, EC4A 3AE as its agent for service of process in any proceedings in the courts of England arising out of or in connection with this Agreement and agrees that failure by its process agent to notify it of such service shall not affect the validity of such service. If its process agent is or becomes unable or unwilling for any reason to act as agent for service of process in England, LOXO shall promptly appoint another process agent who is able and willing so to act and notify the other Parties in writing of the new process agent's name and address. If its process agent moves to a new address within England, LOXO shall promptly notify the other Parties of its process agent's new address.

IN WITNESS THEREOF this deed was executed and delivered by the Parties on the date stated at the beginning of this document.

EXECUTED AND DELIVERED
for and on behalf of **REDX PHARMA PLC**
(in administration)
by as its deed in the presence of

Signature

Print name

EXECUTED AND DELIVERED
for and on behalf of by one **ADMINISTRATOR** for
and on behalf of both of them
by as its deed in the presence of

Signature

Print name

EXECUTED AND DELIVERED
for and on behalf of **REDX ONCOLOGY LIMITED (in administration)**
by as its deed in the presence of

Signature

Print name

EXECUTED AND DELIVERED
for and on behalf of **LOXO ONCOLOGY, INC.**
by as its deed in the presence of

Signature

Print name

EXECUTED AND DELIVERED
for and on behalf of **[***]**
by as its deed in the presence of

Signature

Print name

SCHEDULE 1

Work Orders to be Novated pursuant to this Deed

PO number	Description	PO value (net)	Invoiced Net	Invoiced VAT	Invoiced Gross	Invoice Nos	Not yet invoiced Net	Not yet invoiced VAT	Not yet invoiced Gross	Paid	Outstanding (Gross)
[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]
	Total	[***]	[***]	[***]	[***]		[***]	[***]	[***]	[***]	[***]

SCHEDULE 2

Executed copy of the Master Services Agreement and relevant Work Orders

(1) Master Services Agreement between [***] and RedX Pharma Plc, dated March 17, 2016; (2) Quotation and Work Order from [***], dated March 7, 2017; and (3) Quotation and Work Order from [***], dated March 20, 2017; (4) Quotation and Work Order from [***], dated May 14, 2017.

Schedule 3C

[***]Novation Agreement

THIS DEED is made the [ ] day of [ ] 2017

BETWEEN:

(1) **REDX PHARMA PLC** and **REDX ONCOLOGY LIMITED** (both in administration) c/o FRP Advisory LLP, 110 Cannon Street, London, EC4N 6EU, UK (together "**REDX**");

(2) **LOXO ONCOLOGY INC** a corporation whose offices are at 281 Tresser Boulevard, 9th Floor Stamford, CT 06901, USA ("**LOXO**"); and

(3) **JASON BAKER** and **MILES NEEDHAM** both of FRP Advisory LLP, 110 Cannon Street, London, EC4N 6EU, UK (together "**Administrators**"); and

(4) **[***]**, a company registered in England and Wales with company number [***], whose offices are at [***] (**"[***]"**) (the "**Continuing Party**").

together the **"Parties**" and each a "**Party**".

BACKGROUND:

(A) On 24 May 2017, the Administrators were appointed as administrators of REDX.

(B) This deed (also "**Novation Agreements**") is supplemental to an agreement for [***] made between the REDX and the Continuing Party pursuant to a number of Purchase Orders, subject to [***]'s Standard Conditions of Sale (together the "**Contract**"). The relevant Purchase Orders are identified and particularised in Schedule 1 to this deed. Copies of [***]'s Standard Conditions of Sale and the Purchase Orders are annexed hereto at Schedule 2 and initialled by the Parties for the purpose of identification.

(C) Pursuant to an agreement dated the same date as this Agreement, REDX and LOXO have completed the sale to LOXO of specific assets.

(D) In relation to those assets, REDX wishes to be released and discharged from the Contract as from [DATE] ("**Effective Date**") and the Continuing Party has agreed to release and discharge REDX from the Effective Date upon the terms of LOXO's undertaking to perform the Contract and be bound by the terms of the Contract in place of REDX.

IT IS AGREED:

1. Novation

1.1 As from the Effective Date, LOXO undertakes to each of REDX and the Continuing Party to perform the Contract and be bound by its terms in every way as if LOXO had been a party to it in place of REDX.

1.2 With effect from the Effective Date, REDX transfers all its rights and obligations under the Contract to LOXO. LOXO shall enjoy all the rights and benefits of REDX under the Contract, and all references to REDX in the Contract shall be read and construed as references to LOXO. The Continuing Party agrees to perform the Contract and be bound by its terms in every way as if LOXO were the original party to it in place of REDX.

2. Release

2.1 REDX and the Continuing Party hereby mutually release each other from their obligations under the Contract as from the Effective Date.

2.2 The Continuing Party releases and discharges REDX from all future claims and demands whatsoever in respect of the Contract, whether arising before or on the Effective Date, and accepts the liability of LOXO under the Contract from the Effective Date.

2.3 LOXO and the Continuing Party shall have the right to enforce the Contract and pursue any claims and demands under the Contract against the other with respect to matters arising before, on or after the Effective Date as though LOXO were the original party Contract instead of REDX.

3. Intellectual Property

3.1 The Continuing Party hereby confirms that it has assigned under the Contract, all of its right, title and interest in and to the Intellectual Property Rights arising, or to arise, from work and research carried out in or in connection with the services it has provided to REDX ("Project IP").

3.2 To the extent any Project IP is not properly vested in REDX, the Continuing Party hereby jointly and severally assigns to LOXO with effect from the Effective Date, by way of present and future assignment, absolutely and with full title guarantee free from encumbrances all its right, title and interest in and to the Project IP, including the right to bring, make, oppose, defend, appeal proceedings, claims or actions and obtain relief (and to retain any damages recovered) in respect of any infringement, or any other cause of action arising from ownership, of any of such rights whether occurring before, on, or after the date of this Deed.

3.3 The Continuing Party shall provide all assistance reasonably required by LOXO in relation to the registration, enforcement or protection of the Project IP.

4. Payments

4.1 LOXO shall pay the invoices set out at Schedule 1 to the Novation Agreements. The Parties hereby confirm that there are no other invoices outstanding as of the Effective Date.

5. Confidentiality

5.1 Each Party (the "**Receiving Party**") undertakes to keep confidential any Confidential Information directly or indirectly belonging or relating to any other Party (the "**Disclosing Party**") and disclosed by or on behalf of the Disclosing Party to the Receiving Party.

5.2 The obligations contained in this Clause 5 shall survive the expiry or termination of this Deed for any reason, but shall not apply to any Confidential Information which Disclosing Party and/or

received or learned by the Receiving Party pursuant to or in the course of this Deed (including through their presence at the other Parties premises) and which:

5.2.1 is publicly known at the time of disclosure to the receiving Party; or

5.2.2 becomes publicly known otherwise than through a breach of this Deed by the receiving Party, its officers, employees or professional advisers or any other person to whom the receiving Party discloses Confidential Information (whether or not in breach of this Deed); or

5.2.3 can be proved by the Receiving Party to have reached it otherwise than by being communicated by or at the request of the Disclosing Party including:

(a) being known to it prior to disclosure; or

(b) having been developed by or for it wholly independently of the other Party; or

(c) having been obtained from a Third Party without any restriction on disclosure on such Third Party; or

(d) is required by law, regulation or order of a competent authority (including any regulatory or governmental body or securities exchange) to be disclosed by the receiving Party, provided that, where permitted by law and regulation, the Disclosing Party is given reasonable advance notice of time, place and content of the intended disclosure, giving the opportunity to the Disclosing Party to object to the necessity of the disclosure or any of it. The receiving Party shall, to the extent permitted by law and regulation, comply with any reasonable request of the Disclosing Party in connection with any such disclosure.

6. Variation

6.1 No variation of or amendment to this Deed shall bind any Party unless made in writing and signed by all Parties.

7. Announcements

7.1 The Parties shall not make any press statement, circular or other public announcement in connection with this Agreement without the prior written approval of the text of such statement or announcement by each other (such consent not to be unreasonably withheld or delayed). Once any such statement, circular or announcement is so approved, either Party may make subsequent public disclosure of the content thereof without the further approval of the other Party. Notwithstanding the foregoing, to the extent a public disclosure is required by law (including the requirements of any nationally recognized securities exchange, quotation system or over-the-counter market on which such Party has its securities listed or traded or pursuant to the Insolvency Act 1986) the disclosing Party may make such disclosure without consent of the other Party, provided that the disclosing Party shall make good faith efforts to provide the other Party with notice beforehand and to coordinate with the other Party with respect to the wording and timing of any such disclosure.

8. General

8.1 The Administrators are a party to this Agreement in their own capacity solely for receiving and enforcing the obligations, undertakings and waivers on the part of LOXO. The Administrators have entered into and signed this Agreement as agent for and on behalf of REDX and the Administrators, their firm, employees and agents shall incur no personal liability whatsoever whether on their own part or in respect of any failure on the part of REDX to observe perform or comply with any such obligations hereunder or under or in relation to any associated arrangements or negotiations whether such liability would arise under the Insolvency Act 1986 or otherwise.

8.2 The Parties acknowledge that the liability under this Agreement of REDX and that of the Administrators shall constitute an expense of the administration (within the meaning of rule 3.51 of the Insolvency Rules 2016) and shall have the ranking conferred by paragraph 99(4) of Schedule B1 of the Insolvency Act 1986. However, as to ranking, LOXO agrees that any claim it may make in respect of any such liability will be subordinated to and will rank in order of priority below each of the expenses of the administration listed in Rule 3.51(2) of the Insolvency Rules 2016 and for sake of clarity LOXO agrees that that the Administrators may, no earlier than 30 calendar days from the Effective Date (such restriction shall not apply in respect of the payment of secured, preferential and administration expense creditors), pay ahead of LOXO (and with no recourse from LOXO) all creditors of REDX that exist on the Effective Date and owe no duty to LOXO to protect the value of the charged assets after their appointment ceases.

8.3 The rights and remedies of LOXO, REDX and the Administrators under this Agreement are cumulative and not exclusive of any rights and remedies provided by law, and all such rights and remedies may be enforced separately or concurrently with any other right or remedy. No failure to exercise or delay in exercising any right or remedy shall constitute a waiver of that right or remedy. No single or partial exercise of any right or remedy, and no waiver of any right or remedy, shall prevent or restrict the further exercise of that or any other right or remedy. Any waiver of any right or remedy shall be effective only if it is made in writing, expressly states that it is a waiver of the relevant right or remedy and is duly executed by or on behalf of LOXO, REDX and/ or the Administrators (as applicable) by an authorised representative.

8.4 No term of this deed shall be enforceable by a person who is not a Party to this deed.

8.5 The Contract and this deed constitute the entire agreement between the Parties relating to its subject matter and supersede any and all previous agreements (whether written or oral) between the Parties or any of them relating to that subject matter. Each Party agrees that no representation has been made (innocently or negligently) by or on behalf of any other Party (or relied on by it) in relation to the subject matter of this deed. Each Party agrees that it shall have no claim for innocent or negligent misrepresentation or negligent misstatement based on any statement expressly set out in this deed. Nothing in this Clause 8.5 however, shall limit or reduce any liability of any person except to the extent permitted by law.

8.6 The Parties shall deliver or cause to be delivered such instruments and other documents at such times and places as are reasonably necessary or desirable, and shall take any other action reasonably requested by the other Party for the purpose of putting this deed into effect.

9. Law and Jurisdiction

9.1 This Agreement and any dispute or claim arising out of or in connection with it or its subject matter or formation, including any question regarding its existence, validity or termination, (including non-contractual disputes or claims) (**"Dispute"**) shall be governed by and construed in accordance with the laws of England.

9.2 Disputes shall be referred to the courts of England and which shall have exclusive jurisdiction to settle any Dispute.

9.3 This Clause 9 shall be without prejudice to either Party's rights to at any time seek interim relief from the courts to protect their confidential information, or their rights or assets.

9.4 LOXO irrevocably appoints TMF Global Services (UK) Limited of 6 St. Andrew Street, 5th Floor, London, EC4A 3AE as its agent for service of process in any proceedings in the courts of England arising out of or in connection with this Agreement and agrees that failure by its process agent to notify it of such service shall not affect the validity of such service. If its process agent is or becomes unable or unwilling for any reason to act as agent for service of process in England, LOXO shall promptly appoint another process agent who is able and willing so to act and notify the other Parties in writing of the new process agent's name and address. If its process agent moves to a new address within England, LOXO shall promptly notify the other Parties of its process agent's new address.

IN WITNESS THEREOF this deed was executed and delivered by the Parties on the date stated at the beginning of this document.

EXECUTED AND DELIVERED
for and on behalf of **REDX PHARMA PLC**
(in administration)
by as its deed in the presence of

Signature

Print name

EXECUTED AND DELIVERED
for and on behalf of by one ADMINISTRATOR for and on behalf of both of them
by as its deed in the presence of

Signature

Print name

EXECUTED AND DELIVERED
for and on behalf of REDX ONCOLOGY
LIMITED (in administration)
by as its deed in the presence of

Signature

Print name

EXECUTED AND DELIVERED
for and on behalf of **LOXO ONCOLOGY, INC.**
by as its deed in the presence of

Signature

Print name

EXECUTED AND DELIVERED
for and on behalf of [***]
by as its deed in the presence of

Signature

Print name

SCHEDULE 1

Purchase Orders to be Novated pursuant to this Deed

PO number	Description	PO value (net)	Invoiced Pre Appt Net	Invoiced Pre Appt VAT	Invoiced Pre Appt Gross	Pre Appt Invoice Nos	Invoiced Post Appt Net	Invoiced Post Appt VAT	Invoiced Post Appt Gross	Post Appt Invoice Nos	Paid Post Appt	Outstanding (Gross)
[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]		[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]		[***]	[***]		[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]	[***]		[***]	[***]		[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]	[***]		[***]	[***]		[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]		[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]		[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]	[***]		[***]	[***]		[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]	[***]		[***]	[***]		[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]	[***]		[***]	[***]		[***]	[***]
	Total	[***]	[***]	[***]	[***]		[***]	[***]	[***]		[***]	[***]

SCHEDULE 2

Executed copy of the [***]***Standard Terms and Conditions and Purchase Orders***

(1) [***]' Standard Conditions of Sale; (2) The POs listed in Schedule 1 (initialled copies); and (3) Quotation dated February16, 2017 if parties intend to novate it.

Schedule 4: Form of Confirmatory Patent Assignment

THIS ASSIGNMENT is made the day of 2017

(1) **REDX PHARMA PLC** and **REDX ONCOLOGY LIMITED** (both in administration) c/o FRP Advisory LLP, 110 Cannon Street, London, EC4N 6EU, UK (together the "**Assignor**");

(2) **LOXO ONCOLOGY, INC.** a corporation whose offices are at 281 Tresser Boulevard, 9th Floor Stamford, CT 06901, USA (the "**Assignee**"); and

(3) **JASON BAKER** and **MILES NEEDHAM** both of FRP Advisory LLP, 110 Cannon Street, London, EC4N 6EU, UK (together "**Administrators**").

BACKGROUND:

(A) On 24 May 2017, the Administrators were appointed as administrators of the Assignor.

(B) The Assignor wishes to assign whatever right title and interest it has in the patent applications listed in Schedule 1, and of all PCT applications (including national stages thereof) and domestic patents, patent applications, including continuations, divisionals, continuations-in-part, patents issuing therefrom, including reissues, re-examinations, extensions (such as patent term extensions), supplementary protection certificates, certificates of invention, and the like that derive priority from, or claim the benefit of the filing date of, the patent applications listed in Schedule 1 (the "**Patent Applications**") and of all new and useful inventions and improvements that are disclosed in the Patent Applications (the "**Inventions**") to the Assignee. The Patent Applications and the Inventions are collectively referred to as the "**Patent Assets**."

IT IS AGREED:

1. Assignor hereby assigns to Assignee, absolutely, its entire worldwide right, title, and interest in and to the Patent Assets, including the right to file and prosecute, in its own name wherever so permitted by law or in the name of Assignee wherever necessary, patent applications, including corresponding and continuations, divisionals, continuations-in-part, patents issuing therefrom, including reissues, re-examinations, extensions (such as patent term extensions), supplementary protection certificates, certificates of invention, and the like based on any of the Patent Assets, the right to claim priority to any of the Patent Applications pursuant to the International Convention for the Protection of Industrial Property, the Patent Cooperation Treaty, the European Patent Convention, and all other treaties of like purposes, the absolute entitlement to any patents granted pursuant to any of the Patent Applications or in respect of the Inventions, and the right to bring, make, oppose, defend, appeal proceedings, claims or actions and obtain relief (and to retain any damages recovered) in respect of any infringement, or any other cause of action arising from ownership, of any patents granted in relation to any of the Patent Assets, whether occurring before on or after the date of this Assignment. Assignor acknowledges receipt of [***], and other good and valuable consideration, in consideration for this Assignment.

2. Assignor shall, when requested by Assignee and at no cost to Assignor, (i) execute or cause to be executed all rightful oaths, assignments and all other papers necessary and proper to carry out the intent and purpose of this Assignment, (ii) execute all papers necessary in connection with the Patent Applications, and any continuing, divisional, reissue, reexamination or other corresponding application thereof or post-grant proceeding relating thereto and to execute any

separate assignment in connection with any such application as Assignee may deem necessary or expedient; and (iii) perform all affirmative acts that may be necessary to obtain a grant of a valid patent to Assignee on any of the Inventions. The Assignor hereby appoints the Assignee to be its attorney in his name and on its behalf to execute documents, use the Assignor's name and do all things which are necessary or desirable for the Assignee to obtain for itself or its nominee the full benefit of this Assignment in relation to the Patent Assets. This power of attorney is irrevocable and is given by way of security to secure the performance of the Assignor's obligations under this clause and the proprietary interest of the Assignee in the Patent Assets and so long as such obligations of the Assignor remain undischarged, or the Assignee has such interest, the power may not be revoked by the Assignor, save with the consent of the Assignee.

3. Assignor hereby assigns to Assignee all of Assignor's right, title, and interest in and to any claims, whether known or unknown, suspected or unsuspected, of any nature, including choses in action, that Assignor has or may have against any party for infringement of the Patent Applications, and acknowledges receipt of [***], and other good and valuable consideration, in consideration for this Assignment.

4. This Assignment is binding upon and inures to the benefit of the successors and assigns of the parties.

5. The Administrators are a party to this agreement in their own capacity solely for receiving and enforcing the obligations, undertakings and waivers on the part of the Assignee. The Administrators have entered into and signed this agreement as agent for and on behalf of the Assignor and the Administrators, their firm, employees and agents shall incur no personal liability whatsoever whether on their own part or in respect of any failure on the part of the Assignor to observe perform or comply with any such obligations hereunder or under or in relation to any associated arrangements or negotiations whether such liability would arise under the Insolvency Act 1986 or otherwise. The Parties acknowledge that the liability under this Agreement of the Assignor and that of the Administrators shall constitute an expense of the administration (within the meaning of rule 3.51 of the Insolvency Rules 2016) and shall have the ranking conferred by paragraph 99(4) of Schedule B1 of the Insolvency Act 1986. However, as to ranking, the Assignee agrees that any claim it may make in respect of any such liability will be subordinated to and will rank in order of priority below each of the expenses of the administration listed in Rule 3.51(2) of the Insolvency Rules 2016 and for sake of clarity the Assignor agrees that the Administrators can pay ahead of LOXO (and with no recourse from LOXO) all creditors of REDX that exist on the Effective Date and owe no duty to the Assignor to protect the value of the charged assets after their appointment ceases.

6. The Assignee agrees that neither the Assignor nor the Administrators shall incur any liability to it by reason of any fault or defect in or in title or otherwise of any or all of the Patent Assets.

7. This agreement and any dispute or claim (including non-contractual disputes or claims) arising out of or in connection with it or its subject matter or formation shall be governed by and construed in accordance with the law of England and Wales.

8. Each party irrevocably agrees that the courts of England and Wales shall have exclusive jurisdiction to settle any dispute or claim (including non-contractual disputes or claims) arising out of or in connection with this agreement or its subject matter or formation.

This document has been executed as a deed and is delivered and takes effect on the date stated at the beginning of it.

[ASSIGNMENT CONTINUES ON SIGNATURE PAGE]

EXECUTED AND DELIVERED
for and on behalf of **REDX PHARMA PLC**
(in administration)
by as its deed in the presence of

Signature

Print name

EXECUTED AND DELIVERED
for and on behalf of **REDX ONCOLOGY**
LIMITED (in administration)
by as its deed in the presence of

Signature

Print name

EXECUTED AND DELIVERED
for and on behalf of **LOXO ONCOLOGY, INC.**
by as its deed in the presence of

Signature

Print name

EXECUTED AND DELIVERED
for and on behalf of by one **ADMINISTRATOR**
for and on behalf of both of them
by as its deed in the presence of

Signature

Print name

Schedule 1: Patent Applications

Subject	Country	Application Number	Filing date	Status	Grant date	Expiry date*	Publication Number
[***]	[***]	[***]	[***]	[***]			
[***]	[***]	[***]	[***]	[***]			
	[***]	[***]	[***]	[***]			[***]
[***]	[***]	[***]	[***]	[***]			[***]
[***]	[***]	[***]	[***]	[***]			[***]
[***]	[***]	[***]	[***]	[***]			
	[***]	[***]	[***]	[***]			[***]
[***]	[***]	[***]	[***]	[***]			
	[***]	[***]	[***]	[***]			[***]
	[***]	[***]	[***]	[***]		[***]	[***]
	[***]	[***]	[***]	[***]		[***]	[***]
	[***]	[***]	[***]	[***]		[***]	[***]
	[***]	[***]	[***]	[***]		[***]	[***]
	[***]	[***]	[***]	[***]		[***]	[***]
	[***]	[***]	[***]	[***]		[***]	
	[***]	[***]	[***]	[***]		[***]	
[***]	[***]	[***]	[***]	[***]			

	[***]	[***]	[***]	[***]	
	[***]	[***]	[***]	[***]	
	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	
	[***]	[***]	[***]	[***]	
	[***]	[***]	[***]	[***]	[***]

* Expiry date does not take into account any potential extension or termination of term (e.g., patent term adjustment or the filing of terminal disclaimers)

Schedule 5: Confirmation

To: Loxo Oncology, Inc.
281 Tresser Boulevard
9th Floor Stamford
CT 06901
USA

2017

Dear Sirs

Agreement for the Assignment of Patents and other Rights and for the Novation of certain Agreements, including for Product Manufacturing dated July 2017 and entered into between (1) Redx Pharma PLC (in administration) and Redx Oncology Limited (in administration), (2) Jason Baker and Miles Needham in their capacity as joint administrators of Redx Pharma PLC (in administration) and Redx Oncology Limited (in administration) and (3) Loxo Oncology, Inc. ("Loxo") (the "Agreement")

1. INTRODUCTION

1.1 We refer to the Agreement.

1.2 Unless otherwise defined herein or the context so requires, capitalised terms used in this letter have the meanings given to them in the Agreement. The provisions of Clause 1.2 of the Agreement apply to this letter as though they were set out in full in this letter except that references to the Agreement are to be construed as references to this letter.

1.3 This letter constitutes the Confirmation to be provided by REDX in accordance with Clause 2.3 of the Agreement.

2. CONFIRMATION

2.1 I, ***[insert name]***, am a current director of REDX and am authorised to make the statements set out in this letter.

2.2 REDX warrants and represents to LOXO on the date of this letter that it has satisfied its obligations in full in relation to the supply or making available (as applicable) of any and all assets included in the Data Package in accordance with Clause 2.2 of the Agreement.

2.3 The parties to this letter acknowledge and agree that the provisions of Clause 6.1 and 6.2 of the Agreement shall not apply to this letter.

3. MISCELLANEOUS

3.1 A person who is not a party to this letter has no right under the Contracts (Rights of Third Parties) Act 1999 to enforce or to enjoy the benefit of any term of this letter provided that the Administrators may enforce the terms of this letter.

3.2 This letter may be executed in any number of counterparts, and by the parties on separate counterparts, but will not be effective until all the parties have executed at least one counterpart. All the counterparts will together constitute one and the same instrument and each counterpart will constitute an original of this letter.

3.3 If any provision of this letter is void or unenforceable by reason of any provision of applicable law, such provision will be deemed to be modified to the extent necessary to render it legal, valid and enforceable. If no such modification is possible, it will be deleted and the remaining provisions of this letter will continue in full force and effect and, if necessary, be so amended as is necessary to give effect to the spirit of this letter so far as possible.

4. GOVERNING LAW AND ENFORCEMENT

4.1 This letter and any non-contractual obligations arising out of or in connection with it are governed by English law.

4.2 The courts of England have exclusive jurisdiction to settle any dispute arising out of or in connection with this letter (including a dispute relating to the existence, validity or termination of this letter or any non-contractual obligation arising out of or in connection with this letter) (a "**Dispute**").

4.3 The Parties agree that the courts of England are the most appropriate and convenient courts to settle Disputes and accordingly no party to this letter will argue to the contrary.

Yours faithfully

For and on behalf of
REDX PHARMA PLC

Name:
Title: Director

For and on behalf of
REDX ONCOLOGY LIMITED

Name:
Title: Director

We hereby acknowledge and accept the terms of this letter:

For and on behalf of
LOXO ONCOLOGY, INC.

Exhibit 10.2

THIS ASSIGNMENT is made the 29 day of July 2017

(A) **REDX PHARMA PLC** and **REDX ONCOLOGY LIMITED** (both in administration) c/o FRP Advisory LLP, 110 Cannon Street, London, EC4N 6EU, UK (together the "**Assignor**");

(B) **LOXO ONCOLOGY, INC.** a corporation whose offices are at 281 Tresser Boulevard, 9th Floor Stamford, CT 06901, USA (the "**Assignee**"); and

(C) **JASON BAKER** and **MILES NEEDHAM** both of FRP Advisory LLP, 110 Cannon Street, London, EC4N 6EU, UK (together "**Administrators**").

BACKGROUND:

(1) On 24 May 2017, the Administrators were appointed as administrators of the Assignor.

(2) The Assignor wishes to assign whatever right title and interest it has in the patent applications listed in Schedule 1, and of all PCT applications (including national stages thereof) and domestic patents, patent applications, including continuations, divisionals, continuations-in-part, patents issuing therefrom, including reissues, re-examinations, extensions (such as patent term extensions), supplementary protection certificates, certificates of invention, and the like that derive priority from, or claim the benefit of the filing date of, the patent applications listed in Schedule 1 (the "**Patent Applications**") and of all new and useful inventions and improvements that are disclosed in the Patent Applications (the "**Inventions**") to the Assignee. The Patent Applications and the Inventions are collectively referred to as the "**Patent Assets**."

IT IS AGREED:

1. Assignor hereby assigns to Assignee, absolutely, its entire worldwide right, title, and interest in and to the Patent Assets, including the right to file and prosecute, in its own name wherever so permitted by law or in the name of Assignee wherever necessary, patent applications, including corresponding and continuations, divisionals, continuations-in-part, patents issuing therefrom, including reissues, re-examinations, extensions (such as patent term extensions), supplementary protection certificates, certificates of invention, and the like based on any of the Patent Assets, the right to claim priority to any of the Patent Applications pursuant to the International Convention for the Protection of Industrial Property, the Patent Cooperation Treaty, the European Patent Convention, and all other treaties of like purposes, the absolute entitlement to any patents granted pursuant to any of the Patent Applications or in respect of the Inventions, and the right to bring, make, oppose, defend, appeal proceedings, claims or actions and obtain relief (and to retain any damages recovered) in respect of any infringement, or any other cause of action arising from ownership, of any patents granted in relation to any of the Patent Assets, whether occurring before on or after the date of this Assignment. Assignor acknowledges receipt of [***], and other good and valuable consideration, in consideration for this Assignment.

2. Assignor shall, when requested by Assignee and at no cost to Assignor, (i) execute or cause to be executed all rightful oaths, assignments and all other papers necessary and proper to carry out the intent and purpose of this Assignment, (ii) execute all papers necessary in connection with the Patent Applications, and any continuing, divisional, reissue, reexamination or other corresponding application thereof or post-grant proceeding relating thereto and to execute any separate assignment in connection with any such application as Assignee may deem necessary or expedient; and (iii) perform all affirmative acts that may be necessary to obtain a grant of a valid patent to Assignee on any of the Inventions. The Assignor hereby appoints the Assignee to be its attorney in his name and on its behalf to execute documents, use the

Assignor's name and do all things which are necessary or desirable for the Assignee to obtain for itself or its nominee the full benefit of this Assignment in relation to the Patent Assets. This power of attorney is irrevocable and is given by way of security to secure the performance of the Assignor's obligations under this clause and the proprietary interest of the Assignee in the Patent Assets and so long as such obligations of the Assignor remain undischarged, or the Assignee has such interest, the power may not be revoked by the Assignor, save with the consent of the Assignee.

3. Assignor hereby assigns to Assignee all of Assignor's right, title, and interest in and to any claims, whether known or unknown, suspected or unsuspected, of any nature, including choses in action, that Assignor has or may have against any party for infringement of the Patent Applications, and acknowledges receipt of [***], and other good and valuable consideration, in consideration for this Assignment.

4. This Assignment is binding upon and inures to the benefit of the successors and assigns of the parties.

5. The Administrators are a party to this agreement in their own capacity solely for receiving and enforcing the obligations, undertakings and waivers on the part of the Assignee. The Administrators have entered into and signed this agreement as agent for and on behalf of the Assignor and the Administrators, their firm, employees and agents shall incur no personal liability whatsoever whether on their own part or in respect of any failure on the part of the Assignor to observe perform or comply with any such obligations hereunder or under or in relation to any associated arrangements or negotiations whether such liability would arise under the Insolvency Act 1986 or otherwise. The Parties acknowledge that the liability under this Agreement of the Assignor and that of the Administrators shall constitute an expense of the administration (within the meaning of rule 3.51 of the Insolvency Rules 2016) and shall have the ranking conferred by paragraph 99(4) of Schedule B1 of the Insolvency Act 1986. However, as to ranking, the Assignee agrees that any claim it may make in respect of any such liability will be subordinated to and will rank in order of priority below each of the expenses of the administration listed in Rule 3.51(2) of the Insolvency Rules 2016 and for sake of clarity the Assignor agrees that the Administrators can pay ahead of LOXO (and with no recourse from LOXO) all creditors of REDX that exist on the Effective Date and owe no duty to the Assignor to protect the value of the charged assets after their appointment ceases.

6. The Assignee agrees that neither the Assignor nor the Administrators shall incur any liability to it by reason of any fault or defect in or in title or otherwise of any or all of the Patent Assets.

7. This agreement and any dispute or claim (including non-contractual disputes or claims) arising out of or in connection with it or its subject matter or formation shall be governed by and construed in accordance with the law of England and Wales.

8. Each party irrevocably agrees that the courts of England and Wales shall have exclusive jurisdiction to settle any dispute or claim (including non-contractual disputes or claims) arising out of or in connection with this agreement or its subject matter or formation.

This document has been executed as a deed and is delivered and takes effect on the date stated at the beginning of it.

[ASSIGNMENT CONTINUES ON SIGNATURE PAGE]

EXECUTED AND DELIVERED
for and on behalf of **REDX PHARMA PLC**
(in administration)
by as its deed in the presence of

/s/ Jason D. Baker

/s/ Charlotte Quince
Signature

Charlotte Quince
Print name

EXECUTED AND DELIVERED
for and on behalf of **REDX ONCOLOGY**
LIMITED (in administration)
by as its deed in the presence of

/s/ Jason D. Baker

/s/ Charlotte Quince
Signature

Charlotte Quince
Print name

EXECUTED AND DELIVERED
for and on behalf of **LOXO ONCOLOGY, INC.**
by Joshua H. Bilenker as its deed in the presence of

/s/ Joshua H. Bilenker

/s/ Stephanie Bilenker
Signature

Stephanie Bilenker
Print name

EXECUTED AND DELIVERED
for and on behalf of by one **ADMINISTRATOR**
for and on behalf of both of them
by as its deed in the presence of

/s/ Jason D. Baker

/s/ Charlotte Quince
Signature

Charlotte Quince
Print name

Schedule 1: Patent Applications

Subject	Country	Application Number	Filing date	Status	Grant date	Expiry date*	Publication Number
[***]	[***]	[***]	[***]	[***]			
[***]	[***]	[***]	[***]	[***]			
	[***]	[***]	[***]	[***]			[***]
[***]	[***]	[***]	[***]	[***]			[***]
[***]	[***]	[***]	[***]	[***]			[***]
[***]	[***]	[***]	[***]	[***]			
	[***]	[***]	[***]	[***]			[***]
[***]	[***]	[***]	[***]	[***]			
	[***]	[***]	[***]	[***]			[***]
	[***]	[***]	[***]	[***]		[***]	[***]
	[***]	[***]	[***]	[***]		[***]	[***]
	[***]	[***]	[***]	[***]		[***]	[***]
	[***]	[***]	[***]	[***]		[***]	[***]
	[***]	[***]	[***]	[***]		[***]	[***]
	[***]	[***]	[***]	[***]		[***]	
	[***]	[***]	[***]	[***]		[***]	
[***]	[***]	[***]	[***]	[***]			

Subject	Country	Application Number	Filing date	Status	Grant date	Expiry date*	Publication Number
	[***]	[***]	[***]	[***]			
	[***]	[***]	[***]	[***]			
	[***]	[***]	[***]	[***]			[***]
[***]	[***]	[***]	[***]	[***]			
	[***]	[***]	[***]	[***]			
	[***]	[***]	[***]	[***]			[***]

* Expiry date does not take into account any potential extension or termination of term (e.g., patent term adjustment or the filing of terminal disclaimers)

Exhibit 31.1

Certification of Principal Executive Officer of Loxo Oncology, Inc.
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Joshua H. Bilenker, M.D., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Loxo Oncology, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. Evaluated the effectiveness of the registrant's disclosure controls and procedures, and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 2, 2017

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

Exhibit 31.2

Certification of Principal Financial Officer of Loxo Oncology, Inc.
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Jennifer Burstein, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Loxo Oncology, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. Evaluated the effectiveness of the registrant's disclosure controls and procedures, and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 2, 2017

/s/ Jennifer Burstein
Jennifer Burstein
Vice President of Finance (Principal Accounting Officer and Principal Financial Officer)

Exhibit 32.1

Certification Of
Principal Executive Officer
Pursuant To 18 U.S.C. Section 1350,
As Adopted Pursuant To
Section 906 of The Sarbanes-Oxley Act Of 2002

In connection with the Quarterly Report of Loxo Oncology, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2017, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Joshua H. Bilenker, M.D., President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2) The information contained in the Report fairly presents, in all material respects, the financial condition of the Company at the end of the period covered by the Report and results of operations of the Company for the period covered by the Report.

Date: November 2, 2017

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

This certification accompanies the Report and shall not be deemed "filed" by the Company with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Report), irrespective of any general incorporation language contained in such filing.

Exhibit 32.2

Certification Of
Principal Financial Officer
Pursuant To 18 U.S.C. Section 1350,
As Adopted Pursuant To
Section 906 Of The Sarbanes-Oxley Act Of 2002

In connection with the Quarterly Report of Loxo Oncology, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2017, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Jennifer Burstein, Vice President of Finance of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2) The information contained in the Report fairly presents, in all material respects, the financial condition of the Company at the end of the period covered by the Report and results of operations of the Company for the period covered by the Report.

Dated: November 2, 2017

/s/ Jennifer Burstein
Jennifer Burstein
Vice President of Finance
(Principal Financial Officer and Principal Accounting Officer)

This certification accompanies the Report and shall not be deemed "filed" by the Company with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Report), irrespective of any general incorporation language contained in such filing.