UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 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, 2019

OR

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

For the transition period from _____ to _____

Commission File Number: 001-38871

Turning Point Therapeutics, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**46-3826166**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
10628 Science Center Drive, Ste. 200 San Diego, California	**92121**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (858) 926-5251

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

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, $0.0001 par value per share	TPTX	The Nasdaq Stock Market LLC

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 every Interactive Data File required to be submitted 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 such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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	☒		

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 ☒

As of October 15, 2019, the registrant had 35,849,541 shares of common stock, $0.0001 par value per share, outstanding.

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PART I—FINANCIAL INFORMATION

Item 1. Financial Statements

Turning Point Therapeutics, Inc.

Condensed Balance Sheets

(In thousands, except share amounts)

	September 30, 2019 (Unaudited)	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 172,421	$ 101,029
Marketable securities	251,154	–
Prepaid expenses and other current assets	5,795	494
Total current assets	429,370	101,523
Property and equipment, net	2,184	1,000
Right-of-use assets from operating leases	4,761	–
Security deposits	73	73
Deferred financing costs	–	684
Total assets	$ 436,388	$ 103,280
Liabilities, convertible preferred stock, and stockholders' equity (deficit)		
Liabilities:		
Current liabilities:		
Accounts payable	$ 3,811	$ 1,494
Accrued expenses and other current liabilities	2,950	2,415
Accrued compensation	3,784	1,413
Current portion of operating lease liabilities	1,175	–
Total current liabilities	11,720	5,322
Operating lease liabilities, net of current portion	4,144	448
Commitments and contingencies (Note 7)		
Convertible preferred stock, $0.0001 par value; zero shares issued and outstanding as of September 30, 2019 and 65,423,901 shares issued and outstanding as of December 31, 2018; aggregate liquidation preference of $0 and $146,460 as of September 30, 2019 and December 31, 2018, respectively	–	145,916
Stockholders' equity (deficit):		
Common stock, $0.0001 par value; 200,000,000 shares authorized as of September 30, 2019 and 104,000,000 shares authorized as of December 31, 2018; 35,839,196 shares issued and outstanding as of September 30, 2019; 3,411,516 shares issued and outstanding at December 31, 2018	4	1
Additional paid-in capital	522,123	2,346
Accumulated other comprehensive income	322	–
Accumulated deficit	(101,925)	(50,753)
Total stockholders’ equity (deficit)	420,524	(48,406)
Total liabilities, convertible preferred stock, and stockholders’ equity (deficit)	$ 436,388	$ 103,280

See accompanying notes.

Turning Point Therapeutics, Inc.

Condensed Statements of Operations and Comprehensive Loss

(In thousands, except share and per share amounts)

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Operating expenses:				
Research and development	$ 16,640	$ 5,129	$ 40,802	$ 13,841
General and administrative	5,500	1,000	13,857	2,319
Total operating expenses	22,140	6,129	54,659	16,160
Loss from operations	(22,140)	(6,129)	(54,659)	(16,160)
Interest income	1,657	132	3,487	393
Net loss	$ (20,483)	$ (5,997)	$ (51,172)	$ (15,767)
Other comprehensive income:				
Unrealized gain (loss) on marketable securities, net of tax	(24)	–	322	-
Comprehensive loss	$ (20,507)	$ (5,997)	$ (50,850)	$ (15,767)
Net loss per share, basic and diluted	$ (0.63)	$ (1.77)	$ (2.54)	$ (4.66)
Weighted-average common shares outstanding, basic and diluted	32,312,814	3,394,423	20,178,979	3,381,404

See accompanying notes.

Turning Point Therapeutics, Inc.

Condensed Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)

(In thousands, except share amounts)

(Unaudited)

	Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive income (loss)	Accumulated Deficit	T Stock Equity
	Shares	Amount	Shares	Amount				
Balance at December 31, 2018	65,423,901	$ 145,916	3,411,516	$ 1	$ 2,346	$ –	$ (50,753)	$
Option exercises	–	–	12,337	–	22	–	–	
Stock-based compensation expense	–	–	–	–	1,926	–	–	
Net loss	–	–	–	–	–	–	(13,547)	
Balance at March 31, 2019	65,423,901	145,916	3,423,853	1	4,294	–	(64,300)	
Issuance of common stock in connection with an initial public offering, net of underwriting discounts, commissions, and offering costs	–	–	10,637,500	1	175,150	–	–	
Conversion of convertible preferred stock into common stock	(65,423,901)	(145,916)	16,993,194	2	145,914	–	–	
Option exercises	–	–	242,876	–	591	–	–	
Stock-based compensation expense	–	–	–	–	3,059	–	–	
Net loss	–	–	–	–	–	–	(17,142)	
Other comprehensive income	–	–	–	–	–	345	–	
Balance at June 30, 2019	–	–	31,297,423	4	329,008	345	(81,442)	
Option exercises	–	–	41,773	–	96	–	–	
Stock-based compensation expense	–	–	–	–	3,493	–	–	
Issuance of common stock in connection with an equity offering, net of underwriting discounts, commissions, and offering costs	–	–	4,500,000	–	189,526	–	–	
Net loss	–	–	–	–	–	–	(20,483)	
Other comprehensive loss	–	–	–	–	–	(23)	–	
Balance at September 30, 2019	–	–	35,839,196	$ 4	$ 522,123	$ 322	$ (101,925)	$

	Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive income (loss)	Accumulated Deficit	T Stock D
	Shares	Amount	Shares	Amount				
Balance at December 31, 2017	39,135,778	$ 66,161	3,367,742	$ 1	$ 1,123	$ –	$ (25,968)	$
Option exercises	–	–	2,597	–	6	–	–	
Stock-based compensation expense	–	–	–	–	85	–	–	
Net loss	–	–	–	–	–	–	(4,733)	
Balance at March 31, 2018	39,135,778	66,161	3,370,339	1	1,214	–	(30,701)	
Option exercises	–	–	20,777	–	39	–	–	
Stock-based compensation expense	–	–	–	–	137	–	–	
Net loss	–	–	–	–	–	–	(5,037)	
Balance at June 30, 2018	39,135,778	$ 66,161	3,391,116	$ 1	$ 1,390	$ –	$ (35,738)	$
Option exercises	–	–	17,478	–	26	–	–	
Stock-based compensation expense	–	–	–	–	179	–	–	
Net loss	–	–	–	–	–	–	(5,997)	
Balance at September 30, 2018	39,135,778	66,161	3,408,594	$ 1	$ 1,595	$ –	$ (41,735)	$

See accompanying notes.

Turning Point Therapeutics, Inc.

Condensed Statements of Cash Flows

(In thousands)

(Unaudited)

	Nine Months Ended September 30,	
	2019	**2018**
Operating activities		
Net loss	$ (51,172)	$ (15,767)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	8,478	401
Depreciation	322	64
Accretion of discount on marketable securities	(846)	–
Amortization of right-of-use operating lease asset	707	–
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(4,618)	(49)
Accounts payable	1,196	506
Accrued expenses and other current liabilities	(122)	(1,257)
Accrued compensation	2,370	427
Net cash used in operating activities	(43,685)	(15,675)
Investing activities		
Purchases of marketable securities	(264,909)	–
Maturities of marketable securities	14,923	–
Purchases of property and equipment	(983)	(221)
Net cash used in investing activities	(250,969)	(221)
Financing activities		
Proceeds from issuance of common stock in initial public offering, net	175,151	–
Proceeds from issuance of common stock in public offering, net	190,186	–
Proceeds from issuance of common stock from stock option exercises	709	71
Net cash provided by financing activities	366,046	71
Net increase (decrease) in cash and cash equivalents	71,392	(15,825)
Cash and cash equivalents at the beginning of period	101,029	45,033
Cash and cash equivalents at the end of period	$ 172,421	$ 29,208
Supplemental disclosure of cash flow information:		
Cash paid for income taxes	$ 1	$ 1
Supplemental disclosure of non-cash investing and financing information:		
Purchases of property and equipment in accounts payable	$ 523	$ –
Costs incurred in connection with the public offering included in accounts payable and accrued expenses	$ 660	$ -
Operating lease liabilities arising from obtaining right-of-use assets	$ 5,554	$ -

See accompanying notes.

1. Formation and Business of the Company; Basis of Presentation

Organization

Turning Point Therapeutics, Inc. (the Company) was organized in 2013 and commenced operations in 2014. The Company is a clinical stage biopharmaceutical company designing and developing novel small molecule, targeted oncology therapies. The Company's principal operations are in the United States and the Company operates in one segment, with its headquarters in San Diego, California.

The Company's primary activities since inception have been to build infrastructure, conduct research and development, including clinical trials, perform business and financial planning, and raise capital.

The accompanying unaudited condensed financial statements have been prepared in accordance with U.S. generally accepted accounting principles (GAAP) for interim financial information and pursuant to Form 10-Q and Article 10 of Regulation S-X of the Securities and Exchange Commission (SEC). Accordingly, since they are interim statements, the accompanying condensed financial statements do not include all of the information and notes required by GAAP for complete financial statements. The unaudited interim financial statements reflect all adjustments which, in the opinion of management, are necessary for a fair statement of the results for the periods presented. All such adjustments are of a normal and recurring nature. The condensed balance sheet at December 31, 2018 has been derived from the audited consolidated financial statements at that date, but does not include all information and footnotes required by GAAP for complete financial statements. The operating results presented in these unaudited condensed financial statements are not necessarily indicative of the results that may be expected for any future periods. These unaudited condensed financial statements should be read in conjunction with the audited consolidated financial statements and the notes thereto for the year ended December 31, 2018 included in the Company's prospectus dated April 16, 2019 that forms a part of the Company's Registration Statements on Form S-1, as filed with the SEC pursuant to Rule 424 promulgated under the Securities Act of 1933, as amended, on April 18, 2019.

Public Offerings

On April 22, 2019, the Company completed an initial public offering (IPO) of its common stock. In connection with its IPO, the Company issued and sold 10,637,500 shares of its common stock at a price to the public of $18.00 per share. The net proceeds from the IPO were approximately $175.2 million after deducting underwriting discounts and commissions of $13.4 million and offering expenses of approximately $2.9 million paid by the Company. At the closing of the IPO, 65,423,901 shares of outstanding convertible preferred stock were automatically converted into 16,993,194 shares of common stock. Following the IPO, there were no shares of preferred stock outstanding.

On September 10, 2019, the Company completed an underwritten public offering of its common stock, which resulted in the issuance and sale of an aggregate of 4,500,000 shares of common stock at a public offering price of $45.00 per share. The net proceeds from the offering were approximately $189.5 million, after deducting underwriting discounts and commissions of $12.2 million and offering expenses of approximately $0.8 million payable by the Company.

Reverse Stock Split

On April 5, 2019, the Company effected a 1-for-3.85 reverse stock split of its common stock. The par value and the authorized number of shares of the common stock were not adjusted as a result of the reverse stock split. The accompanying financial statements and notes to the financial statements give retroactive effect to the reverse stock split for all periods presented.

Liquidity

Substantial doubt about an entity's ability to continue as a going concern exists when relevant conditions and events, considered in the aggregate, indicate that it is probable that the entity will be unable to meet its obligations as they become due within one year from the financial statement issuance date. The Company determined that there are no conditions or events that raise substantial doubt about its ability to continue as a going concern within one year after the date that the condensed financial statements for the quarter ended September 30, 2019 are issued.

2. Summary of Significant Accounting Policies

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that impact the reported amounts of assets, liabilities and expenses and the disclosure of contingent assets and liabilities in the Company's financial statements and accompanying notes. The most significant estimates in the Company's financial statements relate to preclinical and clinical study accruals and stock-based compensation costs. Management bases its estimates on historical experience and on various other market-specific and relevant assumptions that management believes to be reasonable under the circumstances. Although these estimates are based on the Company's knowledge of current events and actions it may undertake in the future, actual results may ultimately materially differ from these estimates and assumptions.

Marketable securities

The Company classifies all marketable securities as available for sale, as the sale of such securities may be required prior to maturity. These marketable securities are carried at fair value, with unrealized gains and losses reported as accumulated other comprehensive income (loss) until realized. The cost of debt securities is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization and accretion, as well as interest and dividends, are included in interest income. Realized gains and losses from the sale of available for sale securities, if any, are determined on a specific identification basis and are also included in interest income. The Company's marketable securities are classified as current assets, even though the stated maturity date may be one year or more beyond the current balance sheet date, which reflects management's intention to use the proceeds from sales of these securities to fund our operations, as necessary.

At each reporting date, the Company performs an evaluation of impairment to determine if any unrealized losses are other-than-temporary. Factors considered in determining whether a loss is other-than-temporary include the length of time and extent to which fair value has been less than the cost basis, the financial condition of the issuer, and the Company's intent and ability to hold the investment until recovery of the amortized cost basis. The Company intends, and has the ability, to hold its investments until their amortized cost basis has been recovered.

Concentration of Credit Risk

Substantially all the Company's cash and money market funds are held with a single financial institution. Due to its size, the Company believes this financial institution represents a minimal credit risk. Cash amounts held at financial institutions are insured by the Federal Deposit Insurance Corporation (FDIC) up to $250,000. At September 30, 2019, the Company had $423.4 million in excess of the FDIC insured limit. At September 30, 2019, the Company's money market funds and marketable securities are not subject to FDIC insurance. The Company's money market funds and marketable securities are invested in short term, high grade securities. As a result, the Company believes its money market and marketable securities represent a minimal credit risk.

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation. Depreciation is calculated using the straight-line method over the estimated useful life of the assets, which ranges between three to seven years. Tenant improvements are stated at cost and depreciated over the shorter of the estimated useful life or the remaining life of the lease at the time the asset is placed into service.

Intellectual Property

The legal and professional costs incurred by the Company to maintain its patent rights have been expensed as part of general and administrative expenses since inception. As of September 30, 2019, the Company has determined that these expenses have not met the criteria to be capitalized. Intellectual property related expenses were $0.3 million and $0.1 million for the three months ended September 30, 2019 and 2018, respectively and were $0.6 million and $0.3 million for the nine months ended September 30, 2019 and 2018, respectively.

Research and Development Expenses

Research and development costs are expensed as incurred. These costs consist primarily of salaries and other personnel-related expenses, including stock-based compensation; facility-related expenses; depreciation of facilities and equipment; laboratory consumables; and services performed by clinical research organizations, clinical manufacturing services, research institutions, and other outside service providers.

Income Taxes

Deferred tax assets and liabilities are determined based on the differences between the financial reporting and tax basis of assets and liabilities using enacted tax rates which will be in effect when the differences reverse. The Company provides a valuation allowance against net deferred tax assets unless, based upon the available evidence, it is more likely than not that the deferred tax asset will be realized.

The Company follows the provisions of the Income Taxes Topic of the Financial Accounting Standards Board (FASB) Accounting Standards Codification that defines a recognition threshold and measurement attributes for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. Under the Income Taxes Topic, the impact of an uncertain income tax position on the income tax return must be recognized at the largest amount that is more-likely-than-not to be sustained upon audit by the relevant taxing authority. An uncertain income tax position will not be recognized if it has less than a 50% likelihood of being sustained.

Stock-Based Compensation

Stock-based compensation expense represents the cost of the grant date fair value of employee and non-employee stock option grants recognized over the requisite service period of the awards (usually the vesting period) on a straight-line basis, net of actual forfeitures during the period. The Company estimates the fair value of stock option grants using the Black-Scholes option pricing model. Prior to the Company's IPO, the exercise price for all stock options granted was at the estimated fair value of the underlying common stock as determined on the date of grant by the Company's Board of Directors.

Net Loss Per Share

The Company computes basic loss per share by dividing the net loss available to common stockholders by the weighted average number of common shares outstanding for the period, without consideration for common stock equivalents. Diluted net loss assumes the conversion, exercise or issuance of all potential common stock equivalents, unless the effect of inclusion would be anti-dilutive. For purposes of this calculation, common stock equivalents include the Company's stock options and convertible preferred stock, which is convertible into shares of the Company's common stock. No shares related to the convertible preferred stock were included in the diluted net loss calculation for the three and nine months ended September 30, 2019 or 2018 because the inclusion of such shares would have had an anti-dilutive effect. The shares to be issued upon exercise of certain outstanding stock options were also excluded from the diluted net loss calculation for the three and nine months ended September 30, 2019 and 2018 because such shares are anti-dilutive.

Historical outstanding anti-dilutive securities not included in the diluted net loss per share calculation include the following:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Convertible preferred stock (as converted)	–	10,165,120	–	10,165,120
Common stock options	5,119,383	1,030,176	5,119,383	1,030,176
Total	5,119,383	11,195,296	5,119,383	11,195,296

Recent Accounting Pronouncements Not Yet Adopted

In June 2016, the FASB issued Accounting Standards Update (ASU) No. 2016-13, *Financial Instruments – Credit Losses*, which changes the accounting for recognizing impairments of financial assets. Under the new guidance, credit losses for certain types of financial instruments will be estimated based on expected losses. The new guidance also modifies the impairment models for available for sale debt securities and for purchased financial assets with credit deterioration since their origination. This update is effective for annual periods beginning after December 15, 2019, and interim periods within those periods, and early adoption is permitted. The Company is in the process of determining the effects the adoption will have on its financial statements.

In August 2018, the FASB issued ASU No. 2018-13, *Fair Value Measurement: Disclosure Framework – Changes to the Disclosure Requirements for Fair Value Measurement*, which adds and modifies certain disclosure requirements for fair value measurements. Under the new guidance, entities will no longer be required to disclose the amount of and reasons for transfers between Level 1 and Level 2 of the fair value hierarchy, or valuation processes for Level 3 fair value measurements. However, public companies will be required to disclose the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements, and related changes in unrealized gains and losses included in other comprehensive income. This update is effective for annual periods beginning after December 15, 2019, and interim periods within those periods, and early adoption is permitted. The Company is in the process of determining the impact the adoption will have on its financial statements.

Recently Adopted Accounting Standards Updates

In February 2016, the FASB issued ASU No. 2016-02, "*Leases*". ASU 2016-02 requires lessees to recognize most leases on their balance sheet as a right-of-use asset and a lease liability. The Company adopted the new standard beginning January 1, 2019 using a modified retrospective approach. ASU 2016-02 provides a number of optional practical expedients and accounting policy elections. The Company elected the package of practical expedients requiring no reassessment of whether any expired or existing contracts are

or contain leases, the lease classification of any expired or existing leases, or initial direct costs for any existing leases. As a result of these decisions, financial information will not be updated, and the disclosures required under this guidance will not be provided for dates and periods prior to January 1, 2019. Additionally, the Company elected the hindsight provision for determining the lease term and elected to aggregate all lease and non-lease components for each class of underlying assets into a single lease component.

The Company currently has one operating lease for office and laboratory spaces in San Diego, California. The operating lease was impacted by the new accounting standard and resulted in the present values of the future lease payments being presented as a right-to-use asset, with a corresponding lease liability at the date of adoption. The financial impact from the adoption of this guidance is discussed in Note 7.

3. Marketable Securities

The Company invests its excess cash in marketable securities, including debt instruments of financial institutions, corporations with investment grade credit ratings, commercial paper and government agencies.

At September 30, 2019, marketable securities consisted of the following (in thousands):

	Maturity	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
U.S. government agency securities	2 years or less	$ 28,607	$ 13	$ (4)	$ 28,616
Corporate debt securities	2 years or less	119,313	233	(6)	119,540
Commercial paper	1 years or less	102,913	101	(16)	102,998
Total marketable securities		$ 250,833	$ 347	$ (26)	$ 251,154

The Company's marketable securities are classified as current assets, even though the stated maturity date may be one year or more beyond the current balance sheet date, which reflects management's intention to use the proceeds from sales of these securities to fund our operations, as necessary. Gross realized gains and losses on available for sale securities were immaterial during the three and nine months ended September 30, 2019. At December 31, 2018, the Company had no marketable securities.

None of the investments have been in a gross unrealized loss for a period greater than 12 months. The Company did not identify any other-than-temporary losses as of September 30, 2019.

4. Fair Value Measurements

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants at the measurement date. Fair value should maximize the use of observable inputs and minimize the use of unobservable inputs. The Company determines the fair value of financial assets and liabilities using three levels of inputs as follows:

Level 1 – Inputs which include quoted prices in active markets for identical assets or liabilities at the measurement date.

Level 2 – Inputs (other than quoted market prices included in Level 1) that are either directly or indirectly observable, 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 instrument's anticipated life.

Level 3 – Unobservable inputs for assets or liabilities and include little or no market activity.

A financial instrument's categorization within the valuation hierarchy is based upon the lowest level of input that is significant to the fair value measurement. During the three and nine months ended September 30, 2019, the Company had no Level 3 financial assets or liabilities that were subject to fair value measurements on a recurring basis. During the three and nine months ended September 30, 2018, the Company had no Level 2 or 3 financial assets or liabilities that were subject to fair value measurements on a recurring basis.

The Company's financial assets subject to fair value measurements on a recurring basis and the level of inputs used for such measurements were as follows (in thousands):

	Fair Value Measurements at September 30, 2019 Using:			
	Level 1	Level 2	Level 3	Total
Money market funds included in cash and cash equivalents	$ 163,403	$ -	$ -	$ 163,403
U.S. government agency securities	-	28,616	-	28,616
Corporate debt securities	-	119,540	-	119,540
Commercial paper	-	111,608	-	111,608
Total marketable securities	$ 163,403	$ 259,764	$ -	$ 423,167

	Fair Value Measurements at December 31, 2018 Using:			
	Level 1	Level 2	Level 3	Total
Money market funds included in cash and cash equivalents	$ 98,268	-	-	$ 98,268

5. Property and Equipment, Net

Property and equipment, net consisted of the following (in thousands):

	September 30, 2019	December 31, 2018
Laboratory equipment	$ 785	$ 388
Computer equipment and software	708	138
Tenant improvements	911	679
Furniture and fixtures	201	66
	2,605	1,271
Less: accumulated depreciation	(421)	(271)
Total	$ 2,184	$ 1,000

Depreciation expense was $0.1 million and $25,000 for the three months ended September 30, 2019 and 2018, respectively and depreciation expense was $0.3 million and $0.1 million for the nine months ended September 30, 2019 and 2018, respectively.

6. Accrued Expenses and Other Current Liabilities

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

	September 30, 2019	December 31, 2018
Accrued research and development expenses	$ 2,514	$ 1,677
Accrued general and administrative expenses	332	548
Other current liabilities	104	190
Total	$ 2,950	$ 2,415

7. Commitments and Contingencies

Operating Leases

The Company entered into a lease agreement during January 2016, which commenced in July 2016, for its current office and primary research facility located in San Diego, California. In June 2018, the Company amended its existing lease agreement to expand its office and laboratory space within the same building, which the Company occupied commencing September 2018. The amended lease term for all leased premises had an expiration date of December 31, 2021, and an option to extend the lease term on all leased space for one additional five-year term. As of the date of adoption of ASC 842, the Company was not reasonably certain that it would exercise the extension option, and as such, did not include this option in the determination of the total lease term. The lease includes both discounts of certain base rents during 2016 and 2019, and escalating lease payments over the term.

On January 1, 2019, in conjunction with the adoption of the guidance in ASU 2016-02 - *"Leases"*, the Company recognized a right-of-use asset and corresponding lease liability for its facility lease as the present value of lease payments not yet paid at January 1, 2019. The right-of-use asset and corresponding lease liability was estimated assuming the remaining lease term of 36 months at January 1, 2019, and an estimated discount rate of 8.5%, which was the Company's incremental borrowing rate at the date of adopting ASC 842. The Company recorded a lease liability of $2.3 million and a right-of-use asset of $1.7 million, which is net of $0.6 million of the Company's previously capitalized tenant improvement allowance and deferred rent, upon adoption.

In June 2019, the Company amended the terms of its existing facility lease in conjunction with entering into a lease for additional office and laboratory space and agreed to surrender a portion of its current laboratory and office space and to extend the lease term for its remaining laboratory and office space to June 30, 2023. The execution of the new lease and the amendment to the Company's existing facility lease were accounted for as a single contract for accounting purposes, as the counterparty to both contracts is the Company's existing landlord and both agreements were negotiated contemporaneously as a whole to achieve the same commercial objective.

In June 2019, the Company accounted for the partial surrender of office and laboratory space as a reduction to its existing right-of-use asset and liability totaling $0.6 million, and $0.9 million, respectively. The difference between these amounts was recorded as a deferred gain of $0.3 million. The deferred gain was recorded as an offset to the right of use asset recorded by the Company on July 1, 2019.

In June 2019, and in connection with the extension of the lease term of the Company's previously existing office and laboratory space, the Company recognized an incremental increase of $0.5 million to its existing right of use asset and lease liability. The adjustment was computed assuming a lease term ending in June 2023 and an estimated incremental borrowing rate of 8.5%. This right-of-use asset was recorded net of $0.3 million associated with the lease extension, which represents the Company's net unamortized capitalized tenant improvement allowance and deferred rent.

The new lease commenced in July 2019 and the lease expiration date is June 30, 2023. In addition to base rental payments under this lease, which escalate over the term of the lease, the Company will also be responsible for the payment of its share of the estimated annual operating expenses, property tax expenses, and utilities costs related to this lease of additional space. The lease also contains an option to extend the lease term on all leased space for one additional five-year term. As of July 1, 2019, the Company was not reasonably certain that it would exercise the extension option, and as such, will not include this option in the determination of the total lease term for accounting purposes. The right-of-use asset and corresponding lease liability was estimated assuming the remaining lease term of 48 months at July 1, 2019, and an estimated discount rate of 8.5%, which was the Company's incremental borrowing rate at the date of the lease commencement. The Company recorded a lease liability of $4.0 million and a right-of-use asset of $3.7 million, which is net of $0.3 million of the Company's deferred gain from the office and laboratory space surrendered in June 2019.

Future minimum payments under the amended lease as of September 30, 2019 are as follows (in thousands):

2019 (Three months remaining)	$	375
2020		1,619
2021		1,668
2022		1,718
2023		872
Total future minimum lease payments		6,252
Less: Amounts representing interest		(933)
Total lease liability	$	5,319
Remaining lease term		3.8 years

Rent expense was $0.4 million and $0.1 million for the three months ended September 30, 2019 and 2018, respectively and was $0.7 million and $0.3 million for the nine months ended September 30, 2019 and 2018, respectively. The Company made cash payments related to its operating lease agreement of $0.4 million and $0.1 million for the three months ended September 30, 2019 and 2018, respectively and $0.8 million and $0.3 million for the nine months ended September 30, 2019 and 2018, respectively.

8. Related Party Transactions

The Company has entered into several contracts for drug product development and manufacturing with a vendor for which one of the Company's former directors is a co-founder and part owner. The Company paid this related party $0.1 million for the nine months ended September 30, 2019 and 2018, respectively, for drug product development and manufacturing services. The Company did not make any related party payments for the three months ended, September 30, 2019 and 2018, respectively and did not have any unpaid invoices with the related party as of each of September 30, 2019 and 2018.

9. Equity

The Company's 2019 Equity Incentive Plan as amended (the Plan), provides for the grant of stock options, restricted stock and other equity awards of the Company's common stock to employees, officers, consultants, and directors. As of September 30, 2019, the Plan had a maximum of 2,834,049 total shares available for issuance.

Options expire within a period of not more than ten years from the date of grant. Initial option grants to employees typically vest 25% after one year and monthly thereafter over a three-year period and expire between one and three months after employee termination. Subsequent option grants to employees and grants to non-employees typically vest monthly over a four-year period. The majority of options outstanding at September 30, 2019, had vesting periods of four years.

The weighted-average grant-date fair value of options granted to employees was $32.92 and zero for the three months ended September 30, 2019 and 2018, respectively and was $20.12 and $3.64, for the nine months ended September 30, 2019 and 2018, respectively.

The following summarizes option activity under the Plan for the nine months ended September 30, 2019 (amounts in thousands, except share amounts):

	Outstanding Options	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Balances as of December 31, 2018	3,597,638	$ 4.40	9.50	$ 15,056
Options granted	2,120,923	$ 24.59		
Options exercised	(296,986)	$ 2.39		
Options cancelled	(302,192)	$ 6.14		
Balances as of September 30, 2019	5,119,383	$ 12.78	9.08	$ 133,525
Options exercisable as of September 30, 2019	924,997	$ 4.44	8.17	$ 30,681

Stock-Based Compensation Expense

The weighted-average assumptions used in the Black-Scholes option pricing model to determine the fair value of the employee and nonemployee stock option grants were as follows:

Expected Term— The Company uses the "simplified method" for estimating the expected term of employee options, whereby the expected term equals the arithmetic average of the vesting term and the original contractual term of the option (generally 10 years).

Expected Volatility— Due to the Company's limited operating history and a lack of company specific historical and implied volatility data, the Company estimates expected volatility based on the historical volatility of a group of similar companies that are publicly traded. The historical volatility data was computed using the daily closing prices for the selected companies' shares during the equivalent period of the calculated expected term of the stock-based awards.

Risk-Free Interest Rate—The risk-free rate assumption is based on the U.S. Treasury instruments with maturities similar to the expected term of the stock options.

Expected Dividend— The Company has not issued any dividends and does not expect to issue dividends over the life of the options. As a result, the Company has estimated the dividend yield to be zero.

The fair values of the employee stock options granted under the Plan were estimated using the following assumptions:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Risk-free interest rate	1.64%	–%	2.18%	2.79%
Volatility	80.2%	–%	79.6%	82.5%
Expected term (in years)	6.06	—	6.05	6.04
Dividend yield	–%	–%	–%	–%

Stock-based compensation expense, net of forfeitures, is reflected in the statements of operations and comprehensive loss as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Research and development	$ 1,771	$ 120	$ 4,052	$ 237
General and administrative	1,722	59	4,426	163
Total stock-based compensation	$ 3,493	$ 179	$ 8,478	$ 400

As of September 30, 2019, there was $50.7 million in total unrecognized compensation expense to be recognized over a weighted average period of 3.11 years.

Common Stock Reserved for Future Issuance

Common stock reserved for future issuance consists of the following:

	September 30, 2019	December 31, 2018
Conversion of preferred stock outstanding	–	16,993,194
Common stock options outstanding	5,119,383	3,597,638
Shares available for issuance under equity incentive plans	2,834,049	1,816,266
Total	7,953,432	22,407,098

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

*The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited condensed financial statements and related notes included in this Quarterly Report on Form 10-Q and the audited financial statements and notes thereto as of and for the year ended December 31, 2018 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our final prospectus filed with the Securities and Exchange Commission (SEC), on April 18, 2019 relating to our Registration Statements on Form S-1 (File Nos. 333-*230428 and 333-230911*) (the Prospectus). Unless the context requires otherwise, references in this Quarterly Report on Form 10-Q to "we," "us," and "our" refer to Turning Point Therapeutics, Inc.*

Forward-Looking Statements

In addition to historical financial information, this discussion contains forward-looking statements based upon current expectations that involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth in the section titled "Risk Factors" under Part II, Item 1A below. In some cases, you can identify forward-looking statements by terminology such as "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potentially," "predict," "should," "will" or the negative of these terms or other similar expressions.

In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Quarterly Report on Form 10-Q, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements.

Overview

We are a clinical-stage biopharmaceutical company designing and developing novel small molecule, targeted oncology therapies to address key limitations of existing therapies and improve the lives of patients. Our internally developed and wholly owned pipeline of next-generation tyrosine kinase inhibitors (TKIs) targets numerous genetic drivers of cancer in both TKI-naive and TKI-pretreated patients. The pervasive challenges of intrinsic and acquired treatment resistance often limit the response rate and durability of existing therapies. One of these challenges is the emergence of solvent front mutations, which are a common cause of acquired resistance to currently approved therapies for ROS1, TRK and ALK kinases. We have developed a macrocycle platform enabling us to design proprietary small, compact TKIs with rigid three-dimensional structures that potentially bind to their targets with greater precision and affinity than other kinase inhibitors. We believe the TKIs generated from our macrocycle platform have the potential to be best-in-class.

Our lead drug candidate, repotrectinib, is being evaluated in an ongoing Phase 1/2 trial called TRIDENT-1 for the treatment of patients with *ROS1+* advanced non-small cell lung cancer (NSCLC) and patients with *ROS1+*, *NTRK+* or *ALK+* advanced solid tumors. We initiated the multi-cohort Phase 2 registrational portion of TRIDENT-1 in June 2019 and are planning an early interim data read-out from initial patients from some of the registrational cohorts within the Phase 2 portion of TRIDENT-1 in the second half of 2020. We plan to conduct the trial in approximately 100 sites in the United States, Europe and Asia-Pacific regions, and to enroll a total of approximately 310 patients with *ROS1+* advanced NSCLC or *NTRK+* advanced solid tumors across five single-arm basket cohorts, which are potentially registrational, with one additional cohort which will enroll patients with *ALK+* and *ROS+* tumors that are not NSCLC, and is not registrational. We also anticipate initiating our Phase 1/2 open label, multi-center, dose-escalation, safety, pharmacokinetics and pharmacodynamics clinical trial of repotrectinib in pediatric patients with *ROS1+*, *NTRK+* or *ALK+* advanced solid tumors in the fourth quarter of 2019. The Phase 1 portion of the study plans to enroll up to 12 pediatric patients under the age of 12 at the adult equivalent dose of 160 mg QD. In parallel, the Phase 2 portion will enroll approximately 60 patients aged 12 to 25 years into 3 cohorts: *NTRK TKI*-treatment naïve; *NTRK TKI*-pretreated patients; and other solid tumors with *ALK* or *ROS1* or *NTRK* alterations who are not eligible for Cohort 1 or 2, each at the recommended Phase 2 dose regimen currently utilized in the ongoing Phase 2 TRIDENT-1 study.

In addition to repotrectinib, our pipeline includes two multi-targeted kinase inhibitors, TPX-0022 (a novel MET/CSF1R/SRC inhibitor) and TPX-0046 (a novel RET/SRC inhibitor), and a series of next-generation ALK inhibitors, from which we anticipate selecting a final candidate for investigational new drug application (IND)-enabling studies later this year. We initiated our Phase 1 clinical trial of TPX-0022 in patients with advanced solid tumors harboring genetic alterations in *MET* in July 2019 following clearance of the IND in May 2019. The Phase 1 trial is designed to evaluate the overall safety profile, pharmacokinetics and preliminary efficacy of TPX-0022 and includes a dose-escalation portion starting at 20 mg daily, or QD, followed by dose expansion cohorts with a targeted enrollment of 120 patients at sites in the United States, Europe, and Asia-Pacific regions. The dose expansion cohorts are planned to enroll MET therapy-naïve and pretreated NSCLC patients with *MET* exon 14 skipping mutations; patients with *MET*-amplified NSCLC, hepatocellular, gastric or gastroesophageal cancer; and patients with other solid tumors harboring *MET* kinase domain mutations or *MET* fusions. We anticipate reporting initial data from this Phase 1 trial in the second half of 2020. Our IND for TPX-0046 cleared in September 2019, and we anticipate initiating our Phase 1/2 clinical trial in patients with advanced solid tumors harboring *RET* genetic alterations in the fourth quarter of 2019. The trial is designed to enroll TKI-naïve and TKI-pretreated patients with *RET*-altered non-small-cell lung, thyroid, and other advanced cancers in multiple cohorts to assess safety, tolerability, pharmacokinetics and preliminary clinical activity of TPX-0046, with a targeted enrolment of approximately 50 patients in the Phase 1 dose escalation portion, and approximately 300 patients in the Phase 2 expansion portion at sites in the United States, Europe and Asia-Pacific regions. The study design allows intra-patient dose escalation based on tolerability in both RET TKI-treatment naïve and -pretreated patients.

Since our inception, we have incurred significant operating losses. Our ability to generate product revenue sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of one or more of our drug candidates. As of September 30, 2019, we had an accumulated deficit of $101.7 million and we incurred net losses of approximately $51.2 million for the nine months ended September 30, 2019. We expect to continue to incur significant expenses and increasing operating losses for at least the next several years.

We will not generate revenue from product sales unless we successfully complete clinical development and obtain regulatory approval for our drug candidates. If we obtain regulatory approval for any of our drug candidates and do not enter into a commercialization partnership, we expect to incur significant expenses related to developing our internal commercialization capability to support product sales, marketing and distribution. We also expect to incur additional costs associated with operating as a public company.

As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through a combination of equity offerings, debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements. We may be unable to raise additional funds or enter into such other agreements or arrangements when needed on favorable terms, or at all. If we fail to raise capital or enter into such agreements we may have to significantly delay, scale back or discontinue the development and commercialization of one or more of our drug candidates.

On April 22, 2019, we completed an initial public offering whereby we sold an aggregate of 10,637,500 shares of our common stock at a price of $18.00 per share, resulting in net proceeds of $175.2 million after deducting underwriting discounts, commissions and other offering costs.

On September 10, 2019, we completed an additional public offering of our common stock which resulted in the issuance and sale of 4,500,000 shares of common stock at a price of $45.00 per share, resulting in net proceeds of $189.5 million after deducting underwriting discounts and commissions and other offering costs.

Components of Our Results of Operations

Revenue

To date, we have not generated any revenue from product sales, licenses or collaborations and do not expect to generate any revenue from the sale of products in the foreseeable future, if ever. If our development efforts for our drug candidates are successful and result in regulatory approval, we may generate revenue from future product sales. If we enter into license or collaboration agreements for any of our drug candidates or intellectual property, we may generate revenue in the future from payments as a result of such license or collaboration agreements. We cannot predict if, when, or to what extent we will generate revenue from the commercialization and sale of our drug candidates. We may never succeed in obtaining regulatory approval for any of our drug candidates.

Operating Expenses

Research and Development Expenses

Research and development expenses consist primarily of costs incurred for our research activities, including our drug discovery efforts, and the development of our drug candidates, which include:

- employee-related expenses, including salaries, related benefits, travel and stock-based compensation expense for employees engaged in research and development functions;
- expenses incurred in connection with the preclinical and clinical development of our drug candidates, including expenses incurred under agreements with contract research organizations (CROs);
- the cost of consultants and contract manufacturing organizations (CMOs) that manufacture drug products for use in our preclinical studies and clinical trials; and
- facilities, depreciation and other expenses, which include allocated expenses for rent and maintenance of facilities, insurance and supplies.

We expense research and development costs to operations as incurred. Nonrefundable advance payments for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses. The prepaid amounts are expensed as the related goods are delivered or the services are performed.

Our direct research and development expenses are tracked on a program-by-program basis and consist primarily of external costs, such as fees paid to consultants, central laboratories, contractors, CMOs and CROs in connection with our preclinical and clinical development activities. We allocate indirect expenses, such as employee salaries, fringe benefits, facilities, travel and other miscellaneous expenses, based on an estimated percentage of time worked on programs.

The table below summarizes research and development expenses incurred by development program (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Research and development expenses				
Repotrectinib	$ 10,689	$ 2,435	$ 26,664	$ 8,130
Other research programs	5,951	2,694	14,138	5,711
Total research and development expenses	$ 16,640	$ 5,129	$ 40,802	$ 13,841

We anticipate that our research and development expenses will increase as a result of increased headcount, expanded infrastructure and higher consulting related to the initiation and expansion of our new and ongoing clinical and preclinical activities.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and related costs for personnel in executive, finance and administrative functions. General and administrative expenses also include travel expenses and direct and allocated facility-related costs, as well as professional fees for legal, accounting and tax-related services and insurance costs.

We anticipate that our general and administrative expenses will increase as a result of increased headcount, expanded infrastructure and higher consulting, legal, tax-related services and insurance costs associated being a public company.

Interest Income

Interest income consists of interest earned on cash and cash equivalents and our marketable securities.

Income Taxes

We are subject to typical corporate U.S. federal and state income taxation. As of December 31, 2018, we had federal and state net operating loss carryforwards of approximately $40.4 million and $47.2 million, respectively. The $20.5 million of federal tax loss carryforwards is available to offset 100% of taxable income and will begin to expire in 2033, if not utilized. The $19.9 million of federal net operating loss generated post 2017 is limited to eighty-percent of taxable income generated in any given year and can be carried forward indefinitely. As of December 31, 2018, we had federal and state research and development tax credits of approximately $0.3 million and $0.6 million, respectively. As of December 31, 2018, we had federal Orphan Drug tax credits of approximately $6.7 million. If not utilized, the federal research tax credit will begin to expire in 2035 and the Orphan Drug credit will begin to expire in 2037. The California research tax credit can be carried forward indefinitely.

Utilization of the net operating loss carryforwards may be subject to a substantial annual limitation due to the ownership change limitations provided by the Internal Revenue Code of 1986, as amended, and similar state provisions. The annual limitation may result in the expiration of net operating losses and credits before utilization. An analysis to determine the limitation of the net operating loss carryforwards has not been performed.

Critical Accounting Policies and Estimates

Management's discussion and analysis of our financial condition and results of operations are based upon our financial statements, which are prepared in accordance with accounting principles that are generally accepted in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets and liabilities, related disclosure of contingent liabilities at the date of the financial statements, and the reported amounts of expenses and other income during the reporting period. We continually evaluate our estimates and judgments, the most critical of which are those related to preclinical and clinical study accruals and stock-based compensation costs. We base our estimates and judgments on historical experience and other factors that we believe to be reasonable under the circumstances. Materially different results can occur as circumstances change and additional information becomes known.

There were no significant changes during the nine months ended September 30, 2019 to the items that we disclosed as our critical accounting policies and estimates in Note 2 to our audited financial statements included in the Prospectus.

Results of Operations

Comparison of the Three Months Ended September 30, 2019 and 2018

The following table summarizes our results of operations for the three months ended September 30, 2019 and 2018 (in thousands):

	Three Months Ended September 30,		
	2019	2018	Change
Statement of Operations Data:			
Operating expenses:			
Research and development	$ 16,640	$ 5,129	$ 11,511
General and administrative	5,500	1,000	4,500
Total operating expenses	22,140	6,129	16,011
Loss from operations	(22,140)	(6,129)	16,011
Other income, net	1,657	132	1,525
Net loss	$ (20,483)	$ (5,997)	$ 14,486

Research and Development Expenses

The $11.5 million increase in research and development expenses was primarily attributable to higher personnel related expenses as a result of additional employee headcount and for higher research and development costs associated with developing repotrectinib, TPX-0022 and TPX-0046.

General and Administrative Expenses

The $4.5 million increase in general and administrative expenses was primarily attributable to higher personnel related expenses as a result of increased employee headcount and professional fees for legal and accounting services incurred in connection with our transition to becoming a public company.

Other Income, Net

The $1.5 million, net increase in other income was primarily driven by an increase in interest income earned due to higher average investment account balances period over period.

Comparison of the Nine Months Ended September 30, 2019 and 2018

The following table summarizes our results of operations for the nine months ended September 30, 2019 and 2018 (in thousands):

	Nine Months Ended September 30,		
	2019	2018	Change
Statement of Operations Data:			
Operating expenses:			
Research and development	$ 40,802	$ 13,841	$ 26,961
General and administrative	13,857	2,319	11,538
Total operating expenses	54,659	16,160	38,499
Loss from operations	(54,659)	(16,160)	38,499
Other income, net	3,487	393	3,094
Net loss	$ (51,172)	$ (15,767)	$ 35,405

Research and Development Expenses

The $27.0 million increase in research and development expenses was primarily attributable to higher personnel related expenses as a result of additional employee headcount and for higher research and development costs associated with developing repotrectinib, TPX-0022 and TPX-0046.

General and Administrative Expenses

The $11.5 million increase in general and administrative expenses was primarily attributable to higher personnel related expenses as a result of increased employee headcount and professional fees for legal and accounting services incurred in connection with our transition to becoming a public company. In the second quarter of 2019, we incurred severance expense of $0.9 million as a result of the resignation of an executive.

Other Income, Net

The $3.1 million increase in other income, net was primarily driven by an increase in interest income earned due to higher average investment account balances period over period.

Liquidity and Capital Resources

Based on our current and anticipated level of operations, we believe that our cash and cash equivalents and marketable securities will be sufficient to fund current operations for at least one year from the date that this Quarterly Report on Form 10-Q is filed with the SEC. At September 30, 2019, we had $423.6 million of cash and cash equivalents and marketable securities. Our cash and cash equivalents and marketable securities include money market funds, government agency securities, corporate debt and commercial paper. We maintain established guidelines relating to diversification and maturities of our investments to preserve principal and maintain liquidity.

Since inception, our operations have been financed primarily through the sale of equity and convertible preferred stock. Through September 30, 2019, we received net proceeds of approximately $511.4 million from the issuance of common stock and convertible preferred stock. Most recently, on April 22, 2019, we completed our initial public offering whereby we sold an aggregate of 10,637,500 shares of our common stock at a price of $18.00 per share, resulting in net proceeds of $175.2 million after deducting underwriting discounts, commissions and offering costs payable by us. In addition, on September 10, 2019, we completed an additional public offering of our common stock, which resulted in the issuance and sale of an aggregate of 4,500,000 shares of common stock at a price of $45.00 per share, resulting in net proceeds of $189.5 million after deducting underwriting discounts and commissions and other offering costs.

Since inception, we have primarily devoted our resources to funding research and development programs, including discovery research, preclinical and clinical development activities. To fund future operations, we will need to raise significant additional capital. The amount and timing of future funding requirements will depend on many factors, including the timing and results of our ongoing development activities, the potential expansion of our current development programs, potential new development programs and related general and administrative support. We may seek to obtain additional financing in the future through equity or debt financings or other sources, such as potential collaboration agreements. We cannot make assurances that anticipated additional financing will be available to us on favorable terms, or at all. Although we have previously been successful in obtaining financing through our equity securities offerings, there can be no assurance that we will be able to do so in the future.

Cash Flows

The following table summarizes our sources and uses of cash for each of the periods presented (in thousands):

	Nine Months Ended September 30,		
	2019	2018	Change
Statement of Cash Flows Data:			
Cash used in operating activities	$ (43,685)	$ (15,675)	$ (28,010)
Cash used in investing activities	(250,969)	(221)	(250,748)
Cash provided by financing activities	366,046	71	365,975

Operating Activities

During the nine months ended September 30, 2019, operating activities used approximately $43.7 million due to increased activities for the initiation of the Phase 2 portion of our TRIDENT-1 clinical trial and the increase in headcount to support the development of our pipeline. During the nine months ended September 30, 2018, operating activities used approximately $15.7 million due to increase in headcount to support the development of our pipeline.

Investing Activities

During the nine months ended September 30, 2019, investing activities used approximately $251.0 million primarily resulting from the purchase of marketable securities of $264.9 million and purchases of property and equipment of $1.5 million, offset by maturities of investments of $14.9 million.

During the nine months ended September 30, 2018, investing activities used approximately $0.2 million primarily resulting from the purchases of property and equipment.

Financing Activities

During the nine months ended September 30, 2019, financing activities provided $366.0 million of cash, primarily resulting from the net proceeds from our IPO and public offering in September 30, 2019 and for option exercises. During the nine months ended September 30, 2018, financing activities provided approximately $0.1 million primarily as a result from the proceeds from option exercises.

Off-Balance Sheet Arrangements

During the periods presented, we did not have, nor do we currently have, any off-balance sheet arrangements as defined under SEC rules.

Recent Accounting Pronouncements

Please refer to Note 2 to our unaudited condensed financial statements appearing under Part 1, Item 1 for a discussion of new accounting standards updates that may impact us.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are exposed to market risks in the ordinary course of our business. These risks primarily relate to equity price risk and interest rate fluctuations. Substantially all our cash and cash equivalents are held with a single financial institution. Due to its size, we believe this financial institution represents a minimal credit risk. Cash amounts held at financial institutions are insured by the Federal Deposit Insurance Corporation (“FDIC”) up to $250,000. At September 30, 2019, cash and cash equivalents and marketable securities totaling $423.4 million are either not subject to FDIC insurance, or exceed the FDIC insured limit. Our cash and cash equivalents and marketable securities are invested in short term, high grade securities. As a result, we believe that our cash and cash equivalents and marketable securities represent a minimal credit risk.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our periodic and current reports that we file with the SEC 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 President and Chief Executive Officer and Executive Vice President and Chief Financial Officer (our principal financial officer), as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and

procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable and not absolute assurance of achieving the desired control objectives. In reaching a reasonable level of assurance, management was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. In addition, the design of any system of controls is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

As of September 30, 2019, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of September 30, 2019.

Changes in Internal Control over Financial Reporting

There has been no change in our internal control over financial reporting during our most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

We are not currently subject to any material legal proceedings. From time to time, we may be involved in legal proceedings or subject to claims incident to the ordinary course of business. Regardless of the outcome, such proceedings or claims can have an adverse impact on us because of defense and settlement costs, diversion of resources and other factors, and there can be no assurances that favorable outcomes will be obtained.

Item 1A. Risk Factors.

RISK FACTORS

An investment in shares of our common stock involves a high degree of risk. You should carefully consider the following risk factors, as well as the other information in this report, before deciding whether to purchase, hold or sell shares of our common stock. The occurrence of any of the following risks could harm our business, financial condition, results of operations and/or growth prospects or cause our actual results to differ materially from those contained in forward-looking statements we have made in this report and those we may make from time to time. You should consider all of the risk factors described when evaluating our business. We have marked with an asterisk (*) those risk factors that reflect changes from the similarly titled risk factors included in the Prospectus.

Risks Related to Our Financial Position and Need for Additional Capital

We have incurred significant operating losses since our inception and have not generated any revenue. We expect to incur continued losses for the foreseeable future and may never achieve or maintain profitability. *

Investment in drug development is a highly speculative undertaking and involves a substantial degree of risk. We are a clinical-stage biopharmaceutical company that was formed in 2013 and commenced operations in 2014. We have no approved products for commercial sale and have not generated any revenue from product sales or from licenses or collaborations. We continue to incur significant research and development and other expenses related to our ongoing operations. As a result, we have never been profitable and have incurred losses in each year since inception. For the nine months ended September 30, 2019, we reported a net loss of $51.2 million. As of September 30, 2019, we had an accumulated deficit of $101.7 million.

Since our inception, we have focused substantially all of our efforts and financial resources on the research and development of our lead drug candidate, repotrectinib, and our other drug candidates. To date, we have funded our operations primarily with proceeds from sales of shares of our common stock and convertible preferred stock. From inception through September 30, 2019, we received an aggregate of $511.4 million in net proceeds from such sales. As of September 30, 2019, our cash and cash equivalents and marketable securities were $423.6 million.

We expect to incur increasing levels of operating losses for the foreseeable future, particularly as we advance repotrectinib through clinical development. Our prior losses, combined with expected future losses, have had, and will continue to have, an adverse

effect on our stockholders' equity and working capital. We expect our research and development expenses to significantly increase in connection with our ongoing and planned clinical trials, including the ongoing Phase 2 portion of TRIDENT-1, our ongoing Phase 1 clinical trial of TPX-0022, our planned Phase 1/2 clinical trial of repotrectinib in pediatric patients, and our planned Phase 1/2 clinical trial of TPX-0046, and any other clinical trials or development activities we may choose to pursue. In addition, if we obtain marketing approval for repotrectinib, we will incur significant sales, marketing and outsourced manufacturing expenses in connection with the commercialization of repotrectinib. We will also incur additional costs associated with operating as a public company. As a result, we expect to continue to incur significant and increasing operating losses for the foreseeable future. Because of the numerous risks and uncertainties associated with developing pharmaceutical products, we are unable to predict the extent of any future losses or when we will become profitable, if at all. Even if we do become profitable, we may not be able to sustain or increase our profitability on a quarterly or annual basis.

Our ability to become profitable depends upon our ability to generate revenue. To date, we have not generated any revenue and we do not know when, or if, we will generate any revenue. We do not expect to generate significant revenue unless and until we obtain marketing approval for, and begin to sell, repotrectinib or another drug candidate. Our ability to generate revenue depends on a number of factors, including, but not limited to, our ability to:

- successfully complete the Phase 2 portion of TRIDENT-1;
- initiate and successfully complete all safety, pharmacokinetic and other studies required to obtain U.S. and foreign marketing approval for repotrectinib as a treatment for patients with *ROS1+* advanced NSCLC and patients with *NTRK+* advanced solid tumors;
- initiate and successfully complete other later-stage clinical trials that meet their clinical endpoints;
- obtain favorable results from our clinical trials and apply for and obtain marketing approval for repotrectinib;
- establish licenses, collaborations or strategic partnerships that may increase the value of our programs;
- successfully manufacture or contract with others to manufacture repotrectinib and our other drug candidates;
- commercialize repotrectinib, if approved, by building a sales force or entering into collaborations with third parties;
- obtain, maintain, protect and defend our intellectual property portfolio; and
- achieve market acceptance of repotrectinib in the medical community and with third-party payors.

To become and remain profitable, we must succeed in designing, developing and eventually commercializing products that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing preclinical testing and clinical trials for our drug candidates, designing additional drug candidates, establishing arrangements with third parties for the manufacture of clinical supplies of our drug candidates, obtaining marketing approval for our drug candidates and manufacturing, marketing and selling any products for which we may obtain marketing approval. We are only in the preliminary stages of most of these activities. We may never succeed in these activities and, even if we do, may never generate revenues that are significant enough to achieve profitability.

In cases where we are successful in obtaining regulatory approval to market one or more of our drug candidates, our revenue will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval, the accepted price for the product, the ability to obtain coverage and reimbursement, and whether we own the commercial rights for that territory. If the number of our addressable patients is not as significant as we estimate, the indication approved by regulatory authorities is narrower than we expect, or the treatment population is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such products, even if approved.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses we will incur or when, or if, we will be able to achieve profitability. If we decide to or are required by the FDA or other regulatory authorities to perform studies or clinical trials in addition to those currently expected, or if there are any delays in establishing appropriate manufacturing arrangements for, in initiating or completing our current and planned clinical trials for, or in the development of, any of our drug candidates, our expenses could increase materially and profitability could be further delayed.

Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our product offerings or even continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

We will require substantial additional funding. If we are unable to raise capital on favorable terms when needed, we could be forced to delay, reduce or eliminate our research or drug development programs or any future commercialization efforts. *

We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we advance our lead drug candidate, repotrectinib, and other drug candidates through clinical development and further develop our pipeline. We expect increased expenses as we continue our research and development, initiate additional clinical trials, and seek marketing approval for our lead program and our other drug candidates. In addition, if we obtain marketing approval for any of our drug candidates, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. Furthermore, we expect to continue to incur significant costs associated with operating as a public company.

In addition, our drug candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of products that we do not expect to be commercially available for sale for at least the next several years, if ever, and such funds, if raised, may not be sufficient to enable us to continue to implement our business strategy. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. Adequate additional financing may not be available to us on favorable terms, or at all. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. If we are unable to raise capital when needed or on favorable terms, we could be forced to delay, reduce or eliminate our research and development programs, our commercialization plans or other operations. We believe that our existing cash and cash equivalents and marketable securities will be sufficient to enable us to fund our operating expenses for at least the next 12 months. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. Changes beyond our control may occur that would cause us to use our available capital before that time, including changes in and progress of our drug development activities and changes in regulation. Our future capital requirements will depend on many factors, including:

- the progress and results of our Phase 2 portion of TRIDENT-1 and any other additional planned clinical trials evaluating repotrectinib;
- the scope, rate of progress, results and costs of drug design, preclinical development and clinical trials for the other drug candidates in our pipeline, including TPX-0022 and TPX-0046;
- the extent to which we develop, in-license or acquire other pipeline drug candidates or technologies;
- the number and development requirements of other drug candidates that we may pursue, and other indications for our current drug candidates that we may pursue;
- the costs, timing and outcome of regulatory review of our drug candidates and any companion diagnostics we may pursue;
- the scope and costs of making arrangements with third-party manufacturers, or establishing manufacturing capabilities, for both clinical and commercial supplies of our drug candidates;
- the cost associated with commercializing any approved drug candidates, including to establish sales and marketing capabilities;
- the cost associated with completing any post-marketing studies or trials required by the FDA or other regulatory authorities;
- the revenue, if any, received from commercial sales of repotrectinib, if approved, or our other pipeline drug candidates that receive marketing approval;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims that we may become subject to; and
- to the extent we pursue strategic collaborations, including collaborations to commercialize repotrectinib or any of our other pipeline drug candidates, our ability to establish and maintain collaborations on favorable terms, if at all.

We will require additional capital to complete our planned clinical development programs for our current drug candidates to obtain regulatory approval. Any additional capital-raising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our current and future drug candidates, if approved.

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

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements. We do not currently have any committed external source of funds. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating

plans. 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 acquisitions or capital expenditures or declaring dividends.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or drug candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed, we may be required to delay, limit, reduce or terminate our research, product development or future commercialization efforts or grant rights to third parties to develop and market drug candidates that we would otherwise prefer to develop and market ourselves.

Risks Related to the Design and Development of Our Drug Candidates

We are early in our development efforts and our lead drug candidate, repotrectinib, is currently in a Phase 2 potentially registrational clinical trial. We have not successfully completed late-stage clinical trials or obtained regulatory approval for any drug candidate. We may never obtain approval for any of our drug candidates or achieve or sustain profitability. *

We currently have no products that are approved for sale. We are early in our development efforts and have only recently initiated and begun patient dosing in the Phase 2 registrational portion of our TRIDENT-1 clinical trial for our lead drug candidate, repotrectinib. Our only other drug candidate currently in clinical trials, TPX-0022, has only recently entered into a Phase 1 study. There can be no assurance that repotrectinib or our other drug candidates in development will achieve success in their clinical trials or obtain regulatory approval.

Our ability to generate product revenues, which we do not expect will occur for many years, if ever, will depend heavily on the successful development and eventual commercialization of repotrectinib or other drug candidates in development. The success of our drug candidates, including repotrectinib, will depend on several factors, including the following:

- successful completion of preclinical studies and clinical trials;
- acceptance of INDs by the FDA or other clinical trial or similar applications from foreign regulatory authorities for our future clinical trials for our pipeline drug candidates;
- timely and successful enrollment of patients in, and completion of, clinical trials with favorable results;
- demonstration of safety, efficacy and acceptable risk-benefit profiles of our drug candidates to the satisfaction of the FDA and foreign regulatory agencies;
- our ability, or that of our collaborators, to develop and obtain clearance or approval of companion diagnostics, on a timely basis, or at all;
- receipt and related terms of marketing approvals from applicable regulatory authorities, including the completion of any required post-marketing studies or trials;
- raising additional funds necessary to complete clinical development of and commercialize our drug candidates;
- obtaining and maintaining patent, trade secret and other intellectual property protection and regulatory exclusivity for our drug candidates;
- making arrangements with third-party manufacturers, or establishing manufacturing capabilities, for both clinical and commercial supplies of our drug candidates;
- developing and implementing marketing and reimbursement strategies;
- establishing sales, marketing and distribution capabilities and launching commercial sales of our products, if and when approved, whether alone or in collaboration with others;
- acceptance of our products, if and when approved, by patients, the medical community and third-party payors;
- effectively competing with other therapies;
- obtaining and maintaining third-party payor coverage and adequate reimbursement;
- protecting and enforcing our rights in our intellectual property portfolio; and
- maintaining a continued acceptable safety profile of the products following approval.

Many of these factors are beyond our control, and it is possible that none of our drug candidates will ever obtain regulatory approval even if we expend substantial time and resources seeking such approval. If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize our drug candidates, which would materially harm our business. For example, our business could be harmed if results of our clinical trials of repotrectinib or our other drug candidates vary adversely from our expectations.

Drug development involves a lengthy and expensive process. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of repotrectinib or our other drug candidates. *

We currently have two drug candidates in clinical development, and the risk of failure is high. We are unable to predict when or if our drug candidates will prove effective or safe in humans or will obtain marketing approval. Before obtaining marketing approval from regulatory authorities for the sale of any drug candidate, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of our drug candidates in humans. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to the outcome. A failure of one or more clinical trials can occur at any stage of testing. The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and interim or preliminary results of a clinical trial do not necessarily predict final results. In particular, the small number of patients in our early clinical trials may make the results of these trials less predictive of the outcome of later clinical trials. In addition, although we have observed encouraging preliminary overall response rates in the dose escalation and dose expansion stage of the Phase 1 portion of our ongoing TRIDENT-1 clinical trial of repotrectinib, the primary objectives were to determine the safety, tolerability and maximum tolerated dose of repotrectinib and to determine a recommended Phase 2 dose and not to demonstrate efficacy. The assessments of efficacy from this portion of the clinical trial were not designed to demonstrate statistical significance and may not be predictive of the results of further clinical trials of repotrectinib. For example, based on the lack of responses in the pretreated evaluable *ALK*+ patients enrolled in the Phase 1 portion of TRIDENT-1, we do not plan to enroll *ALK*+ NSCLC patients in the Phase 2 portion of TRIDENT-1.

We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to obtain marketing approval or commercialize our drug candidates, including:

- regulators or institutional review boards (IRBs)/ethics committees (ECs) may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may experience delays in reaching, or fail to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;
- clinical trials for our drug candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials, delay clinical trials or abandon product development programs;
- the number of patients required for clinical trials for our drug candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate, participants may drop out of these clinical trials at a higher rate than we anticipate or the duration of these clinical trials may be longer than we anticipate;
- competition for clinical trial participants from investigational and approved therapies may make it more difficult to enroll patients in our clinical trials;
- we or third-party collaborators may fail to obtain the clearance or approval of companion diagnostic tests, if required, on a timely basis, or at all;
- our third-party contractors may fail to meet their contractual obligations to us in a timely manner, or at all, or may fail to comply with regulatory requirements;
- we may have to suspend or terminate clinical trials for our drug candidates for various reasons, including a finding that the participants are being exposed to unacceptable health risks;
- our drug candidates may have undesirable or unexpected side effects or other unexpected characteristics, causing us or our investigators, regulators or IRBs/ECs to suspend or terminate the trials;
- the cost of clinical trials for our drug candidates may be greater than we anticipate;
- the supply or quality of our drug candidates or other materials necessary to conduct clinical trials for our drug candidates may be insufficient or inadequate and result in delays or suspension of our clinical trials; and
- we or a diagnostic development partner may fail to receive regulatory approval of a companion diagnostic for use with a marketed product.

Our product development costs will increase if we experience delays in preclinical studies or clinical trials or in obtaining marketing approvals. We do not know whether any of our planned preclinical studies or clinical trials will begin on a timely basis or at all, will need to be restructured or will be completed on schedule, or at all. For example, the FDA may place a partial or full clinical hold on, any of our clinical trials for a variety of reasons. In February 2018, we received a Deficiency–Potential Hold Issues letter from the FDA stating that the number of patients treated in the Phase 1 portion of our ongoing TRIDENT-1 clinical trial exceeded the protocol-specified dose escalation enrollment plan. Additionally, the Development Safety Update Report (DSUR) and the Investigator's Brochure (IB) had not been updated with available clinical safety information. Following discussion with the FDA, our IND was placed on partial clinical hold pending the submission of an amended protocol, an updated DSUR and updated IB. The partial clinical hold was removed on June 29, 2018 after the requested documents were revised and TRIDENT-1 resumed patient enrollment.

Significant preclinical or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our drug candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our drug candidates and may harm our business and results of operations.

Any delays in the commencement or completion, or termination or suspension, of our ongoing, planned or future clinical trials could result in increased costs to us, delay or limit our ability to generate revenue and adversely affect our commercial prospects. *

Before we can initiate clinical trials of a drug candidate in any indication, we must submit the results of preclinical studies to the FDA along with other information, including information about the drug candidate's chemistry, manufacturing and controls and our proposed clinical trial protocol, as part of an IND or similar regulatory filing.

Before obtaining marketing approval from the FDA for the sale of repotrectinib or any other drug candidate in any indication, we must conduct extensive clinical studies to demonstrate safety and efficacy. Clinical testing is expensive, time consuming and uncertain as to outcome. In addition, we expect to rely in part on preclinical, clinical and quality data generated by our contract research organizations (CROs) and other third parties for regulatory submissions for our drug candidates. While we have or will have agreements governing these third parties' services, we have limited influence over their actual performance. If these third parties do not make data available to us, or, if applicable, make regulatory submissions in a timely manner, in each case pursuant to our agreements with them, our development programs may be significantly delayed and we may need to conduct additional studies or collect additional data independently. In either case, our development costs would increase. To date, we have submitted three INDs: one IND for the current Phase 1/2 clinical trial of repotrectinib; one IND for the current Phase 1 clinical trial of TPX-0022; and one IND for the planned Phase 1/2 clinical trial of TPX-0046. We will require the acceptance by the FDA of an IND prior to initiating any clinical trials in the United States for any of our other potential drug candidates. The FDA may require us to conduct additional preclinical studies for any drug candidate before it allows us to initiate clinical trials under any IND, which may lead to additional delays and increase the costs of our preclinical development programs.

Any delays in the commencement or completion of our ongoing, planned or future clinical trials could significantly affect our product development costs. We do not know whether our planned trials will begin on time or at all, or be completed on schedule, if at all. The commencement and completion of clinical trials can be delayed for a number of reasons, including delays related to:

- the FDA disagreeing as to the design or implementation of our clinical trials or with our recommended dose for any of our pipeline programs;
- obtaining FDA authorization to commence a trial or reaching a consensus with the FDA on trial design;
- failing to obtain regulatory clearance or approval of companion diagnostics we may use to identify patients for enrollment in our clinical trials;
- any failure or delay in reaching an agreement with CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtaining approval from one or more IRBs/ECs;
- IRBs/ECs refusing to approve, suspending or terminating the trial at an investigational site, precluding enrollment of additional subjects, or withdrawing their approval of the trial;
- changes to clinical trial protocol;
- clinical sites deviating from trial protocol or dropping out of a trial;
- failing to manufacture or obtain sufficient quantities of drug candidate or, if applicable, combination therapies for use in clinical trials;
- patients failing to enroll or remain in our trial at the rate we expect, or failing to return for post-treatment follow-up;

- patients choosing an alternative treatment, or participating in competing clinical trials;
- lack of adequate funding to continue the clinical trial;
- patients experiencing severe or unexpected drug-related adverse effects;
- occurrence of serious adverse events in trials of the same class of agents conducted by other companies;
- selecting or being required to use clinical end points that require prolonged periods of clinical observation or analysis of the resulting data;
- a facility manufacturing our drug candidates or any of their components being ordered by the FDA to temporarily or permanently shut down due to violations of current good manufacturing practice (cGMP) regulations or other applicable requirements, or infections or cross-contaminations of drug candidates in the manufacturing process;
- any changes to our manufacturing process that may be necessary or desired;
- third-party clinical investigators losing the licenses or permits necessary to perform our clinical trials, not performing our clinical trials on our anticipated schedule or consistent with the clinical trial protocol, good clinical practices (GCP) or other regulatory requirements;
- us, or our third-party contractors not performing data collection or analysis in a timely or accurate manner or improperly disclosing data prematurely or otherwise in violation of a clinical trial protocol; or
- third-party contractors becoming debarred or suspended or otherwise penalized by the FDA or other government or regulatory authorities for violations of regulatory requirements, in which case we may need to find a substitute contractor, and we may not be able to use some or all of the data produced by such contractors in support of our marketing applications.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs/ECs of the institutions in which such trials are being conducted, by a Data Safety Monitoring Board for such trial or by the FDA. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a pharmaceutical, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. In addition, changes in regulatory requirements and policies may occur, and we may need to amend clinical trial protocols to comply with these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs/ECs for reexamination, which may impact the costs, timing or successful completion of a clinical trial.

Certain of our scientific advisors or consultants who receive compensation from us are investigators for our clinical trial. Under certain circumstances, we may be required to report some of these relationships to the FDA. Although we believe our existing relationships are within the FDA's guidelines, the FDA may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the study. The FDA may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA and may ultimately lead to the denial of marketing approval of repotrectinib. If we experience delays in the completion of, or termination of, any clinical trial of repotrectinib or any other drug candidate, the commercial prospects of such drug candidate will be harmed, and our ability to generate product revenues will be delayed. Moreover, any delays in completing our clinical trials will increase our costs, slow down our development and approval process and jeopardize our ability to commence product sales and generate revenues which may harm our business, financial condition, results of operations and prospects significantly.

If we experience delays or difficulties in enrolling patients in our ongoing or planned clinical trials, our receipt of necessary regulatory approval could be delayed or prevented. *

We may not be able to initiate or continue our ongoing or planned clinical trials for our drug candidates if we are unable to identify and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA. In addition, some of our competitors may have ongoing clinical trials for drug candidates that would treat the same patients as repotrectinib or our other drug candidates, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' drug candidates. This is acutely relevant for our development of repotrectinib for the treatment of patients with *NTRK*+ advanced solid tumors, an indication for which the approved TKIs, larotrectinib and entrectinib, are required to complete post-marketing studies, and our development of repotrectinib for the treatment of patients with *ROS1*+ advanced NSCLC and patients with *NTRK*+ advanced solid

tumors, an indication for which investigational drugs are competing for clinical trial participants. Patient enrollment is also affected by other factors, including:

- severity of the disease under investigation;
- our ability to recruit clinical trial investigators of appropriate competencies and experience;
- the incidence and prevalence of our target indications;
- clinicians' and patients' awareness of, and perceptions as to the potential advantages and risks of our drug candidates in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating;
- invasive procedures required to enroll patients and to obtain evidence of the drug candidate's performance during the clinical trial;
- availability and efficacy of approved medications for the disease under investigation;
- eligibility criteria defined in the protocol for the trial in question;
- the size of the patient population required for analysis of the trial's primary endpoints;
- efforts to facilitate timely enrollment in clinical trials;
- whether we are subject to a partial or full clinical hold on any of our clinical trials;
- reluctance of physicians to encourage patient participation in clinical trials;
- the ability to monitor patients adequately during and after treatment;
- our ability to obtain and maintain patient consents; and
- proximity and availability of clinical trial sites for prospective patients.

Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs, which would cause the value of our company to decline and limit our ability to obtain additional financing.

Adverse side effects or other safety risks associated with repotrectinib or our other drug candidates could delay or preclude approval, cause us to suspend or discontinue clinical trials or abandon further development, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any. *

As is the case with pharmaceuticals generally, we have observed side effects and adverse events associated with repotrectinib. As of the July 22, 2019 data cut-off date for the Phase 1 portion of our ongoing Phase 1/2 clinical trial of repotrectinib, TRIDENT-1, the most common treatment emergent adverse events were dizziness, dysgeusia, anemia, constipation, fatigue, dyspnea, paresthesia, nausea, cough, pyrexia, headache, vomiting, ataxia, myalgia, upper respiratory tract infection, abdominal pain, muscular weakness, and pain in extremity, most of which were Grade 1 or Grade 2. In patients treated at 160 mg QD or above, the majority of TEAEs of dizziness, ataxia and paresthesia occurred within the first 14 days after dosing.

Of all 93 patients in the safety population, three patients discontinued treatment due to adverse events (one with a Grade 3 pleural effusion, another with a dose limiting toxicity, or DLT, of Grade 3 hypoxia/dyspnea, and one with Grade 1 dyspnea) that were determined to be related to study treatment. As of the July 22, 2019 data cut-off date, five Grade 5 TEAEs have occurred, with four, respiratory failure (n=2), pneumonia (n=1), and sepsis (n=1), determined not to be related to treatment. The four Grade 5 TEAEs that were determined to not be treatment related include: one patient with *NTRK*+ angiosarcoma on the right leg with a pre-existing open wound infection on the left leg who was treated at 40 mg QD and developed Grade 5 sepsis and died seven days after stopping repotrectinib; one patient with *ROS1*+ NSCLC treated at 40 mg QD who developed Grade 5 respiratory failure due to disease progression five days after repotrectinib discontinuation; one *ROS1*+ NSCLC patient with Grade 5 respiratory failure reported as related to disease progression and not treatment-related, who was initially treated at 120 mg QD and dose escalated to 160 mg BID due to disease progression 30 days prior to the event; and one *ROS1*+ NSCLC patient who had a past medical history of pericardial tamponade prior to study entry and was previously treated with multiple rounds of chemotherapy/immunotherapy and crizotinib, who was initially treated at 160 mg QD and dose escalated to 160 mg BID, who developed worsening pneumonia and died 10 days after discontinuing repotrectinib. The fifth Grade 5 TEAE involved a patient with *ALK*+ NSCLC and a past medical history of diabetes, obesity and hypertension who was dosed at 240 mg QD (once daily) of repotrectinib and experienced a Grade 5 event of sudden death on day 10 of cycle 1, which we determined to be possibly related to study treatment.

Results of our ongoing and planned clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. Undesirable side effects caused by our drug candidates could result in the delay, suspension or termination of clinical trials by us or the FDA for a number of reasons. Additionally, due to the high mortality rates of the cancers for which we are initially pursuing development and the pretreated nature of many patients in our ongoing and planned clinical trials of repotrectinib, a material percentage of patients in these clinical trials may die during a trial, which could impact development of repotrectinib. If we elect or are required to delay, suspend or terminate any clinical trial, the commercial prospects of our drug candidates will be harmed and our ability to generate product revenues from this drug candidate will be delayed or eliminated. Serious adverse events observed in clinical trials could hinder or prevent market acceptance of our drug candidates. Any of these occurrences may harm our business, prospects, financial condition and results of operations significantly.

Moreover, if our drug candidates are associated with undesirable side effects in clinical trials or have characteristics that are unexpected, we may elect to abandon or limit their 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, which may limit the commercial expectations for our drug candidates, if approved. For example, we are required to conduct an embryo-fetal toxicology study of repotrectinib, and any adverse findings from this study may delay, prevent or adversely impact any marketing approval we may be able to obtain for repotrectinib in humans. We may also be required to modify our study plans based on findings in our clinical trials. Many drugs that initially showed promise in early stage testing have later been found to cause side effects that prevented further development. In addition, regulatory authorities may draw different conclusions or require additional testing to confirm these determinations.

It is possible that as we test our drug candidates in larger, longer and more extensive clinical trials, including with different dosing regimens, or as the use of our drug candidates becomes more widespread following any regulatory approval, illnesses, injuries, discomforts and other adverse events that were observed in earlier trials, as well as conditions that did not occur or went undetected in previous trials, will be reported by patients. If such side effects become known later in development or upon approval, if any, such findings may harm our business, financial condition, results of operations and prospects significantly.

In addition, if any of our drug candidates receive marketing approval, and we or others later identify undesirable side effects caused by treatment with such drug, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approval of the drug;
- we may be required to recall a product or change the way the drug is administered to patients;
- regulatory authorities may require additional warnings on the label, such as a “black box” warning or a contraindication, or issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or other safety information about the product;
- we may be required to implement a Risk Evaluation and Mitigation Strategy (REMS) or create a medication guide outlining the risks of such side effects for distribution to patients;
- additional restrictions may be imposed on the marketing or promotion of the particular product or the manufacturing processes for the product or any component thereof;
- we could be sued and held liable for harm caused to patients;
- the drug could become less competitive; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of our drug candidates, if approved, and could significantly harm our business, financial condition, results of operations and prospects.

Interim, topline and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available, and are subject to audit and verification procedures that could result in material changes in the final data. *

From time to time, we may publicly disclose preliminary, interim or topline data from our clinical trials, such as the preliminary data analyses for the Phase 1 portion of our TRIDENT-1 trial announced in June and September 2018, and interim updates from the data cut-off dates of March 2019 and July 2019. These interim updates are based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the topline

results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, topline data should be viewed with caution until the final data are available. In addition, we may report interim analyses of only certain endpoints rather than all endpoints. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse changes between interim data and final data could significantly harm our business and prospects. Further, additional disclosure of interim data by us or by our competitors in the future could result in volatility in the price of our common stock.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular drug candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is typically selected from a more extensive amount of available information. You or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular drug, drug candidate or our business. If the preliminary or topline data that we report differ from late, final or actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, repotrectinib or any other drug candidates may be harmed, which could harm our business, financial condition, results of operations and prospects.

If we are unable to successfully develop companion diagnostic tests for our drug candidates that require such tests, or experience significant delays in doing so, we may not realize the full commercial potential of these drug candidates. *

We plan to develop, either by ourselves or with collaborators, companion diagnostic tests for our drug candidates for certain indications. To be successful, we or our collaborators will need to address a number of scientific, technical, regulatory and logistical challenges. We have no prior experience with medical device or diagnostic test development. If we choose to develop and seek FDA approval for companion diagnostic tests on our own, we will require additional personnel. We may rely on third parties for the design, development and manufacture of companion diagnostic tests for our therapeutic drug candidates that require such tests. If these parties are unable to successfully develop companion diagnostics for these therapeutic drug candidates, or experience delays in doing so, we may be unable to enroll enough patients for our current and planned clinical trials, the development of these therapeutic drug candidates may be adversely affected, these therapeutic drug candidates may not obtain marketing approval, and we may not realize the full commercial potential of any of these therapeutics that obtain marketing approval. We are co-developing repotrectinib with a next-generation sequencing-based companion diagnostic. A prototype companion diagnostic has been developed and is being used as a clinical trial assay to confirm the presence of *ROS1+*, *NTRK+* or *ALK+* gene fusions in patients prior to enrollment into the Phase 2 portion of TRIDENT-1. We have selected a diagnostic partner to support development of the companion diagnostic and filing of a pre-market approval (PMA) application to the FDA. In May 2019, the FDA approved an investigational device exemption (IDE) for use of this clinical trial assay in the Phase 2 portion of TRIDENT-1. An approved companion diagnostic may be required in order to obtain marketing approval of repotrectinib in patients with *ROS1+* advanced NSCLC and patients with *NTRK+* advanced solid tumors. Any failure to successfully develop this companion diagnostic may prevent us from ultimately seeking approval for repotrectinib in patients with *ROS1+* advanced NSCLC and patients with *NTRK+* advanced solid tumors. As a result, our business, results of operations and financial condition could be materially harmed.

***The failure to obtain required regulatory clearances or approvals for any companion diagnostic tests that we may pursue may prevent or delay approval of any of our drug candidates. Moreover, the commercial success of any of our drug candidates that require a companion diagnostic will be tied to the receipt of any required regulatory clearances or approvals and the continued availability of such tests. **

In connection with the clinical development of our drug candidates for certain indications, we may work with collaborators to develop or obtain access to companion diagnostic tests to identify appropriate patients for our drug candidates. We may rely on third parties for the development, testing and manufacturing of these companion diagnostics, the application for and receipt of any required regulatory clearances or approvals, and the commercial supply of these companion diagnostics. The FDA and foreign regulatory authorities regulate companion diagnostics as medical devices that will likely be subject to clinical trials in conjunction with the clinical trials for drug candidates, and which will require separate regulatory clearance or approval prior to commercialization. This process could include additional meetings with health authorities, such as a pre-submission meeting and the requirement to submit an IDE. In the case of a companion diagnostic that is designated as "significant risk device," such as the clinical trial assay we are using in the Phase 2 portion of TRIDENT-1, approval of an IDE by the FDA and IRB is required before such diagnostic is used in conjunction with the clinical trials for a corresponding drug candidate. In May 2019 the FDA approved an IDE for the clinical trial assay we are using in the Phase 2 portion of TRIDENT-1. We or our third-party collaborators may fail to obtain the required regulatory clearances or approvals, which could prevent or delay approval of our drug candidates. In addition, the commercial success of any of our drug candidates that require a companion diagnostic will be tied to and dependent upon the receipt of required regulatory clearances or approvals and the continued ability of such third parties to make the companion diagnostic commercially available to us on reasonable terms in the relevant geographies.

We may expend our limited resources to pursue a particular drug candidate or indication and fail to capitalize on drug 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 focus on research programs and drug candidates that we identify for specific indications. As a result, we may forego or delay pursuit of opportunities with other drug 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 research and development programs and drug candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular drug candidate, we may relinquish valuable rights to that drug candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such drug candidate.

We may not be successful in our efforts to design additional potential drug candidates.

A key element of our strategy is to apply our knowledge and our understanding of the structure, biology and activity of kinase inhibitors to design drug candidates. The therapeutic design and development activities that we are conducting may not be successful in developing drug candidates that are useful in treating cancer or other diseases. Our research programs may initially show promise in identifying potential drug candidates, yet fail to yield drug candidates for clinical development for a number of reasons, including:

- the research methodology used may not be successful in identifying potential drug candidates;
- potential drug candidates may, on further study, be shown to have harmful side effects or other characteristics that indicate that they are unlikely to be drugs that will obtain marketing approval or achieve market acceptance; or
- potential drug candidates may not be effective in treating their targeted diseases.

Research programs to identify and design new drug candidates require substantial technical, financial and human resources. We may choose to focus our efforts and resources on a potential drug candidate that ultimately proves to be unsuccessful. If we are unable to identify and design suitable drug candidates for preclinical and clinical development, we will not be able to obtain revenues from the sale of products in future periods, which likely would result in significant harm to our financial position and adversely impact our stock price.

We may not be able to obtain or maintain orphan drug designation or exclusivity for our drug candidates.

Regulatory authorities in some jurisdictions, including the United States, may designate drugs for relatively small patient populations as "orphan drugs." Under the Orphan Drug Act, the FDA may designate a drug candidate as an orphan drug if it is intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals in the United States, or if the disease or condition affects more than 200,000 individuals in the United States and there is no reasonable

expectation that the cost of developing and making a drug product available in the United States for the type of disease or condition will be recovered from sales of the product.

Orphan drug designation entitles a party to financial incentives, such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. Additionally, if a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity. This means that the FDA may not approve any other applications to market the same drug or biological product for the same indication for seven years, except in certain circumstances, including proving clinical superiority (*i.e.*, another product is safer, more effective or makes a major contribution to patient care) to the product with orphan exclusivity. Competitors, however, may receive approval of different products for the indication for which the orphan product has exclusivity, or obtain approval for the same product but for a different indication than that for which the orphan product has exclusivity. In addition, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan-designated indication or may be lost if the FDA later determines that the request for designation was materially defective.

We have obtained orphan drug designation in the United States for use of repotrectinib in treatment of NSCLC with adenocarcinoma histology. We may apply for similar designations in other geographies or for our other drug candidates in the future. Orphan drug status does not ensure that we will receive marketing exclusivity in a particular market, and we cannot assure you that any future application for orphan drug designation in any other geography or with respect to any other drug candidate will be granted. Orphan drug designation neither shortens the development time or regulatory review time of a drug, nor gives the drug any advantage in the regulatory review or approval process.

Risks Related to Our Dependence on Third Parties

We rely, and intend to continue to rely, on third parties to conduct our clinical trials and perform some of our research and preclinical studies. If these third parties do not satisfactorily carry out their contractual duties, fail to comply with applicable regulatory requirements or do not meet expected deadlines, our development programs may be delayed or subject to increased costs or we may be unable to obtain regulatory approval, each of which may have an adverse effect on our business, financial condition, results of operations and prospects. *

We do not have the ability to independently conduct all aspects of our preclinical testing or clinical trials ourselves. As a result, we are dependent on third parties to conduct our ongoing and planned clinical trials and other studies of repotrectinib and your other drug candidates. The timing of the initiation and completion of these studies and trials will therefore be partially controlled by such third parties and may result in delays to our development programs. Specifically, our CROs, clinical investigators and consultants play a significant role in the conduct of these trials and the subsequent collection and analysis of data. However, we will not be able to control all aspects of their activities. Nevertheless, we are responsible for ensuring that each clinical trial is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on the CROs and other third parties does not relieve us of our regulatory responsibilities. We and our CROs are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA for drug candidates in clinical development. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, clinical trial investigators and clinical trial sites. If we or any of our CROs or clinical trial sites fail to comply with applicable GCP requirements, the data generated in our clinical trials may be deemed unreliable, and the FDA may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, the FDA will determine that our clinical trials comply with GCPs. In addition, our clinical trials must be conducted with product produced under cGMP regulations. Our failure or the failure of third parties on whom we rely to comply with these regulations may require us to stop and/or repeat clinical trials, which would delay the marketing approval process.

There is no guarantee that any such CROs, clinical trial investigators or other third parties on which we rely will devote adequate time and resources to our development activities or perform as contractually required. If any of these third parties fail to meet expected deadlines, adhere to our clinical protocols or meet regulatory requirements, otherwise perform in a substandard manner, or terminate their engagements with us, the timelines for our development programs may be extended or delayed or our development activities may be suspended or terminated. If our clinical trial site terminates for any reason, we may experience the loss of follow-up information on subjects enrolled in such clinical trial unless we are able to transfer those subjects to another qualified clinical trial site, which may be difficult or impossible. In addition, certain of our scientific advisors or consultants who receive compensation from us are clinical trial investigators for our clinical trial. Although we believe our existing relationships are within the FDA's guidelines, if these relationships and any related compensation result in perceived or actual conflicts of interest, or the FDA concludes that the financial relationship may have affected the interpretation of the trial, the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized, which could result in the delay or rejection of any marketing application we submit by the FDA. Any such delay or rejection could prevent us from commercializing repotrectinib or any other drug candidates.

Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors for whom they may also be conducting clinical trials or other pharmaceutical product development activities that could harm our competitive position. 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 repotrectinib or any other drug candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our products.

Manufacturing pharmaceutical products is complex and subject to product loss for a variety of reasons. We contract with third parties for the manufacture of our drug candidates for preclinical testing and clinical trials 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 drug candidates or products or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts.

We do not have any manufacturing facilities. We produce in our laboratory very small quantities of small molecules for evaluation in our research programs. We rely, and expect to continue to rely, on third parties for the manufacture of our drug candidates for preclinical and clinical testing, as well as for commercial manufacture if any of our drug candidates obtain marketing approval. Some of our manufacturers represent our sole source of supply, including the China-based supplier of repotrectinib starting material. This reliance on third parties increases the risk that we will not have sufficient quantities of our drug candidates or products or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts.

We may be unable to establish any agreements with third-party manufacturers or to do so on favorable 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;
- operations of our third-party manufacturers or suppliers could be disrupted by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier or the issuance of an FDA Form 483 notice or warning letter;
- 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;
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us;
- carrier disruptions or increased costs that are beyond our control; and
- failure to deliver our drugs under specified storage conditions and in a timely manner.

We have only limited supply arrangements in place with respect to our drug candidates, and these arrangements do not extend to commercial supply. We acquire many key materials on a purchase order basis. As a result, we do not have long-term committed arrangements with respect to our drug candidates and other materials. If we obtain marketing approval for any of our drug candidates, we will need to establish an agreement for commercial manufacture with a third party.

Third-party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside of the United States. Our failure, or the failure of our third-party manufacturers and suppliers, 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 drug candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products. In addition, our third-party manufacturers and suppliers are subject to numerous environmental, health and safety laws and regulations, including those governing the handling, use, storage, treatment and disposal of waste products, and failure to comply with such laws and regulations could result in significant costs associated with civil or criminal fines and penalties for such third parties. Based on the severity of regulatory actions that may be brought against these third parties in the future, our clinical or commercial supply of drug and packaging and other services could be interrupted or limited, which could harm our business.

Our drug candidates and any products that we may develop may compete with other drug candidates and products for access to manufacturing facilities. As a result, we may not obtain access to these facilities on a priority basis or at all. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us.

As we prepare for later-stage clinical trials and potential commercialization, we will need to take steps to increase the scale of production of our drug candidates. We have not yet scaled up the manufacturing process for any of our drug candidates. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects and other supply

disruptions. If microbial, viral or other contaminations are discovered in our drug candidates or in the manufacturing facilities in which our drug candidates are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination.

Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval. We do not currently have arrangements in place for redundant supply or a second source for bulk drug substance. If our current contract manufacturers for preclinical and clinical testing cannot perform as agreed, we may be required to replace such manufacturers. Although we believe that there are several potential alternative manufacturers who could manufacture our drug candidates, we may incur added costs and delays in identifying and qualifying any such replacement manufacturer or be able to reach agreement with any alternative manufacturer.

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

We may enter into collaborations with third parties for the development and commercialization of our drug candidates. If those collaborations are not successful, we may not be able to capitalize on the market potential of these drug candidates.

We may in the future seek third-party collaborators for the development and commercialization of some of our drug candidates on a selected basis. Our likely collaborators for any collaboration arrangements include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies. We face significant competition in seeking appropriate collaborators. Our ability to reach a definitive agreement for a 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 do enter into any such arrangements with any third parties, we will likely have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our drug candidates. Our ability to generate revenues from these arrangements will depend on our collaborators' abilities and efforts to successfully perform the functions assigned to them in these arrangements. Collaborations involving our drug candidates would pose numerous risks to us, including the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations and may not perform their obligations as expected;
- collaborators may de-emphasize or not pursue development and commercialization of our drug candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus, including as a result of a sale or disposition of a business unit or development function, or available funding or external factors such as an acquisition that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a drug candidate, repeat or conduct new clinical trials or require a new formulation of a drug candidate for clinical testing;

- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or drug candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- a collaborator with marketing and distribution rights to multiple products may not commit sufficient resources to the marketing and distribution of our product relative to other products;
- collaborators may not properly obtain, maintain, defend or enforce our intellectual property rights or may use our proprietary information and intellectual property in such a way as to invite litigation or other intellectual property related proceedings that could jeopardize or invalidate our proprietary information and intellectual property or expose us to potential litigation or other intellectual property related proceedings;
- disputes may arise between the collaborators and us that result in the delay or termination of the research, development or commercialization of our products or drug candidates or that result in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable drug candidates;
- collaboration agreements may not lead to development or commercialization of drug candidates in the most efficient manner or at all; and
- if a collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program could be delayed, diminished or terminated.

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

The development and commercialization of pharmaceutical products are subject to extensive regulation, and we may not obtain regulatory approvals for repotrectinib or any other drug candidates, on a timely basis or at all.*

The clinical development, manufacturing, labeling, packaging, storage, recordkeeping, advertising, promotion, export, import, marketing, distribution, adverse event reporting, including the submission of safety and other post-marketing information and reports, and other possible activities relating to repotrectinib, TPX-0022 and TPX-0046, are subject to extensive regulation. Marketing approval of drugs in the United States requires the submission of a new drug application (NDA) to the FDA and we are not permitted to market any drug candidate in the United States until we obtain approval from the FDA of the NDA for that product. An NDA must be supported by extensive clinical and preclinical data, as well as extensive information regarding pharmacology, chemistry, manufacturing and controls.

FDA approval of an NDA is not guaranteed, and the review and approval process is an expensive and uncertain process that may take several years. The FDA also has substantial discretion in the approval process. The number and types of preclinical studies and clinical trials that will be required for NDA approval varies depending on the drug candidate, the disease or the condition that the drug candidate is designed to treat and the regulations applicable to any particular drug candidate. For example, if successful, we believe that the Phase 2 portion of TRIDENT-1 may be sufficient to support FDA approval of an NDA for repotrectinib, but the FDA may disagree with the sufficiency of our data and require additional clinical trials. Additionally, depending upon the results of the Phase 2 portion of TRIDENT-1, we may choose to seek Subpart H Accelerated Approval for repotrectinib, which would require completion of a confirmatory trial or trials to validate the clinical benefit of the drug. Despite the time and expense associated with preclinical studies and clinical trials, failure can occur at any stage. The results of preclinical and early clinical trials of repotrectinib or any other drug candidate may not be predictive of the results of our later-stage clinical trials.

Clinical trial failure may result from a multitude of factors including flaws in trial design, dose selection, placebo effect, patient enrollment criteria and failure to demonstrate favorable safety or efficacy traits, and failure in clinical trials can occur at any stage. Companies in the pharmaceutical industry frequently suffer setbacks in the advancement of clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Based upon negative or inconclusive results, we may decide, or regulators may require us, to conduct additional clinical trials or preclinical studies. In addition, data obtained from clinical trials are susceptible to varying interpretations, and regulators may not interpret our data as favorably as we do, which may further delay, limit or prevent marketing approval.

The FDA could delay, limit or deny approval of a drug candidate for many reasons, including because they:

- may not deem our drug candidate to be adequately safe and effective as compared to available therapies;

- may not agree that the data collected from preclinical studies and clinical trials are acceptable or sufficient to support the submission of an NDA or other submission or to obtain regulatory approval, and may impose requirements for additional preclinical studies or clinical trials;
- may determine that adverse events experienced by participants in our clinical trials represent an unacceptable level of risk;
- may determine that population studied in the clinical trial may not be sufficiently broad or representative to assure safety in the full population for which we seek approval;
- may not accept clinical data from trials, which are conducted at clinical facilities or in countries where the standard of care is potentially different from that of the United States;
- may disagree regarding the formulation, labeling and/or the specifications;
- may not approve the manufacturing processes or facilities associated with our drug candidate;
- may change approval policies or adopt new regulations; or
- may not accept a submission due to, among other reasons, the content or formatting of the submission.

Generally, public concern regarding the safety of pharmaceutical products could delay or limit our ability to obtain regulatory approval, result in the inclusion of unfavorable information in our labeling, or require us to undertake other activities that may entail additional costs. We have not obtained FDA approval for any product. This lack of experience may impede our ability to obtain FDA approval in a timely manner, if at all, for repotrectinib.

If we experience delays in obtaining approval or if we fail to obtain approval of repotrectinib or our other drug candidates, our commercial prospects will be harmed and our ability to generate revenues will be materially impaired which would adversely affect our business, prospects, financial condition and results of operations.

Our failure to obtain marketing approval in foreign jurisdictions would prevent our drug candidates from being marketed abroad, and any approval we are granted for our drug candidates in the United States would not assure approval of drug candidates in foreign jurisdictions.

In order to market and sell our products in any jurisdiction outside the United States, we must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, it is required that the product be approved for reimbursement before the product can be approved for sale in that country. We 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. We may not be able to submit for marketing approvals and may not receive necessary approvals to commercialize our products in any market.

Even if we obtain marketing approval for our drug candidates, the terms of approvals and ongoing regulation of our products may limit how we manufacture and market our products and compliance with such requirements may involve substantial resources, which could materially impair our ability to generate revenue.

Even if marketing approval of a drug candidate is granted, an approved product and its manufacturer and marketer are subject to ongoing review and extensive regulation, which may include the requirement to implement a REMS or to conduct costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of the product. We must also comply with requirements concerning advertising and promotion for any of our drug candidates for which we obtain marketing approval. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved labeling. Thus, we will not be able to promote any products we develop for indications or uses for which they are not approved. In addition, manufacturers of approved products and those manufacturers' facilities are required to ensure that quality control and manufacturing procedures conform to cGMPs, which include requirements relating to quality control and quality assurance as well as the corresponding maintenance of records and documentation and reporting requirements. We and our contract manufacturers could be subject to periodic unannounced inspections by the FDA to monitor and ensure compliance with cGMPs.

Accordingly, assuming we obtain marketing approval for one or more of our drug candidates, we and our contract manufacturers will continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing,

production, product surveillance and quality control. If we are not able to comply with post-approval regulatory requirements, we could have the marketing approvals for our products withdrawn by regulatory authorities and our ability to market any future products could be limited, which could adversely affect our ability to achieve or sustain profitability. As a result, the cost of compliance with post-approval regulations may have a negative effect on our operating results and financial condition.

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

Any drug candidate for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data, labeling, advertising and promotional activities for such product, will be subject to continual requirements of and review by the FDA and other regulatory authorities. These requirements include, but are not limited to, restrictions governing promotion of an approved product, submissions of safety and other post-marketing information and reports, registration and listing requirements, cGMP requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, and requirements regarding drug distribution and the distribution of samples to physicians and recordkeeping.

The FDA and other federal and state agencies, including the Department of Justice, closely regulate compliance with all requirements governing prescription drug products, including requirements pertaining to marketing and promotion of drugs in accordance with the provisions of the approved labeling and manufacturing of products in accordance with cGMP requirements. For example, the FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability. Violations of such requirements may lead to investigations alleging violations of the Food, Drug, and Cosmetic Act (FDCA) and other statutes, including the False Claims Act and other federal and state healthcare fraud and abuse laws as well as state consumer protection laws. Our failure to comply with all regulatory requirements, and later discovery of previously unknown adverse events or other problems with our products, manufacturers or manufacturing processes, may yield various results, including:

- litigation involving patients taking our products;
- restrictions on such products, manufacturers or manufacturing processes;
- restrictions on the labeling or marketing of a product;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning or untitled letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- damage to relationships with any potential collaborators;
- unfavorable press coverage and damage to our reputation;
- refusal to permit the import or export of our products;
- product seizure; or
- injunctions or the imposition of civil or criminal penalties.

Non-compliance by us or any future collaborator with regulatory requirements, including safety monitoring or pharmacovigilance, and with requirements related to the development of products for the pediatric population can also result in significant financial penalties.

Our relationships with customers and third-party payors may 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 drug candidates for which we obtain marketing approval. Our current and future arrangements with healthcare providers, 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 civil and criminal false claims laws, including the False Claims Act, which can be enforced by civil whistleblower or qui tam actions on behalf of the government, and the civil monetary penalties law, prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented false or fraudulent claims for payment by a federal government program, or making a false statement or record material to payment of a false claim or avoiding, decreasing or concealing an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), as amended by the Health Information Technology for Economic and Clinical Health Act (HITECH), and their implementing regulations, impose criminal and civil liability for executing a scheme to defraud any healthcare benefit program and also impose obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services;
- the federal transparency requirements under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively the ACA), requires manufacturers of drugs, devices, biologics and medical supplies to report to the Centers for Medicare & Medicaid Services (CMS) information related to physician payments and other transfers of value and ownership and investment interests held by physicians and their immediate family members; and
- analogous state laws and regulations such as state anti-kickback and false claims laws and analogous non-U.S. fraud and abuse laws and regulations, 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 regulations 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, marketing expenditures, or drug pricing. State and local laws require the registration of pharmaceutical sales representatives. State and non-U.S. laws that 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, disgorgement, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional integrity reporting and oversight obligations, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. If 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 significant criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs, which could have a material adverse effect on our business, results of operations, financial condition and prospects.

Recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our drug candidates and decrease 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 drug candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any drug 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 applies only to drug benefits for Medicare beneficiaries, private third-party 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 third-party payors.

In March 2010, the former U.S. President signed into law the ACA, 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 ACA of importance to our potential drug candidates are the following:

- annual fees and taxes on manufacturers of certain branded prescription drugs;
- an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic products;
- a new Medicare Part D coverage gap discount program, in which manufacturers must now agree to offer 70% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer’s outpatient drugs to be covered under Medicare Part D;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program and extended the rebate program to individuals enrolled in Medicaid managed care organizations;
- expansion of healthcare fraud and abuse laws, including the False Claims Act and the federal Anti-Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance;
- 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;
- requirements to report financial arrangements with physicians and teaching hospitals;
- a requirement to annually report drug samples that manufacturers and distributors provide to physicians; and
- a Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

Some of the provisions of the ACA have yet to be fully implemented, while certain provisions have been subject to judicial and Congressional challenges as well as recent efforts by the current U.S. President's administration to repeal or replace certain aspects of the ACA. Since January 2017, the current U.S. President has signed two Executive Orders and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, it has enacted laws that modify certain provisions of the ACA such as removing penalties, starting January 1, 2019, for not complying with the ACA's individual mandate to carry health insurance, delaying the implementation of certain ACA-mandated fees, and increasing the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D. On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas (Texas District Court Judge) ruled that the individual mandate is a critical and inseverable feature of the ACA, and therefore, because it was repealed as part of the Tax Cuts and Jobs Act, the remaining provisions of the ACA are invalid as well. While the Texas District Court Judge, as well as the current U.S. President's administration and CMS, have stated that the ruling will have no immediate effect, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the ACA will impact the ACA and our business.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. On August 2, 2011, the Budget Control Act of 2011 was signed into law, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals for spending reductions. The Joint Select Committee did not achieve a targeted deficit reduction, triggering the legislation's automatic reduction to several government programs. These changes include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, starting in 2013, and due to subsequent legislative amendments to the statute, will remain in effect through 2027 unless additional Congressional action is taken. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, 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 laws may result in additional reductions in Medicare and other healthcare funding.

Further, there has been heightened governmental scrutiny recently over the manner in which drug manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. At the federal level, the current U.S. President's administration issued budget proposals for fiscal years 2019 and 2020 that contained further drug price control measures that could be enacted during the budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. In addition, the current U.S. President's administration released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. The Department of Health and Human Services has started soliciting feedback on some of these measures and, at the same, is implementing others under its existing authority. Although some of these measures may require additional authorization to become effective, Congress and the current U.S. President's administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. In addition, at the state level, individual states have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

Additionally, on May 30, 2018, the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017 (the Right to Try Act) was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase I clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a pharmaceutical manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act.

We expect that the ACA, 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. 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 drug 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 of 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 (EU), 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 drug 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. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various EU member states, and parallel trade, i.e., arbitrage between low-priced and high-priced member states, can further reduce prices. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any products, if approved in those countries. In addition, the recent United Kingdom referendum on its membership in the EU resulted in a majority of United Kingdom voters voting to leave the EU, often referred to as "Brexit". Brexit could lead to legal and regulatory uncertainty in the United Kingdom and may lead to the United Kingdom and EU adopting divergent laws and regulations, including those related to the pricing of prescription pharmaceuticals, as the United Kingdom determines which EU laws to replicate or replace. If the United Kingdom were to significantly alter its regulations affecting the pricing of prescription pharmaceuticals, we could face significant new costs. As a result, Brexit could impair our ability to transact business in the EU and the United Kingdom.

Laws and regulations governing any international operations we may have in the future may preclude us from developing, manufacturing and selling certain drug candidates and products outside of the United States and require us to develop and implement costly compliance programs.

If we expand our operations outside of the United States, we must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate. The Foreign Corrupt Practices Act (FCPA) prohibits any U.S. individual or business from paying, offering, authorizing payment or offering anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of such third party in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the company, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

Various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. If we expand our presence outside of the United States, it will require us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing or selling certain drug candidates and products outside of the United States, which could limit our growth potential and increase our development costs.

The failure to comply with laws governing international business practices may result in substantial civil and criminal penalties and suspension or debarment from government contracting. The Securities and Exchange Commission also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions.

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 foreign, federal, state and local 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, including any available insurance.

In addition, our leasing and operation of real property may subject us to liability pursuant to certain of these laws or regulations. Under existing U.S. environmental laws and regulations, current or previous owners or operators of real property and entities that disposed or arranged for the disposal of hazardous substances may be held strictly, jointly and severally liable for the cost of investigating or remediating contamination caused by hazardous substance releases, even if they did not know of and were not responsible for the releases.

We could incur significant costs and liabilities which may adversely affect our financial condition and operating results for failure to comply with such laws and regulations, including, among other things, civil or criminal fines and penalties, property damage and personal injury claims, costs associated with upgrades to our facilities or changes to our operating procedures, or injunctions limiting or altering our operations.

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, which are becoming increasingly more stringent, may impair our research, development or production efforts. Our failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

We are subject to certain U.S. and certain foreign anti-corruption, anti-money laundering, export control, sanctions and other trade laws and regulations. We can face serious consequences for violations.

U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions and other trade laws and regulations prohibit, among other things, companies and their employees, agents, CROs, legal counsel, accountants, consultants, contractors and other partners from authorizing, promising, offering, providing, soliciting, or receiving directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Violations of these laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. We also expect our non-U.S. activities to increase over time. We expect to rely on third parties for research, preclinical studies and clinical trials and/or to obtain necessary permits, licenses, patent registrations and other marketing approvals. We can be held liable for the corrupt or other illegal activities of our personnel, agents, or partners, even if we do not explicitly authorize or have prior knowledge of such activities.

Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain sufficient patent protection for our drug candidates, or if the scope of the patent protection is not sufficiently broad, third parties, including our competitors, could develop and commercialize products similar or identical to ours, and our ability to commercialize our drug candidates successfully may be adversely affected. *

Our success depends in large part on our ability to protect our proprietary technologies that we believe are important to our business, including pursuing, obtaining and maintaining patent protection in the United States and other countries intended to cover the composition of matter of our drug candidates, for example, repotrectinib, the methods of use, related technologies and other inventions that are important to our business. In addition to patent protection, we also rely on trade secrets to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection. If we do not adequately pursue, obtain, maintain, protect or enforce our intellectual property, third parties, including our competitors, may be able to erode or negate any competitive advantage we may have, which could harm our business and ability to achieve profitability.

To protect our proprietary position, we file patent applications in the United States and abroad related to our drug candidates that we consider important to our business. The patent application and approval process is expensive, time-consuming and complex.

We may not be able to file, prosecute and maintain all necessary or desirable patent applications at a reasonable cost or in a timely manner or in all jurisdictions. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, depending on the terms of any future license agreements to which we may become a party, we may not have the right to control the preparation, filing, and prosecution of patent applications, or to maintain the patents, covering technology licensed from third parties. Therefore, these patents and patent applications may not be prosecuted and enforced in a manner consistent with the best interests of our business.

Furthermore, the patent position of biotechnology and pharmaceutical companies generally is highly uncertain. No consistent policy regarding the breadth of claims allowed in biotechnology and pharmaceutical patents has emerged to date in the United States or in many foreign jurisdictions. The standards applied by the United States Patent and Trademark Office (USPTO) and foreign patent offices in granting patents are not always applied uniformly or predictably. In addition, the determination of patent rights with respect to biological and pharmaceutical products commonly involves complex legal and factual questions, which have in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Thus, we cannot offer any assurances about which, if any, patents will issue, the breadth of any such patents, whether any issued patents will be found invalid and unenforceable or will be threatened by third parties or whether any issued patents will effectively prevent others from commercializing competing technologies and drug candidates. While we have filed patent applications covering aspects of our drug candidates, we currently only have issued patents in the United States, Europe, Japan, Eurasia, and Colombia covering the composition of matter of repotrectinib, TPX-0022, certain structurally related compounds, and methods of using the compounds in the treatment of cancer. We also have one issued patent in China covering the composition of matter of repotrectinib, certain structurally related compounds, and their use in the treatment of certain diseases, including cancer.

Our pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until at least one patent issues from such applications. Assuming the other requirements for patentability are met, currently, the first to file a patent application is generally entitled to the patent. However, prior to March 16, 2013, in the United States, the first to invent was entitled to the patent. 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. Since patent applications in the United States and most other countries are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that we were the first to file or invent (prior to March 16, 2013) any patent application related to our drug candidates. In addition, we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, collaborators, CROs, contract manufacturers, hospitals, independent treatment centers, consultants, independent contractors, suppliers, advisors and other third parties; however, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. Furthermore, if third parties have filed patent applications related to our drug candidates or technology, we may not be able to obtain our own patent rights to those drug candidates or technology.

Moreover, because the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, our patents or pending patent applications may be challenged in the courts or patent offices in the United States and abroad. For example, we may be subject to a third-party pre-issuance submission of prior art to the USPTO or become involved in post-grant review procedures, oppositions, derivations, revocation, reexaminations, *inter partes* review or interference proceedings, in the United States or elsewhere, 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 rights. Moreover, we may have to participate in interference proceedings declared by the USPTO to determine priority of invention or in post-grant challenge proceedings, such as oppositions in a foreign patent office, that challenge priority of invention or other features of patentability. Such challenges may result in loss of exclusivity or in our 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. Such challenges also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations, and prospects.

In addition, given the amount of time required for the development, testing and regulatory review of new drug candidates, our patents protecting such drug candidates might expire before or shortly after such drug candidates are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Moreover, some of our patents and patent applications may in the future be co-owned with third parties. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co-owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

Our pending and future patent applications may not result in patents being issued that protect our drug candidates, in whole or in part, or which effectively prevent others from commercializing competitive 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. In addition, the laws of foreign countries may not protect our rights to the same extent or in the same manner as the laws of the United States. For example, European patent law restricts the patentability of methods of treatment of the human body more than United States law does.

Even if our patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us or otherwise provide us with any competitive advantage. Moreover, the coverage claimed in a patent application can be significantly reduced before the patent is issued and its scope can be reinterpreted after issuance. Consequently, we do not know whether any of our drug candidates will be protectable or remain protected by valid and enforceable patents. Our competitors and other third parties may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner. Our competitors and other third parties may also seek approval to market their own products similar to or otherwise competitive with our products. Alternatively, our competitors or other third parties may seek to market generic versions of any approved products by submitting abbreviated NDAs to the FDA during which process they may claim that patents owned by us are invalid, unenforceable or not infringed. In these circumstances, we may need to defend or assert our patents, or both, including by filing lawsuits alleging patent infringement. In any of these types of proceedings, a court or other agency with jurisdiction may find our patents invalid or unenforceable, or that our competitors are competing in a non-infringing manner. Thus, even if we have valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

Furthermore, future patents may be subject to a reservation of rights by one or more third parties. For example, to the extent the research resulting in future patent rights or technologies is funded in the future in part by the U.S. government, the government could have certain rights in any resulting patents and technology, including a non-exclusive license authorizing the government to use the invention or to have others use the invention on its behalf for non-commercial purposes. If the U.S. government then decides to exercise these rights, it is not required to engage us as its contractor in connection with doing so. These rights may also permit the government to disclose our confidential information to third parties and to exercise march-in rights to use or allow third parties to use our licensed technology. The government may also exercise its march-in rights if it determines that action is necessary because we failed to achieve practical application of the government-funded technology, because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations, or to give preference to U.S. industry. In addition, our rights in such government-funded inventions may be subject to certain requirements to manufacture products embodying such inventions in the United States.

Any exercise by the government of aforementioned proprietary rights could harm our competitive position, business, financial condition, results of operations, and prospects.

Changes to the patent law in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products.

As is the case with other pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the pharmaceutical industry involves both technological and legal complexity and is therefore costly, time consuming and inherently uncertain. Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. Recent patent reform legislation in the United States and other countries, including the Leahy-Smith America Invents Act (the Leahy-Smith Act) signed into law in September 2011, could increase those uncertainties and costs. 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, redefine prior art and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. For example, the Leahy-Smith Act allows third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, *inter partes* review, and derivation proceedings. In addition, the Leahy-Smith Act has transformed the U.S. patent system from a "first-to-invent" system to a "first-to-file" system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. The first-to-file provisions, however, only became effective on March 16, 2013. Accordingly, it is not yet 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 make it more difficult to obtain patent protection for our inventions and increase the uncertainties and costs surrounding the prosecution of our or our collaboration partners' patent applications and the enforcement or defense of our or our collaboration partners' issued patents, all of which could harm our business, results of operations, financial condition and prospects.

In addition, the patent positions of companies in the development and commercialization of biologics and pharmaceuticals are particularly uncertain. The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. This combination of events has created uncertainty with respect to the validity and enforceability of patents, once obtained. Additionally, there have been recent proposals for additional changes to the patent laws of the United States and other countries that, if adopted, could impact our ability to enforce our proprietary technology. Depending on future actions by the U.S. Congress, the U.S. courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our existing patent portfolio and weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

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

Competitors and other third parties may infringe, misappropriate or otherwise violate our patents, trademarks, copyrights, trade secrets or other intellectual property. To counter infringement, misappropriation or other violations, we may be required to file infringement, misappropriation or other violation claims, which can be expensive and time consuming and divert the time and attention of our management and business and scientific personnel. In addition, many of our adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we can.

Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe, misappropriate or otherwise violate their patents or their other intellectual property, in addition to counterclaims asserting that our patents are invalid or unenforceable, or both. In patent litigation in the United States, counterclaims challenging the validity, enforceability or scope of asserted patents are commonplace. Similarly, third parties may initiate legal proceedings against us seeking a declaration that certain of our intellectual property is non-infringed, invalid or unenforceable. The outcome of any such proceeding is generally unpredictable.

In any patent infringement proceeding, there is a risk that a court will decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent's claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patent claims do not cover the invention. An adverse outcome in a litigation or proceeding involving our patents could limit our ability to assert our patents against those parties or other competitors, and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. If a defendant were to prevail on a legal assertion of invalidity or unenforceability of our patents covering one of our drug

candidates, we could lose at least a part, and perhaps all, of the patent protection covering such a drug candidate. Competing drugs may also be sold in other countries in which our patent coverage might not exist or be as strong. If we lose a foreign patent lawsuit, alleging our infringement of a competitor's patents, we could be prevented from marketing our drugs in one or more foreign countries. Any of these occurrences could adversely affect our competitive business position, business prospects and financial condition. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of shares of our common stock. Moreover, there can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings.

Furthermore, third parties may also raise invalidity or unenforceability claims before administrative bodies in the United States or foreign authorities, even outside the context of litigation. Such mechanisms include re-examination, *inter partes* review, post-grant review, interference proceedings, derivation proceedings and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in revocation, cancellation or amendment to our patents in such a way that they no longer cover and protect our drug candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement or written description. Grounds for an unenforceability assertion could be an allegation that someone connected with the prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution of the patent. With respect to the validity of our patents, for example, we cannot be certain that there is no invalidating prior art of which we, our licensors, our patent counsel and the patent examiner were unaware during prosecution. Moreover, it is possible that prior art may exist that we are aware of but do not believe is relevant to our current or future patents, but that could nevertheless be determined to render our patents invalid. If a third party were to prevail on a legal assertion of invalidity or unenforceability, we could lose at least part, and perhaps all, of the patent protection on one or more of our drug candidates. Any such loss of patent protection could have a material adverse impact on our business, financial condition, results of operations and prospects.

We may not be able to effectively enforce our intellectual property and proprietary rights throughout the world.

Filing, prosecuting and defending patents with respect to our drug candidates in all countries throughout the world would be prohibitively expensive, and the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. The requirements for patentability may differ in certain countries, particularly in developing countries. In addition, any future intellectual property license agreements may not always include worldwide rights. Consequently, competitors and other third parties may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we may obtain patent protection, but where patent enforcement is not as strong as that in the United States and where our ability to enforce our patents to stop infringing activities may be inadequate. These products may compete with our products in such territories and in jurisdictions where we do not have any patent rights or where any future patent claims or other intellectual property or proprietary rights may not be effective or sufficient to prevent them from competing with us, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Moreover, our ability to protect and enforce our intellectual property and proprietary rights may be adversely affected by unforeseen changes in foreign intellectual property laws. Additionally, the laws of some countries outside of the United States and Europe do not afford intellectual property protection to the same extent as the laws of the United States and Europe. Many companies have encountered significant problems in protecting and defending intellectual property and proprietary rights in certain foreign jurisdictions. The legal systems of some countries, including, for example, India, China and other developing countries, do not favor the enforcement of patents and other intellectual property or proprietary rights, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement, misappropriation or other violation of our patents or other intellectual property or proprietary rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. Consequently, we may not be able to prevent third parties from practicing our inventions in certain countries outside the United States and Europe. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we are forced to grant a license to third parties with respect to any patents relevant to our business, our

competitive position may be impaired, and our business, financial condition, results of operations, and prospects may be adversely affected. Proceedings to enforce our intellectual property and proprietary rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and resources from other aspects of our business, could put our patents, trademarks or other intellectual property and proprietary rights at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Furthermore, while we intend to protect our intellectual property and proprietary rights in major markets for our products, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our products. Accordingly, our efforts to protect our intellectual property and proprietary rights in such countries may be inadequate.

If we are sued for infringing, misappropriating or otherwise violating intellectual property or proprietary rights of third parties, such litigation or disputes could be costly and time consuming and could prevent or delay us from developing or commercializing our drug candidates.

Our commercial success depends, in part, on our ability to develop, manufacture, market and sell our drug candidates and use our proprietary technologies without infringing, misappropriating or otherwise violating the intellectual property and other proprietary rights of third parties. If any third-party patents, patent applications or other proprietary rights are found to cover our drug candidates or any related companion diagnostics or their compositions, methods of use or manufacturing, we may be required to pay damages, which could be substantial, and we would not be free to manufacture or market our drug candidates or to do so without obtaining a license, which may not be available on commercially reasonable terms, or at all.

We may in the future become party to, or threatened with, adversarial proceedings or litigation regarding intellectual property or proprietary rights with respect to our drug candidates and technologies we use in our business. Our competitors or other third parties may assert infringement claims against us, alleging that our drug candidates are covered by their patents. We cannot be certain that we do not infringe existing patents or that we will not infringe patents that may be granted in the future. Furthermore, because patent applications can take many years to issue and may be confidential for 18 months or more after filing, and because patent claims can be revised before issuance, there may be applications now pending which may later result in issued patents that may be infringed by the manufacture, use or sale of our drug candidates. If a patent holder believes our drug candidate infringes its patent rights, the patent holder may sue us even if we have received patent protection for our technology. Moreover, we may face patent infringement claims from non-practicing entities that have no relevant drug revenue and against whom our own patent portfolio may thus have no deterrent effect.

There is a substantial amount of intellectual property litigation in the biotechnology and pharmaceutical industries, and we may become party to, or threatened with, litigation or other adversarial proceedings regarding intellectual property or proprietary rights with respect to our drug candidates, including interference proceedings before the USPTO. Third parties may assert infringement, misappropriation or other claims against us based on existing or future intellectual property or proprietary rights. The outcome of intellectual property litigation and other disputes is subject to uncertainties that cannot be adequately quantified in advance. The pharmaceutical and biotechnology industries have produced a significant number of patents, and it may not always be clear to industry participants, including us, which patents cover various types of products or methods of using or manufacturing products. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we were sued for patent infringement, we would need to demonstrate that our drug candidates, products or methods of use, manufacturing or other applicable activities either do not infringe the patent claims of the relevant patent or that the patent claims are invalid or unenforceable, and we may not be successful in doing so. However, proving invalidity or unenforceability is difficult. For example, in the United States, proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if we believe third-party intellectual property claims are without merit, there is no assurance that a court would find in our favor on questions of infringement, validity, or enforceability. Even if we are successful in these proceedings, we may incur substantial costs and the time and attention of our management and business and scientific personnel could be diverted in pursuing these proceedings, which could significantly harm our business and operating results. In addition, we may not have sufficient resources to bring these actions to a successful conclusion.

If we are found to infringe, misappropriate or otherwise violate a third party’s intellectual property or proprietary rights and we are unsuccessful in demonstrating that such intellectual property or proprietary rights are invalid or unenforceable, we could be forced, including by court order, to cease developing, manufacturing or commercializing the infringing drug candidate or product. Alternatively, we may be required to obtain a license from such third party in order to use the infringing technology and continue developing, manufacturing or marketing the infringing drug candidate. 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 such a license, it could be granted on non-exclusive terms, thereby giving our competitors and other third parties access to the same technologies licensed to us. In addition, we could be found liable for significant monetary damages, including treble damages and attorneys’ fees if we are found to have willfully infringed such third-party patent rights. A finding of infringement could prevent us from commercializing our drug 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, financial condition, results of operations and prospects.

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

Some of our employees and consultants are currently or have been previously employed at universities or at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. These employees and consultants may have executed proprietary rights, non-disclosure and non-competition agreements, or similar agreements, in connection with such other current or previous employment. Although we try to ensure that our employees and consultants do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these individuals have used or disclosed intellectual property, including trade secrets or other proprietary information, of third parties. Litigation may be necessary to defend against such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property or personnel or sustain damages. Such intellectual property could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products. Such a license may not be available on commercially reasonable terms or at all. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to our management. Any of the foregoing would have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, while it is our policy to require our employees, consultants and contractors who may be involved in the conception or 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, conceives or develops intellectual property that we regard as our own, which may result in claims by or against us related to the ownership of such intellectual property. In addition, such agreements may not be self-executing such that the intellectual property subject to such agreements may not be assigned to us without additional assignments being executed, and we may fail to obtain such assignments. In addition, such agreements may be breached. Accordingly, we may be forced to bring claims against third parties, or defend claims that 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. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our senior management and scientific personnel, which would have a material adverse effect on our business, financial condition, results of operations and prospects.

Rights to improvements to our drug candidates may be held by third parties.

In the course of testing our drug candidates, we have entered into agreements with third parties to conduct clinical testing, which provide that improvements to our drug candidates may be owned solely by a party or jointly between the parties. If we determine that rights to such improvements owned solely by a third party are necessary to commercialize our drug candidates or maintain our competitive advantage, we may need to obtain a license from such third party in order to use the improvements and continue developing, manufacturing or marketing the drug candidates. 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 such a license, it could be granted on non-exclusive terms, thereby giving our competitors and other third parties access to the same technologies licensed to us. Failure to obtain a license on commercially reasonable terms or at all, or to obtain an exclusive license, could prevent us from commercializing our drug candidates or force us to cease some of our business operations, which could materially harm our business. If we determine that rights to improvements jointly owned between us and a third party are necessary to commercialize our drug candidates or maintain our competitive advantage, we may need to obtain an exclusive license from such third party. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in such improvements, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co-owners of our intellectual property in order to enforce such intellectual property against third parties, and such cooperation may not be provided to us. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

The term of our patents may be inadequate to protect our competitive position on our products.

Given the amount of time required for the development, testing and regulatory review of new drug candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. Depending upon the timing, duration and other factors relating to any FDA marketing approval we receive for any of our drug candidates, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Action of 1984 (Hatch-Waxman Amendments). We expect to seek extensions of patent terms in the United States and, if available, in other countries where we are prosecuting patents. In the United States, the Hatch-Waxman Amendments permit a patent term extension of

up to five years beyond the normal expiration of the patent, limited to the approved indication (or any additional indications approved during the period of extension), as compensation for patent term lost during the regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent applicable to an approved drug is eligible for the extension and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended, and the application for the extension must be submitted prior to the expiration of the patent. However, the applicable authorities, including the FDA and the USPTO in the United States, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available for our patents, may refuse to grant extensions to our patents, or may grant more limited extensions than we request. We may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. If we are unable to obtain patent term extension or the term of any such extension is less than we request, our competitors and other third parties may be able to obtain approval of competing products following our patent expiration and take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case. Any of the foregoing would have a material adverse effect on our business, financial condition, results of operations and prospects.

Obtaining and maintaining our patent protection depends on compliance with various procedural, documentary, fee payment and other requirements imposed by governmental patent offices, 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 government fees on any issued patent are due to be paid to the USPTO and patent offices in foreign countries in several stages over the lifetime of the patent. The USPTO and patent offices in foreign countries require compliance with a number of procedural, documentary, fee payment and other requirements during the patent application process. In the future, we may rely on licensing partners to pay these fees due to U.S. and non-U.S. patent agencies and to comply with these other requirements with respect to any future licensed patents and patent applications. While an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of a patent or patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In such an event, our competitors and other third parties might be able to enter the market with similar or identical products of technology, which would have a material adverse effect on our business, financial condition, results of operations and prospects.

If we are unable to protect the confidentiality of our trade secrets, the value of our technology could be materially adversely affected and our business would be harmed. *

While we have obtained composition of matter patents with respect to two of our drug candidates, we also rely on proprietary know-how and trade secret protection and confidentiality agreements to protect proprietary know-how or trade secrets that are not patentable or that we elect not to patent. We seek to protect our trade secrets and proprietary know-how in part by entering into non-disclosure and confidentiality agreements with parties who have access to such knowledge, such as our employees, consultants, independent contractors, advisors, contract manufacturers, CROs, hospitals, independent treatment centers, suppliers, collaborators and other third parties. We also enter into confidentiality and invention or patent assignment agreements with employees and certain consultants. However, we cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary know-how. Additionally, our confidentiality agreements and other contractual protections may not be adequate to protect our intellectual property from unauthorized disclosure, third-party infringement or misappropriation. Any party with whom we have executed such an agreement may breach that agreement 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 in the United States and certain foreign jurisdictions 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 or other third party, we would have no right to prevent such third party, or those to whom they communicate such technology or information, 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 or other third party, our business, financial condition, results of operations and prospects our business and competitive position could be materially harmed.

Intellectual property rights do not necessarily address all potential threats.

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

- others may be able to make products similar to any drug candidates we may develop or utilize similarly related technologies that are not covered by the claims of the patents that we may license or may own in the future;
- we, or any future license partners or current or future collaborators, might not have been the first to make the inventions covered by the issued patent or pending patent application that we license or may own in the future;
- we, or any future license partners or current or future collaborators, might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing, misappropriating or otherwise violating any of our owned or licensed intellectual property rights;
- it is possible that our pending patent applications or those that we may own in the future will not lead to issued patents;
- issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors or other third parties;
- our competitors or other third parties might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may harm our business; and
- we may choose not to file a patent in order to maintain certain trade secrets or know how, and a third party may subsequently file a patent covering such intellectual property.

Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations and prospects.

Risks Related to the Commercialization of Our Drug Candidates

The incidence and prevalence for target patient populations of our drug candidates have not been established with precision. If the market opportunities for our drug candidates are smaller than we estimate or if any approval that we obtain is based on a narrower definition of the patient population, our revenue potential and ability to achieve profitability will be adversely affected. ***

The total addressable market opportunity for repotrectinib and our other drug candidates will ultimately depend upon, among other things, the diagnosis criteria included in the final label for each such drug candidate if our drug candidates are approved for sale for these indications, acceptance by the medical community and patient access, drug and any related companion diagnostic pricing and their reimbursement. The number of patients in our targeted commercial markets and elsewhere may turn out to be lower than expected, patients may not be otherwise amenable to treatment with our drugs, or new patients may become increasingly difficult to identify or gain access to, all of which would adversely affect our results of operations and our business.

Even if any of our drug 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 drug 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, such as existing targeted therapies, chemotherapy, and radiation therapy, are well established in the medical community, and doctors may continue to rely on these treatments. If our drug 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 drug candidates, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy and potential advantages compared to alternative treatments;
- the prevalence and severity of any side effects, in particular compared to alternative treatments;
- limitations or warnings contained in the labeling approved for our drug candidates by the FDA;
- the size of the target patient population;

- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- our ability to offer our products for sale at competitive prices;
- the convenience and ease of administration compared to alternative treatments;
- the strength of marketing and distribution support;
- publicity for our drug candidates and competing products and treatments;
- the existence of distribution and/or use restrictions, such as through a REMS;
- the availability of third-party payor coverage and adequate reimbursement;
- the timing of any marketing approval in relation to other product approvals;
- support from patient advocacy groups; and
- any restrictions on the use of our products together with other medications.

We currently have no marketing and sales organization and have no experience as a company in commercializing products and we may have to invest significant resources to develop these capabilities. If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our products, we may not be able to generate revenue.

We do not have a sales or marketing infrastructure and have no experience in the sale, marketing or distribution of pharmaceutical products. To achieve commercial success for any product for which we obtain marketing approval, we will need to establish sales, marketing and distribution capabilities, either ourselves or through collaboration or other arrangements with third parties.

There are risks involved with establishing our own sales and marketing capabilities. For example, recruiting and training a sales force is expensive and time-consuming and could delay any product launch. If the commercial launch of a drug candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. These efforts are expected to be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to commercialize our products on our own include:

- our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;
- our inability to raise financing necessary to build our commercialization infrastructure;
- the inability of sales personnel to obtain access to physicians or educate an adequate number of physicians as to the benefits of our products;
- unfavorable third-party payor coverage and reimbursement in any geography;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

As a result of any potential partnerships in markets outside of the United States, or if we are unable to establish our own sales and marketing capabilities in the United States and instead enter into arrangements with third parties to perform these services, our product revenues and our profitability, if any, are likely to be lower than if we were to market and sell any products that we develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to market and sell our drug candidates or may be unable to do so on terms that are acceptable to us. We likely will have little control over such third parties, and any of these third parties may fail to devote the necessary resources and attention to sell and market our products effectively. If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing any of our drug candidates for which we receive marketing approval.

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

The development and commercialization of pharmaceutical products is highly competitive. We face competition with respect to our current drug candidates, and will face competition with respect to any drug 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 drug candidates. Some of these competitive products and therapies are based on scientific approaches that are 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.

There are a large number of pharmaceutical and biotechnology companies developing or marketing targeted treatments for cancer that would be competitive with the drug candidates we are developing, if our drug candidates are approved. Many of these companies are developing cancer therapeutics that are also kinase inhibitors. We expect that repotrectinib will compete against approved drugs, including: crizotinib, which is marketed by Pfizer Inc. under the name Xalkori for the treatment of *ROS1*+ and *ALK*+ NSCLC, and entrectinib, which is marketed by F. Hoffman La Roche AG under the name Rozlytrek, for the treatment of *ROS1*+ NSCLC; lorlatinib, which is marketed by Pfizer Inc. under the name Lorbrena for the treatment of *ALK*+ NSCLC; ceritinib, which is marketed by Novartis Pharmaceuticals Corporation under the name Zykadia for the treatment of *ALK*+ NSCLC; and both larotrectinib, which is marketed by Bayer AG under the trade name Vitrakvi, and entrectinib, which is marketed by F. Hoffman La Roche AG under the name Rozlytrek, which were recently approved by the FDA for the treatment of *TRK*+ solid tumors. We also expect that repotrectinib will compete against other compounds which are currently in late-stage clinical development, including TKIs in Phase 2, or later, clinical development for the treatment of *ROS1*+ NSCLC at companies including against Pfizer Inc. (lorlatinib), Betta Pharmaceuticals Co., Ltd. (ensartinib) and Exelixis, Inc. (cabozantinib) and TKIs in Phase 2, or later, clinical development for the treatment of *TRK*+ solid tumors at companies including Loxo Oncology Inc. (LOXO-195) and Exelixis, Inc. (cabozantinib).

We expect that TPX-0022 will compete against other compounds which are in phase 2 or later clinical development for the treatment of MET+ tumors at companies including Novartis Pharmaceutical Corporation (capmatinib), Astrazeneca (savolitinib), Merck KGaA (tepotinib), Pfizer Inc. (crizotinib), and Exelixis, Inc. (cabozantinib). We expect that TPX-0046 will compete against other compounds in phase 2 or later clinical development for the treatment of RET+ cancers at companies including Eli Lilly and

Company (selpercatinib) and Blueprint Medicines (pralsetinib) and approved drugs for the treatment of medullary thyroid cancer including cabozantinib which is marketed by Exelixis, Inc. as Cometriq and vandetinib which is marketed by Sanofi Genzyme as Caprelsa.

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 marketing approvals and marketing and selling 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, management and sales and marketing personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

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 approved for broader indications or patient populations, are more convenient or are less expensive than any products that we may develop. Our competitors also may obtain FDA or other marketing approval for their products more rapidly than any approval we may obtain for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. 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 some of the indications that we are pursuing, and additional products are expected to become available on a generic basis over the coming years. If our drug candidates achieve marketing approval, we expect that they will be priced at a significant premium over any competitive generic products. The key competitive factors affecting the success of repotrectinib are likely to be its efficacy, safety, scope and limitations of marketing approval, and availability of reimbursement.

Even if we are able to commercialize any drug candidates, the products may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, which would harm our business. *

The regulations that govern marketing approvals, pricing, coverage and reimbursement for new drug products vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. 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 drug candidate to other available therapies. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a drug candidate in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenues, if any, we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more drug candidates, even if such drug candidates obtain marketing approval.

Our ability to commercialize any drug candidates successfully also will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from third-party payors, including government healthcare programs, private health insurers and other organizations. Third-party payors decide which medications they will pay for and establish reimbursement levels. Additionally, companion diagnostic tests we may develop for use with our product candidates require coverage and reimbursement separate and apart from the coverage and reimbursement for their companion pharmaceutical or biological products. Similar challenges to obtaining coverage and reimbursement, applicable to pharmaceutical or biological products, will apply to companion diagnostics.

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Coverage and reimbursement may not be available for any product that we commercialize and, even if these are available, the level of reimbursement may not be satisfactory. Reimbursement may affect the demand for, or the price of, any drug candidate for which we obtain marketing approval. Obtaining and maintaining coverage and adequate reimbursement for our products may be difficult. We may be required to conduct expensive pharmacoeconomic studies to justify coverage and reimbursement or the level of reimbursement relative to other therapies. If coverage and adequate reimbursement are not available or reimbursement is available only to limited levels, we may not be able to successfully commercialize any drug candidate for which we obtain marketing approval.

Additionally, we plan to develop, either by ourselves or with collaborators, *in vitro* companion diagnostic tests for our drug candidates for certain indications. We, or our collaborators, will be required to obtain coverage and reimbursement for these tests separate and apart from the coverage and reimbursement we seek for our product candidates, once approved. While we have not yet

developed any companion diagnostic test for our product candidates, if we do, there is significant uncertainty regarding our ability to obtain coverage and adequate reimbursement for the same reasons applicable to our product candidates.

There may also be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or similar regulatory authorities outside of the United States. Moreover, eligibility for coverage and reimbursement does not imply that a drug will be paid for in all cases or at a rate that covers our costs, including research, development, intellectual property, manufacture, sale and distribution expenses. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies, but also have their own methods and approval process apart from Medicare determinations. Our inability to promptly obtain coverage and adequate reimbursement rates from third-party payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

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 drug candidates in human clinical trials and will face an even greater risk if we commercialize any products that we may develop. If we cannot successfully defend ourselves against any claims that our drug 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 drug 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.

Our current product liability insurance coverage for the United States and certain other jurisdictions may not be adequate to cover all liabilities that we may incur. We likely will need to increase our insurance coverage as we expand our clinical trials or if we commence commercialization of our drug 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 Employee Matters, Managing Growth and Other Risks Related to Our Business

***Our future success depends on our ability to retain key employees and to attract, retain and motivate qualified personnel. **

We are highly dependent on the development and managerial expertise of Athena Countouriotis, M.D., our President and Chief Executive Officer, and the research expertise of Jingrong Jean Cui, Ph.D., our founder and Chief Scientific Officer, as well as the other principal members of our management, scientific and clinical team. Although we have entered into employment agreements with our executive officers, each of them may terminate their employment with us at any time.

Our industry has experienced a high rate of turnover in recent years. Our ability to compete in the highly competitive pharmaceuticals industry depends upon our ability to attract, retain and motivate highly skilled and experienced personnel with scientific, clinical, regulatory, manufacturing and management skills and experience. We conduct our operations in the greater San Diego area, a region that is home to many other pharmaceutical companies as well as many academic and research institutions, resulting in fierce competition for qualified personnel. We may not be able to attract or retain qualified personnel in the future due to the intense competition for a limited number of qualified personnel among pharmaceutical companies. Many of the other pharmaceutical companies against which we compete have greater financial and other resources, different risk profiles and a longer

history in the industry than we do. Our competitors may provide higher compensation, more diverse opportunities and/or better opportunities for career advancement. Any or all of these competing factors may limit our ability to continue to attract and retain high quality personnel, which could negatively affect our ability to successfully develop and commercialize our drug candidates and to grow our business and operations as currently contemplated.

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. *

As of September 30, 2019, we had 87 full-time employees. We expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of clinical development, clinical operations, manufacturing, regulatory affairs and, if any of our drug 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 and with developing sales, marketing and distribution infrastructure, 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.

Further, we currently rely, and for the foreseeable future will continue to rely, in substantial part on certain third-party contract organizations, advisors and consultants to provide certain services, including assuming substantial responsibilities for the conduct of our clinical trials and the manufacture of repotrectinib or any of our other current or future drug candidates. We cannot assure you that the services of such third-party contract organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by our vendors or consultants is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain marketing approval of repotrectinib or any of our other current or future drug candidates or otherwise advance our business. We cannot assure you that we will be able to properly manage our existing vendors or consultants or find other competent outside vendors and consultants on economically reasonable terms, or at all.

If we are not able to effectively manage growth and expand our organization, we may not be able to successfully implement the tasks necessary to further develop and commercialize repotrectinib, our other pipeline drug candidates or any future drug candidates and, accordingly, may not achieve our research, development and commercialization goals.

Our employees, clinical trial investigators, CROs, consultants, vendors and any potential commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading. *

We are exposed to the risk of fraud or other misconduct by our employees, clinical trial investigators, CROs, consultants, vendors and any potential commercial partners. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violates: (i) FDA regulations or those of comparable foreign regulatory authorities, including those laws that require the reporting of true, complete and accurate information, (ii) manufacturing standards, (iii) federal and state health and data privacy, security, fraud and abuse, government price reporting, transparency reporting requirements, and other healthcare laws and regulations in the United States and abroad, (iv) sexual harassment and other workplace misconduct, or (v) laws that require the true, complete and accurate reporting of financial information or data. Such misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. We maintain a written code of business conduct and ethics that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or person performing similar functions, as well as a disclosure program and other applicable policies and procedures, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from government funded healthcare programs, such as Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional integrity reporting and oversight obligations, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Our internal information technology systems, or those of our third-party CROs or other vendors, contractors or consultants, may fail or suffer security breaches, loss or leakage of data and other disruptions, which could result in a material disruption of our development programs, compromise sensitive information related to our business or prevent us from accessing critical information, potentially exposing us to liability or otherwise adversely affecting our business. *

We are increasingly dependent upon information technology systems, infrastructure and data to operate our business. In the ordinary course of business, we collect, store and transmit confidential information (including but not limited to intellectual property, proprietary business information and personal information). It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. We also have outsourced elements of our operations to third parties, and as a result we manage a number of third-party CROs, vendors, and other contractors and consultants who have access to our confidential information.

Despite the implementation of security measures, given their size and complexity and the increasing amounts of confidential information that they maintain, our internal information technology systems and those of our third-party CROs, vendors and other contractors and consultants are potentially vulnerable to breakdown or other damage or interruption from service interruptions, system malfunction, natural disasters, terrorism, war and telecommunication and electrical failures, as well as security breaches from inadvertent or intentional actions by our employees, third-party CROs, vendors, contractors, consultants, business partners and/or other third parties, or from cyber-attacks by malicious third parties (including the deployment of harmful malware, ransomware, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information), which may compromise our system infrastructure, or that of our third-party CROs, vendors and other contractors and consultants, or lead to data leakage. The risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. We may not be able to anticipate all types of security threats, nor may we be able to implement preventive measures effective against all such security threats. The techniques used by cyber criminals change frequently, may not be recognized until launched and can originate from a wide variety of sources, including outside groups such as external service providers, organized crime affiliates, terrorist organizations or hostile foreign governments or agencies. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or those of our third-party CROs, vendors and other contractors and consultants, or inappropriate disclosure of confidential or proprietary information, we could incur liability and reputational damage and the further development and commercialization of repotrectinib or any other drug candidates could be delayed. The costs related to significant security breaches or disruptions could be material and exceed the limits of the cybersecurity insurance we maintain against such risks. If the information technology systems of our third-party CROs, vendors and other contractors and consultants become subject to disruptions or security breaches, we may have insufficient recourse against such third parties and we may have to expend significant resources to mitigate the impact of such an event, and to develop and implement protections to prevent future events of this nature from occurring.

While we have not experienced any such system failure, accident or security breach to date, and believe that our data protection efforts and our investment in information technology reduce the likelihood of such incidents in the future, we cannot assure you that our data protection efforts and our investment in information technology will prevent significant breakdowns, data leakages, breaches in our systems, or those of our third-party CROs, vendors and other contractors and consultants, or other cyber incidents that could have a material adverse effect upon our reputation, business, operations or financial condition. For example, if such an event were to occur and cause interruptions in our operations, or those of our third-party CROs, vendors and other contractors and consultants, it could result in a material disruption of our programs and the development of our drug candidates could be delayed. In addition, the loss of clinical trial data for repotrectinib or any other drug candidates could result in delays in our marketing approval efforts and significantly increase our costs to recover or reproduce the data. Furthermore, significant disruptions of our internal information technology systems or those of our third-party CROs, vendors and other contractors and consultants, or security breaches could result in the loss, misappropriation and/or unauthorized access, use, or disclosure of, or the prevention of access to, confidential information (including trade secrets or other intellectual property, proprietary business information and personal information), which could result in financial, legal, business and reputational harm to us. For example, any such event that leads to unauthorized access, use, or disclosure of personal information, including personal information regarding our clinical trial subjects or employees, could harm our reputation directly, compel us to comply with federal and/or state breach notification laws and foreign law equivalents, subject us to mandatory corrective action, and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information, which could result in significant legal and financial exposure and reputational damages that could potentially have an adverse effect on our business.

Failure to comply with health and data protection laws and regulations could lead to government enforcement actions (which could include civil or criminal penalties), private litigation and/or adverse publicity and could negatively affect our operating results and business. *

We and any potential collaborators may be subject to federal, state and foreign data protection laws and regulations (i.e., laws and regulations that address privacy and data security). In the United States, numerous federal and state laws and regulations, including federal health information privacy laws, state data breach notification laws, state health information privacy laws and federal and state consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), that govern the collection, use, disclosure and protection of health-related and other personal information could apply to our operations or the operations of our collaborators. In addition, we may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under the HIPAA, as amended by HITECH. Depending on the facts and circumstances, we could be subject to criminal penalties if we knowingly obtain, use, or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA.

International data protection laws, including Regulation 2016/679, known as the General Data Protection Regulation (GDPR) may also apply to health-related and other personal information obtained outside of the United States. The GDPR went into effect on May 25, 2018. The GDPR introduced new data protection requirements in the European Union, as well as potential fines for noncompliant companies of up to the greater of €20 million or 4% of annual global revenue. The regulation imposes numerous new requirements for the collection, use and disclosure of personal information, including more stringent requirements relating to consent and the information that must be shared with data subjects about how their personal information is used, the obligation to notify regulators and affected individuals of personal data breaches, extensive new internal privacy governance obligations and obligations to honor expanded rights of individuals in relation to their personal information (e.g., the right to access, correct and delete their data). In addition, the GDPR includes restrictions on cross-border data transfer. The GDPR will increase our responsibility and liability in relation to personal data that we process, and we may be required to put in place additional mechanisms to ensure compliance with the new EU data protection rules. In addition, the GDPR prohibits the transfer of personal data to countries outside of the European Economic Area (EEA), such as the United States, which are not considered by the European Commission to provide an adequate level of data protection. Switzerland has adopted similar restrictions. Although there are legal mechanisms to allow for the transfer of personal data from the EEA and Switzerland to the United States, they are subject to pending legal challenges that, if successful, could invalidate these mechanisms, restrict our ability to process personal data of Europeans outside of Europe and adversely impact our business.

In addition, California recently enacted the California Consumer Privacy Act (CPPA), which creates new individual privacy rights for California consumers (as defined in the law) and places increased privacy and security obligations on entities handling certain personal data of consumers or households. The CCPA will require covered companies to provide new disclosure to consumers about such companies' data collection, use and sharing practices, provide such consumers new ways to opt-out of certain sales or transfers of personal information, and provide consumers with additional causes of action. The CCPA goes into effect on January 1, 2020, and the California Attorney General may bring enforcement actions for violations beginning July 1, 2020. The CCPA was amended on September 23, 2018, and it remains unclear what, if any, further modifications will be made to this legislation or how it will be interpreted. As currently written, the CCPA may impact our business activities and exemplifies the vulnerability of our business to the evolving regulatory environment related to personal data and protected health information.

Compliance with U.S. and international data protection laws and regulations could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. Failure to comply with U.S. and international data protection laws and regulations could result in government enforcement actions (which could include civil, criminal, and administrative penalties), private litigation and/or adverse publicity and could negatively affect our operating results and business. Moreover, clinical trial subjects about whom we or our potential collaborators obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time consuming to defend and could result in adverse publicity that could harm our business.

We or the third parties upon whom we depend may be adversely affected by natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Our company is located in San Diego, California, an area prone to wild fires and earthquakes. These and other natural disasters could severely disrupt our operations, and have a material adverse effect on our business, results of operations, financial condition and prospects. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as the manufacturing facilities of our third-party contract manufacturers, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial

period of time. Any disaster recovery and business continuity plans we have in place may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which, could have a material adverse effect on our business.

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

We have incurred substantial losses during our history and do not expect to become profitable in the near future, and we may never achieve profitability. Unused losses for the tax year ended December 31, 2017 will carry forward to offset future taxable income, if any, until such unused losses expire. Unused losses generated after December 31, 2017, under recent U.S. federal tax legislation (H.R. 1, "An Act to provide for reconciliation pursuant to titles II and V of the concurrent resolution on the budget for fiscal year 2018", informally titled the Tax Cuts and Jobs Act), will not expire and may be carried forward indefinitely but will be only deductible to the extent of 80% of current year taxable income in any given year. It is uncertain if and to what extent various states will conform to the recent U.S. federal tax legislation. In addition, both our current and our future unused losses and other tax attributes may be subject to limitation under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the Code) if we undergo an "ownership change," generally defined as a greater than 50 percentage point change (by value) in our equity ownership by certain stockholders over a three-year period. We have not completed a Section 382 study to assess whether an ownership change has occurred or whether there have been multiple ownership changes since our formation due to the complexity and cost associated with such a study and the fact that there may be additional such ownership changes in the future. As a result, if we earn net taxable income our pre-2018 net operating loss carryforwards may expire prior to being used, our net operating loss carryforwards generated in 2018 and thereafter will be subject to a percentage limitation and, if we undergo an ownership change (or if we previously underwent such an ownership change), our ability to use all of our pre-change net operating loss carryforwards (NOLs) and other pre-change tax attributes (such as research tax credits) to offset our post-change income or taxes may be limited. Similar provisions of state tax law may also apply to limit our use of accumulated state tax attributes. 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. As a result, even if we attain profitability, we may be unable to use all or a material portion of our NOLs and other tax attributes, which could adversely affect our future cash flows.

We may engage in strategic transactions that could impact our liquidity, increase our expenses and present significant distractions to our management.

From time to time, we may consider strategic transactions, such as acquisitions of companies, businesses or assets and out-licensing or in-licensing of products, drug candidates or technologies. Additional potential transactions that we may consider include a variety of different business arrangements, including spin-offs, strategic partnerships, joint ventures, restructurings, divestitures, business combinations and investments. Any such transaction may require us to incur non-recurring or other charges, may increase our near term or long-term expenditures and may pose significant integration challenges or disrupt our management or business, which could adversely affect our operations and financial results. For example, these transactions may entail numerous operational and financial risks, including:

- exposure to unknown liabilities;
- disruption of our business and diversion of our management's time and attention in order to develop acquired products, drug candidates or technologies;
- incurrence of substantial debt or dilutive issuances of equity securities to pay for acquisitions;
- higher than expected acquisition and integration costs;
- write-downs of assets or goodwill or impairment charges;
- increased amortization expenses;
- difficulty and cost in combining the operations, systems and personnel of any acquired businesses with our operations, systems and personnel;
- impairment of relationships with key suppliers or customers of any acquired businesses due to changes in management and ownership; and
- inability to retain key employees of any acquired businesses.

Risks Related to Our Common Stock

The trading price of our common stock may be volatile and fluctuate substantially, which could result in substantial losses. *

Our stock price is volatile. For example, the closing price of our common stock since April 17, 2019 through September 30, 2019, has ranged from a low of $26.67 to a high of $57.76. The stock market in general and the market for smaller pharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. The market price for our common stock may be influenced by many factors, including:

- the degree of success of competitive products or technologies;
- the commencement, enrollment or results of clinical trials and preclinical studies of our drug candidates or those of our competitors;
- adverse results from, delays in or termination of clinical trials;
- unanticipated serious safety concerns related to the use of our product candidates;
- regulatory or legal developments in the United States and other countries;
- any delay in our regulatory filings for our drug candidates and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings, including without limitation the FDA's issuance of a "refusal to file" letter or a request for additional information;
- receipt of, or failure to obtain, regulatory approvals;
- lower than expected market acceptance of our product candidates following approval, if any, for commercialization;
- 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 drug candidates or clinical development programs;
- the results of our efforts to design, develop, acquire or in-license additional technologies or drug candidates;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- publication of research reports about us or our industry or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- announcements of investigations or regulatory scrutiny of our operations or lawsuits filed against us;
- variations in our financial results or those of companies that are perceived to be similar to us;
- rumors or announcements regarding transactions involving our company or drug candidates;
- proposed changes to healthcare laws in the United States or foreign jurisdictions, or speculation regarding such changes;
- market conditions or trends in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions; and
- the other events or factors, including those described in this "Risk Factors" section.

Our executive officers, directors and principal stockholders, if they choose to act together, have the ability to significantly influence all matters submitted to stockholders for approval. *

Our executive officers and directors, combined with our stockholders who owned more than 5% of our outstanding capital stock beneficially own shares representing a significant percentage of our common stock. As a result, if these stockholders were to choose to act together, they would be able to significantly influence 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 be able to significantly influence 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.

Delaware law and provisions in our amended and restated certificate of incorporation and amended and restated bylaws could make a merger, tender offer or proxy contest difficult, thereby depressing the trading price of our common stock. *

Provisions of our amended and restated certificate of incorporation and amended and restated bylaws may delay or discourage transactions involving an actual or potential change in our control or change in our management, including transactions in which stockholders might otherwise receive a premium for their shares or transactions that our stockholders might otherwise deem to be in their best interests. Therefore, these provisions could adversely affect the price of our common stock. Among other things, our amended and restated certificate of incorporation and amended and restated bylaws:

- permit our board of directors to issue up to 10,000,000 shares of preferred stock, with any rights, preferences and privileges as they may designate (including the right to approve an acquisition or other change in our control);
- provide that the authorized number of directors may be changed only by resolution of the board of directors;
- provide that our board of directors or any individual director may only be removed with cause and the affirmative vote of the holders of at least 66-2/3% of the voting power of all of our then-outstanding common stock;
- provide that all vacancies, including newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;
- divide our board of directors into three classes;
- require that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and not be taken by written consent;
- provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide notice in writing in a timely manner and also specify requirements as to the form and content of a stockholder's notice;
- do not provide for cumulative voting rights (therefore allowing the holders of a majority of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election, if they should so choose);
- provide that special meetings of our stockholders may be called only by the chair of our board of directors, our Chief Executive Officer or by the board of directors pursuant to a resolution adopted by a majority of the total number of authorized directors; and
- provide that the Court of Chancery of the State of Delaware will be the sole and exclusive forum for the following types of actions or proceedings under Delaware statutory or common law: (i) any derivative action or proceeding brought on our behalf; (ii) any action or proceeding asserting a claim of breach of a fiduciary duty owed by any of our current or former directors, officers or other employees to us or our stockholders; (iii) any action or proceeding asserting a claim against us or any of our current or former directors, officers or other employees, arising out of or pursuant to any provision of the Delaware General Corporation Law, our certificate of incorporation or our bylaws; (iv) any action or proceeding to interpret, apply, enforce or determine the validity of our certificate of incorporation or our bylaws; (v) any action or proceeding as to which the Delaware General Corporation Law confers jurisdiction to the Court of Chancery of the State of Delaware; and (vi) any action asserting a claim against us or any of our directors, officers or other employees governed by the internal affairs doctrine, in all cases to the fullest extent permitted by law and subject to the court's having personal jurisdiction over the indispensable parties named as defendants; provided these provisions of our amended and restated certificate of incorporation and amended and restated bylaws will apply to suits brought to enforce a duty or liability created by the Securities Act of 1933, as amended (Securities Act), but stockholders will not be deemed to have waived our compliance with the federal securities laws and the regulations thereunder; and provided these provisions of our amended and restated certificate of incorporation and amended and restated bylaws will not apply to suits brought to enforce a duty or liability created by the Securities Exchange Act of 1934, as amended (Exchange Act), or any other claim for which the federal courts have exclusive jurisdiction.

The amendment of any of these provisions, with the exception of the ability of our board of directors to issue shares of preferred stock and designate any rights, preferences and privileges thereto, would require approval by the holders of at least 66-2/3% of our then-outstanding common stock.

In addition, as a Delaware corporation, we are subject to Section 203 of the Delaware General Corporation Law. These provisions may prohibit large stockholders, in particular those owning 15% or more of our outstanding voting stock, from merging or combining with us for a certain period of time. A Delaware corporation may opt out of this provision by express provision in its

original certificate of incorporation or by amendment to its certificate of incorporation or bylaws approved by its stockholders. However, we have not opted out of this provision.

These and other provisions in our amended and restated certificate of incorporation, amended and restated bylaws and Delaware law could make it more difficult for stockholders or potential acquirors to obtain control of our board of directors or initiate actions that are opposed by our then-current board of directors, including delay or impede a merger, tender offer or proxy contest involving our company. The existence of these provisions could negatively affect the price of our common stock and limit opportunities for you to realize value in a corporate transaction.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for certain disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees. *

Our amended and restated certificate of incorporation provides that, to the fullest extent permitted by law and subject to the court's having personal jurisdiction over the indispensable parties named as defendants, the Court of Chancery of the State of Delaware is the exclusive forum for the following types of actions or proceedings under Delaware statutory or common law: (i) any derivative action or proceeding brought on our behalf, (ii) any action or proceeding asserting a breach of fiduciary duty owed by any of our current or former directors, officers or other employees to us or our stockholders, (iii) any action or proceeding asserting a claim against us or any of our current or former directors, officers or other employees arising out of or pursuant to any provision of the Delaware General Corporation Law, our certificate of incorporation or bylaws; (iv) any action or proceeding to interpret, apply, enforce or determine the validity of our certificate of incorporation or our bylaws; (v) any action or proceeding as to which the Delaware General Corporation Law confers jurisdiction to the Court of Chancery of the State of Delaware and (vi) any action asserting a claim against us or any of our directors, officers or other employees that is governed by the internal affairs doctrine; provided these provisions of our amended and restated certificate of incorporation and amended and restated bylaws will apply to suits brought to enforce a duty or liability created by the Securities Act, but stockholders will not be deemed to have waived our compliance with the federal securities laws and the regulations thereunder; and provided, that, this provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act, or any other claim for which the federal courts have exclusive jurisdiction. These choice of forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees and may discourage these types of lawsuits. Furthermore, the enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that a court could find these types of provisions to be inapplicable or unenforceable. If a court were to find the choice of forum provisions contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions.

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

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

A significant portion of our total outstanding shares have recently become 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 could occur at any time. These sales, 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. As of October 15, 2019, we had 35,849,541 shares of common stock issued and outstanding. While the lock-up agreements from our initial public offering expired on October 14, 2019, in connection with our September 2019 public offering, we, and our directors, executive officers and certain of our stockholders have agreed that for a period of 90 days following September 5, 2019, subject to certain exceptions, we or they will not dispose of or hedge any shares of our common stock or securities convertible into or exchangeable or exercisable for any shares of our common stock without prior written consent of Goldman Sachs & Co. LLC and SVB Leerink LLC. We refer to such period as the lock-up period. When the lock-up period expires, we and our securityholders subject to a lock-up agreement will be able to sell our shares in the public market. In addition, Goldman Sachs & Co. LLC and SVB Leerink LLC may, in their sole discretion, release all or some portion of the shares subject to lock-up agreements at any time and for any reason. Sales of a substantial number of such shares upon expiration of the lock-up agreements, the perception that such sales may occur, or early release of these agreements, could cause our market price to fall or make it more difficult for you to sell your common stock at a time and price that you deem appropriate.

Moreover, holders of an aggregate of 16,993,194 shares of our common stock have rights, subject to specified conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. We have registered on Form S-8 all shares of common stock that we may issue under our equity compensation plans. As a consequence, these shares can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates.

Our business could be negatively affected as a result of actions of activist stockholders, and such activism could impact the trading value of our securities. *

Stockholders may, from time to time, engage in proxy solicitations or advance stockholder proposals, or otherwise attempt to effect changes and assert influence on our board of directors and management. Activist campaigns that contest or conflict with our strategic direction or seek changes in the composition of our board of directors could have an adverse effect on our operating results and financial condition. A proxy contest would require us to incur significant legal and advisory fees, proxy solicitation expenses and administrative and associated costs and require significant time and attention by our board of directors and management, diverting their attention from the pursuit of our business strategy. Any perceived uncertainties as to our future direction and control, our ability to execute on our strategy, or changes to the composition of our board of directors or senior management team arising from a proxy contest could lead to the perception of a change in the direction of our business or instability which may result in the loss of potential business opportunities, make it more difficult to pursue our strategic initiatives, or limit our ability to attract and retain qualified personnel and business partners, any of which could adversely affect our business and operating results. If individuals are ultimately elected to our board of directors with a specific agenda, it may adversely affect our ability to effectively implement our business strategy and create additional value for our stockholders. We may choose to initiate, or may become subject to, litigation as a result of the proxy contest or matters arising from the proxy contest, which would serve as a further distraction to our board of directors and management and would require us to incur significant additional costs. In addition, actions such as those described above could cause significant fluctuations in our stock price based upon temporary or speculative market perceptions or other factors that do not necessarily reflect the underlying fundamentals and prospects of our business.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud. *

We are subject to the periodic reporting requirements of the Exchange Act. We designed our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. For example, our directors or executive officers could inadvertently fail to disclose a new relationship or arrangement causing us to fail to make any related party transaction disclosures. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected. In addition, we do not have a risk management program or processes or procedures for identifying and addressing risks to our business in other areas.

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 JOBS Act. We will remain an emerging growth company until the earliest of (i) December 31, 2024, (ii) the first fiscal year after our annual gross revenues exceed $1.07 billion, (iii) the date on which we have, during the immediately preceding three-year period, issued more than $1.0 billion in non-convertible debt securities or (iv) date on which we qualify as a large accelerated filer.

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 this prospectus, 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 non-binding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

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

As a public company, and particularly after we are no longer an emerging growth company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of The Nasdaq Global Select 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 will be required to furnish a report by our management on our internal control over financial reporting. However, while we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by Section 404. If we identify one or more material weaknesses, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

Legal, political and economic uncertainty surrounding the planned exit of the UK from the EU may be a source of instability in international markets, create currency fluctuations and pose additional risks to our business operations and financial condition.*

The United Kingdom's referendum to leave the EU, or "Brexit," has caused and may continue to cause disruptions to capital and currency markets worldwide. The full impact of the Brexit decision, however, remains uncertain. A process of negotiation will determine the future terms of the United Kingdom's relationship with the EU and there is the potential that the United Kingdom and the EU may not agree to a withdrawal arrangement before the date the United Kingdom leaves the EU. During this period of negotiation and afterwards, our results of operations and access to capital may be negatively affected by interest rate, exchange rate and other market and economic volatility, as well as political uncertainty. In the short and medium term, there is a risk of disrupted import and export processes due to a lack of administrative processing capacity by the respective United Kingdom and EU customs

agencies, which may have a detrimental effect on our customers, distributors and suppliers, which would, in turn, adversely affect our revenues and financial condition.

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 we may enter into 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.

We could be subject to securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because pharmaceutical companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

Item 2. Unregistered Sales Of Equity Securities And Use Of Proceeds

Unregistered Sales of Equity Securities

Stock Option Grants

For the nine months ended September 30, 2019, we granted options to purchase 2,120,923 shares of our common stock to certain of our employees and our Board of Directors with a weighted average exercise price of $24.59 per share. The offer, sale and issuance of these options were deemed to be exempt from registration under the Securities Act in reliance on either Rule 701 in that the transactions were under compensatory benefit plans and contracts relating to compensation as provided under Rule 701 or Section 4(a)(2) in that the issuance of securities was to accredited investors in a private placement transaction that did not involve a public offering.

Issuances of Common Stock upon Conversion of Preferred Stock

On April 22, 2019, upon the closing of our initial public offering, all shares of our then-outstanding convertible preferred stock automatically converted into 16,993,194 shares of our common stock. The common stock was issued pursuant to the exemption from the registration requirements of the Securities Act provided by Section 3(a)(9) or Section 4(2) of the Securities Act.

Use of Proceeds

We commenced our initial public offering pursuant to registration statements on Form S-1 (File Nos. 333-230428 and 333-230911) that were declared or became effective on April 16, 2019 and registered an aggregate of 10,637,500 shares of our common stock. On April 16, 2019, we sold 10,637,500 shares of our common stock at a public offering price of $18.00 per share for an aggregate gross offering price of $191.5 million. On April 22, 2019, we completed our initial public offering. Goldman Sachs & Co. LLC and SVB Leerink LLC acted as joint book-running managers for the offering. Wells Fargo, LLC also served as a joint book-running manager. Canaccord Genuity LLC acted as lead manager.

The underwriting discounts and commissions for the offering totaled approximately $13.4 million. We incurred additional costs of approximately $2.9 million in offering expenses, which when added to the underwriting discounts and commissions paid by us, amounts to total fees and costs of approximately $16.3 million. Thus, net offering proceeds to us, after deducting underwriting discounts and commissions and offering costs, were approximately $175.2 million. No offering costs were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning ten percent or more of any class of our equity securities or to any other affiliates.

Upon receipt, the net proceeds from our initial public offering were held in cash and cash equivalents, primarily bank money market accounts. Through September 30, 2019, we have not used any of the net proceeds from our initial public offering. We are investing these funds in a combination of short- and intermediate-term, interest-bearing obligations, investment grade instruments, certificates of deposit or direct or guaranteed obligations of the U.S. government. We expect to use the net proceeds from our initial public offering as described under "Use of Proceeds" in the Prospectus. We cannot predict with certainty all of the particular uses for the net proceeds from our initial public offering, or the amounts that we will actually spend on the uses described under "Use of Proceeds" in the Prospectus. The amounts and timing of our actual use of the net proceeds will vary depending on numerous factors, including our ability to access additional financing, the relative success and cost of our research, preclinical and clinical development programs and whether we are able to enter into future licensing arrangements. As a result, our management will have broad discretion

in the application of the net proceeds, and investors will be relying on our judgment regarding the application of the net proceeds from our initial public offering.

Item 3. Defaults Upon Senior Securities

None

Item 4. Mine Safety Disclosures.

Not applicable

Item 5. Other Information.

None

Item 6. Exhibits.

Furnish the exhibits required by Item 601 of Regulation S-K (§ 229.601 of this chapter).

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation of the Registrant (filed as Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on April 22, 2019, and incorporated by reference herein).
3.2	Amended and Restated Bylaws of the Registrant (filed as Exhibit 3.2 to the Registrant's Current Report on Form 8-K, filed with the SEC on April 22, 2019, and incorporated by reference herein).
4.1	Specimen Common Stock Certificate of the Registrant (filed as Exhibit 4.1 to the Registrant's Registration Statement on Form S-1, as amended, filed with the SEC on April 8, 2019, and incorporated by reference herein).
10.1†	Executive Employment Agreement, dated July 25, 2019, by and between the Registrant and Yi Larson (filed as Exhibit 10.1 to the Registrant's Current on Form 8-K, filed with the SEC on July 29, 2019, and incorporated by reference herein).
10.2†	Turning Point Therapeutics, Inc. Severance Benefit Plan, as amended (C-Suite) (filed as Exhibit 10.2 to the Registrant's Current on Form 8-K, filed with the SEC on July 29, 2019, and incorporated by reference herein).
10.3†	Executive Employment Agreement, dated October 30, 2019, by and between the Registrant and Mohammad Hirmand, M.D.
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Principal Executive Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	Certification of Principal Financial Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document
†	Indicates management contract or compensatory plan.
*	This certification shall not be deemed filed for purposes of Section 18 of the Exchange Act or otherwise subject to the liability of that Section, nor shall it be deemed incorporated by reference into any filing under the Securities Act or the Exchange Act.

SIGNATURES

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

Company Name

Date: November 4, 2019

By: /s/ Athena Countouriotis
Athena Countouriotis
President & Chief Executive Officer
(Principal Executive Officer)

Date: November 4, 2019

By: /s/ Yi Larson
Yi Larson
Executive Vice President and Chief Financial Officer
(Principal Financial Officer)

TURNING POINT THERAPEUTICS, INC.
EXECUTIVE EMPLOYMENT AGREEMENT
for
MOHAMMAD HIRMAND, M.D.

This Executive Employment Agreement (this "**Agreement**"), is made and entered into as of October 30, 2019, by and between Mohammad Hirmand, M.D., ("**Executive**") and Turning Point Therapeutics, Inc. (the "**Company**").

WHEREAS, the Company desires for Executive to provide services to the Company, and wishes to provide Executive with certain compensation and benefits in return for such employment services; and

WHEREAS, Executive wishes to be employed by the Company and to provide personal services to the Company in return for certain compensation and benefits.

NOW, THEREFORE, in consideration of the mutual promises and covenants contained herein and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the parties hereto agree as follows:

1. Employment by the Company.

1.1 Position. Executive shall serve as the Company's Executive Vice President and Chief Medical Officer, reporting to Athena Countouriotis, M.D., the Company's President & CEO (the "**CEO**"). Executive's commencement of employment with the Company will be on or before December 2, 2019 (such actual date of commencement of employment with the Company, the "**Start Date**"). During the term of Executive's employment with the Company, Executive will devote Executive's best efforts and substantially all of Executive's business time and attention to the business of the Company, except for approved vacation periods and reasonable periods of illness or other incapacities permitted by the Company's general employment policies.

1.2 Duties and Location. Executive shall perform such duties as are customarily associated with the position of Executive Vice President and Chief Medical Officer and such other duties as are assigned to Executive by the CEO. Executive's primary office location shall be the Company's headquarters located in San Diego, California. For the Executive's regular work week, Executive is agreeing to be on-site at the Company's San Diego, CA headquarters for three (3) consecutive days per week every month unless the Company is closed for the holiday week or the Executive is traveling to another location on a business-related event. In weeks that Executive is traveling to another location on a business-related event, it is still expected that when practicable, Executive will come to the San Diego office for a minimum of two (2) consecutive days per week. It is anticipated that Executive will utilize a Company office in the San Francisco area two (2) days per week. Subject to the terms of this Agreement, the Company reserves the right to reasonably require Executive to perform Executive's duties at places other than Executive's primary office location from time to time and to require reasonable business travel.

1.3 Policies and Procedures. The employment relationship between the parties shall be governed by the general employment policies and practices of the Company, except that when the terms of this Agreement differ from or are in conflict with the Company's general employment policies or practices, this Agreement shall control.

2. Compensation.

2.1 Base Salary. For services to be rendered hereunder, Executive shall receive a base salary at the rate of $16,875 semi-monthly, which equates to $405,000 per year (the "**Base Salary**"), less standard payroll deductions and withholdings and payable in accordance with the Company's regular payroll schedule.

2.2 Annual Bonus. Executive will be eligible for an annual discretionary bonus (the "**Annual Bonus**") of up to 40% of Executive's then current annual Base Salary (the "**Target Bonus Amount**"). Whether Executive receives an Annual Bonus for any given year, and the amount of any such Annual Bonus, will be determined in the good faith discretion of the Company's Board of Directors (the "**Board**") (or the Compensation Committee thereof) and the CEO, based upon the Company's and Executive's achievement of corporate and individual objectives and milestones to be determined on an annual basis by the Board (or Compensation Committee thereof). No Annual Bonus is guaranteed and, in addition to the other conditions for earning such compensation, Executive must remain an employee in good standing of the Company on the scheduled Annual Bonus payment date in order to be eligible for any Annual Bonus. Executive will not be eligible for an Annual Bonus for 2019.

3. Standard Company Benefits. Executive shall, in accordance with Company policy and the terms and conditions of the applicable Company benefit plan documents, be eligible to participate in the benefit and fringe benefit programs provided by the Company to its executive officers and other employees from time to time. Any such benefits shall be subject to the terms and conditions of the governing benefit plans and policies and may be changed by the Company in its discretion. As an executive at the Company, Executive will be eligible to take paid time off ("**PTO**") under the Company's Discretionary PTO Policy (the "**Discretionary PTO Policy**"). Under the Discretionary PTO Policy, Executive does not accrue PTO. Rather, Executive is permitted to use discretion in achieving an appropriate work/life balance by taking time off as needed and consistent with job demands. There is no set minimum or maximum amount of time off that may be taken in a given year, however Executive must obtain prior approval from the CEO before taking PTO, except for absences that qualify under state and local paid sick leave laws. Although there is no limit on the amount of time that may be taken under the Discretionary PTO Policy, Executive is expected to exercise this right responsibly and continue to satisfy all professional obligations. Neglect of professional obligations may result in disciplinary action, up to and including termination of employment.

4. Expenses. The Company will reimburse Executive for reasonable travel, entertainment or other expenses incurred by Executive in furtherance or in connection with the performance of Executive's duties hereunder, in accordance with the Company's expense reimbursement policy as in effect from time to time.

5. Commuting Allowance. To assist the Executive with housing and commuting expenses in connection with Executive's commute to the Company's San Diego office, the Company will provide Executive with a commuting allowance payment of $4,000 per month. The commuting allowance payments will be treated as taxable compensation and will be grossed up to compensate for income taxes, which tax gross-up shall be paid in accordance with Treasury Regulation Section 1.409A-3(i)(1)(v).

6. Stock Option Grant. Subject to approval by the Board, Executive shall be granted an option to purchase 179,192 shares of Common Stock of the Company at the fair market value on the date of grant (the "**Option**"). The Option shall be governed in all respects by the terms of the governing equity plan documents and option agreement between Executive and the Company, and shall be subject to a vesting schedule whereby 25% of the shares subject to the Option shall vest one year after grant, with the remaining shares vesting in equal monthly installments over the following three years thereafter, subject to Executive's continuous service.

7. Proprietary Information Obligations.

7.1 Proprietary Information Agreement. Executive shall execute, and will abide by, the Company's standard Employment, Confidential Information and Invention Assignment Agreement ("**Proprietary Agreement**").

7.2 Third-Party Agreements and Information. Executive represents and warrants that Executive's employment by the Company does not conflict with any prior employment or consulting agreement or other agreement with any third party, and that Executive will perform Executive's duties to the Company without violating any such agreement. Executive represents and warrants that Executive does not possess confidential information arising out of prior employment, consulting, or other third party relationships, that would be used in connection with Executive's employment by the Company, except as expressly authorized by that third party. During Executive's employment by the Company, Executive will use in the performance of Executive's duties only information that is generally known and used by persons with training and experience comparable to Executive's own, common knowledge in the industry, otherwise legally in the public domain, or obtained or developed by the Company or by Executive in the course of Executive's work for the Company.

8. Outside Activities and Non-Competition During Employment.

8.1 Outside Activities. Throughout Executive's employment with the Company, Executive may engage in civic and not-for-profit activities so long as such activities do not interfere with the performance of Executive's duties hereunder or present a conflict of interest with the Company or its affiliates. Subject to the restrictions set forth herein, and only with prior written disclosure to and consent of the Board, Executive may engage in other types of business or public activities. The Board may rescind such consent, if the Board determines, in its sole discretion, that such activities compromise or threaten to compromise the Company's or its affiliates' business interests or conflict with Executive's duties to the Company or its affiliates.

8.2 Non-Competition During Employment. Except as otherwise provided in this Agreement, during Executive's employment by the Company, Executive will not, without the express written consent of the Board, directly or indirectly serve as an officer, director,

stockholder, employee, partner, proprietor, investor, joint ventures, associate, representative or consultant of any person or entity engaged in, or planning or preparing to engage in, business activity competitive with any line of business engaged in (or planned to be engaged in) by the Company or its affiliates; provided, however, that Executive may purchase or otherwise acquire up to (but not more than) 1% of any class of securities of any enterprise (without participating in the activities of such enterprise) if such securities are listed on any national or regional securities exchange. In addition, Executive will be subject to certain restrictions (including restrictions continuing after Executive's employment ends) under the terms of the Proprietary Agreement.

9. Termination of Employment; Severance and Change in Control Benefits.

9.1 At-Will Employment. Executive's employment relationship is at-will. Either Executive or the Company may terminate the employment relationship at any time, with or without Cause (as such term is defined in the Company's Severance Benefit Plan – C-Suite (the "**Severance Plan**")) or advance notice.

9.2 Covered Termination Unrelated to Change in Control. In the event Executive's employment with the Company is terminated due to a Covered Termination (as defined in the Severance Plan) at any time except during the Change in Control Protection Period (as defined in the Severance Plan), then Executive shall be entitled to the benefits provided under, and subject to the terms and conditions of, the Severance Plan.

9.3 Covered Termination During Change in Control Protection Period. In the event Executive's employment with the Company is terminated due to a Covered Termination during the Change in Control Protection Period, then in lieu of (and not additional to) the severance benefits described in Section 9.2, Executive shall be entitled to the benefits provided under, and subject to the terms and conditions of, the Severance Plan.

9.4 Termination for Cause; Death or Disability. Executive will not be eligible for, or entitled to any severance benefits, including (without limitation) the Severance Benefits and Change in Control benefits listed in Sections 9.2 and 9.3 above, if the Company terminates Executive's employment for Cause, or Executive's employment terminates due to Executive's death or disability.

10. Dispute Resolution. To ensure the rapid and economical resolution of disputes that may arise in connection with Executive's employment with the Company, Executive and the Company agree that any and all disputes, claims, or causes of action, in law or equity, including but not limited to statutory claims, arising from or relating to the enforcement, breach, performance, or interpretation of this Agreement, Executive's employment with the Company, or the termination of Executive's employment from the Company, will be resolved pursuant to the Federal Arbitration Act, 9 U.S.C. §1-16, and to the fullest extent permitted by law, by final, binding and confidential arbitration conducted in San Diego, California by JAMS, Inc. ("**JAMS**") or its successors, under JAMS' then applicable rules and procedures for employment disputes (which can be found at http://www.jamsadr.com/rules-clauses/, and which will be provided to Executive on request); provided that the arbitrator shall: (a) have the authority to compel adequate discovery for the resolution of the dispute and to award such relief as would otherwise be permitted by law; and (b) issue a written arbitration decision including the arbitrator's essential findings and conclusions and a statement of the award. Executive and the

Company shall be entitled to all rights and remedies that either would be entitled to pursue in a court of law. **Both Executive and the Company acknowledge that by agreeing to this arbitration procedure, they waive the right to resolve any such dispute through a trial by jury or judge or administrative proceeding**. The Company shall pay all filing fees in excess of those which would be required if the dispute were decided in a court of law, and shall pay the arbitrator's fee. Nothing in this Agreement is intended to prevent either the Company or Executive from obtaining injunctive relief in court to prevent irreparable harm pending the conclusion of any such arbitration.

11. General Provisions.

11.1 Notices. Any notices provided must be in writing and will be deemed effective upon the earlier of personal delivery (including personal delivery by fax) or the next day after sending by overnight carrier, to the Company at its primary office location and to Executive at the address as listed on the Company payroll.

11.2 Severability. Whenever possible, each provision of this Agreement will be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Agreement is held to be invalid, illegal or unenforceable in any respect under any applicable law or rule in any jurisdiction, such invalidity, illegality or unenforceability will not affect any other provision or any other jurisdiction, but this Agreement will be reformed, construed and enforced in such jurisdiction to the extent possible in keeping with the intent of the Parties.

11.3 Waiver. Any waiver of any breach of any provisions of this Agreement must be in writing to be effective, and it shall not thereby be deemed to have waived any preceding or succeeding breach of the same or any other provision of this Agreement.

11.4 Complete Agreement. This Agreement, together with the Severance Plan and the Proprietary Agreement, constitutes the entire agreement between Executive and the Company with regard to the subject matter hereof and is the complete, final, and exclusive embodiment of the Company's and Executive's agreement with regard to this subject matter. This Agreement is entered into without reliance on any promise or representation, written or oral, other than those expressly contained herein, and it supersedes any other such promises, warranties or representations. It cannot be modified or amended except in a writing signed by a duly authorized officer of the Company, with the exception of those changes expressly reserved to the Company's discretion in this Agreement.

11.5 Counterparts. This Agreement may be executed in separate counterparts, any one of which need not contain signatures of more than one party, but both of which taken together will constitute one and the same Agreement.

11.6 Headings. The headings of the paragraphs hereof are inserted for convenience only and shall not be deemed to constitute a part hereof nor to affect the meaning thereof.

11.7 Successors and Assigns. This Agreement is intended to bind and inure to the benefit of and be enforceable by Executive and the Company, and their respective successors,

assigns, heirs, executors and administrators, except that Executive may not assign any of Executive's duties hereunder and Executive may not assign any of Executive's rights hereunder without the written consent of the Company, which shall not be withheld unreasonably.

11.8 Tax Withholding. All payments and awards contemplated or made pursuant to this Agreement will be subject to withholdings of applicable taxes in compliance with all relevant laws and regulations of all appropriate government authorities. Executive acknowledges and agrees that the Company has neither made any assurances nor any guarantees concerning the tax treatment of any payments or awards contemplated by or made pursuant to this Agreement. Executive has had the opportunity to retain a tax and financial advisor and fully understands the tax and economic consequences of all payments and awards made pursuant to this Agreement.

11.9 Non-Solicitation. Executive agrees that for the one year period after the date Executive's employment ends, Executive will not, as an officer, director, employee, consultant, owner, partner, or in any other capacity, either directly or through others, solicit, induce, encourage, or participate in soliciting, inducing or encouraging any employee, consultant, or independent contractor of the Company to terminate his, her or its relationship with the Company or its affiliates, even if Executive did not initiate the discussion or seek out the contact.

11.10 Non-disparagement. Executive agrees not to disparage the Company and its affiliates, and the Company's and its affiliates' officers, directors, employees, shareholders, investors and agents, in any manner likely to be harmful to them or their business, business reputation or personal reputation; provided that Executive may respond accurately and fully to any question, inquiry or request for information when required by legal process or as part of a government investigation. Notwithstanding the foregoing, nothing herein shall limit Executive's right to voluntarily communicate with the Equal Employment Opportunity Commission, United States Department of Labor, the National Labor Relations Board, the Securities and Exchange Commission, other federal government agency or similar state or local agency or to discuss the terms and conditions of Executive's employment with others to the extent expressly permitted by Section 7 of the National Labor Relations Act.

11.11 Choice of Law. All questions concerning the construction, validity and interpretation of this Agreement will be governed by the laws of the State of California.

[SIGNATURES ON FOLLOWING PAGE]

In Witness Whereof, the parties have executed this Agreement on the day and year first written above.

Turning Point Therapeutics, Inc.

By: /s/ Athena Countouriotis
Athena Countouriotis, M.D.
President & Chief Executive Officer
(*Principal Executive Officer*)

Executive

By: /s/ Mohammad Hirmand
Mohammad Hirmand, M.D.

Exhibit 31.1

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Athena Countouriotis, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Turning Point Therapeutics, 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)) [omitted pursuant to Rules 13a-14(a) and 15d-14(a)] 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) [Omitted pursuant to Rules 13a-14(a) and 15d-14(a)];

   (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 4, 2019

By: /s/ Athena Countouriotis
Athena Countouriotis, M.D.
President & Chief Executive Officer
(*Principal Executive Officer*)

Exhibit 31.2

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Yi Larson, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Turning Point Therapeutics, 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)) [omitted pursuant to Rules 13a-14(a) and 15d-14(a)] 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) [Omitted pursuant to Rules 13a-14(a) and 15d-14(a)];

   (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 4, 2019

By: /s/ Yi Larson
Yi Larson
Executive Vice President and Chief Financial Officer
(*Principal Financial Officer*)

Exhibit 32.1

CERTIFICATION 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 Turning Point Therapeutics, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(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 and result of operations of the Company.

Date: November 4, 2019:

By: /s/ Athena Countouriotis
Athena Countouriotis, M.D.
President & Chief Executive Officer
(*Principal Executive Officer*)

Exhibit 32.2

CERTIFICATION 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 Turning Point Therapeutics, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(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 and result of operations of the Company.

Date: November 4, 2019

By: /s/ Yi Larson
Yi Larson
Executive Vice President and Chief Financial Officer
(*Principal Financial Officer*)