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

FORM 10-Q

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

For the quarterly period ended September 30, 2020

☐ 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: 001-39614

TARSUS PHARMACEUTICALS, INC.
(Exact name of Registrant as specified in its charter)

Delaware	**81-4717861**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification Number)**
15440 Laguna Canyon Road, Suite 160	
Irvine, California	**92618**
(Address of principal executive offices)	**(Zip Code)**

(949) 409-9820
(Registrant's telephone number, including area code)

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

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

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 7(a)(2)(B) of the Securities Act. ☒

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

20,320,426 shares of common stock, $0.0001 par value, outstanding as of November 23, 2020

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PART I—FINANCIAL INFORMATION

Item I. Financial Statements (Unaudited)

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TARSUS PHARMACEUTICALS, INC.

CONDENSED BALANCE SHEETS
(In thousands, except share and par value amounts)

	September 30, 2020 (unaudited)	December 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	$ 86,329	$ 57,952
Restricted cash	20	20
Other receivables	1	36
Prepaid expenses and other current assets	2,722	22
Total current assets	89,072	58,030
Property and equipment, net of accumulated depreciation	604	154
Operating lease right-of-use asset	759	126
Other assets	1,750	6
Total assets	$ 92,185	$ 58,316
LIABILITIES, PREFERRED STOCK AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable and other accrued liabilities	$ 5,624	$ 520
Accrued payroll and benefits	520	299
Total current liabilities	6,144	819
Other long-term liabilities	711	100
Total liabilities	6,855	919
Commitments and contingencies (Note 9)		
Series A Preferred Stock, $0.0001 par value; 1,575,030 shares authorized, issued and outstanding at September 30, 2020 (unaudited) and December 31, 2019; liquidation preference of $3,650 at September 30, 2020 (unaudited) and December 31, 2019	3,564	3,564
Series B Preferred Stock, $0.0001 par value; 6,731,649 shares authorized and 6,674,909 shares issued and outstanding at September 30, 2020 (unaudited) and December 31, 2019; liquidation preference of $60,010 at September 30, 2020 (unaudited) and December 31, 2019	59,838	59,838
Series C Preferred Stock, $0.0001 par value; 2,857,084 shares authorized and 2,857,079 shares issued and outstanding at September 30, 2020 (unaudited) and zero shares authorized, issued or outstanding at December 31, 2019; liquidation preference of $40,000 at September 30, 2020 (unaudited) and $0 at December 31, 2019	39,757	—
Stockholders' (deficit) equity:		
Common stock, $0.0001 par value; 17,502,288 shares authorized; 3,067,363 shares issued and 2,887,988 outstanding, which excludes 179,375 shares subject to repurchase at September 30, 2020 (unaudited); 2,650,919 shares issued and 2,646,619 outstanding, which excludes 4,300 shares subject to repurchase at December 31, 2019	2	2
Additional paid-in capital	3,548	27
Accumulated deficit	(21,379)	(6,034)
Total stockholders' deficit	(17,829)	(6,005)
Total liabilities, preferred stock and stockholders' deficit	$ 92,185	$ 58,316

See accompanying notes to these unaudited condensed financial statements.

TARSUS PHARMACEUTICALS, INC.

CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(Unaudited)
(In thousands, except share and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Operating expenses:				
Research and development	$ 7,991	$ 399	$ 11,239	$ 2,465
General and administrative	2,150	234	4,282	749
Total operating expenses	10,141	633	15,521	3,214
Loss from operations before other income (expense) and income taxes	(10,141)	(633)	(15,521)	(3,214)
Other income (expense):				
Interest income (expense), net	4	(21)	178	(16)
Change in fair value of derivative liabilities	—	(27)	—	(27)
Total other income (expense)	4	(48)	178	(43)
Provision for income taxes	(1)	—	(1)	(1)
Net loss and comprehensive loss	$ (10,138)	$ (681)	$ (15,344)	$ (3,258)
Net loss per share attributable to common stockholders, basic and diluted	$ (3.71)	$ (0.28)	$ (5.73)	$ (1.41)
Weighted-average common shares outstanding, basic and diluted	2,729,685	2,471,237	2,677,315	2,311,788

See accompanying notes to these unaudited condensed financial statements.

TARSUS PHARMACEUTICALS, INC.

CONDENSED STATEMENTS OF PREFERRED STOCK AND STOCKHOLDERS' DEFICIT
(Unaudited)
(In thousands, except share data)

	Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount			
Balance as of December 31, 2019	8,249,939	$ 63,402	2,646,619	$ 2	$ 27	$ (6,034)	$ (6,005)
Net loss	—	—	—	—	—	(1,957)	(1,957)
Recognition of stock-based compensation expense	—	—	—	—	4	—	4
Lapse of repurchase rights related to common stock issued pursuant to early exercises	—	—	4,300	—	—	—	—
Balance as of March 31, 2020	8,249,939	$ 63,402	2,650,919	$ 2	$ 31	$ (7,991)	$ (7,958)
Net loss	—	—	—	—	—	(3,250)	(3,250)
Recognition of stock-based compensation expense	—	—	—	—	173	—	173
Exercise of vested stock options	—	—	1,077	—	—	—	—
Balance as of June 30, 2020	8,249,939	$ 63,402	2,651,996	$ 2	$ 204	$ (11,241)	$ (11,035)
Net loss	—	—	—	—	—	(10,138)	(10,138)
Recognition of stock-based compensation expense	—	—	—	—	223	—	223
Exercise of vested stock options	—	—	13,532	—	6	—	6
Shares issued as consideration for in-license rights (Note 9 (b))	—	—	222,460	—	3,115	—	3,115
Issuance of Series C Preferred Stock in September 2020 at $14.0003 per share, net of issuance costs of $243	2,857,079	39,757	—	—	—	—	—
Balance as of September 30, 2020	11,107,018	$ 103,159	2,887,988	$ 2	$ 3,548	$ (21,379)	$ (17,829)

	Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount			
Balance as of December 31, 2018	1,575,030	$ 3,564	2,078,918	$ 1	$ 9	$ (1,364)	$ (1,354)
Net loss	—	—	—	—	—	(1,745)	(1,745)
Recognition of stock-based compensation expense	—	—	—	—	4	—	4
Vesting of founder shares subject to repurchase	—	—	134,632	—	—	—	—
Lapse of repurchase rights related to common stock issued pursuant to early exercises	—	—	25,243	—	—	—	—
Balance as of March 31, 2019	1,575,030	$ 3,564	2,238,793	$ 1	$ 13	$ (3,109)	$ (3,095)
Net loss	—	—	—	—	—	(831)	(831)
Recognition of stock-based compensation expense	—	—	—	—	5	—	5
Vesting of founder shares subject to repurchase	—	—	134,632	1	—	—	1
Lapse of repurchase rights related to common stock issued pursuant to early exercises	—	—	25,243	—	—	—	—
Balance as of June 30, 2019	1,575,030	$ 3,564	2,398,668	$ 2	$ 18	$ (3,940)	$ (3,920)
Net loss	—	—	—	—	—	(681)	(681)
Recognition of stock-based compensation expense	—	—	—	—	5	—	5
Vesting of founder shares subject to repurchase	—	—	134,632	—	—	—	—
Lapse of repurchase rights related to common stock issued pursuant to early exercises	—	—	11,779	—	—	—	—
Balance as of September 30, 2019	1,575,030	$ 3,564	2,545,079	$ 2	$ 23	$ (4,621)	$ (4,596)

See accompanying notes to these unaudited condensed financial statements.

TARSUS PHARMACEUTICALS, INC.

CONDENSED STATEMENTS OF CASH FLOWS
(Unaudited)
(In thousands)

	Nine Months Ended September 30,	
	2020	**2019**
Cash Flows From Operating Activities:		
Net loss	$ (15,344)	$ (3,258)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	56	18
Stock-based compensation *(Note 5)*	401	13
Amortization of operating lease right-of-use asset *(Note 9(a))*	94	26
Change in fair value of derivative liabilities *(Note 8)*	—	27
Non-cash related party interest expense	—	27
Issuance of common stock pursuant to in-license agreement (*Note 9(b)*)	3,115	—
Changes in operating assets and liabilities:		
Other receivables	34	4
Prepaid expenses and other current assets	(2,700)	(1)
Other non-current assets	(27)	(6)
Accounts payable and other accrued liabilities	3,025	256
Accrued payroll and benefits	221	27
Net cash used in operating activities	(11,125)	(2,867)
Cash Flows From Investing Activities:		
Purchases of property and equipment	(506)	(151)
Cash used in investing activities	(506)	(151)
Cash Flows From Financing Activities:		
Proceeds from issuance of Series B Preferred Stock, net of issuance costs *(Note 4)*	(28)	—
Proceeds from issuance of Series C Preferred Stock, net of issuance costs *(Note 4)*	40,000	—
Proceeds from issuance of convertible notes, net of issuance costs *(Note 8)*	—	1,000
Issuance costs for initial public offering	(330)	—
Proceeds from exercise of vested stock options	6	—
Proceeds from early exercise of stock options	360	—
Net cash provided by financing activities	40,008	1,000
Net increase (decrease) in cash, cash equivalents and restricted cash	28,377	(2,018)
Cash, cash equivalents, and restricted cash — beginning of year	57,972	2,375
Cash, cash equivalents, and restricted cash — end of period	$ 86,349	$ 357
Reconciliation of cash, cash equivalents and restricted cash		
Cash and cash equivalents	$ 86,329	$ 337
Restricted cash	20	20
Cash, cash equivalents and restricted cash	$ 86,349	$ 357
Supplemental Disclosures Noncash Investing and Financing Activities:		
Operating lease right-of-use asset obtained in exchange for operating lease liability	$ 726	$ 163
Additions of property and equipment in accounts payable and other accrued liabilities *(Note 3(b))*	$ —	$ 23
Series C Preferred Stock issuance costs in accounts payable and other accrued liabilities	$ 243	$ —
Convertible notes issuance costs included in accounts payable and accrued liabilities	$ —	$ 6
Deferred offering costs included in accounts payable and accrued liabilities	$ 1,388	$ —

See accompanying notes to these unaudited condensed financial statements.

TARSUS PHARMACEUTICALS, INC.

NOTES TO THE FINANCIAL STATEMENTS
(all tabular amounts presented in thousands, except share, per share, per unit, and number of years)
(Unaudited)

1. DESCRIPTION OF BUSINESS AND PRESENTATION OF FINANCIAL STATEMENTS

(a) Description of Business

Tarsus Pharmaceuticals, Inc. (“Tarsus” or the “Company”) is a late clinical-stage biopharmaceutical company focused on the development and commercialization of novel therapeutic candidates to address large market opportunities initially in ophthalmic conditions where there are limited treatment alternatives.

(b) Initial Public Offering and Reverse Stock Split

On October 20, 2020, the Company completed its initial public offering ("IPO") through an underwritten sale of 5,500,000 shares of its common stock at a price of $16.00 per share. The aggregate net proceeds from the offering, inclusive of an additional 825,000 common shares sold upon the full exercise of the underwriters’ purchase option, after deducting underwriting discounts and commissions and other offering expenses, were approximately $91.7 million.

Concurrent with the IPO, all then-outstanding shares of the Company's convertible preferred stock outstanding (see *Note 4*) were automatically converted into an aggregate of 11,107,018 issued common shares and were reclassified into permanent equity. Following the IPO, there were no shares of Preferred Stock outstanding.

In advance of the IPO, on October 8, 2020, the Tarsus Board of Directors approved a 1-for-7.4276 reverse stock split of the Company’s capital stock. The Company filed a certificate of amendment to its restated certificate of incorporation to reflect this reverse split, though the common stock par value was not affected by the reverse split. All share and per share information included in the accompanying financial statements has been adjusted to reflect this reverse stock split.

The condensed financial statements as of September 30, 2020, including share and per share amounts, do not give effect to the IPO, the conversion of the preferred stock into common stock and related reclassification into permanent equity, as the IPO and such conversions and reclassifications into permanent equity were completed subsequent to September 30, 2020.

(c) Liquidity Risks

The Company has no revenue, and since inception, has accumulated losses and negative cash flows from operations. This has resulted in the Company's accumulated deficit of $21.4 million as of September 30, 2020 and $6.0 million as of December 31, 2019. The Company’s cash and cash equivalents was $86.3 million and $58.0 million as of September 30, 2020 and December 31, 2019, respectively. The Company has financed its operations to date primarily through equity capital raises.

The Company believes that existing capital resources, including the net proceeds from the IPO in October 2020, will be sufficient to meet projected operating requirements for at least 12 months from the date of issuance of the accompanying condensed financial statements, though expects to continue to incur operating losses and negative cash flows. The Company will be required to raise additional capital to fund future operations, however, no assurance can be given as to whether additional needed financing will be available on terms acceptable to the Company, if at all. If sufficient funds on acceptable terms are not available when needed, the Company may be required to curtail planned activities to preserve cash resources. These factors may adversely impact the Company’s ability to achieve its business objectives and would likely have an adverse effect on its future business prospects, or even its ability to remain a going concern.

As such, the condensed financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The condensed financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty. Management expects to continue to incur additional substantial losses in the foreseeable future as a result of the Company’s research and development activities.

(d) Operating Segment

TARSUS PHARMACEUTICALS, INC.

NOTES TO THE FINANCIAL STATEMENTS
(all tabular amounts presented in thousands, except share, per share, per unit, and number of years)
(Unaudited)

To date, the Company has operated and managed its business and financial information on an aggregate basis for the purposes of evaluating financial performance and the allocation of resources. Accordingly, the Company's management determined that it operates in one reportable operating segment that is focused exclusively on developing pharmaceutical products for eventual commercialization.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES AND USE OF ESTIMATES

(i) Basis of Presentation

The Company's condensed financial statements have been prepared in conformity with accounting principles generally accepted in the United States ("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, the accompanying condensed financial statements do not include all of the information and footnotes required by GAAP for complete financial statements.

The interim condensed balance sheet as of September 30, 2020, and the interim condensed statements of operations and comprehensive loss, changes in preferred stock and stockholders' deficit and cash flows for the three and nine months ended September 30, 2020 and 2019 are unaudited. These unaudited interim financial statements have been prepared on the same basis as the Company's annual financial statements and, in the opinion of management, reflect all adjustments, which consist of only normal and recurring adjustments, necessary for the fair statement of the Company's financial information. The financial data and other information disclosed in these notes related to the three and nine-month periods are also unaudited. The condensed balance sheet as of December 31, 2019 has been derived from the audited financial statements at that date but does not include all information and footnotes required by GAAP for complete financial statements. The condensed interim operating results for the three and nine months ended September 30, 2020 are not necessarily indicative of results to be expected for the year ending December 31, 2020, any other interim periods or any future year or period.

The accompanying interim unaudited condensed financial statements should be read in conjunction with the audited financial statements and the related notes thereto for the year ended December 31, 2019, which are included in the Company's prospectus related to the IPO, filed with the SEC on September 25, 2020 (the "Prospectus"), pursuant to Rule 424(b)(4) promulgated under the Securities Act of 1933, as amended (the "Securities Act").

The preparation of financial statements in conformity with GAAP and with the rules and regulations of the Securities and Exchange Commission ("SEC") requires management to make informed estimates and assumptions that affect the amounts reported in these financial statements and accompanying notes. These amounts may materially differ from the amounts ultimately realized and reported due to the inherent uncertainty of any estimate or assumption. On an on-going basis, management evaluates its most critical estimates and assumptions, including those related to the (i) fair value of stock-based awards and periodic recognition of stock-based compensation, (ii) the realization of income tax assets and estimates of tax liabilities, (iii) expense accruals related to research and development activities, including clinical trials, and (iv) valuation of convertible notes, derivative instruments, and preferred stock.

Accounting policies and estimates that most significantly impact the presented amounts within the accompanying financial statements are further described below:

(ii) Cash and Cash Equivalents

Cash and cash equivalents consist of bank deposits and highly liquid investments, including money market fund accounts, with original maturities of three months or less from the purchase date.

(iii) Restricted Cash

Restricted cash represents cash held as collateral for the Company's corporate credit card program. Any cash that is legally or contractually restricted from immediate use is classified as restricted cash.

(iv) Concentration of Credit Risk and Other Risks and Uncertainties

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash and cash equivalents in deposits at financial institutions that exceed federally insured limits.

In March 2020, the World Health Organization declared a pandemic related to the global novel coronavirus disease 2019 ("COVID-19") outbreak. To date, the Company's operations have not been significantly impacted by the COVID-19

pandemic, though the Company has been carefully monitoring the potential impact COVID-19 may have on its ongoing and planned clinical trials. However, the Company cannot at this time predict the specific extent, duration, or full impact that the COVID-19 outbreak will have on these activities or its financial condition.

The Company's results of operations involve numerous risks and uncertainties. Factors that could adversely impact the Company's operating results and business objectives include, but are not limited to, (1) uncertainty of results of clinical trials, (2) uncertainty of regulatory approval of the Company's potential product candidates, including TP-03 for ophthalmic conditions, TP-04 for treatment of skin conditions and TP-05 for prophylaxis of Lyme and community malaria reduction, (3) uncertainty of market acceptance of its product candidates, (4) competition from substitute products and larger companies, (5) securing and protecting proprietary technology and strategic relationships, and (6) and dependence on key individuals and sole source suppliers.

The Company's product candidates require approvals from the U.S. Food and Drug Administration ("FDA") and comparable foreign regulatory agencies prior to commercial sales in their respective jurisdictions. There can be no assurance that any product candidates will receive these necessary approvals. If the Company is denied approval, approval is delayed, or is unable to maintain approval for any product candidate, it could have a materially adverse impact on its business.

(v) Research and Development Costs

The Company's research and development costs are expensed as incurred or as certain milestone payments become contractually due to the Company's licensors, as triggered by the achievement of clinical or regulatory events.

(vi) Deferred Offering Costs

Costs directly related to the Company's IPO were deferred for expense recognition. These deferred offering costs are temporarily capitalized and consist of legal fees, accounting fees, and other applicable professional services. As of September 30, 2020, $1.7 million of these deferred offering costs are reported on the accompanying condensed Balance Sheets within "other assets." There were no deferred offering costs capitalized as of December 31, 2019. With the Company's IPO on October 20, 2020, these deferred offering costs were concurrently reclassified to additional paid in capital and will be reported as such as of December 31, 2020.

(vii) Stock-Based Compensation

Stock-based awards issued to employees, consultants, and members of the Company's Board of Directors are valued as of the grant date. Corresponding compensation expense is recognized over the applicable vesting period. For awards with a service condition for vesting, the related expense is recognized on a straight-line basis over each award's actual or implied vesting period. For awards that are subject to a performance condition for vesting, the Company recognizes compensation cost if and when it concludes that it is probable that the performance condition will be achieved and the related expense is recognized on an accelerated attribution method. As applicable, the Company reverses previously recognized expense for forfeitures of unvested awards in the period of occurrence.

The Company uses the Black-Scholes option pricing model to estimate the fair value of stock-based awards as of the date of grant. This requires management assumptions that involve inherent uncertainties and the application of judgment, including (a) the fair value of the Company's common stock on the date of the option grant, (b) the expected term of the stock option until its exercise by the recipient, (c) expected stock price volatility over the expected term, (d) the prevailing risk-free interest rate over the expected term, and (e) expected dividend payments over the expected term.

Management estimates the expected term of awarded stock options utilizing the "simplified method" as the Company does not yet have sufficient exercise history since its November 2016 formation. Further, through September 30, 2020 the Company remained privately-held and therefore lacked company-specific historical and implied volatility information of its stock. Accordingly, management estimates this expected volatility using that of its designated peer-group of publicly-traded companies for a look-back period, as of the date of grant, that corresponds with the expected term of the awarded stock option. The Company estimates the risk-free interest rate based upon the U.S. Department of the Treasury yield curve in effect

at award grant for time periods that correspond with the expected term of the awarded stock option. The Company's expected dividend yield is zero because it has never paid cash dividends and does not expect to for the foreseeable future.

Prior to the IPO, given the absence of a public trading market, the Company's Board of Directors, with input from management, considered numerous objective and subjective factors to determine the fair value of its common stock. The factors included: (1) third-party valuations of the Company's common stock; (2) the Company's stage of development; (3) the status of research and development efforts; (4) the rights, preferences and privileges of the Company's preferred stock relative to common stock; (5) the Company's operating results and financial condition, including the Company's levels of available capital resources; (6) equity market conditions affecting comparable public companies; (7) general U.S. market conditions; and (8) the lack of current marketability of the Company's common stock.

(viii) Preferred Stock

The Company classifies preferred stock outside of stockholders' deficit on the accompanying condensed balance sheets. The requirements of a deemed liquidation event, as defined within its amended and restated certificate of incorporation filed in September 2020 (the "2020 Amended and Restated Certificate of Incorporation") were not entirely within the Company's control. In the event of such a deemed liquidation event, the proceeds from the event are distributed in accordance with the liquidation preferences, provided that the holders of preferred stock have not converted their shares into common stock. The Company recorded the issuance of preferred stock at the issuance price less related issuance costs. The Company has not adjusted the carrying value of outstanding preferred stock to its liquidation preference because a deemed liquidation event is not probable of occurring as of the end of the reporting period.

(ix) Net Loss per Share Attributable to Common Stockholders

Basic net loss per share attributable to common stockholders is calculated by dividing the net loss by the weighted-average number of shares of common stock outstanding for the period, without the consideration for potential dilutive shares of common stock. Diluted net loss per share is computed by dividing the net loss by the weighted-average number of common share equivalents outstanding for the period determined using the treasury-stock method and if-converted method, as applicable. Basic and diluted net loss per share attributable to common stockholders is presented in conformity with the two-class method required for participating securities. The Company's participating securities include preferred stock, unvested common stock to founders, and unvested common stock awards issued upon early exercise of certain stock options. The Company's participating securities do not have a contractual obligation to share in the Company's losses. As such, the net loss was attributed entirely to common stockholders. Shares of common stock subject to repurchase by the Company are excluded from the weighted-average shares. Due to net losses in all periods presented, all otherwise potentially dilutive securities are antidilutive. Accordingly, basic net loss per share equals diluted net loss per share for all period presented in the accompanying financial statements.

(x) Fair Value Measurements

Assets and liabilities recorded at fair value on a recurring basis in the balance sheets are categorized based upon the level of judgment associated with the inputs used to measure their fair values. Fair value is defined as the exchange price that would be received for an asset or an exit price that would be paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. The authoritative guidance on fair value measurements establishes a three-tier fair value hierarchy for disclosure of fair value measurements as follows:

- *Level 1:* Quoted prices (unadjusted) in active markets for identical assets or liabilities that are publicly accessible at the measurement date.
- *Level 2:* Observable prices that are based on inputs not quoted on active markets, but that are corroborated by market data. These inputs may include quoted prices for similar assets or liabilities or quoted market prices in markets that are not active to the general public.

(all tabular amounts presented in thousands, except share, per share, per unit, and number of years)

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

The carrying amounts for financial instruments consisting of cash and cash equivalents, accounts payable and accrued liabilities approximate fair value due to their short maturities. Derivative instruments are carried at fair value based on unobservable market inputs.

(xi) Comprehensive Loss

Comprehensive loss represents all changes in stockholders' deficit, except those resulting from distributions to stockholders. For all periods presented, comprehensive loss was the same as reported net loss.

(xii) Recently Issued or Effective Accounting Standards

Recently issued or effective accounting pronouncements that impact, or may have an impact, on the Company's financial statements have been discussed within the footnote to which each relates. Other recent accounting pronouncements not disclosed in these condensed financial statements have been determined by the Company's management to have no impact, or an immaterial impact, on its current and expected future financial position, results of operations, or cash flows.

3. BALANCE SHEET ACCOUNT DETAIL

The composition of selected financial statement captions that comprise the accompanying balance sheets are summarized below:

(a) Prepaid Expenses and Other Current Assets

"Prepaid expenses and other current assets" consists of the following:

	September 30, 2020	December 31, 2019
Prepaid expenses	$ 412	$ 22
Clinical research organization service assets	2,310	—
Prepaid expenses and other current assets	$ 2,722	$ 22

(b) Property and Equipment, net of Accumulated Depreciation

"Property and equipment, net of accumulated depreciation" consists of the following:

	September 30, 2020	December 31, 2019
Furniture and fixtures	$ 295	$ 5
Office equipment	74	26
Lab equipment	138	92
Leasehold improvements	110	69
Software licenses	80	—
Property and equipment, at cost	697	192
(Less): Accumulated depreciation	93	38
Property and equipment, net of accumulated depreciation	$ 604	$ 154

(all tabular amounts presented in thousands, except share, per share, per unit, and number of years)

Depreciation expense (included within "total operating expenses" in the accompanying Statements of Operations and Comprehensive Loss) for the three and nine months ended September 30, 2020 and 2019 was $24 thousand, $9 thousand, $56 thousand, and $18 thousand, respectively.

(c) Accounts Payable and Other Accrued Liabilities

"Accounts payable and other accrued liabilities" consists of the following:

	September 30, 2020	December 31, 2019
Trade accounts payable	$ 4,706	$ 456
Operating lease liability, current portion	190	64
Accrued clinical studies	8	—
Employee stock option early exercise liability, current portion	273	—
Other accrued liabilities	447	—
Accounts payable and other accrued liabilities	$ 5,624	$ 520

(d) Other Long-Term Liabilities

"Other long-term liabilities" consists of the following:

	September 30, 2020	December 31, 2019
Operating lease liability, non-current portion	$ 625	$ 100
Employee stock option early exercise liability, non-current portion	86	—
Other long-term liabilities	$ 711	$ 100

4. STOCKHOLDERS' EQUITY

Authorized Stock

Under the September 2020 Amended and Restated Certificate of Incorporation, the Company is authorized to issue two classes of stock: common and preferred. The total number of shares authorized for issuance is 17.5 million of common shares and 11.2 million of preferred shares, of which 1.6 million shares are designated as Series A Preferred Stock, 6.7 million shares are designated as Series B Preferred Stock, and 2.9 million are designated as Series C Preferred Stock.

Preferred Stock Overview

Series A Preferred Stock Issuance

In March and May 2018, the Company executed a private placement Series A Stock Purchase Agreement and issued 1.6 million shares of Series A Preferred Stock at $2.3174 per share for net proceeds of $3.6 million, after issuance costs of $0.1 million.

Series B Preferred Stock Issuance

In December 2019, the Company executed a private placement Series B Stock Purchase Agreement of 6.7 million shares of Series B Preferred Stock at $8.9904 per share for net proceeds of $57.4 million, after issuance costs of $0.2 million. Concurrently, convertible notes issued in May, August, and October 2019 for aggregate proceeds of $2.0 million were converted into preferred stock based on principal and accrued interest, and the Company issued 0.3 million shares of Series B Preferred Stock at its contractual conversion price (see *Note 8*).

(all tabular amounts presented in thousands, except share, per share, per unit, and number of years)

Series C Preferred Stock Issuance

In September 2020, the Company executed a private placement Series C Stock Purchase agreement of 2.9 million shares of Series C Preferred Stock at a purchase price of $14.0003 per share for net proceeds of $39.8 million, after issuance costs of $0.2 million.

The tables below include preferred stock details as of September 30, 2020 and December 31, 2019.

As of September 30, 2020	Authorized	Outstanding	Net Carrying Value	Liquidation Preference	Original Issue Price
Series A Preferred Stock	1,575,030	1,575,030	$ 3,564	$ 3,650	$ 2.3174
Series B Preferred Stock	6,731,649	6,674,909	59,838	60,010	8.9904
Series C Preferred Stock	2,857,084	2,857,079	39,757	40,000	14.0003
Total	11,163,763	11,107,018	$ 103,159	$ 103,660	

As of December 31, 2019	Authorized	Outstanding	Net Carrying Value	Liquidation Preference	Original Issue Price
Series A Preferred Stock	1,575,030	1,575,030	$ 3,564	$ 3,650	$ 2.3174
Series B Preferred Stock	6,731,649	6,674,909	59,838	60,010	8.9904
Total	8,306,679	8,249,939	$ 63,402	$ 63,660	

Upon the completion of the IPO, all outstanding shares of convertible preferred stock converted into an aggregate of 11,107,018 shares of the Company's common stock.

Significant Provisions of Series A, Series B, and Series C Preferred Stock

Conversion Rights and Mandatory Conversion

Each share of Series A, Series B, and Series C Preferred Stock was convertible into common shares determined by dividing the original issuance price by the conversion price and at the sole option of the holder on a one-to-one basis. The conversion price will be adjusted for stock splits, distributions, dividends, noncash distributions, share purchase rights, and capital reorganizations. In addition, subject to customary exceptions, the conversion price for each series of preferred stock will be reduced upon the issuance or sale of common shares or instruments convertible or exercisable into common shares, for consideration or with an exercise price that is less than the conversion price applicable to such series. Such reduction may result in recognition of a deemed dividend to preferred stockholders if the resulting conversion price is less than the fair value per share of common stock as of the date preferred stock was issued.

Mandatory conversion into common shares will occur upon either (i) the closing of a Qualified Public Offering, which is defined in the September 2020 Amended and Restated Certificate of Incorporation to include the sale of common stock in a firm commitment underwritten public offering on Form S-1, with a pre-money valuation of at least $260 million and that results in at least $75 million of proceeds, or (ii) by vote or written consent or agreement of the holders of a majority of the then-outstanding shares of Series A, Series B, and Series C Preferred Stock, voting together as a single class on an as-converted basis.

Liquidation Preference

In the event of any Liquidation Event (as defined in the September 2020 Amended and Restated Certificate of Incorporation), the holders of Series A, Series B, and Series C Preferred Stock are first entitled to proceeds or assets available for distribution that are in preference of any distribution to common stockholders (the "Liquidation Preference"); provided, however, that if the holders of Series A, Series B, and Series C Preferred Stock would receive greater proceeds in a Liquidation Event as a result of their conversion to common stock such shares of Series A, Series B, and/or Series C Preferred Stock shall be deemed to have automatically thus converted. This Liquidation Preference is equal to the *sum of* (i) the original issue price of Series A, Series B and Series C Preferred Stock ($2.3174, $8.9904, and $14.0003 per share, respectively) for each outstanding

(all tabular amounts presented in thousands, except share, per share, per unit, and number of years)

share of Series A, Series B, and Series C Preferred Stock and (ii) any declared but unpaid dividends for each outstanding share of Series A, Series B, and Series C Preferred Stock. If the proceeds from the Liquidation Event are less than the Liquidation Preference, then all available proceeds will be distributed ratably to the holders of Series A, Series B, and Series C Preferred Stock in proportion to the preferential amount each is otherwise entitled to receive. After the distributions described above have been paid in full, the remaining assets of the Company will be distributed among the holders of common stock pro rata based on the number of shares held by each holder.

Voting Rights

The holder of each share of preferred stock has the right to one vote for each share of common stock into which such preferred stock could then be converted, and with respect to such vote, such holder has full voting rights and powers equal to the voting rights and powers of the holders of common stock. So long as the majority of the Series A Preferred Stock originally issued remains outstanding, its holders are additionally entitled to elect one director ("Series A Director"). So long as at least 1.3 million shares of Series B or Series C Preferred Stock remain outstanding, the holders of the majority of such shares of Series B and Series C Preferred Stock (voting together as a single class) shall be entitled to elect two directors (each a "Series B/C Director"). The holders of outstanding common stock are entitled to elect three directors. The holders of preferred stock and common stock (voting together as a single class and on an as-converted basis) are entitled to elect any of the Company's remaining directors.

Dividend Rights

The holders of Preferred Stock are entitled to receive dividends, when, as and if declared by the Board of Directors at the applicable dividend rate set forth in the September 2020 Amended and Restated Certificate of Incorporation ($0.19, $0.72, and $1.12 per annum for each share of Series A, Series B, and Series C Preferred Stock, respectively), prior and in preference to any declaration or payment of any cash dividend on the common stock. The Company cannot declare, pay, or set aside any dividends on shares of any class or series of capital stock unless the Series A, Series B, and Series C Preferred Stockholders first receive a dividend in an amount equal to the greater of (i) applicable dividend rate, or (ii) the dividend payable to such other class or series of capital stock. No cash dividends have been declared to date.

Redemption Rights

The Series A, Series B, and Series C Preferred Stock are not redeemable at the option of its holder under the terms of the September 2020 Amended and Restated Certificate of Incorporation. Upon certain change in control events that are outside of the Company's control, including its liquidation, sale or transfer of control, the preferred stock is contingently redeemable.

Common Stock Overview and Reserve for Future Issuance

Common stockholders have one vote for each share of common stock held and are entitled to receive any dividends declared by the Company's Board of Directors when legally available for distribution, then-subject to the dividend rights of the holders of Series A and Series B preferred stock discussed above. For the nine months ended September 30, 2020 and for the year ended December 31, 2019, no dividends were declared.

As of September 30, 2020 and December 31, 2019, the Company had 3.1 million and 2.7 million common shares issued, respectively. At September 30, 2020 and December 31, 2019, the Company had 2.9 million, and 2.6 million common shares outstanding, respectively. The following shares of common stock were reserved for issuance:

	September 30, 2020	December 31, 2019
Preferred Stock outstanding	11,107,018	8,249,939
Stock options issued and outstanding under the 2016 Plan	1,842,627	297,142
Stock options available for future grant under the 2016 Plan	411,397	2,150,867
Total shares of common stock reserved	13,361,042	10,697,948

(all tabular amounts presented in thousands, except share, per share, per unit, and number of years)

5. STOCK-BASED COMPENSATION

2016 Stock Plan

Through September 30, 2020, the Company had one active stockholder-approved stock-based compensation plan (the "2016 Plan") that was adopted in December 2016 (see *Note 10(b)* for discussion of the adoption of a new plan in October 2020). The 2016 Plan permits the grant of incentive stock options, nonqualified stock options, stock awards and certain other awards to its employees, members of its Board of Directors, and consultants.

The stated maximum availability of common stock under the 2016 Plan is 2.7 million shares. As of September 30, 2020 and December 31, 2019, the Company had 0.4 million and 2.2 million shares of common stock available for issuance under the 2016 Plan, respectively.

Stock-Based Compensation Summary

Stock-based compensation expense is recorded in the accompanying condensed statements of operations and comprehensive loss based on the assigned department of the award recipient. Stock-based compensation expense for the three and nine months ended September 30, 2020 and 2019 was as follows:

	Three months ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Research and development	$ 102	$ 2	$ 118	$ 4
General and administrative	121	3	283	9
Total stock-based compensation	$ 223	$ 5	$ 401	$ 13

Early Exercise Feature of Certain Stock Options

The 2016 Plan permits certain option holders to exercise awarded options prior to vesting. Upon this early exercise, the options become subject to a restricted stock agreement and remain subject to the same vesting provisions in the corresponding stock option award. These unvested options are subject to repurchase by the Company upon termination — at the same price previously exercised. These unvested shares are reported as issued (but not outstanding) on our accompanying Balance Sheets while subject to repurchase by the Company. These shares are also excluded from the basic and diluted net loss per share calculation until the repurchase right lapses upon vesting.

The Company initially records a liability for these early exercises that is subsequently reclassified into stockholders' equity on a pro rata basis as vesting occurs. There were no such repurchases during the nine months ended September 30, 2020 or 2019. As of September 30, 2020, the Company has recorded $0.4 million as a liability from these early exercise proceeds in the accompanying condensed Balance Sheets, reported within "accounts payable and other accrued liabilities" and "other long-term liabilities" (see *Note 3(c) and (d)*).

6. NET LOSS PER SHARE

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Net loss	$ (10,138)	$ (681)	$ (15,344)	$ (3,258)
Weighted-average shares—basic and diluted	2,729,685	2,471,237	2,677,315	2,311,788
Net loss per share attributable to common stockholders—basic and diluted	$ (3.71)	$ (0.28)	$ (5.73)	$ (1.41)

The following outstanding potentially dilutive securities were excluded from the calculation of diluted net loss per share attributable to common stockholders because their impact under the "treasury stock method" and "if-converted method" would have been anti-dilutive for the periods presented:

	Three months ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Stock options, unexercised—vested and unvested	1,842,627	297,142	1,842,627	297,142
Series A, Series B, and Series C Preferred Stock, outstanding	8,467,325	1,575,030	8,322,930	1,575,030
Shares subject to repurchase from its founders	—	89,755	—	89,755
Stock options early-exercised and unvested	179,375	43,007	179,375	43,007
Convertible promissory notes	—	124,857	—	55,958
Total	10,489,327	2,129,791	10,344,932	2,060,892

(all tabular amounts presented in thousands, except share, per share, per unit, and number of years)

7. FAIR VALUE MEASUREMENTS

The table below summarizes certain financial instruments measured at fair value that are included within the accompanying balance sheets, and their designation among the three fair value measurement categories (see *Note 2(xiii)*):

	September 30, 2020 Fair Value Measurements			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds	$ 86,329	$ —	$ —	$ 86,329
Total assets measured at fair value	$ 86,329	$ —	$ —	$ 86,329

	December 31, 2019 Fair Value Measurements			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds	$ 57,952	—	—	$ 57,952
Total assets measured at fair value	$ 57,952	—	—	$ 57,952

Money Market Funds

Money market fund holdings are included in cash and cash equivalents on the accompanying balance sheets and are classified within *Level 1* of the fair value hierarchy because of its readily-available market prices in active markets that are publicly accessible at the measurement date. These money market funds are invested in U.S. Treasury, bills, notes, and other obligations issued or guaranteed as to principal and interest by the U.S. Government or its agencies.

Convertible Promissory Notes – Derivative Liabilities

The following table sets forth a summary of the changes in fair value of the bifurcated derivative liability associated with the convertible promissory notes issued and settled during 2019 to certain related parties (see *Note 8*). The measurement of the derivative liabilities represents a *Level 3* financial instrument:

	Derivative Liabilities
Fair value as of December 31, 2018	$ —
Initial fair value of derivative liability upon issuance of May 2019 Notes	28
Initial fair value of derivative liability upon issuance of August 2019 Notes	50
Initial fair value of derivative liability upon issuance of October 2019 Notes	209
Revaluation of derivative liabilities included in other income (expense), net within the Statement of Operations for the year ended December 31, 2019	76
Settlement of derivative liabilities through conversion of all Notes	(363)
Fair value as of December 31, 2019	$ —
Fair value as of September 30, 2020	$ —

The fair values of the derivative liabilities presented above were estimated at the date of issuance and at subsequent balance sheet dates using a two-step approach to valuation. Management utilized a probability-weighted valuation method and then compared the instrument's value with-and-without the derivative features in order to estimate their combined fair value, using unobservable inputs, which are classified as *Level 3* within the fair value hierarchy. The significant inputs not included in the market and thus represents a *Level 3* measurement in the valuation approach included the probability of achieving a settlement that provides the note holders the rights or the obligations to receive cash or a variable number of shares upon the completion of a then-future capital transaction. The convertible notes were issued and settled in full during the year ended December 31, 2019 (see *Note 8*).

8. CONVERTIBLE PROMISSORY NOTES PAYABLE

Overview of Notes and Conversion in December 2019

In May 2019, the Company entered into a Note Purchase Agreement (the "May 2019 Purchase Agreement") with its co-founders and certain other related parties (the "Note Holders"). Under the terms of the May 2019 Purchase Agreement, the Company received cash proceeds of $0.5 million and issued $0.5 million of convertible promissory notes (the "May 2019 Notes") with a stated maturity of December 2020. These notes bore interest at a rate of 8.0% per annum, compounded annually, and payable at maturity. In the event of a qualified equity financing, the outstanding principal of the May 2019 Notes plus all accrued and previously unpaid interest would, at the option of the holder, either (i) automatically convert into shares of stock issued in the qualified equity financing based on a conversion price equal to 90% of the issuance price paid by these new investors, or (ii) be repaid in full.

In August 2019, the Company amended and restated the May 2019 Purchase Agreement with the Note Holders and received an additional $0.5 million of proceeds and issued new $0.5 million convertible promissory notes to the same parties (the "August 2019 Notes") with identical terms.

In October 2019, the Company entered into a new Note Purchase Agreement (the "October 2019 Purchase Agreement") with the Note Holders. Under the terms of the October 2019 Purchase Agreement, the Company received proceeds of $1.0 million and issued $1.0 million of convertible promissory notes (the "October 2019 Notes," collectively with the May 2019 Notes and the August 2019 Notes, the "Notes") with a conversion price equal to 80% of the issuance price in a qualified equity financing.

In December 2019, the Company completed an issuance of Series B Preferred Stock (see *Note 5*). Upon this issuance, the $2.0 million of Note principal value, along with accrued interest, were converted into 0.3 million shares of Series B Preferred Stock under its contractual terms. The Company recorded "loss on extinguishment of convertible notes" (non-cash) of $0.3 million within "other income (expense)" in the accompanying Statements of Operations and Comprehensive Loss for the year ended December 31, 2019.

Embedded Derivative and its Accounting

These notes contained stock-settled redemption features that were required to be separately accounted for as a derivative liability until December 13, 2019, when the Company completed a "qualified equity financing" and these then-outstanding notes converted, at the option of the holder, into 2.0 million shares of Series B Preferred Stock. The fair value adjustments for this derivative liability consists of changes in the fair value of these stock-settled redemption features.

The Company accounted for this derivative feature as an implied discount in presenting the carrying value of these Notes. This discount was accreted over the term to maturity of the Notes using the effective interest method, resulting in aggregate interest expense recognition (non-cash) of $22 thousand and $27 thousand for the three and nine months ended September 30, 2019, respectively. As the Notes were converted in December 2019, no interest expense was recorded for the nine months ended September 30, 2020.

Changes in the embedded derivatives' fair value at each reporting period were recognized in the accompanying statements of operations and comprehensive loss within "changes in fair value of derivative liabilities," resulting in incremental "other expense" recognition (non-cash) of $27 thousand during the three and nine months ended September 30, 2019. As the Notes were converted in December 2019, no expense related to changes in fair value of derivative liabilities was recorded for the nine months ended September 30, 2020.

9. COMMITMENTS & CONTINGENCIES

(a) Facility Leases

Overview

In the ordinary course of business, the Company enters lease agreements with unaffiliated parties for the use of office and laboratory facilities and office equipment. As of December 31, 2019, the Company had one active facility lease in Irvine, California, that commenced on March 1, 2019 and expires April 30, 2022. This lease has a renewal option at the end of term, for which the Company was not reasonably certain to exercise at the lease commencement. As such, the renewal option was not included in the lease term used to calculate the right-of-use lease asset and lease liability. Prior to March 1, 2019, the Company did not have any material lease arrangements.

The Company entered into two additional facility leases that commenced on June 1, 2020 for adjacent administrative and laboratory suites in Irvine, California. These leases expire on January 31, 2024. One of these leases included a renewal option at the end of its term, for which the Company was not reasonably certain to exercise at the lease commencement. As such, the renewal option was not included in the lease term used to calculate the right-of-use lease asset and lease liability. In connection with these two leases the Company capitalized right-of-use assets along with an accompanying lease liability of $0.7 million.

All of the Company's facility leases have minimum annual rent, payable monthly, and carry fixed annual rent increases. Under the arrangements, real estate taxes, certain operating expenses, and common area maintenance are reimbursable to the lessor. These amounts are expensed as incurred, as they are variable in nature and therefore excluded from the measurement of the reported right-of-use asset and liability discussed below. During the years ended December 31, 2019 and during the nine months ended September 30, 2020, the Company had no sublease arrangements with it as lessor.

Components of Lease Expense

The liability associated with each lease is amortized over the respective lease term using the effective interest rate method. The Company's right-of-use asset is amortized over the lease term on a straight-line basis to lease expense, as reported on an allocated basis within "research and development" and "general and administrative" expenses on the accompanying Statements of Operations and Comprehensive Loss. For the three months ended September 30, 2020 and 2019, the Company recognized lease expense of $0.1 million and $16 thousand, respectively. For the nine months ended September 30, 2020 and 2019, the Company recognized lease expense of $0.1 million, and $36 thousand, respectively. There were no significant variable lease payments, including including non-lease components such as common area maintenance fees, recognized as lease expense for the three and nine months ended September 30, 2020 and 2019.

Weighted-Average Remaining Lease Term and Applied Discount Rate

The Company had one active lease for its Irvine office and laboratory facility, with a remaining lease term of 2 years, 4 months as of December 31, 2019 and a remaining lease term of 1 year, 7 months as of September 30, 2020. The Company had two additional facility leases commence on June 1, 2020, with remaining lease terms of 3 years, 4 months as of September 30, 2020. The estimated incremental borrowing rate of 10% is utilized to present value future minimum lease payments since an implicit interest rate is not readily determinable each lease. The weighted average remaining lease term for the Company's leases as of September 30, 2020 is 3 years, 1 month.

Future Contractual Lease Payments as of September 30, 2020

The below table summarizes the (i) minimum lease payments over the next five years and thereafter, (ii) lease arrangement imputed interest, and (iii) present value of future lease payments:

(all tabular amounts presented in thousands, except share, per share, per unit, and number of years)

Operating Leases - future payments	September 30, 2020
2020 (remaining three months)	$ 5
2021	349
2022	298
2023	281
2024	25
Total future lease payments, undiscounted	$ 958
(Less): Imputed interest	(143)
Present value of operating lease payments	$ 815

(b) In-License Agreement for Lotilaner

Skin and Eye Disease or Conditions in Humans

In January 2019, the Company entered into a license agreement with Elanco Tiergesundheit AG (“Elanco”), granting it a worldwide license to certain intellectual property for the development and commercialization of lotilaner for the treatment or cure of any eye or skin disease or condition in humans (the "January 2019 Agreement"). The Company has sole responsibility for related development, regulatory, and commercialization activities.

The Company made a $1.0 million upfront payment at execution of the January 2019 Agreement, which is reported within “research and development” expense within the accompanying unaudited Statements of Operations and Comprehensive Loss for the nine months ended September 30, 2019. The Company also made a required $1.0 million clinical milestone payment in the September 2020 as part of an achieved Phase 2b/3 clinical trial milestone for the treatment of Demodex blepharitis; this amount is reported within “research and development” expense within the accompanying Statements of Operations and Comprehensive Loss for the three and nine months ended September 30, 2020.

The Company will make further payments to Elanco under the January 2019 Agreement upon achievement of various clinical milestones for an aggregate maximum of $5.0 million and various commercial and sales threshold milestones for an aggregate maximum of $79.0 million. In addition, the Company will be obligated to pay contractual royalties to Elanco in the single digits of its net sales. If the Company receives payments from any sublicensees, it will be obligated to pay Elanco a variable percentage in the low to mid double-digits of such proceeds, except for territories in which the Company achieved applicable regulatory approval prior to sublicense execution.

All Other Disease or Conditions in Humans

In September 2020, the Company executed an expanded license agreement with Elanco, granting it a worldwide license to certain intellectual property for the development and commercialization of lotilaner treatment or cure of all other diseases and conditions in humans – beyond that of the eye or skin (the “September 2020 Agreement”).

The Company issued Elanco 222,460 shares of its common stock at the execution of the September 2020 Agreement. The value of these shares was then-determined to equate to $3.1 million (at $14.0003 per share, approximating the Company's Series C preferred stock issuance price – see *Note 4*) and is reported within “research and development” expense within the accompanying Statements of Operations and Comprehensive Loss for the three and nine months ended September 30, 2020. In addition, upon the 18-month anniversary of contract execution, if not terminated by the Company prior to the anniversary, it is obligated to grant Elanco additional shares that aggregate to $3.0 million (valued as of the Company’s IPO price of $16.00 per share - see *Note 10(a)*), amounting to a fixed 187,500 shares.

The Company accounted for the transaction as an asset acquisition as substantially all of the fair value of the gross assets acquired were concentrated in a group of similar identifiable assets thus satisfying the requirements of the screen test in ASU 2017-01. The assets acquired in the transaction were measured based on the upfront payment to Elanco and the fair value

of the common stock shares issued to Elanco, as the fair value of the consideration given was more readily determinable than the fair value of the assets received. Because the assets had not yet received regulatory approval and have no alternative future use, the fair value attributable to these assets were initially recorded as in process research and development expenses.

The Company will make further payments to Elanco under the September 2020 Agreement upon achievement of various clinical milestones for an aggregate maximum of $4.5 million, and various commercial and sales threshold milestones for an aggregate maximum of $77.0 million. In addition, the Company will be obligated to pay contractual royalties to Elanco in the single digits of its net sales. If the Company receives payments from any sublicensees, it will be obligated to pay Elanco a variable percentage in the low to mid double-digits of such proceeds, except for territories in which the Company achieved applicable regulatory approval prior to sublicense execution.

(c) Employment Agreements

The Company has entered into employment agreements with four of its named executive officers. These agreements provide for the payment of certain benefits upon separation of employment under specified circumstances, such as termination without cause, or termination in connection with a change in control event.

(d) Contingencies

From time to time, the Company may be subject to various litigation and related matters arising in the ordinary course of business. The Company is currently not aware of any such matters where there is at least a reasonable probability that a material loss has been or will be incurred for financial statement recognition.

(e) Indemnities and Guarantees

The Company has certain indemnity commitments, under which it may be required to make payments to its officers and directors in relation to certain transactions to the maximum extent permitted under applicable laws. The duration of these indemnities varies, and in certain cases, is indefinite and does not provide for any limitation of maximum payments. The Company has not been obligated to make any such payments to date and no liabilities have been recorded for this contingency in the accompanying condensed balance sheets.

10. SUBSEQUENT EVENTS

(a) Completion of Initial Public Offering

On October 20, 2020, the Company completed its IPO selling 5,500,000 shares of common stock at a price to the public of $16.00 per share. An incremental 825,000 common shares were also sold upon the full exercise of the underwriters' purchase option. The aggregate net proceeds from the offering, after deducting underwriting discounts and commissions and other related expenses, were approximately $91.7 million. In addition, upon closing the IPO, all outstanding shares of convertible preferred stock outstanding (see *Note 4*) converted into an aggregate of 11,107,018 shares of the Company's common stock.

(b) 2020 Equity Incentive Plan Adoption

The Company's Board of Directors and stockholders adopted and approved the Company's 2020 Equity Incentive Plan ("2020 Plan") on October 8, 2020. The 2020 Plan replaces the 2016 Plan (see *Note 5*), however, awards outstanding under the 2016 Plan will continue to be governed by their existing terms. The number of shares of the Company's common stock available for issuance under the 2020 Plan will equal the sum of 9,000,000 shares plus up to 2,433,395 shares remaining available for issuance under the 2016 Plan, or issued pursuant to or subject to awards granted under the 2016 Plan. The 2020 Plan provides for the following types of awards: incentive and non-statutory stock options, stock appreciation rights, restricted shares, and restricted stock units.

The number of common shares reserved for issuance under the 2020 Plan will be increased automatically on the first business day of each fiscal year, commencing in 2021 and ending in 2030, by a number equal to the lesser of: (i) 4% of the shares of common stock outstanding on the last business day of the prior fiscal year; or (ii) the number of shares determined by the Company's Board of Directors. In general, to the extent that any awards under the 2020 Plan are forfeited, terminate, expire or lapse without the issuance of shares, or if the Company reacquires the shares subject to awards granted under the 2020 Plan, those shares will again become available for issuance under the 2020 Plan, as will shares applied to pay the exercise or purchase price of an award or to satisfy tax withholding obligations related to any award.

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 "Selected Financial Data" and our financial statements and the related notes to those statements included elsewhere in this report. In addition to historical financial information, the following discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. Our actual results and timing of selected events may differ materially from those anticipated in these forward-looking statements as a result of many factors, including, but not limited to, those discussed under the section titled "Risk Factors" and elsewhere in this report. See the section titled "Special Note Regarding Forward-Looking Statements" elsewhere in this report..

Overview of our Business

We are a late clinical-stage biopharmaceutical company focused on the development and commercialization of therapeutic candidates to address large market opportunities initially in ophthalmic conditions where there are limited treatment alternatives. Our lead product candidate, TP-03, is a novel therapeutic in Phase 2b/3 that is being developed for the treatment of blepharitis caused by the infestation of Demodex mites, which is referred to as Demodex blepharitis. Blepharitis ("Blephar" is a reference to eyelid and "itis" is a reference to inflammation) is a condition characterized by inflammation of the eyelid margin, redness and ocular irritation, including a specific type of eyelash dandruff called collarettes in Demodex blepharitis. The healthy interaction of the eyelid and the surface of the eyeball is crucial to ocular health. Poorly controlled and progressive blepharitis can lead to worsening of corneal damage over time and, in extreme cases, blindness.

According to published studies, there are an estimated 20 million patients in the United States who suffer from blepharitis, with approximately 45%, or approximately nine million, of cases caused by Demodex infestation. Further, our estimates indicate the possibility that the number of Demodex blepharitis cases may be as high as approximately 25 million, based on our internal research indicating approximately 58% of patients presenting to eye care clinics have collarettes and a published study estimating that at least 45 million people annually visit an eye care clinic.

To date, we have completed four Phase 2 trials for TP-03 in Demodex blepharitis, all of which met their primary, secondary and/or exploratory endpoints, as applicable, and during which TP-03 was well tolerated. We have commenced our Phase 2b/3 trial, Saturn-1, in September 2020, and intend to commence our Phase 3 trial, Saturn-2, in 2021, both with primary and secondary endpoints consistent with those of our Europa and Io Phase 2 trials. If successful, we expect these trials to support the submission of a new drug application ("NDA") to the United States Food and Drug Administration ("FDA") for TP-03 for the treatment of Demodex blepharitis. Furthermore, we intend to pursue marketing authorizations in jurisdictions outside the United States, including Europe and Japan. We believe that, if approved, TP-03 has the potential to be the first FDA-approved therapeutic and become the standard of care for the treatment of Demodex blepharitis.

Our current therapeutic strategy is focused on the clinical development of, for the first time in human medicine, the novel drug, lotilaner, which is designed to paralyze and eradicate mites and other parasites through the inhibition of parasite-specific gamma-aminobutyric acid-gated chloride ("GABA-Cl") channels. We are advancing our pipeline to address a number of diseases across therapeutic categories including eye care, dermatology and other diseases with high, unmet needs. These diseases include Demodex blepharitis, Meibomian Gland Disease ("MGD"), rosacea, Lyme disease, and malaria.

Corporate and Financial Overview

We were incorporated as a Delaware corporation in November 2016, and our headquarters is located in Irvine, California. Since our inception in November 2016, we have devoted substantially all of our resources to organizing and staffing our company, acquiring intellectual property, clinical development of our product candidates, building our research and development capabilities, raising capital, and enhancing our corporate infrastructure.

To date we have financed our operations through private placements of preferred stock and convertible promissory notes. From inception through September 30, 2020, we have raised net proceeds of approximately $101.0 million through private placements of preferred stock.

On October 20, 2020, we completed our initial public offering ("IPO") through an underwritten sale of 5,500,000 shares of common stock at a price of $16.00 per share. The aggregate net proceeds from the offering, inclusive of an additional 825,000 shares sold upon the full exercise of the underwriters' option to purchase additional shares of common stock, after deducting underwriting discounts and commissions and other offering expenses, were approximately $91.7 million. Concurrent with the IPO, all then-outstanding shares of our convertible preferred stock outstanding (see *Note 4*) automatically converted into an aggregate of 11,107,018 issued common shares.

In advance of the IPO, on October 8, 2020, our board of directors approved a 1-for-7.4276 reverse stock split of our capital stock. All share and per share information included in the accompanying financial statements has been adjusted to reflect this reverse stock split.

We have incurred significant net operating losses in every year since our inception and expect to continue to incur significant operating expenses and increasing operating losses for the foreseeable future. Our net losses were $15.3 million and $3.3 million for the nine months ended September 30, 2020 and 2019, respectively. Our net losses may fluctuate significantly from quarter to quarter and year to year and could be substantial. As of September 30, 2020 and December 31, 2019, we had an accumulated deficit of $21.4 million and $6.0 million, respectively, from research and development and general and administrative activities since our inception. We anticipate that our operating expenses will increase significantly as we:

- conduct additional clinical trials of our lead product candidate, TP-03, for the treatment of Demodex blepharitis including our Phase 2b/3 trial, Saturn-1, and our Phase 3 trial, Saturn-2;
- advance the clinical development of TP-03 for the treatment of MGD, TP-04 for the potential treatment of rosacea and TP-05 for potential Lyme prophylaxis and community malaria reduction;
- seek regulatory and marketing approvals for product candidates that successfully complete clinical development, if any;
- establish our own salesforce in the United States to commercialize our products for which we obtain regulatory approval;
- engage with contract manufacturers to ensure a sufficient supply chain capacity to provide commercial quantities of any products for which we may obtain marketing approval;
- maintain, expand and protect our intellectual property portfolio;
- hire additional staff, including clinical, scientific, technical, regulatory, marketing, operations, financial, and other support personnel, to execute our business plan; and
- add information systems and personnel to support our product development and potential future commercialization efforts, and to enable us to operate as a public company.

We do not have any products approved for sale and we have not yet generated any revenue from product sales or other sources. We do not expect to generate revenues from product sales unless and until we successfully complete clinical development and obtain regulatory approval for a product candidate and commercially launch such product. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through private or public equity or debt financings, or collaborations, strategic alliances, or licensing arrangements with third parties. Adequate funding may not be available to us when needed on acceptable terms, or at all. If we raise additional funds through collaborations, strategic alliances, or licensing arrangements with third parties, we may have to relinquish valuable rights to our intellectual property, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional capital or enter into such agreements as and when needed, we could be forced to significantly delay, scale back, or discontinue our product development and/or commercialization plans, which would negatively and adversely affect our financial condition.

Because of the numerous risks and uncertainties associated with drug product development, we are unable to accurately predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability. Even if we are able to generate revenue from product sales, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels.

As of September 30, 2020, our aggregate cash and cash equivalents was $86.3 million. We believe that our existing cash and cash equivalents and proceeds from our IPO will enable us to fund our operating expenses and capital expenditure requirements into the fourth quarter of 2022 – see “Liquidity and Capital Resources.”

Impact of the COVID-19 Pandemic on our Operations

Efforts to contain the spread of COVID-19 in the United States (including in California where our corporate headquarters and laboratory facility are located) and other countries have included quarantines, shelter-in-place orders, and various other government restrictions in order to control the spread of this virus.

We have been carefully monitoring the COVID-19 pandemic as it continues to progress and its potential impact on our business. We have taken important steps to ensure the workplace safety of our employees when working within our laboratory and administrative offices, or when traveling to our clinical trial sites. We have also implemented an interim work-from-home policy and we may take further actions as may be required by federal, state or local authorities.

To date, we have been able to continue our key business activities and advance our clinical programs. However, in the future, it is possible that our clinical development timelines and business plans could be adversely affected. We maintain regular communication with our vendors and clinical sites to appropriately plan for, and mitigate, the impact of the COVID-19 pandemic on our operations. Specifically, for our Phase 2b/3 Saturn-1 trial, we have instituted various protocols for our sites, including increasing health screening of individuals and providing enhanced communication and training to staff regarding COVID-19. We have also over-enrolled trial participants and identified additional clinical sites in case there are site closures due to COVID-19. However, the ultimate effect from this pandemic on our development timelines for TP-03 and our other product candidates is inherently uncertain.

See the section titled “Risk Factors” in this report for a further discussion of the potential adverse impact of COVID-19 on our business, results of operations and financial condition.

Components of our Results of Operations

Operating Expenses

Our operating expenses since inception have consisted solely of research and development expenses and general and administrative expenses.

Research and Development Expenses

Our research and development expenses consist of expenses incurred in connection with the development of our product candidates, including:

- fees paid to third parties to conduct certain research and development activities on our behalf, including under agreements with contract research organizations ("CROs");
- payments under licensing agreements, such as our upfront in-license fee for lotilaner and subsequent clinical development milestone achievements;
- consulting costs and certain allocated payroll and employee-related expenses (including stock-based compensation and salaries) for personnel engaged in research and development functions;
- costs related to compliance with clinical regulatory requirements;
- costs of procuring drug products for use in our preclinical studies and clinical trials; and
- facilities expenses, which include direct and allocated expenses for rent of our laboratory.

We expense both internal and external research and development expenses as incurred or as certain upfront or milestone payments become contractually due to licensors upon achievement of clinical or regulatory events. We recognize external research and development costs based on an evaluation of the progress-to-completion of (i) specific tasks performed, or deliverables provided, by CROs or contract manufacturing organizations ("CMOs") and (ii) patient visits and dosing. To estimate period expense for recognition, we use information provided to us by our service providers and we then apply the corresponding fee schedule.

We track our external research and development expenses on a program-by-program basis, such as fees paid to CROs, CMOs and research laboratories in connection with our pre-clinical development, process development, manufacturing and clinical development activities. However, we do not currently track our internal research and development expenses on a program-by-program basis as they primarily relate to employee compensation and other costs which are deployed across

multiple projects under development. For the nine months ended September 30, 2020 and 2019, substantially all of our research and development expenses are attributable to our TP-03 program for Demodex blepharitis.

Research and development activities are central to our business model. Product candidates in later stages of clinical development, such as TP-03, generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect our research and development expenses to increase substantially and in the future, as we seek to initiate and progress additional clinical trials for our product candidates, including TP-03 for the potential treatment of MGD, TP-04 for the potential treatment of rosacea and TP-05 for potential Lyme prophylaxis and community malaria reduction, complete our clinical programs, pursue regulatory approval of our product candidates, and prepare for the possible commercialization of these product candidates. The successful development of our product candidates is highly uncertain. As this time, we cannot precisely estimate the aggregate costs required to complete significant portions of our clinical programs or additional costs associated with the validation of our contract manufacturers and suppliers as required by the FDA. See the section titled “Risk Factors” in this report for a discussion of risks and uncertainties associated with our research and development projects.

General and Administrative Expenses

Our general and administrative expenses consist of personnel-related costs including payroll, benefits, and stock-based compensation for our executive, finance, and other administrative functions. Other general and administrative expenses include consulting fees, legal services, rent and other facilities costs, and other general operating expenses not otherwise classified as research and development expenses.

We expect that our general and administrative expenses will increase substantially in the future as a result of expanding our operations, including hiring personal, preparing for potential commercialization of our product candidates, and additional facility occupancy costs, as well various incremental costs associated with being a public company (including increased legal and accounting fees, regulatory costs associated with maintaining compliance with the rules of the Nasdaq Stock Market and SEC regulations, investor relations activities, directors and officers liability insurance premiums, and other accompanying compliance and governance costs).

Other Income (Expense), Net

Other income (expense), net consists primarily of interest expense on our convertible promissory notes and other expense from the change in fair value of the derivative liabilities associated with these notes. Interest expense is comprised of coupon interest, amortization of debt issuance costs, and non-cash accretion of an estimated discount on the convertible promissory notes (as part of the separate recognition of an embedded derivative liability). Our recognized interest expense was partially offset by interest income earned on our cash and cash equivalents.

Income Tax Provision

Since our inception, we have not recorded any U.S. federal or state income tax benefits for the net operating losses we have incurred in each year, or for our earned research and development tax credits, due to our uncertainty of realizing a benefit from either. As a result of the Tax Cuts and Jobs Act of 2017, net operating losses (for U.S. income tax purposes) generated prior to December 31, 2018 can be carried forward for up to 20 years, while net operating losses generated after December 31, 2017 can be carried forward indefinitely, but are limited to 80% utilization against taxable income. Our California net operating losses will begin to expire in 2037. The federal research and development tax credits begin to expire in 2037 unless previously utilized, and the California credit carryforwards are available indefinitely.

Result of Operations

Comparison of the Three Months Ended September 30, 2020 and 2019

The following table summarizes our results of operations for the periods indicated:

	Three Months Ended September 30,		
	2020	2019	Change
	(in thousands)		
Operating expenses:			
Research and development	$ 7,991	$ 399	$ 7,592
General and administrative	2,150	234	1,916
Total operating expenses	10,141	633	9,508
Loss from operations before other income (expense) and income taxes	(10,141)	(633)	(9,508)
Other income (expense):			
Interest income (expense), net	4	(21)	25
Change in fair value of derivative liabilities	—	(27)	27
Total income (expense), net	4	(48)	52
Provision for income taxes	(1)	—	(1)
Net loss	$ (10,138)	$ (681)	$ (9,457)

Research and Development Expenses

Research and development expenses increased by $7.6 million for the three months ended September 30, 2020. The increase was primarily due to (i) an upfront payment to our licensor (in the form of our common stock issuance) then valued at $3.1 million as consideration for an expanded in-license agreement executed in September 2020 for lotilaner to cure or treat all diseases and conditions in humans (beyond that of the eye or skin that we already held exclusive rights to treat), (ii) a Demodex blepharitis clinical milestone achievement in September 2020 requiring a $1.0 million payment to our licensor, (iii) increased manufacturing and development activities of $3.1 million to support our clinical studies, and (iv) increased payroll and personnel-related expenses (including stock-based compensation) of $0.4 million due to additional clinical and formulation development employees to drive our product development initiatives.

General and Administrative Expenses

General and administrative expenses increased by $1.9 million for the three months ended September 30, 2020. The increase was primarily due to (i) $0.9 million increase in payroll and personnel-related expenses (including stock-based compensation) for employee additions, (ii) increased professional fees and outside services of $0.6 million, and (iii) increased market research activities of $0.4 million.

Interest Income (Expense), Net

The increase in interest income (expense), net of $25 thousand was primarily due to interest expense from our convertible notes. The $2.0 million of this note principal value was converted into shares of Series B Preferred Stock under its contractual terms in December 2019.

Change in Fair Value of Derivative Liabilities

During May and August, and October 2019, we issued convertible promissory notes to our co-founders and certain other related parties, aggregating $2.0 million in principal value. These notes contained stock-settled redemption features that were required to be separately accounted for as derivative liabilities on the balance sheet until December 13, 2019, when we completed a "qualified equity financing". These then-outstanding notes converted, at the option of the holder, into 2.0 million shares of Series B preferred stock. The fair value adjustment of this derivative liability consisted of non-cash changes in the fair value of these stock-settled redemption features.

Results of Operations

Comparison of the Nine Months Ended September 30, 2020 and 2019

The following table summarizes our results of operations for the nine months ended September 30, 2020 and 2019 (in thousands):

	Nine Months Ended September 30,		
	2020	2019	Change
	(in thousands)		
Operating expenses:			
Research and development	$ 11,239	$ 2,465	$ 8,774
General and administrative	4,282	749	3,533
Total operating expenses	15,521	3,214	12,307
Loss from operations before other income (expense) and income taxes	(15,521)	(3,214)	(12,307)
Other income (expense):			
Interest income (expense), net	178	(16)	194
Change in fair value of derivative liabilities	—	(27)	27
Total income (expense), net	178	(43)	194
Provision for income taxes	(1)	(1)	—
Net loss	$ (15,344)	$ (3,258)	$ (12,113)

Research and Development Expenses

Research and development expenses increased by $8.8 million for the nine months ended September 30, 2020. The increase was primarily due to (i) an upfront payment to our licensor (in the form of our common stock issuance) then valued at $3.1 million as consideration for an expanded in-license agreement executed in September 2020 for lotilaner to cure or treat all diseases and conditions in humans (beyond that of the eye or skin that we already held exclusive rights to treat), (ii) a Demodex blepharitis clinical milestone achievement in September 2020 requiring a $1.0 million payment to our licensor, (iii) increased payroll and personnel related expenses (including stock-based compensation) of $1.0 million due to additional clinical and formulation development employees to drive our product development initiatives, and (iv) increased manufacturing and clinical trial activities of $4.7 million to support our clinical development programs. This increase was partially offset by a $1.0 million payment due to the same licensor in January 2019 at agreement execution for lotilaner to cure or treat all eye or skin diseases and conditions in humans.

General and Administrative Expenses

General and administrative expenses increased by $3.5 million for the nine months ended September 30, 2020. The increase was primarily due to (i) $1.6 million increase in payroll and personnel-related expenses (including stock-based compensation) for employee additions, (ii) increased professional fees and outside services of $1.3 million, and (iii) increased market research activities of $0.6 million.

Interest Income (Expense), Net

The increase in interest income (expense), net of $0.2 million was primarily due to interest earned on our money market funds that were attributable to our invested $57.4 million net proceeds from the issuance of our Series B convertible preferred stock in December 2019.

Change in Fair Value of Derivative Liabilities

During May and August, and October 2019, we issued convertible promissory notes to our co-founders and certain other related parties, aggregating $2.0 million in principal value. These notes contained stock-settled redemption features that were required to be separately accounted for as a derivative liability on the balance sheet until December 13, 2019 when we completed a "qualified equity financing". These then-outstanding notes converted, at the option of the holder, into 2.0 million shares of Series B preferred stock. The fair value adjustment of this derivative liability consisted of non-cash changes in the fair value of these stock-settled redemption features.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception in 2016 through September 30, 2020, our operations have been substantially financed by net cash proceeds of $101.0 million from private placements of Series A, Series B, and Series C preferred stock. We will continue to be dependent upon equity, debt financing, and/or other forms of capital raises at least until we are able to generate significant positive cash flows from our operations. As of September 30, 2020, we had cash and cash equivalents of $86.3 million. We have no ongoing material financing commitments, such as lines of credit or guarantees, that are expected to affect our liquidity over the next five years.

On October 20, 2020, we completed our IPO through an underwritten sale of 5,500,000 shares of our common stock at a price of $16.00 per share. The aggregate net proceeds from the offering, inclusive of an additional 825,000 common shares sold upon the full exercise of the underwriters' purchase option, after deducting underwriting discounts and commissions and other offering expenses, were approximately $91.7 million.

Funding Requirements

Our primary use of cash is to fund operating expenditures, consisting of research and development expenses (including activities within our pre-clinical, clinical, regulatory, and drug manufacturing initiatives) and general and administrative expenses. Our use of cash is impacted by the timing and extent of the required payments for each of these activities.

We believe that the net proceeds from our IPO, in combination with our existing cash and cash equivalents, will enable us to fund our operating expenses and capital expenditure requirements into the fourth quarter of 2022. We have based these estimates on our current assumptions that may require future adjustments based on our ongoing business decisions. Accordingly, we may require additional capital resources earlier than we currently expect.

To date, we have not generated any revenue. We do not expect to generate any product revenue unless and until we (1) complete development of any of our product candidates; (2) obtain applicable regulatory approvals; and (3) successfully commercialize or enter into collaborative agreements for our product candidates. We do not know with certainty when, or if, any of these items will ultimately occur. We expect to incur continuing significant losses for the foreseeable future and our losses to increase as we ramp up our clinical development programs and begin activities related to commercial launch readiness. We may encounter unforeseen expenses, difficulties, complications, delays and other currently unknown factors that could adversely affect our business.

We will require additional capital to develop our product candidates and fund our operations into the foreseeable future. We anticipate that we will eventually need to raise substantial additional capital, the requirements for which will depend on many factors, including:

- the scope, timing, rate of progress and costs of our drug discovery efforts, preclinical development activities, laboratory testing and clinical trials for our product candidates;
- the number and scope of clinical programs we decide to pursue;
- the cost, timing and outcome of preparing for and undergoing regulatory review of our product candidates;
- the scope and costs of development and commercial manufacturing activities;
- the cost and timing associated with commercializing our product candidates, if they receive marketing approval;
- the amount of revenue, if any, received from commercial sales of our product candidates, should any of our product candidates receive marketing approval;
- the achievement of milestones or occurrence of other developments that trigger payments under any collaboration agreements we might have at such time;
- the extent to which we acquire or in-license other product candidates and technologies;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- our ability to establish and maintain collaborations on favorable terms, if at all;

- our efforts to enhance operational systems and our ability to attract, hire and retain qualified personnel, including personnel to support the development of our product candidates and, ultimately, the sale of our products, following FDA approval;
- our implementation of various computerized information systems;
- impact of COVID-19 on our clinical development or operations; and
- the costs associated with being a public company.

A change in the outcome of any of these or other variables with respect to the development of any of our product candidates could significantly change the costs and timing associated with the development of that product candidate. Furthermore, our operating plans may change in the future, and we will continue to require additional capital to meet operational needs and capital requirements associated with such operating plans. If we raise additional funds by issuing equity securities, our stockholders may experience dilution. Any future debt financing into which we enter may impose upon us additional covenants that restrict our operations, including limitations on our ability to incur liens or additional debt, pay dividends, repurchase our common stock, make certain investments or engage in certain merger, consolidation or asset sale transactions. Any debt financing or additional equity that we raise may contain terms that are not favorable to us or our stockholders.

Adequate funding may not be available to us on acceptable terms or at all. Our potential inability to raise capital when needed could have a negative impact on our financial condition and our ability to pursue our business strategies. If we are unable to raise additional funds as required, we may need to delay, reduce, or terminate some or all development programs and clinical trials. We may also be required to sell or license our rights to product candidates in certain territories or indications that we would otherwise prefer to develop and commercialize ourselves. If we are required to enter into collaborations and other arrangements to address our liquidity needs, we may have to give up certain rights that limit our ability to develop and commercialize our product candidates or may have other terms that are not favorable to us or our stockholders, which could materially and adversely affect our business and financial prospects. See the section titled “Risk Factors” in this report for additional risks associated with our substantial capital requirements.

Convertible Notes

From May 2019 through October 2019, we issued convertible promissory notes with an aggregate principal amount of $2.0 million. These notes were fully converted into an aggregate of 268,056 shares of Series B preferred stock in December 2019.

Summary Statement of Cash Flows

The following table sets forth the primary sources and uses of cash, cash equivalents and restricted cash for each of the periods presented below:

	Nine Months Ended September 30,	
	2020	2019
	(in thousands)	
Net cash (used in) provided by:		
Operating activities	$ (11,125)	$ (2,867)
Investing activities	(506)	(151)
Financing activities	40,008	1,000
Net increase in cash, cash equivalents and restricted cash	$ 28,377	$ (2,018)

Net Cash Used in Operating Activities

Net cash used in operating activities was $11.1 million for the nine months ended September 30, 2020 and primarily represented our net loss of $15.3 million. This amount was partially offset by non-cash items totaling $3.8 million and a net increase in liabilities of $0.7 million associated with accounts payable and accrued bonuses.

Net cash used in operating activities was $2.9 million for the nine months ended September 30, 2019 and primarily represented our net loss of $3.3 million. This amount was partially offset by an increase in accrued liabilities of $0.3 million associated with clinical and manufacturing activities.

Net Cash Used in Investing Activities

Net cash used in investing activities was $0.5 million for the nine months ended September 30, 2020, which consisted of property and equipment purchases and leasehold improvements to our laboratory and administrative offices.

Net cash used in investing activities was $0.2 million for the nine months ended September 30, 2019, which consisted of property and equipment purchases.

Net Cash Provided by Financing Activities

Net cash provided by financing activities was $40.0 million for the nine months ended September 30, 2020 and was attributable to our issuance of Series C preferred stock for net proceeds of $39.8 million and proceeds from pre-vesting exercises of stock options aggregating to $0.4 million.

Net cash provided by financing activities was $1.0 million for the nine months ended September 30, 2019 due to our issuance of convertible promissory notes for proceeds of $1.0 million.

Critical Accounting Policies, Significant Judgments and Use of Estimates

The preparation of our condensed financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and notes to the financial statements. Some of those judgments can be subjective and complex, and therefore, actual results could differ materially from those estimates are different assumptions and conditions. A summary of our critical accounting policies is presented in our filed Form S-1. There were no material changes to our critical accounting policies during the nine months ended September 30, 2020.

Recent Accounting Pronouncements

A description of recent accounting pronouncements that may potentially impact our financial position, results of operations or cash flows are disclosed in the footnote to which each relates within these accompanying condensed financial statements.

Off-Balance Sheet Arrangements

Since our inception, we have not engaged in any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

Contractual Obligations and Commitments

There have been no material changes outside the ordinary course of business to the Company’s contractual obligations disclosed in “Management’s Discussion and Analysis of Financial Condition and Results of Operations” included in the prospectus dated October 15, 2020 filed with the SEC pursuant to Rule 424(b)(4) under the Securities Act.

Indemnification Agreements

As permitted under Delaware law and in accordance with our amended and restated bylaws, we indemnify our officers and directors for certain events or occurrences while the officer or director is or was serving in such capacity. We are also party to indemnification agreements with our officers and directors. We believe the fair value of the indemnification rights and agreements is minimal. Accordingly, we have not recorded any liabilities for these indemnification rights and agreements as of September 30, 2020 or December 31, 2019.

JOBS Act Accounting Election

The Jumpstart Our Business Startups Act of 2012, as amended (the "JOBS Act") permits an “emerging growth company” such as us to take advantage of an extended transition period to comply with new or revised accounting standards

applicable to public companies. We have irrevocably elected to opt out of this provision and, as a result, we will comply with new or revised accounting standards as required when they are adopted.

We will remain an emerging growth company until the earliest of (1) the last day of our first fiscal year (a) following the fifth anniversary of the completion of our IPO, (b) in which we have total annual gross revenues of at least $1.07 billion or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds $700 million of the prior June 30th and (2) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This filing contains forward-looking statements. All statements other than statements of historical facts contained in this report, including statements regarding our future results of operations and financial position, future revenue, business strategy, prospects, product candidates, planned preclinical studies and clinical trials, results of clinical trials, research and development costs, regulatory approvals, timing and likelihood of success, as well as plans and objectives of management for future operations, are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that are in some cases beyond our control and may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

The words “anticipate,” “believe,” contemplate,” “continue” “could,” “estimate,” “expect,” “intend,” “may,” “might,” “plan,” “potential” “predict,” “project,” “should,” “target,” “will” or “would” or the negative of these terms or other similar expressions are intended to identify forward looking statements. Forward-looking statements contained in this report include, but are not limited to, statements about:

- the likelihood of our clinical trials demonstrating safety and efficacy of our product candidates, and other positive results;
- the timing and progress of our current clinical trials and timing of initiation of our future clinical trials, and the reporting of data from our current and future trials;
- our plans relating to the clinical development of our current and future product candidates, including the size, number and disease areas to be evaluated;
- the prevalence of Demodex blepharitis and the size of the market opportunity for our product candidates;
- the rate and degree of market acceptance and clinical utility of our product candidates;
- our plans relating to commercializing our product candidates, if approved, including sales strategy;
- the impact of COVID-19 on our business and operations;
- the success of competing therapies that are or may become available;
- our estimates of the number of patients in the United States or globally, as applicable, who suffer from Demodex blepharitis, MGD, rosacea, Lyme disease and malaria and the number of patients that will enroll in our clinical trials;
- the beneficial characteristics, safety, efficacy, therapeutic effects and potential advantages of our product candidates;
- the timing or likelihood of regulatory filings and approval for our product candidates;
- our ability to obtain and maintain regulatory approval of our product candidates and our product candidates to meet existing or future regulatory standards;

- our plans relating to the further development and manufacturing of our product candidates, including additional indications for which we may pursue;
- our ability to identify additional products, product candidates or technologies with significant commercial potential that are consistent with our commercial objectives;
- the expected potential benefits of strategic collaborations with third parties and our ability to attract collaborators with development, regulatory and commercialization expertise;
- existing regulations and regulatory developments in the United States and other jurisdictions;
- our plans and ability to obtain or protect intellectual property rights, including extensions of existing patent terms where available;
- our continued reliance on third parties to conduct additional clinical trials of our product candidates, and for the manufacture of our product candidates for preclinical studies and clinical trials;
- the need to hire additional personnel, in particular sales personnel, and our ability to attract and retain such personnel;
- the accuracy of our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- our financial performance;
- the sufficiency of our existing capital resources to fund our future operating expenses and capital expenditure requirements;
- our competitive position;
- our expectations regarding the period during which we will qualify as an emerging growth company under the JOBS Act; and
- our anticipated use of our existing resources and the proceeds from our IPO.

These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described in the section titled “Risk Factors” elsewhere in this report. Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this report may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that the future results, advancements, discoveries, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur. Moreover, except as required by law, neither we nor any other person assumes responsibility for the accuracy and completeness of the forward-looking statements. We undertake no obligation to update publicly any forward-looking statements for any reason after the date of this report to conform these statements to actual results or to changes in our expectations.

You should read this report and the documents that we reference in this report and have filed with the SEC as exhibits to this report with the understanding that our actual future results, levels of activity, performance and events and circumstances may be materially different from what we expect.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Interest Rate Risk

The market risk inherent in our financial instruments and in our financial position represents the potential loss arising from adverse changes in interest rates. As of September 30, 2020, we had cash and cash equivalents of $86.3 million, consisting of interest-bearing money market accounts, for which the fair market value would be affected by changes in the general level of United States interest rates. However, due to the short-term maturities and the low-risk profile of our investments, an immediate 100 basis point change in interest rates would not have a material effect on the fair market value of our cash and cash equivalents.

We do not believe that inflation, interest rate changes, or foreign currency exchange rate fluctuations had a significant impact on our results of operations for any periods presented herein.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act of 1934, as amended ("Exchange Act")) as of the end of the period covered by this report. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of the end of the period covered by this report, our disclosure controls and procedures were effective to provide reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms and to provide reasonable assurance that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the period covered by this report that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. We have not experienced any material impact on our internal control over financial reporting despite the fact that most of our employees are working remotely due to the COVID-19 pandemic. We are continually monitoring and assessing the COVID-19 situation on our internal controls to minimize the impact on their design and operating effectiveness.

Inherent Limitations on Effectiveness of Controls

Our management, including our Chief Executive Officer and Chief Financial Officer, do not expect that our disclosure controls or our internal control over financial reporting will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by management override of the controls. The design of any system of controls is also 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.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings

We are not currently a party to any material legal proceedings. From time to time, we may become involved in legal proceedings arising in the ordinary course of our business. Regardless of outcome, litigation can have an adverse impact on us due to defense and settlement costs, diversion of management resources, negative publicity, reputational harm and other factors.

Item 1A. Risk Factors

Investing in our common stock is speculative and involves a high degree of risk. You should consider and read carefully all of the risks and uncertainties described below, together with the all of the other information contained in this report, including the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and the related notes, before investing in our common stock. The risks and uncertainties described below are on the only ones we face. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition and/or operating results. If any of the following risks occur, our business, financial condition, results of operations and future growth prospects could be materially and adversely affected. In these circumstances, the market price of our common stock could decline, and you may lose all or part of your investment. This report also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of a number of factors, including the risks described below. See "Special Note Regarding Forward-Looking Statements."

Summary of Risks Associated with our Business

We face risks and uncertainties associated with our business, many of which are beyond our control. Some of the more significant risks associated with our business include the following:

- We are a late clinical-stage biopharmaceutical company with limited operating history. We have incurred significant losses and negative cash flows from operations since our inception and anticipate that we will continue to incur significant expenses and losses for the foreseeable future.
- We may need to obtain additional funding to complete the development and any commercialization of our product candidates, if approved. If we are unable to raise this necessary capital when needed, we would be forced to delay, reduce or eliminate our product development programs, commercialization efforts or other operations.
- We are heavily dependent on the success of our lead product candidate, TP-03 for the treatment of Demodex blepharitis.
- The COVID-19 pandemic, which began in late 2019 and has spread worldwide, may affect our ability to initiate and complete preclinical studies and clinical trials, disrupt regulatory activities, disrupt our manufacturing and supply chain or have other adverse effects on our business and operations.
- Even if TP-03 or any other product candidate that we develop receives marketing approval, we may not be successful in educating eye care physician ("ECPs"), and the market about the need for treatments specifically for Demodex blepharitis and or other diseases or conditions targeted by our product candidates, and TP-03 or other product candidates that we may develop may fail to achieve market acceptance by ECPs, other healthcare providers and patients, or adequate formulary coverage, pricing or reimbursement by third-party payors and others in the medical community, and the market opportunity for these products may be smaller than we estimate.
- The development and commercialization of our products, including our lead product candidate, TP-03 for the potential treatment of Demodex blepharitis and Meibomian Glad Disease ("MGD") TP-04 for the potential treatment of rosacea and TP-05 for potential Lyme prophylaxis and community malaria reduction, is dependent on intellectual property we license from Elanco Tiergesundheit AG ("Elanco"). If we breach our agreements with Elanco or the agreements are terminated, we could lose license rights that are important to our business.

- We will need to develop and expand our company and we may encounter difficulties in managing our growth, which could disrupt our operations.
- The sizes of the market opportunity for our product candidates, particularly TP-03 for the treatment of Demodex blepharitis and MGD, have not been established with precision and may be smaller than we estimate, possibly materially. If our estimates of the sizes overestimate these markets, our sales growth may be adversely affected. We may also not be able to grow the markets for our product candidates as intended or at all.
- Clinical drug development involves a lengthy and expensive process with uncertain timelines and uncertain outcomes, and results of earlier studies and trials may not be predictive of future results.
- Any termination or suspension of, or delays in the commencement or completion of, our planned clinical trials could result in increased costs to us, delay or limit our ability to generate revenue and adversely affect our commercial prospects.
- We rely on third parties to conduct our clinical trials and perform some of our research and preclinical studies.
- If we are unable to obtain and maintain sufficient intellectual property protection for our product candidates, or if the scope of the intellectual property protection is not sufficiently broad, our competitors could develop and commercialize products similar or identical to ours, and our ability to successfully commercialize our products may be adversely affected.
- Patent terms may be inadequate to protect our competitive position on our product candidates and preclinical programs for an adequate amount of time.
- The concentration of our stock ownership will likely limit your ability to influence corporate matters, including the ability to influence the outcome of director elections and other matters requiring stockholder approval.

Risks Related to our Financial Position and Need for Additional Capital

We have incurred significant losses and negative cash flows from operations since our inception and anticipate that we will continue to incur significant expenses and losses for the foreseeable future.

We do not have any products approved for sale, we have not generated any revenue and have incurred net losses in each reporting period since our company's formation in 2016. We have funded our operations primarily from the sale and issuance of redeemable convertible preferred stock, convertible promissory notes and the sale of our common stock in our IPO. For the years ended December 31, 2019 and 2018, our net losses were $4.7 million and $1.3 million, respectively. For the nine months ended September 30, 2020 and 2019, our net losses were $15.3 million and $3.3 million, respectively. As of September 30, 2020 and December 31, 2019, we had an accumulated deficit of $21.4 million and $6.0 million, respectively. Additionally, the net losses we incur may fluctuate significantly from quarter to quarter such that a period-to-period comparison of our results of operations may not be a good indicator of our future performance. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. We expect that it will be a few years, if ever, before we have a product candidate ready for commercialization. We expect to incur increasing levels of operating losses over the next several years and for the foreseeable future as we advance and commercialize, if approved, our product candidates. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our accumulated deficit and working capital.

We expect to continue incurring significant expenses and increasing operating losses for the foreseeable future. We expect that our expenses will increase substantially if and as we:

- prepare for and initiate additional preclinical, clinical and other studies for our product candidates;
- change or add additional manufacturers or suppliers, some of which may require additional permits or other governmental approvals;
- create additional infrastructure to support our operations as a public company, including adding operational, financial and management information systems and personnel;

- enhance our product development and planned future commercialization efforts, including through hiring additional clinical, regulatory, quality control and scientific personnel;
- seek marketing approvals and reimbursement for our product candidates;
- establish a sales, marketing, and distribution infrastructure to commercialize any products for which we may obtain marketing approval;
- seek to identify, assess, acquire or develop additional product candidates;
- acquire or in-license other product candidates and technologies;
- make milestone or other payments in connection with the development or approval of our product candidates;
- maintain, protect, enforce and expand our intellectual property portfolio; and
- experience any delays or encounter issues with any of the above.

Because of the numerous risks and uncertainties associated with biopharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. Our expenses could increase beyond our expectations if, among other things:

- we are required by regulatory authorities to perform trials or studies in addition to, or different than, those that we currently expect;
- there are any delays in establishing appropriate manufacturing arrangements for or completing the development of any of our product candidates; or
- there are any third-party challenges to our intellectual property or we need to defend against any intellectual property-related claim.

Even if we obtain regulatory approval for and are successful in commercializing one or more of our product candidates, we expect to incur substantial additional research and development and other expenditures to develop and market additional product candidates or to expand the approved indications of any marketed product. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business.

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

We commenced activities in 2016. Our limited operating history may make it difficult to evaluate the success of our business to date and to assess our future viability. Our operations to date have been limited to organizing our company, raising capital, identifying and developing product candidates, establishing licensing arrangements and/or acquiring necessary technology, undertaking research, preclinical studies and clinical trials of our product candidates, establishing arrangements for the manufacture of product candidates and longer-term planning for potential commercialization. Our prospects must be considered in light of the uncertainties, risks, expenses and difficulties frequently encountered by companies in their early stages of operations. We have limited experience in and have not yet demonstrated our ability to obtain marketing approvals, manufacture a commercial scale product or arrange for a third party to do so on our behalf, or conduct sales, marketing and distribution activities necessary for successful product commercialization. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing, obtaining marketing approval for and commercializing products. In addition, as our business grows, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown obstacles. We will need to transition at some point from a company with a research and development focus to a company capable of supporting commercial activities. We may not be successful in such a transition.

We are heavily dependent on the success of our lead product candidate, TP-03, for the treatment of Demodex blepharitis. If we are unable to successfully complete the clinical development program, obtain regulatory approval for, or commercialize, TP-03, or experience significant delays in doing so, our business will be materially harmed.

We currently have no products that are approved for commercial sale and we have never had any products approved for sale or commercialized. To date, we have invested a substantial majority of our business efforts and financial resources to the preclinical and clinical development of TP-03 for the treatment of Demodex blepharitis. Our future success is dependent on our ability to successfully develop, obtain regulatory approval for, and commercialize TP-03 for the treatment of Demodex blepharitis, and we cannot accurately predict when or if TP-03 will be proven to be effective or safe in humans or whether it will receive regulatory approval. Before we can generate any revenue from sales of TP-03, we will be required to conduct additional clinical development, seek and obtain regulatory approval, secure adequate manufacturing supply to support commercial sales and build a commercial organization. We have not yet demonstrated our ability to complete pivotal clinical trials. Further, the commercial success of TP-03 will also depend on patent protection, successfully educating eye care physicians ("ECPs") about Demodex blepharitis and related diagnosis, acceptance of TP-03 by patients, the medical community and third-party payors, TP-03's ability to compete with other therapies, secure adequate healthcare coverage and reimbursement, and maintenance of an acceptable safety profile following approval, among other factors. 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 TP-03, which would materially harm our business. If we were required to discontinue development of TP-03, or if TP-03 does not receive regulatory approval, fails to achieve significant market acceptance, or fails to receive adequate reimbursement, we would be delayed by many years in our ability to achieve profitability, if ever, and may not be able to generate sufficient revenue to continue our business.

We may need to obtain additional funding to complete the development and any commercialization of our product candidates, if approved. If we are unable to raise this necessary capital when needed, we would be forced to delay, reduce or eliminate our product development programs, commercialization efforts or other operations.

Since our inception, we have funded our operations through private placements of preferred stock, convertible promissory notes and the sale of our common stock in our IPO. Over the next few years, we expect our expenses to increase substantially and we will require a larger amount of capital to fund the development of our product candidates. As our product candidates enter and advance through preclinical studies and clinical trials, we will need substantial additional funds to expand our clinical, regulatory, quality and manufacturing capabilities. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to marketing, sales, manufacturing and distribution. Furthermore, as a public company, we incur significant legal, accounting and other costs associated with operating as a public company.

As of September 30, 2020, we had $86.3 million in cash and cash equivalents. Based on our current business plans, in addition to the completed IPO in October 2020, we believe that our existing cash and cash equivalents will be sufficient to fund our anticipated level of operations through at least the next 12 months. We believe that our cash and cash equivalents will be sufficient to fund our operating expenses and capital expenditure requirements into the fourth quarter of 2022. Accordingly, our existing cash and cash equivalents will be insufficient for us to concurrently fund our product candidates through regulatory approval and commercialization. We will need to raise substantial additional capital to complete the development and commercialization of our product candidates through equity offerings, debt financings, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements or other sources. We may also need to raise additional funds earlier than currently anticipated if we choose to pursue additional indications for our product candidates, acquire new product candidates or otherwise expand our business more rapidly than we presently planned.

We have based these estimates on assumptions that may prove to be incorrect or require adjustment because of our ongoing business decisions, and we could utilize our available capital resources sooner than we currently expect. Our future capital requirements will depend on many factors, including:

- the scope, rate of progress, costs and results of our drug discovery, preclinical development activities, laboratory testing and clinical trials for our product candidates;
- the number and scope of clinical programs we decide to pursue;
- the scope and costs of manufacturing development and commercial manufacturing activities and our ability to scale them up;
- the extent to which we acquire or in-license other product candidates and technologies;
- the cost, timing and outcome of regulatory review of our product candidates, including the potential for regulatory authorities to require that we conduct more studies and trials than those that we currently expect to conduct and the costs of post-marketing studies or risk evaluation and mitigation strategies that could be required by regulatory authorities;

- potential changes in the regulatory environment and enforcement rules;
- the cost and timing of establishing sales and marketing capabilities, if any of our product candidates 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;
- our ability to establish and maintain collaborations on favorable terms, if at all;
- our efforts to enhance operational systems and our ability to attract, hire and retain qualified personnel, including personnel to support the development of our product candidates;
- potential changes in pharmaceutical pricing and reimbursement infrastructure;
- the costs associated with being a public company; and
- the cost associated with commercializing our product candidates, if they receive marketing approval.

Identifying potential product candidates and conducting preclinical studies and clinical trials is a time consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval. In addition, our product candidates, if approved, may not achieve adequate product sales or commercial success. We do not expect to have any products commercially available for sale for many years, if at all. 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 acceptable terms, or at all, and may be impacted by the economic climate and market conditions. For example, market volatility resulting from the COVID-19 pandemic or any other future infectious diseases, epidemics or pandemics could also adversely impact our ability to access capital as and when needed. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, limit, reduce or eliminate our research and development programs or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. In addition, attempting to secure additional financing may divert the time and attention of management from day-to-day activities and distract from our research and development efforts. Alternatively, 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.

We currently generate no revenues from sales of any products and may never generate revenue or be profitable.

We have no products approved for commercial sale and do not anticipate generating any revenue unless and until either TP-03 or another product candidate receives the regulatory approvals necessary for commercialization in one or more jurisdictions. Our ability to generate revenue and achieve profitability depends significantly on our ability, or any future collaborator's ability, to achieve a number of challenging objectives, including:

- successful and timely completion of preclinical and clinical development of our product candidates, including the clinical development of TP-03 for the treatment of Demodex blepharitis or other indications and any other future product candidates;
- establishing and maintaining relationships with contract research organizations, or CROs, and clinical sites for the clinical development, both in the United States and internationally, of our product candidates;
- timely receipt of regulatory approvals from applicable regulatory authorities for TP-03 or any other product candidates for which we successfully complete clinical development;
- making any required post-marketing approval commitments to applicable regulatory authorities;
- establishing and maintaining commercially viable supply and manufacturing relationships with third parties that can provide adequate, in both amount and quality, products and services to support clinical development and meet the market demand for product candidates that we develop, if approved;
- obtaining an investigational new drug application ("IND") prior to commencing clinical trials in the United States for a particular indication, such as TP-04 for the potential treatment of rosacea (although for TP-04 we first intend

to conduct a Phase 1/2 trial outside the United States and thus do not plan to submit an IND prior to this trial) and TP-05 for potential Lyme prophylaxis and community malaria reduction;

- successful commercial launch following any regulatory approval, including the development of a commercial infrastructure, whether in-house or with one or more collaborators;
- a continued acceptable safety and efficacy profile both prior to and following any marketing approval of our product candidates;
- successfully educating ECPs about Demodex blepharitis and related diagnosis;
- commercial acceptance of TP-03 and any of our other product candidates by patients, the medical community and third-party payors;
- identifying, assessing and developing new product candidates;
- obtaining, maintaining and expanding patent protection, trade secret protection and regulatory exclusivity, both in the United States and internationally;
- protecting our rights in our intellectual property portfolio;
- defending against third-party interference or infringement claims, if any;
- obtaining favorable terms in any collaboration, licensing or other arrangements that may be necessary or desirable to develop, manufacture or commercialize our existing or acquired product candidates;
- obtaining coverage and adequate reimbursement for customers and patients from government and third-party payors for product candidates that we develop;
- addressing any competing therapies and technological and market developments; and
- attracting, hiring and retaining qualified personnel.

We may never be successful in achieving our objectives and, even if we do, may never generate revenue that is significant or large enough to achieve profitability. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis and we will continue to incur substantial research and development and other expenditures to develop and market additional product candidates. In addition, as a young business, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown challenges. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to maintain or further our research and development efforts, raise additional necessary capital, grow our business, retain key employees and continue our operations.

The COVID-19 pandemic, which began in late 2019 and has spread worldwide, may affect our ability to initiate and complete preclinical studies and clinical trials, disrupt regulatory activities, disrupt our manufacturing and supply chain or have other adverse effects on our business and operations. In addition, this pandemic has caused substantial disruption in the financial markets and may adversely impact economies worldwide, both of which could result in adverse effects on our business and operations.

The COVID-19 pandemic, which began in December 2019 and has spread worldwide, has caused many governments to implement measures to slow the spread of the outbreak through quarantines, travel restrictions, heightened border scrutiny and other measures. The outbreak and government measures taken in response have also had a significant impact, both directly and indirectly, on businesses and commerce, as worker shortages have occurred, supply chains have been disrupted, facilities and production have been suspended, and demand for certain goods and services, such as medical services and supplies, has spiked, while demand for other goods and services, such as travel, has fallen. The future progression of the outbreak and its effects on our business and operations are uncertain.

Our business, operations and clinical development timelines and plans have been and could continue to be adversely affected by COVID-19, and could be adversely impacted by other health epidemics in regions where we have concentrations of clinical trial sites or other business operations, and could cause significant disruption in the operations of CROs upon whom we rely. The COVID-19 pandemic has affected multiple countries worldwide, including those where we

have planned and ongoing preclinical studies and clinical trials. In addition, in response to the COVID-19 pandemic, many state, local and foreign governments have put in place quarantines, executive orders, shelter-in-place orders and similar government orders and restrictions in order to control the spread of the disease. Such orders or restrictions, and the perception that such orders or restrictions could continue or, after being lifted, be reinstated for a period of time, have resulted in business closures, work stoppages, slowdowns and delays, work-from-home policies, travel restrictions and cancellation of events, among other effects that could negatively impact productivity and disrupt our business and operations. We have implemented a work-from-home policy for our employees and have also implemented enhanced travel-safe policies for our employees' travel to our clinical sites. We may take further actions that alter our operations as may be required by federal, state or local authorities, or which we determine are in the best interests of our employees.

Moreover, our clinical development timelines and plans could be affected by the COVID-19 pandemic as we and the third-party manufacturers and clinical research organizations that we engage may face disruptions. Site initiation and patient enrollment could be delayed or suspended due to prioritization of hospital resources toward the COVID-19 pandemic or patients not having a desire to enroll in clinical trials due to concerns regarding COVID-19. In addition, some patients may not be able to comply with clinical trial protocols and the ability to conduct follow up visits with treated patients may be limited if patients do not want to participate in follow up visits due to concerns regarding COVID-19 or if quarantines impede patient movement or interrupt healthcare services. There may be shortages in the raw materials used in the manufacturing of our product candidates or laboratory supplies for our preclinical studies and clinical trials, in each case, because of ongoing efforts to address the outbreak.

We cannot assure that the inability to collect such clinical data would not have an adverse impact on our clinical trial results. Similarly, our ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19 could be adversely impacted.

We may experience disruptions that could severely impact our business, preclinical studies, and clinical trials, including:

- delays in receiving approval from local regulatory authorities to initiate our planned clinical trials, including receiving any required investigational new drug applications, or INDs;
- delays or difficulties in enrolling and retaining patients in our clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- manufacturing disruptions;
- delays in clinical sites receiving the supplies and materials needed to conduct our clinical trials;
- delays in the transport of clinical trial materials;
- changes in local regulations as part of a response to the COVID-19 coronavirus pandemic which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue the clinical trials altogether;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- difficulties recruiting or retaining patients for our planned clinical trials if patients are affected by the virus or are fearful of visiting or traveling to clinical trial sites because of the outbreak;
- interruption of or changes in key clinical trial activities, such as clinical trial site monitoring, implementation of virtual monitoring, use of local testing labs, or home delivery of study drugs, due to limitations on travel imposed or recommended by federal or state governments, employers and others, use of new digital technologies for subject visits or interruption of clinical trial subject visits and study procedures, the occurrence of which could affect the integrity of clinical trial data;

- risk that participants enrolled in our clinical trials will acquire COVID-19 while the clinical trial is ongoing, which could impact the results of the clinical trial, including by increasing the number of observed adverse events;
- delays in necessary interactions with local regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees;
- limitations in employee resources that would otherwise be focused on the conduct of our clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people;
- interruption or delays in the operations of the FDA which may impact review and approval timelines;
- delays in regulatory approvals for our product candidates due to the FDA focusing on clinical trials related to therapies and vaccines targeting COVID-19;
- refusal of the FDA to accept data, including from clinical trials in affected geographies or failure to comply with updated FDA guidance and expectations related to the conduct of clinical trials during the COVID-19 pandemic; and
- interruption or delays to our sourced discovery and clinical activities.

The response to the COVID-19 pandemic may redirect resources with respect to regulatory matters in a way that would adversely impact our ability to pursue marketing approvals. In addition, we may face impediments to regulatory meetings and potential approvals due to measures intended to limit in-person interactions. Furthermore, third parties, including manufacturers, medical institutions, clinical investigators, CROs and consultants with whom we conduct business, are similarly adjusting their operations and assessing their capacity in light of the COVID-19 pandemic. If these third parties continue to experience shutdowns or business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially and negatively impacted.

The extent to which the COVID-19 pandemic impacts our business, clinical trials, results of operations and financial condition will depend on future developments, which are highly uncertain and cannot be predicted, including, but not limited to, the duration of the pandemic, its severity, the actions to contain the virus or address its impact, and how quickly and to what extent normal economic and operating activities can resume. Further, while the potential economic impact brought by and the duration of COVID-19 may be difficult to assess or predict, the COVID-19 pandemic has resulted in significant disruptions of global financial markets, which could reduce our ability to access capital, which could in the future negatively affect our liquidity. To the extent the COVID-19 pandemic adversely affects our business, clinical trials, results of operations and financial condition, it may also have the effect of heightening many of the other risks described in this “Risk Factors” section.

The ultimate impact of the COVID-19 pandemic or a similar health epidemic is highly uncertain and subject to change.

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

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through possible combinations of equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. 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, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt or liens, making acquisitions, selling or licensing our assets, redeeming our stock, making certain investments, making capital expenditures or declaring dividends.

If we raise funds through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we raise funds through research grants, we may be subject to certain requirements, which may limit our ability to use the funds or require us to share information from our research and development. Raising additional capital through any of these or other means could adversely affect our business and the

holdings or rights of our stockholders, and may cause the market price of our shares to decline. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

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

We are highly dependent on the expertise of our executive officers, as well as the other members of our scientific and clinical teams and certain advisors to develop and soundly execute our business strategy. Although we have employment offer letters with each of our executive officers, each of them may terminate their employment with us at any time. We do not maintain "key person" insurance for any of our executives or employees.

Recruiting and retaining qualified scientific and clinical personnel and, if we are successful in obtaining marketing approval for TP-03 or other product candidates, sales and marketing personnel, are critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval for and commercialize our product candidates. Competition to hire qualified personnel in our industry is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel.

Furthermore, to the extent we hire personnel from competitors, we may be subject to allegations that they have been improperly solicited or that they have divulged proprietary or other confidential information, or that their former employers own their research output. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited, and our business, prospects, financial condition and results of operations may be adversely affected.

Many of our employees have become or will soon become vested in a substantial amount of our common stock or a number of common stock options. Our employees may be more likely to leave us if the shares they own have significantly appreciated in value relative to the original purchase prices of the shares, or if the exercise prices of the options that they hold are significantly below the market price of our common stock, particularly after the expiration of the lock-up agreements described herein. Our future success also depends on our ability to continue to attract and retain additional executive officers and other key employees.

We will need to develop and expand our company, and we may encounter difficulties in managing this development and expansion, which could disrupt our operations.

In connection with becoming a public company, we expect to increase our number of employees and the scope of our operations. To manage our anticipated development and expansion, 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. Also, our management may need to divert a disproportionate amount of its attention away from its day-to-day activities and devote a substantial amount of time to managing these development activities. This may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. If our management is unable to effectively manage our expected development and expansion, our expenses may increase more than expected, our ability to generate revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize our product candidates, if approved, and compete effectively will depend, in part, on our ability to effectively manage the future development and expansion of our company.

We may not realize the benefits of any acquisitions, in-license or other collaborations or strategic alliances that we enter into.

We may form or seek strategic alliances, create joint ventures or collaborations or enter into additional licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our product candidates and any future product candidates that we may develop. Any of these relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing stockholders or disrupt our management and business. In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our product candidates because we are unable to agree on commercial terms, or because third parties may not view our product candidates as having the requisite potential to demonstrate safety and efficacy. If we license products or businesses, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture. We cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that justifies such transaction. Any delays in entering into new strategic partnership agreements related to our product candidates could delay the development and commercialization of our product candidates in certain geographies for certain indications, which would harm our business prospects, financial condition and results of operations.

We expect to expand our development, regulatory and operational 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, 2020, we had 18 full-time employees. As we advance our research and development programs, 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, quality, regulatory affairs, manufacturing and quality control and, if any of our product candidates receives marketing approval, sales, marketing and distribution. To manage our anticipated future growth, we must:

- identify, recruit, integrate, maintain and motivate additional qualified personnel;
- manage our development efforts effectively, including the initiation and conduct of clinical trials for our product candidates; and
- improve our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to develop, manufacture and commercialize our product candidates will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert financial and other resources, and a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time, to managing these growth activities. If we do not effectively manage the expansion of our operations, we could experience weaknesses in our infrastructure, operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. The expansion of our operations also could lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

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 our product 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 our product 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.

Many of the biotechnology and pharmaceutical companies that we compete against for qualified personnel and consultants have greater financial and other resources, different risk profiles and a longer history in the industry than we do. If we are unable to continue to attract and retain high quality personnel and consultants, the rate and success at which we can discover and develop product candidates and operate our business will be limited. If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, we may not be able to successfully implement the tasks necessary to further develop and commercialize our product candidates and, accordingly, may not achieve our research, development and commercialization goals.

We may engage in acquisitions or strategic partnerships that could disrupt our business, cause dilution to our stockholders, reduce our financial resources, cause or to incur debt or assume contingent liabilities, and subject us to other risks.

In the future, we may enter into transactions to acquire other businesses, products or technologies or enter into strategic partnerships, including licensing. If we do identify suitable acquisition or partnership candidates, we may not be able to make such acquisitions or partnerships on favorable terms, or at all. Any acquisitions or partnerships we make may not strengthen our competitive position, and these transactions may be viewed negatively by customers or investors. We may decide to incur debt in connection with an acquisition or issue our common stock or other equity securities to the stockholders of the acquired company, which would reduce the percentage ownership of our existing stockholders. For example, pursuant to the terms of the license agreement with Elanco Tiergesundheit AG ("Elanco") granting us a worldwide, sublicensable license for the development and marketing of lotilaner for all applications in humans outside the treatment or cure of any eye or skin condition in humans ("All Human Uses Elanco Agreement") if is not terminated, or if we have not provided notice to terminate the All Human Uses Elanco Agreement, within 18 months of its effective date, we will be required to issue Elanco additional shares of our common stock equating to $3.0 million of aggregate value.

We could incur losses resulting from undiscovered liabilities of the acquired business or partnership that are not covered by the indemnification we may obtain from the seller or our partner. In addition, we may not be able to successfully integrate any acquired personnel, technologies and operations into our existing business in an effective, timely and non-disruptive manner. Acquisitions or partnerships may also divert management attention from day-to-day responsibilities, lead to a loss of key personnel, increase our expenses and reduce our cash available for operations and other uses. We cannot predict the number, timing or size of future acquisitions or partnerships or the effect that any such transactions might have on our operating results.

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

Earthquakes or 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. The disaster recovery and business continuity plans we have in place currently are limited and are unlikely to prove adequate 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, particularly when taken together with our lack of earthquake insurance, could have a material adverse effect on our business.

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

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. The recent global financial crisis caused extreme volatility and disruptions in the capital and credit markets. Additionally, the COVID-19 pandemic has caused significant disruptions to the U.S., regional and global economies and has contributed to significant volatility and negative pressure in financial markets. A severe or prolonged economic downturn, or any prolonged economic downturn caused by the COVID-19 pandemic, could result in a variety of risks to our business, including reduced ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

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

We have incurred substantial losses during our history which we expect to continue, do not expect to become profitable in the near future, and we may never achieve profitability. Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the "Code"), if a corporation undergoes an "ownership change," generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a three-year period, the corporation's ability to use its pre-change net operating loss carryforwards("NOLs"), and other pre-change tax attributes (such as research tax credits) to offset its post-change income or taxes may be limited. We have not yet completed an ownership change analysis. If a requisite ownership change occurs, the amount of remaining tax attribute carryforwards available to offset taxable income and reduce income tax expense in future years may be restricted or eliminated. 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 a material portion of our NOLs and other tax attributes, which could adversely affect our future cash flows.

U.S. federal income tax reform and the implementation of such reforms could adversely affect us.

On December 22, 2017, the United States enacted the "Tax Cuts and Jobs Act," (" TCJA"), that significantly reformed the Code. The TCJA, among other things, includes contained significant changes to corporate taxation, including a reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, the limitation of the tax deduction for net interest expense to 30% of adjusted earnings (except for certain small businesses), the limitation of the deduction for NOLs arising in taxable years beginning after December 31, 2017 to 80% of current year taxable income and elimination of NOL carrybacks for losses arising in taxable years ending after December 31, 2017 (though any such NOLs may be carried forward indefinitely), the imposition of a one-time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, the elimination of U.S. tax on foreign earnings (subject to certain important exceptions), the allowance of immediate deductions for certain new investments instead of deductions for depreciation expense over time, and the modification or repeal of many business deductions and credits. The financial statements contained herein reflect the effects of the TCJA based on current guidance. However, there remain uncertainties and ambiguities in the application of certain provisions of the TCJA, and, as a result, we made certain judgments and assumptions in the interpretation thereof.

As part of Congress's response to the COVID-19 pandemic, the Families First Coronavirus Response Act ("FFCR Act") was enacted on March 18, 2020, and the Coronavirus Aid, Relief, and Economic Security Act ("CARES Act") was enacted on March 27, 2020. Both contain numerous tax provisions. In particular, the CARES Act retroactively and temporarily (for taxable years beginning before January 1, 2021) suspends application of the 80%-of-income limitation on the use of NOLs, which was enacted as part of the TCJA. It also provides that NOLs arising in any taxable year beginning after December 31, 2017 and before January 1, 2021 are generally eligible to be carried back up to five years. The CARES Act also temporarily (for taxable years beginning in 2019 or 2020) relaxes the limitation of the tax deductibility for net interest expense by increasing the limitation from 30% to 50% of adjusted taxable income.

Regulatory guidance under the TCJA, the FFCR Act and the CARES Act is and continues to be forthcoming, and such guidance could ultimately increase or lessen impact of these laws on our business and financial condition. It is also likely that Congress will enact additional tax legislation in connection with the COVID-19 pandemic, some of which could have an impact on our company. In addition, it is uncertain if and to what extent various states will conform to the TCJA, the FFCR Act or the CARES Act.

Risks Related to Development and Commercialization of Our Product Candidates

Clinical drug development is a lengthy, expensive and risky process with uncertain timelines and uncertain outcomes, and results of earlier studies and trials may not be predictive of future results. If clinical trials of our product candidates, particularly TP-03 for the treatment of Demodex blepharitis, do not meet safety or efficacy endpoints or are prolonged or delayed, we may be unable to obtain required regulatory approvals, and therefore be unable to commercialize our product candidates on a timely basis or at all.

Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of the product candidates in humans. The research and development of drugs is an extremely risky industry. Only a small percentage of product candidates that enter the development process ever receive marketing approval. Failure or delay can occur at any time during the clinical trial process. To date, we have focused substantially all of our efforts and financial resources on identifying, acquiring, and developing our product candidates, including conducting preclinical studies and clinical trials. Clinical testing is expensive and can take many years to complete, and we cannot be certain that any clinical trials will be conducted as planned or completed on schedule, if at all. Furthermore, product candidates are subject to continued preclinical safety studies, which may be conducted concurrently with our clinical testing. The outcomes of these safety studies may delay the launch of or enrollment in future clinical trials and could impact our ability to continue to conduct our clinical trials. Our inability to successfully complete preclinical and clinical development could result in additional costs to us and negatively impact our ability to generate revenue. Our future success is dependent on our ability to successfully develop, obtain regulatory approval for, and then successfully commercialize product candidates. We currently generate no revenues from sales of any products, and we may never be able to develop or commercialize a marketable product.

We have not yet completed any Phase 2b/3 or Phase 3 trials for any product candidate. The results of preclinical and early clinical trials of our product candidates and other products with the same mechanism of action may not be predictive of the results of later-stage clinical trials. For example, we may not be able to replicate the safety and efficacy results of our Phase 2 clinical trials for Demodex blepharitis in our Phase 2b/3 trial, Saturn-1, or our Phase 3 trial, Saturn-2. Clinical trial

failure may result from a multitude of factors including flaws in trial design, dose selection, placebo effect, patient enrollment criteria, relatively smaller sample size in earlier trials, and failure to demonstrate favorable safety or efficacy traits. As such, failure in clinical trials can occur at any stage of testing. A number of companies in the biopharmaceutical industry have suffered setbacks in the advancement of clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials, and we cannot be certain that we will not face similar setbacks. 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. Furthermore, as more product candidates within a particular class of drugs proceed through clinical development to regulatory review and approval, the amount and type of clinical data that may be required by regulatory authorities may increase or change. The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and preliminary or interim results of a clinical trial do not necessarily predict final results. For example, our product candidates may fail to show the desired safety and efficacy in clinical development despite positive results in preclinical studies or having successfully advanced through initial clinical trials. The failure of any of our product candidates to demonstrate safety and efficacy in any clinical trial could negatively impact the perception of our other product candidates or cause regulatory authorities to require additional testing before approving any of our product candidates.

We currently have one product candidate, TP-03, in clinical development and its risk of failure is high. For example, use of TP-03 requires the patient to follow a prescribed technique to administer the eye drops. Failure to properly administer the eye drops by the patient or inappropriate technique demonstration by the eye care practitioners, may adversely affect the outcome of TP-03 in demonstrating efficacy in one or more clinical trials. We are unable to predict if this product candidate or any of our future product candidates that advance into clinical trials will prove safe or effective in humans or will obtain marketing approval. If we are unable to complete preclinical or clinical trials of current or future product candidates, due to safety concerns, or if the results of these trials are not satisfactory to convince regulatory authorities of their safety or efficacy, we will not be able to obtain marketing approval for commercialization. Even if we are able to obtain marketing approvals for any of our product candidates, those approvals may be for indications that are not as broad as desired or may contain other limitations that would adversely affect our ability to generate revenue from sales of those products. Moreover, if we are not able to differentiate our product against other approved products within the same class of drugs, or if any of the other circumstances described above occur, our business would be materially harmed and our ability to generate revenue from that class of drugs would be severely impaired.

Each of our product candidates will require additional clinical development, management of clinical, preclinical (for some of our product candidates) and manufacturing activities, regulatory approval in multiple jurisdictions, achieving and maintaining commercial-scale supply, building of a commercial organization, substantial investment and significant marketing efforts before we generate any revenues from product sales. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the FDA or comparable foreign regulatory authorities, and we may never receive such regulatory approval for any of our product candidates. We may experience delays in our ongoing clinical trials, and we do not know whether planned clinical trials will begin on time, need to be redesigned, enroll patients on time or be completed on schedule, if at all. For example, the FDA has recommended that for TP-03 we conduct carcinogenicity testing as well as embryofetal development studies in a second species. Any further recommendations by the FDA could cause delay of any regulatory approval by the FDA and cause our expenses to increase. We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize TP-03, our other product candidates, or any other product candidates that we may develop, including:

- we may experience delays in or failure to reach agreement on acceptable terms with prospective CROs, vendors and clinical sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs, vendors and trial sites;
- we may fail to obtain sufficient enrollment in our clinical trials, our enrollment needs may grow larger than we anticipate, or participants may fail to complete our clinical trials at a higher rate than we anticipate;
- clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- we may decide, or regulators or institutional review boards or ethics committees may require us, to suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- regulators or institutional review boards or ethics committees may not authorize us or our investigators to commence a clinical trial at a prospective clinical trial site or at all or may require us to perform additional or

unanticipated clinical trials to obtain approval or we may be subject to additional post-marketing testing requirements to maintain regulatory approval;

- regulators may revise the requirements for approving our product candidates, or such requirements may not be as we anticipate;
- the cost of clinical trials of our product candidates may be greater than we anticipate, and we may need to delay or suspend one or more trials until we complete additional financing transactions or otherwise receive adequate funding;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate or may be delayed;
- our product candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators or institutional review boards or ethics committees to suspend or terminate trials;
- regulatory authorities may determine that the planned design of our clinical trials is flawed or inadequate;
- regulatory authorities may suspend or withdraw their approval of a product or impose restrictions on its distribution;
- we may not be able to timely or at all obtain INDs for a product candidate;
- we may modify a preclinical study or clinical trial protocol;
- third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we may be unable to establish clinical endpoints that applicable regulatory authorities consider clinically meaningful, or, if we seek accelerated approval, biomarker efficacy endpoints that applicable regulatory authorities consider likely to predict clinical benefit;
- we may experience delays due to the ongoing COVID-19 pandemic, including with respect to the conduct of ongoing clinical trials, receipt of product candidates or other materials, submission of New Drug Applications, or NDAs, filing of INDs, and starting any clinical trials for other indications or programs; and
- we may experience manufacturing delays due to the recent COVID-19 pandemic in our supply chain caused by a shortage of raw materials, a lack of employees on site at our suppliers due to illness, or a lack of productivity at our suppliers due to local or national government quarantine restrictions on coming to the workplace.

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

- incur unplanned costs;
- be delayed in obtaining marketing approval for our product candidates;
- not obtain marketing approval at all;
- obtain marketing approval in some countries and not in others;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings;
- be subject to additional post-marketing testing requirements; or

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

We cannot be certain whether any of our planned clinical trials will begin on schedule or any preclinical studies we plan to initiate will begin on our intended schedule, or whether any such studies or clinical trials will need to be restructured or will be completed on schedule, or at all. If we experience delays in the completion of, or termination of, any clinical trial of our product candidates, or are unable to achieve clinical endpoints due to unforeseen events, such as the COVID-19 pandemic, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues. Significant clinical trial delays could also allow our competitors to bring products to market before we do or shorten any periods during which we have the exclusive right to commercialize our product candidates and impair our ability to commercialize our product candidates and may harm our business and results of operations.

Even if TP-03 or any other product candidate that we develop receives marketing approval, we may not be successful in educating ECPs and the market about the need for treatments specifically for Demodex blepharitis and other diseases or conditions targeted by our product candidates, and TP-03 or other product candidates that we may develop may fail to achieve market acceptance by ECPs, other healthcare providers and patients, or adequate formulary coverage, pricing or reimbursement by third-party payors and others in the medical community, and the market opportunity for these products may be smaller than we estimate.

If TP-03 or any other product candidate that we are developing or develop receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by ECPs or other healthcare providers, patients,third-party payors and others in the medical community. There is no approved prescription therapeutic for Demodex blepharitis and current treatments include over-the-counter and off-label remedies such as tea tree oil, lid wipes and artificial tears, as well as off-label prescription products. Efforts to educate the medical community, patients and third-party payors on the benefits of our product candidates may require significant resources and may not be successful.

Further, even if TP-03 demonstrates promising or superior clinical results and receives FDA or other regulatory marketing approval, including the treatment of both signs and symptoms of Demodex blepharitis, ECPs and potential patients may not have sufficient information about, or recognize the need for a treatment specifically targeting Demodex blepharitis, it is possible that ECPs may continue to rely on other treatments for treating symptoms consistent with Demodex blepharitis. A key tenant of our commercialization strategy is to educate ECPs on Demodex blepharitis and how to diagnose it with a simple slit lamp examination as well as raise patient awareness of Demodex blepharitis. However, our efforts may prove to be unsuccessful, and we may not be able to develop this new market for which there is no approved treatment. If TP-03 receives FDA or other regulatory marketing approval, we may still not achieve success in promotional efforts for TP-03, and ECPs may continue to use existing treatments rather than TP-03 or any other product candidate and potential patients may not inquire as to TP-03. It is also possible that ECPs and patients may not be willing to adopt TP-03 for the treatment of Demodex blepharitis because of the likelihood that the disease will recur despite mite eradication and the necessity for periodic use of TP-03.

In addition, if generic versions of any products that compete with any of our product candidates are approved for marketing by the FDA or comparable foreign regulatory authorities, they would likely be offered at a substantially lower price than we expect to offer for our product candidates, if approved. As a result, ECPs, patients and third-party payors may choose to rely on such products rather than our product candidates.

If TP-03 or any other product candidate that we develop does not achieve an adequate level of acceptance, formulary coverage, pricing or reimbursement we may not generate significant product revenues and we may not become profitable. The degree of market acceptance of TP-03 or any other product candidate that we develop, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy, safety and potential advantages of our product candidates compared to alternative treatments, including the existing standard of care, and the perceptions by members of the healthcare community of the same;
- our ability to offer our products for sale at competitive prices, particularly in light of the lower cost of alternative treatments;
- the clinical indications for which the product is approved;
- the convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of ECPs to prescribe these therapies;

- the strength and effectiveness of our marketing and distribution support, which may be adversely impacted by the COVID-19 pandemic;
- publicity concerning our products or competing products and treatments;
- the timing of market introduction of competitive products;
- the perception by patients or physicians that the diseases we are targeting, including Demodex blepharitis, are not burdensome;
- the potential for our competitors to limit our access to the market through anti-competitive contracts or other arrangements;
- the availability of third-party formulary coverage and adequate reimbursement;
- product labeling or product insert requirements of the FDA or other regulatory authorities;
- the prevalence and severity of any side effects; and
- any restrictions on the use of our products, if approved, together with other medications.

Our product candidates still require significant testing. We only recently began clinical trials to test TP-03 in humans and, as a company, we have limited experience in this area.

Most of our operations to date have been limited to preclinical studies and clinical trials. We have completed Phase 2 clinical trials for TP-03 for the treatment of Demodex blepharitis and have commenced our Phase 2b/3 clinical trial for the same indication, Saturn-1, for TP-03 in September 2020 and expect to initiate our Phase 3 clinical trial, Saturn-2, for TP-03 in 2021 and initiate clinical trials for our other product candidate in the future. As a result, we will need to expand our clinical operations, quality and regulatory capabilities to support these activities.

Additionally, we are early in our development efforts for certain of our product candidates and indications, including TP-03 for the treatment of MGD, TP-04 for the treatment of rosacea and TP-05 for potential Lyme prophylaxis and community malaria reduction. The risk of failure for product candidates in early development is high. Extensive clinical trials are necessary to demonstrate the safety and efficacy of such product candidates in humans. Clinical trials may fail to demonstrate that such product candidates are safe for humans and effective for indicated uses. Further, we intend to leverage data from the TP-03 preclinical studies and clinical safety assessments for the treatment of Demodex blepharitis to satisfy the preclinical study requirements for TP-04 and TP-05 and other indications. For MGD, we intend to rely on preclinical studies and clinical safety assessments from the Demodex blepharitis program. We have not conducted and do not intend to conduct any preclinical studies with TP-03 for the treatment of MGD in order to advance to Phase 2a. For our preservative-free formulation of Demodex blepharitis, we intend to leverage all preclinical, Phase 2 and Phase 3 data from TP-03 Demodex blepharitis program. We intend to conduct in vitro or in vivo bioequivalence studies with our preservative-free formulation to compare it to the current preserved formulation of TP-03 in Demodex blepharitis after NDA submission and file a supplement. For rosacea, we intend to leverage data from TP-03 preclinical studies and augment with additional preclinical studies to select formulation in order to advance to Phase 1/2. We have not conducted any preclinical studies in rosacea with TP-04 to date. In relation to Lyme disease and malaria, we intend to leverage data from our TP-03 preclinical studies for Demodex blepharitis as well as third-party preclinical studies for Lyme disease or malaria, respectively (and will not conduct our own preclinical studies for Lyme disease and malaria). Subject to FDA feedback, we intend to conduct Phase 1/2 trials in rosacea, Lyme disease and malaria based on these preclinical studies. In relation to malaria, we may conduct our Phase 1/2 trial outside the United States. The FDA may reject our use of data from TP-03 preclinical studies for the treatment of Demodex blepharitis for other indications or require additional studies to augment the data to advance for clinical development. The FDA may also reject our use of data from preclinical studies conducted by third parties for Lyme disease and malaria and require us to conduct additional preclinical studies before advancing to clinical trials. In addition, data from preclinical studies conducted by third parties may not be as reliable as data from studies conducted by us and since we did not conduct the studies, there may be weaknesses in the studies design or results that we may not be aware of.

In part because of our limited infrastructure, experience conducting clinical trials as a company and regulatory interactions, we cannot be certain that our clinical trials will be completed on time, that our planned clinical trials will be initiated on time, if at all, that our planned development programs would be acceptable to

the FDA or other comparable foreign regulatory authorities, or that, if approval is obtained, such product candidates can be successfully commercialized.

Our clinical trials to date have been small, and we may not be able to replicate our results from completed trials in Phase 3 trials.

Our clinical trials conducted to date, including for TP-03 for the treatment of Demodex blepharitis, have been small, each with fewer than 60 persons, and have advanced through Phase 1 and Phase 2. For example, the clinical trial which had the highest patient population to date was our Phase 2b Europa clinical trial, which enrolled 54 patients. Our Phase 2b/3 and Phase 3 clinical trials, Saturn-1 and Saturn-2, will be conducted with larger patient populations to evaluate TP-03 for the treatment of Demodex blepharitis, in which we expect to enroll at least 350 patients each. In these later trials, additional risks, including previously unidentified low incidence safety risks or lack of efficacy may materialize. Adverse or inconclusive results in these later clinical trials may, despite initially promising results, result in such product candidate not receiving requisite approvals for marketing and sale, and there is a risk that additional clinical trials will be required to obtain such approvals or that our clinical development program will be required to be altered, which would result in increased costs, significant delays to filing with regulatory authorities, filing for a narrower indication than previously anticipated or the abandonment of efforts to commercialization such product candidate.

If we encounter difficulties or delays enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the study until its conclusion. We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. The enrollment of patients depends on many factors, including:

- the patient eligibility criteria defined in the protocol;
- size of the patient population required for analysis of the trial's primary endpoints;
- the proximity of patients to study sites;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating;
- our ability to obtain and maintain patient consents;
- costs to, or lack of adequate compensation for, prospective patients;
- difficulties of enrolling patients or patients continuing to participate in follow-up visits due to the ongoing COVID-19 pandemic; and
- the risk that patients enrolled in clinical trials will drop out of the trials before completion.

In addition, our clinical trials may compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition would reduce the number and types of
patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials in such clinical trial site. Moreover, potential patients and their doctors may be inclined to use existing therapies rather than enroll patients in any future clinical trial.

Delays in patient enrollment may result in increased costs or may affect the timing or outcome of the planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our product candidates.

Our current or future product candidates may cause significant adverse events, toxicities or other undesirable side effects which may delay or prevent marketing approval or cause us to abandon or limit further clinical development of those product candidates. In addition, if we obtain approval for any of our product candidates, significant adverse events, toxicities or other undesirable side effects may be identified during post-marketing surveillance, which could result in regulatory action or negatively affect our ability to market the product.

Adverse events or other undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA, the European Commission or other comparable foreign regulatory authorities.

During the conduct of clinical trials, subjects report changes in their health, including illnesses, injuries, and discomforts, to their study doctor. Often, it is not possible to determine whether or not the product candidate being studied caused these conditions. It is possible that as we test our product candidates in larger, longer and more extensive clinical trials, or as use of these product candidates becomes more widespread if they receive regulatory approval, illnesses, injuries, discomforts and other adverse events that were not observed in earlier trials, as well as conditions that did not occur or went undetected in previous trials, will be reported by subjects. Many times, side effects are only detectable after investigational products are tested in large-scale, Phase 3 clinical trials or, in some cases, after they are made available to subjects on a commercial scale after approval.

The most commonly reported adverse events in TP-03 to date were mild transient ocular burning after administration for less than 10 seconds. One patient in the Europa clinical trial also reported mild burning and blurriness after administration that lasted the entire treatment period. Our understanding of the relationship between our product candidates and these adverse events may change as we gather more information, and additional unexpected adverse events or an increase in adverse event rates may occur. If additional clinical experience indicates that TP-03 or any other product candidate has side effects or causes serious or life-threatening side effects, participant recruitment for trials and the ability of enrolled subjects to complete trials could be negatively impacted, and the development of the product candidate may fail or be delayed, which would severely harm our business, prospects, operating results and financial condition.

Additionally, if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects or adverse events caused by such products, a number of potentially significant negative consequences could result, including, but not limited to:

- regulatory authorities may withdraw approvals of such product or 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;
- the product may be seized by regulatory authorities;
- there may be a recall of the product;
- we may be required to change the way the product is administered or conduct additional clinical trials or post-approval studies;
- we may be required to create and implement a Risk Evaluation and Mitigation Strategy ("REMS") plan, which could include a medication guide outlining the risks of such side effects for distribution to patients, a communication plan for healthcare providers, including ECPs, and/or other elements to assure safe use;
- the product may become less competitive;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer and there may be resulting harm to physician or patient acceptance of our product.

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

Any termination or suspension of, or delays in the commencement or completion of, our planned 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 in the United States for our product candidates, we must submit the results of preclinical testing and any previous clinical studies to the FDA along with other information, including information about product candidate chemistry, manufacturing and controls ("CMC") and our proposed clinical trial protocol, as part of an IND. The initiation of clinical trials in the European Union("EU") Member States will be subject to similar requirements concerning approval by competent national authorities and the receipt of a positive opinion from the relevant ethics committees. We do not know whether our planned trials will begin on time 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 or comparable foreign regulatory authorities placing the clinical trial on hold;
- subjects failing to enroll or remain in our trial at the rate we expect;
- subjects choosing an alternative treatment or other product candidates, or participating in competing clinical trials;
- lack of adequate funding to continue the clinical trial;
- subjects experiencing severe or unexpected drug-related adverse effects;
- failure to demonstrate efficacy of the product;
- any interruptions or delays in the supply of our product candidates for our clinical trials;
- a facility manufacturing any of our product candidates or any of their components being ordered by the FDA or comparable foreign regulatory authorities to temporarily or permanently shut down due to violations of good manufacturing practice ("cGMP") regulations or other applicable requirements, or infections or cross-contaminations of product candidates in the manufacturing process;
- any changes to our manufacturing process that may be necessary or desired;
- any failure or delay in reaching an agreement with CROs, vendors and clinical trial sites;
- 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 regulatory requirements or other third parties not performing data collection or analysis in a timely or accurate manner;
- third-party contractors becoming debarred, disqualified or suspended or otherwise penalized by the FDA or other comparable foreign regulatory authorities for violations of applicable 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;
- one or more Institutional Review Boards ("IRBs"), other ethics committees refusing to approve, suspending or terminating the trial at an investigational site, precluding enrollment of additional subjects, or withdrawing its approval of the trial; or
- changes in regulatory requirements and policies, which may require us to amend clinical trial protocols to comply with these changes and resubmit our clinical trial protocols to IRBs or ethics committees for reexamination.

For example, while we have received, in connection with our IND application, a "no-objection" letter from the FDA regarding the trial design for Saturn-1, the FDA may still require additional studies be conducted prior to submitting an NDA for TP-03. For instance, we will also need to perform a pharmacokinetic study for TP-03 to support our NDA submission for Demodex blepharitis and the FDA is recommending carcinogenicity testing for TP-03 as well as embryofetal development studies in a second species, any result of which, or any additional requests by the FDA, could cause delays in regulatory approval by the FDA. Any delays in completing our clinical trials will increase our costs, slow down our product candidate

development and approval process and jeopardize the commercial prospects of our product candidates and our ability to commence product sales and generate revenue.

In addition, many of the factors that cause, or lead to, termination or suspension of, or a delay in the commencement or completion of, clinical trials may also ultimately lead to the denial of regulatory approval of a product candidate. For example, if we make manufacturing or formulation changes to our product candidates, we may need to conduct additional studies to bridge our modified product candidates to earlier versions. Further, if one or more clinical trials are delayed, our competitors may be able to bring products to market before we do, and the commercial viability of our product candidates could be significantly reduced. Any of these occurrences may harm our business, financial condition and prospects significantly. Any termination of any clinical trial of our product candidates will harm our commercial prospects and our ability to generate revenue.

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to sell and market our product candidates on acceptable terms, we may be unable to successfully commercialize our product candidates that obtain regulatory approval.

We currently have a very limited marketing team and no sales team. In order to commercialize any product candidates, if approved, we must build marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services for each of the territories in which we may have approval to sell and market our product candidates. We may not be successful in accomplishing these required tasks.

Establishing an internal sales and marketing team with technical expertise and supporting distribution capabilities to commercialize our product candidates will be expensive and time-consuming, and will require significant attention of our executive officers to manage. Any failure or delay in the development of our internal
sales, marketing and distribution capabilities could adversely impact the commercialization of any of our product candidates that we obtain approval to market, if we do not have arrangements in place with third parties to provide such services on our behalf. Alternatively, if we choose to collaborate, either globally or on a territory-by-territory basis, with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems, we will be required to negotiate and enter into arrangements with such third parties relating to the proposed collaboration. If we are unable to enter into such arrangements when needed, on acceptable terms, or at all, we may not be able to successfully commercialize any of our product candidates that receive regulatory approval or any such commercialization may experience delays or limitations. If we are unable to successfully commercialize our approved product candidates, either on our own or through collaborations with one or more third parties, our future product revenue will suffer and we may incur significant additional losses.

The sizes of the market opportunities for our product candidates, particularly TP-03 for the treatment of Demodex blepharitis and for the treatment of MGD, have not been established with precision and may be smaller than we estimate, possibly materially. If our estimates of the sizes overestimate these markets, our sales growth may be adversely affected. We may also not be able to grow the markets for our product candidates as intended or at all.

Our assessment of the potential market opportunity for TP-03 and other product candidates that we develop is based on industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties and our own internal epidemiology and market research studies. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. While we believe these industry publications and third-party research, surveys and studies are reliable, we have not independently verified such data. Similarly, although the studies we have conducted are based on information that we believe to be complete and reliable, we cannot guarantee that such information is accurate or complete. The potential market opportunities for the treatment of Demodex blepharitis and for the treatment of MGD is difficult to precisely estimate, because patients often have multiple ocular surface diseases and the symptoms have significant overlap, leading to frequent misdiagnosis of the various conditions. Therefore, our estimates of the potential market opportunities for our product candidates include several key assumptions based on our industry knowledge, industry publications, third-party research and our own epidemiology studies and market research, which may be based on a small sample size and fail to accurately reflect market opportunities. While we believe that our internal assumptions and the bases of the studies and research we have conducted are reasonable, no independent source has verified such assumptions or bases. If any of our assumptions or estimates, or these publications, research, surveys or studies prove to be inaccurate, then the actual market for TP-03 or any of our other product candidates may be smaller than we expect, and as a result our product revenue may be limited and it may be more difficult for us to achieve or maintain profitability.

Due to the patients presenting at ECP clinics with multiple ocular surface diseases, there is overlap in market size estimates for blepharitis and MGD. Therefore, if TP-03 receives regulatory approval for the treatment of Demodex blepharitis

and MGD, our opportunity could be less than our forecasts because the actual market for TP-03 might be significantly smaller than our estimates.

The market for blepharitis and Demodex blepharitis may be not be similar to the market for dry eye.

The markets for blepharitis and Demodex blepharitis may prove to be materially different from the dry eye market that grew significantly once there was an approved product. Even if we obtain approval for TP-03 for the treatment of Demodex blepharitis and commercialize TP-03 in this indication, we may not be able to expand the market for Demodex blepharitis materially or at all or increase awareness of Demodex blepharitis to an extent similar to the dry eye market expansion induced by the commercial dry eye product or at all. Our inability to grow the market in a similar way to the dry eye market may occur due to differences in the underlying diseases, different ECP or patient attitudes towards the diseases, symptoms or treatment, changes over time in attitudes towards direct to patient marketing, different reimbursement and coverage, differences in company strategy, marketing or operations and differences in key assumptions which we have not taken into account in our analysis. Additionally, there may be differences in symptoms, regulatory approval and market dynamics. Dry eye had numerous over-the-counter options that reinforced the disease and promoted disease management. Further, patient awareness for dry eye may have been higher due to the various over-the-counter options for dry eye, which do not exist to such a degree for Demodex blepharitis.

We may not be able to demonstrate the safety and efficacy of TP-03, TP-04 and TP-05 in the indications we are pursuing even though the API underlying such product candidates is safe and effective in animals.

TP-03, TP-04 and TP-05 are presentations of lotilaner, the API, formulated into an eye drop, topical cream and oral formulation, respectively. Lotilaner, which is designed to paralyze and eradicate mites and other parasites through the inhibition of parasite-specific GABA-Cl channels, has been found to be safe and effective in animals. However, despite being safe and effective in animals, we may not be able to demonstrate that TP-03, TP-04 and TP-05 are safe and effective for human use in the indications we are pursuing for these product candidates. This may be in part because the requirements and regulations applicable to approval of a product candidate for human use are significantly more stringent than for animals and that there may be other ocular or other relevant differences between animals and humans.

We face significant competition, and if our competitors develop and market technologies or products more rapidly than we do or that are more effective, safer or less expensive than the product candidates we develop, our commercial opportunities will be negatively impacted. Our product candidates will, if approved, also compete with existing branded, generic and off-label products.

The development and commercialization of new drug products is highly competitive. We face competition with respect to our product candidates that we may seek to develop or commercialize in the future, from many different sources, including major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide and existing treatments. 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.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than our products. Our competitors also may obtain FDA approval or other regulatory authority approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market.

In addition, our ability to compete may be affected in many cases by insurers or other third-party payors, particularly Medicare and the competent authorities of the individual EU Member States, seeking to encourage the use of generic products. Generic products are currently being used for certain of the indications that we are pursuing, and additional products are expected to become available on a generic basis over the coming years.

Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in

recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Additionally, while there are no currently available on-label prescription pharmaceutical treatments available for the treatment of blepharitis or Demodex blepharitis specifically, a number of other treatments are currently available for the treatment of blepharitis in the United States. Current treatments for blepharitis in the United States include over the counter remedies such as tea tree oil, lid wipes and artificial tears, as well as off-label prescription products. If ECPs were to continue to prescribe these other existing treatments instead of TP-03, our business would be adversely affected.

Product liability lawsuits against us could cause us to incur substantial liabilities, could divert our resources and could limit or delay our commercialization of any product candidates that we may develop.

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and will face an even greater risk if we commercially sell any products that we may develop. While we currently have no products that have been approved for commercial sale, the use of product candidates by us in clinical trials, and the sale of any approved products in the future, may expose us to liability claims. These claims might be made by patients that use the product, healthcare providers, pharmaceutical companies or others selling such products. On occasion, large judgments have been awarded in class action lawsuits based on products that had unanticipated adverse effects. If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, product liability claims may result in:

- delay, variation or termination of clinical trials;
- decreased demand for any product candidates or products that we may develop;
- withdrawal of regulatory approval, recall, restriction on the approval or a “black box” warning or contraindication for an approved drug;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial subjects;
- initiation of investigations by regulators;
- significant costs to defend the related litigation and diversion of management’s time and our resources;
- substantial monetary awards to study subjects or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue; and
- the inability or delay of our efforts to commercialize any products that we may develop.

Although we maintain product liability insurance coverage, it may not be adequate to cover all liabilities that we may incur. We anticipate that we will need to increase our insurance coverage as our product candidates advance through clinical trials and if we successfully commercialize any products. Insurance coverage is increasingly expensive, thus 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. If a successful clinical trial or product liability claim or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, our assets may not be sufficient to cover such claims and our business operations could be impaired.

Even if we obtain FDA approval of any of our product candidates, we may never obtain approval or authorization or commercialize such products outside of the United States, which would limit our ability to realize their full market potential.

In order to market any products outside of the United States, we will need to comply with additional onerous but varying regulatory requirements of other countries regarding safety and efficacy. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval procedures vary among countries and can involve

additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approvals could result in significant delays, difficulties and costs for us and may require additional preclinical studies or clinical trials which would be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. Satisfying these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. In addition, our failure to obtain regulatory approval in any country may delay or have negative effects on the process for regulatory approval in other countries. We do not have any product candidates approved for sale in any jurisdiction, including international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, our ability to realize the full market potential of our products will be harmed.

Our future growth may depend, in part, on our ability to penetrate foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties.

Our future profitability may depend, in part, on our ability to commercialize our product candidates in foreign markets for which we may rely on collaboration with third parties. We are evaluating the opportunities for the development and commercialization of our product candidates in foreign markets. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the applicable regulatory authority in that foreign market, and we may never receive such regulatory approval for any of our product candidates. To obtain separate regulatory approvals in other countries we may be required to comply with numerous and varying regulatory requirements of such countries regarding the safety and efficacy of our product candidates and governing, among other things, clinical trials and commercial sales, pricing and distribution of our product candidates, and we cannot predict success in these jurisdictions. If we obtain approval of our product candidates and ultimately commercialize our product candidates in foreign markets, we would be subject to additional risks and uncertainties, including:

- our customers' ability to obtain reimbursement for our product candidates in foreign markets;
- our inability to directly control commercial activities if we are relying on third parties;
- the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements;
- different medical practices and customs in foreign countries affecting acceptance in the marketplace;
- import or export licensing requirements;
- longer accounts receivable collection times;
- longer lead times for shipping;
- language barriers for technical training and the need for language translations;
- reduced protection of intellectual property rights in some foreign countries;
- the existence of additional potentially relevant third-party intellectual property rights;
- foreign currency exchange rate fluctuations; and
- the interpretation of contractual provisions governed by foreign laws in the event of a contract dispute.

Foreign sales of our product candidates could also be adversely affected by the imposition of governmental controls, political and economic instability, trade restrictions and changes in tariffs. In some countries, particularly the countries in Europe, 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 drug. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed, possibly materially.

We have conducted all of our completed clinical trials for our product candidates at sites outside the United States, and the FDA may not accept data from trials conducted in such locations.

We have conducted all of our clinical trials outside the United States, including our Phase 2 clinical trials for the treatment of Demodex blepharitis which were conducted in Mexico City, Mexico, at a well-established site for ocular therapy trials. We may in the future choose to conduct other clinical trials outside the United States. Since we have yet to complete any clinical trials in the United States, it is possible that we may not be able to replicate the efficacy and safety results of our completed Phase 2 trials in the United States. We expect that the FDA will primarily consider the efficacy results of our Saturn-1 and Saturn-2 trials in addition to safety data from all human trials, our preclinical studies data as well as preclinical data for lotilaner in support of our potential NDA submission for TP-03 for the treatment of Demodex blepharitis.

Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of this data is subject to conditions imposed by the FDA. For example, the clinical trial must be well designed and conducted and be performed by qualified investigators in accordance with ethical principles. The trial population must also adequately represent the U.S. population, and the data must be applicable to the U.S. population and U.S. medical practice in ways that the FDA deems clinically meaningful. In addition, while these clinical trials are subject to the applicable local laws, FDA acceptance of the data will depend on its determination that the trials also complied with all applicable U.S. laws and regulations. There can be no assurance the FDA will accept data from clinical trials conducted outside of the United States. There can also be no assurance that the comparable foreign regulatory authority in any jurisdiction in which we seek regulatory approval for our product candidates will accept data from clinical trials conducted outside such jurisdiction. If the FDA or any such foreign regulatory authority does not accept the data from any trial that we have conducted outside the United States, it would likely result in the need for additional trials, which would be costly and time-consuming and could delay or permanently halt our development of the applicable product candidates.

In addition, there are risks inherent in conducting clinical trials in multiple jurisdictions, inside and outside of the United States and if return to conduct trials outside of the United States, we may face risks, such as:

- regulatory and administrative requirements of the jurisdiction where the trial is conducted that could burden or limit our ability to conduct our clinical trials;
- foreign exchange rate fluctuations;
- manufacturing, customs, shipment and storage requirements;
- cultural differences in medical practice and clinical research;
- diminished protection of intellectual property in some countries;
- different cultural attitudes to self-reported adverse events (such as burning, stinging, blurry vision) leading to a different safety profile; and
- the risk that the patient populations in such trials are not considered representative as compared to the patient population in the target markets where approval is being sought.

Even if we obtain regulatory approval with respect to TP-03 for Demodex blepharitis, we may not be able to obtain regulatory approval for additional indications, such as MGD, or we may be required to conduct additional trials, which would limit our ability to realize the full market potential of TP-03 or increase the costs of developing TP-03 for MGD.

If we obtain regulatory approval with respect to TP-03 for the treatment of Demodex blepharitis, we intend explore the therapeutic potential for TP-03 in MGD as an additional indication. If we are successful, the indication for use of TP-03 could potentially be broadened beyond the treatment of Demodex blepharitis to include MGD as an additional indication. However, there can be no assurance that, even if we obtain approval for Demodex blepharitis, we will obtain approval for any other indication, including MGD or for any broadened indication beyond the treatment of Demodex blepharitis. If we fail to obtain and maintain required approvals for these additional or broadened indications, or if regulatory approvals are delayed, we will not realize the full market potential of TP-03. Additionally, the FDA or other comparable foreign regulatory authority may require us to conduct additional clinical trials before seeking regulatory approval. For example, we intend to rely on preclinical studies we have conducted with TP-03 for Demodex blepharitis instead of conducting preclinical studies for MGD. The FDA may not approve of this approach and may require us to conduct preclinical studies with TP-03 in MGD, which may delay our expected timelines for approval and increase costs. If we were required to conduct additional clinical trials, our costs for developing TP-03 for treating MGD would be substantially higher and the timing of any regulatory approval, if any, would be substantially extended, which could adverse effect our results of operations.

Changes in methods of product candidate manufacturing or formulation may result in additional costs or delay.

As product candidates proceed through pre-clinical studies to late-stage clinical trials towards potential approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials. Such changes may also require additional testing, FDA notification or FDA approval. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and jeopardize our ability to commence sales and generate revenue. For example, we intend to develop a preservative-free formulation for TP-03, which we expect to be completed after the submission of the NDA for Demodex blepharitis and used for commercialization. We intend to initiate preclinical equivalence studies with this preservative-free formulation after the NDA submission of the current formulation of TP-03 for Demodex blepharitis. However, there can be no assurance that the FDA will not require us to conduct studies or trials in addition to these preclinical equivalence studies, which would mean additional costs and potentially delays in our approval of TP-03 for the treatment of Demodex blepharitis.

Managing our obligations under our in-license agreements and other strategic agreements may divert management time and attention, causing delays or disruptions to our business.

We have entered into two license agreements with Elanco: (i) an agreement granting us a worldwide, sublicensable license for the development and marketing of lotilaner for the treatment or cure of any eye or skin condition in humans,as amended("Eye and Derm Elanco Agreement") and (ii) the All Human Uses Elanco Agreement, and may in the future enter into in-license agreements with multiple licensors and strategic agreements, which, subject us to various obligations, including diligence obligations, reporting and notification obligations, payment obligations for achievement of certain milestone as well as other material obligations. We may need to devote substantial time and attention to ensuring that we successfully integrate these transactions into our existing operations and are compliant with our obligations under these agreements, which may divert management's time and attention away from our research and development programs or other day-to-day activities.

Our in-license and strategic agreements are also complex and certain provisions in those agreements may be susceptible to multiple interpretations. In the event of any disagreement about the interpretation of these provisions, our management may need to devote a disproportionate amount of its attention to resolving these disagreements. Such disruptions may cause delays in our research and development programs and other business objectives.

Our operating activities may be restricted by certain covenants in our license and other strategic agreements, which could limit our development and commercial opportunities.

In connection with our in-license or other collaborations or strategic alliances, we may agree to and be bound by negative covenants which may limit our development and commercial opportunities. For example, pursuant to the Eye and Derm Elanco Agreement and the All Human Uses Elanco Agreement, we made certain covenants to only engage with third party suppliers previously approved by Elanco, and only under certain circumstances. These provisions may inhibit our development efforts, prevent us from forming strategic collaborations to develop and potentially commercialize any other product candidates and may materially harm our business, financial condition, results of operations and prospects.

We may expend our limited resources to pursue TP-03 for the treatment of Demodex blepharitis and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we must prioritize our research programs and will need to focus our product candidates on the potential treatment of certain indications. We are currently focused on the development and commercialization, if approved, of TP-03 for the treatment of Demodex blepharitis. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on the most viable commercial products or profitable market opportunities. Our spending on current and future research and development programs for TP-03 for the treatment of Demodex blepharitis may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for TP-03, we may also relinquish valuable rights to that product 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 product candidate.

Even if we obtain regulatory approvals for any product candidates we develop, the terms of approvals and ongoing regulation of our products could require substantial expenditure of resources and may limit how we manufacture and market our products, which could materially impair our ability to generate revenue.

Any product candidate for which we obtain regulatory 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, the EMA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, cGMP requirements relating to quality control, quality assurance and corresponding maintenance of records and documents, and requirements regarding the distribution of samples to physicians and recordkeeping. Even if regulatory approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product.

Accordingly, assuming we receive regulatory approval for one or more product candidates we develop, 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 regulatory 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. Further, the cost of compliance with post-approval regulations may have a negative effect on our business, operating results, financial condition, and prospects.

Interim top-line and preliminary results from our clinical trials that we announce or publish from time to time may change as more participant data become available and are subject to audit and verification procedures, which could result in material changes in the final data.

From time to time, we may publish interim top-line or preliminary results from our clinical trials. Interim results from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as participant enrollment continues and more participant data become available. 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 evaluate all data. Preliminary or top-line results 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, interim and preliminary data should be viewed with caution until the final data are available. Adverse differences between preliminary or interim data and final data could be material and could significantly harm our reputation and business prospects and may cause the trading price of our common stock to fluctuate significantly.

Risks Related to Reliance on Third Parties

We 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 or fail to meet expected deadlines, our development programs may be delayed or subject to increased costs, each of which may have an adverse effect on our business and prospects.

We do not have the ability to independently conduct our clinical trials. We currently rely on third parties, such as CROs, clinical data management organizations, medical institutions and clinical investigators, to conduct our current and planned clinical trials of TP-03, TP-04 and TP-05 and other product candidates, and we expect to continue to rely upon third parties to conduct additional clinical trials of potential future product candidates. Third parties have a significant role in the conduct of our clinical trials and the subsequent collection and analysis of data. These third parties are not our employees, and except for remedies available to us under our agreements with such third party, we have limited ability to control the amount or timing of resources that any such third party will devote to our clinical trials. Some of these third parties may terminate their engagements with us at any time. If we need to enter into alternative arrangements with a third party, it would delay our development activities.

Our reliance on these third parties for such development activities will reduce our control over these activities but will not relieve us of our regulatory responsibilities. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with GCP standards, regulations for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. The EC also requires us to comply with similar standards. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs fail to comply with applicable GCP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, EC or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP or other applicable

regulations. In addition, our clinical trials must be conducted with product produced under current applicable cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the marketing approval process. We also are required to register certain ongoing clinical trials and post the results of certain completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

The third parties we rely on for these services may also have relationships with other entities, some of which may be our competitors. In addition, the operations of our CROs and other third-party service providers may be constrained or disrupted by the ongoing COVID-19 pandemic. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates.

If any of our relationships with these third parties terminate, we may not be able to enter into arrangements with alternative third parties or do so on commercially reasonable terms. Switching or adding additional CROs, investigators and other third parties involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays can occur, which could materially impact our ability to meet our desired clinical development timelines. The COVID-19 pandemic and government measures taken in response have also had a significant impact on many CROs. Although we plan to carefully manage our relationships with our CROs, investigators and other third parties, we may nonetheless encounter challenges or delays in the future, which could have a material and adverse impact on our business, financial condition and prospects.

In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA. 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 trial. 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 any product candidates.

We contract with third parties for the manufacture of our product candidates for preclinical studies, clinical trials and for eventual commercialization. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or compounds or that such supply will not be available to us at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We do not have any, and have no plans to acquire any, manufacturing facilities. We produce in our laboratory relatively small quantities of compounds for evaluation in our research programs. We rely, and expect to continue to rely, on third parties for the manufacture of our product candidates for preclinical and clinical testing, as well as for commercial manufacture if any of our product candidates are approved. We currently have limited manufacturing arrangements and expect that each of our product candidates will only be covered by single source suppliers for the foreseeable future. This reliance increases the risk that we will not have sufficient quantities of our product candidates or products, if approved, or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts.

Furthermore, all entities involved in the preparation of therapeutics for clinical trials or commercial sale, including our existing contract manufacturers for our product candidates, are subject to extensive regulation. Components of a finished therapeutic product approved for commercial sale or used in clinical trials must be manufactured in accordance with cGMP requirements. These regulations govern manufacturing processes and procedures, including record keeping, and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Poor control of production processes can lead to the introduction of contaminants, or to inadvertent changes in the properties or stability of our product candidates that may not be detectable in final product testing. We or our contract manufacturers must supply all necessary documentation in support of an NDA on a timely basis and must adhere to the FDA's Good Laboratory Practice regulations and cGMP regulations enforced by the FDA through its facilities inspection program. Foreign regulatory authorities, including the European Commission and the competent authorities of the EU Member States, may require compliance with similar requirements. The facilities and quality systems of our third-party contractor manufacturers must pass a pre-approval inspection for compliance with the applicable regulations as a condition of marketing approval of our product candidates. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with cGMP regulations.

In the event that any of our manufacturers fails to comply with such requirements or to perform its obligations to us in relation to quality, timing or otherwise, or if our supply of components or other materials becomes limited or interrupted for

other reasons, we may be forced to manufacture the materials ourselves, for which we currently do not have the capabilities or resources, or enter into an agreement with another third party, which we may not be able to do on commercially reasonable terms, if at all. In particular, any replacement of our manufacturers could require significant effort and expertise because there may be a limited number of qualified replacements. In some cases, the technical skills or technology required to manufacture our product candidates may be unique or proprietary to the original manufacturer and we may have difficulty transferring such skills or technology to another third party and a feasible alternative may not exist. These factors would increase our reliance on such manufacturer or require us to obtain a license from such manufacturer in order to have another third party manufacture our product candidates. If we elect to or are required to change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines. If any of our current contract manufacturers 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 product candidates, we may incur added costs and delays in identifying and qualifying any such replacement or be unable to reach agreement with an alternative manufacturer. In addition, the COVID-19 pandemic may impact our ability to procure sufficient supplies for the development of our product candidates. The extent of this impact will depend on the severity and duration of the spread of the virus, and the actions undertaken to contain COVID-19 or treat its effects. The delays associated with the verification of a new manufacturer could negatively affect our ability to develop product candidates in a timely manner or within budget.

Our or a third party's failure to execute on our manufacturing requirements, to do so on commercially reasonable terms and comply with cGMP could adversely affect our business in a number of ways, including:

- an inability to initiate or continue clinical trials of our product candidates under development;
- delay in submitting regulatory applications, or receiving marketing approvals, for our product candidates;
- loss of the cooperation of an existing or future collaborator, including by Elanco under the license agreements with Elanco;
- subjecting third-party manufacturing facilities or our manufacturing facilities to additional inspections by regulatory authorities;
- requirements to cease development or to recall batches of our product candidates; and
- in the event of approval to market and commercialize our product candidates, an inability to meet commercial demands for our product or any other future product candidates.

Our product candidates and any products that we may develop may compete with other product 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. Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval.

We or our third-party manufacturers may encounter shortages in the raw materials or active pharmaceutical ingredients necessary to produce our product candidates in the quantities needed for our clinical trials or, if our product candidates are approved, in sufficient quantities for commercialization or to meet an increase in demand, as a result of capacity constraints or delays or disruptions in the market for the raw materials or active pharmaceutical ingredients, including shortages caused by the purchase of such raw materials or active pharmaceutical ingredients by our competitors or others. The failure of us or our third-party manufacturers to obtain the raw materials or active pharmaceutical ingredients necessary to manufacture sufficient quantities of our product candidates, may have a material adverse effect on our business.

If any of our product candidates are approved for marketing and commercialization and we are unable to establish sales, marketing and distribution capabilities or enter into agreements with third parties to sell, market and distribute our product candidates, we will be unable to successfully commercialize our product candidates if and when they are approved.

We have no sales, marketing or distribution capabilities or experience. To achieve commercial success for any approved product for which we retain sales and marketing responsibilities, we must either develop a sales and marketing organization, which would be expensive and time consuming, or outsource these functions to other third parties, or use a hybrid model incorporating both of these approaches.

There are risks involved with both establishing our own sales and marketing capabilities and entering into arrangements with third parties to perform these services. 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 product 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. This may 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 medicines on our own include:

- our inability to recruit, train and retain adequate numbers of effective sales, marketing, coverage or reimbursement, customer service, medical affairs and other support personnel;
- our inability to equip sales personnel with effective materials, including medical and sales literature to help them educate ECPs regarding the indications we are targeting and our products, if approved;
- the inability of sales personnel to obtain access to ECPs or persuade adequate numbers of ECPs to prescribe any future medicines;
- the inability of reimbursement professionals to negotiate arrangements for formulary access, reimbursement and other acceptance by payors;
- the lack of complementary medicines to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines;
- the inability to price our products at a sufficient price point to ensure an adequate and attractive level of profitability; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

If we enter into arrangements with third parties to perform sales, marketing and distribution services, our product revenue or the profitability of these product revenue to us are likely to be lower than if we were to market and sell any medicines that we develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell and market our product candidates or may be unable to do so on terms that are favorable to us. In entering into third-party marketing or distribution arrangements, any revenue we receive will depend upon the efforts of the third parties and we cannot assure you that such third parties will establish adequate sales and distribution capabilities or devote the necessary resources and attention to sell and market our medicines 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 our product candidates.

We, or our third-party manufacturers, may be unable to successfully scale-up manufacturing of our product candidates in sufficient quality and quantity, which would delay or prevent us from conducting clinical trials and developing our product candidates.

In order to conduct clinical trials of our product candidates, we will need to manufacture them in large quantities. We, or our manufacturing partners, may be unable to successfully increase the manufacturing capacity for any of our product candidates in a timely or cost-effective manner, or at all. In addition, quality issues may arise during scale-up activities. If we, or our manufacturing partners, are unable to successfully scale up the manufacture of our product candidates in sufficient quality and quantity, the development, testing and clinical trials of that product candidate may be delayed or become infeasible, and marketing approval or commercial launch of any resulting product may be delayed or not obtained, which could significantly harm our business.

Changes in methods of product candidate manufacturing or formulation may result in additional costs or delay.

As product candidates progress through preclinical to late stage clinical trials to marketing approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize yield, manufacturing batch size, minimize costs and achieve consistent quality and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials. This could delay completion of clinical trials, require the conduct of bridging

clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and jeopardize our ability to commercialize our product candidates and generate revenue.

Risks Related to Intellectual Property

The development and commercialization of our products, including our lead product candidate, TP-03 for the potential treatment of Demodex blepharitis and MGD, TP-04 for the potential treatment of rosacea and TP-05 for potential Lyme prophylaxis and community malaria reduction, is dependent on intellectual property we license from Elanco. If we breach our agreements with Elanco or the agreements are terminated, we could lose license rights that are important to our business.

Pursuant to the Eye and Derm Elanco Agreement and the All Human Uses Elanco Agreement, each, an Elanco Agreement, we acquired exclusive, worldwide, sublicensable licenses to certain intellectual property of Elanco for the development, marketing and commercialization of lotilaner for (i) the treatment, prevention, palliation or cure of any eye or skin disease or condition in humans and (b) all other applications in humans, respectively. The Eye and Derm Elanco Agreement and the All Human Uses Elanco Agreement impose various development, regulatory, commercial diligence, financial and other obligations on us. If we fail to comply with our obligations under the Elanco Agreements, or otherwise materially breach either Elanco Agreement, and fail to remedy such failure or cure such breach within 60 days, Elanco will have the right to terminate the applicable Elanco Agreement. If we fail to meet any milestones by the achievement deadlines set forth in either Elanco Agreement for any reason other than those outside of our reasonable control, and such milestones remain unmet for 120 days after Elanco notifies us thereof, Elanco may terminate the applicable Elanco Agreement.

If we fail to meet certain dermatological milestones by the achievement deadlines set forth in the Eye and Derm Elanco Agreement for any reasons other than those outside of our reasonable control, and such milestones remain unmet for 120 days after Elanco notifies us thereof, Elanco may limit our field of use under the Eye and Derm Elanco Agreement to the treatment, palliation, prevention or cure of eye diseases or conditions in humans only. If either Elanco Agreement is terminated or if our field of use in the Eye and Derm Elanco Agreement is reduced to eye and skin conditions only by Elanco, we would lose our applicable license in the country where such license was terminated and all rights therein to the licensed intellectual property would revert to Elanco. The loss of the license from Elanco would prevent us from developing and commercializing TP-03, TP-04 and TP-05 in any country where the license is terminated and could subject us to claims of breach of contract and patent infringement by Elanco if any continued research, development, manufacture or commercialization of TP-03, TP-04 or TP-05 is covered by the affected patents. If Elanco terminates the Eye and Derm Elanco Agreement for our failure to achieve a development milestone by the specified achievement deadline, then we must grant Elanco a non-exclusive, sublicensable, royalty free license to our patents and know-how relating to lotilaner to develop, manufacture and commercialize lotilaner and any licensed products for the treatment, palliation, prevention or cure of any eye or skin disease or condition in humans. If Elanco terminates the All Human Uses Elanco Agreement for our failure to achieve a development milestone by the specified achievement deadline, then we must grant Elanco a non-exclusive, sublicensable, royalty free license to our patents and know-how relating to lotilaner to develop, manufacture and commercialize lotilaner and any licensed products for all applications in humans other than the treatment, palliation, prevention or cure of any eye or skin disease or condition. Accordingly, the loss of our license or the termination of our license for skin diseases and conditions or of our license for other use in humans with Elanco would materially harm our business.

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

We rely upon a combination of patents, trademarks, trade secret protection, and confidentiality agreements to protect the intellectual property related to our development programs and product candidates. Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to our product candidates and research programs. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our novel discoveries and technologies that are important to our business. Our pending and future patent applications may not result in patents being issued which protect our product candidates or their intended uses or which effectively prevent others from commercializing competitive technologies, products or product candidates.

Obtaining and enforcing patents is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications, or maintain and/or enforce patents that may issue based on our patent applications, at a reasonable cost or in a timely manner. Moreover, in some circumstances, we do not have the right to control the preparation, filing and prosecution of patent applications, or to maintain, enforce and defend the patents, covering technology that we license from third parties. It is also possible that we will fail to identify patentable aspects of our research and development results before it is too late to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with

parties who have access to patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, contract research organizations, contract manufacturers, consultants, advisors and other third parties, any of these parties may breach these agreements and disclose such results before a patent application is filed, thereby jeopardizing our ability to seek patent protection.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation, resulting in court decisions, including Supreme Court decisions, which have increased uncertainties as to the ability to enforce patent rights in the future. In addition, the scope of patent protection outside of the United States is uncertain and laws of foreign countries may not protect our rights to the same extent as the laws of the United States, or vice versa. For example, European patent law restricts the patentability of methods of treatment of the human body more than United States law does. With respect to both owned and in-licensed patent rights, we cannot predict whether the patent applications we and our licensors are currently pursuing or will pursue will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient protection from competitors.

Further, we may not be aware of all third-party intellectual property rights potentially relating to our product candidates or their intended uses, and as a result the impact of such third-party intellectual property rights upon the patentability of our own patents and patent applications, as well as the impact of such third-party intellectual property upon our ability to commercialize our products, is highly uncertain. Because we have not yet conducted a formal freedom to operate analysis for patents related to our product candidates, we may not be aware of issued patents that a third party might assert are infringed by one of our current or future product candidates, which could materially impair our ability to commercialize our product candidates. Even if we diligently search third-party patents for potential infringement by our products or product candidates, including TP-03, TP-04 or TP-05, we may not successfully find patents that our products or product candidates, including TP-03, TP-04 or TP-05, may infringe. If we are unable to secure and maintain freedom to operate, others could preclude us from commercializing our product candidates. In addition, 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 published at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our 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 U.S. Patent and Trademark Office, or become involved in post-grant review or interference procedures, oppositions, derivations, revocations, reexaminations, or inter partes review 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 product candidates and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize drugs without infringing third-party patent rights. If the breadth or strength of protection provided by our patents and patent applications is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Our owned and licensed patent estate includes patent applications, many of which are at an early stage of prosecution. The coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if our owned and in-licensed patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and in-licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated, or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. In addition, given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. Furthermore, our competitors may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner. As a result, our owned and in-licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing technology and products similar or identical to any of our technology and product candidates.

Furthermore, while we seek to protect the trademarks we use in the United States and in other countries, we may be unsuccessful in obtaining registrations and/or otherwise protecting these trademarks. If that were to happen, we may be prevented from using our names, brands and trademarks unless we enter into appropriate royalty, license or coexistence agreements, which may not be available or may not be available on commercially reasonable terms. Over the long term, if we are unable to establish name recognition based on our trademarks, trade names, service marks and domain names, then we may

not be able to compete effectively, resulting in a material adverse effect on our business. Our registered or unregistered trademarks or trade names may be challenged, infringed, diluted or declared generic, or determined to be infringing on other marks. We rely on both registration and common law protection for our trademarks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors may adopt trademarks and trade names similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. During trademark registration proceedings, we may receive rejections. Although we would be given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the United States Patent and Trademark Office ("USPTO") and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. Effective trademark protection may not be available or may not be sought in every country in which our products are made available. Any name we propose to use for our products in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA objects to any of our proposed product names, we may be required to expend significant additional resources in an effort to identify a usable substitute name that would qualify under applicable trademark laws, that does not infringe the existing rights of third parties and that is acceptable to the FDA. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected.

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

Periodic maintenance fees, renewal fees, annuities fees and various other governmental fees on patents and/or patent applications are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent and/or patent application. The USPTO and various foreign governmental patent agencies also require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In certain circumstances, we rely on our licensing partners to pay these fees to, or comply with the procedural and documentary rules of, the relevant patent agency While an inadvertent lapse can in many cases 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 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, potential competitors might be able to enter the market with similar or identical products or technology. If we or our licensors fail to maintain the patents and patent applications relating to our product candidates, our competitive position, business, financial condition, results of operations and prospects would be adversely affected.

We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent which might adversely affect our ability to develop and market our products.

We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third party patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction. Because we have not yet conducted a formal freedom to operate analysis for patents related to our product candidates, we may not be aware of issued patents that a third party might assert are infringed by one of our current or future product candidates, which could materially impair our ability to commercialize our product candidates. Even if we diligently search third-party patents for potential infringement by our products or product candidates, we may not successfully find patents that our products or product candidates may infringe. If we are unable to secure and maintain freedom to operate, others could preclude us from commercializing our product candidates.

The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our products. We may incorrectly determine that our products are not covered by a third-party patent or may incorrectly predict whether a third party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our product candidates. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our products.

We may wish to acquire rights to future assets through in-licensing or may attempt to form collaborations in the future with respect to our product candidates, but may not be able to do so, which may cause us to alter or delay our development and commercialization plans.

The development and potential commercialization of our product candidates will require substantial additional capital to fund expenses. We have entered into the Eye and Derm Elanco Agreement and the All Human Uses Elanco Agreement. We plan to utilize these license rights in developing and marketing our TP-03,TP-04 and TP-05 product candidates. We may, in the future, decide to collaborate with other biopharmaceutical companies for the development and potential commercialization of those product candidates. We will face significant competition in seeking appropriate collaborators. We may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view our product candidates as having the requisite potential to demonstrate safety and efficacy. If and when we collaborate with a third party for development and commercialization of a product candidate, we can expect to relinquish some or all of the control over the future success of that product candidate to the third party. 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. Those factors may include the following:

- the design or results of clinical trials;
- the likelihood of approval by the FDA or comparable foreign regulatory authorities;
- the potential market for the product candidate;
- the costs and complexities of manufacturing and delivering such product candidate to patients;
- the potential of competing products;
- the existence of uncertainty with respect to our ownership of technology or other rights, which can exist if there is a challenge to such ownership without regard to the merits of the challenge; and
- industry and market conditions generally.

The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. We may also be restricted under any license agreements from entering into agreements on certain terms or at all with potential collaborators. Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators and changes to the strategies of the combined company. As a result, we may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of such product candidate, reduce or delay one or more of our other development programs, delay the potential commercialization or reduce the scope of any planned sales or marketing activities for such product candidate, or increase our expenditures and undertake development, manufacturing or commercialization activities at our own expense. If we elect to increase our expenditures to fund development, manufacturing or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue.

Collaborations that we enter into may not be successful, and any success will depend heavily on the efforts and activities of such collaborators. Collaborations pose a number of risks, including the following:

- collaborators have significant discretion in determining the amount and timing of efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected;
- collaborators may not pursue development of our product candidates or may elect not to continue or renew development programs based on results of clinical trials or other studies, changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition or business combination, that divert resources or create competing priorities;

- collaborators may not pursue commercialization of any product candidates that achieve marketing approval or may elect not to continue or renew commercialization programs based on results of clinical trials or other studies, changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition or business combination, that may divert resources or create competing priorities;

- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;

- we may not have access to, or may be restricted from disclosing, certain information regarding product candidates being developed or commercialized under a collaboration and, consequently, may have limited ability to inform our stockholders about the status of such product candidates on a discretionary basis;

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

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

- a collaborator may fail to comply with applicable regulatory requirements regarding the development, manufacture, distribution or marketing of a product candidate or product;

- a collaborator may seek to renegotiate or terminate their relationship with us due to unsatisfactory clinical results, manufacturing issues, a change in business strategy, a change of control or other reasons;

- a collaborator with marketing and distribution rights to one or more of our product candidates that achieve marketing approval may not commit sufficient resources to the marketing and distribution of such product or products;

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

- collaborators may not properly obtain, maintain, enforce, defend or protect our intellectual property or proprietary rights or may use our proprietary information in such a way as to potentially lead to disputes or legal proceedings that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;

- disputes may arise with respect to the ownership of intellectual property developed pursuant to our collaborations;

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

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

Collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner, or at all. If any collaborations that we enter into do not result in the successful development and commercialization of products or if one of our collaborators terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under the collaboration. If we do not receive the funding we expect under these agreements, our development of our product candidates could be delayed and we may need additional resources to develop our product candidates. All of the risks relating to product development, regulatory approval and commercialization described in this report also apply to the activities of our collaborators.

In the future, we may need to obtain additional licenses of third-party technology that may not be available to us or are available only on commercially unreasonable terms or we may fail to comply with our obligations under such agreements and our business could be harmed.

In addition to the Eye and Derm Elanco Agreement and the All Human Uses Elanco Agreement, from time to time we may be required to license technology from additional third parties to further develop or commercialize our product candidates. Should we be required to obtain licenses to any third-party technology, including any such patents required to manufacture, use or sell our product candidates, such licenses may not be available to us on commercially reasonable terms, or at all.

If we are unable to license such technology, or if we are forced to license such technology on unfavorable terms, our business could be materially harmed. If we are unable to obtain a necessary license, we may be unable to develop or commercialize the affected product candidates, which could materially harm our business and the third parties owning such intellectual property rights could seek either an injunction prohibiting our sales or an obligation on our part to pay royalties and/or other forms of compensation. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us.

If we are unable to obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may be required to expend significant time and resources to redesign our technology, product candidates, or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected technology and product candidates, which could harm our business, financial condition, results of operations and prospects significantly.

Additionally, if we fail to comply with our obligations under any license agreements, our counterparties may have the right to terminate these agreements, in which event we might not be able to develop, manufacture or market, or may be forced to cease developing, manufacturing or marketing, any product that is covered by these agreements or may face other penalties under such agreements. Such an occurrence could materially adversely affect the value of the product candidate being developed under any such agreement. Termination of these agreements or reduction or elimination of our rights under these agreements, or restrictions on our ability to freely assign or sublicense our rights under such agreements when it is in the interest of our business to do so, may result in our having to negotiate new or reinstated agreements with less favorable terms, cause us to lose our rights under these agreements, including our rights to important intellectual property or technology or impede, or delay or prohibit the further development or commercialization of one or more product candidates that rely on such agreements.

If we enter into in-bound intellectual property license agreements, we may not be able to fully protect the licensed intellectual property rights or maintain those licenses. In each of the Eye and Derm Elanco Agreement and the All Human Uses Elanco Agreement, Elanco retains, and future licensors could retain, the right to prosecute and defend the intellectual property rights licensed to us, in which case we would depend on the ability of our licensors to obtain, maintain and enforce such licensed intellectual property. These licensors may determine not to pursue litigation against other companies or may pursue such litigation less aggressively than we would. If our licensors do not adequately protect such licensed intellectual property, competitors may be able to use such intellectual property and erode or negate any competitive advantage we may have, which could materially harm our business, negatively affect our position in the marketplace, limit our ability to commercialize our products and product candidates and delay or render impossible our achievement of profitability. Further, entering into such license agreements could impose various diligence, commercialization, royalty or other obligations on us. Future licensors may allege that we have breached our license agreement with them, and accordingly seek to terminate our license, which could adversely affect our competitive business position and harm our business prospects.

In addition to the above risks, intellectual property rights that we license in the future may include sublicenses under intellectual property owned by third parties, in some cases through multiple tiers. The actions of our licensors may therefore affect our rights to use our sublicensed intellectual property, even if we are in compliance with all of the obligations under our license agreements. Should our licensors or any of the upstream licensors fail to comply with their obligations under the agreements pursuant to which they obtain the rights that are sublicensed to us, or should such agreements be terminated or amended, our ability to develop and commercialize our product candidates may be materially harmed.

Disputes may arise regarding intellectual property subject to a licensing agreement, including:

- the scope of rights granted under the license agreement and other interpretation related issues;

- the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

In addition, the agreements under which we currently license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected technology and product candidates, which could have a material adverse effect on our business, financial conditions, results of operations and prospects.

We cannot ensure that patent rights relating to inventions described and claimed in our pending patent applications will issue or that our patents or patents based on our patent applications will not be challenged and rendered invalid and/or unenforceable.

We have pending U.S. and foreign patent applications in our portfolio, however, we cannot predict:

- if and when patents may issue based on our patent applications;
- the scope of protection of any patent issuing based on our patent applications;
- whether the claims of any patent issuing based on our patent applications will provide protection against competitors;
- whether or not third parties will find ways to invalidate or circumvent our patent rights;
- whether or not others will obtain patents claiming aspects similar to those covered by our patents and patent applications;
- whether we will need to initiate litigation or administrative proceedings to enforce and/or defend our patent rights which will be costly whether we win or lose; and/or
- whether the patent applications that we own or in-license will result in issued patents with claims that cover our product candidates or uses thereof in the United States or in other foreign countries.

We cannot be certain that the claims in our pending patent applications directed to our product candidates and/or technologies will be considered patentable by the USPTO or by patent offices in foreign countries. One aspect of the determination of patentability of our inventions depends on the scope and content of the “prior art,” information that was or is deemed available to a person of skill in the relevant art prior to the priority date of the claimed invention. There may be prior art of which we are not aware that may affect the patentability of our patent claims or, if issued, affect the validity or enforceability of a patent claim. Even if the patents do issue based on our patent applications, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. Furthermore, even if they are unchallenged, patents in our portfolio may not adequately exclude third parties from practicing relevant technology or prevent others from designing around our claims. If the breadth or strength of our intellectual property position with respect to our product candidates is threatened, it could dissuade companies from collaborating with us to develop and threaten our ability to commercialize our product candidates. In the event of litigation or administrative proceedings, we

cannot be certain that the claims in any of our issued patents will be considered valid by courts in the United States or foreign countries.

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

Our commercial success depends, in part, on our ability to develop, manufacture, market and sell our product candidates without infringing, misappropriating or otherwise violating the intellectual property and other proprietary rights of third parties. Third parties may allege that we have infringed or misappropriated their intellectual property. Litigation or other legal proceedings relating to intellectual property claims, with or without merit, are unpredictable and generally expensive and time consuming and, even if resolved in our favor, are likely to divert significant resources from our core business, including distracting our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the market price of our common stock.

Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

There is a substantial amount of intellectual property litigation in the biotechnology and biopharmaceutical industries, and we may become party to, or threatened with, litigation or other adversarial proceedings regarding intellectual property rights with respect to our product candidates. Third parties may assert infringement claims against us based on existing or future intellectual property rights, regardless of merit. 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 are directed to various types of products or methods of use. As the pharmaceutical and biotechnology industries expand and more patents are issued, the risk increases that our technologies or product candidates that we may identify may be subject to claims of infringement of the patent rights of third parties. The scope of patents is subject to interpretation by the courts, and the interpretation is not always uniform. The legal threshold for initiating litigation or contested proceedings is low, so even lawsuits or proceedings with a low probability of success might be initiated and require significant resources to defend. If we were sued for patent infringement, we would need to demonstrate that our product candidates, products or methods 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 able to do this. Proving invalidity may be difficult. For example, in the United States, proving invalidity in court requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if we are successful in these proceedings, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted in pursuing these proceedings, which could have a material adverse effect on our business and operations. In addition, we may not have sufficient resources to bring these actions to a successful conclusion.

If we are found to infringe a third party's intellectual property rights, we could be forced, including by court order, to cease developing, manufacturing or commercializing the infringing product 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 product 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 a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us and could require us to make substantial licensing and royalty payments. We could be forced, including by court order, to cease developing, manufacturing and commercializing the infringing technology or product. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business, financial condition, results of operations and prospects.

If we do not obtain patent term extension for any product candidates we may develop, our business may be materially harmed.

In the United States, the term of a patent that covers an FDA-approved drug may be eligible for limited patent term extension, which permits patent term restoration as compensation for the patent term lost during the FDA regulatory review

process. The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, permits a patent term extension of up to five years beyond the expiration of the patent. The length of the patent term extension is related to the length of time the drug is under regulatory review. Patent extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, and only one patent applicable to an approved drug may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. Similar provisions are available in Europe and certain other non-United States jurisdictions to extend the term of a patent that covers an approved drug. While, in the future, if and when our product candidates receive FDA approval, we expect to apply for patent term extensions on patents covering those product candidates, there is no guarantee that the applicable authorities will agree with our assessment of whether such extensions should be granted, and even if granted, the length of such extensions. We may not be granted patent term extension either in the United States or in any foreign country 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. Moreover, the term of extension, as well as the scope of patent protection during any such extension, afforded by the governmental authority could be less than we request. If we are unable to obtain any patent term extension or the term of any such extension is less than we request, our competitors may obtain approval of competing products following the expiration of our patent rights, and our business, financial condition, results of operations and prospects could be materially harmed.

Our internal information technology systems, or those of our third-party CROs or other 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 product candidates' 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 contractors 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 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, 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 lead to data leakage. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and reputational damage and the further development and commercialization of our drug candidates could be delayed.

While we have not experienced any such system failure, accident or security breach to date, 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 other cyber incidents that could have a material adverse effect upon our reputation, business, operations or financial condition, whether due to a loss of our trade secrets or other proprietary information or other similar disruptions. For example, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our programs and the development of our product candidates could be delayed. In addition, the loss of clinical trial data for our product 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 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, including private lawsuits or class actions under the California Consumer Privacy Act, which could result in significant legal and financial exposure and reputational damages that could potentially have an adverse effect on our business.

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

Competitors may infringe, misappropriate or otherwise violate our patents, trademarks, copyrights or other intellectual property. It may be difficult to detect infringers who do not advertise the components that are used in their products. Moreover, it may be difficult or impossible to obtain evidence of infringement in a competitor's or potential competitor's product. To counter infringement or unauthorized use, we may be required to file infringement or other intellectual property-related claims, which can be expensive and time consuming and divert the time and attention of our management and scientific personnel. 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. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents, in addition to counterclaims asserting that our patents are invalid or unenforceable, or both. 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 making, using, or selling the invention at issue. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties may institute such claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post-grant review, *inter partes* review, interference proceedings, derivation proceedings, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). The outcome following legal assertions of invalidity and unenforceability is unpredictable. 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 making, using or selling 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, using and selling similar or competitive products. 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, which could materially harm our business and negatively affect our position in the marketplace.

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 also could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of shares of our common stock. Moreover, we cannot assure you 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.

Because of the expense and uncertainty of litigation, we may not be in a position to enforce our intellectual property rights against third parties.

Because of the expense and uncertainty of litigation, we may conclude that even if a third party is infringing our issued patent, any patents that may be issued as a result of our pending or future patent applications or other intellectual property rights, the risk-adjusted cost of bringing and enforcing such a claim or action may be too high or not in the best interest of our company or our stockholders. In such cases, we may decide that the more prudent course of action is to simply monitor the situation or initiate or seek some other non-litigious action or solution.

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

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical 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. Recent patent reform legislation in the United States and other countries, including the Leahy-Smith America Invents Act ("Leahy-Smith Act") signed into law on September

16, 2011, could increase those uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. 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. These include allowing 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. After March 2013, under the Leahy-Smith Act, the United States transitioned to a first inventor to file system in which, assuming that the other statutory requirements 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. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

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. 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 would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

The United States federal government retains certain rights in inventions produced with its financial assistance under the Bayh-Dole Act. The federal government retains a “nonexclusive, nontransferable, irrevocable, paid-up license” for its own benefit. The Bayh-Dole Act also provides federal agencies with “march-in rights”. March-in rights allow the government, in specified circumstances, to require the contractor or successors in title to the patent to grant a “nonexclusive, partially exclusive, or exclusive license” to a “responsible applicant or applicants.” If the patent owner refuses to do so, the government may grant the license itself. If, in the future, we co-own or license in technology which is critical to our business that is developed in whole or in part with federal funds subject to the Bayh-Dole Act, our ability to enforce or otherwise exploit patents covering such technology may be adversely affected.

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

Patents are of national or regional effect, and filing, prosecuting and defending patents on all of our product candidates 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. As such, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Further, the legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to pharmaceuticals or biologics, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. In addition, certain jurisdictions do not protect to the same extent or at all inventions that constitute new methods of treatment. As such, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Furthermore, certain foreign and developing countries, including China and India, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, we and our licensors may have limited remedies if patents are infringed or if we or our licensors are compelled to grant a license to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

We may rely on trade secret and proprietary know how which can be difficult to trace and enforce, and if we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking patents for some of our technology and product candidates, we may also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. Elements of our product candidate, including processes for their preparation and manufacture, may involve proprietary know-how, information, or technology that is not covered by patents, and thus for these aspects we may consider trade secrets and know-how to be our primary intellectual property. Any disclosure, either intentional or unintentional, by our employees, the employees of third parties with whom we share our facilities or third party consultants and vendors that we engage to perform research, clinical trials or manufacturing activities, or misappropriation by third parties (such as through a cybersecurity breach) of our trade secrets or proprietary information could enable competitors to duplicate or surpass our technological achievements, thus eroding our competitive position in our market.

Trade secrets and know-how can be difficult to protect. We require our employees to enter into written employment agreements containing provisions of confidentiality and obligations to assign to us any inventions generated in the course of their employment. We further seek to protect our potential trade secrets, proprietary know-how, and information in part, by entering into non-disclosure and confidentiality agreements with parties who are given access to them, such as our corporate collaborators, outside scientific collaborators, contract research organizations, contract manufacturers, consultants, advisors and other third parties. With our consultants, contractors, and outside scientific collaborators, these agreements typically include invention assignment obligations. While it is our policy to require our employees 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 an enforceable agreement with each party who in fact conceives or develops intellectual property that we regard as our own. Despite these efforts, our assignment agreements may not be self-executing and any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. If we fail in bringing or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Such an outcome could materially, and adversely affect our business, financial condition, results of operations, and growth prospects. Even if we are successful in defending against such claims, litigation could result in substantial costs and distraction to management and other employees. The assignment risks of this paragraph could also pertain to any intellectual property licensed-in to us. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them 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 competitive position would be harmed.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.

We employ individuals who were previously employed at other biotechnology or biopharmaceutical companies, or at research institutions. Although we seek to protect our ownership of intellectual property rights by ensuring that our agreements with our employees, collaborators, and other third parties with whom we do business include provisions requiring such parties to assign rights in inventions to us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of our employees' former employers or other third parties. We or our licensors may also be subject to claims that former employers or other third parties have an ownership interest in our patents. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims, and if we or our licensors fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Even if we are successful, litigation could result in substantial cost and be a distraction to our management and other employees.

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

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

- others may be able to make product candidates that are similar to ours but that are not covered by the claims of the patents that we own or have exclusively licensed;
- we or our licensors or future collaborators might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed;
- we or our licensors or future collaborators might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we own or have exclusively licensed may be held invalid or unenforceable, as a result of legal challenges by our competitors;

- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we cannot ensure that any of our patents, or any of our pending patent applications, if issued, or those of our licensors, will include claims having a scope sufficient to protect our product candidates;
- we cannot ensure that any patents issued to us or our licensors will provide a basis for an exclusive market for our commercially viable product candidates or will provide us with any competitive advantages;
- the Supreme Court of the United States, other U.S. federal courts, Congress, the USPTO or similar foreign authorities may change the standards of patentability and any such changes could narrow or invalidate, or change the scope of, our or our licensors' patents;
- patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time;
- we cannot ensure that our commercial activities or product candidates will not infringe upon the patents of others;
- we cannot ensure that we will be able to successfully commercialize our product candidates on a substantial scale, if approved, before the relevant patents that we own or license expire;
- 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;
- we may not develop additional proprietary technologies that are patentable; and
- the patents of others may have an adverse effect on our business.

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

Patent terms may be inadequate to protect our competitive position on our product candidates and preclinical programs for an adequate amount of time.

Patent rights are of limited duration. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. A patent term extension based on regulatory delay may be available in the United States. However, only a single patent can be extended for each marketing approval, and any patent can be extended only once, for a single product. Moreover, the scope of protection during the period of the patent term extension does not extend to the full scope of the claim, but instead only to the scope of the product as approved. Laws governing analogous patent term extensions in foreign jurisdictions vary widely, as do laws governing the ability to obtain multiple patents from a single patent family. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such product candidates are commercialized. Even if patents covering our product candidates are obtained, once the patent life has expired for a product, we may be open to competition from biosimilar or generic products. Additionally, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. If we are unable to obtain patent term extension or restoration, or the term of any such extension is less than we request, the period during which we will have the right to exclusively market our product will be shortened and our competitors may obtain approval of competing products following our patent expiration, and our revenue could be reduced, possibly materially.

Risks Related to Government Regulation

Our industry is highly regulated by the FDA and comparable foreign regulatory agencies. We must comply with extensive, strictly enforced regulatory requirements to develop, obtain, and maintain marketing approval for any of our product candidates.

Any product candidates we develop and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion,

sale, and distribution are very heavily regulated. We have not received approval to market any product candidates from regulatory authorities in any jurisdiction. We have only limited experience in filing and supporting the applications necessary to gain marketing approvals and expect to rely on third-party contract research organizations to assist us in this process. Securing FDA or comparable foreign regulatory approval such as a marketing authorization from the European Commission or the competent authorities of the individual EU Member States, requires the submission of extensive preclinical and clinical data and supporting information for each therapeutic indication to establish the product candidate's safety and efficacy for its intended use. Securing regulatory approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. It takes years to complete the testing of a new drug and development delays and/or failure can occur at any stage of testing. Any of our present and future clinical trials may be delayed, halted, not authorized, or approval of any of our products may be delayed or may not be obtained due to any of the following:

- any preclinical study or clinical trial may fail to produce safety and efficacy results satisfactory to the FDA or comparable foreign regulatory authorities;
- preclinical and clinical data can be interpreted in different ways, which could delay, limit or prevent marketing approval;
- negative or inconclusive results from a preclinical study or clinical trial or adverse events during a clinical trial could cause a preclinical study or clinical trial to be repeated or a development program to be terminated, even if other studies or trials relating to the development program are ongoing or have been completed and were successful;
- the FDA or comparable foreign regulatory authorities can place a clinical hold on a trial if, among other reasons, it finds that subjects enrolled in the trial are or would be exposed to an unreasonable and significant risk of illness or injury;
- the facilities that we utilize, or the processes or facilities of third-party vendors, including without limitation the contract manufacturers who will be manufacturing drug substance and drug product for us or any potential collaborators, may not satisfactorily complete inspections by the FDA or comparable foreign regulatory authorities; and
- we may encounter delays or rejections based on changes in FDA regulations, standards or policies or the regulations, standards or policies of comparable foreign regulatory authorities during the period in which we develop a product candidate or the period required for review of any final marketing approval before we are able to market any product candidate.

In addition, information generated during the clinical trial process is susceptible to varying interpretations that could delay, limit, or prevent marketing approval at any stage of the approval process.

Moreover, early positive preclinical or clinical trial results may not be replicated in later clinical trials. As more product candidates within a particular class of drugs proceed through clinical development to regulatory review and approval, the amount and type of clinical data that may be required by regulatory authorities may increase or change. Failure to demonstrate adequately the quality, safety and efficacy of any of our product candidates would delay or prevent marketing approval of the applicable product candidate. We cannot assure you that if clinical trials are completed, either we or our potential collaborators will submit applications for required authorizations to manufacture or market potential products or that any such application will be reviewed and approved by appropriate regulatory authorities in a timely manner, if at all. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application.

Changes in healthcare law and implementing regulations, as well as changes in healthcare policy, may impact our business in ways that we cannot currently predict, and may have a significant adverse effect on our business and results of operations.

In the United States and some foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post-approval activities, impact pricing and reimbursement and affect our ability to profitably sell any product candidates for which we obtain marketing approval. Among policy makers and payors both federally

and on the state level in the United States and elsewhere, including in the European Union, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

The Affordable Care Act substantially changed the way healthcare is financed by both the government and private insurers, and significantly impacts the U.S. pharmaceutical industry. The Affordable Care Act, among other things: (i) introduced a new average manufacturer price definition for drugs and biologics that are inhaled, infused, instilled, implanted or injected and not generally dispensed through retail community pharmacies; (ii) increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and expanded rebate liability from fee-for-service Medicaid utilization to include the utilization of Medicaid managed care organizations as well; (iii) established a branded prescription drug fee that pharmaceutical manufacturers of branded prescription drugs must pay to the federal government; (iv) expanded the list of covered entities eligible to participate in the 340B drug pricing program; (v) established a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70% (increased from 50% in 2019) 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; (vi) expanded eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for individuals with income at or below 133% of the federal poverty level, thereby potentially increasing manufacturers' Medicaid rebate liability; (vii) created a licensure framework for follow on biologic products; and (viii) established a Center for Medicare & Medicaid Innovation, CMMI, at the Centers for Medicare & Medicaid Services ("CMS") to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

Since its enactment, there have been judicial challenges to certain aspects of the Affordable Care Act, as well as efforts by Congress to repeal or replace, and the Trump administration to alter the implementation of, certain aspects of the Affordable Care Act. For example, the TCJA includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the Affordable Care Act on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." On December 14, 2018, a federal district court in Texas ruled the individual mandate in the absence of the tax penalty is unconstitutional and, because it is a critical and inseverable feature of the Affordable Care Act, the remaining provisions of the Affordable Care Act are invalid as well. On December 18, 2019, the U.S. Court of Appeals for the Fifth Circuit affirmed the District Court's ruling but remanded the case back to the District Court as to the question of severability. On March 2, 2020, the United States Supreme Court granted certiorari to review this case, which is expected to be decided by mid-2021. Additionally, the Further Consolidated Appropriations Act of 2020, Pub. L. No. 116-94 permanently eliminated, effective January 1, 2020, the Affordable Care Act - mandated "Cadillac" tax on high-cost employer-sponsored health coverage and the medical device excise tax on non-exempt medical devices and, effective January 1, 2021, also eliminates the annual fee imposed on certain health insurance providers based on market share. Further, the Bipartisan Budget Act of 2018, among other things, amended the Affordable Care Act, effective January 1, 2019, to increase from 50 percent to 70 percent the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." In the future, Congress may consider other legislation to repeal or replace elements of the Affordable Care Act, agencies may further alter their implementation of elements of the Affordable Care Act, and other judicial challenges to elements of the Affordable Care Act may be brought. The extent to which any such changes may impact our business or financial condition is uncertain.

Other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. These changes include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year pursuant to the Budget Control Act of 2011 and subsequent laws, which went into effect on April 1, 2013 and will remain in effect through 2020 unless additional Congressional action is taken, , with the exception of a temporary suspension of the 2% cut in Medicare payments from May 1, 2020, through December 31, 2020, pursuant to the CARES Act signed into law in March 2020 and designed to provide financial support and resources to individuals and businesses affected by the COVID-19 pandemic. The American Taxpayer Relief Act of 2012 ("ATRA") among other things, reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. New laws may result in additional reductions in Medicare and other healthcare funding, which may materially adversely affect customer demand and affordability for our products and related services and, accordingly, the results of our financial operations. Additional changes that may affect our business include the expansion of new programs such as Medicare payment for performance initiatives for physicians under the Medicare Access and CHIP Reauthorization Act of 2015 ("MACRA") which first affected physician payment in 2019. At this time, it is unclear how the introduction of the Medicare quality payment program will impact overall physician reimbursement.

Also, there has been heightened governmental scrutiny over the manner in which drug manufacturers set prices for their marketed products, which have resulted in several Congressional inquiries and proposed bills and initiatives, as well as state efforts, 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. For example, at the federal level, the Trump administration's budget for fiscal year 2021 includes a $135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. On March 10, 2020, the Trump administration sent "principles" for drug pricing to Congress, calling for legislation that would, among other things, cap Medicare Part D beneficiary out-of-pocket pharmacy expenses, provide an option to cap Medicare Part D beneficiary monthly out-of-pocket expenses, and place limits on pharmaceutical price increases. On July 24, 2020, President Trump signed several executive orders directed toward lowering drug prices. Individual states in the United States have become increasingly active in passing legislation and implementing 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.

We expect that these and other healthcare reform measures in the future, may result in more rigorous coverage criteria and lower reimbursement, and in additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government-funded programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may hinder us in generating revenue, attaining profitability or commercializing our drugs, once marketing approval is obtained.

In the European Union, coverage and reimbursement status of any product candidates for which we obtain regulatory approval are provided for by the national laws of EU Member States. The requirements may differ across the EU Member States. In markets outside of the United States and the European Union, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. Also, at national level, actions have been taken to enact transparency laws regarding payments between pharmaceutical companies and health care professionals.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action in the United States, the European Union or any other jurisdiction. If we or any third parties we may engage are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, our product candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability.

Our employees, independent contractors, 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 laws and 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 or (iv) laws that require the true, complete and accurate reporting of financial information or data. Specifically, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Activities subject to these laws could also involve the improper use or misrepresentation of information obtained in the course of clinical trials, creation of fraudulent data in preclinical studies or clinical trials or illegal misappropriation of drug product, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third parties, 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 such laws or regulations. We adopted a code of conduct applicable to all of our employees immediately following the completion of our IPO, 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. Additionally, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. 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, monetary fines, disgorgements, possible exclusion from participation in Medicare, Medicaid, other U.S. federal healthcare programs or healthcare programs in other jurisdictions, integrity oversight and reporting obligations to resolve allegations of non-compliance, individual imprisonment, other sanctions, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations.

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 have a material adverse effect on the success of our business.

We, and the third parties with whom we share our facilities, are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Each of our operations involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. Each of 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. We could be held liable for any resulting damages in the event of contamination or injury resulting from the use of hazardous materials by us or the third parties with whom we share our facilities, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

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

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

Further, with respect to the operations of our current and any future third-party contract manufacturers, it is possible that if they fail to operate in compliance with applicable environmental, health and safety laws and regulations or properly dispose of wastes associated with our products, we could be held liable for any resulting damages, suffer reputational harm or experience a disruption in the manufacture and supply of our product candidates or products. In addition, our supply chain may be adversely impacted if any of our third-party contract manufacturers become subject to injunctions or other sanctions as a result of their non-compliance with environmental, health and safety laws and regulations.

We will be subject to federal, state and foreign healthcare and abuse laws and false claims laws, as well as information privacy and security laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties, criminal sanctions, contractual damages, reputational harm, and diminished profits and future earnings.

ECPs and third-party payors will play a primary role in the recommendation and prescription of any future product candidates we may develop and any product candidates for which we obtain marketing approval. Our arrangements with ECPs, patients, third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may affect our business or financial arrangements and relationships through which we would market, sell and distribute our products. As a biopharmaceutical company, federal and state healthcare laws and regulations pertaining to fraud and abuse are applicable to our business and may affect our ability to operate. These laws include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits any person or entity from, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of an item or service reimbursable, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. The term "remuneration" has been broadly interpreted to include anything of value. The Anti-Kickback Statute has also been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers, and formulary managers on the other the other hand. Liability under the Anti-Kickback Statute may be established without proving actual knowledge of the statute or specific intent to violate it. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution or regulatory sanctions, the exemptions and

safe harbors are drawn narrowly, and practices that do not fit squarely within an exemption or safe harbor, or for which no exception or safe harbor is available, may be subject to scrutiny;

- federal civil laws, such as the False Claims Act ("FCA") which prohibits individuals or entities from, among other things, knowingly presenting, or causing to be presented, false or fraudulent claims for payment of government funds, and knowingly making, using or causing to be made or used a false record or statement material to an obligation to pay money to the government or knowingly concealing or knowingly and improperly avoiding, decreasing or concealing an obligation to pay money to the federal government. Actions under the FCA may be brought by the U.S. Attorney General or as a qui tam action by a private individual (a whistleblower) in the name of the government and the individual, and the whistleblower may share in any monetary recovery. Many pharmaceutical companies have been investigated and have reached substantial settlements under the federal civil FCA in connection with their alleged off-label promotion of drugs, purportedly concealing price concessions in the pricing information submitted to the government for government price reporting purposes, and allegedly providing free product to customers with the expectation that the customers would bill federal health care programs for the product. In addition, a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA. In addition, manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to “cause” the submission of false or fraudulent claims. FCA liability is potentially significant in the healthcare industry because the statute provides for treble damages and significant mandatory penalties per false or fraudulent claim or statement for violations. Because of the potential for large monetary exposure, healthcare and pharmaceutical companies often resolve allegations without admissions of liability for significant and material amounts to avoid the uncertainty of treble damages and per claim penalties that may be awarded in litigation proceedings. Settlements may require companies to enter into corporate integrity agreements with the government, which may impose substantial costs on companies to ensure compliance. Pharmaceutical and other healthcare companies also are subject to other federal false claims laws, including, among others, federal criminal healthcare fraud and false statement statutes that extend to non-government health benefit programs;

- the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA") among other things, imposes criminal liability for knowingly or willfully executing or attempting to execute a scheme to defraud any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and creates federal criminal laws that prohibit knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement or representation, or making or using any false writing or document knowing the same to contain any materially false, fictitious or fraudulent statement or entry in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the federal healthcare Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH") and its implementing regulations, which imposes privacy, security and breach reporting obligations with respect to individually identifiable health information upon entities subject to the law, such as health plans, healthcare clearinghouses and healthcare providers and their respective business associates that perform services for them that involve individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in U.S. federal courts to enforce the federal HIPAA laws and seek attorneys’ fees and costs associated with pursuing federal civil actions;

- federal and state consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;

- the Federal Food, Drug and Cosmetic Act, which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices;

- the federal Physician Payments Sunshine Act, implemented as the Open Payments Program, requires, among other things, certain manufacturers of drugs, devices, biologics and medical supplies for which payment I available under Medicare, Medicaid, or the Children’s Health Insurance Program (with certain exceptions) to report annually to the Department of Health and Human Services, Centers for Medicare and Medicaid Services, information related to payments and other transfers of value provided to physicians (defined to include doctors,

dentists, optometrists, podiatrist and chiropractors) and teaching hospitals, as well as physician ownership and investment interests, including such ownership and investment interests held by a physician's immediate family members. Beginning in 2022, applicable manufacturers also will be required to report information regarding payments and transfers of value provided to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, and certified nurse-midwives;

- state and foreign law equivalents of each of the above federal laws, such as anti-kickback laws, false claims laws, transparency laws and misleading advertising laws, that may impose similar or more prohibitive restrictions, and may apply to items or services reimbursed by any non-governmental third-party payors, including private insurers; and

- state and foreign laws that require pharmaceutical companies to implement compliance programs, comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or to track and report gifts, compensation and other remuneration provided to physicians and other health care providers, and other federal, state and foreign laws that govern the privacy and security of health information or personally identifiable information in certain circumstances, including state health information privacy and data breach notification laws which govern the collection, use, disclosure, and protection of health-related and other personal information, many of which differ from each other in significant ways and often are not pre-empted by HIPAA, thus requiring additional compliance efforts.

We have entered into consulting and scientific advisory board arrangements with physicians and other ECPs, including some who could influence the use of our product candidates, if approved. Because of the complex and far-reaching nature of these laws, regulatory agencies may view these transactions as prohibited arrangements that must be restructured, or discontinued, or for which we could be subject to other significant penalties. We could be adversely affected if regulatory agencies interpret our financial relationships with providers who may influence the ordering of and use our product candidates, if approved, to be in violation of applicable laws.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform. Various state and federal regulatory and enforcement agencies continue actively to investigate violations of health care laws and regulations, and the United States Congress continues to strengthen the arsenal of enforcement tools. The BBA of 2018 increased the criminal and civil penalties that can be imposed for violating certain federal health care laws, including the Anti-Kickback Statute. Responding to investigations can be time-and resource-consuming and can divert management's attention from the business. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on our business.

Efforts to ensure that our collaborations or business arrangements with third parties, and our business generally, comply with applicable healthcare laws and regulations will likely be costly. 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 current or future governmental laws and regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, contractual damages, reputational harm, diminished profits and future earnings, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations, any of which could substantially disrupt our operations.

Inadequate funding for the FDA and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new products to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. If a prolonged government

shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, in our operations as a public company, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

We are subject to certain U.S. and 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, which we collectively refer to as Trade Laws, prohibit, among other things, companies and their employees, agents, clinical research organizations, 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 Trade 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.

Even if we receive marketing approval for a product candidate, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and subject us to restrictions, withdrawal from the market, or penalties if we fail to comply with applicable regulatory requirements or if we experience unanticipated problems with our product candidates, when and if approved.

Obtaining coverage and reimbursement approval for a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide supporting scientific, clinical and cost effectiveness data for the use of our products to the payor. There may be significant delays in obtaining such coverage and reimbursement for newly approved products, and coverage may be more limited than the purposes for which the product is approved by the FDA or comparable foreign regulatory authorities. Moreover, eligibility for coverage and reimbursement does not imply that a product 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 products, 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 product and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost products and may be incorporated into existing payments for other services. Net prices for products may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors, by any future laws limiting drug prices and by any future relaxation of laws that presently restrict imports of product from countries where they may be sold at lower prices than in the United States.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting reimbursement policies, but also have their own methods and approval process apart from Medicare coverage and reimbursement determinations.

Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a product is:

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

We cannot be sure that reimbursement will be available for any product that we commercialize and, if coverage and reimbursement are available, what the level of reimbursement will be. Obtaining reimbursement for our products may be

particularly difficult because of the higher prices often associated with branded therapeutics and therapeutics administered under the supervision of a physician. Our inability to promptly obtain coverage and adequate reimbursement rates from both government-funded and private 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.

Reimbursement may impact the demand for, and the price of, any product for which we obtain marketing approval. Assuming we obtain coverage for a given product by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. Patients who are prescribed medications for the treatment of their conditions, and their prescribing physicians, generally rely on third-party payors to reimburse all or part of the costs associated with those medications. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover all or a significant portion of the cost of our products. Therefore, coverage and adequate reimbursement is critical to new product acceptance. Coverage decisions may depend upon clinical and economic standards that disfavor new products when more established or lower cost therapeutic alternatives are already available or subsequently become available.

We expect to experience pricing pressures in connection with the sale of any of our product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations, and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription medicines, medical devices and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the successful commercialization of new products. Further, the adoption and implementation of any future governmental cost containment or other health reform initiative may result in additional downward pressure on the price that we may receive for any approved product.

Outside of the United States, many countries require approval of the sale price of a product before it can be marketed and the pricing review period only begins after marketing or product licensing approval is granted. To obtain reimbursement or pricing approval in some of these countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product 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 product 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 revenue, 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 product candidates, even if such product candidates obtain marketing approval.

Failure to comply with health and data protection laws and regulations could lead to government enforcement actions (which could include civil or criminal penalties), significant fines, private litigation, and/or adverse publicity and could negatively affect our financial condition, 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 FTC 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 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.

Furthermore, states are constantly adopting new laws or amending existing laws, requiring attention to frequently changing regulatory requirements. For example, California has enacted the California Consumer Privacy Act (“CCPA”), which came into effect on January 1, 2020. The CCPA gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing and receive detailed information about how their personal information is used, by requiring covered companies to provide new disclosures to California consumers (as that term is broadly defined) and provide such consumers new ways to opt-out of certain sales of personal information. The California Attorney General may seek substantial monetary penalties and injunctive relief in the event of our non-compliance with the CCPA. The CCPA also provides a private right of action (with the potential for class actions) for certain data breaches that is expected to increase data breach litigation. The CCPA may increase our compliance costs and potential liability, and similar laws have been proposed at the federal level and in other states.

International data protection laws, including the EU General Data Protection Regulation ("GDPR") may also apply to health-related and other personal information obtained outside of the United States. The GDPR extends the geographical scope of EU data protection law to non-EU entities under certain conditions, tightens existing EU data protection principles, creates new obligations for companies and new rights for individuals. Failure to comply with the GDPR may result in substantial fines and other administrative penalties. The GDPR may 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 GDPR. This may be onerous and if our efforts to comply with the GDPR or other applicable EU laws and regulations are not successful, it could adversely affect our business. 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, uncertainty about compliance with EU data protection laws remains and data protection authorities from the different EU Member States may interpret the GDPR differently, and guidance on implementation and compliance practices are often updated or otherwise revised, which adds to the complexity of processing personal data in the European Union. In particular, on July 16, 2020, the Court of Justice of the European Union, in the case of *Data Protection Commissioner v. Facebook Ireland Limited, Maximillian Schrems* (Case C-311/18) ("*Schrems II*"), invalidated the EU-U.S. Privacy Shield Program for transfers of personal data from the EU to the United States, and added further uncertainty and complexity to the use of the Standard Contractual Clauses as a compliance mechanism for transfers of personal data outside the EU.

In addition, the United Kingdom leaving the EU could also lead to further legislative and regulatory changes. It remains unclear how the United Kingdom data protection laws or regulations will develop in the medium to longer term and how data transfers from the EEA to the United Kingdom will be regulated, especially following the United Kingdom's departure from the EU on January 31, 2020 without a deal. However, the United Kingdom has transposed the GDPR into domestic law with the Data Protection Act 2018, which remains in force following the United Kingdom's departure from the EU. During the period of "transition" (i.e., until December 31, 2020), EU law will continue to apply in the UK, including the GDPR, after which the GDPR will be converted into UK law. Beginning in 2021, the UK will be a "third country" under the GDPR. We may incur liabilities, expenses, costs, and other operational losses under GDPR and applicable EU Member States and the United Kingdom privacy laws in connection with any measures we take to comply with them.

Failure to comply with U.S. and international data protection laws and regulations could result in government enforcement actions (which could include civil or criminal penalties), significant fines, private litigation, and/or adverse publicity and could negatively affect our financial condition, 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 cannot assure you that our third-party service providers with access to our or our customers', suppliers', trial patients' and employees' personally identifiable and other sensitive or confidential information in relation to which we are responsible will not breach contractual obligations imposed by us, or that they will not experience data security breaches or attempts thereof, which could have a corresponding effect on our business, including putting us in breach of our obligations under privacy laws and regulations and/or which could in turn adversely affect our business, results of operations and financial condition. We cannot assure you that our contractual measures and our own privacy and security- related safeguards will protect us from the risks associated with the third-party processing, storage and transmission of such information. Furthermore, the laws are not consistent, and compliance in the event of a widespread data breach is costly.

If we are able to successfully commercialize any of our products and if we participate in the Medicaid Drug Rebate Program or other governmental pricing programs, failure to comply with obligations under these programs could result in additional reimbursement requirements, penalties, sanctions and fines which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

If we successfully commercialize any of our product candidates, we may participate in the Medicaid Drug Rebate Program. Participation is required for federal funds to be available for our covered outpatient drugs under Medicaid and, if applicable, Medicare Part B. Under the Medicaid Drug Rebate Program, we would be required to pay a rebate to each state Medicaid program for our covered outpatient drugs that are dispensed to Medicaid beneficiaries and paid for by a state Medicaid program as a condition of having federal funds being made available to the states for our drugs under Medicaid and, if applicable, Part B of the Medicare program.

Federal law requires that any company that participates in the Medicaid Drug Rebate Program also participate in the Public Health Service's 340B drug pricing program in order for federal funds to be available for the manufacturer's drugs under Medicaid and Medicare Part B. The 340B drug pricing program requires participating manufacturers to agree to charge

statutorily-defined covered entities no more than the 340B "ceiling price" for the manufacturer's covered outpatient drugs. These 340B covered entities include a variety of community health clinics and other entities that receive health services grants from the Public Health Service, as well as hospitals that serve a disproportionate share of low-income patients.

In addition, in order to be eligible to have its products paid for with federal funds under the Medicaid and Medicare Part B programs and purchased by certain federal agencies and grantees, a manufacturer also must participate in the U.S. Department of Veterans Affairs ("VA"), Federal Supply Schedule ("FSS") pricing program. Under this program, the manufacturer is obligated to make its innovator and single source products available for procurement on an FSS contract and charge a price to four federal agencies, U.S. Department of Veterans Affairs, U.S. Department of Defense, or the DoD, Public Health Service and U.S. Coast Guard, that is no higher than the statutory Federal Ceiling Price. Moreover, pursuant to regulations issued by the DoD Defense Health Agency to implement Section 703 of the National Defense Authorization Act for Fiscal Year 2008, manufacturers are required to provide rebates on utilization of their innovator and single source products that are dispensed to TRICARE beneficiaries by TRICARE network retail pharmacies.

The requirements under the Medicaid, 340B, FSS, and TRICARE programs could reduce the revenue we may generate from any products that are commercialized in the future and could adversely affect our business and operating results. If we fail to comply with any applicable obligations under governmental pricing programs that we participate in, we could be subject to additional reimbursement requirements, significant civil monetary penalties, sanctions and fines, and those could negatively impact our business, financial condition, results of operations and growth prospects.

Risks Related to Ownership of our Common Stock

The stock price of our common stock may be volatile or may decline regardless of our operating performance and you may not be able to resell your shares at or above the initial public offering price.

The market price of our common stock may fluctuate significantly in response to numerous factors, many of which are beyond our control, including:

- overall performance of the equity markets;
- our operating performance and the performance of other similar companies;
- results from our ongoing clinical trials and future clinical trials with our current and future product candidates or of our competitors;
- delays in the commencement, enrollment and the ultimate completion of clinical trials;
- changes in our projected operating results that we provide to the public, our failure to meet these projections or changes in recommendations by securities analysts that elect to follow our common stock;
- regulatory actions with respect to our product candidates;
- regulatory or legal developments in the United States and other countries;
- the level of expenses related to future product candidates or clinical development programs;
- our failure to achieve product development or commercialization goals or regulatory approval milestones in the timeframe we announce;
- changes in hospital or ECP practices;
- announcements of acquisitions, strategic alliances or significant agreements by us or by our competitors;
- developments or disputes concerning patent applications, issued patents or other intellectual property or proprietary rights;
- recruitment or departure of key personnel;
- the economy as a whole and market conditions in our industry, including conditions resulting from COVID-19;

- variations in our financial results or the financial results of companies that are perceived to be similar to us;
- financing or other corporate transactions, or inability to obtain additional funding;
- trading activity by a limited number of stockholders who together beneficially own a majority of our outstanding common stock;
- the expiration of market standoff or contractual lock-up agreements;
- the size of our market float; and
- any other factors discussed in this report.

In addition, the stock markets have experienced extreme price and volume fluctuations that have affected and continue to affect the market prices of equity securities of many biopharmaceutical companies. Stock prices of many biopharmaceutical companies have fluctuated in a manner unrelated or disproportionate to the operating performance of those companies. In the past, stockholders have filed securities class action litigation following periods of market volatility. If we were to become involved in securities litigation, it could subject us to substantial costs, divert resources and the attention of management from our business and adversely affect our business.

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

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. Securities and industry analysts do not currently, and may never, publish research on our company. If no or only very few securities analysts commence coverage of us, or if industry analysts cease coverage of us, the trading price for our common stock would be negatively affected. 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.

We are an "emerging growth company" and "smaller reporting company" and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies will make our common stock less attractive to investors.

We are an "emerging growth company" as defined in the Jumpstart our Business Startups Act of 2012, as amended (the "JOBS Act") and we intend to take advantage of some of the exemptions from reporting requirements that are applicable to other public companies that are not emerging growth companies, including:

- the option to present only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure;
- not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes Oxley Act of 2002, as amended (the "Sarbanes Oxley Act");
- 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;
- not being required to disclose certain executive compensation-related items such as the correlation between executive compensation and performance and comparisons of the chief executive officer's compensation to median employee compensation; and
- not being required to submit certain executive compensation matters to stockholder advisory votes, such as "say-on-pay," "say-on-frequency," and "say-on-golden parachutes."

The JOBS Act permits an "emerging growth company" such as us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies. We have irrevocably elected to opt

out of this provision and, as a result, we will comply with new or revised accounting standards as required when they are adopted.

We cannot predict if investors will find our common stock less attractive because we will 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. We may take advantage of these reporting exemptions until we are no longer an emerging growth company. We will remain an emerging growth company until the earlier of (1) December 31, 2025, the last day of the fiscal year following the fifth anniversary of the completion of our initial public offering, (b) the last day of the fiscal year (a) in which we have total annual gross revenue of at least $1.07 billion or (b) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds $700 million as of the prior June 30th and (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period. We are also a "smaller reporting company" as defined in the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as our voting and non-voting common stock held by non-affiliates is less than $250.0 million measured on the last business day of our second fiscal quarter, or our annual revenue is less than $100.0 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is less than $700.0 million measured on the last business day of our second fiscal quarter.

Investors may find our common stock less attractive to the extent we rely on the exemptions and relief granted by the JOBS Act. 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 decline or become more volatile.

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

Sales of a substantial number of shares of our common stock in the public market should occur at any time. The price of our common stock could decline if there are substantial sales of our common stock, particularly sales by our directors, executive officers and significant stockholders, or if there is a large number of shares of our common stock available for sale and the market perceives that sales will occur. As of November 23, 2020, we had 20,320,426 shares of common stock outstanding. Of these shares, approximately 6,325,000 shares sold in our IPO may be resold in the public market, unless purchased by our affiliates or existing stockholders. Of the remaining shares, a significant percentage of these shares of common stock are currently restricted as a result of securities laws or lock-up agreements entered into in connection with the IPO. These shares will become available to be sold in the public market as early as 180 days following the date of our final prospectus filed with the SEC on October 16, 2020 pursuant to Rule 424(b) under the Securities Act of 1933, as amended ("Securities Act"). Shares held by directors, executive officers and other affiliates will be subject to volume limitations under Rule 144 under the Securities Act and various vesting agreements. The underwriters of the IPO may, in their discretion, permit our stockholders to sell shares prior to the expiration of the restrictive provisions contained in those lock-up agreements.

Moreover, holders of an aggregate of 11,107,018 shares of our common stock have rights under our registration rights agreement, subject to specified conditions, to require us to file registration statements covering their shares and to include their shares in registration statements that we may file for ourselves or for other stockholders, subject to lockup agreements. In addition, on October 20, 2020, we filed a registration statement on Form S-8 registering 13,732,980 shares of common stock that we have issued and may issue under our employee equity incentive plans. As a result, shares registered under this registration statement on Form S-8 can be freely sold in the public market subject to the satisfaction of vesting arrangements and the exercise of such options, volume limitations applicable to affiliates or lock-up agreements.

The market price of the shares of our common stock could decline as a result of the sale of a substantial number of our shares of common stock in the public market or the perception in the market that the holders of a large number of shares intend to sell their shares.

The concentration of our stock ownership will likely limit your ability to influence corporate matters, including the ability to influence the outcome of director elections and other matters requiring stockholder approval.

Immediately following our IPO, our officers, directors and the holders of more than 5% of our outstanding stock collectively beneficially own approximately 68% of our common stock. As a result, these stockholders, acting together, will have significant influence over all matters that require approval by our stockholders, including the election of directors and approval of significant corporate transactions. Corporate actions might be taken even if other stockholders oppose them. This concentration of ownership might also have the effect of delaying or preventing a change of control of our company that other stockholders may view as beneficial.

Requirements associated with being a public company will increase our costs significantly, as well as divert significant company resources and management attention.

As a public company, we are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended(the "Exchange Act"), or the other rules and regulations of the Securities and Exchange Commission (the "SEC"), or any securities exchange relating to public companies. Compliance with the various reporting and other requirements applicable to public companies requires considerable time and attention of management and we will incur significant legal, accounting and other expenses. We cannot assure you that we will satisfy our obligations as a public company on a timely basis.

In addition, as a public company, it may be more difficult or more costly for us to obtain certain types of insurance, including directors' and officers' liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified personnel to serve on our board of directors, our board committees or as executive officers.

If we fail to maintain proper and effective internal controls, our ability to produce accurate and timely financial statements could be impaired, which could result in sanctions or other penalties that would harm our business.

We are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act and the rules and regulations of the Nasdaq Stock Market ("Nasdaq"). The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal controls over financial reporting. Commencing in the fiscal year ending December 31, 2021, we must perform system and process design evaluation and testing of the effectiveness of our internal controls over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting in our Form 10-K filing for that year, as required by Section 404 of the Sarbanes-Oxley Act. 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, including through hiring additional financial and accounting personnel, 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. This will require that we incur substantial additional professional fees and internal costs to expand our accounting and finance functions and that we expend significant management efforts. Prior to our IPO, we have never been required to test our internal controls within a specified period and, as a result, we may experience difficulty in meeting these reporting requirements in a timely manner.

We may discover weaknesses in our system of internal financial and accounting controls and procedures that could result in a material misstatement of our financial statements. Our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, or if we are unable to maintain proper and effective internal controls over financial reporting, we may not be able to produce timely and accurate financial statements. If that were to happen, our investors could lose confidence in our reported financial information, the market price of our stock could decline and we could be subject to sanctions or investigations by the SEC or other regulatory authorities including equivalent foreign authorities.

We do not intend to pay dividends for the foreseeable future.

We have never declared nor paid cash dividends on our capital stock. We currently intend to retain any future earnings to finance the operation and expansion of our business, and we do not expect to declare or pay any dividends in the foreseeable future. Consequently, stockholders must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any future gains on their investment.

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 biopharmaceutical 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.

Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or our guidance.

Our quarterly and annual operating results may fluctuate significantly in the future, which makes it difficult for us to predict our future operating results. Our operating results may fluctuate due to a variety of factors, many of which are outside of our control and may be difficult to predict, including the following:

- the timing and success or failure of clinical trials for our product candidates or competing product candidates, or any other change in the competitive landscape of our industry, including consolidation among our competitors or partners;
- our ability to successfully recruit patients for preclinical studies and clinical trials, and any delays caused by difficulties in such recruitment efforts;
- our ability to obtain regulatory approval for our product candidates, and the timing and scope of any such approvals we may receive;
- the timing and cost of, and level of investment in, research and development activities relating to our product candidates, which may change from time to time;
- the cost of manufacturing our product candidates, which may vary depending on the quantity of production and the terms of our agreements with manufacturers;
- our ability to attract, hire and retain qualified personnel;
- expenditures that we will or may incur to develop additional product candidates;
- the level of demand for our product candidates should they receive approval, which may vary significantly;
- the risk/benefit profile, cost and reimbursement policies with respect to our product candidates, if approved, and existing and potential future drugs that compete with our product candidates;
- the changing and volatile U.S., European and global economic environments, including impact of COVID-19; and
- future accounting pronouncements or changes in our accounting policies.

The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated guidance we may provide.

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.

Our status as a Delaware corporation and the anti-takeover provisions of the Delaware General Corporation Law may discourage, delay or prevent a change in control by prohibiting us from engaging in a business combination with an interested stockholder for a period of three years after the person becomes an interested stockholder, even if a change of control would be beneficial to our existing stockholders. In addition, our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that may make the acquisition of our company more difficult, including the following:

- a classified board of directors with three-year staggered terms, which could delay the ability of stockholders to change the membership of a majority of our board of directors;
- the ability of our board of directors to issue shares of preferred stock and to determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquiror;
- the exclusive right of our board of directors to elect a director to fill a vacancy created by the expansion of our board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors;
- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;
- the requirement that a special meeting of stockholders may be called only by a majority vote of our entire board of directors, the chairman of our board of directors or our chief executive officer, which could delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors;
- the requirement for the affirmative vote of holders of at least 66 2/3% of the voting power of all of the then-outstanding shares of the voting stock, voting together as a single class, to amend the provisions of our amended and restated certificate of incorporation or our amended and restated bylaws, which may inhibit the ability of an acquiror to effect such amendments to facilitate an unsolicited takeover attempt; and
- advance notice procedures with which stockholders must comply to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquiror from conducting a solicitation of proxies to elect the acquiror's own slate of directors or otherwise attempting to obtain control of us.

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 and the U.S. federal district courts are the exclusive forums for substantially all 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 the Court of Chancery of the State of Delaware is the exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a breach of fiduciary duty, any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our certificate of incorporation or our bylaws or any action asserting a claim against us that is governed by the internal affairs doctrine.

This provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our certificate of incorporation will further provide that the U.S. federal district courts will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our certificate of incorporation. This may require significant

additional costs associated with resolving such action in other jurisdictions and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions.

This choice of forum provision 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. Alternatively, if a court were to find the choice of forum provision 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.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

Unregistered Sales of Equity Securities

The following sets forth information regarding all unregistered securities sold by us from July 1, 2020 through September 30, 2020. No underwriters were involved in the sales and the certificates representing the securities sold and issued contain legends restricting transfer of the securities without registration under the Securities Act or an applicable exemption from registration.

(a) In July 2020 we granted certain of our employees stock options to purchase an aggregate of 320,829 shares of common stock upon the exercise of options under our 2016 Plan at an exercise price per share of $2.0055, for an aggregate exercise price of approximately $0.6 million.

(b) Pursuant to the terms of that certain License Agreement between the Company and Elanco Tiergesundheit AG ("Elanco"), dated September 3, 2020 (the "All Human Uses Elanco Agreement"), in September 2020 we issued 222,460 shares of our common stock to Elanco as consideration for licenses included in the All Human Uses Elanco Agreement.

(c) In September 2020, we issued and sold to 11 accredited investors an aggregate of 2,857,079 shares of our Series C preferred stock at a purchase price of $14.0003 per share, for aggregate consideration of approximately $40.0 million.

(d) In September 2020 we granted certain of our employees stock options to purchase an aggregate of 416,688 shares of common stock upon the exercise of options under our 2016 Plan at an exercise price per share of $10.99, for an aggregate exercise price of approximately $4.6 million.

The offers, sales and issuances of the securities described in Items (a) and (d) above were exempt from registration under the Securities Act under either (1) Rule 701 in that the transactions were under compensatory benefit plans and contracts relating to compensation as provided under Rule 701 or (2) Section 4(a)(2) of the Securities Act or Regulation D promulgated thereunder as transactions by an issuer not involving any public offering. The recipients of such securities were the registrant's directors, officers, employees, consultants or other service providers and received the securities under our 2016 Plan. The recipients of securities in each of these transactions represented their intention to acquire the securities for investment only and not with view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the securities issued in these transactions.

The offers, sales and issuances of the securities described in Items (b) and (c) above were exempt from registration under the Securities Act under Section 4(a)(2) of the Securities Act or Regulation D promulgated thereunder as transactions by an issuer not involving a public offering. The recipients of securities in each of these transactions acquired the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the securities issued in these transactions. Each of the recipients of securities in these transactions was an accredited person and had adequate access, through employment, business or other relationships, to information about the registrant.

Use of Proceeds from Public Offering of Common Stock

On October 16, 2020, our Registration Statement on Form S-1 (File No. 333-249076) ("Registration Statement") relating to the initial public offering of our common stock was declared effective by the SEC. Pursuant to such Registration Statement, we sold an aggregate of 6,325,000 shares of our common stock, which includes 825,000 shares sold pursuant to the underwriters' full exercise of their option to purchase additional shares, at a price of $16.00 per share. The aggregate offering price for shares sold in the offering was $101.2 million. On October 20, 2020, we closed the sale of such shares, resulting in

aggregate cash proceeds to us of approximately $91.7 million, net of underwriting discounts, commissions and offering expenses paid or payable by us. No offering expenses were paid or are payable, directly or indirectly, to our directors or officers, to persons owning 10% or more of any class of our equity securities or to any of our affiliates.

There has been no material change in the planned use of proceeds from our initial public offering as described in the final prospectus, dated October 15, 2020, filed with the SEC on October 16, 2020, pursuant to Rule 424(b) of the Securities Act.

Item 3. Defaults upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

None.

Item 5. Other Information.

None.

Item 6. Exhibits

Exhibit Number	Description	Form	File Number	Incorporated by Reference Exhibit	Date	Filed Herewith
3.1	Amended and Restated Certificate of Incorporation of Registrant.	8-K	001-39614	3.1	10/20/20	
3.2	Amended and Restated Bylaws of Registrant	8-K	001-39614	3.2	10/20/20	
4.2	Amended and Restated Investors' Rights Agreement, dated September 24, 2020, by and among the Registrant and the other parties thereto.	S-1/A	333-249076	4.2	10/9/20	
10.1	Form of Indemnification Agreement between the Registrant and each of its directors and executive officers.	S-1/A	333-249076	10.1	10/9/20	
10.2#	Tarsus Pharmaceuticals, Inc. 2016 Stock Plan, as amended and forms of agreements thereunder.	S-1	333-249076	10.2	9/25/20	
10.3#	Tarsus Pharmaceuticals, Inc. 2020 Equity Incentive Plan and form of agreements thereunder.	S-8	333-249571	99.2	10/20/20	
10.4#	Tarsus Pharmaceuticals, Inc. 2020 Employee Stock Purchase Plan.	S-8	333-249571	99.3	10/20/20	
10.5#	Amended and Restated Offer Letter, dated October 8, 2020, between the Registrant and Bobak Azamian, M.D., Ph.D.	S-1/A	333-249076	10.5	10/9/20	
10.6†	License Agreement, dated January 31, 2019, between the Registrant and Elanco Tiergesundheit AG.	S-1/A	333-249076	10.10	10/9/20	
10.7†	Amendment to License Agreement, dated September 3, 2020, between the Registrant and Elanco Tiergesundheit AG.	S-1/A	333-249076	10.11	10/9/20	
10.8†^	License Agreement, dated September 3, 2020, between the Registrant and Elanco Tiergesundheit AG.	S-1/A	333-249076	10.12	10/9/20	
10.9#	Management Cash Incentive Plan.	S-1/A	333-249076	10.15	10/9/20	
10.10^	Sublease Agreement, dated May 29, 2020, between the Registrant and Avent, Inc., as amended by First Amendment to Sublease Agreement, dated July 30, 2020, between the Registrant and Avent, Inc.	S-1/A	333-249076	10.14	10/9/20	
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.					X
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.					X
32.1	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					X
32.2	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					X
101.INS	XBRL Instance Document - The instance document does not appear in the interactive data file because its XBRL tags are embedded within the inline XBRL document.					X
101.SCH	XBRL Taxonomy Extension Schema Document.					X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.					X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.					X
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.					X
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.					X
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).					X

^ Pursuant to Item 601(a)(5) of Regulation S-K, certain exhibits and schedules have been omitted. The Company hereby undertakes to furnish supplementally a copy of any omitted exhibit or schedule upon request by the SEC.

† Pursuant to Item 601(b)(10) of Regulation S-K, certain confidential portions of this exhibit have been omitted by means of marking such portions with asterisks as the identified confidential portions (i) are not material and (ii) would likely cause competitive harm to the registrant if publicly disclosed.

Indicates a management contract or compensatory plan.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Quarterly Report on Form 10-Q to be signed on its behalf by the undersigned, thereunto duly authorized.

TARSUS PHARMACEUTICALS, INC.

Date: November 25, 2020

/s/ Bobak Azamian, M.D., Ph.D.
Bobak Azamian, M.D., Ph.D.
President and Chief Executive Officer
(Principal Executive Director)

TARSUS PHARMACEUTICALS, INC.

Date: November 25, 2020

/s/ Leo M. Greenstein
Leo M. Greenstein
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

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, Bobak Azamian, M.D., Ph.D., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Tarsus Pharmaceuticals, 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(s) 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)) 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) 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

    (c) 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(s) 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 25, 2020

By: /s/ Bobak Azamian, M.D., Ph.D.

Bobak Azamian, M.D., Ph.D.
President and 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, Leo M. Greenstein, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Tarsus Pharmaceuticals, 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(s) 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)) 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) 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

    (c) 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(s) 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 25, 2020

By: /s/ Leo M. Greenstein

Leo M. Greenstein
Chief Financial Officer
(*Principal Financial Officer and Principal Accounting Officer*)

Exhibit 32.1

CERTIFICATIONS OF PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL OFFICER
PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Tarsus Pharmaceutials, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Bobak Azamian, hereby 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, as amended; 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 25, 2020

By: /s/ Bobak Azamian, M.D., Ph.D.
Bobak Azamian, M.D., Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATIONS OF PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL OFFICER
PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Tarsus Pharmaceutials, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Leo M. Greenstein, hereby 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, as amended; 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 25, 2020

By: /s/ Leo M. Greenstein
Leo M. Greenstein
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)