UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2020

OR

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

For the transition period from _____ to _____

Commission File Number: 001-39381

PANDION THERAPEUTICS, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**83-3015614**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
134 Coolidge Avenue **Watertown, Massachusetts**	**02472**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (617) 393-5925

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, par value $0.001 per share	PAND	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, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☒

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

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

As of August 31, 2020, the registrant had 29,519,902 shares of common stock, $0.001 par value per share, outstanding.

FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q includes forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical fact, contained in this Quarterly Report on Form 10-Q, including statements regarding our strategy, future operations, future financial position, future revenue, projected costs, prospects, plans and objectives of management, are forward-looking statements. The words “anticipate,” “believe,” “continue” “could,” “estimate,” “expect,” “intend,” “may,” “might,” “plan,” “potential,” “predict,” “project,” “should,” “target,” “would,” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

The forward-looking statements in this Quarterly Report on Form 10-Q include, among other things, statements about:

- our ongoing Phase 1a clinical trial of PT101;
- the initiation, timing, progress and results of our current and future preclinical studies and clinical trials, and our research and development programs;
- our plans to develop our current and future product candidates;
- the utility of our TALON platform in identifying and discovering product candidates;
- the timing of and our ability to submit applications for and obtain and maintain regulatory approvals for our current and future product candidates;
- our expectations regarding our ability to fund our operating expenses and capital expenditure requirements with our cash and cash equivalents;
- the potential advantages of our current and future product candidates;
- the rate and degree of market acceptance and clinical utility of our products, if approved;
- our estimates regarding the potential market opportunity for our current and future product candidates;
- our commercialization, marketing and manufacturing capabilities and strategy;
- our intellectual property position;
- our ability to identify additional products, product candidates or technologies with significant commercial potential that are consistent with our commercial objectives;
- our estimates regarding expenses, future revenue, timing of any future revenue, capital requirements and needs for additional financing;
- the impact of government laws and regulations;
- our competitive position;
- developments relating to our competitors and our industry;
- our ability to maintain and establish collaborations or obtain additional funding;
- the potential direct or indirect impact of the COVID-19 pandemic on our business, operations, and the markets and communities in which we and our partners, collaborators, vendors and customers operate; and
- our expectations regarding the time during which we will be an emerging growth company under the JOBS Act.

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in this Quarterly Report on Form 10-Q, particularly in the “Risk Factors” section, that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, collaborations, joint ventures or investments we may make or enter into.

You should read this Quarterly Report on Form 10-Q and the documents that we reference in this Quarterly Report on Form 10-Q and have filed as exhibits to our other filings with the SEC completely and with the understanding that our actual future results may be materially different from what we expect. The forward-looking statements contained in this Quarterly Report on Form 10-Q are made as of the date of this Quarterly Report on Form 10-Q, and we do not assume any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by applicable law.

BASIS OF PRESENTATION

As used in this Quarterly Report on Form 10-Q, unless the context otherwise requires, references to "we," "us," "our," the "Company," "Pandion" and similar references refer: (1) following the consummation of our conversion to a Delaware corporation on July 16, 2020 in connection with our initial public offering, to Pandion Therapeutics, Inc., and (2) prior to the completion of such conversion, to Pandion Therapeutics Holdco LLC. See "Management's Discussion and Analysis of Financial Condition and Results of Operations—Corporate Conversion" in this Quarterly Report on Form 10-Q for further information.

Table of Contents

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

PANDION THERAPEUTICS HOLDCO LLC
Condensed Consolidated Balance Sheets
(in thousands, except share and per share amounts)

	June 30, 2020 (unaudited)	December 31, 2019
Assets		
Current assets		
Cash and cash equivalents	$ 105,725	$ 15,970
Accounts receivable	1,318	1,035
Prepaid expenses and other current assets	3,377	2,960
Total current assets	110,420	19,965
Property and equipment, net	2,592	1,054
Restricted cash	502	—
Total assets	$ 113,514	$ 21,019
Liabilities and members' deficit		
Current liabilities:		
Accounts payable	$ 3,742	$ 1,207
Accrued expenses and other current liabilities	2,260	1,455
SAFE agreement	6,000	—
Current portion of deferred revenue	4,748	4,365
Total current liabilities	16,750	7,027
Deferred revenue, net of current portion	4,582	6,053
Long-term debt, net of issuance costs	1,815	3,676
Other long-term liabilities	253	85
Total liabilities	23,400	16,841
Commitments and contingencies (Note 7)		
Redeemable convertible preferred shares, no par value; 91,534,629 and 51,217,321 shares authorized at June 30, 2020 and December 31, 2019, respectively; 91,441,336 and 35,524,212 shares issued and outstanding at June 30, 2020 and December 31, 2019, respectively; liquidation value of $152,596 at June 30, 2020	152,596	46,967
Members' deficit		
Common shares, no par value; 100,000,000 and 62,000,000 shares authorized at June 30, 2020 and December 31, 2019, respectively; 1,237,639 shares issued at June 30, 2020 and December 31, 2019; 1,195,794 and 1,110,767 shares outstanding at June 30, 2020 and December 31, 2019, respectively	—	—
Incentive shares, no par value; 13,182,678 and 7,717,678 shares authorized at June 30, 2020 and December 31, 2019, respectively; 2,364,595 and 946,751 shares issued and outstanding at June 30, 2020 and December 31, 2019, respectively	382	172
Accumulated deficit	(62,864)	(42,961)
Total members' deficit	(62,482)	(42,789)
Total liabilities, redeemable convertible preferred shares and members' deficit	$ 113,514	$ 21,019

See accompanying notes to the condensed consolidated financial statements.

PANDION THERAPEUTICS HOLDCO LLC
Condensed Consolidated Statements of Operations
(in thousands, except share and per share amounts)
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Revenue	$ 1,955	$ —	$ 3,956	$ —
Operating expenses				
Research and development	8,860	4,934	15,802	10,019
General and administrative	2,297	840	3,863	1,614
Total operating expenses	11,157	5,774	19,665	11,633
Loss from operations	(9,202)	(5,774)	(15,709)	(11,633)
Interest income	4	89	45	143
Interest expense	(39)	—	(82)	—
Fair value adjustments to convertible note	—	—	89	—
Net loss	(9,237)	(5,685)	(15,657)	(11,490)
Change in redemption value of redeemable convertible preferred shares	(2,712)	(982)	(4,245)	(1,936)
Net loss attributable to common shareholders	(11,949)	(6,667)	(19,902)	(13,426)
Net loss per common share, basic and diluted	$ (10.15)	$ (6.30)	$ (17.23)	$ (13.19)
Weighted-average number of shares outstanding used in computing net loss per common share, basic and diluted	1,177,479	1,057,617	1,154,856	1,018,254

See accompanying notes to the condensed consolidated financial statements.

PANDION THERAPEUTICS HOLDCO LLC
Condensed Consolidated Statements of Redeemable Convertible Preferred Shares and Members' Deficit (Unaudited)
(in thousands, except share amounts)

	Redeemable Convertible Preferred Stock		Redeemable Convertible Preferred Shares		Common Stock		Common Shares		Incentive Shares		Additional Paid-In Capital	Accumulated Deficit	Total Members' Deficit
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
Balance, January 1, 2019	19,831,103	$ 24,977	—	$ —	940,713	$ —	—	$ —	—	$ —	$ 52	$ (17,109)	$ (17,057)
Reorganization	(19,831,103)	(24,977)	19,831,103	24,977	(940,713)	—	940,713	—	—	52	(52)	—	—
Issuance of Series A redeemable convertible preferred shares, net of issuance costs of $34	—	—	15,693,109	17,966	—	—	—	—	—	—	—	—	—
Accretion of redeemable convertible preferred shares to redemption value	—	—	—	954	—	—	—	—	—	—	—	(954)	(954)
Issuance of incentive shares	—	—	—	—	—	—	—	—	230,968	9	—	—	9
Vesting of restricted common shares	—	—	—	—	—	—	79,283	—	—	—	—	—	—
Net loss	—	—	—	—	—	—	—	—	—	—	—	(5,805)	(5,805)
Balance, March 31, 2019	—	$ —	35,524,212	$43,897	—	$ —	1,019,996	$ —	230,968	$ 61	$ —	$ (23,868)	$ (23,807)
Accretion of redeemable convertible preferred shares to redemption value	—	—	—	982	—	—	—	—	—	—	—	(982)	(982)
Issuance of incentive shares	—	—	—	—	—	—	—	—	66,532	11	—	—	11
Vesting of restricted common shares	—	—	—	—	—	—	79,283	—	—	—	—	—	—
Net loss	—	—	—	—	—	—	—	—	—	—	—	(5,685)	(5,685)
Balance, June 30, 2019	—	$ —	35,524,212	$44,879	—	$ —	1,099,279	$ —	297,500	$ 72	$ —	$ (30,535)	$ (30,463)

PANDION THERAPEUTICS HOLDCO LLC
Condensed Consolidated Statements of Redeemable Convertible Preferred Shares and Members' Deficit (Unaudited)
(in thousands, except share amounts)

	Redeemable Convertible Preferred Shares		Common Shares		Incentive Shares		Accumulated Deficit	Total Members' Deficit
	Shares	Amount	Shares	Amount	Shares	Amount		
Balance, January 1, 2020	35,524,212	$ 46,967	1,110,767	$ —	946,751	$ 172	$ (42,961)	$ (42,789)
Issuance of Series A redeemable convertible preferred shares, net of issuance costs of $20	15,693,109	17,980	—	—	—	—	—	—
Issuance of Series A Prime redeemable convertible preferred shares on conversion of JDRF note	948,225	1,811	—	—	—	—	—	—
Issuance of Series B redeemable convertible preferred shares, net of issuance costs of $271	19,158,922	39,728	—	—	—	—	—	—
Accretion of redeemable convertible preferred shares to redemption value	—	1,534	—	—	—	—	(1,534)	(1,534)
Issuance of incentive shares	—	—	—	—	—	60	—	60
Vesting of restricted common shares	—	—	54,770	—	—	—	—	—
Net loss	—	—	—	—	—	—	(6,420)	(6,420)
Balance, March 31, 2020	71,324,468	$ 108,020	1,165,537	$ —	946,751	$ 232	$ (50,915)	$ (50,683)
Issuance of Series B redeemable convertible preferred shares, net of issuance costs of $136	20,116,868	41,864	—	—	—	—	—	—
Accretion of redeemable convertible preferred shares to redemption value	—	2,712	—	—	—	—	(2,712)	(2,712)
Issuance of incentive shares	—	—	—	—	1,417,844	150	—	150
Vesting of restricted common shares	—	—	30,257	—	—	—	—	—
Net loss	—	—	—	—	—	—	(9,237)	(9,237)
Balance, June 30, 2020	91,441,336	$ 152,596	1,195,794	$ —	2,364,595	$ 382	$ (62,864)	$ (62,482)

See accompanying notes to the condensed consolidated financial statements.

PANDION THERAPEUTICS HOLDCO LLC
Condensed Consolidated Statements of Cash Flows
(in thousands)
(Unaudited)

	Six Months Ended June 30,	
	2020	2019
Cash flows from operating activities		
Net loss	$ (15,657)	$ (11,490)
Adjustment to reconcile net loss to net cash used in operating activities:		
Depreciation expense	171	112
Equity-based compensation expense	210	20
Fair value adjustments on convertible notes	(89)	—
Noncash interest expense	39	—
Changes in operating assets and liabilities:		
Accounts receivable	(283)	—
Prepaid expenses and other current assets	132	518
Accounts payable	1,630	103
Accrued expenses and other current liabilities	847	(886)
Deferred revenue	(1,088)	—
Net cash used in operating activities	(14,088)	(11,623)
Cash flows from investing activities		
Purchases of property and equipment	(1,228)	(437)
Net cash used in investing activities	(1,228)	(437)
Cash flows from financing activities		
Proceeds from simple agreement for future equity	6,000	—
Proceeds from issuance of Series A redeemable convertible preferred shares	18,000	18,000
Series A redeemable convertible preferred share issuance costs	(20)	(33)
Proceeds from issuance of Series B redeemable convertible preferred shares	82,000	—
Series B redeemable convertible preferred share issuance costs	(407)	—
Net cash provided by financing activities	105,573	17,967
Net increase in cash and cash equivalents	90,257	5,907
Cash, cash equivalents and restricted cash, beginning of period	15,970	10,172
Cash, cash equivalents and restricted cash, end of period	$ 106,227	$ 16,079
Components of cash, cash equivalents, and restricted cash		
Cash and cash equivalents	105,725	16,079
Restricted cash	502	—
Total cash, cash equivalents, and restricted cash	$ 106,227	$ 16,079
Supplemental cash flow disclosures:		
Cash paid for interest	$ 43	$ —
Supplemental disclosures of noncash activities:		
Exchange of JDRF note and accrued interest for Series A redeemable convertible preferred shares	$ 1,811	$ —
Deferred offering costs not yet paid	$ 549	$ —
Purchase of property and equipment included in accounts payable	$ 481	$ —

See accompanying notes to the condensed consolidated financial statements.

1. DESCRIPTION OF BUSINESS, ORGANIZATION AND LIQUIDITY

Business

Pandion Therapeutics Holdco LLC is a clinical stage biopharmaceutical company developing novel therapeutics designed to address the unmet needs of patients suffering from autoimmune diseases. We have combined a network-based conceptualization of the immune system with expertise in advanced protein engineering to develop our TALON (Therapeutic Autoimmune reguLatOry proteiN) drug design and discovery platform.

As used in these financial statements, unless the context otherwise requires, references to the "company", "we," "us," and "our" refer to Pandion Therapeutics Holdco LLC, its wholly owned subsidiaries Pandion Therapeutics, Inc. and Pandion Program Co 1, Inc., and Pandion Securities Corp., a subsidiary of Pandion Therapeutics, Inc.

Pandion Therapeutics, Inc. was incorporated on September 19, 2016 as a Delaware corporation. We began operations in January 2017. Our principal offices are located in Watertown, Massachusetts. On December 31, 2018, Pandion Therapeutics Holdco LLC was formed in the state of Delaware. On January 1, 2019, we completed a series of transactions in which Pandion Therapeutics, Inc. became a direct wholly owned subsidiary of Pandion Therapeutics Holdco LLC and all outstanding equity securities of Pandion Therapeutics, Inc. were canceled and converted on a one-for-one basis into equity securities of Pandion Therapeutics Holdco LLC, which we refer to as the Restructuring. In accordance with the terms of the LLC Operating Agreement, and on the effective date of the Restructuring;

- each share of Pandion Therapeutics, Inc. common stock issued and outstanding immediately prior to the effective date of the Restructuring was converted into one common share of Pandion Therapeutics Holdco LLC;
- each share of Pandion Therapeutics, Inc. Series A redeemable convertible preferred stock issued and outstanding immediately prior to the effective date of the Restructuring was converted into one Series A redeemable convertible preferred share of Pandion Therapeutics Holdco LLC;
- all outstanding stock options to purchase shares of Pandion Therapeutics, Inc. common stock were cancelled and replaced with the same number of incentive shares in Pandion Therapeutics Holdco LLC;
- each warrant issued by Pandion Therapeutics, Inc. that was outstanding immediately prior to the effective date of the Restructuring was cancelled and an equivalent number of incentive shares of Pandion Therapeutics Holdco LLC were issued; and
- Pandion Therapeutics, Inc. became a wholly owned subsidiary of Pandion Therapeutics Holdco LLC.

We determined that the Restructuring lacked economic substance and was therefore accounted for in a manner consistent with a common control transaction. Similarly, as there was no change in fair value between shareholders, individually or as a class, we determined that the exchange of shares occurring in the Restructuring should be accounted for as a modification of the equity securities and presented as a reclassification of the components of equity.

Initial Public Offering and Corporate Conversion

As described in Note 14, in July 2020 we completed our initial public offering. In contemplation of the initial public offering, on July 10, 2020, our wholly owned subsidiary Pandion Therapeutics, Inc. changed its name to Pandion Operations, Inc. and we subsequently engaged in the following transactions, which we refer to collectively as the Conversion:

- we converted from a Delaware limited liability company to a Delaware corporation by filing a certificate of conversion with the Secretary of State of the State of Delaware; and
- we changed our name from Pandion Therapeutics Holdco LLC to Pandion Therapeutics, Inc.

As part of the Conversion:

- holders of Series A preferred shares of Pandion Therapeutics Holdco LLC received one share of Series A preferred stock of Pandion Therapeutics, Inc. for each Series A preferred share held immediately prior to the Conversion;
- holders of Series A prime preferred shares of Pandion Therapeutics Holdco LLC received one share of Series A prime preferred stock of Pandion Therapeutics, Inc. for each Series A prime preferred share held immediately prior to the Conversion;

- holders of Series B preferred shares of Pandion Therapeutics Holdco LLC received one share of Series B preferred stock of Pandion Therapeutics, Inc. for each Series B preferred share held immediately prior to the Conversion;
- holders of common shares of Pandion Therapeutics Holdco LLC received one share of common stock of Pandion Therapeutics, Inc. for each common share held immediately prior to the Conversion;
- holders of outstanding incentive shares in Pandion Therapeutics Holdco LLC, all of which were intended to constitute profits interests for U.S. federal income tax purposes, received a number of shares of common stock of Pandion Therapeutics, Inc. based upon a conversion price determined by our board of directors immediately prior to the Conversion. Of the shares of common stock issued in respect of incentive shares, 1,368,515 continue to be subject to vesting in accordance with the vesting schedule applicable to such incentive shares. Based on the determined fair value of $18.00 per common share, the incentive shares converted into an aggregate of 1,504,586 shares of our common stock, and we granted options to purchase an aggregate of 859,147 shares of our common stock.

Following the Conversion, Pandion Therapeutics, Inc. held all property and assets of Pandion Therapeutics Holdco LLC and assumed all of the debts and obligations of Pandion Therapeutics Holdco LLC. On the effective date of the Conversion, the members of the board of directors of Pandion Therapeutics Holdco LLC became the members of the board of directors of Pandion Therapeutics, Inc. and the officers of Pandion Therapeutics Holdco LLC became the officers of Pandion Therapeutics, Inc.

Liquidity

Since inception, we have devoted substantially all our efforts to business planning, research and development, recruiting management and technical staff, and raising capital and have financed our operations primarily through the issuance of redeemable convertible preferred shares, debt financings, a simple agreement for future equity, or SAFE, and a collaboration.

We are subject to risks and uncertainties common to early-stage companies in the biotechnology industry, including, but not limited to, development by competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, compliance with government regulations and ability to secure additional capital to fund operations. Product candidates currently under development will require significant additional research and development efforts, including extensive preclinical and clinical testing and regulatory approval prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel and infrastructure and extensive compliance-reporting capabilities. Even if our product development efforts are successful, it is uncertain when, if ever, we will realize significant revenue from product sales.

We have evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about our ability to continue as a going concern within one year after the date the condensed consolidated financial statements are issued. As of June 30, 2020, we had an accumulated deficit of $62.9 million. We have incurred losses and negative cash flows from operations since inception, including net losses of $15.7 million and $21.9 million for the six months ended June 30, 2020 and for the year ended December 31, 2019, respectively. We expect that our operating losses and negative cash flows will continue for the foreseeable future as we continue to develop our product candidates. We currently expect that our cash and cash equivalents of $105.7 million as of June 30, 2020 together with the net proceeds from our IPO, after deducting underwriting discounts and commissions but before deducting offering costs, of $142.2 million in July and August 2020, will be sufficient to fund our operating expenses and capital requirements for more than 12 months from the date the condensed consolidated financial statements are issued. However, additional funding will be necessary to fund future clinical and pre-clinical activities and we do not currently have any. If we are unable to obtain funding, we could be forced to delay, reduce or eliminate our research and development programs, product portfolio expansion or commercialization efforts, which could adversely affect our business prospects and our ability to continue operations.

Coronavirus Pandemic

In March 2020, the World Health Organization declared the global novel coronavirus disease 2019, or COVID-19, outbreak a pandemic. Our operations have not been significantly impacted by the COVID-19 pandemic. However, we cannot at this time predict the specific extent, duration, or full impact that the COVID-19 pandemic will have on our financial condition and operations, including ongoing and planned clinical trials. The impact of the COVID-19 pandemic on our financial performance will depend on future developments, including the duration and spread of the pandemic and related governmental advisories and restrictions. These developments and the impact of the COVID-19 pandemic on the financial markets and the overall economy are highly uncertain and cannot be predicted. If the financial markets and/or the overall economy are impacted for an extended period, our results may be materially adversely affected.

On March 27, 2020, the United States enacted the Coronavirus Aid, Relief and Economic Security Act, or CARES Act. The Cares Act is an emergency economic stimulus package that includes spending and tax breaks to strengthen the United States economy and fund a nationwide effort to curtail the effect of the COVID-19 pandemic. The CARES Act provides sweeping tax changes in response to the COVID-19 pandemic, some of the more significant provisions include removal of certain limitations on utilization of net operating losses, increasing the loss carryback period for certain losses to five years, increasing the ability to deduct interest expense, and deferring social security payments, as well as amending certain provisions of the previously enacted Tax Cuts and Jobs Act. We do not believe the CARES Act will have a material impact on our financial position and results of operations.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

There have been no changes to the significant accounting policies as disclosed in Note 2 to our annual consolidated financial statements for the year ended December 31, 2019 included in our final prospectus for our IPO filed pursuant to Rule 424(b)(4) under the Securities Act with the SEC on July 17, 2020.

Deferred Offering Costs

We capitalize certain legal, accounting and other third-party fees that are directly associated with in-process equity financings as deferred offering costs until such financings are consummated. Upon the closing of our initial public offering, these costs will be reclassified to additional paid-in capital. If the equity financing is no longer considered probable of being consummated, the deferred offering costs would be expensed immediately to operating expenses in the statement of operations. There were $2.3 million of deferred offering costs capitalized at June 30, 2020 and no deferred offering costs at December 31, 2019.

Unaudited Financial Information

Our condensed consolidated financial statements included herein have been prepared in conformity with accounting principles generally accepted in the United States of America, or GAAP, and pursuant to the rules and regulations of the Securities and Exchange Commission, or SEC. In our opinion, the information furnished reflects all adjustments, all of which are of a normal and recurring nature, necessary for a fair presentation of the financial position and results of operations for the reported interim periods. We consider events or transactions that occur after the balance sheet date but before the financial statements are issued to provide additional evidence relative to certain estimates or to identify matters that require additional disclosure. The results of operations for interim periods are not necessarily indicative of results to be expected for the full year or any other interim period.

Recently Issued Accounting Pronouncements

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)*, as amended, with guidance regarding the accounting for and disclosure of leases. The update requires lessees to recognize the liabilities related to all leases, including operating leases, with a term greater than 12 months on the balance sheet. This update also requires lessees and lessors to disclose key information about their leasing transactions. This guidance will become effective for us for annual reporting periods beginning after December 15, 2020, and interim periods within annual periods beginning after December 15, 2021. Early adoption is permitted. We are currently assessing the impact of adopting ASU 2016-02 on our consolidated financial statements and related disclosures.

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments-Credit Losses: Measurement of Credit Losses on Financial Instruments (Topic 326)*. ASU 2016-13 requires measurement and recognition of expected credit losses for financial assets. In April 2019, the FASB issued clarification to ASU 2016-13 within ASU 2019-04, Codification Improvements to Topic 326, Financial Instruments-Credit Losses, Topic 815, Derivatives and Hedging, and Topic 825, Financial Instruments. The guidance will become effective for us for fiscal years beginning after December 15, 2022. We are currently evaluating the impact that ASU 2016-13 will have on our consolidated financial statements and related disclosures.

In December 2019, the FASB issued ASU 2019-12, *Simplifying the Accounting for Income Taxes*. ASU 2019-12 eliminates certain exceptions related to the approach for intra-period tax allocation, the methodology for calculating income taxes in an interim period and the recognition of deferred tax liabilities for outside basis differences. It also clarifies and simplifies other aspects of the accounting for income taxes. This guidance is effective for us for fiscal years beginning after December 15, 2021, and interim periods within fiscal years beginning after December 15, 2022. Early adoption is permitted. We are currently evaluating the impact that ASU 2019-12 will have on our consolidated financial statements and related disclosures.

3. FAIR VALUE MEASUREMENTS

The following tables present information about our financial assets and liabilities measured at fair value on a recurring basis and indicate the level of the fair value hierarchy utilized to determine such fair values (in thousands):

	As of June 30, 2020			
	Total	Level 1	Level 2	Level 3
Assets—money market funds	$ 55,225	$ 55,225	$ —	$ —
Total financial assets measured at fair value	$ 55,225	$ 55,225	$ —	$ —
Liabilities—SAFE	$ 6,000	$ —	$ —	$ 6,000
Total financial liabilities measured at fair value	$ 6,000	$ —	$ —	$ 6,000

	As of December 31, 2019			
	Total	Level 1	Level 2	Level 3
Assets—money market funds	$ 3,517	$ 3,517	$ —	$ —
Total financial assets measured at fair value	$ 3,517	$ 3,517	$ —	$ —
Liabilities—convertible note	$ 1,900	$ —	$ —	$ 1,900
Total financial liabilities measured at fair value	$ 1,900	$ —	$ —	$ 1,900

The following table presents a roll-forward of the fair value of the convertible note and SAFE for which fair value is determined by Level 3 inputs (in thousands):

	Six Months Ended June 30,	
	2020	2019
Balance at beginning of the period	$ 1,900	$ 2,010
Fair value adjustment to convertible note	(89)	—
Conversion of convertible note into Series A prime redeemable convertible preferred shares	(1,811)	—
Initial fair value of SAFE	6,000	—
Balance at end of the period	$ 6,000	$ 2,010

Our money market funds are highly liquid investments that are valued based on quoted market prices in active markets, which represent a Level 1 measurement within the fair value hierarchy.

Valuation techniques used to measure fair value maximize the use of relevant observable inputs and minimize the use of unobservable inputs. Our convertible note and SAFE is classified within Level 3 of the fair value hierarchy because the fair value measurement is based, in part, on significant inputs not observed in the market.

The fair value of the SAFE on issuance was determined to be equal to the proceeds received. Fair value of the SAFE on conversion into common stock (Note 8) was determined to be equal to the fair value of the 333,333 common stock received of $6.0 million. Given the proximity of the conversion of the SAFE to the financial reporting period end, the fair value of the SAFE as of June 30, 2020 was also determined to be equal to the fair value of the common stock, of $6.0 million, received on conversion.

In December 2018, we entered into an agreement for the sale of up to $4.0 million of convertible notes with the Juvenile Diabetes Research Foundation, or JDRF, T1D Fund, or JDRF Note, of which $2.0 million was initially sold. We have elected to account for the JDRF Note at fair value. We determine fair value of the JDRF Note using a scenario-based valuation method and a Monte Carlo simulation model with inputs based on certain subjective assumptions, including (a) expected stock price volatility, (b) calculation of a forecast horizon, (c) a risk-free interest rate, and (d) a discount rate. This approach results in the classification of these securities as Level 3 of the fair value hierarchy. The assumptions utilized to value the JDRF Note obligation as of December 31, 2019 were (a) expected stock price volatility of 90%; (b) a forecast horizon of 1.9 years: (c) a risk-free interest rate of 1.6%; and (d) a discount rate of 14.8%. For the year ended December 31, 2019, we recognized a $110,000 gain in the condensed consolidated statements of operations as fair value adjustments on convertible note with respect to changes to the fair value of the JDRF Note during the year.

In February 2020, the outstanding principal and accrued interest under the JDRF Note automatically converted at a price of $2.294 per share into 948,225 Series A prime redeemable convertible preferred shares. The final fair value adjustment to the JDRF Note in the six months ended June 30, 2020 was determined to be equal to the fair value of the Series A prime redeemable convertible preferred shares into which the JDRF Note was converted. We determine the fair value of our Series A prime redeemable convertible preferred shares using a probability-weighted hybrid method combining (i) an option pricing model, or OPM, and (ii) an IPO scenario with reference to guideline IPOs in the biotechnology sector. For purposes of the OPM the key inputs include an 80.3% volatility rate, a 1.6-year estimated term, a risk-free rate of 0.3% and dividends of zero. For our IPO scenario, the key inputs include a weighted average cost of capital of 25% and a 0.8-year term to a liquidity event. For the six months ended June 30, 2020, we recognized a $89,000 gain in the condensed consolidated statements of operations as fair value adjustments on convertible note with respect to changes to the fair value of the JDRF Note.

There were no transfers among Level 1, Level 2 or Level 3 categories in the six months ended June 30, 2020 and 2019.

4. PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets consist of the following (in thousands):

	June 30, 2020	December 31, 2019
Loss recovery receivable	$ —	$ 1,875
Contract research	489	487
Tax receivable	163	334
Deferred offering costs	2,256	—
Other	469	264
Total prepaid expenses and other current assets	$ 3,377	$ 2,960

In October 2019, several batches of our drug substance were inadvertently disposed of by a vendor resulting in a loss of approximately $1.9 million for the year ended December 31, 2019. During the first quarter of 2020, we entered into a settlement agreement to recover the full cost of replacing the drug substance, resulting in a loss recovery receivable being recorded at December 31, 2019. We received the full loss recovery receivable during the six months ended June 30, 2020.

5. ACCRUED EXPENSES AND OTHER CURRENT LIABILITIES

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

	June 30, 2020	December 31, 2019
Employee compensation costs	$ 853	$ 915
Research and development costs	1,083	275
Professional costs	293	243
Other	31	22
Total accrued expenses and other current liabilities	$ 2,260	$ 1,455

6. LONG-TERM DEBT

Convertible Note

In February 2020, the outstanding principal and accrued interest under the JDRF Note automatically converted at an adjusted price of $2.294 per share into 948,225 Series A prime redeemable convertible preferred shares (Note 3).

Term Loan

In November 2019, we entered into a secured term loan facility with Silicon Valley Bank in the amount of $10.0 million, with an initial advance of $2.0 million, or the Term Loan. In response to the financial impact of the COVID-19 coronavirus pandemic, in April 2020 the lender to our Term Loan extended monthly interest-only payments on the Term Loan through November 2021 and the final maturity date on the Term Loan to May 2024. In July 2020, we repaid the $2.0 million of principal outstanding under the Term Loan and, in connection with such repayment, the facility was terminated pursuant to its terms. We have no further payment obligations under the Term Loan and no amounts under the secured term loan facility are available for borrowing.

7. COMMITMENTS AND CONTINGENCIES

We record a provision for contingent losses when it is both probable that a liability has been incurred and the amount of the loss can be reasonably estimated. As of June 30, 2020 and December 31, 2019, we had not recorded a provision for any contingent losses.

8. REDEEMABLE CONVERTIBLE PREFERRED SHARES

There have been no changes to the rights, preferences, privileges and restrictions of the redeemable convertible preferred shares as disclosed in Note 9 to our annual consolidated financial statements for the years ended December 31, 2019 and 2018 included in our final prospectus for our IPO filed pursuant to Rule 424(b)(4) under the Securities Act with the SEC on July 17, 2020.

The following table summarizes outstanding redeemable convertible preferred shares (in thousands, except share and per share amounts):

	Series A		Series A prime		Series B		Total	
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount
Balance, January 1, 2019	—	$ —	—	$ —	—	$ —	—	$ —
Restructuring	19,831,103	24,977	—	—	—	—	19,831,103	24,977
Issuance of Series A Preferred Shares, net of issuance costs of $34	15,693,109	17,966	—	—	—	—	15,693,109	17,966
Accretion of redeemable convertible preferred shares to redemption value	—	954	—	—	—	—	—	954
Balance, March 31, 2019	35,524,212	$43,897	—	$ —	—	$ —	35,524,212	$ 43,897
Accretion of redeemable convertible preferred shares to redemption value	—	982	—	—	—	—	—	982
Balance, June 30, 2019	35,524,212	$44,879	—	$ —	—	$ —	35,524,212	$ 44,879
Balance, January 1, 2020	35,524,212	46,967	—	—	—	—	35,524,212	46,967
Issuance of Series A Preferred Shares	15,693,109	17,980	—	—	—	—	15,693,109	17,980
Issuance of Series A Prime Preferred Shares, on conversion of JDRF note	—	—	948,225	1,811	—	—	948,225	1,811
Issuance of Series B Preferred Shares, net of issuance costs of $271	—	—			19,158,922	39,728	19,158,922	39,728
Accretion of redeemable convertible preferred shares to redemption value	—	1,193	—	3	—	338	—	1,534
Balance, March 31, 2020	51,217,321	$66,140	948,225	$ 1,814	19,158,922	$40,066	71,324,468	$108,020
Issuance of Series B Preferred Shares, net of issuance costs of $136	—	—			20,116,868	41,864	20,116,868	41,864
Accretion of redeemable convertible preferred shares to redemption value	—	1,465	—	45	—	1,202	—	2,712
Balance, June 30, 2020	51,217,321	$67,605	948,225	$ 1,859	39,275,790	$83,132	91,441,336	$152,596

In January 2019, we issued 15,693,109 Series A redeemable convertible preferred shares at a price of $1.147 per share for gross cash proceeds of $18.0 million and incurred issuance costs of $34,000.

In February 2020, we issued 15,693,109 Series A redeemable convertible preferred shares at a price of $1.147 per share for gross cash proceeds of $18.0 million. At this closing, the outstanding principal and accrued interest under the JDRF Note automatically converted at a price of $2.294 per share into 948,225 Series A prime redeemable convertible preferred shares.

In March 2020, we completed an $80.0 million Series B financing comprised of an initial closing and issuance of 19,158,922 Series B redeemable convertible preferred shares at $2.0878 per share to new and existing investors for gross cash proceeds of $40.0 million and incurred issuance costs of $271,000.

In connection with the initial issuance of the Series B redeemable convertible preferred shares, the holders received the right to purchase, and we were under the obligation to sell, an additional 19,158,922 shares of Series B redeemable convertible preferred shares upon achieving a certain clinical development milestone, or the Tranche Right.

We determined that the Tranche Right did not meet the definition of a freestanding financial instrument because it is not legally detachable. Further, we determined that the Tranche Right does not meet the definition of an embedded derivative that requires bifurcation from the equity instrument. Therefore, at the initial issuance of the Series B redeemable convertible preferred shares, there was no accounting for the Tranche Right.

In June 2020, we issued 19,158,922 Series B redeemable convertible preferred shares at $2.0878 per share in a second closing of our Series B financing to existing investors for gross cash proceeds of $40.0 million and issued 957,946 Series B redeemable convertible preferred shares to JDRF per the terms of the JDRF Note for gross cash proceeds of $2.0 million.

Simple Agreement for Future Equity

In June 2020, we entered into a simple agreement for future equity, or SAFE, with a related party, pursuant to which we received $6.0 million in cash in exchange for the providing the investor the right to receive shares of our capital stock. The SAFE contained a number of conversion and redemption provisions, including settlement upon liquidity or dissolution events. We elected the fair value option of accounting for the SAFE. Upon consummation of our initial public offering in July 2020, the SAFE was converted, by its terms, into 333,333 shares of our common stock based on the initial public offering price of $18.00 per share.

9. INCENTIVE SHARES AND EQUITY-BASED COMPENSATION

We granted profits interest awards to employees, consultants and non-employee members of our Board of Directors. The LLC Operating Agreement of Pandion Therapeutics Holdco LLC initially provided for the grant of up to 1,717,678 incentive shares, subject to certain restrictions as described below. Each unvested incentive share represented a non-voting equity interest in Pandion Therapeutics Holdco LLC that entitled the holder to a percentage of the profits and appreciation in the equity value of Pandion Therapeutics Holdco LLC arising after the date of grant and after such time as an applicable threshold amount was met.

As part of the Restructuring (Note 1), all of the outstanding stock options and warrants issued under our 2017 Stock Incentive Plan were cancelled and exchanged for incentive shares. On January 1, 2019, we exchanged 195,630 stock options and 14,031 warrants for 209,661 incentive shares with a weighted average fair value of $0.66. We consider this exchange of awards to be a modification with no additional compensation expense. In March 2020, the LLC Operating Agreement was amended to authorize the issuance of up to an aggregate of 13,182,678 incentive shares.

As of June 30, 2020, there were 10,818,083 incentive shares available for future grant.

During the six months ended June 30, 2019, we granted 87,839 incentive shares with a weighted average fair value of $1.25 per share. During the six months ended June 30, 2020, we granted 1,417,844 incentive shares with a weighted average fair value of $2.01 per share. The fair value of incentive shares issued was determined using a Black-Scholes option pricing model with the following assumptions:

	Six Months Ended June 30,	
	2020	2019
Expected Term	2.0	1.2
Risk Free Rate	0.14% - 0.17%	1.96% - 2.60%
Volatility	82.7% - 83.7%	71.5% - 72.3%
Dividend Yield	0%	0%

We recorded equity-based compensation expense related to the issuance of incentive shares of $210,000 and $20,000 during the six months ended June 30, 2020 and 2019, respectively, and $150,000 and $11,000 during the three months ended June 30, 2020 and 2019, respectively. As of June 30, 2020, there was $3.4 million of unrecognized compensation cost that is expected to be recognized over a weighted-average period of approximately 3.4 years.

Equity-based compensation expense recorded in the accompanying condensed consolidated statements of operations is as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Research and development	$ 58	$ 5	$ 70	$ 9
General and administrative	92	6	140	11
Total equity-based compensation	$ 150	$ 11	$ 210	$ 20

10. ASTELLAS AGREEMENT

In October 2019, we entered into a license and collaboration agreement, or the Astellas Agreement, with Astellas Pharma Inc., or Astellas, to develop locally acting immunomodulators for autoimmune diseases of the pancreas. Under the Astellas Agreement, we will be responsible for design and discovery of bispecific drug candidates based on our proprietary modular immune effector and tissue tether platform and Astellas will be responsible for conducting preclinical, clinical and commercialization activities for the selected candidates developed under the Astellas Agreement. In connection with our services to Astellas, we have granted a non-exclusive, non-transferable research license to Astellas and an exclusive, non-transferable, royalty-bearing, perpetual license to our technology with respect to the designated compound(s) for Astellas to further develop and ultimately commercialize for the treatment of autoimmune diseases of the pancreas. We do not share in the rights to clinical data and results under the Astellas Agreement. In addition, we are obligated under the Astellas Agreement to certain governance activities, reporting obligations and have made other ancillary commitments. The Astellas Agreement has a contractual term of five years.

We identified our research and development services, the licenses granted to Astellas and our governance obligations to Astellas as the material promises under the Astellas Agreement. For purposes of identifying our performance obligations under the Astellas Agreement, we believe that while the licenses were granted to Astellas at the outset of the Astellas Agreement, the grant of those licenses did not singularly result in the transfer of our broader obligation to Astellas under the Astellas Agreement, as the license has no true value without the performance of our research and development services, the technology transfer and joint steering committee participation.

Our research and development work with respect to bispecific drug candidates are unique with respect to our proprietary knowledge and know how in the design of bispecific antibodies and coupling bispecific antibodies with effector molecules to modulate immune activity. While capable of being distinct, those research and development activities are not distinct within the context of the Astellas Agreement. The licenses provided to Astellas are not transferable and we believe of limited value without our specific research and development services, and thus are not capable of being distinct. While our governance obligations are capable of being distinct, those activities are integrated with our research and development efforts under the Astellas Agreement and are not distinct in the context of the contract. Taken together with our research and development activities, including the governance oversight to those activities, the licenses granted under the Astellas Agreement will enable us to further advance designated licensed compounds into and through clinical development, regulatory approval and ultimately commercialization. Therefore, we believe the licenses bundled together with our research and development services and our governance obligations therein constitute a single distinct performance obligation under the Astellas Agreement for accounting purposes, or the Performance Obligation.

Under the Astellas Agreement, we received a non-refundable, upfront payment of $10.0 million in November 2019. As of June 30, 2020, we estimate that we will receive a further $17.0 million of research funding and external cost reimbursement. We have the right to receive, on a licensed compound-by licensed compound basis, potential research and development milestone payments up to an aggregate of $43.0 million for the first Licensed Compound and $38.0 million for subsequent Licensed Compounds and regulatory milestones up to an aggregate of $105.0 million upon achievement of specified regulatory milestones. If any Astellas licensed products are successfully commercialized, we would be eligible to receive, on a licensed compound-by licensed compound basis, up to $150.0 million from potential commercial milestone payments based on the worldwide net sales of all licensed products containing the same licensed compound. We may also receive tiered mid to high single-digit royalty payments on worldwide net sales of any commercial products developed through our work together under the Astellas Agreement. The achievement and timing of the milestones depend on the success of development, approval and sales progress, if any, of commercial products developed through the collaboration in the future.

Provided Astellas designates at least one compound to progress in development under the Astellas Agreement, Astellas may designate up to five further compounds during a period of three years following the expiration of the five-year term of the Astellas Agreement for their further evaluation to progress towards development. We have no further obligation to Astellas during this period or in the evaluation of any such compounds they may designate. Astellas may request us to conduct services in connection with their evaluations, however we are not obligated to conduct such additional services. We assessed this provision as a potential material right and determined that we have no obligation to provide services (if requested) relating to the designated compounds during the additional period and, as such, this provision does not provide Astellas with a material right.

While the contractual term under the Astellas Agreement is five years, based on the research plan and budget agreed to by the joint steering committee established under the Astellas Agreement, we initially estimate our research and development commitments will be completed by the end of 2022. As of June 30, 2020, we estimated a total transaction price of $29.9 million, consisting of the fixed upfront payment and estimated research funding and reimbursement of external costs of $19.9 million presently budgeted under the Astellas Agreement to be incurred through 2022, the effective term of our Performance Obligation to Astellas. Upon execution of the Astellas Agreement and as of June 30, 2020, contingent and variable consideration consisting of milestone payments has been constrained and excluded from the transaction price given the significant uncertainty of achievement of the development and regulatory milestones.

We have allocated the transaction price entirely to the single, bundled performance obligation. We recorded the $10.0 million up-front payment from Astellas as deferred revenue in November 2019 and will record future invoices under the Astellas Agreement as deferred revenue. We will recognize the estimated total transaction price over the estimated period the research and development services are expected to be provided which, as of June 30, 2020, is through 2022. We believe the Performance Obligation is satisfied over the course of our performance of the research and development activities under the Astellas Agreement and, depicting our performance in satisfaction of the Performance Obligation, we use input method as a measure of progress towards completion of the Performance Obligation according to actual costs incurred compared to estimated total costs to estimate progress toward satisfaction of the Performance Obligation. We will remeasure our progress towards completion of the Performance Obligation at the end of each reporting period. For the three and six months ended June 30, 2020, we recognized $2.0 million and $4.0 million, respectively, of revenue under the Astellas Agreement. No revenue was recognized during the three and six months ended June 30, 2019.

We invoice Astellas under the Astellas agreement quarterly in arrears for the cost of external services, quarterly in advance for our estimated internal services and annually to true-up our advance invoicing for estimated internal services. Invoiced amounts under the Astellas Agreement expected to be recognized as revenue within the 12 months following the balance sheet date are classified as a current portion of deferred revenue in the accompanying condensed consolidated balance sheets. Invoiced amounts not expected to be recognized as revenue within the 12 months following the balance sheet date are classified as deferred revenue, net of current portion. As of June 30, 2020, we had no contract assets and short-term and long-term deferred revenues of $4.7 million and $4.6 million, respectively, which is presently estimated to be recognized through 2022. The aggregate amount of the transaction price allocated to the Performance Obligation that remains unsatisfied as of June 30, 2020 is estimated to be $25.0 million, of which we expect to recognize $7.6 million, $8.3 million and $9.1 million in the remainder of 2020, 2021 and 2022, respectively.

11. INCOME TAXES

We did not record a provision or benefit for income taxes during the six months ended June 30, 2020 and 2019. We continue to maintain a full valuation allowance against all of our deferred tax assets.

We have evaluated the positive and negative evidence involving our ability to realize our deferred tax assets. We have considered our history of cumulative net losses incurred since inception and our lack of any commercially ready products. We have concluded that it is more likely than not that we will not realize the benefits of our deferred tax assets. We reevaluate the positive and negative evidence at each reporting period.

12. NET LOSS PER SHARE

Net Loss Per Share

Basic and diluted net loss per share attributable to common shareholders is calculated as follows (in thousands except share and per share amounts):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Net loss	$ (9,237)	$ (5,685)	$ (15,657)	$ (11,490)
Change in redemption value of redeemable convertible preferred shares	(2,712)	(982)	(4,245)	(1,936)
Net loss attributable to common shares – basic and diluted	$ (11,949)	$ (6,667)	$ (19,902)	$ (13,426)
Net loss per common share, basic and diluted	$ (10.15)	$ (6.30)	$ (17.23)	$ (13.19)
Weighted-average number of shares outstanding used in computing net loss per common share, basic and diluted	1,177,479	1,057,617	1,154,856	1,018,254

The following outstanding potentially dilutive securities have been excluded from the calculation of diluted net loss per share, as their effect is anti-dilutive:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Redeemable convertible preferred shares	91,441,336	35,524,212	91,441,336	35,524,212
Incentive shares	2,364,595	297,500	2,364,595	297,500
Warrants to purchase Series A redeemable convertible preferred shares	55,976	—	55,976	—

13. RELATED PARTY TRANSACTIONS

We engage a firm managed by an executive of the company for professional services related to accounting, finance and other administrative functions. The costs incurred under this arrangement totaled $599,000 and $178,000 for the six months ended June 30, 2020 and 2019, respectively, and $364,000 and $97,000 for the three months ended June 30, 2020 and 2019, respectively, which were recorded as general and administrative expense in the accompanying condensed consolidated statements of operations. As of June 30, 2020 and December 31, 2019, amounts owed under this arrangement totaled approximately $95,000 and $34,000, respectively, and are included in accounts payable in the accompanying condensed consolidated balance sheets.

We engaged a director of the company to provide advice and services as requested by the board of directors. The costs incurred under this arrangement totaled $63,000 and $75,000 for the six months ended June 30, 2020 and 2019, respectively, and $25,000 and $38,000 for the three months ended June 30, 2020 and 2019, respectively, which were recorded as general and administrative expense in the accompanying condensed consolidated statements of operations. As of June 30, 2020 and December 31, 2019, there were no amounts owed to the director under this arrangement. This agreement was terminated in July 2020.

In March 2020, we issued 19,158,922 Series B preferred redeemable convertible shares at a price of $2.0878 per share, for gross cash proceeds of $40.0 million, of which 12,883,010 shares were sold to our 5% stockholders and their affiliates, executive officers and non-employee directors. In June 2020, we issued 19,158,922 Series B redeemable convertible preferred shares in an additional closing at the same price per share as the first closing for gross cash proceeds of $40.0 million, of which 12,883,010 shares were sold to our 5% stockholders and their affiliates, executive officers and non-employee directors.

14. SUBSEQUENT EVENTS

2020 Stock Incentive Plan

In anticipation of our IPO, in July 2020, our board of directors adopted and our stockholders approved the 2020 Stock Incentive Plan (the "2020 Plan"), which became effective on July 16, 2020. The 2020 Plan provides for the grant of incentive stock options, nonstatutory stock options, stock appreciation rights, awards of restricted stock, restricted stock units and other stock-based awards. The number of shares of our common stock reserved for issuance under the 2020 Plan is equal to the sum of: (1) 2,519,375; plus (2) the number of shares (up to 1,504,613) equal to the number of shares of common stock issued in respect of restricted common shares and incentive shares of Pandion Therapeutics Holdco LLC that are subject to vesting immediately prior to the effectiveness of the registration statement for our IPO that expire, terminate or are otherwise surrendered, canceled, forfeited or repurchased by us at their original issuance price pursuant to a contractual repurchase right; plus (3) an annual increase, to be added on the first day of each fiscal year, beginning with the fiscal year ending December 31, 2021 and continuing until, and including, the fiscal year ending December 31, 2030, equal to the lowest of (i) 6,000,000 shares of our common stock, (ii) 4% of the number of shares of our common stock outstanding on such date and (iii) an amount determined by our board of directors.

2020 Employee Stock Purchase Plan

In July 2020, our board of directors adopted and our stockholders approved the 2020 Employee Stock Purchase Plan (the "ESPP"), which became effective on July 16, 2020. A total of 209,948 shares of common stock were reserved for issuance under the ESPP. The number of shares of our common stock reserved for issuance under the ESPP will automatically increase on the first day of each fiscal year, beginning with the fiscal year commencing on January 1, 2021 and continuing for each fiscal year until, and including, the fiscal year commencing on January 1, 2031, in an amount equal to the lowest of (1) 1,500,000 shares of our common stock, (2) 1% of the number of shares of our common stock outstanding on the first day of such fiscal year and (3) an amount determined by our board of directors.

Reverse Share Split

Our board of directors and shareholders approved a one-for-5.0994 reverse share split of our issued and outstanding common shares and incentive shares and a proportional adjustment to the existing conversion ratios for our preferred shares effective as of July 13, 2020. Accordingly, all share and per share amounts for all periods presented in the accompanying condensed consolidated financial statements and notes thereto have been retroactively adjusted, where applicable, to reflect the reverse share split.

Initial Public Offering

As described in Note 1, on July 16, 2020 and immediately prior to the effectiveness of the IPO, Pandion Therapeutics Holdco LLC converted from a Delaware limited liability company to a Delaware corporation by filing a certificate of conversion with the Secretary of State of the State of Delaware, and changed its name to Pandion Therapeutics, Inc.

In the third quarter of 2020, we completed our IPO, selling an aggregate of 8,494,166 shares of common stock at a price to the public of $18.00 per share, which included 994,166 shares issued upon the partial exercise by the underwriters of their option to purchase additional shares of common stock in August 2020. We received net proceeds from the IPO, after deducting underwriting discounts and commissions but before deducting offering costs, of approximately $142.2 million.

Immediately prior to consummation of the IPO, all outstanding shares of our Series A, Series A Prime and Series B convertible preferred stock were converted into 17,950,189 shares of common stock. Additionally, all of our outstanding incentive shares were converted into 1,504,586 shares of common stock. Upon the closing of the IPO on July 21, 2020, a total of 28,525,762 shares of common stock were outstanding. Our common stock began trading on the Nasdaq Global Select Market on July 17, 2020 under the symbol "PAND".

On July 21, 2020, we amended and restated the certificate of incorporation of Pandion Therapeutics, Inc to authorize 200,000,000 shares of common stock and 5,000,000 shares of preferred stock, which shares of preferred stock are currently undesignated.

Term Loan

We repaid our Term Loan of $2.0 million in July 2020 as disclosed in Note 6.

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

You should read the following discussion and analysis of our financial condition and results of operations together with the unaudited financial statements and related notes included in this Quarterly Report on Form 10-Q. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the section entitled "Risk Factors," our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis. You should carefully read the section entitled "Risk Factors" to gain an understanding of the important factors that could cause actual results to differ materially from our forward- looking statements.

Overview

We are a clinical stage biopharmaceutical company developing novel therapeutics designed to address the unmet needs of patients suffering from autoimmune diseases. We have combined a network-based conceptualization of the immune system with expertise in advanced protein engineering to develop our TALON (Therapeutic Autoimmune reguLatOry proteiN) drug design and discovery platform. Our TALON platform enables us to employ a modular approach to create a pipeline of product candidates using immunomodulatory effector modules that act at known control nodes within the immune network. We are also able to combine an effector module with a tissue-targeted tether module in a bifunctional format to guide delivery of the effector to a targeted tissue. Our lead product candidate, PT101, a combination of our interleukin-2, or IL-2, mutein effector module with a protein backbone, is designed to selectively expand regulatory T cells, or Treg cells, systemically, without activating proinflammatory cells, such as conventional T cells and natural killer, or NK, cells. We are initially developing PT101 for the treatment of patients with moderate-to-severe ulcerative colitis, or UC, and are currently conducting a Phase 1a clinical trial of PT101 in healthy volunteers, with final data expected in the first half of 2021. We continue to develop and expand our library of effector and tether modules as part of our early stage research and discovery pipeline.

We were formed under the laws of the State of Delaware in September 2016 as a corporation under the name Immunotolerance, Inc. and began operations in January 2017. We changed our name to Pandion Therapeutics, Inc. in June 2017. On January 1, 2019, we completed a series of transactions in which Pandion Therapeutics, Inc. became a direct wholly owned subsidiary of Pandion Therapeutics Holdco LLC, or Pandion LLC, a Delaware limited liability company, and all outstanding equity securities of Pandion Therapeutics, Inc. were canceled and converted on a one-for-one basis into equity securities of Pandion LLC.

On July 10, 2020, Pandion Therapeutics, Inc. changed its name to Pandion Operations, Inc. and we subsequently engaged in the following transactions, which we refer to collectively as the Conversion:

- we converted from a Delaware limited liability company to a Delaware corporation by filing a certificate of conversion with the Secretary of State of the State of Delaware; and
- we changed our name from Pandion Therapeutics Holdco LLC to Pandion Therapeutics, Inc.

As part of the Conversion:

- holders of Series A preferred shares of Pandion Therapeutics Holdco LLC received one share of Series A preferred stock of Pandion Therapeutics, Inc. for each Series A preferred share held immediately prior to the Conversion;
- holders of Series A prime preferred shares of Pandion Therapeutics Holdco LLC received one share of Series A prime preferred stock of Pandion Therapeutics, Inc. for each Series A prime preferred share held immediately prior to the Conversion;
- holders of Series B preferred shares of Pandion Therapeutics Holdco LLC received one share of Series B preferred stock of Pandion Therapeutics, Inc. for each Series B preferred share held immediately prior to the Conversion;
- holders of common shares of Pandion Therapeutics Holdco LLC received one share of common stock of Pandion Therapeutics, Inc. for each common share held immediately prior to the Conversion;
- holders of outstanding incentive shares in Pandion Therapeutics Holdco LLC, all of which were intended to constitute profits interests for U.S. federal income tax purposes, received a number of shares of common stock of Pandion Therapeutics, Inc. based upon a conversion price determined by our board of directors immediately prior to the Conversion. Of the shares of common stock issued in respect of incentive shares, 1,368,515 continue to be subject to vesting in accordance with the vesting schedule applicable to such incentive shares. Based on the determined fair value of $18.00 per common share, the incentive shares converted into an aggregate of 1,504,586 shares of our common stock, and we granted options to purchase an aggregate of 859,147 shares of our common stock.

In connection with the Conversion, Pandion Therapeutics, Inc. continues to hold all property and assets of Pandion Therapeutics Holdco LLC and has assumed all of the debts and obligations of Pandion Therapeutics Holdco LLC. On July 16, 2020, Pandion LLC converted into a corporation by filing a certificate of conversion with the Secretary of State of the State of Delaware and we changed our name to Pandion Therapeutics, Inc. On the effective date of the Conversion, the members of the board of directors of Pandion Therapeutics Holdco LLC became the members of the board of directors of Pandion Therapeutics, Inc. and the officers of Pandion Therapeutics Holdco LLC became the officers of Pandion Therapeutics, Inc.

Our lead product candidate, PT101, is in Phase 1 clinical development and our other product candidates and our discovery stage programs are in preclinical or earlier stages of development. Our ability to generate revenue from product sales sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of one or more of our product candidates. To date, our operations have been financed primarily through the issuance of redeemable convertible preferred shares, a simple agreement for future equity, or SAFE, convertible notes and a term loan and, most recently, common stock in our initial public offering, or IPO. On July 21, 2020, we completed an IPO of our common stock and issued and sold 7,500,000 shares of common stock at a public offering price of $18.00 per share, resulting in net proceeds of $122.3 million after deducting underwriting discounts and commissions and estimated offering expenses. In addition, on August 11, 2020, we issued and sold an additional 994,166 shares of our common stock at the public offering price of $18.00 per share upon the partial exercise of the underwriters' option to purchase additional shares of common stock.

Since inception, we have had significant operating losses. Our net loss was $21.9 million and $10.9 million for the years ended December 31, 2019 and 2018, respectively, and our net loss was $15.7 million for the six months ended June 30, 2020. As of June 30, 2020, we had an accumulated deficit of $62.9 million.

Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our accounts payable and accrued expenses. We expect to continue to incur net losses for the foreseeable future, and we expect our research and development expenses, general and administrative expenses, and capital expenditures will continue to increase. In particular, we expect our expenses to increase as we continue our development of, and seek regulatory approvals for, our product candidates, as well as hire additional personnel, pay fees to outside consultants, lawyers and accountants, and incur other increased costs associated with being a public company. In addition, if and when, if ever, we seek and obtain regulatory approval to commercialize any product candidate, we will also incur increased expenses in connection with commercialization and marketing of any such product. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of our clinical trials and our expenditures on other research and development activities.

Based upon our current operating plan, we believe that the net proceeds from our IPO together with our existing cash and cash equivalents of $105.7 million as of June 30, 2020 will be sufficient to fund our operating expenses and capital expenditure requirements through the first half of 2024. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. To finance our operations beyond that point we will need to raise additional capital, which cannot be assured.

To date, we have not had any products approved for sale and, therefore, have not generated any product revenue. We do not expect to generate any revenues from product sales unless and until we successfully complete development and obtain regulatory approval for one or more of our product candidates. If we obtain regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. As a result, until such time, if ever, that we can generate substantial product revenue, we expect to finance our cash needs through equity offerings, debt financings or other capital sources, including collaborations, licenses or similar arrangements. However, we may be unable to raise additional funds or enter into such other arrangements when needed or on favorable terms, if at all. Any failure to raise capital as and when needed could have a negative impact on our financial condition and on our ability to pursue our business plans and strategies, including our research and development activities. If we are unable to raise capital, we will need to delay, reduce or terminate planned activities to reduce costs.

In March 2020, the World Health Organization declared the COVID-19 outbreak a pandemic. To date, our financial condition and operations have not been significantly impacted by the COVID-19 pandemic. However, we cannot at this time predict the specific extent, duration, or full impact that the COVID-19 pandemic will have on our financial condition and operations, including ongoing and planned clinical trials. The impact of the COVID-19 pandemic on our financial performance will depend on future developments, including the duration and spread of the pandemic and related governmental advisories and restrictions. These developments and the impact of the COVID-19 pandemic on the financial markets and the overall economy are highly uncertain and cannot be predicted. If the financial markets and/or the overall economy are impacted for an extended period, our results may be materially adversely affected.

Components of Operating Results

Revenue

We have not generated any revenue from product sales and do not expect to generate revenue from the sale of products for several years, if at all. If our development efforts for our current or future product candidates are successful and result in regulatory marketing approval, we may generate revenue in the future from product sales. However, we cannot predict if, when or to what extent we will generate revenue from the commercialization and sale of our product candidates, and we may never succeed in obtaining regulatory approval for, or commercializing, any of our product candidates.

In October 2019, we entered into a license and collaboration agreement, or the Astellas agreement, with Astellas Pharma Inc., or Astellas, to develop locally acting immunomodulators for autoimmune diseases of the pancreas. Under the terms of the Astellas agreement, we are responsible for the design and discovery of bifunctional product candidates based on our TALON platform, and Astellas will conduct preclinical, clinical and commercialization activities for any candidates developed in the collaboration. The initial research plan is focused on three tissue-selective tether targets in the pancreas. The primary indication for which we and Astellas will seek to develop compounds is type 1 diabetes. We received an upfront payment of $10.0 million and have the right to receive research, development and regulatory milestone payments under the collaboration. We also have the right to receive tiered royalties on worldwide net sales of any commercial products developed under the collaboration.

We may also in the future enter into additional license or collaboration agreements for our product candidates or intellectual property, and we may generate revenue in the future from payments as a result of such license or collaboration agreement.

Operating Expenses: Research and Development

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

- personnel costs, which include salaries, benefits and equity-based compensation expense;
- expenses incurred under agreements with consultants and third-party contract organizations that conduct research and development activities on our behalf;
- costs related to sponsored research service agreements;
- costs related to production of preclinical and clinical materials, including fees paid to contract manufacturers;
- laboratory and vendor expenses related to the execution of preclinical studies and planned clinical trials; and
- laboratory supplies and equipment used for internal research and development activities.

We expense all research and development costs in the periods in which they are incurred. Costs for certain research and development activities are recognized based on an evaluation of the progress to completion of specific tasks using information and data provided to us by our vendors and third-party service providers.

We use our personnel and infrastructure resources across multiple research and development programs directed toward identifying and developing product candidates. Our direct research and development expenses are tracked on a program-by-program basis and consist primarily of internal personnel costs and external costs, such as fees paid to consultants, contractors and contract research organizations, or CROs, in connection with our development activities. We do not fully allocate costs to programs as many of our research and development costs are indirect or are deployed across multiple programs.

We expect our research and development expenses to increase substantially for the foreseeable future as we continue to invest in research and development activities related to developing our product candidates, including investments in manufacturing, advancing our programs and conducting clinical trials. The process of conducting the necessary clinical research to obtain regulatory approval is costly and time-consuming and the successful development of our product candidates is highly uncertain.

Because of the numerous risks and uncertainties associated with product development and the current stage of development of our product candidates and programs, we cannot reasonably estimate or know the nature, timing and estimated costs necessary to complete the remainder of the development of our product candidates or programs. The duration, costs and timing of preclinical studies and clinical trials and development of our product candidates will depend on a variety of factors, including:

- successfully completing preclinical studies and initiating clinical trials;
- successful enrollment and completion of clinical trials;

- data from our clinical program that support an acceptable risk-benefit profile of our product candidates in the intended patient populations;
- acceptance by the U.S. Food and Drug Administration, or FDA, European Medicines Agency, Health Canada or other regulatory agencies of the investigational new drug applications, clinical trial applications or other regulatory filings for PT101 and future product candidates;
- expanding and maintaining a workforce of experienced scientists and others to continue to develop our product candidates;
- successfully applying for and receiving marketing approvals from applicable regulatory authorities;
- obtaining and maintaining intellectual property protection and regulatory exclusivity for our product candidates;
- making arrangements with third-party manufacturers for, or establishing, commercial manufacturing capabilities; and
- maintaining a continued acceptable safety profile of our products following receipt of any marketing approvals.

We may never succeed in achieving regulatory approval for any of our product candidates. We may obtain unexpected results from our preclinical studies and clinical trials. We may elect to discontinue, delay or modify clinical trials of some product candidates or focus on others. A change in the outcome of any of these factors could mean a significant change in the costs and timing associated with the development of our current and future preclinical and clinical product candidates. For example, if the FDA or another regulatory authority were to require us to conduct clinical trials beyond those that we currently anticipate will be required for the completion of clinical development, or if we experience significant delays in execution of or enrollment in any of our preclinical studies or clinical trials, we could be required to expend significant additional financial resources and time on the completion of preclinical and clinical development.

Research and development activities account for a significant portion of our operating expenses. We expect our research and development expenses to increase for the foreseeable future as we continue to implement our business strategy, which includes advancing PT101 through clinical development and other product candidates into clinical development, expanding our research and development efforts, including hiring additional personnel to support our research and development efforts, and seeking regulatory approvals for our product candidates that successfully complete clinical trials. In addition, product candidates in later stages of clinical development generally incur higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. As a result, we expect our research and development expenses to increase as our product candidates advance into later stages of clinical development. However, we do not believe that it is possible at this time to accurately project total program-specific expenses through commercialization. There are numerous factors associated with the successful commercialization of any of our product candidates, including future trial design and various regulatory requirements, many of which cannot be determined with accuracy at this time based on our stage of development.

Operating Expenses: General and Administrative Expenses

Our general and administrative expenses consist primarily of personnel costs, depreciation expense and other expenses for outside professional services, including legal, human resources, audit and accounting services and facility-related fees not otherwise included in research and development expenses. Personnel costs consist of salaries, benefits and equity-based compensation expense, for our personnel in executive, finance and accounting, business operations and other administrative functions. We expect our general and administrative expenses to increase over the next several years to support our continued research and development activities, manufacturing activities, increased costs of expanding our operations and operating as a public company. These increases will likely include increases related to the hiring of additional personnel and legal, regulatory and other fees and services associated with maintaining compliance with Nasdaq listing rules and SEC requirements, director and officer insurance premiums and investor relations costs associated with being a public company.

Other Income (Expense), Net

Our other income (expense), net is comprised of interest income earned on cash reserves in our operating account, interest expense principally on our term loan, and fair value adjustments on the JDRF convertible promissory note for which we have elected the fair value option of accounting.

Results of Operations

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

The following sets forth our results of operations for the three months ended June 30, 2020 and 2019:

	Three Months Ended June 30,		Change	
	2020	2019	Dollar	Percent
	(dollars in thousands)			
Revenue	$ 1,955	$ —	$ 1,955	—
Operating expenses				
Research and development	8,860	4,934	3,926	80%
General and administrative	2,297	840	1,457	173%
Total operating expenses	11,157	5,774	5,383	93%
Loss from operations	(9,202)	(5,774)	(3,428)	59%
Other income (expense), net	(35)	89	(124)	(139%)
Net loss	$ (9,237)	$ (5,685)	$ (3,552)	62%

Revenue

For the three months ended June 30, 2020, we recognized $2.0 million in revenue under the Astellas agreement. While the contractual term under the Astellas agreement is five years, based on the research plan and budget agreed to by the joint steering committee established under the Astellas agreement, we initially estimate our research and development commitments will be completed by the end of 2022. As of June 30, 2020, we estimated a total transaction price of $29.9 million, consisting of the fixed upfront payment and estimated research funding and reimbursement of external costs of $19.9 million presently budgeted under the Astellas agreement to be incurred through 2022. As of June 30, 2020, we have no contract assets and short-term and long-term deferred revenues of $4.7 million and $4.6 million, respectively, which is presently estimated to be recognized through 2022. The aggregate amount of the transaction price that remains unsatisfied as of June 30, 2020 is estimated to be $25.0 million, of which we expect to recognize $7.6 million in 2020, $8.3 million in 2021 and $9.1 million in 2022.

Research and Development Expenses

Research and development expenses were comprised of:

	Three Months Ended June 30,		Change	
	2020	2019	Dollar	Percent
	(dollars in thousands)			
Personnel	$ 2,056	$ 864	$ 1,192	138%
Services	5,289	2,929	2,360	81%
Facilities and equipment	806	315	491	156%
Supplies	705	811	(106)	(13%)
Other	4	15	(11)	(73%)
Total research and development expenses	$ 8,860	$ 4,934	$ 3,926	80%

Direct and allocated research and development expenses by program were comprised of:

	Three Months Ended June 30,		Change	
	2020	2019	Dollar	Percent
	(dollars in thousands)			
PT101	$ 3,352	$ 2,358	$ 994	42%
PT002	180	552	(372)	(67%)
PT627	439	—	439	—
PT001	443	786	(343)	(44%)
All other programs	1,495	503	992	197%
Non-program specific and unallocated research and development expenses	2,951	735	2,216	301%
Total research and development expenses	$ 8,860	$ 4,934	$ 3,926	80%

Research and development activities are central to our business model. We expect that our research and development expenses will continue to increase substantially for the foreseeable future as we advance PT101 through clinical trials, including our Phase 1 clinical trial, and we continue to develop our other additional product candidates, PT002, PT627 and PT001, and seek to discover and develop additional product candidates. We have increased our headcount as our product pipeline has advanced.

Research and development expenses were $8.9 million for the three months ended June 30, 2020, compared to $4.9 million for the three months ended June 30, 2019. The increase of $3.9 million was due to an increase in activities across most of our programs and cost categories.

We initiated our Phase 1a clinical trial of PT101 in February 2020. We have continued to advance our other product candidates and seek to discover and develop other programs. Personnel-related costs increased $1.2 million primarily related to our research and development headcount increasing from 22 employees as of June 30, 2019, to 41 employees as of June 30, 2020. Preclinical and consulting services and development activities outsourced to CROs increased an aggregate of $2.4 million across our programs. Our facility costs increased $0.5 million during the three months ended June 30, 2020 as compared to the three months ended June 30, 2019, commensurate with the expansion of our pipeline of research and development programs.

General and Administrative Expenses

General and administrative expenses to support our business activities were comprised of:

	Three Months Ended June 30,		Change	
	2020	2019	Dollar	Percent
	(dollars in thousands)			
Personnel	$ 643	$ 308	$ 335	109%
Professional services	1,383	354	1,029	291%
Facilities and travel	110	115	(5)	(4%)
Other	161	63	98	156%
Total general and administrative expenses	$ 2,297	$ 840	$ 1,457	173%

The increase in general and administrative expenses for the three months ended June 30, 2020 as compared to the three months ended June 30, 2019 was primarily attributable to an increase of $1.0 million in third-party professional services to support our in-house personnel in various aspects of developing and supporting the business including human resources, information technology, audit, tax, public relations, communications and other general and administrative activities. It was also partially attributable to an increase of $0.3 million in personnel costs from additions to general and administrative employees.

Other Income (Expense), Net

Our other income (expense), net was comprised of:

	Three Months Ended June 30,		Change	
	2020	2019	Dollar	Percent
	(dollars in thousands)			
Interest income	$ 4	$ 89	$ (85)	(96%)
Interest expense	(39)	—	(39)	—
Other income (expense), net	$ (35)	$ 89	$ (124)	(139%)

Our other income (expense) consists primarily of interest income earned on our cash balance and interest expense and other costs related to our term debt, which was repaid in July 2020.

Comparison of the Six Months Ended June 30, 2020 and 2019

The following sets forth our results of operations for the six months ended June 30, 2020 and 2019:

	Six Months Ended June 30,		Change	
	2020	2019	Dollar	Percent
	(dollars in thousands)			
Revenue	$ 3,956	$ -	$ 3,956	—
Operating expenses				
Research and development	15,802	10,019	5,783	58%
General and administrative	3,863	1,614	2,249	139%
Total operating expenses	19,665	11,633	8,032	69%
Loss from operations	(15,709)	(11,633)	(4,076)	35%
Other income (expense), net	52	143	(91)	(64%)
Net loss	$ (15,657)	$ (11,490)	$ (4,167)	36%

Revenue

For the six months ended June 30, 2020, we recognized $4.0 million in revenue under the Astellas agreement. While the contractual term under the Astellas agreement is five years, based on the research plan and budget agreed to by the joint steering committee established under the Astellas agreement, we initially estimate our research and development commitments will be completed by the end of 2022. As of June 30, 2020, we estimated a total transaction price of $29.9 million, consisting of the fixed upfront payment and estimated research funding and reimbursement of external costs of $19.9 million presently budgeted under the Astellas agreement to be incurred through 2022. As of June 30, 2020, we have no contract assets and short-term and long-term deferred revenues of $4.7 million and $4.6 million, respectively, which is presently estimated to be recognized through 2022. The aggregate amount of the transaction price that remained unsatisfied as of June 30, 2020 is estimated to be $25.0 million, of which we expect to recognize $7.6 million in 2020, $8.3 million in 2021 and $9.1 million in 2022.

Research and Development Expenses

Research and development expenses were comprised of:

	Six Months Ended June 30,		Change	
	2020	2019	Dollar	Percent
	(dollars in thousands)			
Personnel	$ 3,326	$ 1,591	$ 1,735	109%
Services	9,424	6,442	2,982	46%
Facilities and equipment	1,381	573	808	141%
Supplies	1,415	1,383	32	2%
Other	256	30	226	753%
Total research and development expenses	$ 15,802	$ 10,019	$ 5,783	58%

Direct and allocated research and development expenses by program were comprised of:

	Six Months Ended June 30,		Change	
	2020	2019	Dollar	Percent
	(dollars in thousands)			
PT101	$ 6,446	$ 5,747	$ 699	12%
PT002	439	860	(421)	(49%)
PT627	915	—	915	—
PT001	894	1,252	(358)	(29%)
All other programs	2,716	823	1,893	230%
Non-program specific and unallocated research and development expenses	4,392	1,337	3,055	228%
Total research and development expenses	$ 15,802	$ 10,019	$ 5,783	58%

Research and development activities are central to our business model. We expect that our research and development expenses will continue to increase substantially for the foreseeable future as we advance PT101 through clinical trials, including our Phase 1 clinical trial, and we continue to develop our other additional product candidates, PT002, PT627 and PT001, and seek to discover and develop additional product candidates. We have increased our headcount as our product pipeline has advanced.

Research and development expenses were $15.8 million for the six months ended June 30, 2020, compared to $10.0 million for the six months ended June 30, 2019. The increase of $5.8 million was due to an increase in activities across most of our programs and cost categories.

We initiated our Phase 1a clinical trial of PT101 in February 2020. We have continued to advance our other product candidates and seek to discover and develop other programs. Personnel-related costs increased $1.7 million primarily related to our research and development headcount increasing from 22 employees as of June 30, 2019, to 41 employees as of June 30, 2020. Preclinical and consulting services and development activities outsourced to CROs increased an aggregate of $3.0 million across our programs. Our facility costs increased $0.8 million during the six months ended June 30, 2020 as compared to the six months ended June 30, 2019, commensurate with the expansion of our pipeline of research and development programs.

General and Administrative Expenses

General and administrative expenses to support our business activities were comprised of:

	Six Months Ended June 30,		Change	
	2020	2019	Dollar	Percent
	(dollars in thousands)			
Personnel	$ 1,073	$ 583	$ 490	84%
Professional services	2,331	754	1,577	209%
Facilities and travel	192	208	(16)	(8%)
Other	267	69	198	287%
Total general and administrative expenses	$ 3,863	$ 1,614	$ 2,249	139%

The increase in general and administrative expenses for the six months ended June 30, 2020 as compared to the six months ended June 30, 2019 was primarily attributable to an increase of $1.6 million in third-party professional services to support our in-house personnel in various aspects of developing and supporting the business including human resources, information technology, audit, tax, public relations, communications and other general and administrative activities. It was also partially attributable to an increase of $0.5 million in personnel costs from additions to general and administrative employees.

Other Income (Expense), Net

Our other income (expense), net was comprised of:

	Six Months Ended June 30,		Change	
	2020	2019	Dollar	Percent
	(dollars in thousands)			
Interest income	$ 45	$ 143	$ (98)	(69%)
Interest expense	(82)	—	(82)	—
Fair value adjustments to convertible note	89	—	89	—
Other income (expense), net	$ 52	$ 143	$ (91)	(64%)

Our other income (expense) consists primarily of interest income earned on our cash balance and interest expense and other costs related to our term loan, which was repaid in July 2020. We have elected to account for the JDRF convertible promissory note at fair value and recorded a gain of $89,000 in the fair value of the convertible note for the six months ended June 30, 2020.

Liquidity and Capital Resources

Sources of Liquidity

Through June 30, 2020, we have been financed primarily by aggregate net proceeds of $149.0 million from the issuance of redeemable convertible preferred shares, the SAFE, convertible notes and a term loan. In July and August 2020, we completed our IPO and issued and sold 8,494,166 shares of common stock at a public offering price of $18.00 which includes 994,166 shares sold upon the partial exercise of the underwriters' option to purchase additional shares of common stock in August 2020 resulting in aggregate net proceeds of $142.2 million after deducting underwriting discounts and commissions but before deducting offering costs of approximately $3.2 million. Since inception, we have had significant operating losses. Our net loss was $21.9 million and $10.9 million for the years ended December 31, 2019 and 2018, respectively, and our net loss was $15.7 million for the six months ended June 30, 2020. As of June 30, 2020, we had an accumulated deficit of $62.9 million and $105.7 million in cash and cash equivalents.

In June 2020, we issued 20,116,868 additional Series B redeemable convertible preferred shares for gross proceeds of $42.0 million and we entered into the SAFE, pursuant to which we issued rights to one investor to receive shares of our capital stock for an aggregate purchase price of $6.0 million. Upon closing of our IPO in July 2020, the SAFE converted, by its terms, into 333,333 shares of our common stock based on the initial public offering price of $18.00 per share.

Cash in excess of immediate requirements is invested in accordance with our investment policy, primarily with a view to liquidity and capital preservation. Our primary use of cash is to fund operating expenses, which consist primarily of research and development expenditures, and to a lesser extent, general and administrative expenditures. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our outstanding accounts payable and accrued expenses.

Cash Flows

The following table summarizes our cash flows:

	Six Months Ended June 30,	
	2020	2019
	(in thousands)	
Net cash used in operating activities	$ (14,088)	$ (11,623)
Net cash used in investing activities	(1,228)	(437)
Net cash provided by financing activities	105,573	17,967
Net increase in cash, cash equivalents and restricted cash	$ 90,257	$ 5,907

Net Cash Used in Operating Activities

Cash used in operating activities of $14.1 million during the six months ended June 30, 2020 was attributable to our net loss of $15.7 million and a decrease of $1.1 million in our deferred revenue under the Astellas agreement, offset by a $2.3 million net increase in our working capital and non-cash charges of $0.3 million principally with respect to equity-based compensation and depreciation expense.

Cash used in operating activities of $11.6 million during the six months ended June 30, 2019 was attributable to our net loss of $11.5 million, a $0.3 million net decrease in our working capital and non-cash charges of $0.1 million principally with respect to equity-based compensation and depreciation expense.

Net Cash Used in Investing Activities

Investing activities for all periods presented consist of purchases of property and equipment.

Net Cash Provided by Financing Activities

Cash provided by financing activities for the six months ended June 30, 2020 amounted to $105.6 million comprised of $81.6 million net proceeds from the sale and issuance of our Series B redeemable convertible preferred shares in March 2020 and June 2020, $18.0 million net proceeds upon the third issuance of our Series A redeemable convertible preferred shares in February 2020 and $6.0 million net proceeds from the SAFE in June 2020.

Cash provided by financing activities for the six months ended June 30, 2019 amounted to $18.0 million comprised of net proceeds upon the second issuance of our Series A redeemable convertible preferred shares in January 2019.

Loan and Security Agreement

In November 2019, we entered into a secured term loan facility with Silicon Valley Bank in the amount of $10.0 million, or the Term Loan Facility, with an initial advance of $2.0 million. A second advance of $4.0 million was available to be drawn prior to June 30, 2020 and a third advance of $4.0 million was available to be drawn based upon the achievement of certain events prior to June 30, 2020. The loans under the Term Loan Facility bear interest at the greater of (i) the prime rate less 1% and (ii) 4.25%. In response to the financial impact of the COVID-19 pandemic, in April 2020 the lender extended monthly interest-only payments on the outstanding term loan through November 2021 and the final maturity date on the term loan to May 2024. The Term Loan Facility is collateralized by a first priority perfected security interest in all of our tangible and intangible property, with the exception of our intellectual property, and by a negative pledge on our intellectual property. In July 2020, we repaid the $2.0 million of principal outstanding under the Term Loan Facility and, in connection with such repayment, the facility was terminated pursuant to its terms. We have no further payment obligations under the Term Loan Facility and no amounts under the secured term loan facility are available for borrowing.

Funding Requirements

Any product candidates we may develop may never achieve commercialization and we anticipate that we will continue to incur losses for the foreseeable future. We expect that our research and development expenses, general and administrative expenses, and capital expenditures will continue to increase. As a result, until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity offerings, debt financings or other capital sources, including potentially collaborations, licenses and other similar arrangements. Our primary uses of capital are, and we expect will continue to be, compensation and related expenses, third-party clinical research, manufacturing and development services, costs relating to the build-out of our headquarters, laboratories and manufacturing facility, license payments or milestone obligations that may arise, laboratory and related supplies, clinical costs, manufacturing costs, legal and other regulatory expenses and general overhead costs.

Based upon our current operating plan, we believe that the net proceeds from our IPO, together with our cash and cash equivalents of $105.7 million as of June 30, 2020, will be sufficient to fund our operating expenses and capital expenditure requirements through the first half of 2024. To finance our operations beyond that point we will need to raise additional capital, which cannot be assured. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. We will continue to require additional financing to advance our current product candidates through clinical development, to develop, acquire or in-license other potential product candidates and to fund operations for the foreseeable future. We currently have no credit facility or committed sources of capital. We will continue to seek funds through equity offerings, debt financings or other capital sources, including potentially collaborations, licenses and other similar arrangements. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. If we do raise additional capital through public or private equity offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Any failure to raise capital as and when needed could have a negative impact on our financial condition and on our ability to pursue our business plans and strategies. If we are unable to raise capital, we will need to delay, reduce or terminate planned activities to reduce costs.

Because of the numerous risks and uncertainties associated with research, development and commercialization of pharmaceutical products, we are unable to estimate the exact amount of our operating capital requirements. Our future funding requirements will depend on many factors, including, but not limited to:

- the progress, costs and results of our ongoing Phase 1a clinical trial of PT101;
- the scope, progress, results and costs of discovery research, preclinical development, laboratory testing and clinical trials for our product candidates, including our planned Phase 1b/2a clinical trial of PT101;
- the number of, and development requirements for, other product candidates that we pursue;
- the costs, timing and outcome of regulatory review of our product candidates;
- our ability to enter into contract manufacturing arrangements for supply of active pharmaceutical ingredient and manufacture of our product candidates and the terms of such arrangements;
- the success of our collaboration with Astellas;
- our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of such arrangements;
- the payment or receipt of milestones and receipt of other collaboration-based revenues, if any;

- the costs and timing of any future commercialization activities, including product manufacturing, sales, marketing and distribution, for any of our product candidates for which we may receive marketing approval;
- the amount and timing of revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property and proprietary rights and defending any intellectual property-related claims;
- the extent to which we acquire or in-license other products, product candidates, technologies or data referencing rights;
- the impacts of the COVID-19 pandemic;
- the ability to receive additional non-dilutive funding, including grants from organizations and foundations; and
- the costs of operating as a public company.

Further, our operating plans may change, and we may need additional funds to meet operational needs and capital requirements for clinical trials and other research and development activities. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated product development programs.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with generally accepted accounting principles, or GAAP. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. We believe that the accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates.

Revenue Recognition

All of our revenue to date relates to the Astellas agreement. We account for revenue in accordance with ASC Topic 606, *Revenue from Contracts with Customers*, or ASC 606. Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services in an amount that reflects the consideration that the entity expects to receive in exchange for those goods or services. To determine the appropriate amount of revenue to be recognized for arrangements determined to be within the scope of ASC 606, we perform the following five steps: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations, including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) we satisfy each performance obligation. We only apply the five-step model to contracts when it is probable that we will collect consideration to which we are entitled in exchange for the goods or services we transfer to the customer.

We are required to make a number of estimates and judgments in the process of recording our revenue. These estimates include determining the performance obligations, estimating the total transaction price, determining the period over which we record our revenue, estimating the total costs to completion and costs incurred to date. We have allocated the estimated $29.9 million accounting transaction price entirely to a single, bundled performance obligation comprised of the licenses provided to Astellas, our research services and other ancillary promises. We recorded the $10.0 million upfront payment from Astellas as deferred revenue in November 2019 and will record future invoices under the Astellas agreement as deferred revenue. While the contractual term under the Astellas agreement is five years, based on the research plan and budget agreed to by the joint steering committee established under the Astellas agreement, we will recognize the estimated total transaction price over the estimated period the research and development services are expected to be provided which, as of June 30, 2020, is approximately three years through 2022. We believe our performance obligation to Astellas is satisfied over the course of our performance of the research and development activities under the Astellas agreement and, depicting our performance in satisfaction of our performance obligation, we use input method as a measure of progress towards completion according to actual costs incurred compared to estimated total costs to estimate progress toward satisfaction of our performance. We will remeasure our progress towards completion of our performance obligation at the end of each reporting period.

Research and Development Costs

We estimate costs of research and development activities conducted by service providers, which include the conduct of sponsored research, preclinical studies and contract manufacturing activities. We record the estimated costs of research and development activities based upon the estimated amount of services provided but not yet invoiced and include these costs in the accrued and other current liabilities or prepaid expenses on the balance sheets and within research and development expense on the consolidated statements of operations.

We estimate these costs based on factors such as estimates of the work completed and budget provided and in accordance with agreements established with our collaboration partners and third-party service providers. We make significant judgments and estimates in determining the accrued liabilities and prepaid expense balances in each reporting period. As actual costs become known, we adjust our accrued liabilities or prepaid expenses. We have not experienced any material differences between accrued costs and actual costs incurred since our inception.

Our expenses related to clinical trials are based on estimates of patient enrollment and related expenses at clinical investigator sites as well as estimates for the services received and efforts expended pursuant to contracts with multiple research institutions and CROs that may be used to conduct and manage clinical trials on our behalf. We generally accrue expenses related to clinical trials based on contracted amounts applied to the level of patient enrollment and activity. If timelines or contracts are modified based upon changes in the clinical trial protocol or scope of work to be performed, we modify our estimates of accrued expenses accordingly on a prospective basis.

Equity-based Compensation

Prior to our IPO, we issued equity-based compensation awards through the granting of incentive shares, which generally vest over a four-year period. The incentive shares represented a separate substantive class of members' equity with defined rights within our LLC operating agreement. The incentive shares represented profits interests in the increase in the value of the entity over a floor amount, or Floor Amount, as determined at the time of grant. The Floor Amount is established for tax compliance purposes related to Internal Revenue Code Revenue Procedure 93-27 and 2001-43 pursuant to which we allocate equity value to our share classes in a hypothetical liquidation transaction as of the date of grant.

We account for equity-based compensation in accordance with ASC 718, *Compensation-Stock Compensation*, or ASC 718. In accordance with ASC 718, compensation cost is measured at estimated fair value and is included as compensation expense over the vesting period during which service is provided in exchange for the award.

We used a Black-Scholes option pricing model to determine fair value of our incentive shares. The Black-Scholes option pricing model includes various assumptions, including the fair value of common shares, expected life of incentive shares, the expected volatility and the expected risk-free interest rate. These assumptions reflect our best estimates, but they involve inherent uncertainties based on market conditions generally outside our control. As a result, if other assumptions had been used, equity-based compensation cost could have been materially impacted. Furthermore, if we use different assumptions for future grants, share-based compensation cost could be materially impacted in future periods.

The fair value of each of our grants and awards has been estimated using Black-Scholes based on the following assumptions:

	Six Months Ended June 30,	
	2020	2019
Expected Term (in years)	2.0	1.2
Risk Free Rate	0.14% - 0.17%	1.96% - 2.60%
Volatility	82.7% - 83.7%	71.5% - 72.3%
Dividend Yield	0%	0%

We will continue to use judgment in evaluating the assumptions utilized for our equity-based compensation expense calculations on a prospective basis. In addition to the assumptions used in Black-Scholes, the amount of equity-based compensation expense we recognize in our financial statements includes incentive share forfeitures as they occurred.

As there has been no public market for our common shares as of June 30, 2020, our board of directors, with input from management, has determined the estimated fair value of our common shares as of the date of each incentive share grant considering our then-most recently available third-party valuation of common shares. Valuations are updated when facts and circumstances indicate that the most recent valuation is no longer valid, such as changes in the stage of our development efforts, various exit strategies and their timing, and other scientific developments that could be related to the valuation of our company, or, at a minimum, annually. Third-party valuations were performed in accordance with the guidance outlined in the American Institute of Certified Public Accountants' Accounting and Valuation Guide, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*. Our common share valuations in 2019 and 2018 were prepared using market approaches as follows:

- For grants of options we made in March through June 2018, we utilized a probability-weighted hybrid method combining (i) trade-sale scenario and the back-solve method for inferring the equity value predicated on the closing of our Series A redeemable convertible preferred shares, and (ii) a sale at or below the liquidation preference. Under the hybrid method, the per share value calculated under the two scenarios is weighted based on expected exit outcomes and the quality of the information specific to each allocation methodology to arrive at a final estimated fair value per common share before a discount for lack of marketability is applied.
- For awards of incentive shares in January through June 2019 we utilized the back-solve method for inferring the equity value predicated on the likely second closing of our Series A redeemable convertible preferred shares financing and employed an option-pricing method, or OPM, framework to allocate equity to our common shares.
- For awards of incentive shares in September, October and December 2019 we utilized a guideline transactions market approach for inferring the equity value implied by a selection of guideline transactions and employed an OPM framework to allocate equity to our common shares.
- For awards of incentive shares in May and June 2020 we utilized a hybrid methodology that employed a probability-weighted value across multiple scenarios including an OPM framework and an IPO scenario. The total value of equity under each scenario was allocated among equity classes and the estimated probabilities for each scenario were then applied to derive the fair value per common share.

The estimates of fair value of our common shares are highly complex and subjective. There are significant judgments and estimates inherent in the determination of the fair value of our common shares. These judgments and estimates include assumptions regarding our future operating performance, the valuations associated with our IPO and other liquidity events, and the determinations of the appropriate valuation methods at each valuation date. The assumptions underlying these valuations represent our best estimates, which involve inherent uncertainties and the application of management judgment. If we had made different assumptions, our equity-based compensation expense, net loss and net loss per share applicable to common shareholders could have been materially different.

Following our IPO, we intend to determine the fair value of our common stock based on the closing price of our common stock on the date of grant.

Determination of the Fair Value of Convertible Note and Series A Prime Convertible Preferred Shares

We have elected the fair value option for the accounting for the JDRF convertible promissory note issued in 2018. Fair value adjustments to the convertible notes are included in our other income (expenses).

- The fair value of the initial closing of our convertible notes in December 2018 was determined to be equal to the proceeds of $2.0 million on issuance.
- The fair value of the convertible note as of December 31, 2019 and 2018 was determined using a Monte Carlo simulation model. Application of the Monte Carlo simulation model involves making assumptions for the expected time to the applicable financing dates, probability of each respective financing scenario versus holding to maturity, total value of equity as of each valuation date, volatility, and risk-free rate. The Monte Carlo simulation model iteratively solves for the calibrated discount rate such that the fair value of the convertible note as of the issuance date is equivalent to the total proceeds on issuance. The selected discount rate as of December 31, 2019 considers the calibrated discount rate as of the issuance date, risk-free rate, and changes in the credit risk for the company.
- The fair value of the JDRF convertible promissory note on conversion was determined to be equal to the value of our Series A prime redeemable convertible preferred shares into which the convertible note was converted. In valuing our Series A prime redeemable convertible preferred shares for purposes of accounting for the conversion of the JDRF convertible promissory note, we utilized a probability-weighted hybrid method combining (i) trade-sale scenario and the back-solve method for inferring the equity value predicated on the likely closing of our Series B redeemable convertible preferred shares financing, and (ii) an IPO scenario with reference to guideline IPOs in the biotech sector. Under the hybrid method, the per share value calculated under the two scenarios is weighted based on expected exit outcomes and the quality of the information specific to each allocation methodology to arrive at a final estimated fair value per share value of the Series A prime redeemable convertible preferred shares.

Recently Adopted Accounting Pronouncements

Refer to Note 2 of the notes to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q for a summary of recently issued and adopted accounting pronouncements.

Contractual Obligations and Commitments

The following table summarizes our contractual obligations as of June 30, 2020:

	Payments due by period (in thousands)				
	Total	Less than one year	One to three years	Three to five years	More than five years
Term loan(1)	$ 2,000	$ —	$ 1,067	$ 933	$ —
Interest(2)	252	85	142	25	—
Operating lease(3)	10,056	1,636	3,262	3,460	1,698
Total contractual obligations	$ 12,308	$ 1,721	$ 4,471	$ 4,418	$ 1,698

(1) In response to the financial impact of the COVID-19 pandemic, in April 2020 our term loan lender extended monthly interest-only payments on the outstanding term loan through November 2021 and the final maturity date on the term loan to May 2024. In July 2020, we repaid the $2.0 million of principal outstanding under the Term Loan.

(2) Interest expense reflects our obligation to make cash interest payments in connection with our term loan at a rate of 4.25%.

(3) Represents our future minimum lease obligation under our non-cancelable operating a lease for our corporate headquarters in Watertown, Massachusetts, which expires in March 2026.

In addition, under various licensing and related agreements to which we are a party, we may be required to make milestone and earnout payments and to pay royalties and other amounts to third parties. We have not included any such contingent payment obligations in the table above as the amount, timing and likelihood of such payments are not known. Such contingent payment obligations are described below.

Pursuant to the antibody library subscription agreement, or Distributed Bio library agreement, with Distributed Bio, Inc., or Distributed Bio, we obtained a non-exclusive license to use an antibody library of Distributed Bio, or the Antibody Library, anti-PD-1 antibodies isolated from the Antibody Library by Distributed Bio, or the Anti-PD-1 Antibodies, and certain software to conduct research and development related to the discovery of antibodies against biological targets of interest to us. We refer to the Antibody Library, the Anti-PD-1 Antibodies and the software collectively as the Deliverables. Distributed Bio has also agreed to assign to us and we own all rights in the sequences of any Anti-PD-1 Antibody and antibody sequences that we identify by panning the Antibody Library, or the Panned Antibodies, including any derivative sequences and any molecules or products containing or any method of manufacture or use of any of the foregoing, which we refer to collectively as the Assigned Antibody Rights. Under the Distributed Bio library agreement, we paid subscription fees to Distributed Bio in connection with the use of the Deliverables. We are also required to make milestone payments to Distributed Bio upon achievement of certain clinical and regulatory milestones with respect to any antibody that has a target recognition site derived from an Anti-PD-1 Antibody, a Panned Antibody or an antibody provided by Distributed Bio under any other agreement with us, and that is included in the Assigned Antibody Rights, which we refer to as an Antibody Product. We may be required to pay up to $4.3 million in clinical milestones and $12.0 million in regulatory milestones for each Antibody Product. Each such milestone payment will be paid only once with respect to any set of targets to which any Antibody Product is directed. The milestone payments may be offset by up to 50% of any amount paid by us to any third party for the achievement of the same or similar milestones with respect to any Antibody Product.

We also pay Distributed Bio for antibody discovery services under a master services agreement that we entered into with Distributed Bio concurrently with the Distributed Bio library agreement, which we refer to as the Distributed Bio MSA. We are required to make the same milestone payments to Distributed Bio upon achievement of certain clinical and regulatory milestones as described in the Distributed Bio library agreement for any Antibody Product, but we will not owe milestone payments more than once for the same Antibody Product if such milestone is achieved under both of the Distributed Bio library agreement and the Distributed Bio MSA.

We paid an aggregate of approximately $1.8 million in subscription fees and other fees under the Distributed Bio library agreement and Distributed Bio MSA through June 30, 2020. Beginning in 2020, we ceased subscribing to the Distributed Bio antibody library, and as a result are no longer obligated to pay subscription fees under such agreement. We continue to engage Distributed Bio for antibody discovery services pursuant to the Distributed Bio MSA and we pay for such services on a service-by-service basis.

Off-Balance Sheet Arrangements

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Interest Rate Risk

We are exposed to market risks in the ordinary course of our business. These risks primarily include interest rate sensitivities. We held cash and cash equivalents of $105.7 million as of June 30, 2020. Historically, we have generally held our cash equivalents in money market funds. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. Due to the short-term maturities of our cash equivalents 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 equivalents.

Emerging Growth Company Status

As an emerging growth company, or EGC, under the Jumpstart Our Business Startups Act of 2012, or JOBS Act, we can take advantage of an extended transition period for complying with new or revised accounting standards. This provision allows an EGC to delay the adoption of some accounting standards until those standards would otherwise apply to private companies. We have elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date we (i) are no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act.

Item 4. Controls and Procedures.

Disclosure Controls and Procedures

Our management, with the participation of our chief executive officer and interim chief financial officer, evaluated the effectiveness of our disclosure controls and procedures as of June 30, 2020. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, mean controls and other procedures of a company that are designed to ensure 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. Disclosure controls include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company on the reports that it files or submits under the Exchange Act is accumulated and communicated to management, including, our principal executive and principal financial officers, as appropriate, to allow timely decisions regarding required disclosure.

Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgement in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of June 30, 2020, our chief executive officer and interim chief financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable level.

Changes in Internal Control

There has been no change in our internal control over financial reporting as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act during our most recently completed fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

We are currently not a party to any material legal proceedings.

Item 1A. Risk Factors.

Our future operating results could differ materially from the results described in this Quarterly Report on Form 10-Q due to the risks and uncertainties described below. You should consider carefully the following information about risks below in evaluating our business. If any of the following risks actually occur, our business, financial conditions, results of operations and future growth prospects would likely be materially and adversely affected. In these circumstances, the market price of our common stock would likely decline. In addition, we cannot assure investors that our assumptions and expectations will prove to be correct. Important factors could cause our actual results to differ materially from those indicated or implied by forward-looking statements. See page i of this Quarterly Report on Form 10-Q for a discussion of some of the forward-looking statements that are qualified by these risk factors. Factors that could cause or contribute to such differences include those factors discussed below.

Risks Related to our Financial Position and Need for Additional Capital

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

Since our inception, we have devoted substantially all of our financial resources and efforts to research and development, including preclinical studies and our clinical trials, and have incurred significant operating losses. Our net loss was $15.7 million for the six months ended June 30, 2020 and $10.9 million and $21.9 million for the years ended December 31, 2018 and 2019, respectively. As of June 30, 2020, we had an accumulated deficit of $62.9 million. To date, we have financed our operations primarily through sales of our preferred stock and preferred shares, issuances of convertible promissory notes, proceeds from a simple agreement for future equity, or SAFE, borrowings under our loan and security agreement with Silicon Valley Bank, which we refer to as our loan agreement, an upfront payment received under the license and collaboration agreement, or the Astellas agreement, with Astellas Pharma Inc., or Astellas and sales of our common stock in our initial public offering, or IPO, which closed on July 21, 2020. We have devoted substantially all of our financial resources and efforts to research and development, including clinical trials and preclinical studies. We are still in the early stages of development of our product candidates, and we have not completed development of any product candidates. We expect to continue to incur significant expenses and operating losses over the next several years. Our net losses may fluctuate significantly from quarter to quarter and year to year. We anticipate that our expenses will increase substantially as we:

- continue our clinical development of PT101, including our ongoing Phase 1a clinical trial and planned Phase 1b/2a clinical trial;
- leverage our TALON (Therapeutic Autoimmune reguLatOry proteiN) drug design and discovery platform to advance additional product candidates into preclinical and clinical development;
- pursue the discovery of drug targets for other autoimmune and inflammatory diseases and the subsequent development of any resulting product candidates;
- seek marketing approvals for any product candidates that successfully complete clinical trials;
- scale up our manufacturing processes and capabilities, or arrange for a third party to do so on our behalf, to support our clinical trials of our product candidates and commercialization of any of our product candidates for which we may obtain marketing approval;
- establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval;
- acquire or in-license products, product candidates, technologies and/or data referencing rights;
- maintain, expand, enforce, defend and protect our intellectual property;
- hire additional clinical, regulatory, quality control and scientific personnel; and
- add operational, financial and management information systems and personnel, including personnel to support our research, product development and planned future commercialization efforts and our operations as a public company.

In addition, our expenses will increase if, among other things:

- we are required by the U.S. Food and Drug Administration, or the FDA, the European Medicines Agency, or the EMA, Health Canada or other regulatory authorities to perform trials or studies in addition to, or different than, those expected;

- there are any delays in completing our clinical trials or 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.

We have no products for which we have obtained marketing approval and have not generated any revenue from product sales. Even if we obtain marketing 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. 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 have never generated revenue from product sales and may never achieve or maintain profitability.

We have never generated revenue from product sales. We expect that it will be a number of years, if ever, before we have a product candidate ready for commercialization. To become and remain profitable, we must succeed in developing, and eventually commercializing, a product or products that generate significant revenue. The ability to achieve this success will require us to be effective in a range of challenging activities, including completing preclinical testing and clinical trials of our product candidates, discovering additional product candidates, obtaining marketing approval for these product candidates and manufacturing, marketing and selling any products for which we may obtain marketing approval. We are only in the preliminary stages of these activities and there is no assurance that we will be successful in these activities. Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability.

Our ability to generate revenue from product sales and achieve profitability depends on our ability to successfully develop and obtain the marketing approvals necessary to commercialize our product candidates. We do not have any products approved for sale and do not anticipate generating revenue from product sales for the next several years, if ever. Our ability to generate future revenue from product sales depends heavily on our success in:

- completing preclinical and clinical development of our product candidates and identifying and developing new product candidates;
- seeking and obtaining marketing approvals for any of our product candidates;
- launching and commercializing product candidates for which we obtain marketing approval by establishing a sales force, marketing, medical affairs and distribution infrastructure or, alternatively, collaborating with a commercialization partner;
- achieving formulary status in hospitals and adequate coverage and reimbursement by government and third-party payors for our product candidates, if approved;
- establishing and maintaining supply and manufacturing relationships with third parties that can provide adequate products and services, in both amount and quality, to support clinical development and the market demand for our product candidates, if approved;
- obtaining market acceptance of our product candidates, if approved, as viable treatment options;
- addressing any competing technological and market developments;
- negotiating favorable terms in any collaboration, licensing or other arrangements into which we may enter and performing our obligations in such collaborations;
- maintaining, protecting and expanding our portfolio of intellectual property rights, including patents, trade secrets and know-how;
- defending against third-party interference or infringement claims, if any; and
- attracting, hiring and retaining qualified personnel.

Even if one or more of our product candidates is approved for commercial sale, we anticipate incurring significant costs in commercializing any approved product candidate. Our expenses could increase beyond expectations if we are required by the FDA, EMA, Health Canada or other regulatory agencies to perform clinical trials or studies in addition to those that we currently anticipate. Even if we are able to generate revenue from the sale of any approved products, we may not become profitable and may need to obtain additional funding to continue operations. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our pipeline of product candidates or even continue our operations. A decline in the value of our company could also cause our stockholders to lose all or part of their investment.

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

We expect to devote substantial financial resources to our ongoing and planned activities, particularly as we continue our Phase 1a clinical trial of PT101, prepare for the planned Phase 1b/2a clinical trial of PT101 and continue research and development and initiate additional clinical trials of, and seek marketing approval for, PT101 and other product candidates. We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we advance our preclinical activities and clinical trials. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to product manufacturing, sales, marketing and distribution. Furthermore, we have incurred and expect to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. We currently have no credit facility or committed sources of capital. If we are unable to raise capital or obtain adequate funds when needed or on acceptable terms, we may be required to delay, limit, reduce or terminate our research and development programs or any future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Our future capital requirements will depend on many factors, including:

- the progress, costs and results of our ongoing Phase 1a clinical trial of PT101;
- the scope, progress, results and costs of discovery research, preclinical development, laboratory testing and clinical trials for our product candidates, including our planned Phase 1b/2a clinical trial of PT101;
- the number of, and development requirements for, other product candidates that we pursue;
- the costs, timing and outcome of regulatory review of our product candidates;
- our ability to enter into contract manufacturing arrangements for supply of active pharmaceutical ingredient, or API, and manufacture of our product candidates and the terms of such arrangements;
- the success of our collaboration with Astellas;
- our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of such arrangements;
- the payment or receipt of milestones and receipt of other collaboration-based revenues, if any;
- the costs and timing of any future commercialization activities, including product manufacturing, sales, marketing and distribution, for any of our product candidates for which we may receive marketing approval;
- the amount and timing of revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property and proprietary rights and defending any intellectual property-related claims;
- the extent to which we acquire or in-license other products, product candidates, technologies or data referencing rights;
- the impacts of the COVID-19 pandemic;
- the ability to receive additional non-dilutive funding, including grants from organizations and foundations; and
- the costs of operating as a public company.

As of June 30, 2020, we had cash and cash equivalents of approximately $105.7 million, which does not include $142.2 million of aggregate net proceeds that we received from our IPO in the third quarter of 2020. We believe that the net proceeds from our IPO, together with our existing cash and cash equivalents, will enable us to fund our operating expenses and capital expenditure requirements through the first half of 2024. However, we have based this estimate on assumptions that may prove to be wrong, and our operating plan may change as a result of many factors currently unknown to us. As a result, we could deplete our capital resources sooner than we currently expect.

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 revenues from product sales, we expect to finance our cash needs through a combination of equity offerings, current or future debt facilities, debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, our stockholders' ownership interests will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, selling or licensing our assets, making capital expenditures or declaring dividends.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings 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 limited operating history may make it difficult for stockholders to evaluate the success of our business to date and to assess our future viability.

We commenced activities in 2017 and are an early-stage company. Our operations to date have been limited to organizing and staffing our company, business planning, raising capital, developing our technology, identifying drug targets and potential product candidates, securing intellectual property rights, undertaking preclinical studies and initiating one early-stage clinical trial. We have not yet demonstrated our ability to successfully develop any product candidate, obtain marketing approvals, manufacture a commercial scale product or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Consequently, any predictions stockholders 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 and commercializing products.

In addition, as our business grows, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. 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 expect our financial condition and operating results to fluctuate significantly from quarter-to-quarter and year-to-year due to a variety of factors, many of which are beyond our control. Accordingly, our stockholders should not rely upon the results of any quarterly or annual periods as indications of future operating performance.

Any future indebtedness may limit cash flow available to invest in the ongoing needs of our business.

As of June 30, 2020, we had $2.0 million of borrowings outstanding under our loan agreement, which borrowings were repaid in full in July 2020. No amounts are available for borrowing under our loan agreement. Our obligations under this agreement were secured by substantially all of our personal property, other than our intellectual property, and by a negative pledge on our intellectual property. We could in the future incur additional indebtedness.

Any future indebtedness combined with our other financial obligations and contractual commitments could have significant adverse consequences, including:

- requiring us to dedicate a substantial portion of cash flow from operations or cash on hand to the payment of interest on, and principal of, our debt, which will reduce the amounts available to fund working capital, capital expenditures, product development efforts and other general corporate purposes;
- increasing our vulnerability to adverse changes in general economic, industry and market conditions;
- subjecting us to restrictive covenants that may reduce our ability to take certain corporate actions, such as paying dividends, or obtain further debt or equity financing;
- limiting our flexibility in planning for, or reacting to, changes in our business and our industry; and
- placing us at a competitive disadvantage compared to our competitors that have less debt or better debt servicing options.

We intend to satisfy any future debt service obligations with our existing cash and funds from external sources. Nonetheless, we may not have sufficient funds or may be unable to arrange for additional financing to pay the amounts due under our existing or any future debt. Funds from external sources may not be available on acceptable terms, if at all. In addition, a failure to comply with the covenants under any future loan agreements we may enter into could result in an event of default and acceleration of amounts due. If an event of default occurs and the lenders accelerate the amounts due under such loan agreements, we may not be able to make accelerated payments, and such lenders could seek to enforce security interests in the collateral securing such indebtedness.

Changes in tax laws or in their implementation or interpretation may adversely affect our business and financial condition.

Recent changes in tax law may adversely affect our business or financial condition. On December 22, 2017, the U.S. government enacted the Tax Cuts and Jobs Act, or TCJA, which significantly reformed the Internal Revenue Code of 1986, as amended, or the Code. The TCJA, among other things, contains significant changes to corporate taxation, including reducing the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limiting the tax deduction for net interest expense to 30% of adjusted taxable income (except for certain small businesses), limiting the deduction for net operating losses, or 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), imposing a one-time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, eliminating U.S. tax on foreign earnings (subject to certain important exceptions), allowing immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits.

As part of Congress' response to the COVID-19 pandemic, the Families First Coronavirus Response Act, or FFCR Act, was enacted on March 18, 2020, and the Coronavirus Aid, Relief, and Economic Security Act, or 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 their impact on our business and financial condition. It is also likely that Congress will enact additional legislation in connection with the COVID-19 pandemic, some of which could have an impact on us. In addition, it is uncertain if and to what extent various states will conform to the TCJA, the FFCR Act or the CARES Act. We urge investors in our common stock to consult with their legal and tax advisors with respect to any recently enacted tax legislation, or proposed changes in law, and the potential tax consequences of investing in or holding our common stock.

Our ability to use our NOLs and research and development tax credit carryforwards to offset future taxable income may be subject to certain limitations.

As of December 31, 2019, we had federal and state net operating loss carryforwards of $30.4 million and $29.1 million, respectively, which each begin to expire in 2037. Approximately $27.8 million of the federal net operating losses can be carried forward indefinitely. As of December 31, 2019, we also had federal and state research and development tax credit carryforwards of $1.4 million and $0.7 million, respectively, which begin to expire in 2038 and 2032, respectively. These net operating loss and tax credit carryforwards could expire unused and be unavailable to offset future income tax liabilities.

We have a history of cumulative losses and anticipate that we will continue to incur significant losses in the foreseeable future; thus, we do not know whether or when we will generate taxable income necessary to utilize our NOLs or research and development tax credit carryforwards.

In general, under Section 382 of the Code and corresponding provisions of state law, a corporation that 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, is subject to limitations on its ability to utilize its pre-change NOLs and research and development tax credit carryforwards to offset future taxable income. We have not conducted a study to assess whether any such ownership changes have occurred. We may have experienced such ownership changes in the past and may experience such ownership changes in the future as a result subsequent changes in our stock ownership (which may be outside our control). As a result, if, and to the extent that, we earn net taxable income, our ability to use our pre-change NOLs and research and development tax credit carryforwards to offset such taxable income may be subject to limitations. Our NOLs or credits may also be impaired under state law.

There is also a risk that due to regulatory changes, such as suspensions on the use of NOLs, or other unforeseen reasons, our existing NOLs could expire or otherwise become unavailable to offset future income tax liabilities. As described above in "Changes in tax laws or in their implementation or interpretation may adversely affect our business and financial condition," the TCJA includes changes to U.S. federal tax rates and the rules governing NOL carryforwards that may significantly impact our ability to utilize our NOLs to offset taxable income in the future. For these reasons, even if we attain profitability, we may be unable to use a material portion of our NOLs and other tax attributes.

Risks Related to the Discovery and Development of our Product Candidates

Our approach to the discovery and development of product candidates is unproven, and we do not know whether we will be able to successfully develop any products.

We focus on using our product candidates to actively rebalance the immune system in either a systemic or a tissue-localized fashion for therapeutic benefit in patients with autoimmune disease, including by using a novel and proprietary variant of interleukin-2, or IL-2, which is a signaling molecule in the immune system, and agonists of programmed death domain-1, or PD-1, which is a protein that is naturally expressed by all activated T cells. To date, there are no approved therapeutic products utilizing IL-2 or an agonist of PD-1 for the treatment of autoimmune disease. Our future success depends on the successful development of this novel therapeutic approach. We have not yet succeeded and may not succeed in demonstrating the efficacy and safety of any of our product candidates in clinical trials or in obtaining marketing approval thereafter. We have not yet completed a clinical trial of any product candidate and we have not yet assessed safety of any product candidate in humans. As such, there may be adverse effects from treatment with any of our current or future product candidates that we cannot predict at this time.

As a result of these factors, it is more difficult for us to predict the time and cost of product candidate development, and we cannot predict whether the application of our TALON platform, or any similar or competitive platforms, will result in the development and marketing approval of any products. There can be no assurance that any development problems we experience in the future related to our TALON platform or any of our research programs will not cause significant delays or unanticipated costs, or that such development problems can be solved. Any of these factors may prevent us from completing our preclinical studies or any clinical trials that we may initiate or commercializing any product candidates we may develop on a timely or profitable basis, if at all.

The COVID-19 pandemic, which began in late 2019 and has spread worldwide, may affect our ability to initiate and complete preclinical studies, delay the initiation of our planned clinical trials or future 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, operations and ability to raise capital.

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 COVID-19 through quarantines, travel restrictions, heightened border scrutiny and other measures. The COVID-19 pandemic 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 COVID-19 pandemic and its effects on our business and operations are uncertain.

To date, enrollment in our ongoing clinical trial of PT101 has not been adversely impacted by the COVID-19 pandemic, and we believe that we have sufficient supply of clinical trial material to conduct our planned clinical trial. We cannot provide assurance, however, that some factors from the COVID-19 pandemic will not delay or otherwise adversely affect our clinical development, research, manufacturing and business operations activities, as well as our business generally, in the future.

The extent to which COVID-19 impacts our operations or those of the third parties on which we rely will depend on many factors, which are highly uncertain and cannot be predicted with confidence, including the duration of the pandemic, additional or modified government actions, new information that will emerge concerning the severity and impact of COVID-19, and the actions to contain the COVID-19 pandemic or address its impact in the short and long term. Additionally, the conduct of our clinical trials, preclinical studies and manufacturing activities is dependent upon the availability of clinical trial sites, contract research and manufacturing organizations, researchers and investigators, regulatory agency personnel and logistics providers, all of which may be adversely affected by the COVID-19 pandemic.

Any negative impact that the COVID-19 pandemic has on recruiting or retaining patients in our clinical trials, the ability of our suppliers to provide materials for our product candidates, or the regulatory review process could cause additional delays with respect to product development activities, which could materially and adversely affect our ability to obtain marketing approval for and to commercialize our product candidates, increase our operating expenses, affect our ability to raise additional capital, and have a material adverse effect on our financial results.

We and the third-party manufacturers and contract research organizations, or CROs, that we engage may face disruptions that could affect our ability to initiate and complete preclinical studies or clinical trials, including disruptions in procuring items that are essential for our research and development activities, such as, for example, raw materials used in the manufacturing of our product candidates, laboratory supplies for our preclinical studies and planned clinical trials, or animals that are used for preclinical testing, in each case, for which there may be shortages because of ongoing efforts to address the COVID-19 pandemic. The response to the COVID-19 pandemic may redirect resources with respect to regulatory and intellectual property matters in a way that would adversely impact our ability to pursue marketing approvals and protect our intellectual property. In addition, we may face impediments to regulatory meetings and potential approvals due to measures intended to limit in-person interactions.

In response to the COVID-19 pandemic and in accordance with direction from state and local governmental authorities, we have restricted access to our facility to those individuals who must perform critical research, translational medicine and laboratory support activities that must be completed on site, limited the number of such people that can be present at our facility at any one time, and required that most of our employees work remotely. In the event that governmental authorities were to keep these restrictions in place for an extended period or impose further restrictions, our employees conducting research and development activities may not be able to access our laboratory space, and our core research activities may be significantly limited or curtailed, possibly for an extended period of time.

The COVID-19 pandemic continues to rapidly evolve, and its ultimate scope, duration and effects are unknown. The extent of the impact of the disruptions to our business, preclinical studies and clinical trials as a result of the COVID-19 pandemic will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the COVID-19 pandemic, travel restrictions and actions to contain the COVID-19 pandemic, such as social distancing and quarantines or lock-downs in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease.

The pandemic has already caused significant disruptions in the financial markets, and may continue to cause such disruptions, which could adversely impact our ability to raise additional funds through public offerings or private placements and may also impact the volatility of our stock price and trading in our stock. Moreover, it is possible the pandemic will significantly impact economies worldwide, which could result in adverse effects on our business and operations. We cannot be certain what the overall impact of the COVID-19 pandemic will be on our business and it has the potential to adversely affect our business, financial condition, results of operations, and prospects.

We are early in our development efforts, and we only have one product candidate in a clinical trial. If we are unable to advance our current or future product candidates into and through clinical trials, obtain marketing approval and ultimately commercialize our product candidates or experience significant delays in doing so, our business will be materially harmed.

We are early in our development efforts, and we have advanced only one candidate into clinical trials, PT101 for the treatment of ulcerative colitis, or UC. Our ability to generate product revenues, which we do not expect will occur for many years, if ever, will depend heavily on the successful development, marketing approval and eventual commercialization of PT101 and our other current and future product candidates discovered using our TALON platform.

The success of PT101 and our other current and future product candidates will depend on several factors, including the following:

- successfully completing preclinical studies and initiating clinical trials for our early stage product candidates;
- successful enrollment and completion of clinical trials for PT101 and any other product candidates that we advance into clinical development;
- data from our clinical program that support an acceptable risk-benefit profile of our product candidates in the intended patient populations;
- acceptance by the FDA, EMA, Health Canada or other regulatory agencies of the investigational new drug applications, or INDs, clinical trial applications, or CTAs, or other regulatory filings for PT101 and our other product candidates;
- expanding and maintaining a workforce of experienced scientists and others to continue to develop our product candidates;
- successfully applying for and receiving marketing approvals from applicable regulatory authorities;
- obtaining and maintaining intellectual property protection and regulatory exclusivity for our product candidates;
- making arrangements with third-party manufacturers for, or establishing, commercial manufacturing capabilities;

- establishing sales, marketing and distribution capabilities and successfully launching commercial sales of our products, if and when approved, whether alone or in collaboration with others;
- acceptance of our products, if and when approved, by patients, the medical community and third-party payors;
- effectively competing with other therapies;
- obtaining and maintaining coverage, adequate pricing and adequate reimbursement from third-party payors, including government payors;
- maintaining, enforcing, defending and protecting our rights in our intellectual property portfolio;
- not infringing, misappropriating or otherwise violating others' intellectual property or proprietary rights; and
- maintaining a continued acceptable safety profile of our products following receipt of any marketing approvals.

We do not have complete control over many of these factors, including certain aspects of clinical development and the regulatory submission process, potential threats to our intellectual property rights and the manufacturing, marketing, distribution and sales efforts of any future collaborator. 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 develop and commercialize our product candidates, which would materially harm our business.

In the near term, we are dependent on the success of PT101. If we are unable to complete the clinical development of, obtain marketing approval for or successfully commercialize PT101, or if we experience significant delays in doing so, our business would be substantially harmed.

We do not currently have products approved for sale and are investing a significant portion of our efforts and financial resources in the development of PT101. Although we have other programs in preclinical development and we intend to develop additional product candidates in the coming years, it will take additional investment and time for such product candidates to reach the same stage of development as PT101, and there can be no assurance that they will ever do so. Our prospects are substantially dependent on our ability to develop and obtain marketing approval for, and successfully commercialize, PT101 in one or more disease indications.

We may not be successful in our efforts to use our TALON platform to build a pipeline of product candidates and advance products through commercial approval.

A key element of our strategy is to combine a network-based conceptualization of the immune system with our TALON platform to discover and design product candidates that harness the intrinsic regulatory elements of the immune system to address autoimmune diseases. Even if we are successful in identifying target diseases and product candidates, the product candidates that we identify may not be suitable for clinical development, including as a result of being shown to have harmful side effects or other characteristics that indicate that they are unlikely to receive marketing approval and achieve market acceptance. We have never commercialized a product using our TALON platform and may never be able to do so. Identifying, developing, obtaining marketing approval for and commercializing additional product candidates will require substantial additional funding and is prone to the risks of failure inherent in product development. We cannot provide stockholders any assurance that we will be able to successfully identify additional product candidates with our TALON platform, advance any of these additional product candidates through the development process or successfully commercialize any such additional product candidates. Regulatory authorities have substantial discretion in the approval process and may cause delays in the approval or rejection of an application. As a result of these factors, it is difficult for us to predict the time and cost of product candidate development. There can be no assurance that any development problems we experience in the future related to our TALON platform or any of our research or development programs will not cause significant delays or unanticipated costs, or that such development problems can be solved. If we do not successfully identify, develop, obtain marketing approval for and commercialize product candidates based upon our technological approach, we will not be able to generate product revenues.

Clinical drug development involves a lengthy and expensive process, with an uncertain outcome. If we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.

We currently only have one product candidate in clinical development. The risk of failure for each of our product candidates is high. It is impossible to predict when or if any of our product candidates will prove effective or safe in humans or will receive marketing approval. The time required to obtain approval from the FDA, EMA, Health Canada or other comparable foreign regulatory authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of regulatory authorities. Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. We have not yet completed a clinical trial of any product candidate. Clinical trials may fail to demonstrate that our product candidates are safe for humans and effective for indicated uses. Even if the clinical trials are successful, changes in marketing approval policies during the development period, changes in or the enactment or promulgation of additional statutes, regulations or guidance or changes in regulatory review for each submitted product application may cause delays in the approval or rejection of an application.

Before we can commence clinical trials for a product candidate, we must complete extensive preclinical testing and studies that support our planned INDs and other regulatory filings in the United States and abroad. We cannot be certain of the timely completion or outcome of our preclinical testing and studies and cannot predict if the outcome of our preclinical testing and studies will ultimately support the further development of our current or future product candidates or whether regulatory authorities will accept our proposed clinical programs. As a result, we may not be able to submit applications to initiate clinical development on the timelines we expect, if at all, and the submission of these applications may not result in regulatory authorities allowing clinical trials to begin. 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.

Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. We cannot guarantee that any of our clinical trials will be conducted as planned or completed on schedule, or at all. A failure of one or more clinical trials can occur at any stage of testing, which may result from a multitude of factors, including, but not limited to, flaws in study design, dose selection issues, placebo effects, patient enrollment criteria and failure to demonstrate favorable safety or efficacy traits.

Preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products. Furthermore, 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 and/or cause the FDA, EMA, Health Canada or other regulatory authorities to require additional testing before approving any of our product candidates.

Our current and future product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA, EMA, Health Canada or other foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA, EMA, Health Canada or other foreign regulatory authorities that a product candidate is safe, pure and potent or effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA, EMA, Health Canada or other foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate’s clinical and other benefits outweigh its safety risks;
- the FDA, EMA, Health Canada or other foreign regulatory authorities may disagree with our interpretation of data from clinical trials or preclinical studies;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of a Biologics License Application, or BLA, to the FDA, or similar foreign submission to the EMA, Health Canada or other foreign regulatory authority, to obtain approval in the United States, the European Union or elsewhere;
- the FDA, EMA, Health Canada or other foreign regulatory authorities may find deficiencies with or fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA, EMA, Health Canada or other foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

This lengthy approval process as well as the unpredictability of clinical trial results may result in our failing to obtain regulatory approval to market any product candidate we develop, which would significantly harm our business, results of operations and prospects.

The FDA, EMA, Health Canada and other comparable foreign regulatory authorities have substantial discretion in the approval process and determining when or whether regulatory approval will be obtained for any product candidate that we develop. Even if we believe the data collected from future clinical trials of our product candidates are promising, such data may not be sufficient to support approval by the FDA, EMA, Health Canada or any other comparable foreign regulatory authorities.

Even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our products, may grant approval contingent on the performance of costly post-marketing clinical trials or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

We may incur unexpected costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

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

- regulators or institutional review boards, or IRBs, or independent ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may experience delays in reaching, or fail to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;
- regulators may decide the design of our clinical trials is flawed, for example if our trial protocol does not evaluate treatment effects in trial subjects for a sufficient length of time;
- 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;
- preclinical testing may produce results based on which we may decide, or regulators may require us, to conduct additional preclinical studies before we proceed with certain clinical trials, limit the scope of our clinical trials, halt ongoing clinical trials or abandon product development programs;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- regulators, IRBs or ethics committees 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;
- 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;
- our product candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators, IRBs or ethics committees to suspend or terminate the trials; and
- regulators may withdraw their approval of a product or impose restrictions on its distribution, such as in the form of a risk evaluation and mitigation strategy, or REMS.

We could encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are conducted or their ethics committees, by the data review committee or data safety monitoring board for such trial or by the FDA, EMA or other foreign regulatory authorities. Such authorities may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA, EMA or other foreign regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, including those relating to the class of products to which our product candidates belong.

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

- be delayed in obtaining marketing approval for our product candidates;
- not obtain marketing approval at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling or a REMS 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.

Our development costs will also increase if we experience delays in preclinical studies or clinical trials or in obtaining marketing approvals. We do not know whether any of our preclinical studies or clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. We may also determine to change the design or protocol of one or more of our clinical trials, including to add additional patients or arms, which could result in increased costs and expenses and/or delays. Significant preclinical study or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our product candidates and may harm our business and results of operations.

Preclinical drug development is uncertain. Some or all of our preclinical programs may experience delays or may never advance to clinical trials, which would adversely affect our ability to obtain marketing approvals or commercialize these product candidates on a timely basis or at all, which would have an adverse effect on our business.

In order to obtain FDA approval to market a new biological product, we must demonstrate proof of safety, purity and potency or efficacy in humans. To satisfy these requirements, we will have to conduct adequate and well-controlled clinical trials. Before we can commence clinical trials for a product candidate, we must complete extensive preclinical testing and studies that support an IND in the United States. Although we are conducting a Phase 1 trial in Canada, we have not yet submitted an IND to the FDA for any of our product candidates. We cannot be certain of the timely completion or outcome of our preclinical testing and studies, and we cannot predict if the FDA will accept our proposed clinical programs or if the outcome of our preclinical testing and studies will ultimately support the further development of these product candidates. As a result, we cannot be sure that we will be able to submit INDs or similar applications for any preclinical programs on the timelines we expect, if at all, and we cannot be sure that submission of INDs or similar applications will result in the FDA or other regulatory authorities allowing clinical trials to begin.

Conducting preclinical testing is a lengthy, time-consuming and expensive process. The length of time may vary substantially according to the type, complexity, novelty and intended use of the product candidate, and often can be several years or more per product candidate. Delays associated with product candidates for which we are conducting preclinical testing and studies ourselves may cause us to incur additional operating expenses. Moreover, we may be affected by delays associated with the preclinical testing and studies of certain product candidates conducted by our potential partners over which we have no control. The commencement and rate of completion of preclinical studies and clinical trials for a product candidate may be delayed by many factors, including, for example:

- inability to generate sufficient preclinical or other in vivo or in vitro data to support the initiation of clinical trials; and
- delays in reaching a consensus with regulatory agencies on study design.

Moreover, even if we do initiate clinical trials for other product candidates, our development efforts may not be successful, and clinical trials that we conduct or that third parties conduct on our behalf may not demonstrate sufficient safety, purity and potency or efficacy necessary to obtain the requisite marketing approvals for any of our product candidates or product candidates employing our technology. Even if we obtain positive results from preclinical studies or initial clinical trials, we may not achieve the same success in future trials.

If we experience delays or difficulties in the enrollment of patients in clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented.

Identifying and qualifying patients to participate in clinical trials for our product candidates is critical to our success. Successful and timely completion of clinical trials will require that we enroll a sufficient number of patients who remain in the trial until its conclusion. We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside of the United States.

Patient enrollment is affected by a variety of other factors, including:

- the prevalence and severity of the disease under investigation;
- the eligibility criteria for the trial in question;
- the perceived risks and benefits of the product candidate under trial;
- the requirements of the trial protocols;
- the availability of existing treatments for the indications for which we are conducting clinical trials;
- the ability to recruit clinical trial investigators with the appropriate competencies and experience;

- the efforts to facilitate timely enrollment in clinical trials;
- the patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment;
- the proximity and availability of clinical trial sites for prospective patients;
- the conduct of clinical trials by competitors for product candidates that treat the same indications or address the same patient populations as our product candidates; and
- the cost to, or lack of adequate compensation for, prospective patients.

Other pharmaceutical and biotechnology companies have reported experiencing delays in enrollment in their ongoing clinical trials as a result of the COVID-19 pandemic, and we could also experience such delays. Our inability to locate and enroll a sufficient number of patients for our clinical trials would result in significant delays, could require us to abandon one or more clinical trials altogether and could delay or prevent our receipt of necessary regulatory approvals. Enrollment delays in our clinical trials may result in increased development costs for our product candidates, which would cause the value of our company to decline and limit our ability to obtain additional financing.

If serious adverse events, undesirable side effects or unexpected characteristics are identified during the development of PT101 or any other current or future product candidate we may develop in the future, we may need to abandon or limit our further clinical development of those product candidates.

If our current or future product candidates are associated with serious adverse events or undesirable side effects in clinical trials or have characteristics that are unexpected in clinical trials or preclinical testing, we may need to abandon their development or limit development to more narrow uses or subpopulations in which the serious adverse events, undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. In pharmaceutical development, many compounds that initially show promise in early-stage or clinical testing are later found to cause side effects that delay or prevent further development of the compound.

Additionally, if results of our clinical trials reveal undesirable side effects, we, the FDA or the IRBs or ethics committees at the institutions in which our studies are conducted could suspend or terminate our clinical trials or the FDA or comparable foreign regulatory authorities could order us to cease clinical trials or deny approval of our product candidates for any or all targeted indications. Treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete any of our clinical trials. If we elect or are forced to suspend or terminate any clinical trial of our product candidates, the commercial prospects of such product candidate will be harmed, and our ability to generate product revenue from such product candidate will be delayed or eliminated. Any of these occurrences could materially harm our business.

Interim 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 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.

Results of preclinical studies and early clinical trials of our product candidates may not be predictive of future trial results.

Success in preclinical studies and early clinical trials does not ensure that later clinical trials will be successful. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. Even if we are able to commence clinical trials, issues may arise that could suspend or terminate such clinical trials. A number of companies in the biotechnology and pharmaceutical industries have suffered significant setbacks in clinical trials, even after positive results in earlier preclinical studies or clinical trials. These setbacks have been caused by, among other things, preclinical findings made while clinical trials were underway and safety or efficacy observations made in clinical trials, including previously unreported adverse events. Notwithstanding any potential promising results in earlier studies and trials, we cannot be certain that we will not face similar setbacks. In addition, the results of our preclinical animal studies, including our oncology mouse studies and animal studies, may not be predictive of the results of outcomes in human clinical trials. For example, our oncology product candidates that are in preclinical development may demonstrate different chemical and biological properties in patients than they do in laboratory animal studies or may interact with human biological systems in unforeseen or harmful ways.

If any of our product candidates receives marketing approval and we, or others, later discover that the drug is less effective than previously believed or causes undesirable side effects that were not previously identified, our ability to market the drug could be compromised.

Clinical trials of our product candidates are conducted in carefully defined subsets of patients who have agreed to enter into clinical trials. Consequently, it is possible that our clinical trials may indicate an apparent positive effect of a product candidate that is greater than the actual positive effect, if any, or alternatively fail to identify undesirable side effects. If one or more of our product candidates receives regulatory approval, and we, or others, later discover that they are less effective than previously believed, or cause undesirable side effects, a number of potentially significant negative consequences could result, including:

- withdrawal or limitation by regulatory authorities of approvals of such product;
- seizure of the product by regulatory authorities;
- recall of the product;
- restrictions on the marketing of the product or the manufacturing process for any component thereof;
- requirement by regulatory authorities of additional warnings on the label, such as a “black box” warning or contraindication;
- requirement that we implement a REMS or create a medication guide outlining the risks of such side effects for distribution to patients;
- commitment to expensive post-marketing studies as a prerequisite of approval by regulatory authorities of such product;
- the product may become less competitive;
- initiation of regulatory investigations and government enforcement actions;
- initiation of legal action against us to hold us liable for harm caused to patients; and
- harm to our reputation and resulting harm to physician or patient acceptance of our products.

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

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

Because we have limited financial and managerial resources, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may 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. Failure to allocate resources or capitalize on strategies in a successful manner will have an adverse impact on our business.

We are conducting a Phase 1a clinical trial of PT101 in healthy volunteers in Canada and currently plan to conduct additional clinical trials for our product candidates, including at sites outside the United States, and the FDA may not accept data from trials conducted in such locations.

We are currently conducting a Phase 1a clinical trial of PT101 in healthy volunteers in Canada, and we plan to conduct additional clinical trials in Canada, the United States and Europe. Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of these 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 and good clinical practices, or GCPs. 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. If the FDA does not accept the data from any trial that we conduct 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.

Risks Related to our Dependence on Third Parties

We rely, and expect to continue to rely, on third parties to conduct our clinical trials, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials, which may harm our business.

We currently rely on third-party CROs to conduct our ongoing Phase 1a clinical trial of PT101 and plan to rely on third-party CROs or third-party research collaboratives to conduct our planned clinical trials. We do not plan to independently conduct clinical trials of our other product candidates. We expect to continue to rely on third parties, such as CROs, clinical data management organizations, medical institutions and clinical investigators, to conduct our clinical trials. These agreements might terminate for a variety of reasons, including a failure to perform by the third parties. If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs on commercially reasonable terms, or at all, and our product development activities might be delayed.

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

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 develop and commercialize our product candidates. Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors.

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

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

We do not own or operate, and currently have no plans to establish, any manufacturing facilities. We rely, and expect to continue to rely, on third parties for the manufacture of PT101 and our other product candidates for preclinical and clinical testing, as well as for commercial manufacture if any of our product candidates receive marketing approval. We also rely on these third parties for packaging, labeling, sterilization, storage, distribution and other production logistics. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts. We may be unable to establish any agreements with third-party manufacturers or to do so on acceptable terms. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

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

We or our third-party manufacturers may encounter shortages in the raw materials or active pharmaceutical ingredient 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 ingredient, including shortages caused by the purchase of such raw materials or active pharmaceutical ingredient by our competitors or others. The failure of us or our third-party manufacturers to obtain the raw materials or active pharmaceutical ingredient necessary to manufacture sufficient quantities of our product candidates may have a material adverse effect on our business.

Our third-party manufacturers are subject to inspection and approval by regulatory authorities before we can commence the manufacture and sale of any of our product candidates, and thereafter subject to ongoing inspection from time to time. Third-party manufacturers may not be able to comply with current good manufacturing practices, or cGMP, regulations or similar regulatory requirements outside of the United States. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in regulatory actions, such as the issuance of FDA Form 483 notices of observations, warning letters or sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products.

Manufacturing biologic products, such as PT101, is complex, especially in large quantities. Biologic products must be made consistently and in compliance with a clearly defined manufacturing process. Accordingly, it is essential to be able to validate and control the manufacturing process to assure that it is reproducible. The manufacture of biologics is extremely susceptible to product loss due to contamination, equipment failure or improper installation or operation of equipment, vendor or operator error, inconsistency in yields, variability in product characteristics and difficulties in scaling the product process. We have not yet scaled up the manufacturing process for any of our product candidates for potential commercialization. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions. If microbial, viral or other contaminations are discovered in our product candidates or in the manufacturing facilities in which our product candidates are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination, which could harm our results of operations and cause potential reputational damage. 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 do not currently have arrangements in place for redundant supply or a source for bulk drug substance nor do we have any agreements with third-party manufacturers for long-term commercial supply. If any of our future 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.

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

We expect to depend on collaborations with third parties for the research, development, manufacture and commercialization of programs or product candidates. If these collaborations are not successful, our business could be adversely affected.

As part of our strategy, we intend to seek to enter into collaborations with third parties for one or more of our programs or product candidates. For example, in October 2019, we entered into the Astellas agreement to develop locally acting immunomodulators for autoimmune diseases of the pancreas. Our likely collaborators for any other collaboration arrangements include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies. In the Astellas agreement and in any other arrangements that we may enter into with any third parties, we will have limited control over the amount and timing of resources that any future collaborators dedicate to the development or commercialization of our product candidates. Our ability to generate revenue from these arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements.

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, that divert resources or create competing priorities;

- collaborators may not pursue commercialization of any product candidates that achieve regulatory 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, that may divert resources or create competing priorities. For example, Astellas is solely responsible for, and has sole authority with respect to, at its own expense, all commercialization activities and all regulatory responsibilities, including preparing and filing INDs, marketing authorization applications and obtaining and maintaining regulatory approvals for products under the Astellas agreement;
- 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 with marketing and distribution rights to one or more of our product candidates that achieve regulatory 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. For example, any time after the first anniversary of the effective date of the Astellas agreement, Astellas may terminate the Astellas agreement for convenience upon advance prior written notice.

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 also apply to the activities of our collaborators.

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

If we are not able to establish or maintain collaborations on commercially reasonable terms, we may have to alter our development and commercialization plans and our business could be adversely affected.

We face significant competition in attracting appropriate collaborators, and a number of more established companies may also be pursuing strategies to license or acquire third-party intellectual property rights that we consider attractive. These established companies may have a competitive advantage over us due to their size, financial resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. Whether we 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 design or results of clinical trials, the likelihood of approval by the FDA, EMA, Health Canada or other regulatory authorities, the potential market for the subject 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, which can exist if there is a challenge to such ownership without regard to the merits of the challenge, the terms of any existing collaboration agreements, and industry and market conditions generally. The collaborator may also have the opportunity to collaborate on other product candidates or technologies for similar indications and will have to evaluate whether such a collaboration could be more attractive than the one with us for our product candidate.

We may also be restricted under existing or future license agreements from entering into agreements on certain terms with potential collaborators. For example, during the term of the Astellas agreement, we are not permitted to use tethers that are identified in the research plan, or develop, manufacture or commercialize any product directed toward tether targets that are identified in the research plan, or, in either case, grant a license to a third party or sublicense to enable any third party to do so.

Collaborations are complex and time-consuming to negotiate, document and execute. In addition, consolidation among large pharmaceutical and biotechnology companies has reduced the number of potential future collaborators.

We may not be able to negotiate additional 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 the product candidate for which we are seeking to collaborate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to fund and undertake development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our product candidates or bring them to market or continue to develop our TALON platform.

If any third-party manufacturer of our product candidates is unable to increase the scale of its production of our product candidates, and/or increase the product yield of its manufacturing, then our costs to manufacture the product may increase and commercialization may be delayed.

In order to produce sufficient quantities to meet the demand for clinical trials and, if approved, subsequent commercialization of any current or future product candidates that we may develop, our third-party manufacturers will be required to increase their production and optimize their manufacturing processes while maintaining the quality of the product. The transition to larger scale production could prove difficult. In addition, if our third-party manufacturers are not able to optimize their manufacturing processes to increase the product yield for our product candidates, or if they are unable to produce increased amounts of our product candidates while maintaining the quality of the product, then we may not be able to meet the demands of clinical trials or market demands, which could decrease our ability to generate profits and have a material adverse impact on our business and results of operation.

Risks Related to our Intellectual Property

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

Our success depends in large part on our ability to obtain and maintain protection of the intellectual property we may own solely and jointly with others or may license from others, particularly patents, in the United States and other countries with respect to any proprietary technology and product candidates we develop. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our product candidates that are important to our business and by in-licensing intellectual property related to our technologies and product candidates. If we are unable to obtain or maintain patent protection with respect to any proprietary technology or product candidate, our business, financial condition, results of operations and prospects could be materially harmed.

The patent prosecution process is expensive, time-consuming and complex, and we may not be able to file, prosecute, maintain, defend or license all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, 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. Therefore, these in-licensed patents and applications may not be prepared, filed, prosecuted, maintained, defended and enforced in a manner consistent with the best interests of our business.

The patent position of pharmaceutical and biotechnology companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. In addition, the 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 our patent rights, we cannot predict whether the patent applications we are currently pursuing 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. We are aware of a notice of allowance issued by the European Patent Office for which a patent would cover a method of use for an IL-2 mutein program for the treatment of arthritis, which may include rheumatoid arthritis. We may in the future evaluate PT101 or other product candidates for the treatment of rheumatoid arthritis, and if this patent were issued in Europe, we may not be able to sell PT101 in Europe for this indication during the term of the patent.

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, neither we nor our licensors can know with certainty whether either we or our licensors were the first to make the inventions claimed in the patents and patent applications we own or in-license now or in the future, or that either we or our licensors were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our owned and in-licensed patent rights are highly uncertain. Moreover, our owned and in-licensed pending and future patent applications may not result in patents being issued which protect our technology and product candidates, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents and our ability to obtain, protect, maintain, defend and enforce our patent rights, narrow the scope of our patent protection and, more generally, could affect the value or narrow the scope of our patent rights.

Moreover, we may be subject to a third-party preissuance submission of prior art to the United States Patent and Trademark Office, or USPTO, or become involved in opposition, derivation, revocation, reexamination, *inter partes* review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or 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.

Additionally, 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 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 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 product candidates. Such proceedings also may result in substantial cost and require significant time from our management and employees, even if the eventual outcome is favorable to us. 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 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.

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

Patents have a limited lifespan. 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. Even if patents covering our product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products, including biosimilars. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

If we are unable to obtain licenses from third parties on commercially reasonable terms or fail to comply with our obligations under such agreements, our business could be harmed.

It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our products, in which case we would be required to obtain a license from these third parties. 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 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.

Our product candidates may face competition from biosimilars approved through an abbreviated regulatory pathway.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the ACA, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or BPCIA, which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-approved reference biological product. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first approved by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first approved. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing the sponsor’s own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of the other company’s product. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty.

We believe that any of our product candidates approved as a biological product under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for biosimilar competition sooner than anticipated. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

If we do not obtain patent term extension in the United States under the Hatch-Waxman Act and in foreign countries under similar legislation, thereby potentially extending the term of our marketing exclusivity for any product candidates we may develop, our business may be materially harmed.

In the United States, the patent 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 clinical development and 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 and that covers an approved drug may be extended. Similar provisions are available in Europe, such as supplementary protection certificates, 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.

It is possible that we will not obtain patent term extension under the Hatch-Waxman Act for a U.S. patent covering any of our product candidates that we may identify even where that patent is eligible for patent term extension, or if we obtain such an extension, it may be for a shorter period than we had sought.

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

Changes in either the patent laws or interpretation of patent laws in the United States, including patent reform legislation such as the Leahy-Smith America Invents Act, or the Leahy-Smith Act, could increase the uncertainties and costs surrounding the prosecution of our patent applications and the maintenance, enforcement or defense of our issued patents. The Leahy-Smith Act includes a number of significant changes to United States patent law. These changes include provisions that affect the way patent applications are prosecuted, redefine prior art, provide more efficient and cost-effective avenues for competitors to challenge the validity of patents, and enable third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent at USPTO-administered post-grant proceedings, including post-grant review, *inter partes* review, and derivation proceedings. Assuming that other requirements for patentability are met, prior to March 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. After March 2013, under the Leahy-Smith Act, the United States transitioned to a first-to-file system in which, assuming that the other statutory requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. As such, 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.

In addition, the patent positions of companies in the development and commercialization of biologics and pharmaceuticals are particularly uncertain. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. This combination of events has created uncertainty with respect to the validity and enforceability of patents once obtained. Depending on future actions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our patent rights and our ability to protect, defend and enforce our patent rights in the future.

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

Competitors and other third parties may infringe, misappropriate or otherwise violate our issued patents or other intellectual property. As a result, we may need to file infringement, misappropriation or other intellectual property related claims, which can be expensive and time-consuming. Any claims we assert against perceived infringers could provoke such parties to assert counterclaims against us alleging that we infringe, misappropriate or otherwise violate their intellectual property. In addition, in a patent infringement proceeding, such parties could counterclaim that the patents we have asserted are invalid or unenforceable. 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.

An adverse result in any such proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put any of our patent applications at risk of not yielding an issued patent. A court may also refuse to stop the third party from using the technology at issue in a proceeding on the grounds that our patents do not cover such technology. 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 or trade secrets could be compromised by disclosure during this type of litigation. Any of the foregoing could allow such third parties to develop and commercialize competing technologies and products and have a material adverse impact on our business, financial condition, results of operations and prospects.

Interference or derivation proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms or at all, or if a non-exclusive license is offered and our competitors gain access to the same technology. Our defense of litigation or interference or derivation proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties, or enter into development partnerships that would help us bring our product candidates to market.

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 this type of litigation. There could also be public announcements of the results of hearings, motions, or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock.

Issued patents covering our product candidates could be found invalid or unenforceable if challenged in court. We may not be able to protect our trade secrets in court.

If we or one of our licensing partners initiates legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that the patent covering our product candidate is invalid or unenforceable. 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, written description or non-enablement. In addition, patent validity challenges may, under certain circumstances, be based upon non-statutory obviousness-type double patenting, which, if successful, could result in a finding that the claims are invalid for obviousness-type double patenting or the loss of patent term, including a patent term adjustment granted by the USPTO, if a terminal disclaimer is filed to obviate a finding of obviousness-type double patenting. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld information material to patentability from the USPTO, or made a misleading statement, during prosecution. Third parties also may raise similar 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 and equivalent proceedings in foreign jurisdictions. Such proceedings could result in the revocation or cancellation of or amendment to our patents in such a way that they no longer cover our product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art of which the patent examiner and we or our licensing partners were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we could lose at least part, and perhaps all, of the patent protection on one or more of our product candidates. Such a loss of patent protection could have a material adverse impact on our business.

In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable or that we elect not to patent, processes for which patents are difficult to enforce and any other elements of our product candidate discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. However, trade secrets can be difficult to protect, and some courts inside and outside the United States are less willing or unwilling to protect trade secrets. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with our employees, consultants, scientific advisors and contractors. We cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors.

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

Our commercial success depends upon our ability and the ability of our collaborators to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing, misappropriating or otherwise violating the intellectual property and proprietary rights of third parties. There is considerable patent and other intellectual property litigation in the pharmaceutical and biotechnology industries. We may become party to, or threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our technology and product candidates, including interference proceedings, post grant review, *inter partes* review, and derivation proceedings before the USPTO and similar proceedings in foreign jurisdictions such as oppositions before the European Patent Office. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are pursuing development candidates. As the biotechnology and pharmaceutical 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 legal threshold for initiating litigation or contested proceedings is low, so that even lawsuits or proceedings with a low probability of success might be initiated and require significant resources to defend. Litigation and contested proceedings can also be expensive and time-consuming, and our adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we can. The risks of being involved in such litigation and proceedings may increase if and as our product candidates near commercialization and as we gain the greater visibility associated with being a public company. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future, regardless of merit. We may not be aware of all such intellectual property rights potentially relating to our technology and product candidates and their uses, or we may incorrectly conclude that third party intellectual property is invalid or that our activities and product candidates do not infringe such intellectual property. Thus, we do not know with certainty that our technology and product candidates, or our development and commercialization thereof, do not and will not infringe, misappropriate or otherwise violate any third party's intellectual property.

While our product candidates are in preclinical studies and clinical trials, we believe that their use in these preclinical studies and clinical trials falls within the scope of the exemptions provided by 35 U.S.C. Section 271(e) in the United States, which exempts from patent infringement liability activities reasonably related to the development and submission of information to the FDA. As our product candidates progress toward commercialization, the possibility of a patent infringement claim against us increases. We attempt to ensure that our product candidates and the methods we employ to manufacture them, as well as the methods for their use we intend to promote, do not infringe other parties' patents and other proprietary rights. We cannot assure our stockholders that they do not, however, and competitors or other parties may assert that we infringe their proprietary rights in any event.

Third parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims to materials, formulations or methods, such as methods of manufacture or methods for treatment, related to the discovery, use or manufacture of the product candidates that we may identify or related to our technologies. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that the product candidates that we may identify may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Moreover, as noted above, there may be existing patents that we are not aware of or that we have incorrectly concluded are invalid or not infringed by our activities. If any third-party patents were held by a court of competent jurisdiction to cover, for example, the manufacturing process of the product candidates that we may identify, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtained a license under the applicable patents, or until such patents expire.

We may test our product candidates administered with other product candidates or products that are covered by patents held by other companies or institutions. In the event that a labeling instruction is required in product packaging recommending that combination, we could be accused of, or held liable for, infringement of the third-party patents covering the product candidate or product recommended for administration with our product candidates. In such a case, we could be required to obtain a license from the other company or institution to use the required or desired package labeling, which may not be available on commercially reasonable terms, or at all.

We are aware of certain U.S. and foreign patents and applications owned by certain third parties with claims that are directed to IL-2 muteins that are conjugated to certain proteins, some of which would expire as late as 2037. These patents could be construed to cover PT101 and we may not be able to commercialize PT101 in such jurisdictions. If the pending patent applications were to issue in certain jurisdictions, we may not be able to commercialize PT101 in such jurisdictions during the term of the patent. In addition, we are aware of certain European and other foreign patents and applications owned by a third party with claims that are broadly directed methods of using IL-2 muteins to treat certain autoimmune disease indications, including rheumatoid arthritis, which would expire as late as 2030. The patents or patents issuing from these pending applications could be construed to cover PT101, as well as other products containing IL-2 muteins.

Generally, conducting clinical trials and other development activities in the United States is not considered an act of infringement. If and when products are approved by the FDA, that certain third party may then seek to enforce its patents by filing a patent infringement lawsuit against us or our licensee(s). In such lawsuit, we or our licensees may incur substantial expenses defending our rights or our licensees rights to commercialize such product candidates, and in connection with such lawsuit and under certain circumstances, it is possible that we or our licensees could be required to cease or delay the commercialization of a product candidate and/or be required to pay monetary damages or other amounts, including royalties on the sales of such products. Moreover, any such lawsuit may also consume substantial time and resources of our management team and board of directors. The threat or consequences of such a lawsuit may also result in royalty and other monetary obligations being imposed on us, which may adversely affect our results of operations and financial condition.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize the product candidates that we may identify. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties, redesign our infringing products or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure.

We may choose to take a license or, if we are found to infringe, misappropriate or otherwise violate a third party's intellectual property rights, we could also be required to obtain a license from such third party to continue developing, manufacturing and marketing our technology and product candidates. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors and other third parties 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 significant monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent or other intellectual property right and could be forced to indemnify our customers or collaborators. 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. In addition, we may be forced to redesign our product candidates, seek new regulatory approvals and indemnify third parties pursuant to contractual agreements. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar material adverse effect on our business, financial condition, results of operations and prospects.

Intellectual property litigation or other legal proceedings relating to intellectual property could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract 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 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 conduct such litigation or proceedings adequately. 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 may also have an advantage in such proceedings due to their more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of intellectual property litigation or other proceedings could compromise our ability to compete in the marketplace.

Obtaining and maintaining 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, renewal and annuity fees and various other government fees on any issued patent and pending patent application must be paid to the USPTO and foreign patent agencies in several stages or annually over the lifetime of our patents and patent applications. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In certain circumstances, we may rely on our licensing partners to pay these fees to, or comply with the procedural and documentary rules of, the relevant patent agency. With respect to our patents, we rely on outside firms and outside counsel to remind us of the due dates and to make payment after we instruct them to do so. 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 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 fail to maintain the patents and patent applications covering our product candidates, it would have a material adverse effect on our business, financial condition, results of operations and prospects.

If we fail to comply with our obligations in our intellectual property licenses arrangements with third parties, or otherwise experience disruptions to our business relationships with our licensors, we could lose intellectual property rights that are important to our business.

We are party to agreements, and we may enter into additional arrangements, with third parties that may impose diligence, development and commercialization timelines, milestone payment, royalty, insurance and other obligations on us. We have existing agreements, pursuant to which we are obligated to pay royalties on net product sales of product candidates or related technologies to the extent they are covered by the agreements. If we fail to comply with such obligations under current or future agreements, our counterparties may have the right to terminate these agreements or require us to grant them certain rights. Such an occurrence could materially adversely affect the value of any product candidate being developed under any such agreement. Termination of these agreements or reduction or elimination of our rights under these agreements may result in our having to negotiate new or reinstated agreements with less favorable terms, or cause us to lose our rights under these agreements, including our rights to important intellectual property or technology, which would have a material adverse effect on our business, financial condition, results of operations and prospects. While we still face all of the risks described herein with respect to those agreements, we cannot prevent third parties from also accessing those technologies. In addition, our licenses may place restrictions on our future business opportunities.

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

- the scope of rights granted under the 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 under our collaborative development relationships;
- our diligence obligations under the 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.

Our current or future licensors may have relied on third-party consultants or collaborators or on funds from third parties such that our licensors are not the sole and exclusive owners of the intellectual property or intellectual property rights we in-license. If other third parties have ownership rights to intellectual property or intellectual property rights we in-license, they may be able to license such intellectual property or intellectual property rights to our competitors, and our competitors could market competing products and technology. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

In spite of our best efforts, our licensors might conclude that we have materially breached our license agreements and might therefore terminate the license agreements, thereby removing our ability to develop and commercialize product candidates and technology covered by these license agreements. If these in-licenses are terminated, or if the underlying intellectual property fails to provide the intended exclusivity, competitors would have the freedom to seek regulatory approval of, and to market, products and technologies identical to ours. This could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

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

Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States, and even where such protection is nominally available, judicial and governmental enforcement of such intellectual property rights may be lacking. Consequently, 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. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection or licenses, but enforcement is not as strong as that in the United States. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. 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 biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our intellectual property and proprietary rights generally. In addition, certain jurisdictions do not protect to the same extent or at all inventions that constitute new methods of treatment.

Proceedings to enforce our intellectual property and proprietary rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property.

We may be subject to claims that former employees, collaborators or other third parties have an interest in our patents, trade secrets or other intellectual property as an inventor or co-inventor. For example, we may have inventorship disputes arise from conflicting obligations of employees, consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship or our ownership of our patents, trade secrets or other intellectual property. If we 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, intellectual property that is important to our product candidates. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

We may be subject to claims by third parties asserting that our employees, consultants or contractors have wrongfully used or disclosed confidential information of third parties, or we have wrongfully used or disclosed alleged trade secrets of their current or former employers or claims asserting we have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property.

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

In addition, while it is our policy to require our employees, consultants and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own. Our intellectual property assignment agreements with them may not be self-executing or may be breached, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, financial conditions, results of operations and prospects.

If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could have a material adverse effect on our competitive business position and prospects. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products, which license may not be available on commercially reasonable terms, or at all, or such license may be non-exclusive. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our management and employees.

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 our some of our technology and product candidates, we also rely on trade secrets and confidentiality agreements to protect our unpatented know-how, technology and other proprietary information, to maintain our competitive position, including certain aspects of our TALON platform. We seek to protect our trade secrets and other proprietary technology, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract research organizations, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants, but we cannot guarantee that we have entered into such agreements with each party that may have or has had access to our trade secrets or proprietary technology. Despite these efforts, 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. Detecting the disclosure or misappropriation of a trade secret and enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside of 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, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor or other third party, our competitive position would be materially and adversely harmed.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Any registered trademarks or trade names may be challenged, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely impact our financial condition or results of operations.

Intellectual property rights do not necessarily address all potential threats.

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

- portions of our TALON platform are protected by trade secrets, but much of our TALON platform is not protected by intellectual property, including patents, trade secrets and know-how, and we may not be able to develop, acquire or in-license any patentable technologies or other intellectual property related to the unprotected portions of our TALON platform;
- 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;
- we, or our current or future collaborators, might not have been the first to make the inventions covered by the issued patent or pending patent applications that we license or may own in the future;
- we, or our current or future collaborators, might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our owned or in-licensed intellectual property rights;
- it is possible that our pending patent applications or those we may own or in-license in the future will not lead to issued patents;
- issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors;

- 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, will include claims having a scope sufficient to protect our product candidates;
- we cannot ensure that any patents issued to us will provide a basis for an exclusive market for our commercially viable product candidates or will provide us with any competitive advantages;
- 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 our relevant patents expire;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may harm our business; and
- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

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

Risks Related to the Commercialization of our Product Candidates

Even if any of our current or future product candidates receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success, and the market opportunity for any of such product candidates, if approved, may be smaller than we estimate.

If any of our current or future product candidates receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. Efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources and may not be successful. If our current or future product candidates do not achieve an adequate level of acceptance, we may not generate significant product revenues and we may not become profitable. The degree of market acceptance of our current or future product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy and potential advantages of such product candidates compared to the advantages and relative risks of alternative treatments;
- the effectiveness of sales and marketing efforts;
- the cost of treatment in relation to alternative treatments, including any similar biosimilar treatments;
- our ability to offer our products, if approved, for sale at competitive prices;
- 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 physicians to prescribe these therapies;
- the strength of marketing and distribution support;
- the timing of market introduction of competitive products;
- the availability of third-party coverage and adequate reimbursement, and patients' willingness to pay out of pocket for required co-payments or in the absence of third-party coverage or adequate reimbursement;
- the prevalence and severity of any side effects; and
- any restrictions on the use of our products, if approved, together with other medications.

Our assessment of the potential market opportunity for our current or future product candidates is based on industry and market data that we obtained from industry publications, research, surveys and studies conducted by third parties and our analysis of these data, research, surveys and 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. Our estimates of the potential market opportunities for our product candidates include a number of key assumptions based on our industry knowledge, industry publications and third-party research, surveys and studies, which may be based on a small sample size and fail to accurately reflect market opportunities. While we believe that our internal assumptions are reasonable, no independent source has verified such assumptions. If any of our assumptions or estimates, or these publications, research, surveys or studies prove to be inaccurate, then the actual market for any of our product candidates may be smaller than we expect, and as a result our revenues from product sales may be limited and it may be more difficult for us to achieve or maintain profitability.

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

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

We are aware of several other companies developing programs that utilize IL-2 for the selective expansion of regulatory T cells, including Amgen Inc., Nektar Therapeutics (in partnership with Eli Lilly & Company, or Eli Lilly), Roche Holding AG, or Roche, and Celgene Corporation, or Celgene. We are also aware of other companies with research or preclinical-stage programs in this area, including Synthorx, Inc., Moderna, Inc. and Xencor, Inc. We are also aware of other companies with PD-1 agonist programs for the treatment of autoimmune diseases, including AnaptysBio, Inc., Celgene and Eli Lilly.

If approved for the treatment of patients with moderate-to-severe UC who are nonresponsive or intolerant to corticosteroids, PT101 would compete with Entyvio, which is an α4β7 integrin antibody marketed by Takeda Pharmaceutical Company Ltd, Humira, which is a TNF antibody marketed by AbbVie, Stelara, which is an IL-12/IL-23 antibody marketed by Johnson & Johnson, Xeljanz, which is a JAK1 inhibitor marketed by Pfizer Inc., and Simponi, which is a TNF antibody marketed by Johnson & Johnson.

We are aware of several companies with product candidates for the treatment of patients with UC, including Rinvoq, which is a JAK1 inhibitor being developed in Phase 3 clinical trials by AbbVie, ozanimod, which is a S1P inhibitor being developed in Phase 3 clinical trials by Celgene, etrolizumab, which is a β7 integrin being developed in Phase 3 clinical trials by Roche, mirikizumab, which is an anti-IL-23 antibody being developed in Phase 3 clinical trials by Eli Lilly and filgotinib, a JAK1 inhibitor being developed in Phase 3 clinical trials by Gilead Sciences, Inc. We are also aware of additional product candidates in clinical trials by AbbVie, Abivax SA, Amgen Inc., Arena Pharmaceuticals, Inc. Boehringer Ingelheim, Bristol-Myers Squibb Company, Celgene, Gilead Sciences, Inc., GlaxoSmithKline plc, Gossamer Bio, Inc., Incyte Corp., Janssen Pharmaceutica N.V., Landos Biopharma, Inc., Pfizer Inc., Protagonist Therapeutics, Inc., and Theravance Biopharma, Inc.

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

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

Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do.

Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

If we are unable to establish sales, marketing and distribution capabilities or enter into sales, marketing and distribution agreements with third parties, we may not be successful in commercializing our current and future product candidates if and when they are approved.

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

In the future, we expect to build a focused, specialty sales and marketing infrastructure to market some of our product candidates in the United States, if and when they are approved. There are risks involved with establishing our own sales, marketing and distribution capabilities. For example, recruiting and training a sales force is expensive and time-consuming and could delay any product launch. If the commercial launch of a 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. These efforts 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 products 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;
- the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe any future products;
- the inability of reimbursement professionals to negotiate arrangements for formulary access, reimbursement and other acceptance by payors;
- the inability to price our products at a sufficient price point to ensure an adequate and attractive level of profitability;
- restricted or closed distribution channels that make it difficult to distribute our products to segments of the patient population;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

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

We expect to rely on contract manufacturing organizations to manufacture our product candidates. If we are unable to enter into such arrangements as expected or if such organizations do not meet our supply requirements, development and/or commercialization of our product candidates may be delayed.

We expect to rely on third parties to manufacture clinical supplies of our product candidates and commercial supplies of our products, if and when approved for marketing by applicable regulatory authorities, as well as for packaging, sterilization, storage, distribution and other production logistics. If we are unable to enter into such arrangements on the terms or timeline we expect, development and/or commercialization of our product candidates may be delayed. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or manufacture our product candidates in accordance with regulatory requirements, if there are disagreements between us and such parties or if such parties are unable to expand capacities to support commercialization of any of our product candidates for which we obtain marketing approval, we may not be able to fulfill, or may be delayed in producing sufficient product candidates to meet, our supply requirements. These facilities may also be affected by pandemics, including the ongoing COVID-19 pandemic, natural disasters, such as floods or fire, or such facilities could face manufacturing issues, such as contamination or regulatory concerns following a regulatory inspection of such facility. In such instances, we may need to locate an appropriate replacement third-party facility and establish a contractual relationship, which may not be readily available or on acceptable terms, which would cause additional delay and increased expense, including as a result of additional required FDA approvals, and may have a material adverse effect on our business.

Our third-party manufacturers will be subject to inspection and approval by the FDA before we can commence the manufacture and sale of any of our product candidates, and thereafter subject to FDA inspection from time to time. Failure by our third-party manufacturers to pass such inspections and otherwise satisfactorily complete the FDA approval regimen with respect to our product candidates may result in regulatory actions such as the issuance of FDA Form 483 notices of observations, warning letters or injunctions or the loss of operating licenses.

We or our third-party manufacturers may also encounter shortages in the raw materials or API 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 API, including shortages caused by the purchase of such raw materials or API by our competitors or others. The failure of us or our third-party manufacturers to obtain the raw materials or API necessary to manufacture sufficient quantities of our product candidates may have a material adverse effect on our business.

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

The regulations that govern marketing approvals, pricing, coverage and reimbursement for new drug products vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. 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 in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenues 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 our product candidates obtain marketing approval.

Our ability to commercialize any product candidates successfully also will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. 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.

The availability and adequacy of coverage and reimbursement by governmental healthcare programs such as Medicare and Medicaid, private health insurers and other third-party payors are essential for most patients to be able to afford our product candidates, if approved. Our ability to achieve acceptable levels of coverage and reimbursement for our product candidates, if approved, by governmental authorities, private health insurers and other organizations will have an effect on our ability to successfully commercialize, our product candidates. 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 patient out-of-pocket costs that patients find unacceptably high.

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

There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or similar regulatory authorities outside of the United States. Moreover, eligibility for coverage and reimbursement does not imply that a drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution expenses. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. 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.

There can be no assurance that our product candidates, even if they are approved for sale in the United States or in other countries, will be considered medically reasonable and necessary for a specific indication or cost-effective by third-party payors, or that coverage and an adequate level of reimbursement will be available or that third-party payors' reimbursement policies will not adversely affect our ability to sell our product candidates profitably.

Our future growth depends, in part, on our ability to penetrate foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties that, if they materialize, could harm our business.

Our future profitability will depend, in part, on our ability to commercialize our product candidates in markets outside of the United States. If we commercialize our product candidates in foreign markets, we will be subject to additional risks and uncertainties, including:

- economic weakness, including inflation, or political instability in particular economies and markets;
- the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements, many of which vary between countries;
- different medical practices and customs in foreign countries affecting acceptance in the marketplace;
- tariffs and trade barriers, as well as other governmental controls and trade restrictions;
- other trade protection measures, import or export licensing requirements or other restrictive actions by U.S. or foreign governments;
- longer accounts receivable collection times;
- longer lead times for shipping;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- workforce uncertainty in countries where labor unrest is common;

- language barriers for technical training;
- reduced protection of intellectual property rights in some foreign countries, and related prevalence of biosimilar alternatives to therapeutics;
- foreign currency exchange rate fluctuations and currency controls;
- differing foreign reimbursement landscapes;
- uncertain and potentially inadequate reimbursement of our products; and
- the interpretation of contractual provisions governed by foreign laws in the event of a contract dispute.

If risks related to any of these uncertainties materializes, it could have a material adverse effect on our business.

Clinical trial and product liability lawsuits against us could divert our resources and could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop.

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

- decreased demand for any product candidates or products that we may develop;
- termination of clinical trials;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend any related litigation;
- substantial monetary awards to trial participants or patients;
- loss of revenue;
- reduced resources of our management to pursue our business strategy; and
- the inability to commercialize any products that we may develop.

We currently hold $5.0 million in clinical trial liability insurance coverage in the aggregate, with a per incident limit of $5.0 million, which may not be adequate to cover all liabilities that we may incur. We may need to increase our insurance coverage as we expand our clinical trials or if we commence commercialization of our product candidates. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. 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.

Risks Related to Regulatory Approval and Other Legal Compliance Matters

Even if we complete the necessary preclinical studies and clinical trials, the marketing approval process is expensive, time-consuming and uncertain and may prevent us from obtaining approvals for the commercialization of any product candidates we develop. If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals, we will not be able to commercialize, or will be delayed in commercializing, product candidates we develop, and our ability to generate revenue will be materially impaired.

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 subject to comprehensive regulation by the FDA and other regulatory authorities in the United States and by comparable authorities in other countries. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate in a given jurisdiction. 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 CROs to assist us in this process. Securing regulatory approval requires the submission of extensive

preclinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the biologic product candidate's safety, purity and potency. 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. Any product candidates we develop may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use.

The process of obtaining marketing approvals, both in the United States and abroad, is expensive, may take many years if additional clinical trials are required, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. 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. The FDA and comparable authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of a product candidate. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

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

Failure to obtain marketing approval in foreign jurisdictions would prevent any product candidates we develop from being marketed in such jurisdictions, which, in turn, would materially impair our ability to generate revenue.

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

Additionally, on June 23, 2016, the electorate in the United Kingdom voted in favor of leaving the European Union, commonly referred to as Brexit. Following protracted negotiations, the United Kingdom left the European Union on January 31, 2020. Under the withdrawal agreement, there is a transitional period until December 31, 2020 (extendable up to two years). Discussions between the United Kingdom and the European Union have so far mainly focused on finalizing withdrawal issues and transition agreements but have been extremely difficult to date. To date, only an outline of a trade agreement has been reached. Much remains open but the Prime Minister has indicated that the United Kingdom will not seek to extend the transitional period beyond the end of 2020. If no trade agreement has been reached before the end of the transitional period, there may be significant market and economic disruption. The Prime Minister has also indicated that the UK will not accept high regulatory alignment with the EU.

Since the regulatory framework for pharmaceutical products in the United Kingdom covering quality, safety, and efficacy of pharmaceutical products, clinical trials, marketing authorization, commercial sales, and distribution of pharmaceutical products is derived from European Union directives and regulations, Brexit could materially impact the future regulatory regime that applies to products and the approval of product candidates in the United Kingdom. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, may force us to restrict or delay efforts to seek regulatory approval in the United Kingdom for our product candidates, which could significantly and materially harm our business.

Fast track designation by the FDA may not actually lead to a faster development or regulatory review or approval process and does not assure FDA approval of our product candidates.

If a product candidate is intended for the treatment of a serious or life-threatening condition and the product candidate demonstrates the potential to address unmet medical need for this condition, the sponsor may apply for FDA fast track designation. However, a fast track designation does not ensure that the product candidate will receive marketing approval or that approval will be granted within any particular timeframe. As a result, while we may seek and receive fast track designation for our product candidates, we may not experience a faster development process, review or approval compared to conventional FDA procedures. In addition, the FDA may withdraw fast track designation if it believes that the designation is no longer supported by data from our clinical development program. Fast track designation alone does not guarantee qualification for the FDA's priority review procedures.

Priority review designation by the FDA may not lead to a faster regulatory review or approval process and, in any event, does not assure FDA approval of our product candidates.

If the FDA determines that a product candidate offers major advances in treatment or provides a treatment where no adequate therapy exists, the FDA may designate the product candidate for priority review. A priority review designation means that the goal for the FDA to review an application is six months, rather than the standard review period of ten months. We may request priority review for certain of our product candidates. The FDA has broad discretion with respect to whether or not to grant priority review status to a product candidate, so even if we believe a particular product candidate is eligible for such designation or status, the FDA may decide not to grant it. Moreover, a priority review designation does not necessarily mean a faster regulatory review process or necessarily confer any advantage with respect to approval compared to conventional FDA procedures. Receiving priority review from the FDA does not guarantee approval within the six-month review cycle or thereafter.

A breakthrough therapy designation by the FDA for our product candidates may not lead to a faster development or regulatory review or approval process, and it does not increase the likelihood that our product candidates will receive marketing approval.

A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drugs and biologics that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs designated as breakthrough therapies by the FDA are also eligible for accelerated approval.

Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. Even if we receive breakthrough therapy designation, the receipt of such designation for a product candidate may not result in a faster development process, review or approval compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as breakthrough therapies, the FDA may later decide that the products no longer meet the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

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

Any product candidate for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data, labeling, advertising, and promotional activities for such product, will be subject to continual requirements of and review by the FDA and other regulatory authorities. These requirements include 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 marketing 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, or any collaborators we may have, receive marketing approval for one or more product candidates we develop, we, and such collaborators, and our and their 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 and such collaborators are not able to comply with post-approval regulatory requirements, we and such collaborators could have the marketing approvals for our products withdrawn by regulatory authorities and our, or such collaborators', 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.

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

The FDA and other regulatory agencies closely regulate the post-approval marketing and promotion of medicines to ensure that they are marketed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA and other regulatory agencies impose stringent restrictions on manufacturers' communications regarding off-label use, and if we market our products, if approved, in a manner inconsistent with their approved labeling, we may be subject to enforcement action for off-label marketing by the FDA and other federal and state enforcement agencies, including the Department of Justice. Violation of the Federal Food, Product, and Cosmetic Act and other statutes, including the False Claims Act, relating to the promotion and advertising of prescription products may also lead to investigations or allegations of violations of federal and state health care fraud and abuse laws and state consumer protection laws.

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

- restrictions on such medicines, manufacturers, or manufacturing processes;
- restrictions on the labeling or marketing of a medicine;
- restrictions on the distribution or use of a medicine;
- requirements to conduct post-marketing clinical trials;
- receipt of warning or untitled letters;
- withdrawal of the medicines from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of medicines;
- fines, restitution, or disgorgement of profits or revenue;
- suspension or withdrawal of marketing approvals;
- suspension of any ongoing clinical trials;
- refusal to permit the import or export of our medicines;
- product seizure; and
- injunctions or the imposition of civil or criminal penalties.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize any product candidates we develop and adversely affect our business, financial condition, results of operations, and prospects.

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

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

- the federal healthcare Anti-Kickback Statute, or AKS, prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving, or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order, or recommendation of, any good or service, for which payment may be made under federal and state healthcare programs such as Medicare and Medicaid. In addition, the government may assert that a claim including items or services resulting from a violation of AKS constitutes a false or fraudulent claim for purposes of the federal False Claims Act or federal civil money penalties statute. Violations of AKS carry potentially significant civil and criminal penalties, including imprisonment, fines, administrative civil monetary penalties, and exclusion from participation in federal healthcare programs. The AKS has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers, and formulary managers on the other. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution; but the exceptions and safe harbors are drawn narrowly and require strict compliance in order to offer protection;

- the federal civil and criminal false claims and civil monetary penalties laws, including the federal False Claims Act imposes criminal and civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment or approval from Medicare, Medicaid, or other government payors that are false or fraudulent or making a false statement to avoid, decrease, or conceal an obligation to pay money to the federal government. Manufacturers can be held liable under the False Claims Act even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. For example, manufacturers have been prosecuted for causing false claims to be submitted because of off-label promotion 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 healthcare programs for the product. When an entity is determined to have violated the federal civil False Claims Act, the government may impose civil fines and penalties for each false claim, plus treble damages, and exclude the entity from participation in Medicare, Medicaid and other federal healthcare programs;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program (including private payors) or making false or fraudulent statements relating to healthcare matters. Similar to the federal AKS, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Additionally, HIPAA, as amended by HITECH and its implementing regulations, also imposes certain requirements, including mandatory contractual terms, with respect to safeguarding the privacy, security, and transmission of individually identifiable health information without appropriate authorization by entities subject to the rule, such as health plans, health care clearinghouses, and health care providers;
- the federal transparency requirements under the federal Physician Payment Sunshine Act, which requires manufacturers of drugs, devices, biologics, and medical supplies to report to the Department of Health and Human Services information related to payments and other transfers of value to physicians (currently defined to include doctors, dentists, optometrists, podiatrists, and chiropractors) and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members and applicable group purchasing organizations. Effective January 1, 2022, these reporting obligations will extend to include transfers of value made to certain non-physician providers such as physician assistants and nurse practitioners; and
- analogous state laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, and certain state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. If our operations are found to be in violation of any of the laws described above or any other government regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from participation in government health care programs, such as Medicare and Medicaid, imprisonment and the curtailment or restructuring of our operations, any of which could adversely affect our business, financial condition, results of operations, and prospects.

The provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order, or use of medicinal products is prohibited in the European Union. The provision of benefits or advantages to physicians is also governed by the national anti-bribery laws of European Union Member States, such as the UK Bribery Act 2010. Infringement of these laws could result in substantial fines and imprisonment.

Payments made to physicians in certain European Union Member States must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician's employer, his or her competent professional organization, and/or the regulatory authorities of the individual European Union Member States. These requirements are provided in the national laws, industry codes, or professional codes of conduct applicable in the European Union Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines, or imprisonment.

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

Current and future legislation may increase the difficulty and cost for us and any collaborators to obtain marketing approval and commercialize our product candidates and affect the prices we, or they, may obtain.

In the U.S. and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could, among other things, prevent or delay marketing approval of our drug candidates, restrict or regulate post-approval activities and affect our ability, or the ability of any collaborators, to profitably sell or commercialize any product candidate for which we, or they, obtain marketing approval. We expect that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we, or any collaborators, may receive for any approved products.

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the ACA, was passed, which substantially changed the way healthcare is financed by both government and private insurers, and significantly impacts the U.S. pharmaceutical industry. Among the provisions of the ACA of potential importance to our business, including, without limitation, our ability to commercialize our products and the prices we may obtain for any of our product candidates that are approved for sale, are the following:

- an annual, non-deductible fee on any entity that manufactures or imports specified branded prescription products and biologic agents;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- expansion of healthcare fraud and abuse laws, including the civil False Claims Act and the federal Anti-Kickback Statute, new government investigative powers and enhanced penalties for noncompliance;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer point-of-sale discounts off negotiated prices to eligible beneficiaries during their coverage gap period, as a condition for a manufacturer’s outpatient products to be covered under Medicare Part D;
- extension of manufacturers’ Medicaid rebate liability;
- expansion of eligibility criteria for Medicaid programs;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- new requirements to report certain financial arrangements with physicians and teaching hospitals;
- a new requirement to annually report drug samples that manufacturers and distributors provide to physicians; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

Since its enactment, some of the provisions of the ACA have yet to be fully implemented, while certain provisions have been subject to judicial, congressional, and executive challenges. As a result, there have been delays in the implementation of, and action taken to repeal or replace, certain aspects of the ACA. The U.S. Supreme Court has upheld certain key aspects of the legislation, including a tax-based shared responsibility payment imposed on certain individuals who fail to maintain qualifying health coverage for all or part of a year, which is commonly known as the requirement that all individuals maintain health insurance coverage or pay a penalty, referred to as the “individual mandate.” However, as a result of tax reform legislation passed in December 2017, the individual mandate’s penalty was decreased to $0, effective January 1, 2019. On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas ruled that the individual mandate is a critical and inseverable feature of the ACA, and therefore, because it was decreased to $0 as part of the Tax Act, the remaining provisions of the ACA are invalid as well. On December 18, 2019, the Fifth Circuit U.S. Court of Appeals held the individual mandate is unconstitutional but remanded the case to the lower court to reconsider its earlier invalidation of the full ACA. In March 2020, the U.S. Supreme Court agreed to hear this case, with arguments likely to take place later this year. Pending review, the ACA remains in effect, but it is unclear at this time what effect the latest ruling will have on the status of the ACA. According to the Congressional Budget Office, the repeal of the individual mandate will cause 13 million fewer Americans to be insured in 2027 and premiums in insurance markets may rise.

Since January 2017, the Trump administration has also taken executive actions to undermine or delay implementation of the ACA. One Executive Order directs federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. A second Executive Order terminates the cost-sharing subsidies that reimburse insurers under the ACA. Several state Attorneys General filed suit to stop the administration from terminating the subsidies, but their request for a restraining order was denied by a federal judge in California on October 25, 2017. On June 14, 2018, the U.S. Court of Appeals for the Federal Circuit ruled that the federal government was not required to pay more than $12 billion in ACA risk corridor payments to third-party payors who argued such payments were owed to them. This decision was appealed to the U.S. Supreme Court, which on April 27, 2020, reversed the U.S. Court of Appeals for the Federal Circuit's decision and remanded the case to the U.S. Court of Federal Claims, concluding the government has an obligation to pay these risk corridor payments under the relevant formula. It is not clear what effect this result will have on our business, but we will continue to monitor any developments. In addition, CMS has recently proposed regulations that would give states greater flexibility in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces. In December 2018, CMS published a final rule permitting further collections and payments to and from certain ACA qualified health plans and health insurance issuers under the ACA risk adjustment program in response to the outcome of the federal district court litigation regarding the method CMS uses to determine this risk adjustment. Since then, the ACA risk adjustment program payment parameters have been updated annually. In addition, CMS published a final rule that would give states greater flexibility, starting in 2020, in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces.

Other legislative changes have been proposed and adopted since the ACA was enacted. These changes include the Budget Control Act of 2011, which, among other things, led to aggregate reductions to Medicare payments to providers of up to 2% per fiscal year that started in April 2013 and, due to subsequent legislative amendments, will stay in effect through 2030 unless additional Congressional action is taken. Pursuant to the CARES Act, these reductions will be suspended from May 1, 2020 through December 31, 2020 due to the COVID-19 pandemic. As the legislation currently stands, the reductions will go back into effect January 2021 and will remain in effect through 2030. In January 2013, President Obama signed into law, and the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several types of providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These laws may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used. Further, there have been several recent U.S. congressional inquiries and proposed state and federal legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, reduce the costs of products under Medicare and reform government program reimbursement methodologies for products.

Further, there have been several recent U.S. congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to pricing, review the relationship between pricing and manufacturer patient programs, reduce the costs of products under Medicare and reform government program reimbursement methodologies for products. At the federal level, the Trump administration's budget proposal contains further price control measures that could be enacted during the budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain products under Medicare Part B, to allow some states to negotiate product prices under Medicaid, and to eliminate cost sharing for generic products for low-income patients. While any proposed measures will require authorization through additional legislation to become effective, Congress and the Trump administration have each indicated that they will continue to seek new legislative and/or administrative measures to control product costs.

Specifically, there have been several recent U.S. congressional inquiries and proposed federal and proposed and enacted state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, reduce the costs of products under Medicare and reform government program reimbursement methodologies for products. At the federal level, Congress and the current administration have each indicated that it will continue to seek new legislative and/or administrative measures to control product costs. The Trump administration released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. 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. While any proposed measures will require authorization through additional legislation to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. The Department of Health and Human Services, or HHS, has solicited feedback on some of these measures and, at the same time, is implementing others under its existing authority. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage Plans the option of using step therapy for Part B drugs beginning January 1, 2020. This final rule codified CMS's policy change that was effective January 1, 2019.

In addition, on December 23, 2019, the Trump Administration published a proposed rulemaking that, if finalized, would allow states or certain other non-federal government entities to submit importation program proposals to the FDA for review and approval. Applicants would be required to demonstrate that their importation plans pose no additional risk to public health and safety and will result in significant cost savings for consumers. At the same time, the FDA issued draft guidance that would allow manufacturers to import their own FDA-approved products that are authorized for sale in other countries (multi-market approved products).

In addition, it is possible that additional governmental action is taken to address the COVID-19 pandemic. For example, on April 18, 2020, CMS announced that qualified health plan issuers under the ACA may suspend activities related to the collection and reporting of quality data that would have otherwise been reported between May and June 2020 given the challenges healthcare providers are facing responding to the COVID-19 virus.

At the state level, individual states are increasingly aggressive 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, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional health care authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription product and other health care programs. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing.

We expect that these healthcare reforms, as well as other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price that we receive for any approved product and/or the level of reimbursement physicians receive for administering any approved product we might bring to market. Reductions in reimbursement levels may negatively impact the prices we receive or the frequency with which our products are prescribed or administered. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors.

Compliance with global privacy and data security requirements could result in additional costs and liabilities to us or inhibit our ability to collect and process data globally, and the failure to comply with such requirements could subject us to significant fines and penalties, which may have a material adverse effect on our business, financial condition or results of operations.

The regulatory framework for the collection, use, safeguarding, sharing, transfer and other processing of information worldwide is rapidly evolving and is likely to remain uncertain for the foreseeable future. Globally, virtually every jurisdiction in which we operate has established its own data security and privacy frameworks with which we must comply. For example, the collection, use, disclosure, transfer, or other processing of personal data regarding individuals in the European Union, including personal health data, is subject to the EU General Data Protection Regulation, or the GDPR, which took effect across all member states of the European Economic Area, or EEA, in May 2018. The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating to processing health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches, and taking certain measures when engaging third-party processors. The GDPR increases our obligations with respect to clinical trials conducted in the EEA by expanding the definition of personal data to include coded data and requiring changes to informed consent practices and more detailed notices for clinical trial subjects and investigators. In addition, the GDPR also imposes strict rules on the transfer of personal data to countries outside the European Union, including the United States and, as a result, increases the scrutiny that clinical trial sites located in the EEA should apply to transfers of personal data from such sites to countries that are considered to lack an adequate level of data protection, such as the United States. The GDPR also permits data protection authorities to require destruction of improperly gathered or used personal information and/or impose substantial fines for violations of the GDPR, which can be up to four percent of global revenues or 20 million Euros, whichever is greater, and it also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. In addition, the GDPR provides that European Union member states may make their own further laws and regulations limiting the processing of personal data, including genetic, biometric or health data.

Similar actions are either in place or under way in the United States. There are a broad variety of data protection laws that are applicable to our activities, and a wide range of enforcement agencies at both the state and federal levels that can review companies for privacy and data security concerns based on general consumer protection laws. The Federal Trade Commission and state Attorneys General all are aggressive in reviewing privacy and data security protections for consumers. New laws also are being considered at both the state and federal levels. For example, the California Consumer Privacy Act—which went into effect on January 1, 2020—is creating similar risks and obligations as those created by GDPR, though the Act does exempt certain information collected as part of a clinical trial subject to the Federal Policy for the Protection of Human Subjects (the Common Rule). In March 2020, the California State Attorney General proposed varying versions of companion draft regulations which are not yet finalized. Despite the delay in

adopting regulations, the California State Attorney General will commence enforcement actions against violators beginning July 1, 2020. Many other states are considering similar legislation. A broad range of legislative measures also have been introduced at the federal level. Accordingly, failure to comply with federal and state laws (both those currently in effect and future legislation) regarding privacy and security of personal information could expose us to fines and penalties under such laws. There also is the threat of consumer class actions related to these laws and the overall protection of personal data. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could harm our reputation and our business.

Given the breadth and depth of changes in data protection obligations, preparing for and complying with these requirements is rigorous and time intensive and requires significant resources and a review of our technologies, systems and practices, as well as those of any third-party collaborators, service providers, contractors or consultants that process or transfer personal data collected in the European Union. The GDPR and other changes in laws or regulations associated with the enhanced protection of certain types of sensitive data, such as healthcare data or other personal information from our clinical trials, could require us to change our business practices and put in place additional compliance mechanisms, may interrupt or delay our development, regulatory and commercialization activities and increase our cost of doing business, and could lead to government enforcement actions, private litigation and significant fines and penalties against us and could have a material adverse effect on our business, financial condition or results of operations.

Our employees, principal investigators, consultants and 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, vendors, consultants and partners, and, if we commence clinical trials, our principal investigators and CROs. Misconduct by these parties could include intentional failures to comply with FDA regulations or the regulations applicable in the European Union and other jurisdictions, provide accurate information to the FDA, the European Commission, and other regulatory authorities, comply with healthcare fraud and abuse laws and regulations in the United States and abroad, report financial information or data accurately, or disclose unauthorized activities to us. In particular, 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 restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs, and other business arrangements. Such misconduct also could involve the improper use of information obtained in the course of clinical trials or interactions with the FDA or other regulatory authorities, which could result in regulatory sanctions and cause serious harm to our reputation. We have adopted a code of conduct applicable to all of our employees, 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 government investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, financial condition, results of operations and prospects, including the imposition of significant fines or other sanctions.

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

We are subject to numerous laws and regulations in each jurisdiction outside the United States in which we operate. The creation, implementation and maintenance of international business practices compliance programs is costly and such programs are difficult to enforce, particularly where reliance on third parties is required.

The Foreign Corrupt Practices Act, or FCPA, prohibits any U.S. individual or business from paying, offering, authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations. The anti-bribery provisions of the FCPA are enforced primarily by the Department of Justice. The SEC is involved with enforcement of the books and records provisions of the FCPA.

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

Various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. Our expansion outside of the United States has required, and will continue to require, us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing, or selling certain products and product candidates outside of the United States, which could limit our growth potential and increase our development costs. The failure to comply with laws governing international business practices may result in substantial penalties, including suspension or debarment from government contracting. Violation of the FCPA can result in significant civil and criminal penalties. Indictment alone under the FCPA can lead to suspension of the right to do business with the U.S. government until the pending claims are resolved. Conviction of a violation of the FCPA can result in long-term disqualification as a government contractor. The termination of a government contract or relationship as a result of our failure to satisfy any of our obligations under laws governing international business practices would have a negative impact on our operations and harm our reputation and ability to procure government contracts. The SEC also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions.

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

In some countries, particularly the countries of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed, possibly materially.

If we or any third-party manufacturer we engage now or in the future we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs or liabilities that could have a material adverse effect on our business.

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

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, development or commercialization efforts. 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.

Inadequate funding for the FDA, the SEC 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 and the COVID-19 pandemic. 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. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. 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. In addition, in April 2020, the FDA stated that its New Drug Program was continuing to meet program user fee performance goals, but due to many agency staff working on COVID-19 activities, it was possible that the FDA would not be able to sustain that level of performance indefinitely.

Risks Related to Employee Matters and Managing Growth

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

We are highly dependent on the research and development, clinical, financial, operational and other business expertise of our executive officers, as well as the other principal members of our management, scientific and clinical teams. Although we have entered into employment agreements with our executive officers, each of them may terminate their employment with us at any time. We do not maintain “key person” insurance for any of our executives or other employees. Recruiting and retaining qualified scientific, clinical, manufacturing, accounting, legal and sales and marketing personnel will also be critical to our success.

The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain marketing approval of and commercialize products. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our 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. Our success as a public company also depends on implementing and maintaining internal controls and the accuracy and timeliness of our financial reporting. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

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

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

Our internal computer systems, or those of our collaborators or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our product development programs.

Our internal computer systems and those of any collaborators, contractors or consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Such systems are also vulnerable to service interruptions or to security breaches from inadvertent or intentional actions by our employees, third-party vendors and/or business partners, or from cyber-attacks by malicious third parties. Cyber-attacks are increasing in their frequency, sophistication and intensity, and have become increasingly difficult to detect. Cyber-attacks could include the deployment of harmful malware, ransomware, denial-of-service attacks, unauthorized access to or deletion of files, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information. We cannot guarantee that the measures we have taken to date, and actions we may take in the future, will be sufficient to remediate any future breaches. Cyber-attacks also could include phishing attempts or e-mail fraud to cause payments or information to be transmitted to an unintended recipient.

To the extent we experience a material system failure, accident, cyber-attack or security breach, it could result in a material disruption of our development programs and our business operations, whether due to a loss of our trade secrets or other proprietary information or other similar disruptions. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. 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, our competitive position could be harmed and the further development and commercialization of our product candidates could be delayed.

Risks Related to our Common Stock

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

As of August 31, 2020, our executive officers and directors and our stockholders who owned more than 5% of our outstanding common stock owned shares representing approximately 73.3% of our capital stock. As a result, if these stockholders were to choose to act together, they would be able to control all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these persons, if they choose to act together, would control the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets.

This concentration of ownership control may:

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

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

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

- establish a classified board of directors such that only one of three classes of directors is elected each year;
- allow the authorized number of our directors to be changed only by resolution of our board of directors;
- limit the manner in which stockholders can remove directors from our board of directors;
- establish advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to our board of directors;

- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent;
- limit who may call stockholder meetings;
- authorize our board of directors to issue preferred stock without stockholder approval, which could be used to institute a "poison pill" that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors; and
- require the approval of the holders of at least 75% of the votes that all our stockholders would be entitled to cast to amend or repeal specified provisions of our certificate of incorporation or bylaws.

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

An active trading market for our common stock may not develop.

Our common stock began trading on the Nasdaq Global Select Market on July 17, 2020. Given the limited trading history of our common stock, there is a risk that an active trading market for our shares may not continue to develop or be sustained. If an active market for our common stock does not continue to develop or is not sustained, it may be difficult for our stockholders to sell their shares without depressing the market price for the shares, or at all.

If securities analysts do not publish or cease publishing research or reports or publish misleading, inaccurate or unfavorable research about our business or if they publish negative evaluations of our stock, the price and trading volume of our stock could decline.

The trading market for our common stock relies, in part, on the research and reports that industry or financial analysts publish about us or our business. There can be no assurance that existing analysts will continue to cover us or that new analysts will begin to cover us. There is also no assurance that any covering analyst will provide favorable coverage. Although we have obtained analyst coverage, if one or more of the analysts covering our business downgrade their evaluations of our stock or publish inaccurate or unfavorable research about our business, or provides more favorable relative recommendations about our competitors, the price of our stock could decline. If one or more of these analysts cease to cover our stock, we could lose visibility in the market for our stock, which in turn could cause our stock price and trading volume to decline.

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

Our stock price is likely to be volatile. The stock market in general and the market for smaller biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, our stockholders may not be able to sell our common stock at or above the price they paid for it. The market price for our common stock may be influenced by many factors, including:

- results of or developments in preclinical studies and clinical trials of our product candidates or those of our competitors or potential collaborators;
- our success in commercializing our product candidates, if and when approved;
- developments with respect to competitive products or technologies;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other intellectual property or proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to any of our product candidates or clinical development programs;
- the results of our efforts to discover, develop, acquire or in-license products, product candidates, technologies, the costs of commercializing any such products and the costs of development of any such product candidates or technologies;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;

- variations in our financial results or the financial results of companies that are perceived to be similar to us;
- sales of common stock by us, our executive officers, directors or principal stockholders, or others;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions, such as the impact of the COVID-19 pandemic on our industry and market conditions; and
- the other factors described in this “Risk Factors” section.

In the past, following periods of volatility in the market price of a company’s securities, securities class-action litigation has often been instituted against that company. Any lawsuit to which we are a party, with or without merit, may result in an unfavorable judgment. We also may decide to settle lawsuits on unfavorable terms. Any such negative outcome could result in payments of substantial damages or fines, damage to our reputation or adverse changes to our offerings or business practices. Such litigation may also cause us to incur other substantial costs to defend such claims and divert management’s attention and resources. Furthermore, negative public announcements of the results of hearings, motions or other interim proceedings or developments could have a negative effect on the market price of our common stock.

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

Sales of a substantial number of shares of our common stock in the public market, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. As of August 31, 2020 we had 29,519,902 shares of common stock outstanding. This includes the 7,500,000 shares that were sold in our IPO, which may be resold in the public market immediately without restriction, unless purchased by our affiliates or existing stockholders. The remaining shares are currently restricted as a result of securities laws or lock-up agreements but will become eligible to be sold at various times after the IPO. Moreover, beginning 180 days after the completion of our IPO, holders of an aggregate of 19,724,868 shares of our common stock will have rights, subject to specified conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. We also registered all shares of common stock that we may issue under our equity compensation plans. These shares can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates and the lock-up agreements entered into in connection with our IPO.

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

We are an “emerging growth company,” or EGC, as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. We may remain an EGC until December 31, 2025, although if the market value of our common stock that is held by non-affiliates exceeds $700 million as of any June 30 before that time or if we have annual gross revenues of $1.07 billion or more in any fiscal year, we would cease to be an EGC as of December 31 of the applicable year. We also would cease to be an EGC if we issue more than $1 billion of non-convertible debt over a three-year period. For so long as we remain an EGC, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not EGCs. These exemptions include:

- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor’s report providing additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We may choose to take advantage of some, but not all, of the available exemptions. We have taken advantage of reduced reporting obligations by providing only two years of audited financial statements.

We cannot predict whether investors will find our common stock less attractive if we rely on certain or all of these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

In addition, the JOBS Act permits an EGC to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies until those standards would otherwise apply to private companies. We have elected not to "opt out" of such extended transition period, which means that when a standard is issued or revised and it has different application dates for public or private companies, we will adopt the new or revised standard at the time private companies adopt the new or revised standard and will do so until such time that we either (i) irrevocably elect to "opt out" of such extended transition period or (ii) no longer qualify as an EGC.

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

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

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

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, we will be required to furnish a report by our management on our internal control over financial reporting beginning with our second filing of an Annual Report on Form 10-K with the SEC. However, while we remain an EGC, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, 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. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by Section 404. If we identify one or more material weaknesses in our internal control over financial reporting, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

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

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

Our certificate of incorporation designates the state courts in the State of Delaware as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders. Our certificate of incorporation further provides that the federal district courts of the United States of the America are the sole and exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act. These choice of forum provisions could discourage lawsuits against the company and our directors, officers and employees.

Our certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, if the Court of Chancery of the State of Delaware does not have jurisdiction, the federal district court for the District of Delaware) will be the sole and exclusive forum for (1) any derivative action or proceeding brought on our behalf, (2) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers, employees or stockholders to our company or our stockholders, (3) any action asserting a claim arising pursuant to any provision of the DGCL or as to which the DGCL confers jurisdiction on the Court of Chancery of the State of Delaware or (4) any action asserting a claim arising pursuant to any provision of our certificate of incorporation or bylaws (in each case, as they may be amended from time to time) or governed by the internal affairs doctrine. This exclusive forum provision will not apply to actions arising under the Securities Act of 1933, as amended, or the Securities Act, or the Securities Exchange Act of 1934, as amended.

We believe this provision benefits us by providing increased consistency in the application of Delaware law by chancellors particularly experienced in resolving corporate disputes, efficient administration of cases on a more expedited schedule relative to other forums and protection against the burdens of multi-forum litigation. However, this exclusive forum provision may limit the ability of our stockholders to bring a claim in a judicial forum that such stockholders find favorable for disputes with us or our directors, officers or employees, which may discourage such lawsuits against us and our directors, officers and employees. The enforceability of a similar choice of forum provision in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that, in connection with any applicable action brought against us, a court could find the choice of forum provision contained in our certificate of incorporation to be inapplicable or unenforceable in such action. If a court were to find the choice of forum provision contained in our certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could materially adversely affect our business, financial condition and operating results.

Our certificate of incorporation further provides that, unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States of America shall, to the fullest extent permitted by law, be the sole and exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act. This exclusive forum provision may limit the ability of our stockholders to bring a claim arising under the Securities Act in a judicial forum that such stockholders find favorable for disputes with us or our directors, officers or employees, which may discourage such lawsuits against us and our directors, officers and employees.

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

Unregistered sales of equity securities

(a) Issuances of Preferred Shares by Pandion Therapeutics Holdco LLC ("Pandion LLC") and Preferred Stock by Pandion Therapeutics, Inc. ("Pandion Inc.)

On February 28, 2020, we issued 15,693,109 Series A preferred shares of Pandion LLC to five investors at a price per share of $1.147, for an aggregate purchase price of $17,999,996.04.

On February 28, 2020, we issued 948,225 Series A prime preferred shares of Pandion LLC to one investor upon conversion of an outstanding promissory note.

On March 23, 2020, we issued 17,951,873 Series B preferred shares of Pandion LLC to 22 investors at a price per share of $2.0878 in cash, for an aggregate purchase price of $37,479,920.55.

On March 25, 2020, we issued 1,207,049 Series B preferred shares of Pandion LLC to one investor at a price per share of $2.0878 in cash, for an aggregate purchase price of $2,520,076.91.

On June 24, 2020, we issued 20,116,868 Series B preferred shares of Pandion LLC to 24 investors at a price per share of $2.0878 in cash, for an aggregate purchase price of $41,999,997.01.

No underwriters were involved in the foregoing issuances of securities. The securities described in this this paragraph (a) of Item 2 were issued to investors in reliance upon the exemption from the registration requirements of the Securities Act, as set forth in Section 4(a)(2) under the Securities Act and, in certain cases, Regulation D thereunder, relative to transactions by an issuer not involving any public offering. All purchasers received written disclosures that the securities had not been registered under the Securities Act and that any resale must be made pursuant to a registration statement or an available exemption from such registration.

(b) Issuance of Incentive Shares

On May 21, 2020, we issued 1,330,614 incentive shares of Pandion LLC to employees, directors, advisors and consultants.

On June 1, 2020, we issued 87,230 incentive shares of Pandion LLC to an employee.

The incentive shares described in this paragraph (b) of Item 2 were issued pursuant to written compensatory plans or arrangements with our employees, directors and consultants, in reliance on the exemption provided by Rule 701 promulgated under the Securities Act, or pursuant to Section 4(a)(2) under the Securities Act, relating to transactions by an issuer not involving any public offering. All recipients either received adequate information about us or had access, through employment or other relationships, to such information.

(c) Simple Agreement for Future Equity

On June 24, 2020, we issued rights to one investor to receive shares of our capital stock for an aggregate purchase price of $6,000,000 pursuant to a simple agreement for future equity.

No underwriters were involved in the foregoing issuance of securities. The securities described in this section (c) of Item 15 were issued to one investor in reliance upon the exemption from the registration requirements of the Securities Act, as set forth in Section 4(a)(2) under the Securities Act relative to transactions by an issuer not involving any public offering. The investor received written disclosures that the securities had not been registered under the Securities Act and that any resale must be made pursuant to a registration statement or an available exemption from such registration.

Use of proceeds from registered securities

On July 21, 2020, after the end of the period covered by this Quarterly Report on Form 10-Q, we completed our initial public offering, or IPO, in which we issued and sold 8,494,166 shares of common stock, $0.001 par value per share, which included an additional 994,166 shares of common stock sold to the underwriters on August 11, 2020 pursuant to the partial exercise by the underwriters of their option to purchase additional shares of common stock at a price to the public of $18.00 per share. The offer and sale of the shares in the IPO was registered under the Securities Act pursuant to registration statements on Form S-1 (File No. 333-239500), which was filed with the SEC on June 26, 2020 and subsequently amended and declared effective on July 16, 2020, and Form S-1 (File No. 333-239894), which was filed pursuant to Rule 462(b) of the Securities Act and declared effective with the SEC on July 16, 2020. The underwriters of the offering were Goldman Sachs & Co. LLC, Morgan Stanley & Co. LLC, SVB Leerink LLC and BMO Capital Markets Corp. The IPO commenced on July 16, 2020 and terminated without the sale of 130,834 shares registered for potential issuance upon exercise of the underwriters' option to purchase additional shares.

We raised approximately $142.2 million in net proceeds after deducting underwriting discounts and commissions of $10.7 million but before deducting other offering expenses of approximately $3.2 million payable by us. No underwriting discounts and commissions or offering expenses were paid directly or indirectly to any of our directors of officers (or their associates) or persons owning ten percent or more of any class of our equity securities or to any other affiliates.

We had not used any of the net proceeds from our IPO as of June 30, 2020 because our IPO closed on July 21, 2020. There has been no material change in the planned use of proceeds from our IPO, as described in our final prospectus filed with the SEC on July 17, 2020 pursuant to Rule 424(b) under the Securities Act.

Repurchases of equity securities by the issuer

None.

Item 6. Exhibits.

Exhibit Number	Description
3.1	Restated Certificate of Incorporation of Pandion Therapeutics, Inc. (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on July 21, 2020).
3.2	Amended and Restated Bylaws of Pandion Therapeutics, Inc. (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K, filed with the SEC on July 21, 2020).
10.1	Simple Agreement for Future Equity, dated June 24, 2020, by and between the Registrant and Versant Vantage I, L.P. (incorporated by reference to Exhibit 10.20 to the Registrant's Registration Statement on Form S-1/A, filed with the SEC on July 13, 2020).
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
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.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

* Filed herewith.

SIGNATURES

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

PANDION THERAPEUTICS, INC.

Date: August 31, 2020

By: /s/ Rahul Kakkar

Rahul Kakkar, M.D.
Chief Executive Officer, Director
(Principal Executive Officer)

Date: August 31, 2020

By: /s/ Gregg Beloff

Gregg Beloff
Interim Chief Financial Officer
(Principal Financial 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, Rahul Kakkar, certify that:

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

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

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

4. The registrant's other certifying officer(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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

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

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

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

5. The registrant's other certifying officer(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: August 31, 2020

By: /s/ Rahul Kakkar

Rahul Kakkar, M.D.
Chief 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, Gregg Beloff, certify that:

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

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

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

4. The registrant's other certifying officer(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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

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

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

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

5. The registrant's other certifying officer(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: August 31, 2020

By: /s/ Gregg Beloff

Gregg Beloff
Interim Chief Financial Officer

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Pandion Therapeutics, Inc. (the "Company") on Form 10-Q for the period ending June 30, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

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

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: August 31, 2020

By: /s/ Rahul Kakkar

Rahul Kakkar, M.D.
Chief Executive Officer

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Pandion Therapeutics, Inc. (the "Company") on Form 10-Q for the period ending June 30, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

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

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: August 31, 2020

By: /s/ Gregg Beloff

Gregg Beloff
Interim Chief Financial Officer