

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-Q**

(Mark One)

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

For the quarterly period ended June 30, 2019

or

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

For the transition period from _____ to _____

Commission File No. 001-38800

Harpoon Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

47-3458693
(I.R.S. Employer
Identification No.)

131 Oyster Point Blvd, Suite 300
South San Francisco, CA 94080
(Address of principal executive offices)

Registrant's telephone number, including area code: (650) 443-7400

4000 Shoreline Court, Suite 250
South San Francisco, CA 94080
(Former name or former address, if changed since last report)

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 \$0.0001 per share	HARP	Nasdaq Global Select Market

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See 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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input checked="" type="checkbox"/>

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

The number of outstanding shares of the Registrant's common stock, par value \$0.0001, as of July 31, 2019 was 24,564,479.

HARPOON THERAPEUTICS, INC.
QUARTERLY REPORT ON FORM 10-Q
FOR THE QUARTERLY PERIOD ENDED JUNE 30, 2019

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements that involve risks and uncertainties. All statements other than statements of historical facts contained in this Quarterly Report on Form 10-Q are forward-looking statements. In some cases, you can identify forward-looking statements by words such as “anticipate,” “believe,” “contemplate,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “seek,” “should,” “target,” “will” or “would,” or the negative of these words or other comparable terminology. These forward-looking statements include, but are not limited to, statements about:

- the timing of the initiation, progress and expected results of our preclinical studies, clinical trials and our research and development programs;
- our ability to retain the continued service of our key executives and to identify, hire and retain additional qualified professionals;
- our ability to advance product candidates into, and successfully complete, preclinical studies and clinical trials;
- the timing or likelihood of regulatory filings and approvals;
- the commercialization of our product candidates, if approved;
- the pricing, coverage and reimbursement of our product candidates, if approved;
- the implementation of our business model, strategic plans for our business and product candidates;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our technology platforms, including TriTAC and ProTriTAC, and product candidates, including the projected terms of patent protection;
- our ability to enter into strategic arrangements and/or collaborations and the potential benefits of such arrangements;
- our estimates regarding the market opportunity for our product candidates;
- our estimates regarding expenses, capital requirements and needs for additional financing and our ability to obtain additional capital;
- our financial performance; and
- developments relating to our competitors and our industry, including competing therapies.

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

In addition, statements that “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based on information available to us as of the date of this report. While we believe that information provides a reasonable basis for these statements, that information may be limited or incomplete. Our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all relevant information.

You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance, or events and circumstances reflected in the forward-looking statements will be achieved or occur. We undertake no obligation to update publicly any forward-looking statements for any reason after the date of this report to conform these statements to new information, actual results or changes in our expectations, except as required by law.

Unless the context otherwise requires, references in this Quarterly Report on Form 10-Q to the “company,” “Harpoon,” “we,” “us” and “our” refer to Harpoon Therapeutics, Inc.

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

HARPOON THERAPEUTICS, INC.
Condensed Balance Sheets
(unaudited)
(in thousands, except share and per share data)

	June 30, 2019	December 31, 2018
Assets		
Current assets		
Cash and cash equivalents	\$ 52,094	\$ 89,493
Short-term marketable securities	81,790	—
Prepaid expenses and other current assets	3,438	730
Total current assets	137,322	90,223
Property and equipment, net	11,773	2,998
Operating lease right-of-use asset	7,454	—
Tenant improvement allowance receivable	—	5,784
Other assets	467	3,575
Total assets	<u>\$ 157,016</u>	<u>\$ 102,580</u>
Liabilities, convertible preferred stock and stockholders' equity (deficit)		
Current liabilities		
Accounts payable	4,519	4,357
Accrued liabilities	4,876	3,341
Deferred revenue, current	4,250	4,250
Operating lease liabilities, current	862	—
Total current liabilities	14,507	11,948
Deferred revenue, noncurrent	5,667	7,792
Operating lease liabilities, net of current portion	14,369	—
Other long-term liabilities	—	6,742
Total liabilities	<u>34,543</u>	<u>26,482</u>
Commitments and contingencies (Note 7)		
Convertible preferred stock, \$0.0001 par value; no shares and 82,000,000 shares authorized at June 30, 2019 and December 31, 2018, respectively; no shares and 16,618,448 shares issued and outstanding at June 30, 2019 and December 31, 2018, respectively; \$0 and \$130,178 aggregate liquidation preference at June 30, 2019 and December 31, 2018, respectively	—	129,577
Stockholders' equity (deficit)		
Common stock, \$0.0001 par value; 150,000,000 shares and 114,000,000 shares authorized at June 30, 2019 and December 31, 2018, respectively; 24,557,526 shares and 1,383,221 shares issued and outstanding at June 30, 2019 and December 31, 2018, respectively	3	1
Additional paid-in capital	210,347	9,111
Accumulated other comprehensive income	110	—
Accumulated deficit	(87,987)	(62,591)
Total stockholders' equity (deficit)	122,473	(53,479)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	<u>\$ 157,016</u>	<u>\$ 102,580</u>

The accompanying notes are an integral part of these condensed financial statements.

HARPOON THERAPEUTICS, INC.
Condensed Statements of Operations and Comprehensive Loss
(unaudited)
(in thousands, except share and per share data)

	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2019</u>	<u>2018</u>	<u>2019</u>	<u>2018</u>
Revenue				
Collaboration and license revenue	\$ 1,063	\$ 1,063	\$ 2,126	\$ 2,626
Total revenue	1,063	1,063	2,126	2,626
Operating expenses				
Research and development	9,971	6,151	19,353	11,684
General and administrative	3,734	967	9,566	1,949
Total operating expenses	13,705	7,118	28,919	13,633
Loss from operations	(12,642)	(6,055)	(26,793)	(11,007)
Interest income	840	66	1,416	139
Other expense	(15)	(5)	(19)	(7)
Net loss	(11,817)	(5,994)	(25,396)	(10,875)
Other comprehensive loss:				
Net unrealized gain on marketable securities	84	—	110	—
Comprehensive loss	\$ (11,733)	\$ (5,994)	\$ (25,286)	\$ (10,875)
Net loss per share, basic and diluted	\$ (0.49)	\$ (5.89)	\$ (1.30)	\$ (10.95)
Weighted-average common shares used in computing net loss per share, basic and diluted	<u>24,294,211</u>	<u>1,017,336</u>	<u>19,548,600</u>	<u>993,418</u>

The accompanying notes are an integral part of these condensed financial statements.

HARPOON THERAPEUTICS, INC.
Condensed Statements of Stockholders' Equity (Deficit)
(unaudited)
(in thousands, except share data)

	<u>Convertible Preferred Stock</u>		<u>Common Stock</u>		<u>Additional Paid-In Capital</u>	<u>Note Receivable from Stockholder</u>	<u>Accumulated Other Comprehensive Income</u>	<u>Accumulated Deficit</u>	<u>Total Stockholders' Equity (Deficit)</u>
	<u>Shares</u>	<u>Amount</u>	<u>Shares</u>	<u>Amount</u>					
Balances at December 31, 2018	16,618,448	129,577	1,211,419	1	9,111	—	—	(62,591)	(53,479)
Conversion of Series A, B, and C convertible preferred stock into common stock	(16,618,448)	(129,577)	16,618,448	1	129,575	—	—	—	129,576
Issuance of common stock upon exercise of warrants	—	—	563,043	—	—	—	—	—	—
Issuance of common stock upon initial public offering, net of offering costs of \$10,122	—	—	5,769,201	1	70,646	—	—	—	70,647
Issuance of common stock for exercise of stock options	—	—	18,036	—	25	—	—	—	25
Vesting of early exercised stock options	—	—	11,900	—	9	—	—	—	9
Stock-based compensation	—	—	—	—	369	—	—	—	369
Vesting of Founder's shares	—	—	16,302	—	—	—	—	—	—
Net loss	—	—	—	—	—	—	—	(13,579)	(13,579)
Other comprehensive income	—	—	—	—	—	—	26	—	26
Balances at March 31, 2019	—	—	24,208,349	3	209,735	—	26	(76,170)	133,594
Issuance of common stock for exercise of stock options	—	—	205,328	—	136	—	—	—	136
Issuance of common stock	—	—	—	—	—	—	—	—	—
Vesting of early exercised stock options	—	—	11,898	—	9	—	—	—	9
Stock-based compensation	—	—	—	—	467	—	—	—	467
Vesting of Founder's shares	—	—	5,879	—	—	—	—	—	—
Repurchase of common stock	—	—	—	—	—	—	—	—	—
Net loss	—	—	—	—	—	—	—	(11,817)	(11,817)
Other comprehensive income	—	—	—	—	—	—	84	—	84
Balances at June 30, 2019	—	—	24,431,454	3	210,347	—	110	(87,987)	122,473

	<u>Convertible Preferred Stock</u>		<u>Common Stock</u>		<u>Additional Paid-In Capital</u>	<u>Note Receivable from Stockholder</u>	<u>Accumulated Other Comprehensive Income</u>	<u>Accumulated Deficit</u>	<u>Total Stockholders' Equity (Deficit)</u>
	<u>Shares</u>	<u>Amount</u>	<u>Shares</u>	<u>Amount</u>					
Balances at December 31, 2017	6,989,973	39,841	948,294	1	8,309	(28)	—	(35,225)	(26,943)
Issuance of common stock for exercise of stock options	—	—	10,248	—	7	—	—	—	7
Issuance of common stock	—	—	—	—	—	—	—	—	—
Vesting of early exercised stock options	—	—	4,575	—	3	—	—	—	3
Stock-based compensation	—	—	—	—	147	—	—	—	147
Vesting of Founder's shares	—	—	20,980	—	—	—	—	—	—
Repurchase of common stock	—	—	—	—	—	—	—	—	—
Net loss	—	—	—	—	—	—	—	(4,881)	(4,881)
Balances at March 31, 2018	6,989,973	39,841	984,097	1	8,466	(28)	—	(40,106)	(31,667)
Issuance of common stock for exercise of stock options	—	—	10,168	—	6	—	—	—	6
Issuance of common stock	—	—	—	—	—	—	—	—	—
Vesting of early exercised stock options	—	—	28,809	—	17	—	—	—	17
Stock-based compensation	—	—	—	—	—	—	—	—	—
Vesting of Founder's shares	—	—	20,201	—	140	—	—	—	140
Repurchase of common stock	—	—	—	—	—	—	—	—	—
Net loss	—	—	—	—	—	—	—	(5,994)	(5,994)
Other comprehensive income	—	—	—	—	—	—	—	—	—
Balances at June 30, 2018	6,989,973	39,841	1,043,275	1	8,629	(28)	—	(46,100)	(37,498)

HARPOON THERAPEUTICS, INC.
Condensed Statements of Cash Flows
(unaudited)
(in thousands)

	Six months ended June 30,	
	2019	2018
Cash flows from operating activities		
Net loss	\$ (25,396)	\$ (10,875)
Adjustments to reconcile net loss to net cash used in operating activities		
Stock-based compensation expense	836	287
Depreciation and amortization	596	288
Non cash lease expense	762	—
Net amortization of discounts on marketable securities	(221)	—
Changes in operating assets and liabilities		
Prepaid expenses and other assets	(2,707)	(762)
Other assets	3,107	—
Accounts payable	(876)	(32)
Accrued liabilities	380	(369)
Deferred revenue	(2,125)	(2,125)
Operating lease liabilities	272	—
Other long-term liabilities	—	8
Net cash used in operating activities	<u>(25,372)</u>	<u>(13,580)</u>
Cash flows from investing activities		
Purchases of property and equipment	(1,393)	(315)
Purchases of marketable securities	(82,294)	—
Maturities and sales of marketable securities	835	—
Net cash used in investing activities	<u>(82,852)</u>	<u>(315)</u>
Cash flows from financing activities		
Proceeds from initial public offering of common stock, net of commissions	70,664	—
Proceeds from issuance of common stock upon exercise of stock options, net	161	32
Net cash provided by financing activities	<u>70,825</u>	<u>32</u>
Net decrease in cash, cash equivalents, and restricted cash	(37,399)	(13,863)
Cash, cash equivalents, and restricted cash at beginning of period	89,960	29,423
Cash, cash equivalents, and restricted cash at end of period	<u>\$ 52,561</u>	<u>\$ 15,560</u>
Supplemental disclosures of non-cash investing and financing information		
Conversion of preferred stock to common stock and additional paid-in capital	\$ 129,577	\$ —
Purchases of property and equipment included in accounts payable and accrued liabilities	\$ 2,195	\$ 62
Right-of-use asset obtained in exchange for lease obligation	\$ 8,404	\$ —
Modification of operating lease	\$ (188)	\$ —
Tenant improvements provided by landlord	\$ 5,784	\$ —

The accompanying notes are an integral part of these condensed financial statements.

HARPOON THERAPEUTICS, INC.
Notes to the Condensed Financial Statements
(unaudited)

1. Organization

Description of Business

Harpoon Therapeutics, Inc. (the "Company") is a clinical-stage immunotherapy company developing a novel class of T cell engagers that harness the power of the body's immune system to treat patients suffering from cancer and other diseases. T cell engagers are engineered proteins that direct a patient's own T cells to kill target cells that express specific proteins, or antigens, carried by the target cells. Using a proprietary Tri-specific T cell Activating Construct, ("TriTAC"), platform, the Company is developing a pipeline of novel T cell engagers, or TriTACs, initially focused on the treatment of solid tumors and hematologic malignancies. The Company was incorporated in Delaware in March 2015 and is headquartered in South San Francisco, California.

Initial Public Offering

On February 7, 2019, the Company's registration statement on Form S-1 relating to its initial public offering ("IPO") was declared effective by the Securities and Exchange Commission and shares of its common stock began trading on the Nasdaq Global Select Market ("Nasdaq") on February 8, 2019. The public offering price of the shares sold in the IPO was \$14.00 per share. The IPO closed in February 2019, pursuant to which the Company sold 5,769,201 shares of common stock, for gross proceeds of approximately \$80.8 million, including the exercise in part of the underwriters' option to purchase additional shares. The Company received net proceeds from the IPO of approximately \$70.7 million, after underwriting discounts, commissions and offering costs.

Immediately prior to the completion of the IPO on February 12, 2019, all outstanding shares of redeemable convertible preferred stock, including preferred stock warrants, were converted into 17,181,491 shares of common stock and \$129.6 million was reclassified from temporary equity to additional paid-in capital on the balance sheet. Subsequent to the closing of the IPO, there were no shares of redeemable convertible preferred stock outstanding.

Liquidity

The Company has incurred significant losses and has negative cash flows from operations. As of June 30, 2019, the Company had an accumulated deficit of \$88.0 million. Management expects to continue to incur additional substantial losses in the foreseeable future as a result of the Company's research and development activities.

As of June 30, 2019, the Company had cash, cash equivalents, and marketable securities of \$133.9 million, which is available to fund future operations. The Company believes that the proceeds from the IPO, along with the Company's cash and cash equivalents balance as of June 30, 2019, provide sufficient capital resources to continue its operations for at least 12 months from the issuance date of the accompanying condensed financial statements. The Company will need to raise additional capital to support the completion of its research and development activities. The Company's activities are subject to significant risks and uncertainties, including failing to secure additional funding to continue to operationalize the Company's current technology and to advance the development of its product candidates.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying unaudited condensed financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP") for interim financial information and the instructions to Form 10-Q and Article 10 of SEC Regulation S-X for interim financial information.

The accompanying unaudited condensed financial statements and notes should be read in conjunction with the audited consolidated financial statements and notes thereto contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2018, as filed with the SEC on March 14, 2019 (the "2018 Annual Report on Form 10-K"). The condensed Balance Sheet as of December 31, 2018 was derived from the audited annual financial statements as of the period then ended. Certain information and footnote disclosures typically included in the Company's audited financial statements have been condensed or omitted. The accompanying unaudited condensed financial statements reflect all adjustments that, in the opinion of management, are necessary for a fair statement of the results of the interim periods presented. All such adjustments are of a normal recurring nature except for the impacts of adopting new accounting standards discussed below. The accompanying unaudited condensed financial results are not necessarily indicative of results expected for the full fiscal year or for any subsequent interim period.

During the three and six months ended June 30, 2019, there were no material changes to the Company's significant accounting and financial reporting policies from those reflected in the 2018 Annual Report on Form 10-K. For further information with regard to the Company's Significant Accounting Policies, please refer to Note 2, "Summary of Significant Accounting Policies," to the Company's audited financial statements included in the 2018 Annual Report on Form 10-K which have been prepared in accordance with GAAP.

Reverse Stock Split

On January 28, 2019, the Company filed an amendment to the Company's amended and restated certificate of incorporation to effect a reverse split of shares of the Company's common stock and convertible preferred stock on a 4.9175-for-one basis (the "Reverse Stock Split"). The par value and the authorized number of shares of the convertible preferred stock and common stock were not adjusted in connection with the Reverse Stock Split. All references to common stock, convertible preferred stock, warrants to purchase common stock, options to purchase common stock, early exercised options, restricted stock, share data, per share data and related information contained in the accompanying condensed financial statements have been retrospectively adjusted to reflect the effect of the Reverse Stock Split for all periods presented.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities as of the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. Significant estimates and assumptions made in the accompanying condensed financial statements include, but are not limited to, the fair value of common stock, the fair value of stock options, the research period of the collaboration agreement with AbbVie Biotechnology Ltd., operating lease liabilities, income tax uncertainties and certain accruals. The Company evaluates its estimates and assumptions on an ongoing basis using historical experience and other factors and adjusts those estimates and assumptions when facts and circumstances dictate. Actual results could differ from those estimates.

Segment Reporting

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the Company's Chief Operating Decision Maker in making decisions regarding resource allocation and assessing performance. To date, the Company has viewed its operations and manages its business as one segment operating primarily in the United States.

Cash, Cash Equivalents and Restricted Cash

The Company considers all highly liquid investments purchased with original maturities of three months or less from the purchase date to be cash equivalents. Cash equivalents consist primarily of amounts invested in money market accounts and are stated at fair value.

The Company maintained restricted cash of \$0.5 million for both periods ended as of June 30, 2019 and December 31, 2018, respectively. This amount as of June 30, 2019 and December 31, 2018 are included within "Other assets" in the accompanying balance sheets and is comprised solely of a letter of credit required pursuant to the lease for the Company's corporate headquarters entered into in August 2018 as discussed in Note 7.

The following table provides a reconciliation of cash and cash equivalents and restricted cash reported within the balance sheets that sum to the total of the same amounts shown in the statement of cash flows.

	As of			
	June 30, 2019	December 31, 2018	June 30, 2018	December 31, 2017
	(in thousands)			
Balance Sheets				
Cash and cash equivalents	\$ 52,094	\$ 89,493	\$ 15,560	\$ 29,423
Restricted cash (included in other assets)	467	467	—	—
Cash, cash equivalents and restricted cash in Statements of Cash Flows	<u>\$ 52,561</u>	<u>\$ 89,960</u>	<u>\$ 15,560</u>	<u>\$ 29,423</u>

Marketable Securities

The Company generally invests its excess cash in money market funds and investment grade short- to intermediate-term fixed income securities. Such investments are included in cash and cash equivalents, short-term marketable securities or long-term marketable securities on the balance sheets. Marketable securities with a maturity date greater than 90 days and less than one year at each balance sheet date are classified as short-term. Marketable securities with a maturity date greater than one year at each balance sheet date are classified as long-term. All of the Company's marketable securities are considered available-for-sale and are reported at fair value with unrealized gains and losses included as a component of stockholders' equity (deficit). The amortized cost of debt securities is adjusted for amortization of premiums and accretion of discounts to maturity, which is included in interest income, net on the statements of operations. Realized gains and losses and declines in value judged to be other-than-temporary, if any, on marketable securities are included in interest income, net on the statements of operations. The cost of securities sold is determined using specific identification.

The Company periodically evaluates whether declines in the fair values of its marketable securities below their book value are other-than-temporary. This evaluation consists of several qualitative and quantitative factors regarding the severity and duration of the unrealized loss, as well as the Company's ability and intent to hold the marketable security until a forecasted recovery occurs. Additionally, the Company assesses whether it has plans to sell the marketable security or it is more likely than not it will be required to sell any marketable securities before recovery of its amortized cost basis. Factors considered include quoted market prices, recent financial results and operating trends, implied values from any recent transactions or offers of investee securities, credit quality of debt instrument issuers, other publicly available information that may affect the value of the marketable security, duration and severity of the decline in value, and the Company's strategy and intentions for holding the marketable security.

Concentration of Credit Risk

Cash, cash equivalents and marketable securities consist of financial instruments that potentially subject the Company to a concentration of credit risk, to the extent of the amounts recorded on the balance sheets. The Company minimizes the amount of credit exposure by investing cash that is not required for immediate operating needs in money market funds and marketable securities.

Leases

The Company evaluates arrangements at inception to determine if an arrangement is or contains a lease. Operating lease assets represent the Company's right to use an underlying asset for the lease term and operating lease liabilities represent the Company's obligation to make lease payments arising from the lease. Operating lease assets and liabilities are recognized at the commencement date of the lease based upon the present value of lease payments over the lease term. When determining the lease term, the Company includes options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. The Company uses an incremental borrowing rate that the Company would expect to incur for a fully collateralized loan over a similar term under similar economic conditions to determine the present value of the lease payments.

The lease payments used to determine the Company's operating lease assets may include lease incentives and stated rent increases and are recognized in the Company's operating lease assets in the condensed balance sheets. Operating lease liabilities are accreted over the term of the lease using the incremental borrowing rate and the associated expense is recorded to operating expenses in the condensed statement of operations and comprehensive loss. Operating lease assets are amortized to rent expense over the lease term and included in operating expenses in the condensed statement of operations and comprehensive loss. Variable lease payments are recognized as the associated obligation is incurred.

Fair Value Measurement

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability, or an exit price, in the principal or most advantageous market for that asset or liability in an orderly transaction between market participants on the measurement date, and established a fair value hierarchy that requires an entity to maximize the use of observable inputs, where available, and minimize the use of unobservable inputs when measuring fair value.

The Company measures fair value based on a three-level hierarchy of inputs, of which the first two are considered observable and the last unobservable. Unobservable inputs reflect the Company's own assumptions about current market conditions. The three-level hierarchy of inputs is as follows:

- Level 1—Observable inputs such as unadjusted, quoted prices in active markets for identical assets or liabilities at the measurement date;
- Level 2—Inputs (other than quoted prices included in Level 1) are either directly or indirectly observable for the asset or liability. These include quoted prices for similar assets or liabilities in active markets and quoted prices for identical or similar assets or liabilities in markets that are not active; and
- Level 3— Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

To the extent that the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized in Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

The carrying amounts reflected in the accompanying balance sheets for cash and cash equivalents, short-term marketable securities, prepaid expenses, other current assets, accounts payable, accrued expenses and other current liabilities approximate their fair values due to their short-term nature.

Property and Equipment, Net

Property and equipment are stated at cost less accumulated depreciation and amortization. Depreciation is computed on a straight-line basis over the estimated useful lives of the related assets, generally three to five years. Leasehold improvements are amortized using the straight-line method over the shorter of the assets' estimated useful lives or the remaining term of the lease. Depreciation and amortization begin at the time the asset is placed in service. Maintenance and repairs are charged to operations as incurred. Upon sale or retirement of assets, the cost and related accumulated depreciation are removed from the balance sheet and the resulting gain or loss is reflected in operations.

Impairment of Long-Lived Assets

The Company evaluates its long-lived assets, including property and equipment, for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets or group of assets may not be fully recoverable. If indicators of impairment exist and the undiscounted future cash flows that the assets are expected to generate are less than the carrying amount of the assets, the Company reduces the carrying amount of the assets through an impairment charge to their estimated fair values based on a discounted cash flow approach or, when available and appropriate, to comparable market values. There were no impairments of long-lived assets for any of the periods presented.

Revenue Recognition

Effective January 1, 2017, the Company early adopted Accounting Standards Codification ("ASC") Topic 606, *Revenue from Contracts with Customers* ("Topic 606") on a full retrospective basis. This standard applies to all contracts with customers. In accordance with Topic 606, the Company recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the Company expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that the Company determines are within the scope of Topic 606, the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the Company satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that it will collect the consideration it is entitled to in exchange for the goods and services it transfers to the customer. At contract inception, the Company assesses the goods or services promised within each contract that falls under the scope of Topic 606, determines those that are performance obligations and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

The Company enters into corporate collaborations under which it may obtain upfront license fees, research and development funding, and development, regulatory and commercial milestone payments and royalty payments. The Company's performance obligations under these arrangements may include licenses of intellectual property, distribution rights, research and development services, delivery of manufactured product and/or participation on joint steering committees.

Licenses of intellectual property: If the license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenue from upfront license fees allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license. For licenses that are bundled with other promises, the Company utilizes judgement to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring proportional performance for purposes of recognizing revenue from non-refundable, up-front fees. The Company evaluates the measure of proportional performance each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

Milestone payments: At the inception of each arrangement that includes development, regulatory or commercial milestone payments, the Company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price. Topic 606 suggests two alternatives to use when estimating the amount of variable consideration: the expected value method and the most likely amount method. Under the expected value method, an entity considers the sum of probability-weighted amounts in a range of possible consideration amounts. Under the most likely amount method, an entity considers the single most likely amount in a range of possible consideration amounts. Whichever method is used, it should be consistently applied throughout the life of the contract; however, it is not necessary for the Company to use the same approach for all contracts. The Company expects to use the most likely amount method for development and regulatory milestone payments. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the Company's or the licensee's control, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. The transaction price is then allocated to each performance obligation on a relative stand-alone selling price basis. The Company recognizes revenue as or when the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, the Company re-evaluates the probability or achievement of each such milestone and any related constraint, and if necessary, adjusts its estimates of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenues and earnings in the period of adjustment.

Commercial milestones and royalties: For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and in which the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue when the related sales occur. To date, the Company has not recognized any royalty revenue resulting from its collaboration arrangements.

Upfront payments and fees are recorded as deferred revenue upon receipt or when due, and may require deferral of revenue recognition to a future period until the Company performs its obligations under these arrangements. Amounts due to the Company are recorded as accounts receivable when the Company's right to consideration is unconditional.

Research and Development Expenses and Accrued Research and Development Costs

The Company expenses research and development costs as incurred. Research and development expenses consist of personnel costs for the Company's research and product development employees. Also included are non-personnel costs such as professional fees payable to third parties for preclinical studies, clinical trials, research services, laboratory supplies and equipment maintenance and depreciation, intellectual property licenses and other consulting costs.

The Company estimates preclinical and clinical study and research expenses based on the services performed, pursuant to contracts with research institutions that conduct and manage preclinical studies, clinical trials and research services on its behalf. The Company estimates these expenses based on discussions with internal management personnel and external service providers as to the progress or stage of completion of services and the contracted fees to be paid for such services. The Company records the estimated costs of research and development activities based upon the estimated amount services provided but not yet invoiced, and includes these costs in development expenses. The Company accrues for these costs based on factors such as estimates of the work completed and in accordance with agreements established with its third-party service providers under the service agreements. The Company makes significant judgments and estimates in determining the accrued liabilities balance in each reporting period. As actual costs become known, the Company adjusts its accrued liabilities. The Company has not experienced any material differences between accrued costs and actual costs incurred. However, the status and timing of actual services performed may vary from the Company's estimates, resulting in adjustments to expense in future periods. Changes in these estimates that result in material changes to the Company's accruals could materially affect the Company's results of operations. Payments associated with licensing agreements to acquire exclusive license to develop, use, manufacture and commercialize products that have not reached technological feasibility and do not have alternate future use are expensed as incurred.

Payments made to third parties under these arrangements in advance of the performance of the related services by the third parties are recorded as prepaid expenses until the services are rendered. Such payments are evaluated for current or long-term classification based on when such services are expected to be received.

Stock-Based Compensation

The Company maintains a stock-based compensation plan as a long-term incentive for employees, consultants and members of the Company's board of directors (the "Board"). The plan allows for the issuance of non-statutory options ("NSOs") and incentive stock options to employees and NSOs to nonemployees.

Share-based payments are measured using fair-value-based measurements and recognized as compensation expense over the service period in which the awards are expected to vest. The Company's fair-value-based measurements of awards to employees and directors as of the grant date utilize the single-option award-valuation approach, and the Company uses the straight-line method for expense attribution. The fair-value-based measurements of options granted to nonemployees are remeasured at each period end until the options vest and are amortized to expense as earned. The valuation model used for calculating the estimated fair value of stock awards is the Black-Scholes option-pricing model. The Black-Scholes model requires the Company to make assumptions and judgments about the variables used in the calculations, including the expected term (weighted-average period of time that the options granted are expected to be outstanding), the expected volatility of the Company's common stock, the related risk-free interest rate and the expected dividend. The Company has elected to recognize forfeitures of share-based payment awards as they occur.

Effective January 1, 2018, the Company early adopted ASU No. 2018-07, *Compensation – Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting*. The new guidance requires equity-classified share-based payment awards issued to nonemployees to be measured on the grant date, instead of being measured through the performance completion date under the current guidance. For stock-based awards issued to non-employees, the Company records expense related to stock options based on the fair value of the options calculated using the Black-Scholes option-pricing model based on the measured grant date.

Convertible Preferred Stock

The Company records all shares of convertible preferred stock at their respective fair values less issuance costs on the dates of issuance. The convertible preferred stock is recorded outside of stockholders' deficit because, in the event of certain deemed liquidation events considered not solely within the Company's control, such as a merger, acquisition and sale of all or substantially all of the Company's assets, the convertible preferred stock will become redeemable at the option of the holders. In the event of a change of control of the Company, proceeds received from the sale of such shares will be distributed in accordance with the liquidation preferences set forth in the Company's Amended and Restated Certificate of Incorporation unless the holders of convertible preferred stock have converted their shares of convertible preferred stock into shares of common stock. The Company has determined not to adjust the carrying values of the convertible preferred stock to the liquidation preferences of such shares because of the uncertainty of whether or when such an event would occur.

Income Taxes

Income taxes are accounted for under the asset and liability method. Under this method, deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates applied to taxable income in the years in which those temporary differences are expected to be realized. The effect on deferred tax assets and liabilities of a change in tax rates is recognized as income in the period that includes the enactment date. A valuation allowance is established when necessary to reduce deferred tax assets to the amount expected to be realized. Financial statement effects of uncertain tax positions are recognized when it is more-likely-than-not, based on the technical merits of the position, that it will be sustained upon examination. Interest and penalties related to unrecognized tax benefits are included as a component of other expense. To date, there have been no interest or penalties charged in relation to the unrecognized tax benefits.

The Company accounts for uncertain tax positions in accordance with ASC 740-10, *Accounting for Uncertainty in Income Taxes*. The Company assesses all material positions taken in any income tax return, including all significant uncertain positions, in all tax years that are still subject to assessment or challenge by relevant taxing authorities. Assessing an uncertain tax position begins with the initial determination of the position's sustainability and is measured at the largest amount of benefit that is greater than fifty percent likely of being realized upon ultimate settlement. As of each balance sheet date, unresolved uncertain tax positions must be reassessed, and the Company will determine whether (i) the factors underlying the sustainability assertion have changed and (ii) the amount of the recognized tax benefit is still appropriate. The recognition and measurement of tax benefits requires significant judgment. Judgment concerning the recognition and measurement of a tax benefit might change as new information becomes available.

The Company includes any penalties and interest expense related to income taxes as a component of provision for income tax as necessary. To date, there have been no interest or penalties charged in relation to the unrecognized tax benefits.

Net Loss Per Share

Basic net loss per share is calculated by dividing the net loss by the weighted-average number of shares of common stock outstanding during the period, without consideration for potentially dilutive securities. As discussed in Note 9, the unvested portion of early exercised stock options are excluded from the computation of weighted average shares as the continuing vesting of such shares is contingent on the holders' continued service to the Company. Diluted net loss per share is the same as basic net loss per share for each period presented, since the effects of potentially dilutive securities are antidilutive given the net loss of the Company.

Comprehensive Income (Loss)

Comprehensive loss includes net loss and certain changes in stockholders' equity (deficit) that are excluded from net loss, primarily unrealized gains or losses on the Company's marketable securities.

Deferred Offering Costs

The Company had deferred offering costs consisting of legal, accounting and other fees and costs directly attributable to the IPO, which was completed in February 2019. The deferred offering costs were offset against the gross proceeds of the IPO. As of June 30, 2019 and December 31, 2018, zero and \$3.0 million of deferred offering costs were included in other assets on the balance sheets, respectively.

Emerging Growth Company Status

The Company is an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"). Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. The Company has 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 that the Company (i) is no longer an emerging growth company or (ii) affirmatively and irrevocably opts out of the extended transition period provided in the JOBS Act. As a result, the accompanying condensed financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates.

As described in "Recently Adopted Accounting Pronouncements" below, the Company early adopted ASU No. 2014-09, *Revenue from Contracts with Customers* (Accounting Standards Codification Topic 606), ASU No. 2016-09, *Stock Compensation—Improvements to Employee Share-Based Payment Accounting*, ASU No. 2018-07, *Compensation – Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting*, and ASU No. 2016-02, (*Topic 842*), *Leases*, as the JOBS Act does not preclude an emerging growth company from adopting a new or revised accounting standard earlier than the time that such standard applies to private companies.

Recently Adopted Accounting Pronouncements

In February 2016, the Financial Accounting Standards Board ("FASB") issued ASU No. 2016-02 (Topic 842), *Leases* ("ASU 2016-02"). ASU 2016-02 requires an entity to recognize assets and liabilities arising from a lease for both financing and operating leases. ASU 2016-02 requires new qualitative and quantitative disclosures to help investors and other financial statement users better understand the amount, timing, and uncertainty of cash flows arising from leases. As a result of the Company having elected the extended transition period for complying with new or revised accounting standards pursuant to Section 107(b) of the JOBS Act, ASU 2016-02 is effective for the Company for the year ending December 31, 2020 and all interim periods thereafter. Effective January 1, 2019, the Company early adopted ASU No. 2016-02 using the alternative transition approach provided by ASU No. 2018-11. The Company elected certain practical expedients permitted under the transition guidance, including the election to carryforward historical lease classification. The Company also elected the short-term lease practical expedient, which allowed the Company to not recognize leases with a term of less than 12 months on the balance sheets. In addition, the Company elected the lease and non-lease components practical expedient, which allowed the Company to calculate the present value of the fixed payments without performing an allocation of lease and non-lease components. Adoption of the new standard resulted in recording operating lease right-of-use assets and operating lease liabilities of approximately \$8.4 million and \$15.1 million, respectively, on the balance sheets as of January 1, 2019. The lease liabilities represent the present value of the remaining lease payments of the Company's Tizona Lease and Cove Lease (see Note 7), discounted using the Company's incremental borrowing rate as of January 1, 2019. The corresponding right-of-use lease assets are recorded based on the lease liabilities, adjusted for the unamortized lease incentives received and the cumulative difference between rent expense and amounts paid under the Tizona Lease and Cove Lease. The adoption of ASU 2016-02 did not have a material impact on either the statement of operations or statement of cash flows for the three or six months ended June 30, 2019.

In February 2018, the FASB issued ASU No. 2018-02, *Income Statement – Reporting Comprehensive Income (Topic 220): Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income*, which provided amended guidance to allow a

reclassification from accumulated other comprehensive income to retained earnings for stranded tax effects resulting from the Tax Cuts and Jobs Act (the “Tax Act”). The Company adopted the new standard on January 1, 2019 and did not have income tax effects of the Tax Act related to unrealized gains and losses on its marketable securities. The adoption of this standard did not have an impact on the Company’s financial statements.

Recently Issued Accounting Pronouncements

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments* and subsequent amendments to the initial guidance: *ASU 2018-19* and *ASU 2019-04* (collectively, Topic 326). Topic 326 requires measurement and recognition of expected credit losses for financial assets held. The amendments apply to entities which hold financial assets that are not accounted for at fair value through net income as well as loans, debt securities, accounts receivables, and any other financial assets not excluded from the scope that have the contractual right to receive cash. Topic 326 requires entities to record expected credit losses for certain financial instruments, including available-for-sale securities, as an allowance that reflect the entity’s current estimate of credit losses expected to be incurred. For available-for-sale debt securities in unrealized loss positions, ASU 2016-13 requires allowances to be recorded instead of reducing the amortized cost of the investment. This guidance is effective for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years. Early adoption is permitted. The Company is currently evaluating the effect of the adoption of this guidance on the its financial statements.

In August 2018, the FASB issued ASU No. 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework – Changes to the Disclosure Requirements for Fair Value Measurement*, which modifies the disclosure requirements on fair value measurements. This guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019. Early adoption is permitted. The Company is currently evaluating the effect the new guidance will have on its financial statements.

3. Fair Value Measurement

The following table presents information about the Company’s financial assets that are measured at fair value and indicates the fair value hierarchy of the valuation:

	Fair Value Measurements at June 30, 2019			
	Total	Level 1	Level 2	Level 3
	(in thousands)			
Assets				
Cash Equivalents:				
Money market funds	\$ 50,333	\$ 50,333	\$ —	\$ —
U.S. government treasuries	—	—	—	—
Corporate debt securities	—	—	—	—
U.S. government agency securities	—	—	—	—
Short-term marketable securities				
U.S. government treasuries	42,775	37,784	4,991	—
Corporate debt securities	21,260	—	21,260	—
U.S. government agency securities	17,756	—	17,756	—
Total assets	\$ 132,124	\$ 88,117	\$ 44,007	\$ —

	Fair Value Measurements at December 31, 2018			
	Total	Level 1	Level 2	Level 3
	(in thousands)			
Assets				
Cash Equivalents:				
Money market funds	\$ 60,396	60,396	\$ —	\$ —
Total assets	\$ 60,396	\$ 60,396	\$ —	\$ —

The Company’s Level 2 securities are valued using third-party pricing sources. The pricing services utilize industry standard valuation models, including both income and market-based approaches, for which all significant inputs are observable, either directly or indirectly.

The Company had no Level 3 assets or liabilities as of June 30, 2019 and December 31, 2018. There were no transfers between Level 1 and Level 2 for the periods ended June 30, 2019 and December 31, 2018.

The Company did not have any financial liabilities subject to fair value measurements on a recurring basis as of June 30, 2019 and December 31, 2018.

4. Available-for-Sale Securities

All marketable securities were considered available-for-sale at June 30, 2019. The amortized cost, gross unrealized holding gains or losses, and fair value of the Company's marketable securities by major security type at each balance sheet date are summarized in the tables below:

	June 30, 2019			
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
(in thousands)				
Cash equivalents				
U.S. government treasuries	\$ —	\$ —	\$ —	\$ —
U.S. government agency securities	—	—	—	—
Corporate debt securities	—	—	—	—
Money market funds	20,853	—	—	20,853
Total cash equivalents	20,853	—	—	20,853
Short-term marketable securities:				
U.S. government treasuries	37,757	27	—	37,784
U.S. government agency securities	17,729	26	—	17,755
U.S. government securities	4,989	1	—	4,990
Corporate debt securities	21,205	56	—	21,261
Total short-term marketable securities	81,680	110	—	81,790
Total	\$ 102,533	\$ 110	\$ —	\$ 102,643

	December 31, 2018			
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
(in thousands)				
Cash equivalents				
Money market funds	\$ 60,396	\$ —	\$ —	\$ 60,396
Total cash equivalents	\$ 60,396	\$ —	\$ —	\$ 60,396

As of June 30, 2019 and December 31, 2018, there were no marketable securities that were in an unrealized loss position. The Company determined that it had the ability and intent to hold all marketable securities that have been in a continuous loss position until maturity or recovery, thus there has been no recognition of any other-than-temporary impairment for the three and six months ended June 30, 2019. All marketable securities with unrealized losses as of each balance sheet date have been in a loss position for less than 12 months or the loss is not material.

All of the Company's marketable securities have an effective maturity of less than two years.

5. Balance Sheet Components

Property and Equipment, Net

Property and equipment, net consists of the following:

	June 30, 2019	December 31, 2018
	(in thousands)	
Laboratory equipment	\$ 2,448	\$ 2,402
Furniture and fixtures	312	312
Computer equipment and software	103	32
Leasehold improvements	361	360
Construction in progress	10,160	906
	13,384	4,012
Less: Accumulated depreciation and amortization	(1,611)	(1,014)
Total property and equipment, net	<u>\$ 11,773</u>	<u>\$ 2,998</u>

Depreciation and amortization expense for property and equipment amounted to \$0.3 million and \$0.1 million for the three months ended June 30, 2019 and 2018, respectively and \$0.6 million and \$0.3 million for the six months ended June 30, 2019 and 2018, respectively.

Accrued Liabilities

Accrued liabilities consist of the following:

	June 30, 2019	December 31, 2018
Accrued research and development	\$ 1,037	\$ 504
Accrued personnel costs	1,205	1,593
Accrued professional and consulting fees	1,010	333
Accrued offering costs	—	709
Other	1,624	202
Total accrued liabilities	<u>\$ 4,876</u>	<u>\$ 3,341</u>

6. Convertible Notes

In May 2017, the outstanding principal balance of the Company's convertible promissory notes issued in November 2016 (the "2016 Notes") and January 2017 (the "2017 Notes"), and the then-outstanding balance of accrued interest, converted into 811,103 shares of the Company's Series B convertible preferred stock in conjunction with the Series B preferred stock financing. The conversion of the 2016 Notes and the 2017 Notes into shares of Series B convertible preferred stock was accounted for as an extinguishment. Upon the closing of the IPO, all shares of convertible preferred stock then outstanding were automatically converted into shares of common stock. The Company had no convertible preferred stock as of June 30, 2019.

Warrants Issued with 2016 and 2017 Notes

As of December 31, 2018, warrants for the purchase of an aggregate of 565,270 shares of the Company's common stock were outstanding, of which 565,270 shares were exercisable. In connection with the IPO, the Company's outstanding warrants of 565,270 shares automatically net exercised at the IPO price of \$14.00 per share and converted into 563,043 shares of common stock.

7. Commitments and Contingencies

Leases

In February 2017, the Company entered into an operating lease agreement with Tizona Therapeutics, Inc. (the "Tizona Lease") for its headquarters in South San Francisco, California. One member of the Board is also the Executive Chairman of Tizona and, as such, Tizona is deemed to be a related party. The lease term is for 36 months. The lease agreement includes escalation clauses for increased rent over the lease term. In addition to the minimum future lease commitments presented below, the lease requires the Company to pay property taxes, insurance, maintenance and repair costs. Rent expense is recognized using the straight-line method over the term of the lease. The Company records a deferred rent liability calculated as the difference between rent expense and cash

rental payments. The current portion of the liability is included within other current liabilities on the balance sheets. The remaining non-current portion is classified in other long-term liabilities.

In June 2019, the Company entered into a sublease termination agreement with Tizona (the "Termination Agreement") with the purpose of terminating the existing Tizona Lease. Under the Termination Agreement, the Company and Tizona have agreed to terminate the obligations, liabilities and benefits under the Tizona Lease as of the reduced lease term date of July 31, 2019. In addition, the Company will pay a termination fee of \$0.4 million to Tizona within 30 days of the executed Termination Agreement.

In August 2018, the Company entered into a lease agreement for the office and laboratory space in South San Francisco, California (the "Cove Lease"). The lease has an initial term of eight years, beginning on the lease commencement date, with an option to extend the lease for an additional period of eight years. The lease commencement date is the later to occur of (i) July 1, 2019 and (ii) the date the premises are ready for occupancy. Pursuant to the terms of the lease, the Company is entitled to a tenant improvement allowance of approximately \$5.2 million with the option for an additional tenant improvement allowance of approximately \$1.4 million. The additional tenant improvement allowance of \$1.4 million would be treated as a loan from the landlord and is expected to be paid back (including interest) by the Company through additional rental payments. In December 2018, the Company exercised this option for the use of the additional tenant improvement allowance of \$1.4 million. As of June 30, 2019, the full tenant improvement allowance of \$6.6 million was utilized under this lease, which was recorded as construction in progress and a reduction to the tenant improvement allowance receivable on the balance sheet.

The Company's leases have remaining terms ranging from 1 year to approximately over 8 years. The Cove Lease includes an option to renew, exercised at the Company's sole discretion, with a renewal term for an additional period of eight years. As of June 30, 2019, the Company has not determined whether it will exercise its option to extend the lease term. Therefore, the operating lease assets and lease liabilities only contemplate the initial lease terms. All of the Company's leases qualify as operating leases. The following table summarizes the presentation in the Company's condensed balance sheets of its operating leases (in thousands):

	As of June 30, 2019
<i>Assets:</i>	
Operating lease right-of-use assets	\$ 7,454
<i>Liabilities</i>	
Operating lease liabilities	\$ 862
Operating lease liabilities, net of current portion	14,369
Total operating lease liabilities	<u>\$ 15,231</u>

The Company incurred \$0.1 million in variable lease costs for each of the three and six months periods ended June 30, 2019.

Future minimum lease payments under the Tizona Lease and the Cove Lease as of June 30, 2019 are as follows (in thousands):

As of June 30, 2019	Operating Lease Commitments
2019	\$ 952
2020	2,487
2021	2,566
2022	2,647
2023	2,731
Thereafter	10,251
Total future minimum lease payments	<u>21,634</u>
Less: Present value adjustment for minimum lease commitments	(6,403)
Total	<u>\$ 15,231</u>

As of June 30, 2019, the weighted average remaining lease term was 7.91 years and the weighted average incremental borrowing rate used to determine the operating lease liability was 8.94%.

Rent expense was \$0.9 million and \$0.3 million for the three months ended June 30, 2019 and 2018, respectively, and \$1.6 million and \$0.5 million for the six months ended June 30, 2019 and 2018, respectively. Amortization of the right-of-use lease assets was \$0.5 million and zero for the three months ended June 30, 2019 and 2018, respectively and \$0.8 million and zero for the six months ended June 30, 2019 and 2018, respectively.

ASC 840 Disclosures

The future minimum lease payments under the Company's operating leases as of December 31, 2018, were as follows (in thousands):

As of December 31, 2018		Operating Lease Commitments
2019	\$	1,308
2020		2,762
2021		2,566
2022		2,647
2023		2,731
Thereafter		10,251
Total	\$	<u>22,265</u>

Rent expense was \$1.2 million for the year ended December 31, 2018.

Indemnification

In the ordinary course of business, the Company enters into agreements that may include indemnification provisions. Pursuant to such agreements, the Company may indemnify, hold harmless and defend an indemnified party for losses suffered or incurred by the indemnified party. Some of the provisions will limit losses to those arising from third-party actions. In some cases, the indemnification will continue after the termination of the agreement. The maximum potential amount of future payments the Company could be required to make under these provisions is not determinable. The Company has never incurred material costs to defend lawsuits or settle claims related to these indemnification provisions. The Company has also entered into indemnification agreements with its directors and officers that may require the Company to indemnify its directors and officers against liabilities that may arise by reason of their status or service as directors or officers to the fullest extent permitted by Delaware corporate law. The Company currently has directors' and officers' insurance.

8. Collaboration & License Agreements

Collaboration Agreement with AbbVie

On October 10, 2017, the Company entered into a Discovery Collaboration and License Agreement (the "Collaboration Agreement") with AbbVie Biotechnology Ltd. ("AbbVie"). Pursuant to the Collaboration Agreement, the Company granted to AbbVie worldwide exclusive rights to develop and commercialize products that incorporate its proprietary TriTAC technology together with soluble T cell receptors ("TCRs") provided by AbbVie that bind to targets accepted by the parties. Under the terms of the Collaboration Agreement, AbbVie is allowed to designate up to two targets, subject to confirmation of target availability. During a period of up to four years following the date of AbbVie's designation of each target for the products, and confirmation of target availability, the Company and AbbVie will conduct certain research and discovery activities under a mutually agreed discovery and research plan in connection with the creation and evaluation of constructs comprising the Company's proprietary TriTAC technology in conjunction with the soluble TCR sequences directed against the agreed upon targets of interest. The Company may not, by itself or through any third party, develop or commercialize any competing product that binds to any of the included targets. Following the discovery phase, AbbVie will be solely responsible, at its cost, for the development, manufacture and commercialization of products that arise from the activities under the discovery plan. AbbVie is required to use commercially reasonable efforts to develop and commercialize one such product directed to each target for which the discovery activities were completed, in the United States and specified European markets.

In addition to an upfront payment of \$17 million, AbbVie will be required to make further payments to the Company of up to \$600 million in the aggregate, for the achievement of specified development, regulatory, and commercial sale milestones for licensed products indicated for human therapeutic or prophylactic use, if such licensed products are successfully progressed against all included targets and indications. The Company will also receive tiered royalties on net sales by AbbVie, its affiliates and sublicensees of licensed products at percentages in the mid-single digits, subject to specified offsets and reductions. If licensed products are developed and commercialized for diagnostic or veterinary use, or certain screening or monitoring uses, the parties have agreed to negotiate an appropriate reduction in the economic terms applicable to such non-therapeutic and prophylactic applications.

In April 2019, the Company and AbbVie amended the Collaboration Agreement to modify certain time periods for selection of collaboration targets by AbbVie. All other elements of the Collaboration Agreement remain unchanged. The first target was selected in 2017 and the Company has satisfied all of its development obligations associated with the first target.

The Collaboration Agreement will terminate upon the date of the expiration of all AbbVie's royalty payment obligations in all countries. The Collaboration Agreement may be terminated by either party immediately for the insolvency of the other party or on 90 days' written notice for an uncured material breach of the Collaboration Agreement by the other party. In the case of a material breach with respect to commercialization diligence with respect to any major market, or with respect to only one of the included targets, the Company may terminate the Collaboration Agreement solely with respect to the affected major markets, or target, as applicable. AbbVie may also terminate the Collaboration Agreement in its entirety or on a target-by-target or country-by-country basis for any reason on 30 days' written notice to the Company. In addition, AbbVie may terminate the Collaboration Agreement immediately in its entirety or on a target-by-target basis if AbbVie considers in good faith that there has been a failure of the discovery or development efforts with respect to such target, or that further development or commercialization of products directed to such target is not advisable as a result of a serious safety issue.

The Company assessed the Collaboration Agreement in accordance with Topic 606 and concluded that AbbVie is a customer. The Company concluded that there are multiple promises under the Collaboration Agreement which include the research and development activities, regulatory documentation and know-how, exclusivity, and the license to the related technology. The Company combined these promises into a single performance obligation, as the Company is obliged to render specialized services for the research program, and other promises have either no significant value or are not distinct. The Company estimates that the \$17.0 million upfront payment will be recognized over the estimated four-year period of ongoing research and development activities based on the projected activities to be performed over each reporting period relative to the total estimated performance period. Such estimates are reviewed by the Company on a periodic basis.

At the inception of the Collaboration Agreement, the Company determined that the transaction price was \$17.0 million, which was all allocated to the single unit of accounting. The Company has evaluated the transaction price and has determined \$17.0 million is still appropriate as of June 30, 2019. For each of the three and six months ended June 30, 2019 and 2018, \$1.1 million and \$2.1 million of revenue has been recognized in the accompanying statement of operations and comprehensive loss, respectively. As of June 30, 2019, the Company has recorded \$9.9 million in deferred revenue, of which \$5.7 million is classified as long-term and \$4.2 million as short-term deferred revenue, in the accompanying balance sheet.

The Company determined that future contingent payments that may be received related to development and regulatory milestones under the Collaboration Agreement are based on the performance of AbbVie and are constrained due to the fact that it was not probable that a significant reversal of cumulative revenue would not occur, as their achievement is highly dependent on the successful completion of the research activities. Accordingly, revenue for the achievement of these milestones will be recognized in the period that it is deemed probable that the milestone will be achieved. Any consideration related to commercialization and sales milestones, and sales-based royalties will be recognized when the related sales occur as they were determined to relate predominantly to the license granted to AbbVie and have been excluded from the transaction price. The Company will re-evaluate the transaction price in each reporting period as uncertain events are resolved or other changes in circumstances occur.

As of June 30, 2019, the Company has not recognized or earned any milestone payments under the Collaboration Agreement. The Company will recognize royalty revenue in the period of sale of the related products, based on the underlying contract terms. No such amounts were recognized during the three and six months ended June 30, 2019.

License Agreement with Werewolf Therapeutics, Inc.

In March 2018, the Company entered into an assignment and license agreement (the "Werewolf Agreement") with Werewolf Therapeutics, Inc. ("Werewolf"). Werewolf is affiliated with a holder of more than 5% of the Company's capital stock, and one member of the Board is also the interim Chief Executive Officer of Werewolf and as such, Werewolf was deemed to be a related party. Pursuant to the Werewolf Agreement, the Company assigned certain patents and granted to Werewolf a non-exclusive, royalty-bearing, sublicensable license under certain other patents. In addition, Werewolf assigned certain patents to the Company. Under the Werewolf Agreement, the Company received an upfront fee of \$0.5 million. If Werewolf commercializes products covered by the licensed patents, then beginning on the first sale of such products, the Company will be eligible to receive a royalty on net sales of such products by Werewolf, its affiliates and licensees at a percentage in the low single digits, subject to a minimum annual royalty payment at an amount in the low hundreds of thousands of dollars.

The Werewolf Agreement will continue on a country-by-country basis until the expiration of the last to expire patent licensed under the Werewolf Agreement, and it may be terminated by either party for the other party's uncured material breach. The Company may terminate the license grant to Werewolf upon Werewolf's insolvency. In addition, Werewolf may terminate the Werewolf Agreement for convenience at any time upon advance notice to the Company. Upon any termination, the license granted to Werewolf under the Werewolf Agreement will immediately terminate.

The Company assessed the Werewolf Agreement in accordance with Topic 606 and concluded that Werewolf is a customer, and there is only one promise and a performance obligation to deliver intellectual property license. The upfront fee of \$0.5 million was recognized upfront during the six month period ended June 31, 2018 upon delivery of the license to Werewolf and royalties on net sales will be recognized when the underlying sales occur. No royalty revenue was recognized under the Werewolf Agreement during the three and six months ended June 30, 2019 or 2018.

9. Equity

Stock-Based Compensation

As of June 30, 2019, there were 2,139,563 shares reserved by the Company to grant under the 2019 Equity Incentive Plan (the "2019 Plan").

The following summarizes option activity under the 2019 Plan:

	Number of Outstanding Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value (in thousands)
Balance as of December 31, 2018	3,323,988	1.61	9.07	\$ 1,675
Options granted	267,412	13.04		
Options exercised	(223,364)	0.72		
Options cancelled	(74,584)	0.86		
Balance as of June 30, 2019	3,293,452	2.62	8.75	\$ 34,354
Vested and expected to vest as of June 30, 2019	3,293,452	2.62	8.75	\$ 34,354
Exercisable as of June 30, 2019	567,315	1.50	7.80	\$ 6,542

As of June 30, 2019, 2,340,438 shares were authorized for the grant of options. The aggregate intrinsic values of options outstanding, vested and exercisable, and vested and expected to vest were calculated as the difference between the exercise price of the options and the estimated fair value of the Company's common stock. The intrinsic value of options exercised was \$2.2 million and \$2.4 million for the three and six months ended June 30, 2019, respectively, and zero for each of the three and six months ended June 30, 2018. There is no future tax benefit related to options exercised, as the Company had accumulated net operating losses at June 30, 2019 and 2018.

During the three months ended June 30, 2019 and 2018, the estimated weighted-average grant-date fair value of the employee options vested was \$0.85 and \$0.67 per share, respectively, and the estimated weighted-average grant-date fair value of the employee options granted was \$7.94 and \$1.18 per share, respectively. During the six months ended June 30, 2019 and 2018, the estimated weighted-average grant-date fair value of employee options vested was \$0.85 and \$0.67, respectively, and the estimated weighted-average grant-date fair value of the employee options granted was \$9.19 and \$1.12 per share, respectively.

As of June 30, 2019, there was \$4.7 million of unrecognized stock-based compensation related to unvested stock options that is expected to be recognized over a weighted-average period of 2.9 years.

The fair value of employee and director stock option awards was estimated at the date of grant using a Black-Scholes option-pricing model with the following weighted-average assumptions:

	Six Months Ended June 30,	
	2019	2018
Expected term (years)	5.84	6.20
Expected volatility	77.80%	73.37%
Risk-free interest rate	2.31%	2.74%
Expected dividend	0%	0%

Total stock-based compensation was as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
	(in thousands)			
Operating Expenses				
Research and development	\$ 150	\$ 70	\$ 297	\$ 139
General and administrative	317	70	539	141
Total stock-based compensation	<u>\$ 467</u>	<u>\$ 140</u>	<u>\$ 836</u>	<u>\$ 280</u>

Stock-based compensation related to non-employee awards, which is included in the table above, was zero and \$0.1 million for the three and six months ended June 30, 2019 and 2018, respectively.

Restricted Stock

In 2015, the Company issued restricted stock awards to employees and directors under the Company's 2015 Equity Incentive Plan (the "2015 Plan") at a purchase price of \$0.0005 per share. The shares related to restricted stock awards are subject to a lapsing repurchase right upon termination of employment at the original purchase price. In order to vest, the holders are required to provide continued service to the Company. For accounting purposes, unvested restricted stock awards are not considered issued and outstanding and therefore are not reflected as issued and outstanding in the accompanying statements of convertible preferred stock and stockholders' equity (deficit) until the awards vest.

A summary of restricted stock activity is shown in the below table:

	Number of of Restricted Stock Outstanding
Restricted shares- December 31, 2018	22,178
Restricted stock awards vested	(22,178)
Unvested shares repurchased	—
Restricted shares- June 30, 2019	<u>—</u>

Early Exercised Stock Options

The terms of the 2015 Plan permit option holders to exercise stock options before they are vested, subject to certain limitations. The shares related to early exercised stock options are subject to the Company's lapsing repurchase right upon termination of employment at the original purchase price. In order to vest, the holders are required to provide continued service to the Company. The proceeds are initially recorded in other current liabilities and are reclassified to common stock and paid-in capital as the repurchase right lapses. As of June 30, 2019 and December 31, 2018, there was \$170,000 and \$188,000, respectively, recorded in other current liabilities relating to shares subject to repurchase. For accounting purposes, unvested early exercised shares are not considered issued and outstanding until the awards vest. As a result of early exercises under the 2015 Plan, 125,749 and 149,565 shares had not vested and were subject to repurchase as of June 30, 2019 and December 31, 2018, respectively.

10. Net Loss Per Share

The following outstanding potentially dilutive common stock equivalents have been excluded from the calculation of diluted net loss per share for the periods presented due to their anti-dilutive effect:

	As of June 30, 2019	As of December 31, 2018
Convertible preferred stock (as converted)	—	16,618,448
Common stock options issued and outstanding	3,293,452	3,323,988
Restricted Stock subject to future vesting	—	22,178
Early exercised stock options subject to future vesting	125,749	149,565
Warrants to purchase shares of common stock	—	565,270
Total	<u>3,419,201</u>	<u>20,679,449</u>

Neither the Company's convertible preferred stock nor restricted stock subject to future vesting participates in losses.

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

	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2019</u>	<u>2018</u>	<u>2019</u>	<u>2018</u>
Net loss	\$ (11,817)	\$ (5,994)	\$ (25,396)	\$ (10,875)
Net loss per share, basic and diluted	\$ (0.49)	\$ (5.89)	\$ (1.30)	\$ (10.95)
Weighted-average shares used to compute basic and diluted net loss per share	<u>24,294,211</u>	<u>1,017,336</u>	<u>19,548,600</u>	<u>993,418</u>

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

The following discussion of our financial condition and results of operations should be read in conjunction with our unaudited condensed financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q. The following discussion and analysis contains forward-looking statements that involve risks and uncertainties. When reviewing the discussion below, you should keep in mind the substantial risks and uncertainties that could impact our business. In particular, we encourage you to review the risks and uncertainties described in Part II, Item 1A "Risk Factors" included elsewhere in this report. These risks and uncertainties could cause actual results to differ materially from those projected in forward-looking statements contained in this report or implied by past results and trends. Forward-looking statements are statements that attempt to forecast or anticipate future developments in our business, financial condition or results of operations. See the section titled "Special Note Regarding Forward-Looking Statements" in this report. These statements, like all statements in this report, speak only as of their date (unless another date is indicated), and we undertake no obligation to update or revise these statements in light of future developments, except as required by law.

Overview

We are a clinical-stage immunotherapy company developing a novel class of T cell engagers that harness the power of the body's immune system to treat patients suffering from cancer and other diseases. T cell engagers are engineered proteins that direct a patient's own T cells to kill target cells that express specific proteins, or antigens, carried by the target cells. Using our proprietary TriTAC platform, we are developing a pipeline of novel T cell engagers, or TriTACs, initially focused on the treatment of solid tumors and hematologic malignancies.

We currently have two TriTAC product candidates in clinical trials. HPN424, is currently in a Phase 1 clinical trial for the treatment of metastatic castration-resistant prostate cancer, or mCRPC. HPN536, is currently in a Phase 1/2a clinical trial for the treatment of ovarian cancer and other mesothelin-, or MSLN-, expressing solid tumors. We also have two TriTAC product candidates in preclinical development, HPN217 and HPN328, targeting tumor-associated antigens for the treatment of multiple myeloma and small cell lung cancer, or SCLC, respectively.

Pipeline Update

HPN424: Our lead product candidate is currently in the dose escalation portion of a Phase 1 clinical trial for the treatment of mCRPC. The dose escalation phase is designed to determine the maximum tolerated dose and a recommended Phase 2 dose. Once a recommended Phase 2 dose is determined, we will initiate the dose expansion phase. Consistent with the TriTAC mechanism of action, we observed T cell activation and cytokine induction with HPN424 treatment, which prompted us to explore the use of dexamethasone as a premedication to limit potential adverse events. We have found that the addition of weekly dexamethasone premedication, tapered over several weeks, has successfully limited adverse events. Several patients have completed the scheduled taper and have successfully continued treatment with HPN424 in the absence of dexamethasone, with no complications observed thus far. Enrollment is ongoing, with patients now being treated in the seventh dose-escalation cohort. Pharmacokinetics observed to date continue to support once-weekly dosing of HPN424. We plan to present interim results from the trial at a medical meeting in the first half of 2020 and to initiate an expansion cohort in 2020.

HPN536: In April 2019, we advanced our second TriTAC, HPN536, a MSLN-targeting T cell engager, into the clinic and dosed the first patient in a Phase 1/2a clinical trial for ovarian and other MSLN-expressing solid tumors. Patient enrollment continues as planned and two dosing cohorts have been completed. The study consists of two phases, an initial dose escalation phase of approximately 20 ovarian cancer patients, followed by an expansion phase of up to three additional parallel cohorts of 20 patients each with ovarian, pancreatic and mesothelioma cancer. The study is collecting data to evaluate the safety, tolerability, pharmacokinetics and activity of HPN536. We expect to present proof of concept data from the trial in 2020.

HPN217: We anticipate submitting an IND to the U.S. Food and Drug Administration, or FDA, for HPN217 by the end of 2019, followed by initiation of a Phase 1 clinical trial initiation in the first quarter of 2020. HPN217 is a TriTAC which targets B-cell maturation antigen for the potential treatment of multiple myeloma.

HPN328: We are developing HPN328, which targets Delta-like 3, for the treatment of SCLC, and we plan to initiate a Phase 1 trial in 2020.

Since commencing operations in 2015, we have devoted substantially all of our resources to performing research and development and manufacturing activities in support of our product development efforts, hiring personnel, raising capital to support and expand such activities and providing general and administrative support for these operations. We do not have any products approved for sale and have not generated any revenue from product sales. We have funded our operations to date primarily from the issuance of convertible notes, the sale of convertible preferred stock, the sale of common stock, payments received under our discovery collaboration agreement with AbbVie Biotechnology Ltd., or AbbVie, and most recently the initial public offering, or IPO, of our common stock on the Nasdaq Global Select Market, or Nasdaq.

Since our inception, we have incurred significant operating losses. Our ability to generate product revenue sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of one or more of our current or future product candidates and programs. Our net losses were \$11.8 million and \$25.4 million for the three and six months ended June 30, 2019, respectively, as compared to \$6.0 million and \$10.9 million for the three and six months ended June 30, 2018. As of June 30, 2019, we had an accumulated deficit of \$88.0 million. 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. 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.

We expect to continue to incur significant expenses and increasing operating losses for at least the next several years. Our net losses may fluctuate significantly from period to period, depending on the timing of our planned clinical trials and expenditures on other research and development activities. We expect our expenses will increase substantially over time as we:

- continue the research and development of HPN424 and HPN536, as well as our other product candidates;
- initiate preclinical studies and clinical trials for any additional product candidates that we may pursue in the future;
- seek marketing approvals for product candidates that successfully complete clinical trials;
- establish a sales, marketing, manufacturing and distribution infrastructure to commercialize any product candidate for which we may obtain marketing approval;
- continue to invest in our technology platforms, including TriTAC and ProTriTAC;
- maintain, protect and expand our portfolio of intellectual property rights, including patents, trade secrets and know-how;
- implement operational, financial and management systems; and
- attract, hire and retain additional administrative, clinical, regulatory and scientific personnel.

Furthermore, we expect to incur additional costs associated with operating as a public company, including significant legal, accounting, investor relations and other expenses that we did not incur as a private company.

In February 2019, we closed the IPO of our common stock, in which we issued and sold an aggregate of 5,400,000 shares of common stock at a price of \$14.00 per share for gross proceeds of approximately \$75.6 million. Shortly following the close of the offering, the underwriters exercised in part their option to purchase an additional 369,201 shares at the IPO price for gross proceeds of approximately \$5.2 million. In the aggregate, we received net proceeds from the offering of approximately \$70.7 million, after deducting underwriting discounts, commissions and offering expenses.

Collaboration Agreement with AbbVie

On October 10, 2017, we entered into a Discovery Collaboration and License Agreement, or the Collaboration Agreement, with AbbVie. Pursuant to the Collaboration Agreement, we granted to AbbVie worldwide exclusive rights to develop and commercialize products that incorporate our proprietary TriTAC technology together with soluble T cell receptors, or TCRs, provided by AbbVie that bind to targets accepted by the parties. Under the terms of the Collaboration Agreement, AbbVie is allowed to designate up to two targets, subject to confirmation of target availability. During a period of up to four years following the date of AbbVie's designation of each target for the products, and confirmation of target availability, we and AbbVie will conduct certain research and discovery activities under a mutually agreed discovery and research plan in connection with the creation and evaluation of constructs comprising our proprietary TriTAC technology in conjunction with the soluble TCR sequences directed at the agreed upon targets of interest. We may not, by ourselves or through any third party, develop or commercialize any competing product that binds to any of the included targets. Following the discovery phase, AbbVie will be solely responsible, at its cost, for the development, manufacture and commercialization of the products that arise from the activities under the discovery plan. AbbVie is required to use commercially reasonable efforts to develop and commercialize one such product directed to each target for which the discovery activities were completed, in the United States and specified European markets.

In addition to an upfront payment to us of \$17.0 million, AbbVie will be required to make further payments to us of up to \$600.0 million in the aggregate, for the achievement of specified development, regulatory and commercial sale milestones for licensed products indicated for human therapeutic or prophylactic use, if such licensed products are successfully progressed against all included targets and indications. We will also receive tiered royalties from AbbVie on net sales by AbbVie, its affiliates and sublicensees of licensed products at percentages in the mid-single digits, subject to specified offsets and reductions. If licensed products are developed and commercialized for diagnostic or veterinary use, or certain screening or monitoring uses, the parties have agreed to negotiate an appropriate reduction in the economic terms applicable to such non-therapeutic and prophylactic applications.

In April 2019, we and AbbVie amended the Collaboration Agreement to modify certain time periods for selection of collaboration targets by AbbVie. The first target was selected in 2017 and we have satisfied all of our development obligations associated with the first target.

We will recognize revenue under the Collaboration Agreement over the four-year research period as research and development activities occur. Accordingly, of the \$17.0 million upfront payment received in 2017, \$1.1 million and \$2.1 million of revenue was recognized during each of the three and six months ended June 30, 2019 and 2018, respectively, and, as of June 30, 2019, we had \$9.9 million of deferred revenue under the Collaboration Agreement.

License Agreement with Werewolf Therapeutics, Inc.

In March 2018, we entered into an assignment and license agreement, or the Werewolf Agreement, with Werewolf Therapeutics, Inc., or Werewolf, a portfolio company of MPM Capital, Inc., a holder of more than 5% of our capital stock. Dr. Evnin, a member of our Board, is the interim Chief Executive Officer and Chairman of the board of directors of Werewolf. Dr. Baeuerle, a member of our Board, serves on the board of directors of Werewolf. Under the Werewolf Agreement, we assigned certain patents that relate to certain inducible polypeptides (and binding moiety for conditional activation of certain polypeptides) to Werewolf and granted to Werewolf a non-exclusive, royalty-bearing, sublicenseable license under certain other patents owned by us and relating to certain proteins, to make, use and commercialize products that are covered by such patents in the field of molecules comprising a certain polypeptide. Werewolf assigned certain patents to us relating to adoptive cell therapies and binding moieties for conditional activation of immunoglobulin and non-immunoglobulin molecules. Under the Werewolf Agreement, Werewolf paid us an upfront fee of \$0.5 million. If Werewolf commercializes products covered by the licensed patents, then beginning on the first sale of such products, Werewolf will be obligated to pay to us a royalty on net sales of such products by Werewolf, its affiliates and licensees at a percentage in the low single digits, subject to an obligation to make a minimum annual royalty payment at an amount in the low hundreds of thousands of dollars.

Royalties on net sales will be recognized when the underlying sales occur. No royalty revenue was recognized under the Werewolf Agreement as of June 30, 2019.

Financial Operations Overview

Revenue

We have no products approved for commercial sale and have not generated any revenue from product sales. Our collaboration revenue to date is deferred revenue related to the upfront payment received by us in October 2017 under the Collaboration Agreement, and is recognized when designated research and development services are performed. To date, we have not received any milestone or royalty payments under the Collaboration Agreement. We expect that any collaboration revenue we generate from the Collaboration Agreement and any future collaboration partners will fluctuate from period to period as a result of the timing and amount of milestones and other payments.

Operating Expenses

Research and Development

Research and development expenses represent costs incurred in performing research, development and manufacturing activities in support of our own product development efforts and those of our collaborators, and include salaries, employee benefits, stock-based compensation, laboratory supplies, outsourced research and development expenses, professional services and allocated facilities-related costs. We expense both internal and external research and development expenses as they are incurred. We do not allocate our costs by product candidates, as our research and development expenses include internal costs, such as payroll and other personnel expenses, and external costs, neither of which are tracked by product candidate. In particular, with respect to internal costs, several of our departments support multiple product candidate research and development programs. Non-refundable advance payments for services that will be used or rendered for future research and development activities are recorded as prepaid expenses and recognized as expenses as the related services are performed.

We expect our research and development expenses to increase substantially in absolute dollars for the foreseeable future as we advance our product candidates into and through preclinical studies and clinical trials, pursue regulatory approval of our product candidates and expand our pipeline of product candidates. The process of conducting the necessary preclinical and clinical research to obtain regulatory approval is costly and time consuming. The actual probability of success for our product candidates may be affected by a variety of factors, including the safety and efficacy of our product candidates, early clinical data, investment in our clinical programs, the ability of collaborators to successfully develop our licensed product candidates, competition, manufacturing capability and commercial viability. We may never succeed in achieving regulatory approval for any of our product candidates. As a result of the uncertainties discussed above, we are unable to determine the duration and completion costs of our research and development projects or when and to what extent we will generate revenue from the commercialization and sale of our product candidates.

General and Administrative

Our general and administrative expenses consist primarily of personnel costs, allocated facilities costs and other expenses for outside professional services, including legal, human resource, audit and accounting services. Personnel costs consist of salaries, benefits and stock-based compensation. We expect to incur additional expenses as a result of operating as a public company, including expenses related to compliance with the rules and regulations of the Securities and Exchange Commission, or the SEC, Nasdaq and any other securities exchange on which our securities are traded, additional insurance expenses, investor relations activities and other administrative and professional services. We also expect to increase the size of our administrative function to support the growth of our business.

Other Expense

Other expense is primarily comprised of foreign currency transaction losses related to certain transactions with European third-party vendors.

Results of Operations

Comparison of the Three and Six Months ended June 30, 2018 and 2019

	Three Months Ended June 30,				Six Months Ended June 30,			
	2019	2018	Change (\$)	Change (%)	2019	2018	Change (\$)	Change (%)
	(dollars in thousands)				(dollars in thousands)			
Revenue:								
Collaboration and license revenue	\$ 1,063	\$ 1,063	\$ —	0%	\$ 2,126	\$ 2,626	\$ (500)	-19%
Total revenue	1,063	1,063	—	0%	2,126	2,626	(500)	-19%
Operating expenses:								
Research and development	9,971	6,151	3,820	62%	19,353	11,684	7,669	66%
General and administrative	3,734	967	2,767	286%	9,566	1,949	7,617	391%
Total operating expenses	13,705	7,118	6,587	93%	28,919	13,633	15,286	112%
Loss from operations	(12,642)	(6,055)	6,587	109%	(26,793)	(11,007)	15,786	143%
Interest income	840	66	774	*	1,416	139	1,277	919%
Other expense	(15)	(5)	10	200%	(19)	(7)	12	171%
Net loss	<u>\$ (11,817)</u>	<u>\$ (5,994)</u>	<u>\$ 5,823</u>	97%	<u>\$ (25,396)</u>	<u>\$ (10,875)</u>	<u>\$ 14,522</u>	134%

* Not meaningful

Revenue

Collaboration and license revenue of \$1.1 million for the three months ended June 30, 2019 and 2018 consisted entirely of the amortized portion of the deferred \$17.0 million upfront payment received by us in October 2017 under the Collaboration Agreement. Collaboration and license revenue decreased by \$0.5 million, or 19%, for the six months ended June 30, 2019 compared to the six months ended June 30, 2018. The decrease was due to the \$0.5 million upfront payment received by us under the Werewolf Agreement in the six months ended June 30, 2018.

Research and Development

The following table summarizes our research and development expenses incurred during the respective periods:

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2019	2018	2019	2018
	(In thousands)		(In thousands)	
Product and clinical development	\$ 4,170	\$ 1,729	\$ 8,163	\$ 3,717
Research and technology services	707	1,088	1,368	1,848
Laboratory supplies and equipment	514	485	1,038	760
Pharmacology services	125	348	323	451
Personnel-related	2,123	1,224	4,264	2,479
Facility and other allocated expenses	1,801	722	3,097	1,459
Consulting	531	555	1,100	970
Total research and development expenses	<u>\$ 9,971</u>	<u>\$ 6,151</u>	<u>\$ 19,353</u>	<u>\$ 11,684</u>

Research and development expenses increased by \$3.8 million, or 62%, for the three months ended June 30, 2019 compared to the three months ended June 30, 2018. The increase was primarily due to a \$2.4 million increase in clinical development expense due to the development of four identified product candidates, which includes conducting preclinical studies and manufacturing runs to support ongoing clinical development, a \$1.1 million increase in facility and other allocated expenses primarily related to the new lease entered into in August 2018, or the Cove Lease, and a \$0.9 million increase in personnel-related expenses due to an increase in headcount, which was offset by a \$0.6 million decrease in research and pharmacology services due to completion of certain research activities as our lead product candidates transitioned into clinical development.

Research and development expenses increased by \$7.7 million, or 66%, for the six months ended June 30, 2019 compared to the six months ended June 30, 2018. The increase was primarily due to a \$4.4 million increase in clinical development expense due to development of four identified product candidates, which includes conducting preclinical studies and manufacturing runs to support ongoing clinical development, a \$1.8 million increase in personnel-related expenses due to an increase in headcount, a \$1.6 million increase in facility and other allocated expenses primarily related to the Cove Lease entered into in August 2018, a \$0.3 million increase in laboratory supplies and equipment to support increased activity related to all of our product candidates, and a \$0.1 million increase in consulting expenses primarily due to preparation for our HPN424 and HPN536 clinical trials, which was offset by a \$0.5 million decrease in research and pharmacology services due to completion of certain research activities as our lead product candidates transitioned into clinical development.

General and Administrative

General and administrative expenses increased by \$2.8 million, or 286%, for the three months ended June 30, 2019 compared to the three months ended June 30, 2018. The increase was primarily due to a \$1.2 million increase in legal fees associated with ongoing litigation with Maverick Therapeutics, Inc., a \$0.8 million increase in personnel-related expenses due to an increase in headcount, \$0.4 million increase in professional services to support our ongoing operations as a public company, a \$0.2 million increase in consulting and accounting services, and a \$0.2 million increase in facility and other allocated expenses related to the Cove Lease.

General and administrative expenses increased by 7.6 million, or 391%, for the six months ended June 30, 2019 compared to the six months ended June 30, 2018. The increase was primarily due to a \$4.1 million increase in legal fees associated with ongoing litigation with Maverick Therapeutics, Inc., a \$1.3 million increase in personnel-related expenses due to an increase in headcount, a \$0.7 million increase in consulting and accounting services primarily related to our FY18 audit, a \$0.7 million increase in other professional services to support our ongoing operations as a public company, and a \$0.2 million increase in facility and other allocated expenses related to the Cove Lease.

Interest Income

Interest income increased by \$0.8 million for the three months ended June 30, 2019 compared to the three months ended June 30, 2018. Interest income increased by \$1.3 million for the six months ended June 30, 2019 compared to the six months ended June 30, 2018. Interest income consisted primarily of interest earned on our cash deposit accounts and marketable securities during the three and six months ended June 30, 2019.

Other Expense

Other expense did not significantly fluctuate period over period.

Liquidity and Capital Resources

Liquidity

Since our inception and through June 30, 2019, we have financed our operations primarily through the issuance of convertible notes, the sale of convertible preferred stock, the sale of common stock, upfront payments received by us under the Collaboration Agreement and the Werewolf Agreement, and most recently the IPO of our common stock on Nasdaq, including the partial exercise of the underwriters' option to purchase additional shares, in which we received an aggregate of approximately \$70.7 million in net proceeds, which amount is net of \$10.1 million in underwriters' discount and offering costs. As of June 30, 2019, we had \$133.9 million in cash, cash equivalents and marketable securities, an accumulated deficit of \$88.0 million and working capital of \$124.4 million. We expect to continue to incur substantial costs in order to conduct research and development activities necessary to develop and commercialize our product candidates. Additional capital will be needed to undertake these activities and commercialization efforts, and, therefore, we intend to raise such capital through the issuance of additional equity, borrowings, and potentially strategic alliances with other companies. However, if such financing is not available at adequate levels or on acceptable terms, we could be required to significantly reduce operating expenses and delay, reduce the scope of or eliminate some of the development programs or commercialization efforts, out-license intellectual property rights to our product candidates and sell unsecured assets, or a combination of the above, any of which may have a material adverse effect on the our business, results of operations, financial condition and/or our ability to fund our scheduled obligations on a timely basis or at all.

Capital Resources

Our primary uses of cash are to fund operating expenses, which consist primarily of funding our clinical and preclinical trials, research and development expenditures and related personnel costs. 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. The timing and amount of our future funding requirements depends on many factors, including the following:

- the scope, rate of progress, results and cost of our preclinical studies, clinical trials and other related activities;
- the cost of manufacturing clinical supplies, and establishing commercial supplies, of our product candidates and any products that we may develop;
- the number and characteristics of product candidates that we pursue;
- the cost, timing and outcomes of regulatory approvals;
- the cost and timing of establishing sales, marketing and distribution capabilities;
- the terms and timing of any other collaborative, licensing and other arrangements that we may establish;
- the timing, receipt and amount of sales, profit sharing or royalties, if any, from our potential products;
- the cost of preparing, filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights
- the extent to which we acquire or invest in businesses, products or technologies, although we currently have no commitments or agreements relating to any of these types of transactions;
- the compliance and administrative costs associated with being a public company; and
- the cost of attracting, hiring and retaining additional administrative, clinical, regulatory and scientific personnel.

Based on our current business plans, we believe that our existing cash, cash equivalents and marketable securities which include the net proceeds generated from our IPO in February 2019, will be sufficient to fund our planned operations for at least the next 12 months from the issuance date of the financial statements. However, we will require additional funding in order to complete development of our product candidates and commercialize our products, if approved. We may seek to raise any necessary additional capital through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing and distribution arrangements. There can be no assurance that we will be successful in acquiring additional funding at levels sufficient to fund our operations or on terms favorable to us. If we are unable to obtain adequate financing when needed, we may have to delay, reduce the scope of or suspend one or more of our preclinical studies and clinical trials, research and development programs or commercialization efforts. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates and the extent to which we may enter into additional collaborations with third parties to participate in their development and commercialization, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated preclinical studies and clinical trials. To the extent that we raise additional capital through additional collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our product candidates, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. If we do raise additional capital through public or private equity or convertible debt 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.

Please see the section entitled “Risk Factors” for additional risks associated with our substantial capital requirements and the challenges we may face in raising capital.

Cash Flows

	Six Months Ended June 30,	
	2019	2018
	(In thousands)	
Net cash (used in) provided by:		
Operating activities	\$ (25,372)	\$ (13,580)
Investing activities	(82,852)	(315)
Financing activities	70,825	32
Net increase (decrease) in cash, cash equivalents, and restricted cash	<u>\$ (37,399)</u>	<u>\$ (13,863)</u>

Cash Flows from Operating Activities

During the six months ended June 30, 2019, cash used in operating activities was \$25.4 million, which consisted of a net loss of \$25.4 million and a net change of \$2.0 million in our net operating assets and liabilities, partially offset by \$2.0 million in non-cash charges. The non-cash charges consisted of stock-based compensation of \$0.8 million, depreciation and amortization of \$0.6 million, amortization operating right-of-use lease asset of \$0.8 million, and net amortization of premiums and discounts on marketable securities of \$0.2 million. The change in operating assets and liabilities was primarily due to an increase of \$1.4 million in other current assets primarily due to insurance recovery related to Maverick litigation, an increase in prepaid expenses of \$1.3 million resulting from the timing payments for operating costs to support our operations as a public company and timing of payments made for ongoing research and development activities, an increase in accounts payable and other current liabilities of \$0.5 million, a decrease of \$3.1 million in other assets due to the recognition of deferred IPO costs, and a decrease in deferred revenue of \$2.1 million resulting from the recognition of collaboration revenue.

During the six months ended June 30, 2018, cash used in operating activities was \$13.6 million, which consisted of a net loss of \$10.9 million, partially offset by \$0.6 million in non-cash charges and a net change of \$3.3 million in our net operating assets and liabilities. The non-cash charges primarily consisted of stock-based compensation of \$0.3 million and depreciation and amortization of \$0.3 million. The change in operating assets and liabilities was primarily due to a decrease in deferred revenue of \$2.1 million resulting from the recognition of collaboration revenue, a decrease in accounts payable and accrued liabilities of \$0.4 million due to timing of research and development activities, and an increase in prepaid expenses and other current assets of \$0.8 million resulting from the timing of payments made for research and development activities.

Cash Flows from Investing Activities

During the six months ended June 30, 2019, cash used in investing activities of \$82.9 million was primarily related to purchases of marketable securities and property and equipment consisting primarily of laboratory equipment.

During the six months ended June 30, 2018, cash used in investing activities of \$0.3 million was primarily related to purchases of property and equipment consisting primarily of laboratory equipment.

Cash Flows from Financing Activities

During the six months ended June 30, 2019, cash provided by financing activities of \$70.8 million was primarily related to the proceeds received from our IPO in February 2019.

During the six months ended June 30, 2018, cash provided by financing activities was primarily due to proceeds from the issuance of common stock upon the exercise of stock options.

Contractual Obligations and Other Commitments

The following table summarizes our contractual obligations as of June 30, 2019:

	Payments due by period				Total
	Less than 1 year	1 to 3 years	4 to 5 years	After 5 years	
	(In thousands)				
Operating lease obligations	\$ 952	\$ 7,699	\$ 5,549	\$ 7,433	\$ 21,633
Total	\$ 952	\$ 7,699	\$ 5,549	\$ 7,433	\$ 21,633

The obligations noted above represent operating lease obligations related to our occupied premises at 4000 Shoreline Court in South San Francisco, California that commenced in March 2017 and expired in July 2019. In addition, in August 2018, we entered into an operating lease for our new office and laboratory space in South San Francisco, California that consists of approximately 35,000 square feet of new office and laboratory space. We moved into the new facility on July 1, 2019 and the lease expires eight years from that date. We have estimated it will cost approximately \$10.3 million to build-out the facility to meet our operational requirements. The lease provides for a tenant improvement allowance of approximately \$5.2 million and the option for an additional tenant improvement allowance of approximately \$1.4 million. The additional tenant improvement allowance of \$1.4 million would be treated as a loan from the landlord and is expected to be paid back (including interest) by us through additional rental payments. In December 2018, we exercised this option for the use of the additional tenant improvement allowance of \$1.4 million. As of June 30, 2019, we utilized the full tenant improvement allowance of \$6.6 million. The initial annual base rent is approximately \$2.2 million, and such amount will increase by 3.5% annually on each anniversary of the commencement date, equaling approximately \$20.0 million over the eight-year lease term. In connection with the lease, we will maintain a letter of credit for the benefit of the landlord in the amount of \$0.5 million.

In December 2016, we entered into a royalty transfer agreement with MPM Oncology Charitable Foundation, Inc. and UBS Optimus Foundation pursuant to which we will pay 0.5% of our annual global net sales to each of the counterparties for products that incorporate or utilize intellectual property that was discovered or developed by us prior to our IPO.

In October 2015, we entered into a collaboration and license agreement with AGC Biologics, Inc. (formerly known as CMC ICOS Biologics, Inc.), or AGC, for certain manufacturing-related technology, and in July 2016, we entered into a development and manufacturing agreement with AGC. Pursuant to these agreements, so long as AGC is our exclusive manufacturer, we will not owe AGC any milestone or royalty payments for the use of their manufacturing technology. However, if AGC is no longer our exclusive manufacturer, and we still use such technology, we will owe AGC specified milestones of up to \$350,000 per specified product and a royalty on net sales of these products of less than 1%. We have an option to buy out these royalty obligations by making a one-time payment to AGC in a dollar amount in the mid-single digit millions.

In addition, we enter into agreements in the normal course of business with contract research organizations for clinical trials and with vendors for preclinical studies and other services and products for operating purposes, which are generally cancelable upon written notice. These payments are not included in this table of contractual obligations.

Off-Balance Sheet Arrangements

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

Critical Accounting Policies and Estimates

The preparation of financial statements requires the use of estimates and assumptions that affect the reported amounts of assets and liabilities and the reported amounts of revenue and expenses. Our critical accounting policies are those that significantly impact our financial condition and results of operations and require the most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain. Because of this uncertainty, actual results may vary from these estimates. There have been no material changes to our critical accounting policies during the six months ended June 30, 2019 from those described in “—Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations” included in our 2018 Annual Report on Form 10-K for the year ended December 31, 2018, as filed with the SEC on March 14, 2019.

Recently Issued Accounting Pronouncements

See Note 2 to our condensed financial statements included elsewhere in this report for more information.

Emerging Growth Company Status

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. We 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 that 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. We expect to use the extended transition period for any other new or revised accounting standards during the period in which we remain an emerging growth company.

We will remain an emerging growth company until the earliest of (i) the last day of our first fiscal year (a) following the fifth anniversary of the completion of our IPO, (b) in which we have total annual gross revenues of at least \$1.07 billion or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds \$700.0 million as of the prior June 30th and (ii) the date on which we have issued more than \$1.0 billion in non-convertible debt securities during the prior three-year period.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended, or the Exchange Act) as of the end of the period covered by this Quarterly Report on Form 10-Q. Our disclosure controls and procedures are designed at a reasonable assurance level and are effective to provide reasonable assurance that information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosures.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the period ended June 30, 2019 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitation on the Effectiveness of Internal Control

The effectiveness of any system of internal control over financial reporting, including ours, is subject to inherent limitations, including the exercise of judgment in designing, implementing, operating, and evaluating the controls and procedures, and the inability to eliminate misconduct completely. Accordingly, in designing and evaluating the disclosure controls and procedures, management recognizes that any system of internal control over financial reporting, including ours, no matter how well designed and operated, can only provide reasonable, not absolute assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply its judgment in evaluating the benefits of possible controls and procedures relative to their costs. Moreover, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. We intend to continue to monitor and upgrade our internal controls as necessary or appropriate for our business, but cannot assure you that such improvements will be sufficient to provide us with effective internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, we may become involved in legal proceedings arising in the ordinary course of our business. On January 3, 2019, Maverick Therapeutics, Inc., or Maverick, filed a complaint against us in the Delaware Court of Chancery and a motion for a temporary restraining order seeking to prohibit us from further developing our ProTriTAC platform. The complaint alleges various claims for breach of contract and misappropriation of trade secrets, and seeks as relief, among other things, a declaration that our ProTriTAC technology impermissibly competes in the Maverick Field (as defined in our Asset Transfer Agreement with Maverick), a preliminary and permanent injunction and unspecified damages. On January 18, 2019, the Court denied Maverick's motion for a temporary restraining order. We believe that the mechanism of action employed by our ProTriTAC platform falls outside the Maverick Field. On May 8, 2019, Millennium Pharmaceuticals, Inc., or Millennium, a wholly owned subsidiary of Takeda Pharmaceutical Company Limited, was granted permission by the court to intervene in the litigation based on a proposed complaint. Millennium and Maverick are parties to a collaboration agreement and a warrant agreement, and Millennium's proposed complaint alleges, in part, that we fraudulently induced Millennium to enter into the agreements with Maverick. Millennium seeks to assert various tort claims against us. We will vigorously defend the claims asserted against us.

We are not currently a party to any other material legal proceedings. Regardless of outcome, litigation can have an adverse impact on us due to defense and settlement costs, diversion of management resources, negative publicity, reputational harm and other factors.

Item 1A. Risk Factors

Risks Related to Our Business and Industry

We are an early clinical-stage company and have incurred significant losses since our inception. We expect to incur losses for the foreseeable future and may never achieve or maintain profitability.

We are an early clinical-stage immunotherapy company with a limited operating history. We have incurred net losses of \$25.4 million and \$10.9 million for the six months ended June 30, 2019 and 2018, respectively. As of June 30, 2019, we had an accumulated loss of \$88.0 million. Our losses have resulted principally from expenses incurred in research and development of our product candidates and from management and administrative costs and other expenses that we have incurred while building our business infrastructure. We expect to continue to incur significant operating losses for the foreseeable future as we continue our research and development efforts and seek to obtain regulatory approval and commercialization of our product candidates. We anticipate that our expenses will increase substantially as we:

- conduct our ongoing Phase 1 trial of HPN424 for the treatment of metastatic castration-resistant prostate cancer, or mCRPC;
- conduct our ongoing Phase 1/2a trial of HPN536 for the treatment of ovarian cancer and other MSLN-expressing tumors;
- continue the research and development of our other product candidates;
- continue the development of our product candidates beyond Phase 1 trials;
- seek to enhance our TriTAC and ProTriTAC platforms and discover and develop additional product candidates;
- apply for regulatory approvals for any product candidates that successfully complete clinical trials;
- potentially establish a manufacturing, sales, marketing and distribution infrastructure to produce and commercialize any products for which we may obtain regulatory approvals;
- maintain, expand and protect our intellectual property portfolio;
- add clinical, scientific, operational, financial and management information systems and personnel, including personnel to support our product development, potential future commercialization efforts and operations as a public company; and
- experience any delays or encounter any issues with any of the above, including but not limited to failed studies, complex results, manufacturing challenges, safety issues or other regulatory challenges.

We have financed our operations to date primarily through private financings, payments received under collaboration and licensing agreements, and the proceeds from our IPO, which was completed in February 2019. We have devoted a significant portion of our financial resources and efforts to developing our TriTAC and ProTriTAC platforms, identifying potential product candidates, conducting preclinical studies of a variety of product candidates, and preparing for and conducting clinical trials of product candidates. We are in the early stages of development of our product candidates, and we have not completed development and commercialization of any TriTAC or ProTriTAC product candidate.

To become and remain profitable, we must succeed in developing and eventually commercializing products that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing preclinical testing and clinical trials of our product candidates, discovering and developing additional product candidates, obtaining regulatory approval for any product candidates that successfully complete clinical trials, accessing manufacturing capacity, establishing marketing capabilities and ultimately selling any products for which we may obtain regulatory approval. We are only in the preliminary stages of most of these activities. We may never succeed in these activities and, even if we do, may never generate revenue that is significant enough to achieve profitability.

Because of the numerous risks and uncertainties associated with pharmaceutical products and biological 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. If we are required by the FDA or other regulatory authorities to perform studies in addition to those we currently anticipate, or if there are any delays in completing our clinical trials or the development of any of our product candidates, our expenses could increase and commercial revenue could be further delayed and more uncertain.

Even if we do generate product sales or royalties, we may never achieve or sustain profitability on a quarterly or annual basis. Our failure to sustain profitability would depress the market price of our common stock and could impair our ability to raise capital, expand our business, diversify our product offerings and continue our operations.

We will require additional funding in order to complete development of our product candidates and commercialize our products, if approved. 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 our expenses to increase in connection with our ongoing activities, particularly as we conduct our ongoing clinical trial of HPN424 and Phase 1/2a trial of HPN536 and continue to research, develop and conduct studies related to HPN424 and HPN536 and preclinical studies of our other product candidates.

In addition, if we obtain regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. Furthermore, we will incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts.

Based on our current business plans, we believe that our existing cash and cash equivalents will be sufficient to fund our planned operations for the next 12 months. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect, requiring us to seek additional funds sooner than planned, through public or private equity or debt financings or other sources, such as strategic collaborations. Such financing may result in dilution to stockholders, the imposition of burdensome debt covenants and repayment obligations or other restrictions that may affect our business. If we raise additional funds through licensing or collaboration arrangements with third parties, we may have to relinquish valuable rights to our product candidates, or grant licenses on terms that are not favorable to us. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. Attempting to secure additional financing may divert our management from our day-to-day activities, which may adversely affect our ability to develop our product candidates. Our future capital requirements will depend on many factors, including:

- the scope, progress, results and costs of developing our product candidates, and conducting preclinical studies and clinical trials, including our Phase 1 trial of HPN424 and Phase 1/2a trial of HPN536;
- the costs, timing and outcome of regulatory review of any of our product candidates;
- the cost of manufacturing clinical supplies of our product candidates;
- the scope, progress, results and costs of preclinical development, laboratory testing and clinical trials for our product candidates;
- the costs and timing of future commercialization activities, including manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive marketing approval;
- the timing and amount of any milestone, royalty or other payments we are required to make pursuant to any current or future collaboration or license agreements;
- the progress of our collaboration with AbbVie to develop product candidates;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims, including any claims by third parties that we are infringing upon their intellectual property rights;

- our ability to maintain existing, and establish new, strategic collaborations, licensing or other arrangements and the financial terms of any such agreements, including the timing and amount of any future milestone, royalty or other payments due under any such agreement;
- the cost of building a sales force in anticipation of product commercialization;
- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
- the effect of competing technological and market developments; and
- the extent to which we acquire or invest in business, products and technologies, including our collaboration with AbbVie and any other licensing or collaboration arrangements for any of our product candidates.

Additional funds may not be available when we need them, on terms that are acceptable to us or at all. If adequate funds are not available to us on a timely basis, we could be required to:

- delay, limit, reduce or terminate preclinical studies, clinical trials or other research and development activities or eliminate one or more of our development programs altogether; or
- delay, limit, reduce or terminate our efforts to access manufacturing capacity, establish sales and marketing capabilities or other activities that may be necessary to commercialize our product candidates, or reduce our flexibility in developing or maintaining our sales and marketing strategy.

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

We depend heavily on the success of our current product candidates, and we cannot guarantee that any of these product candidates will receive regulatory approval, which is necessary before they can be commercialized. If we, or any strategic partners we may enter into collaboration agreements with for the development and commercialization of our product candidates, are unable to commercialize our product candidates, or experience significant delays in doing so, our business, financial condition and results of operations will be materially adversely affected.

We have invested a significant portion of our efforts and financial resources in the development of our current product candidates. Our ability to generate product and royalty revenues, which we do not expect will occur for at least the next several years, if ever, will depend heavily on the successful development and eventual commercialization of these product candidates, which may never occur. We currently generate no revenues from sales of any products, and we may never be able to develop or commercialize a marketable product. Each of our product candidates will require significant clinical development, management of clinical, preclinical and manufacturing activities, regulatory approval in multiple jurisdictions, obtaining manufacturing supply, including commercial manufacturing supply, as well as requiring us to build a commercial organization, and make substantial investment and significant marketing efforts before we generate any revenues from product sales. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the FDA or comparable foreign regulatory authorities, and we may never receive such regulatory approval for any of our product candidates. The success of our product candidates will depend on several factors, including the following:

- for product candidates which we may license to others, the successful efforts of those parties in completing clinical trials of, receipt of regulatory approval for and commercialization of such product candidates;
- for product candidates to which we retain rights, completion of preclinical studies and clinical trials of, receipt of marketing approvals for, establishment of commercial manufacturing supplies of and successful commercialization of such product candidates; and
- for all of our product candidates, if and when approved, acceptance of such product candidates by patients, the medical community and third-party payors, effectively competing with other therapies, a continued acceptable safety profile following approval and qualifying for, maintaining, enforcing and defending our intellectual property rights and claims.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize our product candidates, which would materially adversely affect our business, financial condition and results of operations.

We have not previously submitted a Biologics License Application, or BLA, to the FDA or similar regulatory approval filings to comparable foreign authorities, for any product candidate, and we cannot be certain that any of our product candidates will be successful in clinical trials or receive regulatory approval. Further, our product candidates may not receive regulatory approval even if they are successful in clinical trials. If we do not receive regulatory approvals for our product candidates, we may not be able to continue our operations. Even if we successfully obtain regulatory approvals to market one or more of our product candidates, our revenues will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval and have commercial rights. If the markets for patient subsets that we are targeting are not as significant as we estimate, we may not generate significant revenues from sales of such products, if approved.

We plan to seek regulatory approval to commercialize our product candidates in the United States and, potentially, in other countries. While the scope of regulatory approval is similar in other countries, to obtain separate regulatory approval in many other countries we must comply with the numerous and varying regulatory requirements of such countries regarding safety and efficacy and governing, among other things, clinical trials and commercial sales, pricing and distribution of our product candidates, and we cannot predict success in these jurisdictions.

Our TriTAC and ProTriTAC platforms are unproven, novel classes of T cell engagers and may not result in approvable or marketable products, which exposes us to unforeseen risks and makes it difficult for us to predict the time and cost of product development and potential for regulatory approval.

We have not received regulatory approval for a TriTAC or ProTriTAC product candidates. We cannot be certain that our approach will lead to the development of approvable or marketable products, alone or in combination with other therapies. In addition, our TriTACs and ProTriTACs may have different effectiveness rates in various indications. Our approach involves using biologics to improve efficacy against solid tumors, which is unproven and may not be successful. Further, our TriTAC and ProTriTAC technology could have less efficacy in tumor types with fewer T cells, such as pancreatic cancer. While we believe TriTAC and ProTriTAC T cell engagers will demonstrate potent single-agent activity and therapeutic effect, immunotherapy companies and standard of care continue to evolve toward the use of combination therapies and we may be unsuccessful in developing any of our product candidates as monotherapies. With our TriTAC and ProTriTAC platforms, we have designed T cell engagers that incorporate the strengths of BiTEs and improve upon their critical shortcomings. However, only one BiTE (Amgen's Blincyto) has been approved for the treatment of cancer, and leveraging BiTE technology may not result in approved therapies or be as successful as other forms of therapies. Finally, the FDA or other regulatory agencies may lack experience in evaluating the safety and efficacy of our TriTACs or ProTriTACs, which could result in a longer than expected regulatory review process, increase our expected development costs and delay or prevent commercialization of our product candidates.

We may not be successful in our efforts to use and expand our technology platforms, including TriTAC and ProTriTAC, to build a pipeline of product candidates.

A key element of our strategy is to use and expand our technology platforms, including TriTAC and ProTriTAC, to build a pipeline of product candidates and progress these product candidates through clinical development for the treatment of a variety of different types of diseases. Although our research and development efforts to date have resulted in a pipeline of product candidates directed at various cancers, we may not be able to develop product candidates that are safe and effective. Even if we are successful in continuing to build our pipeline, the potential 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 be products that will receive marketing approval and achieve market acceptance. If we do not continue to successfully develop and begin to commercialize product candidates, we will face difficulty in obtaining product revenues in future periods, which could result in significant harm to our financial position and adversely affect our share price.

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

From time to time, we may publish interim and/or preliminary data from our clinical studies. For example, in January 2019, we announced preliminary data from seven patients who had been enrolled in our Phase 1 clinical trial of HPN424, our lead TriTAC product candidate, as of December 31, 2018. Interim and preliminary data for the trials we may complete are subject to the risk that one or more clinical outcomes may materially change as patient enrollment continues and/or more patient data become available. Interim and preliminary data also remains subject to audit and verification procedures that may result in the final data being materially different from the preliminary data previously published. As a result, any interim and/or preliminary data should be viewed with caution until final data is available. Material adverse changes in the final data could result in significant harm to our business prospects.

Results of earlier preclinical studies of our product candidates may not be predictive of future trial results.

Success in preclinical studies does not ensure that later clinical trials will be successful. 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. 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, we cannot be certain that we will not face similar setbacks. In addition, the results of our preclinical animal studies, including our non-human primate studies, may not be predictive of the results of outcomes in human clinical trials. For example, while we did not observe unacceptable safety events in our preclinical testing of HPN536, given the expression of MSLN on both normal and cancerous cells, we may observe unacceptable levels of toxicity when HPN536 is tested in humans. Product candidates in later stages of clinical trials may fail to show the desired pharmacological properties or safety and efficacy traits despite having progressed through preclinical studies.

The manufacture of our TriTAC and ProTriTAC product candidates is complex. We and our third-party manufacturers may encounter difficulties in production. If we encounter any such difficulties, our ability to supply our product candidates for clinical trials or, if approved, for commercial sale could be delayed or halted entirely.

The manufacture of biopharmaceutical products is complex and requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. The process of manufacturing our product candidates 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 production process. 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. All of our TriTACs and ProTriTACs are manufactured from a vial of a master cell bank of that antibody's production cell line. We have or intend to have one master cell bank for each TriTAC and ProTriTAC that was or will be produced and tested in accordance with current good manufacturing practice, or cGMP, and applicable regulations. Each master cell bank is or will be stored in two independent locations, and we intend to produce working cell banks for each product candidate later in product development. It is possible that we could lose multiple cell banks from multiple locations and have our manufacturing severely impacted by the need to replace the cell banks. However, we believe we have adequate backup should any particular cell bank be lost in a catastrophic event. Any adverse developments affecting manufacturing operations for our product candidates, if any are approved, may result in shipment delays, inventory shortages, lot failures, product withdrawals or recalls, or other interruptions in the supply of our products. We may also have to take inventory write-offs and incur other charges and expenses for products that fail to meet specifications as a result of defects or storage over an extended period of time, undertake costly remediation efforts or seek more costly manufacturing alternatives.

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

Since commencing operations in 2015, we have devoted a significant portion of our resources to developing our product candidates, our other research and development efforts, building our intellectual property portfolio, raising capital and providing general and administrative support for these operations. While we have an ongoing Phase 1 trial of HPN424 and Phase 1/2a trial of HPN536, we have not completed any clinical trials for any product candidate. We have not yet demonstrated our ability to successfully complete any clinical trials (including any Phase 3 or other pivotal clinical trials), obtain regulatory 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. Additionally, we expect our financial condition and operating results to continue to fluctuate significantly from period to period due to a variety of factors, many of which are beyond our control. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history.

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

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through equity or debt financings and upfront and milestone payments, if any, received under our collaboration with AbbVie and any other future licenses or collaborations, together with our existing cash and cash equivalents. In order to accomplish our business objectives and further develop our product pipeline, we will, however, need to seek additional funds. If we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a holder of our common stock. In addition, the possibility of such issuance may cause the market price of our common stock to decline. Debt financing, if available, may result in increased fixed payment obligations and involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, declaring dividends or acquiring, selling or licensing intellectual property rights, which could adversely impact our ability to conduct our business.

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 intellectual property, technologies, future revenue streams or product candidates or grant licenses on terms that may not be favorable to us. We could also be required to seek funds through arrangements with collaborators or others at an earlier stage than otherwise would be desirable. Any of these occurrences may have a material adverse effect on our business, operating results and prospects.

Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. If we are unable to obtain funding on a timely basis, we may be required to significantly curtail, delay or discontinue one or more of our research or development programs or the commercialization of any of our product candidates, or be unable to expand our operations or otherwise capitalize on our business opportunities, as desired, which could materially affect our business, financial condition and results of operations.

Our business may become subject to economic, political, regulatory and other risks associated with international operations.

Our business is subject to risks associated with conducting business internationally. Accordingly, our future results could be harmed by a variety of factors, including:

- economic weakness, including inflation, or political instability, particularly in foreign economies and markets;
- differing regulatory requirements for drug approvals in foreign countries;
- differing jurisdictions could present different issues for securing, maintaining and/or obtaining freedom to operate in such jurisdictions;
- potentially reduced protection for intellectual property rights;
- difficulties in compliance with foreign laws and regulations;
- changes in foreign regulations and customs, tariffs and trade barriers;
- changes in foreign currency exchange rates and currency controls;
- changes in a specific country's or region's political or economic environment;
- trade protection measures, import or export licensing requirements or other actions by the U.S. or foreign governments;
- differing reimbursement regimes and price controls in certain foreign markets;
- negative consequences from changes in tax laws;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- difficulties associated with staffing and managing international operations, including differing labor relations;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism, or natural disasters, including earthquakes, typhoons, floods and fires.

Risks from improper conduct by our employees, agents, contractors or collaborators could adversely affect our reputation, business, prospects, operating results and financial condition.

We cannot ensure that our compliance controls, policies and procedures will in every instance protect us from acts committed by our employees, agents, contractors or collaborators that would violate the laws or regulations of the jurisdictions in which we operate, including, without limitation, employment, foreign corrupt practices, trade restrictions and sanctions, environmental, competition and patient privacy and other privacy laws and regulations. Such improper actions could subject us to civil or criminal investigations and monetary and injunctive penalties, and could adversely impact our ability to conduct business, operating results and reputation.

We are subject to a number of anti-corruption laws, including the U.S. Foreign Corrupt Practices Act, or FCPA, and the U.K. Bribery Act. Our failure to comply with anti-corruption laws applicable to us could result in penalties, which could harm our reputation and harm our business, financial condition, results of operations, cash flows or prospects. The FCPA generally prohibits companies and their intermediaries from making improper payments to foreign officials for the purpose of obtaining or keeping business and/or other benefits. The FCPA also requires public companies to maintain accurate books and records and devise a system of sufficient internal accounting controls. We regularly review and update our policies and procedures and internal controls designed to provide reasonable assurance that we, our employees, distributors and other intermediaries comply with the anti-corruption laws to which we are subject. However, there are inherent limitations to the effectiveness of any policies, procedures and internal controls, including the possibility of human error and the circumvention or overriding of the policies, procedures and internal controls. There can be no assurance that such policies or procedures or internal controls will work effectively at all times or protect us against liability under these or other laws for actions taken by our employees, distributors and other intermediaries with respect to our business.

The SEC and the Department of Justice continue to view FCPA enforcement activities as a high priority. There is no certainty that all of our employees, agents, contractors or collaborators, or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers or our employees, requirements to obtain export licenses, cessation of business activities in sanctioned countries, implementation of compliance programs and prohibitions on the conduct of our business. Any such violations could materially damage our reputation, our brand, our international operations, our ability to attract and retain employees, and our business, prospects, operating results, and financial condition.

Our future growth and ability to compete depends on retaining our key personnel and recruiting additional qualified personnel.

Our success depends upon the continued contributions of our key management, scientific and technical personnel, many of whom have been instrumental for us and have substantial experience with our therapies and related technologies. The loss of key managers and senior scientists could delay our research and development activities. In addition, the competition for qualified personnel in the biopharmaceutical and pharmaceutical field is intense, and our future success depends upon our ability to attract, retain and motivate highly-skilled scientific, technical and managerial employees. We face competition for personnel from other companies, universities, public and private research institutions and other organizations. If our recruitment and retention efforts are unsuccessful in the future, it may be difficult for us to implement business strategy, which could have a material adverse effect on our business.

We conduct substantially all of our operations at our facilities in South San Francisco, California. This region is headquarters to many other biopharmaceutical companies and many academic and research institutions. Competition for skilled personnel in this region is intense and may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all.

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

As of July 31, 2019, we had 54 full-time employees. We expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of drug development, regulatory affairs and sales and marketing. 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.

In addition, future growth imposes significant added responsibilities on members of management, including: identifying, recruiting, integrating, maintaining and motivating additional employees; managing our internal development efforts effectively, including the clinical and FDA review process for our product candidates, while complying with our contractual obligations to contractors and other third parties; and improving our operational, financial and management controls, reporting systems and procedures. Our future financial performance and our ability to commercialize our product candidates will depend, in part, on our ability to effectively manage our growth, and our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

We rely or expect to rely in substantial part on certain independent organizations, advisors and consultants to provide certain services, including strategic, financial, business development services, as well as substantial aspects of regulatory approval, clinical management, manufacturing and preparation for potential commercial launch. There can be no assurance that the services of independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by consultants or contract manufacturing organizations is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval of our product candidates or otherwise advance our business. There can be no assurance that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, or at all.

If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, we may not be able to successfully implement the tasks necessary to further develop and commercialize our product candidates and, accordingly, may not achieve our research, development and commercialization goals.

Acquisitions or joint ventures could disrupt our business, cause dilution to our stockholders and otherwise harm our business.

We actively evaluate various strategic transactions on an ongoing basis. We may acquire other businesses, products or technologies as well as pursue strategic alliances, joint ventures or investments in complementary businesses. Any of these transactions could be material to our financial condition and operating results and expose us to many risks, including:

- disruption in our relationships with existing strategic partners or suppliers as a result of such a transaction;
- unanticipated liabilities related to acquired companies or joint ventures;
- difficulties integrating acquired personnel, technologies and operations into our existing business;
- retention of key employees;

- diversion of management time and focus from operating our business to management of strategic alliances or joint ventures or acquisition integration challenges;
- increases in our expenses and reductions in our cash available for operations and other uses; and
- possible write-offs or impairment charges relating to acquired businesses.

In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic alliance or other alternative arrangements for our product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view our product candidates as having the requisite potential to demonstrate safety and efficacy. Any delays in entering into new strategic transactions related to our product candidates could delay the development and commercialization of our product candidates in certain geographies for certain indications, which would harm our business prospects, financial condition and results of operations.

Foreign acquisitions involve unique risks in addition to those mentioned above, including those related to integration of operations across different cultures and languages, currency risks, potentially adverse tax consequences of overseas operations and the particular economic, political and regulatory risks associated with specific countries.

The anticipated benefit of any strategic alliance, joint venture or acquisition may not materialize or such strategic alliance, joint venture or acquisition may be prohibited. Additionally, future acquisitions or dispositions could result in potentially dilutive issuances of our equity securities, the incurrence of debt, contingent liabilities or amortization expenses or write-offs of goodwill, any of which could harm our financial condition. We cannot predict the number, timing or size of future joint ventures or acquisitions, or the effect that any such transactions might have on our operating results.

Risks Related to the Development and Clinical Testing of Our Product Candidates

All of our product candidates are in preclinical or early-stage clinical development. Clinical drug development is a lengthy and expensive process with uncertain timelines and uncertain outcomes. If clinical trials of our product candidates are prolonged or delayed, we or any collaborators may be unable to obtain required regulatory approvals, and therefore be unable to commercialize our product candidates on a timely basis or at all.

To obtain the requisite regulatory approvals to market and sell any of our product candidates, we or any collaborator for such candidates must demonstrate through extensive preclinical studies and clinical trials that our product candidates are safe and effective in humans. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies and early-stage clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. 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. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Our future clinical trial results may not be successful.

To date, we have not completed any clinical trials required for the approval of any of our product candidates. Although we are conducting a Phase 1 trial of HPN424 and a Phase 1/2a trial of HPN536 and are conducting preclinical studies for other product candidates, we may experience delays in our ongoing clinical trials, and we do not know whether planned clinical trials will begin on time, need to be redesigned, enroll patients on time or be completed on schedule, if at all. Clinical trials can be delayed, suspended, or terminated for a variety of reasons, including the following:

- delays in or failure to reach agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- difficulty in recruiting clinical trial investigators of appropriate competencies and experience;
- delays in establishing the appropriate dosage levels in clinical trials;
- delays in or failure to recruit and enroll suitable patients to participate in a trial;
- the difficulty in certain countries in identifying the sub-populations that we are trying to treat in a particular trial, which may delay enrollment and reduce the power of a clinical trial to detect statistically significant results;
- lower than anticipated retention rates of patients in clinical trials;
- failure to have patients complete a trial or return for post-treatment follow-up;
- clinical sites deviating from trial protocol or dropping out of a trial;

- adding new clinical trial sites;
- safety or tolerability concerns could cause us or our collaborators or governmental authorities, as applicable, to suspend or terminate a trial if it is found that the participants are being exposed to unacceptable health risks;
- delays in or failure to obtain regulatory approval to commence a trial;
- delays in or failure to obtain institutional review board, or IRB, approval at each site;
- our third-party research contractors failing to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- changes in regulatory requirements, policies and guidelines;
- manufacturing sufficient quantities of a product candidate for use in clinical trials;
- the quality or stability of a product candidate falling below acceptable standards;
- changes in the treatment landscape for our target indications that may make our product candidates no longer relevant;
- third-party actions claiming infringement by our product candidates in clinical trials outside the United States and obtaining injunctions interfering with our progress; and
- business interruptions resulting from geo-political actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires.

We could encounter delays if a clinical trial is suspended or terminated by us, by the IRBs or Ethics Committees of the institutions in which such trials are being conducted, by the Data Review Committee or Data Safety Monitoring Board for such trial or by the FDA, or other regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. If we experience delays in the completion of, or termination of, any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues. Significant clinical trial delays could also allow our competitors to bring products to market before we do or shorten any periods during which we have the exclusive right to commercialize our product candidates and impair our ability to commercialize our product candidates and may harm our business and results of operations.

Any of these occurrences may harm our business, financial condition and prospects significantly. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

Clinical trials must be conducted in accordance with the FDA and other applicable regulatory authorities' legal requirements, regulations or guidelines, and are subject to oversight by these governmental agencies and Ethics Committees or IRBs at the medical institutions where the clinical trials are conducted. In addition, clinical trials must be conducted with supplies of our product candidates produced under cGMP requirements and other regulations. Furthermore, we rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials and while we have agreements governing their committed activities, we have limited influence over their actual performance. We depend on our collaborators and on medical institutions and CROs to conduct our clinical trials in compliance with good clinical practice, or GCP, requirements. To the extent our collaborators or the CROs fail to enroll participants for our clinical trials, fail to conduct the study to GCP standards or are delayed for a significant time in the execution of trials, including achieving full enrollment, we may be affected by increased costs, program delays or both, which may harm our business. In addition, clinical trials that are conducted in countries outside the United States may subject us to further delays and expenses as a result of increased shipment costs, additional regulatory requirements and the engagement of non-U.S. CROs, as well as expose us to risks associated with clinical investigators who are unknown to the FDA, and different standards of diagnosis, screening and medical care.

Our product candidates may have serious adverse, undesirable or unacceptable side effects or other properties which may delay or prevent marketing approval. If such side effects are identified during the development of our product candidates or following approval, if any, we may need to abandon our development of such product candidates, the commercial profile of any approved label may be limited, or we may be subject to other significant negative consequences following marketing approval, if any.

Undesirable side effects that may be caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign authorities. In August 2018, we commenced a Phase 1 trial of HPN424 for the treatment of mCRPC. In April 2019, we commenced a Phase 1/2a trial of HPN536, which targets MSLN. MSLN is expressed on malignant cells of multiple tumor types. Given the expression of MSLN on both normal and cancerous cells, HPN536 may result in high or unacceptable levels of

toxicity when tested in humans. Results of our trials could reveal a high and unacceptable severity and prevalence of these or other side effects. In such an event, our trials could be suspended or terminated, and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly. Additionally, if any of our product candidates receives marketing approval and we or others later identify undesirable or unacceptable side effects caused by such products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw or limit approvals of such products and require us to take our approved product off the market;
- regulatory authorities may require the addition of labeling statements, specific warnings, a contraindication or field alerts to physicians and pharmacies, or issue other communications containing warnings or other safety information about the product;
- regulatory authorities may require a medication guide outlining the risks of such side effects for distribution to patients, or that we implement a risk evaluation and mitigation strategy, plan to ensure that the benefits of the product outweigh its risks;
- we may be required to change the dose or the way the product is administered, conduct additional clinical trials or change the labeling of the product;
- we may be subject to limitations on how we may promote or manufacture the product;
- sales of the product may decrease significantly;
- we may be subject to litigation or product liability claims; and
- our reputation may suffer.

Any of these events could prevent us, our collaborators or our potential future partners from achieving or maintaining market acceptance of the affected product or could substantially increase commercialization costs and expenses, which in turn could delay or prevent us from generating significant revenue from the sale of any products.

Monitoring safety of patients receiving our product candidates is challenging, which could adversely affect our ability to obtain regulatory approval and commercialize.

For our ongoing clinical trial and planned clinical trials, we have and expect to contract with academic medical centers and hospitals experienced in the assessment and management of toxicities arising during clinical trials. Nonetheless, these centers and hospitals may have difficulty observing patients and treating toxicities, which may be more challenging due to personnel changes, inexperience, shift changes, house staff coverage or related issues. This could lead to more severe or prolonged toxicities or even patient deaths, which could result in us or the FDA delaying, suspending or terminating one or more of our clinical trials, and which could jeopardize regulatory approval. We also expect the centers using our product candidates, if approved, on a commercial basis could similarly have difficulty in managing adverse events. Medicines used at centers to help manage adverse side effects of our product candidates may not adequately control the side effects and/or may have a detrimental impact on the efficacy of the treatment. Use of these medicines may increase with new physicians and centers administering our product candidates.

We depend on enrollment of patients in our clinical trials for our product candidates. If we experience delays or difficulties enrolling in our clinical trials, our research and development efforts and business, financial condition and results of operations could be materially adversely affected.

Successful and timely completion of clinical trials will require that we enroll a sufficient number of patient candidates. These trials and other trials we conduct may be subject to delays as a result of patient enrollment taking longer than anticipated, patient withdrawal or adverse events. For example, we have an ongoing Phase 1 clinical trial for our lead product candidate, HPN424 and Phase 1/2a clinical trial for HPN536, which could generate adverse events that may cause us to delay these trials or halt further development. While adverse events to date related to our clinical trials have not had a material impact on patient enrollment, our experience to date may differ from future outcomes.

Our clinical trials will likely compete with other clinical trials that are in the same therapeutic areas as our product candidates, and this competition may reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Because the number of qualified clinical investigators and clinical trial sites is limited, we may conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which could reduce the number of patients who are available for our clinical trials at such clinical trial sites.

Patient enrollment depends on many factors, including the size and nature of the patient population, the severity of the disease under investigation, eligibility criteria for the trial, the proximity of patients to clinical sites, the design of the clinical protocol, the ability to obtain and maintain patient consents, the ability to recruit clinical trial investigators with the appropriate competencies and experience, the risk that patients enrolled in clinical trials will drop out of the trials before the administration of our product candidates or trial completion, the availability of competing clinical trials, the availability of new drugs approved for the indication the clinical trial is investigating, and clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies. These factors may make it difficult for us to enroll enough patients to complete our clinical trials in a timely and cost-effective manner. Delays in the completion of any clinical trial of our product candidates will increase our costs, slow down our product candidate development and approval process and delay or potentially jeopardize our ability to commence product sales and generate revenue. In addition, some of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

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

From time to time, we may publicly disclose preliminary or topline or data from our preclinical studies and clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the topline results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, topline data should be viewed with caution until the final data are available. From time to time, we may also disclose interim data from our preclinical studies and clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects. Further, disclosure of interim data by us or by our competitors could result in volatility in the price of our common stock.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general.

If the interim, topline, or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

We may become exposed to costly and damaging liability claims, either when testing our product candidates in the clinic or at the commercial stage, and our product liability insurance may not cover all damages from such claims.

We are exposed to potential product liability and professional indemnity risks that are inherent in the research, development, manufacturing, marketing and use of pharmaceutical products. While we currently have no products that have been approved for commercial sale, the current and future use of product candidates by us and our partners 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, our partners or others selling such products. Any claims against us, regardless of their merit, could be difficult and costly to defend and could materially adversely affect the market for our product candidates or any prospects for commercialization of our product candidates.

Although the clinical trial process is designed to identify and assess potential side effects, it is always possible that a drug, even after regulatory approval, may exhibit unforeseen side effects. If any of our product candidates were to cause adverse side effects during clinical trials or after approval of the product candidate, we may be exposed to substantial liabilities. Physicians and patients may not comply with any warnings that identify known potential adverse effects and patients who should not use our product candidates.

Even successful defense against product liability claims would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in: decreased demand for our product candidates; injury to our reputation; withdrawal of clinical trial participants; initiation of investigations by regulators; costs to defend the related litigation; a diversion of management's time and our resources; substantial monetary awards to trial participants or patients; product recalls, withdrawals or labeling, marketing or promotional restrictions; loss of revenue; exhaustion of any available insurance and our capital resources; the inability to commercialize any product candidate; and a decline in our share price.

Although we maintain adequate product liability insurance for our product candidates, it is possible that our liabilities could exceed our insurance coverage. We intend to expand our insurance coverage to include the sale of commercial products if we obtain marketing approval for any of our product candidates. However, we may not be able to maintain insurance coverage at a reasonable cost or obtain insurance coverage that will be adequate to satisfy any liability that may arise. If a successful 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.

The development and commercialization of biopharmaceutical products is subject to extensive regulation, and the regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable. If we are ultimately unable to obtain regulatory approval for our product candidates on a timely basis if at all, our business will be substantially harmed.

The clinical development, manufacturing, labeling, packaging, storage, recordkeeping, advertising, promotion, export, import, marketing, distribution, adverse event reporting, including the submission of safety and other post-marketing information and reports, and other possible activities relating to our product candidates are subject to extensive regulation. In the United States, marketing approval of biologics requires the submission of a BLA to the FDA, and we are not permitted to market any product candidate in the United States until we obtain approval from the FDA of the BLA for that product. A BLA must be supported by extensive clinical and preclinical data, as well as extensive information regarding pharmacology, chemistry, manufacturing and controls. Outside the United States, many comparable foreign regulatory authorities employ similar approval processes.

FDA approval is not guaranteed, and the time required to obtain approval by the FDA and comparable foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. We have not obtained regulatory approval for any product candidate and it is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval.

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

- the FDA or comparable 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 or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable 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 or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of a BLA or other submission or to obtain regulatory approval in the United States or elsewhere, or regulatory authorities may not accept a submission due to, among other reasons, the content or formatting of the submission;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies;
- the FDA or comparable foreign regulatory authorities may fail to approve the companion diagnostics we contemplate developing with collaborators; and
- the approval policies or regulations of the FDA or comparable 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 future clinical trial results, may result in our failing to obtain regulatory approval to market any of our product candidates, which would significantly harm our business, results of operations and prospects. The FDA and other regulatory authorities have substantial discretion in the approval process, and determining when or whether regulatory approval will be obtained for any of our product candidates. For example, regulatory authorities in various jurisdictions have in the past had, and may in the future have, differing requirements for, interpretations of and opinions on our preclinical and clinical data. As a result, we may be required to conduct additional preclinical studies, alter our proposed clinical trial designs or conduct additional clinical trials to satisfy the regulatory authorities in each of the jurisdictions in which we hope to conduct clinical trials and develop and market our products, if approved. Further, even if we believe the data collected from clinical trials of our product candidates are promising, such data may not be sufficient to support approval by the FDA or any other regulatory authority.

In addition, 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.

Even if our product candidates obtain regulatory approval, we will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense. Additionally, our product candidates, if approved, could be subject to labeling and other restrictions and market withdrawal and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products.

If the FDA or a comparable foreign regulatory authority approves any of our product candidates, the manufacturing processes, labeling, packaging, distribution, import, export, adverse event reporting, storage, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs and GCPs for any clinical trials that we conduct post-approval, all of which may result in significant expense and limit our ability to commercialize such products. In addition, any regulatory approvals that we receive for our product candidates may also be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the product candidate.

Manufacturers and manufacturers' facilities are required to comply with extensive FDA and comparable foreign regulatory authority requirements, including ensuring that quality control and manufacturing procedures conform to cGMP regulations. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any approved marketing application. Accordingly, we and others with whom we work must continue to expend time, money, and effort in all areas of regulatory compliance, including manufacturing, production, and quality control.

If there are changes in the application of legislation or regulatory policies, or if problems are discovered with a product or our manufacture of a product, or if we or one of our distributors, licensees or co-marketers fails to comply with regulatory requirements, the regulators could take various actions. These include imposing fines on us, imposing restrictions on the product or its manufacture and requiring us to recall or remove the product from the market. The regulators could also suspend or withdraw our marketing authorizations, requiring us to conduct additional clinical trials, change our product labeling or submit additional applications for marketing authorization. If any of these events occurs, our ability to sell such product may be impaired, and we may incur substantial additional expense to comply with regulatory requirements, which could materially adversely affect our business, financial condition and results of operations.

In addition, if we have any product candidate approved, our product labeling, advertising and promotion will be subject to regulatory requirements and continuing regulatory review. The FDA strictly regulates the promotional claims that may be made about pharmaceutical products. In particular, a product may not be promoted for uses that are not approved by the FDA as reflected in the product's approved labeling. If we receive marketing approval for a product candidate, physicians may nevertheless prescribe it to their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off-label uses, we may become subject to significant liability. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant sanctions. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed.

If a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, or disagrees with the promotion, marketing or labeling of a product, such regulatory agency may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If we fail to comply with applicable regulatory requirements, a regulatory agency or enforcement authority may, among other things:

- issue warning letters;
- impose civil or criminal penalties;
- suspend or withdraw regulatory approval;
- suspend any of our preclinical studies and clinical trials;
- refuse to approve pending applications or supplements to approved applications submitted by us;
- impose restrictions on our operations, including closing our contract manufacturers' facilities; or
- seize or detain products, or require a product recall.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response, and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenue from our products, if approved. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of our company and our operating results will be adversely affected.

Moreover, the policies of the FDA and of other regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. For example, certain policies of the Trump administration may impact our business and industry. Namely, the Trump administration has taken several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. It is difficult to predict how these orders will be implemented, and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If these executive actions impose restrictions on the FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted. In addition, if we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

We may pursue the development of our product candidates in combination with other approved therapeutics. If the FDA revokes approval of any such therapeutic, or if safety, efficacy, manufacturing or supply issues arise with any therapeutic that we use in combination with one of our product candidates in the future, we may be unable to further develop and/or market our product candidate or we may experience significant regulatory delays or supply shortages, and our business could be materially harmed.

We may pursue the development of our product candidates in combination with other approved therapeutics, and we may commence clinical trials of our product candidates in combination with other approved therapeutics, in the future. In such a case, we will not have developed or obtained regulatory approval for, nor will we manufacture or sell, any of these approved therapeutics. In addition, the combinations will likely not have been previously tested and may, among other things, fail to demonstrate synergistic activity, may fail to achieve superior outcomes relative to the use of single agents or other combination therapies, may exacerbate adverse events associated with one of our product candidates when used as monotherapy or may fail to demonstrate sufficient safety or efficacy traits in clinical trials to enable us to complete those clinical trials or obtain marketing approval for the combination therapy.

If the FDA revokes its approval of any combination therapeutic, we would not be able to continue clinical development of or market any product candidate in combination with such revoked therapeutic. If safety or efficacy issues were to arise with therapeutics that we seek to combine with, we could experience significant regulatory delays, and the FDA could require us to redesign or terminate the applicable clinical trials. In addition, we may need, for supply, data referencing or other purposes, to collaborate or otherwise engage with the companies who market these approved therapeutics. If we are unable to do so on a timely basis, on acceptable terms or at all, we may have to curtail the development of a product candidate or indication, reduce or delay its development program, delay its potential commercialization or reduce the scope of any sales or marketing activities.

Because we are subject to environmental, health and safety laws and regulations, we may become exposed to liability and substantial expenses in connection with environmental compliance or remediation activities which may adversely affect our business and financial condition.

Our operations, including our research, development, testing and manufacturing activities, are subject to numerous environmental, health and safety laws and regulations. These laws and regulations govern, among other things, the controlled use, handling, release and disposal of, and the maintenance of a registry for, hazardous materials and biological materials, such as chemical solvents, human cells, carcinogenic compounds, mutagenic compounds and compounds that have a toxic effect on reproduction, laboratory procedures and exposure to blood-borne pathogens. If we fail to comply with such laws and regulations, we could be subject to fines or other sanctions. Although we believe our procedures for using, handling, storing and disposing of these materials comply with legally prescribed standards, we cannot completely eliminate the risk of contamination or injury resulting from hazardous and biological materials. As a result of any such contamination or injury, we may incur liability or local, city, state or federal authorities may curtail the use of these materials and interrupt our business operations. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources.

As with other companies engaged in activities similar to ours, we face a risk of environmental liability inherent in our current and historical activities, including liability relating to releases of or exposure to hazardous or biological materials. Environmental, health and safety laws and regulations are becoming more stringent. We may be required to incur substantial expenses in connection with future environmental compliance or remediation activities, in which case, our production and development efforts may be interrupted or delayed and our financial condition and results of operations may be materially adversely affected.

Our research and development activities could be affected or delayed as a result of possible restrictions on animal testing.

Certain laws and regulations require us to test our product candidates on animals before initiating clinical trials involving humans. Animal testing activities have been the subject of controversy and adverse publicity. Animal rights groups and other organizations and individuals have attempted to stop animal testing activities by pressing for legislation and regulation in these areas and by disrupting these activities through protests and other means. To the extent the activities of these groups are successful, our research and development activities may be interrupted, delayed or become more expensive.

Risks Related to Our Regulatory Environment

Our business operations and current and future relationships with healthcare professionals, principal investigators, consultants, vendors, customers and third-party payors in the United States and elsewhere are subject to applicable anti-kickback, fraud and abuse, false claims, physician payment transparency, health information privacy and security and other healthcare laws and regulations, which could expose us to substantial penalties.

Healthcare providers, healthcare facilities and institutions, physicians and third-party payors in the United States and elsewhere will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our current and future arrangements with healthcare professionals, healthcare facilities and institutions, principal investigators, consultants, customers and third-party payors may expose us to broadly applicable fraud and abuse and other healthcare laws, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act, that may constrain the business or financial arrangements and relationships through which we sell, market and distribute any product candidates for which we obtain marketing approval. In addition, we may be subject to physician payment transparency laws and patient privacy and security regulation by the federal government and by the states and foreign jurisdictions in which we conduct our business. The applicable federal, state and foreign healthcare laws that affect our ability to operate include, but are not limited to, the following:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or providing any remuneration (including any kickback, bribe, or certain rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under any U.S. federal healthcare program, such as Medicare and Medicaid. The term “remuneration” has been broadly interpreted to include anything of value, including stock options. The federal Anti-Kickback Statute has also been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other the other hand. Any arrangements with prescribers must be for bona fide services and compensated at fair market value. 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;
- the U.S. federal civil and criminal false claims and civil monetary penalties laws, including the civil False Claims Act, which prohibit, among other things, including through civil whistleblower or qui tam actions, individuals or entities from knowingly presenting, or causing to be presented, to the U.S. federal government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. federal government. Pharmaceutical manufacturers can cause false claims to be presented to the U.S. federal government by, among other things, engaging in impermissible marketing practices, such as the off-label promotion of a product for an indication for which it has not received FDA approval. In addition, the government may assert that a claim including items and services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which 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, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the healthcare fraud statute implemented under HIPAA or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, which also imposes certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy and security of individually identifiable health information of covered entities subject to the rule, such as health plans, healthcare clearinghouses and certain healthcare providers as well as their business associates, independent contractors of a covered entity that perform certain services involving the use or disclosure of individually identifiable health information on its behalf;
- the U.S. Federal Food, Drug, and Cosmetic Act, which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices;
- the U.S. Public Health Service Act, which prohibits, among other things, the introduction into interstate commerce of a biological product unless a biologics license is in effect for that product;

- the U.S. Physician Payments Sunshine Act and its implementing regulations, which requires, among other things, certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children’s Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare and Medicaid Services, or CMS, information related to certain payments and other transfers of value to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;
- analogous U.S. state laws and regulations, including: state anti-kickback and false claims laws, which may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payor, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to healthcare professionals and entities; state and local laws requiring the registration of pharmaceutical sales representatives; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts; and
- similar healthcare laws and regulations in foreign jurisdictions, including reporting requirements detailing interactions with and payments to healthcare providers.

We may also be subject to federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that could potentially harm consumers.

Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. We have adopted a code of business conduct and ethics, but it is not always possible to identify and deter employee misconduct or business noncompliance, and the precautions we take to detect and prevent inappropriate conduct may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. Efforts to ensure that our business arrangements will comply with applicable healthcare laws may involve substantial costs. We have entered into consulting and scientific advisory board arrangements with physicians and other healthcare providers, including some who could influence the use of our product candidates, if approved. Compensation under some of these arrangements includes the provision of stock or stock options in addition to cash consideration. Because of the complex and far-reaching nature of these laws, it is possible that governmental authorities could conclude that our payments to physicians may not be fair market value for bona fide services or that our business practices do not comply with current or future statutes, regulations, agency guidance 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 the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, exclusion from government-funded healthcare programs, such as Medicare and Medicaid or similar programs in other countries or jurisdictions, integrity oversight and reporting obligations to resolve allegations of non-compliance, disgorgement, individual imprisonment, contractual damages, reputational harm, diminished profits 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 not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs and imprisonment, which could affect our ability to operate our business. Further, defending against any such actions can be costly, time-consuming and may require significant personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

Our employees, independent contractors, principal investigators, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with FDA regulations, provide accurate information to the FDA, comply with manufacturing standards we may establish, comply with federal and state healthcare fraud and abuse laws and regulations, 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, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such 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 material and adverse effect on our business, financial condition, results of operations and prospects, including the imposition of significant civil, criminal and

administrative penalties, damages, monetary fines, individual imprisonment, disgorgement of profits, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional reporting or oversight obligations if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with the law and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and pursue our strategy.

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

In the United States and other jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes and proposed changes to the healthcare system that could affect our future results of operations. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively the ACA, was enacted, which substantially changed the way healthcare is financed by both governmental and private payors. Among the provisions of the ACA of importance to the pharmaceutical and biotechnology industries are the following:

- an annual, nondeductible fee on any entity that manufactures or imports certain specified branded prescription drugs and biologic agents apportioned among these entities according to their market share in some government healthcare programs;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program, to 23.1% and 13% of the average manufacturer price for most branded and generic drugs, respectively and capped the total rebate amount for innovator drugs at 100% of the Average Manufacturer Price;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for certain drugs and biologics, including our product candidates, that are inhaled, infused, instilled, implanted or injected;
- extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for individuals with income at or below 133% of the federal poverty level, thereby potentially increasing manufacturers' Medicaid rebate liability;
- expansion of the entities eligible for discounts under the Public Health program;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;
- establishment of a Center for Medicare Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending; and
- a licensure framework for follow on biologic products.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. For example, the Tax Cuts and Jobs Act of 2017, or the Tax Act, was enacted, which includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." Since the enactment of the Tax Act, there have been additional amendments to certain provisions of the ACA. On December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Act. While the Texas U.S. District Court Judge, as well as the Trump administration and CMS, have stated that the ruling will have no immediate effect pending appeal of the decision, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the ACA will impact the ACA and our business.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, led to aggregate reductions of Medicare payments to providers of 2% per fiscal year. These reductions went into effect in April 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2027 unless additional action is taken by Congress. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws or any other similar laws introduced in the future may result in additional reductions in Medicare and other healthcare funding, which could negatively affect our customers and accordingly, our financial operations.

Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. For example, CMS may develop new payment and delivery models, such as bundled payment models. In addition, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under government payor programs, and review the relationship between pricing and manufacturer patient programs. The Trump administration's budget proposal for fiscal year 2019 contains further drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. Further, 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. The U.S. Department of Health and Human Services has already started the process of soliciting feedback on certain of these measures and, additionally, is immediately implementing others under its existing authority. For example, in September 2018, CMS announced that it will allow Medicare Advantage Plans the option to use step therapy for Part B drugs beginning January 1, 2019, and in October 2018, CMS proposed a new rule that would require direct-to-consumer television advertisements of prescription drugs and biological products, for which payment is available through or under Medicare or Medicaid, to include in the advertisement the Wholesale Acquisition Cost, or list price, of that drug or biological product. Although a number of these and other 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. We expect that additional U.S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U.S. federal government will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

Individual states in the United States have also increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, results of operations, financial condition and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our product candidates or put pressure on our product pricing.

In the European Union, similar political, economic and regulatory developments may affect our ability to profitably commercialize our product candidates, if approved. In addition to continuing pressure on prices and cost containment measures, legislative developments at the European Union or member state level may result in significant additional requirements or obstacles that may increase our operating costs. The delivery of healthcare in the European Union, including the establishment and operation of health services and the pricing and reimbursement of medicines, is almost exclusively a matter for national, rather than E.U., law and policy. National governments and health service providers have different priorities and approaches to the delivery of healthcare and the pricing and reimbursement of products in that context. In general, however, the healthcare budgetary constraints in most E.U. member states have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. Coupled with ever-increasing European Union and national regulatory burdens on those wishing to develop and market products, this could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to commercialize our product candidates, if approved. In markets outside of the United States and European Union, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies.

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

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

Even if we are able to commercialize any product candidate, coverage and adequate reimbursement may not be available or such product candidate may become subject to unfavorable pricing regulations or third-party coverage and reimbursement policies, which would harm our business.

The regulations that govern regulatory approvals, pricing and reimbursement for drugs products vary widely from country to country. Some countries require approval of the sale price of a drug product before it can be marketed. In many countries, the pricing review period begins after marketing approval is granted. In some foreign markets, prescription drug product pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain regulatory 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 regulatory approval.

Our ability to commercialize any products successfully also will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from third party payors, such as government authorities, private health insurers and other organizations. Even if we succeed in bringing one or more products to the market, these products may not be considered cost-effective, and the amount reimbursed for any products may be insufficient to allow us to sell our products on a competitive basis. Because our programs are in the early stages of development, we are unable at this time to determine their cost effectiveness or the likely level or method of coverage and reimbursement. Increasingly, the third-party payors who reimburse patients or healthcare providers are requiring that drug companies provide them with predetermined discounts from list prices, and are seeking to reduce the prices charged or the amounts reimbursed for drug products. If the price we are able to charge for any products we develop, or the coverage and reimbursement provided for such products, is inadequate in light of our development and other costs, our return on investment could be affected adversely.

There may be significant delays in obtaining reimbursement for newly-approved drug products, and coverage may be more limited than the purposes for which the drug product is approved by the FDA or similar foreign regulatory authorities. Moreover, eligibility for reimbursement does not imply that any drugs product will be reimbursed in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution.

Interim reimbursement levels for new drug products, if applicable, may also be insufficient to cover our costs and may not be made permanent. Reimbursement rates may be based on payments allowed for lower cost drug products that are already reimbursed, may be incorporated into existing payments for other services and may reflect budgetary constraints or imperfections in Medicare data. Net prices for drug products may be reduced by mandatory discounts or rebates required by third party payors and by any future relaxation of laws that presently restrict imports of drug products from countries where they may be sold at lower prices than in the United States. Obtaining coverage and adequate reimbursement for our product candidates may be particularly difficult because of the higher prices often associated with drugs administered under the supervision of a physician. Similarly, because our product candidates are physician-administered injectables, separate reimbursement for the product itself may or may not be available. Instead, the administering physician may or may not be reimbursed for providing the treatment or procedure in which our product is used.

Further, no uniform policy for coverage and reimbursement exists in the United States, and coverage and reimbursement can differ significantly from payor to payor. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement rates, but also have their own methods and approval process apart from Medicare determinations. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Decisions regarding the extent of coverage and amount of reimbursement to be provided for any product candidates that we develop will be made on a payor-by-payor basis. One payor's determination to provide coverage for a drug does not assure that other payors will also provide coverage and adequate reimbursement for the drug. Additionally, a third-party payor's decision to provide coverage for a therapy does not imply that an adequate reimbursement rate will be approved.

Additionally, we may develop companion diagnostic tests for use with our product candidates. We, or our collaborators, will be required to obtain coverage and reimbursement for these tests separate and apart from the coverage and reimbursement we seek for our product candidates, once approved. While we have not yet developed any companion diagnostic test for our product candidates, if we do, there is significant uncertainty regarding our ability to obtain coverage and adequate reimbursement for the same reasons applicable to our product candidates.

Our inability to promptly obtain coverage and adequate reimbursement from both third-party payors for the product candidates and companion diagnostic tests that we develop and for which we obtain regulatory approval could have a material and adverse effect on our business, financial condition, results of operations and prospects.

We face potential liability related to the privacy of health information we obtain from clinical trials sponsored by us or our collaborators, from research institutions and our collaborators, and directly from individuals.

Most healthcare providers, including research institutions from which we or our collaborators obtain patient health information, are subject to privacy and security regulations promulgated under HIPAA, as amended by HITECH. Any person may be prosecuted under HIPAA's criminal provisions either directly or under aiding-and-abetting or conspiracy principles. Consequently, depending on the facts and circumstances, we could face substantial criminal penalties if we knowingly receive individually identifiable health information from a HIPAA-covered healthcare provider or research institution that has not satisfied HIPAA's requirements for disclosure of individually identifiable health information. In addition, we may maintain sensitive personally identifiable information, including health information, that we receive throughout the clinical trial process, in the course of our research collaborations, and directly from individuals (or their healthcare providers) who enroll in our patient assistance programs. As such, we may be subject to state laws requiring notification of affected individuals and state regulators in the event of a breach of personal information, which is a broader class of information than the individually identifiable health information protected by HIPAA.

Our clinical trial programs and research collaborations outside the U.S. may implicate international data protection laws, including, in Europe, the EU Data Protection Directive and, beginning on May 25, 2018, the General Data Protection Regulation, or the GDPR, that is replacing it. The GDPR will implement more stringent operational requirements for processors and controllers of personal data. It also significantly increases penalties for non-compliance. If our privacy or data security measures fail to comply with the GDPR requirements, we may be subject to litigation, regulatory investigations, enforcement notices requiring us to change the way we use personal data and/or fines of up to 20.0 million Euros or up to 4% of the total worldwide annual turnover of the preceding financial year, whichever is higher. In addition to statutory enforcement, a personal data breach can lead to negative publicity and a potential loss of business.

We are also subject to evolving E.U. laws on data export, as we may transfer personal data from the European Union to other jurisdictions. There is currently litigation challenging E.U. mechanisms for adequate data transfer. It is uncertain whether these mechanisms will be invalidated by the E.U. courts. We could be impacted by changes in law as a result of the current challenges to these mechanisms, which may lead to governmental enforcement actions, litigation, fines and penalties or adverse publicity that could have an adverse effect on our business.

We are likely to be required to expend significant capital and other resources to ensure ongoing compliance with applicable privacy and data security laws both inside and outside the United States. Claims that we have violated individuals' privacy rights or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business.

If we or any collaborators fail to comply with applicable federal, state, or local regulatory requirements, we could be subject to a range of regulatory actions that could affect our or any collaborators' ability to seek to commercialize our clinical candidates. Any threatened or actual government enforcement action could also generate adverse publicity and require that we devote substantial resources that could otherwise be used in other aspects of our business.

Risks Related to Commercialization of Our Product Candidates

We operate in highly competitive and rapidly changing industries, which may result in others discovering, developing or commercializing competing products before or more successfully than we do.

The biopharmaceutical and pharmaceutical industries are highly competitive and subject to significant and rapid technological change. Our success is highly dependent on our ability to discover, develop and obtain marketing approval for new and innovative products on a cost-effective basis and to market them successfully. In doing so, we face and will continue to face intense competition from a variety of businesses, including large pharmaceutical and biotechnology companies, academic institutions, government agencies and other public and private research organizations. These organizations may have significantly greater resources than we do and conduct similar research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and marketing of products that compete with our product candidates. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries.

With the proliferation of new oncology drugs and therapies, we expect to face increasingly intense competition as new technologies become available. If we fail to stay at the forefront of technological change, we may be unable to compete effectively. Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future. The highly competitive nature of and rapid technological changes in the biotechnology and pharmaceutical industries could render our product candidates or our technology obsolete, less competitive or uneconomical. Our competitors may, among other things:

- have significantly greater financial, manufacturing, marketing, drug development, technical and human resources than we do;
- develop and commercialize products that are safer, more effective, less expensive, more convenient or easier to administer, or have fewer or less severe side effects;
- obtain quicker regulatory approval;
- establish superior proprietary positions covering our products and technologies;
- implement more effective approaches to sales and marketing; or
- form more advantageous strategic alliances.

Should any of these factors occur, our business, financial condition and results of operations could be materially adversely affected.

In addition, any collaborators may decide to market and sell products that compete with the product candidates that we have agreed to license to them, and any competition by our collaborators could also have a material adverse effect on our future business, financial condition and results of operations.

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 the market opportunity for any product candidate that we or our strategic partners develop is smaller than we believe, our revenue may be adversely affected and our business may suffer.

We intend to initially focus our product candidate development on treatments for various oncology indications. Our projections of addressable patient populations that may benefit from treatment with our product candidates are based on our estimates. These estimates, which have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations and market research, may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these cancers. Additionally, the potentially addressable patient population for our product candidates may not ultimately be amenable to treatment with our product candidates. Our market opportunity may also be limited by future competitor treatments that enter the market. If any of our estimates prove to be inaccurate, the market opportunity for any product candidate that we or our strategic partners develop could be significantly diminished and have an adverse material impact on our business.

The market opportunities for our product candidates may be limited to those patients who are ineligible for or have failed prior treatments and may be small.

Cancer therapies are sometimes characterized by line of therapy (first, second, third, fourth, etc.), and the FDA often initially approves new therapies only for use in a particular line or lines of therapy. When cancer is detected early enough, first line therapy is sometimes adequate to provide a cure or prolong life without a cure. Whenever first line therapy (typically chemotherapy, hormone therapy, surgery or a combination of these) proves unsuccessful, second line therapy (typically more chemotherapy, radiation, antibody drugs, tumor targeted small molecules or a combination of these) may be administered. Third or fourth line therapies can include antibody and small molecule targeted therapies, more invasive forms of surgery and new technologies. We may initially seek approval of our product candidates as a third line therapy for patients who have failed other approved treatments. Subsequently, for product candidates that prove to be sufficiently beneficial, if any, we would expect to seek approval as a second and first line therapy. However, there is no guarantee that our product candidates, even if initially approved, would be subsequently approved as a second or first line therapy. In addition, we may have to conduct additional clinical trials prior to gaining approval as a second or first line therapy. Because the potentially addressable patient target population for our product candidates may be limited to patients who are ineligible for or have failed prior treatments, even if we obtain significant market share for our product candidates, we may never achieve profitability.

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 focus on research programs, therapeutic platforms and product candidates that we identify for specific indications. As a result, we may forego or delay pursuit of opportunities with other therapeutic platforms or 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, therapeutic platforms 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.

Even if approved, our products may not gain market acceptance, in which case we may not be able to generate product revenues, which will materially adversely affect our business, financial condition and results of operations.

Even if the FDA or any other regulatory authority approves the marketing of any product candidates that we develop on our own or with a collaborator, physicians, healthcare providers, patients or the medical community may not accept or use them. If these products do not achieve an adequate level of acceptance, we may not generate significant product revenues or any profits from operations. The degree of market acceptance of any of our product candidates will depend on a variety of factors, including:

- the timing of market introduction;
- the number and clinical profile of competing products;
- our ability to provide acceptable evidence of safety and efficacy;
- the prevalence and severity of any side effects;
- relative convenience and ease of administration;
- cost-effectiveness;
- patient diagnostics and screening infrastructure in each market;
- marketing and distribution support;
- availability of coverage, adequate reimbursement and sufficient payment from health maintenance organizations and other insurers, both public and private, for our product candidates, or the procedures utilizing our product candidates, if approved; and
- other potential advantages over alternative treatment methods.

If our product candidates fail to gain market acceptance, this will have a material adverse impact on our ability to generate revenues to provide a satisfactory, or any, return on our investments. Even if some products achieve market acceptance, the market may prove not to be large enough to allow us to generate significant revenues.

We currently have no marketing, sales or distribution infrastructure. If we are unable to develop sales, marketing and distribution capabilities on our own or through collaborations, or if we fail to achieve adequate pricing and/or reimbursement we will not be successful in commercializing our product candidates.

We currently have no marketing, sales and distribution capabilities because all of our product candidates are still in clinical or preclinical development. If any of our product candidates are approved, we intend either to establish a sales and marketing organization with technical expertise and supporting distribution capabilities to commercialize our product candidates, or to outsource this function to a third party. Either of these options would be expensive and time consuming. These costs may be incurred in advance of any approval of our product candidates. In addition, we may not be able to hire a sales force that is sufficient in size or has adequate expertise in the medical markets that we intend to target. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of our products, if approved.

To the extent that we enter into collaboration agreements with respect to marketing, sales or distribution, our product revenue may be lower than if we directly marketed or sold any approved products. In addition, any revenue we receive will depend in whole or in part upon the efforts of these third-party collaborators, which may not be successful and are generally not within our control. If we are unable to enter into these arrangements on acceptable terms or at all, we may not be able to successfully commercialize any approved products. If we are not successful in commercializing any approved products, either on our own or through collaborations with one or more third parties, our future product revenue will suffer and we may incur significant additional losses.

We have never commercialized a product candidate before and may lack the necessary expertise, personnel and resources to successfully commercialize any products on our own or together with suitable collaborators.

We have never commercialized a product candidate, and we currently have no sales force, marketing or distribution capabilities. To achieve commercial success for the product candidates, which we may license to others, we will rely on the assistance and guidance of those collaborators. For product candidates for which we retain commercialization rights, we will have to develop our own sales, marketing and supply organization or outsource these activities to a third party.

Factors that may affect our ability to commercialize our product candidates on our own include recruiting and retaining adequate numbers of effective sales and marketing personnel, obtaining access to or persuading adequate numbers of physicians to prescribe our product candidates and other unforeseen costs associated with creating an independent sales and marketing organization. Developing a sales and marketing organization will be expensive and time-consuming and could delay the launch of our product candidates. We may not be able to build an effective sales and marketing organization. If we are unable to build our own distribution and marketing capabilities or to find suitable partners for the commercialization of our product candidates, we may not generate revenues from them or be able to reach or sustain profitability.

Our product candidates for which we intend to seek approval as biologic products may face competition sooner than anticipated.

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-licensed 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 their 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 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.

Jurisdictions in addition to the United States have established abbreviated pathways for regulatory approval of biological products that are biosimilar to earlier approved reference products. For example, the European Union has had an established regulatory pathway for biosimilars since 2005.

The increased likelihood of biosimilar competition has increased the risk of loss of innovators' market exclusivity. Due to this risk, and uncertainties regarding patent protection, if our clinical candidates are approved for marketing, it is not possible to predict the length of market exclusivity for any particular product with certainty based solely on the expiration of the relevant patent(s) or the current forms of regulatory exclusivity. It is also not possible to predict changes in United States regulatory law that might reduce biological product regulatory exclusivity. The loss of market exclusivity for a product would likely materially and negatively affect revenues and we may not generate adequate or sufficient revenues from them or be able to reach or sustain profitability.

Risks Related to Our Dependence on Third Parties

We rely, and expect to continue to rely, on third parties, including independent clinical investigators and CROs, to conduct our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties, comply with applicable regulatory requirements or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.

We have relied upon and plan to continue to rely upon third parties, including independent clinical investigators and third-party CROs, to conduct our preclinical studies and clinical trials and to monitor and manage data for our ongoing preclinical and clinical programs. We rely on these parties for execution of our preclinical studies and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies and trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on these third parties does not relieve us of our regulatory responsibilities. We and our third-party contractors and CROs are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for all of our products candidates in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators

and trial sites. If we or any of our CROs fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations. In addition, our clinical trials must be conducted with product produced under cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

Further, these investigators and CROs are not our employees and we will not be able to control, other than by contract, the amount of resources, including time, which they devote to our product candidates and clinical trials. If independent investigators or CROs fail to devote sufficient resources to the development of our product candidates, or if their performance is substandard, it may delay or compromise the prospects for approval and commercialization of any product candidates that we develop. In addition, the use of third-party service providers may require us to disclose our proprietary information to these parties, which could increase the risk that this information will be misappropriated.

Our CROs have the right to terminate their agreements with us in the event of an uncured material breach. In addition, some of our CROs have an ability to terminate their respective agreements with us if it can be reasonably demonstrated that the safety of the subjects participating in our clinical trials warrants such termination, if we make a general assignment for the benefit of our creditors or if we are liquidated.

If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed.

Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Additionally, CROs may lack the capacity to absorb higher workloads or take on additional capacity to support our needs. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

We may not realize the benefits of any collaborative or licensing arrangement we enter into, and if we fail to enter into new strategic relationships our business, financial condition, commercialization prospects and results of operations may be materially adversely affected.

Our product development programs and the potential commercialization of our product candidates will require substantial additional cash to fund expenses. Therefore, for some of our product candidates, we may decide to enter into new collaborations with pharmaceutical or biopharmaceutical companies for the development and potential commercialization of those product candidates. For instance, we have a discovery collaboration and license agreement with AbbVie, pursuant to which we have licensed the development and commercialization of certain of our product candidates.

We face significant competition in seeking appropriate collaborators. Collaborations are complex and time-consuming to negotiate and document. We may also be restricted under existing and future collaboration agreements from entering into agreements on certain terms with other potential collaborators. We may not be able to negotiate collaborations on acceptable terms, or at all. If our strategic collaborations do not result in the successful development and commercialization of product candidates, 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. Moreover, our estimates of the potential revenue we are eligible to receive under our strategic collaborations may include potential payments related to therapeutic programs for which our collaborators have discontinued development or may discontinue development in the future. If that were to occur, we may have to curtail the development of a particular product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of our sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we will not be able to bring our product candidates to market and generate product revenue. If we do enter into a new collaboration agreement, we could be subject to the following risks, each of which may materially harm our business, commercialization prospects and financial condition:

- we may not be able to control the amount and timing of resources that the collaboration partner devotes to the product development program;
- the collaboration partner may experience financial difficulties;

- we may be required to relinquish important rights such as marketing, distribution and intellectual property rights;
- a collaborator could move forward with a competing product developed either independently or in collaboration with third parties, including our competitors; or
- business combinations or significant changes in a collaborator's business strategy may adversely affect our willingness to complete our obligations under any arrangement.

If we license products or businesses, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture. We cannot be certain that, following a strategic transaction or license, we will achieve the results, revenue or specific net income that justifies such transaction.

We rely on third-party manufacturers to produce our product candidates. Any failure by a third-party manufacturer to produce acceptable product candidates for us may delay or impair our ability to initiate or complete our clinical trials or commercialize approved products.

We do not currently own or operate any manufacturing facilities nor do we have any in-house manufacturing experience or personnel. We rely on our strategic partners to manufacture product candidates licensed to them or work with multiple third-party contract manufacturers to produce sufficient quantities of materials required for the manufacture of our product candidates for preclinical testing and clinical trials, in compliance with applicable regulatory and quality standards, and intend to do so for the commercial manufacture of our products, if approved. If we are unable to arrange for such third-party manufacturing sources, or fail to do so on commercially reasonable terms, we may not be able to successfully produce sufficient supply of product candidate or we may be delayed in doing so. Such failure or substantial delay could materially harm our business.

Our TriTAC and ProTriTAC platforms rely on third parties for biological materials. Some biological materials have not always met our expectations or requirements, and any disruption in the supply of these biological materials could materially adversely affect our business. Although we have control processes and screening procedures, biological materials are susceptible to damage and contamination and may contain active pathogens. Improper storage of these materials, by us or any third-party suppliers, may require us to destroy some of our biological raw materials or product candidates.

Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured product candidates ourselves, including reliance on the third party for regulatory compliance and quality control and assurance, volume production, the possibility of breach of the manufacturing agreement by the third party because of factors beyond our control (including a failure to synthesize and manufacture our product candidates in accordance with our product specifications) and the possibility of termination or nonrenewal of the agreement by the third party at a time that is costly or damaging to us. In addition, the FDA and other regulatory authorities require that our product candidates be manufactured according to cGMPs and similar foreign standards. Pharmaceutical manufacturers and their subcontractors are required to register their facilities or products manufactured at the time of submission of the marketing application and then annually thereafter with the FDA and certain state and foreign agencies. They are also subject to periodic unannounced inspections by the FDA, state and other foreign authorities. Any subsequent discovery of problems with a product, or a manufacturing or laboratory facility used by us or our strategic partners, may result in restrictions on the product or on the manufacturing or laboratory facility, including marketed product recall, suspension of manufacturing, product seizure, or a voluntary withdrawal of the drug from the market. We may have little to no control regarding the occurrence of third-party manufacturer incidents. Any failure by our third-party manufacturers to comply with cGMP or failure to scale up manufacturing processes, including any failure to deliver sufficient quantities of product candidates in a timely manner, could lead to a delay in, or failure to obtain, regulatory approval of any of our product candidates.

To date, we have relied on one single-source supplier for bulk drug substance. The loss of this supplier or its failure to supply us with BDS on a timely basis could cause our ability to develop our product candidates and adversely affect our business.

We depend on one single-source supplier for bulk drug substance, or BDS. Although we believe that we have a substantial reserve of BDS to support our current clinical trial programs, there can be no assurance that our supply of BDS will not be limited, interrupted, or of satisfactory quality or continue to be available at acceptable prices. Additionally, we do not have any control over the process or timing of the acquisition or manufacture of materials by our supplier, and cannot ensure that it will deliver to us the BDS we order on time, or at all. The loss of BDS provided by this supplier could require us to change the design of our product candidate development process based on the functions, limitations, features and specifications of the replacement.

In addition, the lead time needed to establish a relationship with a new supplier can be lengthy, and we may experience delays in meeting demand in the event we must switch to a new supplier. The time and effort to qualify a new supplier could result in additional costs, diversion of resources or reduced manufacturing yields, any of which would negatively impact our operating results. Our reliance on this single-source supplier exposes us to certain risks, including the following:

- our supplier may cease or reduce production or deliveries, raise prices or renegotiate terms;
- we may be unable to locate a suitable replacement on acceptable terms or on a timely basis, if at all;

- if there is a disruption to our single-source supplier's operations, and if we are unable to enter into arrangements with alternative suppliers, we may need to halt our clinical trial programs;
- delays caused by supply issues may harm our reputation, frustrate our customers and cause them to turn to our competitors for future projects; and
- our ability to develop our product candidates could be materially and adversely impacted if the single-source supplier upon which we rely were to experience a significant business challenge, disruption or failure due to issues such as financial difficulties or bankruptcy, issues relating to other customers such as regulatory or quality compliance issues, or other financial, legal, regulatory or reputational issues.

Moreover, to meet anticipated demand, our single-source supplier may need to increase manufacturing capacity, which could involve significant challenges. This may require us and our supplier to invest substantial additional funds and hire and retain the technical personnel who have the necessary experience. Neither we nor our supplier may successfully complete any required increase to existing manufacturing capacity in a timely manner, or at all.

We currently rely on third-party suppliers and other third parties for production of our product candidates and our dependence on these third parties may impair the advancement of our research and development programs and the development of our product candidates. Moreover, we intend to rely on third parties to produce commercial supplies of any approved product candidate and our commercialization of any of our product candidates could be stopped, delayed or made less profitable if those third parties fail to obtain approval of the FDA or comparable regulatory authorities, fail to provide us with sufficient quantities of product or fail to do so at acceptable quality levels or prices or fail to otherwise complete their duties in compliance with their obligations to us or other parties.

We do not currently own or operate any manufacturing facilities, nor do we have any in-house manufacturing experience or personnel. We rely on and expect to continue to rely on third-party contract manufacturing organizations, or CMOs, for the supply of current good manufacturing practice-grade, or cGMP-grade, clinical trial materials and commercial quantities of our product candidates and products, if approved. Reliance on third-party providers may expose us to more risk than if we were to manufacture product candidates ourselves. The facilities used by our contract manufacturers to manufacture our product candidates must be approved by the FDA pursuant to inspections that will be conducted after we submit our BLA to the FDA. We have limited control over the manufacturing process of, and beyond contractual terms, we are completely dependent on our contract manufacturing partners for compliance with cGMP for the manufacture of our product candidates. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. In addition, we have limited control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved. In addition, any failure to achieve and maintain compliance with these laws, regulations and standards could subject us to the risk that we may have to suspend the manufacturing of our product candidates or that obtained approvals could be revoked, which would adversely affect our business and reputation. Furthermore, third-party providers may breach existing agreements they have with us because of factors beyond our control. They may also terminate or refuse to renew their agreement because of their own financial difficulties or business priorities, at a time that is costly or otherwise inconvenient for us. If we were unable to find an adequate replacement or another acceptable solution in time, our clinical trials could be delayed or our commercial activities could be harmed. In addition, the fact that we are dependent on our collaborators, our suppliers and other third parties for the manufacture, filling, storage and distribution of our product candidates means that we are subject to the risk that the products may have manufacturing defects that we have limited ability to prevent or control. The sale of products containing such defects could adversely affect our business, financial condition and results of operations.

Growth in the costs and expenses of components or raw materials may also adversely influence our business, financial condition and results of operations. Supply sources could be interrupted from time to time and, if interrupted, there is no guarantee that supplies could be resumed (whether in part or in whole) within a reasonable timeframe and at an acceptable cost or at all.

We rely on our manufacturers to purchase from third-party suppliers the materials necessary to produce our product candidates for our clinical trials. There are a limited number of suppliers for raw materials that we use to manufacture our drugs and there may be a need to assess alternate suppliers to prevent a possible disruption of the manufacture of the materials necessary to produce our product candidates for our clinical trials, and if approved, ultimately for commercial sale. We do not have any control over the process or timing of the acquisition of these raw materials by our manufacturers. Moreover, we currently do not have any agreements for the commercial production of these raw materials. We cannot be sure that these suppliers will remain in business, or that they will not be purchased by one of our competitors or another company that is not interested in continuing to produce these materials for our intended purpose. In addition, the lead time needed to establish a relationship with a new supplier can be lengthy, and we may experience delays in meeting demand in the event a new supplier must be used. The time and effort to qualify a new supplier could result in additional costs, diversion of resources or reduced manufacturing yields, any of which would negatively impact our operating results. Although we generally do not begin a clinical trial unless we believe we have a sufficient supply of a product candidate to complete the clinical trial, any significant delay in the supply of a product candidate, or the raw material components thereof, for an ongoing clinical trial due to the need to replace a third-party manufacturer could considerably delay completion of our clinical trials, product testing and potential regulatory approval of our product candidates. If our manufacturers or we are unable to purchase these raw materials after regulatory approval has been obtained for our product candidates, the commercial launch of our product candidates would be delayed or there would be a shortage in supply, which would impair our ability to generate revenues from the sale of our product candidates.

We rely on our manufacturers and other subcontractors to comply with and respect the proprietary rights of others in conducting their contractual obligations for us. If our manufacturers or other subcontractors fail to acquire the proper licenses or otherwise infringe third party proprietary rights in the course of completing their contractual obligations to us, we may have to find alternative manufacturers or defend against claims of infringement, either of which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved. In addition, although we require manufacturers and service providers to assign or license to us their interest in and to intellectual property rights to improvements made by them in the development and manufacturing process for our products, in future contracts we may enter into with these third parties, we may not own, or may have to share, these intellectual property rights to improvements.

Risks Related to Intellectual Property and Information Technology

We rely on patents and other intellectual property rights to protect our technology, including product candidates and our TriTAC and ProTriTAC platforms, the enforcement, defense and maintenance of which may be challenging and costly. Failure to enforce or protect these rights adequately could harm our ability to compete and impair our business.

Our commercial success depends in part on obtaining and maintaining patents and other forms of intellectual property rights for technology related to our TriTAC and ProTriTAC platforms, including, but not limited to, our product candidates, methods used to manufacture those product candidates, formulations thereof and the methods for treating patients using those product candidates. Given that the development of our technology and product candidates is at an early stage, our intellectual property portfolio with respect to certain aspects of our technology and product candidates is also at an early stage. Failure to protect or to obtain, maintain or extend adequate patent and other intellectual property rights could materially adversely affect our ability to develop and market our product candidates.

We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our novel platform technologies and product candidates that are important to our business. The patent prosecution process is expensive and time-consuming, and we may not be able to prepare, file and prosecute 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 inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Further, the issuance, scope, validity, enforceability and commercial value of our current or future patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology or product candidates, in whole or in part, or which effectively prevent others from commercializing competitive technologies and product candidates. The patent examination process may require us to narrow the scope of the claims of our pending and future patent applications, which may limit the scope of patent protection that may be obtained. We cannot assure you that all of the potentially relevant prior art relating to our patents and patent applications has been found. If such prior art exists, it can invalidate a patent or prevent a patent from issuing from a pending patent application. Even if patents do successfully issue and even if such patents cover our product candidates, third parties may initiate opposition, interference, re-examination, post-grant review, inter partes review, nullification or derivation action in court or before patent offices, or similar proceedings challenging the validity, enforceability or scope of such patents, which may result in the patent claims being narrowed or invalidated. Our patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications, and then only to the extent the issued claims cover the technology.

Because patent applications in the United States and other jurisdictions are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that we were the first to file any patent application related to our technology, including a particular product candidate. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain.

Furthermore, if third parties have filed such patent applications on or before March 15, 2013, an interference proceeding can be initiated by such third parties to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. If third parties have filed such applications after March 15, 2013, a derivation proceeding can be initiated by such third parties to determine whether our invention was derived from theirs. Even where we have a valid and enforceable patent, we may not be able to exclude others from practicing our invention where the other party can show that they used the invention in commerce before our filing date or the other party benefits from a compulsory license.

We may become involved in lawsuits to protect or enforce our issued patents relating to one or more of our product candidates or our TriTAC and ProTriTAC platforms, which could ultimately render our patents invalid or unenforceable and adversely affect our competitive position.

Competitors may infringe our patents or other intellectual property that relate to our TriTAC and ProTriTAC platforms and product candidates, their respective methods of use, manufacture and formulations thereof. To protect our competitive position and counter infringement or unauthorized use, we may from time to time need to resort to litigation to enforce or defend any patents or other intellectual property rights owned by us by filing infringement claims. As enforcement of intellectual property rights is difficult, unpredictable and expensive, we may fail in enforcing our rights—in which case our competitors may be permitted to use our technology without being required to pay us any license fees. In addition, litigation involving our patents carries the risk that one or more of our patents will be held invalid (in whole or in part, on a claim-by-claim basis) or held unenforceable. Such an adverse court ruling could allow third parties to commercialize our product candidates or methods, or our TriTAC and ProTriTAC platforms, and then compete directly with us, without payment to us.

If we were to initiate legal proceedings against a third party to enforce a patent covering one of our product candidates or methods, the defendant could counterclaim that our patent is invalid and/or unenforceable. In patent litigation in the United States or in certain jurisdictions in Europe, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, for example, 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 U.S. Patent and Trademark Office, or made a misleading statement, during prosecution. Third parties may also raise similar invalidity and/or unenforceability claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include inter partes review, ex parte re-examination and post grant review in the United States, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). The outcome following legal assertions of invalidity and unenforceability during patent litigation is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on one or more of our technologies, product candidates, methods or certain aspects of our TriTAC and ProTriTAC platforms. Such a loss of patent protection could have a material adverse impact on our business.

There is also a risk that, even if the validity of our patents is upheld, the court will construe our patent's claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patent claims do not cover the invention. Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation. Patents and other intellectual property rights also will not protect our technology if competitors design around our protected technology without infringing our patents or other intellectual property rights.

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

We may fail to identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent which might adversely affect our ability to develop our TriTAC and ProTriTAC platforms and product candidates.

We cannot guarantee that our operations and activities do not, or will not in the future, infringe existing or future patents. We also cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the United States and abroad that is relevant to our TriTAC and ProTriTAC platforms or necessary for the commercialization of our product candidates in any jurisdiction.

Numerous U.S. and foreign patents and pending patent applications exist in our market that are owned by third parties. Our competitors in both the United States and abroad, many of which have substantially greater resources and have made substantial investments in patent portfolios and competing technologies, may have applied for or obtained or may in the future apply for and obtain, patents that will prevent, limit or otherwise interfere with our ability to make, use and sell our product candidates. We do not always conduct independent reviews of pending patent applications of and patents issued to third parties. Patent applications in the United States and elsewhere are typically published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Certain U.S. applications that will not be filed outside the United States can remain confidential until patents are issued. In addition, patent applications in the United States and elsewhere can be pending for many years before issuance, and unintentionally abandoned patents or applications can be revived. Furthermore, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our technologies, our product candidates or the use thereof. As such, there may be applications of third parties now pending or recently revived patents of which we are unaware. These applications may later result in issued patents, or the revival of previously abandoned patents, that will prevent, limit or otherwise interfere with our ability to make, use or sell our product candidates.

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

We cannot provide any assurances that third-party patents do not exist which might be enforced against our current technology, including our platform technologies, product candidates and their respective methods of use, manufacture and formulations thereof, and could result in either an injunction prohibiting our manufacture or future sales, or, with respect to our future sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties, which could be significant.

Intellectual property rights of third parties could adversely affect our ability to develop or commercialize our product candidates, such that we could be required to litigate or obtain licenses from third parties in order to develop or market our product candidates. Such litigation or licenses could be costly or not available on commercially reasonable terms.

Our commercial success depends, in part, on our ability to develop, manufacture, market and sell our product candidates without infringing the intellectual property and other proprietary rights of third parties. Our competitive position may suffer if patents issued to third parties or other third-party intellectual property rights cover our methods or product candidates or elements thereof, our manufacture or uses relevant to our development plans, our product candidates, or other attributes of our product candidates or our TriTAC and ProTriTAC platforms. In such cases, we may not be in a position to develop or commercialize product candidates unless we successfully pursue litigation to nullify or invalidate the third-party intellectual property right concerned, which can be expensive and time consuming, or enter into a license agreement with the intellectual property right holder, if available on commercially reasonable terms.

There is a substantial amount of intellectual property litigation in the biotechnology and pharmaceutical industries, and we may become party to, or threatened with, litigation or other adversarial proceedings regarding intellectual property rights with respect to our product candidates. For example, on November 25, 2018, we received a letter from counsel for Maverick alleging that our ProTriTAC program is subject to the non-compete provision of our Asset Transfer Agreement with Maverick. On January 3, 2019, Maverick filed a complaint against us in the Delaware Court of Chancery and a motion for a temporary restraining order seeking to prohibit us from further developing our ProTriTAC platform. The complaint alleges various claims, including for breach of contract and misappropriation of trade secrets, and seeks as relief, among other things, a declaration that our ProTriTAC technology impermissibly competes in the Maverick Field (as defined in the Asset Transfer Agreement), a preliminary and permanent injunction and unspecified damages. We believe that the mechanism of action employed by our ProTriTAC platform falls outside the Maverick Field. On May 8, 2019, the court granted Millennium, a wholly owned subsidiary of Takeda Pharmaceutical Company Limited, permission to intervene in the litigation based on a proposed complaint. On May 14, 2019, Millennium filed a Complaint in Intervention, asserting various claims, including fraud and unjust enrichment, and seeking as relief, among other things, an injunction and unspecified damages.

In the event that an injunction is granted, we would be unable to proceed with development of our ProTriTAC platform until the injunction is lifted, if ever and, if Millennium were to prevail on its claims, we could be required to pay damages. The various markets in which we plan to operate are subject to frequent and extensive litigation regarding patents and other intellectual property rights. In addition, many companies in intellectual property-dependent industries, including those producing therapeutics to treat and potentially cure cancer, have employed intellectual property litigation as a means to gain an advantage over competitors. As a result, we may be required to defend against claims of intellectual property infringement that may be asserted by our competitors against us and, if the outcome of any such litigation is adverse to us, it may affect our ability to compete effectively.

Third-party intellectual property right holders, including our competitors, may assert and actively bring infringement claims against us based on existing or future intellectual property rights. The pharmaceutical and biotechnology industries have produced a significant number of patents, and it may not always be clear to industry participants, including us, which patents cover various types of product candidates or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform.

If we are sued for patent infringement, we would need to demonstrate that our product candidates or platform technologies either do not infringe the patent claims of a relevant patent or that the patent claims are invalid or unenforceable, and we may not be able to do this. Proving invalidity may be difficult. For example, in the United States, proving invalidity in court requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if we are successful in these proceedings, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted in pursuing these proceedings, which could have a material adverse effect on our business and operations. In addition, we may not have sufficient resources to bring these actions to a successful conclusion. In addition, we may not be able to successfully settle or otherwise resolve such infringement claims. If we are unable to successfully settle future claims on terms acceptable to us, we may be required to engage or continue costly, unpredictable and time-consuming litigation and may be prevented from or experience substantial delays in marketing our product candidates.

Our involvement in litigation, and in any interferences, opposition proceedings or other intellectual property proceedings inside and outside of the United States may divert management from focusing on business operations, could cause us to spend significant amounts of money and may have no guarantee of success. Any current and potential intellectual property litigation also could force us to do one or more of the following:

- stop selling, incorporating, manufacturing or using our product candidates or any products, if approved, in the United States and/or other jurisdictions that use the subject intellectual property;
- obtain from a third party asserting its intellectual property rights, a license to sell or use the relevant technology, including the obligation to pay royalties, which license may not be available on reasonable terms, or at all, or may be non-exclusive thereby giving our competitors access to the same technologies licensed to us;
- redesign those products or processes that use any allegedly infringing or misappropriated technology, which may result in significant cost or delay to us, or which redesign could be technically infeasible; or
- pay damages, including the possibility of treble damages and attorneys' fees in a patent case if a court finds us to have willfully infringed certain intellectual property rights.

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

Litigation or other legal proceedings relating to intellectual property claims, with or without merit, is unpredictable and generally expensive and time consuming. Even if resolved in our favor, such litigation and other legal proceedings may cause us to incur significant expenses and is likely to divert significant resources from our core business, including distracting our technical and management personnel from their normal responsibilities, and may impact our reputation. 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, we could have a substantial adverse effect on the price of our common shares. Such litigation or proceedings could substantially increase our operating losses and reduce our resources available for development activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

We may need to obtain additional licenses of third-party technology that may not be available to us or are available only on commercially unreasonable terms, and which may cause us to operate our business in a more costly or otherwise adverse manner that was not anticipated.

We currently have rights to the intellectual property, including patent applications relating to our TriTAC and ProTriTAC platforms and our product candidates. From time to time, we may be required to license technologies relating to our therapeutic research programs from additional third parties to further develop or commercialize our platform technologies and product candidates. Similarly, the targets of our product candidates have also been the subject of research by many companies that have filed patent applications or have patents related to such targets and therapeutic methods relating to those targets. There can be no assurance any such patents will not be asserted against us or that we will not need to seek licenses from such third parties. We may not be able to secure such licenses on acceptable terms, if at all, and any such litigation would be costly and time-consuming.

Should we be required to obtain licenses to any third-party technology, including any such patents required to manufacture, use or sell our product candidates, the growth of our business will likely depend in part on our ability to acquire, in-license, maintain or use these proprietary rights. The inability to obtain any third-party license required to develop or commercialize any of our product candidates could cause us to abandon any related efforts, which could seriously harm our business and operations.

In addition, our product candidates may require specific formulations to work effectively and efficiently and the rights to these formulations may be held by others. We may be unable to acquire or in-license any compositions, methods of use, processes, or other third-party intellectual property rights from third parties that we identify as necessary for our product candidates. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, cash resources, and greater clinical development and commercialization capabilities.

Our involvement in litigation, and in any interferences, opposition proceedings or other intellectual property proceedings inside and outside of the United States may divert management from focusing on business operations, could cause us to spend significant amounts of money and may have no guarantee of success. Any current and potential intellectual property litigation also could force us to do one or more of the following:

- stop selling, incorporating, manufacturing or using our product candidates or any products, if approved, in the United States and/or other jurisdictions that use the subject intellectual property;
- obtain from a third party asserting its intellectual property rights, a license to sell or use the relevant technology, including the obligation to pay royalties, which license may not be available on reasonable

In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment. 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 successfully obtain a license to third-party intellectual property rights necessary for the development of a product candidate or program, we may have to abandon development of that product candidate or program and our business and financial condition could suffer.

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.

Our registered or unregistered trademarks or trade names may be challenged, infringed, 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 by potential collaborators, partners or customers in our markets of interest. 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. If other entities use trademarks similar to ours in different jurisdictions, or have senior rights to ours, it could interfere with our use of our current trademarks throughout the world.

During trademark registration proceedings, we may receive rejections. Although we would be given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in both the USPTO and comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, which may not survive such proceedings. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected.

We may license our trademarks and trade names to third parties, such as distributors. Though these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and tradenames by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names.

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 for a product, we may be open to competition from competitive medications, including biosimilar or generic medications. In addition, although upon issuance in the United States a patent's life can be increased based on certain delays caused by the United States Patent and Trademark Office, or the USPTO, this increase can be reduced or eliminated based on certain delays caused by the patent applicant during patent prosecution. If we do not have sufficient patent life to protect our product candidates and any products, if approved, our business and results of operations will be adversely affected. 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 patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

If we do not obtain protection under the Hatch-Waxman Amendments and similar non-U.S. legislation for extending the term of patents covering each of our product candidates, our business may be materially harmed

Depending upon the timing, duration and conditions of FDA marketing approval of our product candidates, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments, and similar legislation in the European Union. The Hatch-Waxman Amendments permit a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. However, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for that product will be shortened and our competitors may obtain approval to market competing products sooner. As a result, our revenue from applicable products could be reduced, possibly materially.

We enjoy only limited geographical protection with respect to certain patents and may not be able to protect our intellectual property rights throughout the world.

Patents are of national or regional effect. While we will endeavor to try to protect our technologies, products and product candidates with intellectual property rights such as patents, as appropriate, the process of obtaining patents is time-consuming, expensive and sometimes unpredictable in other countries. As such, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions.

International applications under the Patent Cooperation Treaty, or PCT, are usually filed within 12 months after the priority filing. Based on the PCT filing, national and regional patent applications may be filed in additional jurisdictions where we believe our product candidates may be marketed. We have so far not filed for patent protection in all national and regional jurisdictions where such protection may be available. Filing, prosecuting and defending patents on all of our research programs and product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, we may decide to abandon national and regional patent applications before grant. Finally, the grant proceeding of each national/regional patent is an independent proceeding which may lead to situations in which applications might in some jurisdictions be refused by the relevant patent offices, while granted by others. Further, the standards applied by the USPTO and foreign patent offices in granting patents are not always applied uniformly or predictably. It is common that depending on the country, the scope of patent protection may vary for the same product candidate and/or technology. As such, we do not know the degree of future protection that we will have on our technologies and product candidates.

Competitors may use our or our collaboration partners' 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 or our collaboration partners have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our product candidates, and our or our collaboration partners' patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

The laws of some jurisdictions, particularly certain developing countries, do not protect intellectual property rights, particularly those relating to pharmaceuticals or biologics, to the same extent as laws in the United States, and many companies have encountered significant difficulties in protecting and defending such rights in such jurisdictions. 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. If we encounter difficulties in protecting, or are otherwise precluded from effectively protecting, the intellectual property rights important for our business in such jurisdictions, the value of these rights may be diminished and we may face additional competition from others in those jurisdictions.

Proceedings to enforce our patent 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 and 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 rights around the world may be inadequate to obtain significant commercial advantage from the intellectual property that we develop or license.

Some countries, including China and India, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, some 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 and results of operations may be adversely affected.

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

We may be subject to claims that former employees, consultants, independent contractors, collaborators or other third parties have an interest in our patents or other intellectual property as an owner, co-owner, inventor or co-inventor. The failure to name the proper inventors on a patent application can result in the patents issuing thereon being unenforceable. Inventorship disputes may arise from conflicting views regarding the contributions of different individuals named as inventors, the effects of foreign laws where foreign nationals are involved in the development of the subject matter of the patent, conflicting obligations of third parties involved in developing our product candidates or as a result of questions regarding co-ownership of potential joint inventions. Litigation may be necessary to resolve these and other claims challenging inventorship and/or ownership. Alternatively, or additionally, we may enter into agreements to clarify the scope of our rights in such 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, valuable intellectual property. Such an outcome could have a material adverse effect on our business. 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.

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

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

- others may be able to make product candidates similar to our product candidates but that are not covered by the claims of the patents that we own or have exclusively licensed;
- the patents of third parties may have an adverse effect on our business;
- we or any future strategic partners might not have been the first to conceive or reduce to practice the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed;
- we or any future strategic partners might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we own or have exclusively licensed may not provide us with any competitive advantage, or may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- we cannot predict the degree and range of protection any issued patents will afford us against competitors, whether or not others will obtain patents claiming aspects similar to those covered by our patents and patent applications, or whether we will need to initiate litigation or administrative proceedings which may be costly whether we win or lose;

- 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;
- third parties performing manufacturing or testing for us using our product candidates or technologies could use the intellectual property of others without obtaining a proper license; and
- we may not develop additional technologies that are patentable.

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

Composition of matter patents for biological and pharmaceutical products such as our product candidates are generally considered to be the strongest form of intellectual property protection for those types of products, as such patents provide protection without regard to any method of use. We cannot be certain that the claims in our pending patent applications covering composition of matter of our product candidates will be considered patentable by the USPTO or by patent offices in foreign countries, or that the claims in any of our issued patents will be considered valid and enforceable by courts in the United States or foreign countries. Method of use patents protect the use of a product for the specified method. This type of patent does not prevent a competitor from making and marketing a product that is identical to our product for an indication that is outside the scope of the patented method. Moreover, even if competitors do not actively promote their product for our targeted indications, physicians may prescribe these products “off-label.” Although off-label prescriptions may infringe or contribute to the infringement of method of use patents, the practice is common and such infringement is difficult to prevent or prosecute.

Changes in patent laws or patent jurisprudence could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involve both technological complexity and legal complexity. 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. Therefore, obtaining and enforcing biopharmaceutical patents is costly, time-consuming and inherently uncertain.

In September 2011, the America Invents Act, or the AIA, was enacted in the United States, resulting in significant changes to the U.S. patent system. An important change introduced by the AIA was a transition to a “first-to-file” system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention, which went into effect on March 16, 2013. Therefore, a third party that now files a patent application in the USPTO before we do could be awarded a patent covering an invention of ours even if we created the invention before it was created by the third party. While we are cognizant of the time from invention to filing of a patent application, circumstances could prevent us from promptly filing patent applications for our inventions.

Among some of the other changes introduced by the AIA were changes that limit where a patentee may file a patent infringement suit and providing opportunities for third parties to challenge any issued patent in the USPTO. This applies to all of our U.S. patents, even those issued before March 16, 2013. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U.S. federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. The AIA and its continued implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications, and the patent applications of our collaborators, and the enforcement or defense of our issued patents.

Depending on decisions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. For example, in the recent case, *Assoc. for Molecular Pathology v. Myriad Genetics, Inc.*, the U.S. Supreme Court held that certain claims to DNA molecules are not patentable. While we do not believe that any of the patents owned or licensed by us will be found invalid based on this decision, we cannot predict how future decisions by the courts, the U.S. Congress or the USPTO may impact the value of our patents. Similarly, there is complexity and uncertainty related to European patent laws. For example, the European Patent Convention was amended in April 2010 to limit the time permitted for filing divisional applications. In addition, the European Patent Convention patent system is relatively stringent in the type of amendments that are allowed during prosecution. These limitations and requirements could adversely affect our ability to obtain new patents in the future that may be important for our business.

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

In addition to seeking patents for some of our technology and product candidates, we may rely on trade secrets and/or confidential know-how to protect our technology, especially where patent protection is believed to be of limited value, to maintain our competitive position with respect to our research programs and product candidates. Elements of our product candidates, including processes for their preparation and manufacture, may involve proprietary know-how, information, or technology that is not covered by patents, and thus for these aspects we may consider trade secrets and know-how to be our primary intellectual property. Any disclosure, either intentional or unintentional, by our employees or by other third parties of our trade secrets or proprietary information could enable competitors to duplicate or surpass our technological achievements, thus adversely eroding our competitive position in our market.

Trade secrets and/or confidential know-how can be difficult to protect or maintain as confidential. To protect this type of information against disclosure or appropriation by competitors, our policy is to require our employees, consultants, contractors, collaborators, advisors and other third parties to enter into confidentiality agreements with us. Despite these efforts, any of these parties may unintentionally or willfully breach the agreements and disclose our confidential information, and confidentiality agreements may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. Enforcing a claim that a third party obtained illegally and is using trade secrets and/or confidential know-how is also expensive, time consuming and unpredictable. The enforceability of confidentiality agreements may vary from jurisdiction to jurisdiction. The laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. Furthermore, if a competitor lawfully obtained or independently developed any of our trade secrets, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets or other proprietary information.

Trade secrets can over time be disseminated within the industry through independent development, the publication of journal articles and the movement of personnel skilled in the art from company to company or academic to industry scientific positions. Though our agreements with third parties typically restrict the ability of our employees, consultants, contractors, collaborators, advisors and other third parties to publish data potentially relating to our trade secrets, our agreements may contain certain limited publication rights. Because from time to time we expect to rely on third parties in the development, manufacture and distribution of our product candidates and provision of our services, we must, at times, share trade secrets with them. Despite employing the contractual and other security precautions described above, the need to share trade secrets increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor or other third party, our competitive position would be harmed.

In addition, our competitors may independently develop substantially equivalent trade secrets, proprietary information or know-how and may even apply for patent protection in respect of the same. If successful in obtaining such patent protection, our competitors could limit our use of our trade secrets and/or confidential know-how. Under certain circumstances and to guarantee our freedom to operate, we may also decide to publish some know-how to prevent others from obtaining patent rights covering such know-how.

We may be subject to third-party claims asserting that our employees, consultants, contractors, collaborators or advisors have misappropriated or wrongfully used or disseminated their intellectual property, or claiming ownership of what we regard as our own intellectual property.

Many of our employees, including our senior management, were previously employed at universities or at other biopharmaceutical companies, including our competitors or potential competitors. Some of these employees executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. Similarly, we work with consultants, contractors, collaborators, advisors or other third parties who have worked with, and do currently work with, other companies, including our competitors or potential competitors, and have executed proprietary rights, non-disclosure and non-competition agreements in connection with such other companies. Although we try to ensure that our employees, consultants, contractors, collaborators, advisors or other third parties do not use or disclose the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees or individuals that we work with have used or disclosed confidential information or intellectual property of others, including trade secrets or other proprietary information, or that we caused an individual to breach the terms of his or her non-competition or non-solicitation agreement with a current or former employer or competitor.

Litigation may be necessary to defend against these claims and, even if we are successful, could result in substantial costs and could be a distraction to management, our employees and our routine business. 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 or sustain damages. 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 develop or commercialize our technology or product candidates. Such a license may not be available on commercially reasonable terms or at all. Moreover, any such litigation or the threat thereof may adversely affect our reputation and our ability to form strategic alliances or sublicense our rights to collaborators, engage with scientific advisors or hire employees or consultants, each of which would have an adverse effect on our business, results of operations and financial condition.

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

Periodic maintenance and annuity fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. 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. 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. If we fail to maintain the patents and patent applications covering our product candidates, our competitors might be able to enter the market, which would have an adverse effect on our business.

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

We may in the future be subject to claims that former employees, collaborators, or other third parties have an interest in our patents or other intellectual property as an inventor or co-inventor. For example, we may have inventorship disputes arise from conflicting obligations of consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship. 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, valuable intellectual property. Such an outcome could have a material adverse effect on our business. 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.

Use of social media could give rise to liability, breaches of data security, or reputational harm.

We and our employees use social media to communicate externally. There is risk that the use of social media by us or our employees to communicate about our product candidates or business may give rise to liability, lead to the loss of trade secrets or other intellectual property, or result in public exposure of personal information of our employees, clinical trial patients, customers, and others. Furthermore, negative posts or comments about us or our product candidates in social media could seriously damage our reputation, brand image, and goodwill. Any of these events could have a material adverse effect on our business, prospects, operating results, and financial condition and could adversely affect the price of our common stock.

Our computer systems, or those used by our CROs or other contractors or consultants, may fail or suffer security breaches, which could adversely affect our business.

Despite the implementation of security measures, our computer systems and data and those of our current or future CROs or other contractors and consultants are vulnerable to compromise or damage from computer hacking, malicious software, fraudulent activity, employee misconduct, human error, telecommunication and electrical failures, natural disasters, or other cybersecurity attacks or accidents. Future acquisitions could expose us to additional cybersecurity risks and vulnerabilities from any newly acquired information technology infrastructure. Cybersecurity attacks are constantly increasing in sophistication and are made by groups and individuals with a wide range of motives (including industrial espionage) and expertise, including by organized criminal groups, "hacktivists," nation states and others. As a company with an increasingly global presence, our systems are subject to frequent attacks. Due to the nature of some of these attacks, there is a risk that an attack may remain undetected for a period of time. While we continue to make investments to improve the protection of data and information technology, there can be no assurance that our efforts will prevent service interruptions or security breaches.

Any cybersecurity incident could adversely affect our business, by leading to, for example, the loss of trade secrets or other intellectual property, demands for ransom or other forms of blackmail or the unauthorized disclosure of personal or other sensitive information of our employees, clinical trial patients, customers and others. Although to our knowledge we have not experienced any material cybersecurity incident to date, if such an event were to occur, it could seriously harm our development programs and our business operations. We could be subject to regulatory actions taken by governmental authorities, litigation under laws that protect the privacy of personal information, or other forms of legal proceedings, which could result in significant liabilities or penalties. Further, a cybersecurity incident may disrupt our business or damage our reputation, which could have a material adverse effect on our business, prospects, operating results, share price and stockholder value, and financial condition. We could also incur substantial remediation costs, including the costs of investigating the incident, repairing or replacing damaged systems, restoring normal business operations, implementing increased cybersecurity protections, and paying increased insurance premiums.

Risks Related to Ownership of Our Common Stock

Our stock price may be volatile or may decline regardless of our operating performance, resulting in substantial losses for investors.

The market price of our common stock may be highly volatile and may fluctuate substantially as a result of a variety of factors, some of which are related in complex ways. Since shares of our common stock were sold in our IPO in February 2019 at a price of \$14.00 per share, the reported high and low sales prices of our common stock has ranged from \$9.07 to \$17.85 through July 31, 2019.

The market price of our common stock may fluctuate significantly in response to numerous factors, many of which are beyond our control, including the factors listed below and other factors describe in this “Risk Factors” section:

- the enrollment or results of our Phase 1 trial of HPN424, Phase 1/2a trial of HPN536, or commencement, enrollment or results of any other future preclinical studies and clinical trials and trials we may conduct, or changes in the development status of our product candidates;
- any delay in our regulatory filings for our product candidates and any adverse development or perceived adverse development with respect to the applicable regulatory authority’s review of such filings, including without limitation the issuance by the FDA of a “refusal to file” letter or a request for additional information;
- adverse results or delays in clinical trials;
- our decision to initiate a preclinical study or clinical trial, not to initiate a preclinical study or clinical trial or to terminate an existing clinical study or trial;
- adverse actions taken by regulatory agencies with respect to our preclinical studies or clinical trials, manufacturing supply chain or sales and marketing activities, including failure to receive regulatory approval of our product candidates;
- changes in laws or regulations, including but not limited to preclinical study or clinical trial requirements for approvals;
- any adverse changes to our relationship with manufacturers or suppliers;
- manufacturing, supply or distribution shortages;
- litigation involving us, our industry or both, or investigations by regulators into our operations or those of our competitors;
- our failure to commercialize our product candidates;
- additions or departures of key scientific or management personnel;
- unanticipated serious safety concerns related to the use of our product candidates;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- variations in our results of operations;
- our cash position;
- our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public;
- publication of research reports about us or our industry, or immuno-oncology in particular, or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- announcements made by us or our competitors of new product and service offerings, acquisitions, strategic relationships, joint ventures or capital commitments;

- our inability to establish collaborations, if needed;
- our ability to effectively manage our growth;
- the size and growth of our initial cancer target markets;
- our ability to successfully treat additional types of cancers or at different stages;
- changes in the market valuations of similar companies;
- press reports, whether or not true, about our business;
- sales or perceived potential sales of our common stock by us or our stockholders in the future;
- overall fluctuations in the equity markets;
- ineffectiveness of our internal controls;
- changes in accounting practices or principles;
- changes or developments in the global regulatory environment;
- general political and economic conditions; and
- other events or factors, many of which are beyond our control.

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

Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

As of July 31, 2019, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates owned approximately 70.6% of our outstanding voting stock. Therefore, these stockholders will have the ability to influence us through this ownership position. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders.

Future sales of our common stock in the public market could cause our common stock price to fall.

Our common stock price could decline as a result of sales of a large number of shares of common stock or the perception that these sales could occur. These sales, or the possibility that these sales may occur, might also make it more difficult for us to sell equity securities in the future at a time and price that we deem appropriate.

As of July 31, 2019, we had outstanding 24,564,479 shares of common stock. The resale of 20,513,375 shares, or 83.5% of our outstanding shares, of common stock is currently prohibited or otherwise restricted as a result of securities law provisions, market standoff agreements entered into by certain of our stockholders with us or lock-up agreements entered into by our stockholders with the underwriters in connection with our IPO. However, subject to applicable securities law restrictions, these shares will be able to be sold in the public market beginning 181 days after February 7, 2019, the date of the final prospectus for our IPO. Shares issued upon the exercise of stock options and warrants outstanding under our equity incentive plans or pursuant to future awards granted under those plans will become available for sale in the public market to the extent permitted by the provisions of applicable vesting schedules, market stand-off agreements and/or lock-up agreements, as well as Rules 144 and 701 under the Securities Act of 1933, as amended, or the Securities Act.

The holders of approximately 18,332,732 shares, or 74.6% of our outstanding shares, of our common stock have rights, subject to some conditions, that to require us to file registration statements covering the sale of their shares or to include their shares in registration statements that we may file for ourselves or our other stockholders. We have also registered the offer and sale of all shares of common stock that we issued under our equity compensation plans. These shares may accordingly be sold in the public market upon issuance, subject to the lock-up agreements entered into by our stockholders with the underwriters in connection with our IPO.

In addition, in the future, we may issue additional shares of common stock, or other equity or debt securities convertible into common stock, in connection with a financing, acquisition, employee arrangement or otherwise. Any such issuance could result in substantial dilution to our existing stockholders and could cause the price of our common stock to decline.

An active trading market for our common stock may not be sustained.

Our common stock is currently listed on the Nasdaq under the symbol "HARP". The price for our common stock may vary and an active or liquid market in our common stock may not be sustainable. The lack of an active market may impair the value of your shares, your ability to sell your shares at the time you wish to sell them and the prices that you may obtain for your shares. An inactive market may also impair our ability to raise capital by selling our common stock and our ability to acquire other companies, products or technologies by using our common stock as consideration.

If securities or industry analysts either do not publish research about us or publish inaccurate or unfavorable research about us, our business or our market, or if they change their recommendations regarding our common stock adversely, the trading price or trading volume of our common stock could decline.

The trading market for our common stock will be influenced in part by the research and reports that securities or industry analysts may publish about us, our business, our market or our competitors. If one or more of these analysts initiate research with an unfavorable rating or downgrade our common stock, provide a more favorable recommendation about our competitors or publish inaccurate or unfavorable research about our business, our common stock price would likely decline. If any analyst who may cover us were to cease coverage of us or fail to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause the trading price or trading volume of our common stock to decline.

In preparing our financial statements for the fiscal years ended December 31, 2016 and 2017, we identified a material weakness in our internal control over financial reporting, and our failure to remedy other material weaknesses could result in material misstatements in our financial statements and cause investors to lose confidence in the accuracy and completeness of our financial reports, either of which could adversely affect the market price of our common stock.

Ensuring that we have adequate internal financial and accounting controls and procedures in place so that we can produce accurate financial statements on a timely basis is a costly and time-consuming effort that needs to be re-evaluated frequently. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with GAAP. We will be required to document, review and improve our internal controls and procedures for compliance with Section 404 of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, which will require annual management assessment of the effectiveness of our internal control over financial reporting beginning with the year ending December 31, 2019.

During the audit of our financial statements for the years ended December 31, 2016 and 2017, a material weakness was identified in our internal control over financial reporting. Under standards established by the Public Company Accounting Oversight Board, a material weakness is a deficiency or combination of deficiencies in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected and corrected on a timely basis. The material weakness related to a lack of qualified personnel within our accounting function to adequately conduct sufficient and timely review and analysis of certain routine transactions within our financial statement close process.

We remediated this material weakness as of December 31, 2018 primarily by implementing measures designed to improve our internal control over financial reporting to address the underlying causes of this material weakness, including increasing the number of qualified accounting personnel to appropriately account for routine transactions and financial statement preparation pursuant to GAAP and strengthening supervisory reviews by management. However, we cannot assure you that the measures we have implemented will be sufficient to avoid future material weaknesses. Further, we and our independent registered public accounting firm were not required to perform an evaluation of our internal control over financial reporting as of December 31, 2016, 2017 or 2018 in accordance with the provisions of the Sarbanes-Oxley Act. Accordingly, we cannot assure you that we have identified all, or that we will not in the future have additional, material weaknesses. If we are unable to maintain effective internal control over financial reporting, the accuracy and timing of our financial reporting, and our stock price, may be adversely affected and we may be unable to maintain compliance with the applicable stock exchange listing requirements.

Implementing any appropriate changes to our internal controls may distract our officers and employees, entail substantial costs to modify our existing processes and take significant time to complete. These changes may not, however, be effective in maintaining the adequacy of our internal controls, and any failure to maintain that adequacy, or consequent inability to produce accurate financial statements on a timely basis, could increase our operating costs and harm our business. In addition, investors' perceptions that our internal controls are inadequate or that we are unable to produce accurate financial statements on a timely basis may harm our stock price.

We are an emerging growth company, and any decision on our part to comply only with certain reduced reporting and disclosure requirements applicable to emerging growth companies could make our common stock less attractive to investors.

We are an “emerging growth company” as defined in the JOBS Act and, for as long as we continue to be an emerging growth company, we may choose to take advantage of exemptions from various reporting requirements applicable to other public companies but not to emerging growth companies, including:

- not being required to have our independent registered public accounting firm audit our internal control over financial reporting under Section 404 of the Sarbanes-Oxley Act;
- reduced disclosure obligations regarding executive compensation in our periodic reports and Annual Report on Form 10-K; and
- exemptions from the requirements of holding non-binding advisory votes on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We could be an emerging growth company for up to five years following the completion of our IPO. Our status as an emerging growth company will end as soon as any of the following takes place:

- the last day of the fiscal year in which we have more than \$1.07 billion in annual revenue;
- the date we qualify as a “large accelerated filer,” with at least \$700 million of equity securities held by non-affiliates;
- the date on which we have issued, in any three-year period, more than \$1.0 billion in non-convertible debt securities; or
- the last day of the fiscal year ending after the fifth anniversary of the completion of our IPO.

We cannot predict if investors will find our common stock less attractive if we choose to rely on any of the exemptions afforded to emerging growth companies. If some investors find our common stock less attractive because we rely on any of these exemptions, there may be a less active trading market for our common stock and the market price of our common stock may be more volatile.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We 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 that 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. As a result, our financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates.

The requirements of being a public company may strain our resources, result in more litigation and divert management’s attention.

As a public company, we are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of Nasdaq and other applicable securities rules and regulations. Complying with these rules and regulations has increased and will increase our legal and financial compliance costs, make some activities more difficult, time consuming or costly and increase demand on our systems and resources. The Exchange Act requires, among other things, that we file annual, quarterly and current reports with respect to our business and operating results. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. We are required to disclose changes made in our internal control and procedures on a quarterly basis. In order to maintain and, if required, improve our disclosure controls and procedures and internal control over financial reporting to meet this standard, significant resources and management oversight may be required. As a result, management’s attention may be diverted from other business concerns, which could adversely affect our business and operating results. We may also need to hire additional employees or engage outside consultants to comply with these requirements, which will increase our costs and expenses.

In addition, changing laws, regulations and standards relating to corporate governance and public disclosure are creating uncertainty for public companies, increasing legal and financial compliance costs and making some activities more time consuming. These laws, regulations and standards are 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. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management’s time and attention from revenue-generating activities to compliance activities. If our efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to their application and practice, regulatory authorities may initiate legal proceedings against us and our business may be adversely affected.

These new rules and regulations may make it more expensive for us to obtain director and officer liability insurance and, in the future, we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These factors could also make it more difficult for us to attract and retain qualified members of our board of directors, particularly to serve on our audit committee and compensation committee, and qualified executive officers.

By disclosing information in filings required of a public company, our business and financial condition are more visible, which we believe may result in threatened or actual litigation, including by competitors and other third parties. If those claims are successful, our business could be seriously harmed. Even if the claims do not result in litigation or are resolved in our favor, the time and resources needed to resolve them could divert our management's resources and seriously harm our business.

We do not currently intend to pay dividends on our common stock and, consequently, our stockholders' ability to achieve a return on their investment will depend on appreciation of the value of our common stock.

We have never declared or paid cash dividends on our common stock. We currently intend to retain all available funds and any future earnings to support operations and to finance the growth and development of our business. We do not intend to declare or pay any cash dividends on our capital stock in the foreseeable future. As a result, any investment return on our common stock will depend upon increases in the value for our common stock, which is not certain.

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

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could depress the trading price of our common stock by acting to discourage, delay or prevent a change of control of our company or changes in our management that our stockholders may deem advantageous. These provisions include the following:

- establish a classified board of directors so that not all members of our board of directors are elected at one time;
- permit our board of directors to establish the number of directors and fill any vacancies and newly created directorships;
- provide that members of our board of directors may only be removed for cause;
- require super-majority voting to amend certain provisions of our amended and restated certificate of incorporation and amended and restated bylaws;
- authorize the issuance of "blank check" preferred stock that our board of directors could use to implement a stockholder rights plan;
- eliminate the ability of our stockholders to call special stockholder meetings;
- prohibit stockholder action by written consent, which requires all stockholder actions to be taken at stockholder meetings;
- provide that our board of directors is expressly authorized to make, alter or repeal our amended and restated bylaws;
- restrict the forum for certain litigation against us to Delaware; and
- establish advance notice requirements for nominations for election to our board of directors or for proposing matters that can be acted upon by stockholders at annual stockholder meetings.

Any provision of our amended and restated certificate of incorporation, our amended and restated bylaws or Delaware law that has the effect of delaying or deterring a change in our control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock, and could also affect the price that some investors are willing to pay for our common stock.

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

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware (or, if and only if the Court of Chancery of the State of Delaware lacks subject matter jurisdiction, any state court located within the State of Delaware or, if and only if all such state courts lack subject matter jurisdiction, the federal district court for the District of Delaware), to the fullest extent permitted by applicable law, is the exclusive forum for:

- any derivative action or proceeding brought on our behalf;
- any action asserting a breach of fiduciary duty;

- any action asserting a claim against us arising under the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws; and
- any action asserting a claim against us that is governed by the internal-affairs doctrine.

However, this exclusive forum provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act. Furthermore, this provision applies to Securities Act claims and Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. Accordingly, there is uncertainty as to whether a court would enforce such provision, and our stockholders will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder.

This exclusive-forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage lawsuits against us and our directors, officers and other employees.

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

Our U.S. net operating loss, or NOL, carryforwards and tax credit carryforwards are potentially subject to annual utilization limits under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code. Our U.S. NOL and tax credit carryforwards could expire unused and be unavailable to offset future taxable income or income tax liabilities because of their limited duration or because of restrictions under U.S. tax law. Under Sections 382 and 383 of the Code, if a corporation undergoes an "ownership change," generally defined as a greater than 50 percentage point change (by value) in its equity ownership during a rolling three-year period, the corporation's ability to use its pre-change tax attributes, such as NOLs and R&D tax credits, to offset its post-change income or taxes may be limited. We have not performed an analysis under Section 382 of the Code and cannot predict or otherwise determine whether our federal tax attribute carryforwards may be limited in the future. As a result, if we earn taxable income in the future, our ability to use existing U.S. NOL and R&D tax credit carryforwards to reduce U.S. taxable income or tax liability may be subject to limitations. This could adversely impact our future operating results by increasing our future tax liabilities. Similar rules may also limit our ability to use accumulated state tax attributes to reduce our state tax liabilities. Also, there may be periods when the use of NOLs is suspended or otherwise limited at the state level, which could accelerate or permanently increase state taxes owed.

We may have ownership changes in the future, due to further changes in our stock ownership. Some of these ownership changes could be outside of our control. If an ownership change occurs and our ability to use our historical NOL and tax credit carryforwards is limited, it could adversely impact our future operating results by increasing our tax obligations.

New or future changes to tax laws could materially adversely affect our company.

The Tax Act, which was enacted on December 22, 2017, significantly amends the Code. The Tax Act, among other things, reduces the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limits the tax deduction for interest expense to 30% of adjusted taxable income, eliminates NOL carrybacks, limits the deduction for NOLs carried forward from taxable years beginning after December 31, 2017 to 80% of taxable income, imposes a one-time tax on offshore earnings at reduced rates regardless of whether they are repatriated, allows immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifies or repeals many business deductions and credits. We continue to examine the impact these changes may have on our business. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the Tax Act is uncertain and our business and financial condition could be adversely affected.

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

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

None.

Item 5. Other Information

None.

Item 6. Exhibits

EXHIBIT INDEX

Number	Exhibit Description	Form	File No.	Exhibit	Filing Date	Filed Herewith
2.1 [‡] *	Asset Transfer Agreement by and between the Registrant and Maverick Therapeutics, Inc., dated as of December 30, 2016, as amended	S-1	333-229040	2.1	1/29/2019	
3.1	Amended and Restated Certificate of Incorporation of the Registrant					X
3.2	Amended and Restated Bylaws of the Registrant	8-K	001-38800	3.2	2/13/2019	
10.1 [‡]	First Amendment to the Discovery Collaboration and License Agreement between the Registrant and AbbVie Biotechnology Ltd., dated as of April 3, 2019	10-Q	001-38800	10.1	5/9/2019	
31.1	Certification of Chief Executive Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					X
31.2	Certification of Chief Financial Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					X
32.1 [†]	Certifications of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002					X
101.INS	XBRL Instance Document					
101.SCH	XBRL Taxonomy Schema Linkbase Document					
101.CAL	XBRL Taxonomy Definition Linkbase Document					
101.DEF	XBRL Taxonomy Calculation Linkbase Document					
101.LAB	XBRL Taxonomy Labels Linkbase Document					
101.PRE	XBRL Taxonomy Presentation Linkbase Document					

[†] The certifications attached as Exhibit 32.1 that accompany this Quarterly Report on Form 10-Q are not deemed filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of the Registrant under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Quarterly Report on Form 10-Q, irrespective of any general incorporation language contained in such filing.

[‡] Portions of this exhibit have been omitted because they are both not material and would be competitively harmful if publicly disclosed.

* Certain schedules and/or exhibits to this agreement have been omitted in accordance with Item 601(b)(2) of Regulation S-K. A copy of any omitted schedule and/or exhibit will be furnished to the Securities and Exchange Commission upon request.

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.

Date: August 5, 2019

HARPOON THERAPEUTICS, INC.

By: /s/ Gerald McMahon, Ph.D.

Gerald McMahon, Ph.D.

President and Chief Executive Officer

(Principal Executive Officer)

By: /s/ Georgia Erbez

Georgia Erbez

Chief Financial Officer

(Principal Financial and Accounting Officer)

**AMENDED AND RESTATED
CERTIFICATE OF INCORPORATION
OF
HARPOON THERAPEUTICS, INC.**

Harpoon Therapeutics, Inc., a corporation organized and existing under and by virtue of the General Corporation Law of the State of the Delaware, hereby certifies that:

ONE: The original name of this corporation was Harpoon Therapeutics, Inc. and the date of filing the original Certificate of Incorporation of this corporation with the Secretary of State of the State of Delaware (the "**Secretary**") was March 19, 2015.

TWO: The Amended and Restated Certificate of Incorporation, attached hereto as **Exhibit A**, is incorporated herein by reference, and restates, integrates and further amends the provisions of the Amended and Restated Certificate of Incorporation as previously amended or supplemented.

THREE: This Amended and Restated Certificate of Incorporation has been duly approved by the Board of Directors of the Corporation.

FOUR: This Amended and Restated Certificate of Incorporation was approved by the holders of the requisite number of shares of said Corporation in accordance with Section 228 of the Delaware General Corporation Law. This Amended and Restated Certificate of Incorporation has been duly adopted in accordance with the provisions of Sections 242 and 245 of the Delaware General Corporation Law by the stockholders of the Corporation.

In Witness Whereof, the Corporation has caused this Amended and Restated Certificate of Incorporation to be signed by its duly authorized officer this 12th day of February, 2019.

Harpoon Therapeutics, Inc.

By: /s/ Gerald

McMahon

Gerald McMahon
President and Chief Executive Officer

EXHIBIT A

**AMENDED AND RESTATED
CERTIFICATE OF INCORPORATION
OF
HARPOON THERAPEUTICS, INC.**

I.

The name of the corporation is **Harpoon Therapeutics, Inc.** (the “*Corporation*”).

II.

The address of the registered office of the Corporation in the State of Delaware is 251 Little Falls Drive, City of Wilmington, County of New Castle, Delaware, 19808 and the name of the registered agent of the Corporation in the State of Delaware at such address is Corporation Service Company.

III.

The purpose of the Corporation is to engage in any lawful act or activity for which a corporation may be organized under the Delaware General Corporation Law (the “*DGCL*”).

IV.

A. The Corporation is authorized to issue two classes of stock to be designated, respectively, “*Common Stock*” and “*Preferred Stock*.” The total number of shares which the Corporation is authorized to issue is 160,000,000 shares. 150,000,000 shares shall be Common Stock, each having a par value of \$0.0001, and 10,000,000 shares shall be Preferred Stock, each having a par value of \$0.0001.

B. The Preferred Stock may be issued from time to time in one or more series. The board of directors of the Corporation (the “*Board of Directors*”) is hereby expressly authorized to provide for the issue of all or any of the shares of the Preferred Stock in one or more series, and to fix the number of shares and to determine or alter for each such series, such voting powers, full or limited, or no voting powers, and such designation, preferences, and relative, participating, optional, or other rights and such qualifications, limitations, or restrictions thereof, as shall be stated and expressed in the resolution or resolutions adopted by the Board of Directors providing for the issuance of such shares and as may be permitted by the DGCL. The Board of Directors is also expressly authorized to increase or decrease the number of shares of any series subsequent to the issuance of shares of that series, but not below the number of shares of such series then outstanding. In case the number of shares of any series shall be decreased in accordance with the foregoing sentence, the shares constituting such decrease shall resume the status that they had prior to the adoption of the resolution originally fixing the number of shares of such series. The number of authorized shares of Preferred Stock may be increased or decreased (but not below the number of shares thereof then outstanding) by the affirmative vote of the holders of a majority of the voting power of the outstanding shares of stock of the Corporation entitled to vote, without a separate

vote of the holders of the Preferred Stock, or of any series thereof irrespective of Section 242(b)(2) of the DGCL, unless a vote of any such holders is required pursuant to the terms of any certificate of designation filed with respect to any series of Preferred Stock.

C. Each outstanding share of Common Stock shall entitle the holder thereof to one vote on each matter properly submitted to the stockholders of the Corporation for their vote; *provided, however*, that, except as otherwise required by law, holders of Common Stock shall not be entitled to vote on any amendment to this Amended and Restated Certificate of Incorporation (including any certificate of designation filed with respect to any series of Preferred Stock) that relates solely to the terms of one or more outstanding series of Preferred Stock if the holders of such affected series are entitled, either separately or together as a class with the holders of one or more other such series, to vote thereon by law or pursuant to this Amended and Restated Certificate of Incorporation (including any certificate of designation filed with respect to any series of Preferred Stock).

V.

For the management of the business and for the conduct of the affairs of the Corporation, and in further definition, limitation and regulation of the powers of the Corporation, of its directors and of its stockholders or any class thereof, as the case may be, it is further provided that:

A. Management of Business.

The management of the business and the conduct of the affairs of the Corporation shall be vested in its Board of Directors. The number of directors which shall constitute the Board of Directors shall be fixed exclusively by resolutions adopted by a majority of the authorized number of directors constituting the Board of Directors.

B. Board of Directors

Subject to the rights of the holders of any series of Preferred Stock to elect additional directors under specified circumstances, following the closing of the initial public offering pursuant to an effective registration statement under the Securities Act of 1933, as amended (the “*1933 Act*”), covering the offer and sale of Common Stock to the public (the “*Initial Public Offering*”), the directors shall be divided into three classes designated as Class I, Class II and Class III, respectively. The Board of Directors is authorized to assign members of the Board of Directors already in office to such classes at the time the classification becomes effective. At the first annual meeting of stockholders following the closing of the Initial Public Offering, the term of office of the Class I directors shall expire and Class I directors shall be elected for a full term of three years. At the second annual meeting of stockholders following the closing of the Initial Public Offering, the term of office of the Class II directors shall expire and Class II directors shall be elected for a full term of three years. At the third annual meeting of stockholders following the closing of the Initial Public Offering, the term of office of the Class III directors shall expire and Class III directors shall be elected for a full term of three years. At each succeeding annual meeting of stockholders, directors shall be elected for a full term of three years to succeed the directors of the class whose terms expire at such annual meeting.

Notwithstanding the foregoing provisions of this section, each director shall serve until his or her successor is duly elected and qualified or until his or her earlier death, resignation or removal. No decrease in the number of directors constituting the Board of Directors shall shorten the term of any incumbent director.

C. Removal of Directors.

Subject to the rights of any series of Preferred Stock to elect additional directors under specified circumstances, following the closing of the Initial Public Offering, neither the Board of Directors nor any individual director may be removed without cause.

Subject to any limitation imposed by applicable law, any individual director or directors may be removed with cause by the affirmative vote of the holders of at least sixty-six and two-thirds percent (66 2/3%) of the voting power of all then outstanding shares of capital stock of the Corporation entitled to vote generally at an election of directors.

D. Vacancies.

Subject to any limitations imposed by applicable law and subject to the rights of the holders of any series of Preferred Stock, any vacancies on the Board of Directors resulting from death, resignation, disqualification, removal or other causes and any newly created directorships resulting from any increase in the number of directors, shall, unless the Board of Directors determines by resolution that any such vacancies or newly created directorships shall be filled by the stockholders and except as otherwise provided by applicable law, be filled only by the affirmative vote of a majority of the directors then in office, even though less than a quorum of the Board of Directors, and not by the stockholders. Any director elected in accordance with the preceding sentence shall hold office for the remainder of the full term of the director for which the vacancy was created or occurred and until such director's successor shall have been elected and qualified.

E. Bylaw Amendments.

The Board of Directors is expressly empowered to adopt, amend or repeal the Bylaws of the Corporation. Any adoption, amendment or repeal of the Bylaws of the Corporation by the Board of Directors shall require the approval of a majority of the authorized number of directors. The stockholders shall also have power to adopt, amend or repeal the Bylaws of the Corporation; *provided, however,* that, in addition to any vote of the holders of any class or series of stock of the Corporation required by law or by this Amended and Restated Certificate of Incorporation, such action by stockholders shall require the affirmative vote of the holders of at least sixty-six and two-thirds percent (66 2/3%) of the voting power of all of the then-outstanding shares of the capital stock of the Corporation entitled to vote generally in the election of directors, voting together as a single class.

F. Stockholder Actions.

1. The directors of the Corporation need not be elected by written ballot unless the Bylaws so provide.

2. No action shall be taken by the stockholders of the Corporation except at an annual or special meeting of stockholders called in accordance with the Bylaws, and no action shall be taken by the stockholders by written consent or electronic transmission.

3. Advance notice of stockholder nominations for the election of directors and of business to be brought by stockholders before any meeting of the stockholders of the Corporation shall be given in the manner provided in the Bylaws of the Corporation.

VI.

A. The liability of the directors for monetary damages shall be eliminated to the fullest extent under applicable law.

B. To the fullest extent permitted by applicable law, the Corporation is authorized to provide indemnification of (and advancement of expenses to) directors, officers and agents of the Corporation (and any other persons to which applicable law permits the Corporation to provide indemnification) through Bylaw provisions, agreements with such agents or other persons, vote of stockholders or disinterested directors or otherwise in excess of the indemnification and advancement otherwise permitted by such applicable law. If applicable law is amended after approval by the stockholders of this Article VI to authorize corporate action further eliminating or limiting the personal liability of directors, then the liability of a director to the Corporation shall be eliminated or limited to the fullest extent permitted by applicable law as so amended.

C. Any repeal or modification of this Article VI shall only be prospective and shall not affect the rights or protections or increase the liability of any director under this Article VI in effect at the time of the alleged occurrence of any act or omission to act giving rise to liability or indemnification.

VII.

Unless the Corporation consents in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware shall (or, if and only if the Court of Chancery of the State of Delaware lacks subject matter jurisdiction, any state court located within the State of Delaware or, if and only if all such state courts lack subject matter jurisdiction, the federal district court for the District of Delaware), to the fullest extent permitted by applicable law, be the sole and exclusive forum for: (A) any derivative action or proceeding brought on behalf of the Corporation; (B) any action or proceeding (including any class action) asserting a claim of breach of a fiduciary duty owed by any director, officer, employee or agent of the Corporation to the Corporation or the Corporation's stockholders; (C) any action or proceeding (including any class action) asserting a claim against the Corporation or any director, officer, employee or agent of the Corporation arising pursuant to any provision of the DGCL, this Amended and Restated Certificate of Incorporation or the Bylaws of the Corporation; (D) any action or proceeding (including any class action) to interpret, apply, enforce or determine the validity of this Amended and Restated Certificate of

Incorporation or the Bylaws of the Corporation; or (E) any action asserting a claim against the Corporation or any director, officer, employee or agent of the Corporation governed by the internal affairs doctrine. Any person or entity purchasing or otherwise acquiring any interest in any security of the Corporation shall be deemed to have notice of and consented to the provisions of this section.

VIII.

A. The Corporation reserves the right to amend, alter, change or repeal any provision contained in this Amended and Restated Certificate of Incorporation, in the manner now or hereafter prescribed by statute, except as provided in paragraph B. of this Article VIII, and all rights conferred upon the stockholders herein are granted subject to this reservation.

B. Notwithstanding any other provisions of this Amended and Restated Certificate of Incorporation or any provision of law which might otherwise permit a lesser vote or no vote, but in addition to any affirmative vote of the holders of any particular class or series of the Corporation required by law or by this Amended and Restated Certificate of Incorporation or any certificate of designation filed with respect to a series of Preferred Stock, the affirmative vote of the holders of at least sixty-six and two-thirds percent (66 2/3%) of the voting power of all of the then outstanding shares of capital stock of the Corporation entitled to vote generally in the election of directors, voting together as a single class, shall be required to alter, amend or repeal Articles V, VI and VII.

* * * *

CERTIFICATION OF PERIODIC REPORT UNDER SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Gerald McMahon, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Harpoon Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer 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 5, 2019

/s/ Gerald McMahon

Gerald McMahon
President and Chief Executive Officer
(Principal Executive Officer)

CERTIFICATION OF PERIODIC REPORT UNDER SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Georgia Erbez, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Harpoon Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer 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 5, 2019

/s/ Georgia Erbez
Georgia Erbez
Chief Financial Officer
(Principal Financial and Accounting Officer)

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

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), I, Gerald McMahon, as Chief Executive Officer of Harpoon Therapeutics, Inc. (the "Company"), and Georgia Erbez, as Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Company's Quarterly Report on Form 10-Q for the period ended June 30, 2019, to which this Certification is attached as Exhibit 32.1 (the "Periodic Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and
- (2) The information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 5, 2019

By: _____
/s/ Gerald McMahon
Gerald McMahon
President and Chief Executive Officer

Date: August 5, 2019

By: _____
/s/ Georgia Erbez
Georgia Erbez
Chief Financial Officer